Risk Management Process for Physiological Monitors on a Medical IT Network. An evaluation of the Process Assessment Model presented in ISO/TR 80001-2-7.

Anthony Fitzgerald

MSc in Health Informatics **2017**

TRINITY COLLEGE DUBLIN
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Risk Management Process for Physiological Monitors on a Medical IT Network. An evaluation of the Process Assessment Model presented in ISO/TR 80001-2-7.

Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7?

Anthony Fitzgerald

A dissertation submitted to the University of Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics

2017

Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics, Trinity College Dublin.

Signed: _____

Anthony Fitzgerald 22th June 2017

Permission to lend and/or copy

I agree that the School of Computer Science and Statistics, Trinity College Dublin, may lend or copy this dissertation upon request.

Signed: _____

Anthony Fitzgerald 22th June 2017

Acknowledgements

There are many people that I would like to thank for their support and encouragement with this dissertation. Firstly I would like to thank and dedicate this work to my family, Jackie my soulmate and my daughters Grace and Leah whose continuous support, patience, encouragement and love enabled me to complete this dissertation.

My work colleagues for encouraging and advising me to do the MSc and also assisting by providing valuable advice, suggestions and proof reading this document. My classmates particularly the “Dream Team” who have provided encouragement and support over the last two years, my supervisor Prof Gaye Stephens for her advice and support throughout the year

Thank you all, it has been a rewarding and worthwhile journey.

Tony Fitzgerald

Abstract

The interoperability of medical devices and the incorporation of these medical devices onto IT networks are becoming pervasive. This coupled with the increase in cyber-attacks on Health Delivery Organisations (HDOs), increases the risks to patient safety and data and system security. IEC 80001-1 was published to help HDOs identify and address the risks associated with medical devices sharing a common IT network with other applications and systems. IEC published a technical report ISO/TR 80001-2-7 containing a process assessment model (PAM) which can be adapted and used by the HDO to identify resources and processes that are required to implement an IEC 80001-1 medical IT network

The Health Service Executive (HSE) has indicated that that the Children's Hospital Group (CHG) will be the first implementation of a National Acute electronic medical record (EMR) with one single heterogeneous IT network planned for the hospital. Therefore it is crucial that all associated risks are identified and appropriate resources and procedures are put in place. The motivation behind this study is to determine if the PAM presented in ISO/TR 80001-2-7 is accessible enough to allow a HDO with a medical IT network self-assess their conformance with IEC 80001-1.

A literature review was conducted which highlighted the difficulties faced by HDOs in understanding and applying the requirements of this standard. One of the factor highlighted which contributed to the lack of adoption, was the lack of a PAM. Adoption and awareness of the standard remained low even after the publication of the PAM in ISO/TR 80001-2-7.

The research consisted of three different stages and was targeted at the Information Technology (IT) and Clinical Engineering (CE) Managers within National HDOs and the CHG. Ethics approval from the three children's hospitals and Trinity College was received.

Stage 1 consisted of a national survey to determine a baseline for the awareness and adoption of the standard nationally and to identify possible barriers to its implementation.

Stage 2 consisted of focus groups with IT and CE manager within the CHG to evaluate the accessibility and usability of the PAM. Combining this information with findings in the literature informed the development on an excel application which was undertaken as part of this research and presented the PAM in a dashboard style.

Stage 3 involved presenting the PAM as represented in the excel application to the same IT and CE manager within the CHG and evaluating its accessibility and usability.

The results of the national survey confirmed the lack of awareness and adoption of IEC 80001-1 and identified: Knowledge of the standard, Clarity over roles and responsibilities and Governance of medical IT network as the top three restrictions to its implementation.

The results of the focus groups confirmed the difficulty that participants were having using the PAM in its current format however when presented in a dashboard style format in the excel application, participants found the PAM much easier to use.

The results highlight that adoption and use of standards within an organisation is greatly increased when the standards are readily available and easy to read and understand. This is consistent with other findings repeated in the literature which also identifies an investment in people, processes and specialised tools as enabling factors.

A number of professional stakeholder groups were identified and a dissemination plan informing them about the standard and results of this research is outlined.

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Abbreviations

Abbreviations	Description
APSF	Anaesthesia Patient Safety Foundation
BEAI	Biomedical & Clinical Engineering Association of Ireland
BP	Base Practice
CE	Clinical Engineering
CHG	Children's Hospital Group
CRCM	Change Release Management & Configuration Management
EC	European Council
ECG	Electrocardiograph
EHR	Electronic Health Record
EMR	Electronic Medical Record
FDA	Food and Drug Administration
HDO	Health-Care Delivery Organisations
HIQA	Health Information and Quality Authority
HISI	Health Informatics Society of Ireland
HSE	Health Service Executive
ICU	Intensive Care Unit
IDE	Integrated Development Environment
IEC	International Electrotechnical Commission
IMD	Implantable Medical Devices
ISO	International Organization for Standardization
IT	Information Technology
LIS	Laboratory Information System
LNRM	Live Network Risk Management
MDD	Medical Device Directive

Abbreviations	Description
MDP	Medical IT Network Documentation and Planning
MRM	Medical IT Network Risk Management Process Group
NASI	National Standards Authority of Ireland
OCIO	The Office of the Chief Information Officer
PACS	Picture Archiving and Communications Systems
PAM	Process Assessment Model
PAS	Patient Administration System
PRM	Process Reference Model
TR	Technical Report
UEPA	User Experience Professionals Association
VA	United States Department of Veterans Affairs
WHO	World Health Organisation

Glossary

Term	Description of Terms
Base Practice	ISO 15504 defines Base Practice as "*an activity that, when consistently performed, contributes to achieving a specific process purpose*"(ISO/IEC, 2004).
Medical IT-Network	ISO 80001 defines a Medical IT network as "*An IT network that incorporates at least one Medical Device*" (ISO/IEC, 2011).
Outcome	"*Observable results of the successful achievement of the proposed process*"(ISO/IEC, 2011).
Process	ISO 80001 defines a Process as "*a set of interrelated or interacting activities which transforms inputs into outputs*" (ISO/IEC, 2011).
Process Assessment Method	A Process Assessment Method provides a documented set of instructions for conducting an assessment in a consistent and repeatable manner. The assessment method includes a set of questions which determine how each process is being performed and also support the assignment of capability rating to each process. The output from the assessment method identifies the strengths and weaknesses of each process enabling the recommendation of improvements (ISO/IEC, 2015b).
Process Assessment Model (PAM)	ISO 15504 defines Process Assessment Model as a "*model suitable for the purpose of assessing process capability, based on one or more Process Reference Models*" (ISO/IEC, 2004) and comprises a set of indicators (base practices) of process performance and process capability. The indicators are used as a basis for collecting the objective evidence that enables an assessor to assign ratings.
Process Outcome	ISO 15504 defines Process Outcome as "*an observable result of a process*"(ISO/IEC, 2004).
Process Reference Model (PRM)	ISO 15504 defines "*Process Reference Model provides definitions of processes in a life cycle described in terms of process purpose and outcomes, together with an architecture describing relationships between the processes*"(ISO/IEC, 2004).

Term	Description of Terms
Risk	ISO 14978 defines Risk as "*Combination of the probability of occurrence of harm and the severity of that harm once it occ*urs" (ISO, 2009)
Risk Management Process	ISO 31000 defines Risk Management as "*the systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, assessing, treating, monitoring and communicating*"(ISO, 2010). A process for identifying, evaluating, controlling and monitoring risk and evaluating the effectiveness of the risk controls measures, in this context of a medical IT network.
Standard	*"A standard is a document that provides requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose*" (ISO, 2017b).

Chapter 1 - Introduction

1.1 Introduction

In 1625, Santorio applying principles established by his friend Galileo published a method of measuring pulse (heart) rate using a pendulum and measuring body temperature using a spirit thermometer. This is the first recorded incident of physiological measurement (Major and d, 1954). Technological improvements in the watch and thermometer over the next two centuries and the invention of a method to measure non-invasive arterial blood pressure (sphygmomanometer) in 1896 by Riva-Rocci allowed for the measurement of the respiratory rate, pulse rate, temperature and arterial blood pressure (Major and d, 1954). These became the standard vital signs for routine physiological monitoring and have been recorded in all hospital charts since 1912 (Glaeser and Thomas, 1975). These vital signs including ECG (electrocardiograph) invented in 1903 by Willem Einthoven have become the primary basis to determine and measure the continuous physiological status of the critically ill patient. As medicine and technology has advanced these physiological vital signs have progressed from just documenting the diagnosis or the demise of a patient to enabling physicians to make life saving decisions for therapeutic intervention (Glaeser and Thomas, 1975).

The 1950s saw the emergence of intensive care units and specialised multidisciplinary care units. These benefited from the post war expansion of the electronics industry and brought laboratory technology to the patient bedside in ICU and theatre, in the form of patient vital signs monitors enabling the measurement and display of real time vital signs (Gardner and Shabot, 2001). The last sixty years have seen a transformation in patient monitors from “bouncing-ball” and analogue-computer technology to digitalised medical devices containing multiple microcomputers. These modern patient monitors are capable of acquiring, displaying and categorising the clinical data from the patient as well incorporating data from external systems such as clinical laboratories, bedside point of care systems and medical devices such as ventilators, infusion pumps and specialised diagnostic equipment. These patient monitors are no longer confined to ICU and theatres and are now extensively used throughout Health Delivery Organisations (HDO) (Gardner and Shabot, 2001).

1.2 Physiological Monitoring and Networks

A major contributing factor in enabling the technological advancement of physiological patient monitors was the improvement in patient care by the incorporation of these devices onto networks. These monitoring networks facilitated the storage, management and display of all clinical data from the patient bedside at a central station, located at the nurse's base. This also allowed clinicians to remotely view individual patient bedside monitors for vital signs, real time information and trend data using the hospitals intranet or the internet. The availability of this data resulted in the development of specialized information systems e.g. ICU clinical information system which enabled the integration of other hospital information system e.g. laboratory information system (LIS), patient administration system (PAS) and picture archiving and communications systems (PACS). These systems support the continuum-of-care approach to patient care and have become widespread throughout HDOs (Gardner and Shabot, 2001).

1.3 Networks - Vendor Specific

These patient monitoring systems were initially installed on stand-alone networks with dedicated infrastructure isolating the monitors on their own network Fig 1-1. These proprietary physiological monitoring networks were supported by hospital clinical engineering (CE) staff in conjunction with specialists from the vendor. Many of these patient monitoring systems have been installed over time in different departments within the HDO, each with its own dedicated infrastructure. Gateways have been introduced which allow data exchange between the patient monitoring systems and hospital administration systems (Sampson Rod, 2016). A McKinsey report in 2010 stated that the simplification of the IT architecture is necessary; if HDO want to integrate information from medical devices and computerized physician order entry systems into an electronic health record (EHR) (McKinsey&Company, 2010).

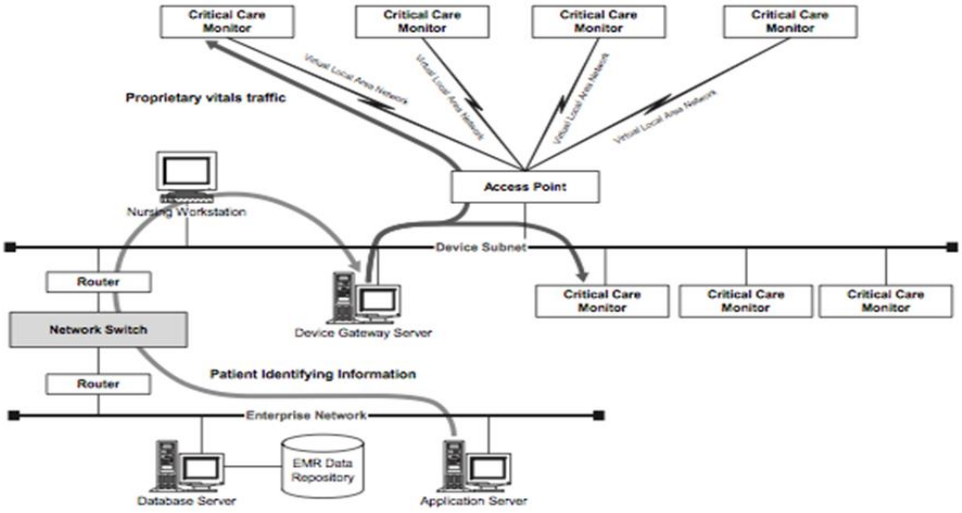

Figure 1-1 Physiological Monitoring Proprietary Network (Zaleski, 2012)

1.4 Network-Heterogeneous

The simplification of the IT architecture involves converging all the HDO systems and applications together on one single infrastructure utilising a common network Fig1-2. The associated reduction in costs combined with increased staff productivity is one of the main drivers contributing towards a single heterogeneous network within HDOs who have limited resources and tight budgets. This shared network would facilitate the transfer of information between medical devices and their related systems while also allowing the transfer of video, telephone and data communication. The purpose of this heterogeneous network is to ensure that the right information is available to the right person, where and when they need it (Sampson Rod, 2016).

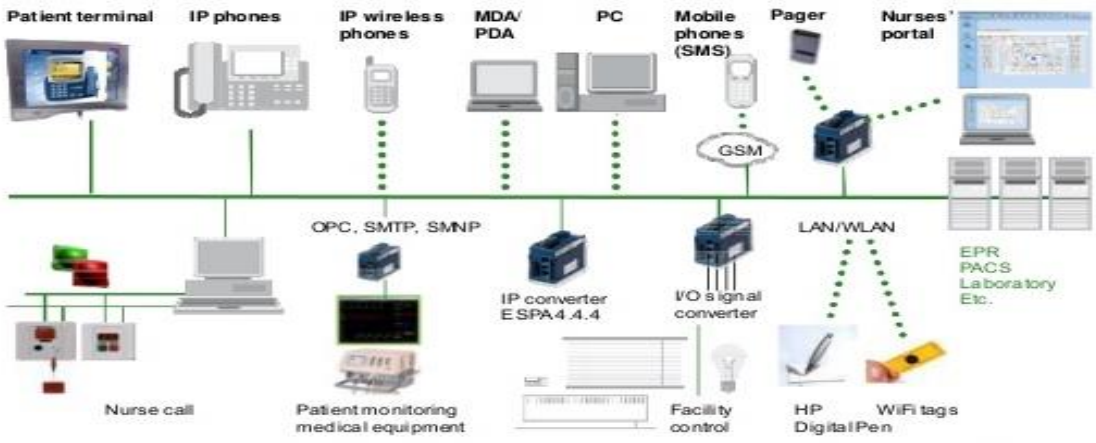

Figure 1-2 HDO Single Heterogeneous Network (Buxó, 2012)

1.5 Patient Safety and Risk

These heterogeneous networks allow the connection and integration of sophisticated systems enabling better patient care by facilitating efficient clinical decision making throughout the hospital. In the last few years, healthcare technologies have become increasingly interconnected and co-dependent. However the complexity of the integration of these medical devices and systems combined with the fact that they are sharing a single network and their pivotal role in the delivery of care to the patient introduces new risks that need to be identified and managed (Delvecchio, 2011)

1.6 IEC 80001-1

The World Health Organisation (WHO) defines a physiological monitor as a medical device which is therefore governed by the medical device directive (MDD) (WHO, 2013b) . This directive ensures that medical device manufactures cannot legally place a medical device for sale on the European market unless it complies with the strict guidelines laid out within the directive (Council, 1993). In 2010 the International Electrotechnical Commission (IEC) released a standard to address the risks associated with medical devices sharing a common IT network with other devices and applications. This standard is called IEC 80001-1: Application of risk management for IT-networks incorporating medical devices (hereafter called IEC 80001-1) (ISO/IEC, 2011).

IEC 80001-1 states that any IT network within a HDO which has at least one medical device connected is categorised as a medical IT network. The goal of IEC 80001-1 is to prevent patient harm and three areas are identified, Safety, Effectiveness and (Data and System) Security. The standard requires that a comprehensive risk management policy be implemented to protect these (ISO/IEC, 2011). This standard defines roles, responsibilities and activities in relation to the management of risk associated with placing a medical device onto an IT network for the following:

- Health Delivery Organisation
- Medical Device Manufacturer
- Other providers of IT equipment on the network

The IEC 80001-1 standard recognises that overall responsibility for the medical IT network belongs with the HDO, who must work in conjunction with the manufacturer of any medical

devices placed on the network and the suppliers of other products incorporated into the network, to ensure that all risks are identified and managed (ISO/IEC, 2011).

1.7 ISO/TR 80001-2-7

In 2015 the IEC published a technical report ISO/TR 80001-2-7:2015 "Application of risk management for IT-networks incorporating medical devices -- Application guidance -- Part 2-7: Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" (hereafter called ISO/TR 80001-2-7). This provides a process assessment model (PAM) consisting of a set of questions which can be adapted and used by the HDO to self–assess their conformance with IEC 80001-1 (ISO/IEC, 2015b).

1.8 Motivation

The motivation behind this study is to determine if the process assessment model presented in ISO/TR 80001-2-7 is accessible enough, to allow a health delivery organisation with a medical IT network self-assess their conformance with IEC 80001-1. A literature review on IEC 80001-1 revealed that while there are numerous papers and articles explaining the standard, there is very little literature on the adoption of the standard or the use of the process assessment model. Hegarty, et al, using the PAM to self-assess a medical IT network in a large academic teaching hospital in Dublin found IEC80001-1 very useful in informing the HDO of their responsibilities and the processes and resources required, however they found that the language used and the specific requirements detailed, difficult to interpret within a health care framework (Hegarty et al., 2014). For the purpose of this research the definition of usability by the User Experience Professionals Association (UEPA) as the amount to which a product e.g. a device, hardware, software, paper based tool etc. is "*fit for purpose*" and easy to use by the people for whom it was designed (Association, 2017) has been adopted.

The Health Service Executive (HSE) has indicated that that the Children's Hospital Group (CHG) will be the first implementation of a National Acute electronic medical record (EMR) and are currently progressing a national eHealth programme which includes the delivery of an EMR solution for the whole of Irish healthcare (HSE, 2015). One single heterogeneous IT network is planned for the new children hospital and it is crucial that all associated resources, procedures and risks are identified and appropriate measures are put in place. Kielty, L.A., in her thesis "Development & Validation of an Assessment Method for the International Standard IEC 80001-1. 2014" observed that the involvement of health care

personnel in the development and assessment of standards helps raise awareness and positively affects the implementation of these standards which ultimately benefit the patient in terms of patient safety. Kielty suggests a national survey of "*healthcare informatics personnel*" within Irish acute hospitals be undertaken to determine the level of awareness of IEC 80001-1 and the process assessment model (PAM) in ISO/TR 80001-2-7 (Kielty, 2014).

1.9 Research Question

The main research question of this study is;

"Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7?"

1.10 Study Aims

The Aims of the study are divided into three stages which are outlined below and in Fig 1-3.

Stage 1

- Investigate the knowledge, accessibility and adoption of IEC 80001-1 and its technical report ISO/TR 80001-2-7 within Irish National healthcare delivery organisations.

Stage 2

- Evaluate the current PAM presented in ISO/TR 80001-2-7 with CE and IT managers within a HDO by:
    - Determining if the PAM as presented in ISO/TR 80001-2-7 is accessible and useable to CE and IT managers within HDOs.
    - Determining if the assessment scoring methodology presented in the PAM is accessible and useable to CE and IT managers within HDOs.
    - Determining if the output recommendations presented in the PAM are accessible to CE and IT managers within HDOs

Stage 3

- Develop an excel tool based on the PAM which will assist the HDOs in self-assessing conformance with IEC 80001-1.
- Present the process scoring mechanism within the excel tool based on the PAM which will assist the HDOs in self-assessing conformance with IEC 80001-1.

- Present the terminology from the PAM, within the excel tool in a more accessible, useable form to medical device and IT managers within HDOs.
- Evaluate if the excel tool can assist medical device and IT managers within HDO to self-assess compliance with IEC 80001-1.
- Evaluate if the excel tool can assist medical device and IT managers within HDOs to identify where resources and processes are required.

1.11 Overview of the Research

This research sets out to determine if the PAM within ISO/TR 80001-2-7 is accessible to HDOs within an Irish healthcare context. To achieve this, the researcher needed to determine the knowledge and accessibility of the International Electrotechnical Commission Standard IEC 80001-1 and its technical report ISO/TR 80001-2-7 within Irish health-care delivery organisation. This standard defines roles, responsibilities and activities in relation to the management of risk associated with placing a medical device onto an IT network and the technical report gives guidance to HDOs on how to self-assess their conformance with IEC 80001-1. The technical report contains a PAM which can be adapted and used by the HDOs to self–assess their conformance with IEC 80001-1.

A literature review was conducted which highlighted the difficulties faced by HDOs in understanding and applying the requirements of this standard. The literature review also highlighted the lack of adoption of IEC 80001-1 and lack of knowledge of ISO/TR 80001-2-7.

The research consisted of three different stages and was targeted at the Information Technology and Clinical Engineering Managers within the HDOs. These are the people responsible for the management of Information Technology and medical devices. An overview of the research process is presented in Fig 1-3.

Stage 1 consisted of,

- Creation of an online questionnaire for Information Technology and Clinical Engineering Managers nationally, to ascertain their knowledge, accessibility and adoption of IEC 80001-1 and its Technical Report ISO/TR 80001-2-7.

The purpose is to determine a baseline for the awareness and adoption of the standard nationally and identify possible barriers to its implementation.

Stage 2 consisted of,

- Focus groups, held with the Information Technology and Clinical Engineering Managers within the Children's Hospital Group consisting of the 3 Children's hospitals (Our Lady's Children's Hospital Crumlin, University Children's Hospital Temple Street, National Children's Hospital Tallaght). These were chosen as the sample group to determine the accessibility and usability of the PAM presented in ISO/TR 80001-2-7.

The purpose of these focus groups is to determine the accessibility and usability of the PAM and inform the development develop an excel tool which will present the PAM in a more useable format.

Stage 3 consisted of,

- Creation of an online questionnaire which was sent to the Information Technology and Clinical Engineering Managers within the Children's Hospital Group to determine the accessibility and usability of the PAM as presented in the Excel tool developed by the researcher.

The purpose is to do a comparison between the usability of the PAM as presented in ISO/TR 80001-2-7 and as presented in the excel tool developed by the researcher. It is envisaged that an optimally designed excel application will help the relevant people in HDOs to self-assess their conformance with IEC 80001-1 using the PAM defined in ISO/TR 80001-2-7, and also identify resources and processes that are required to implement an IEC 80001-1 medical IT network.

Overview of the Research Process

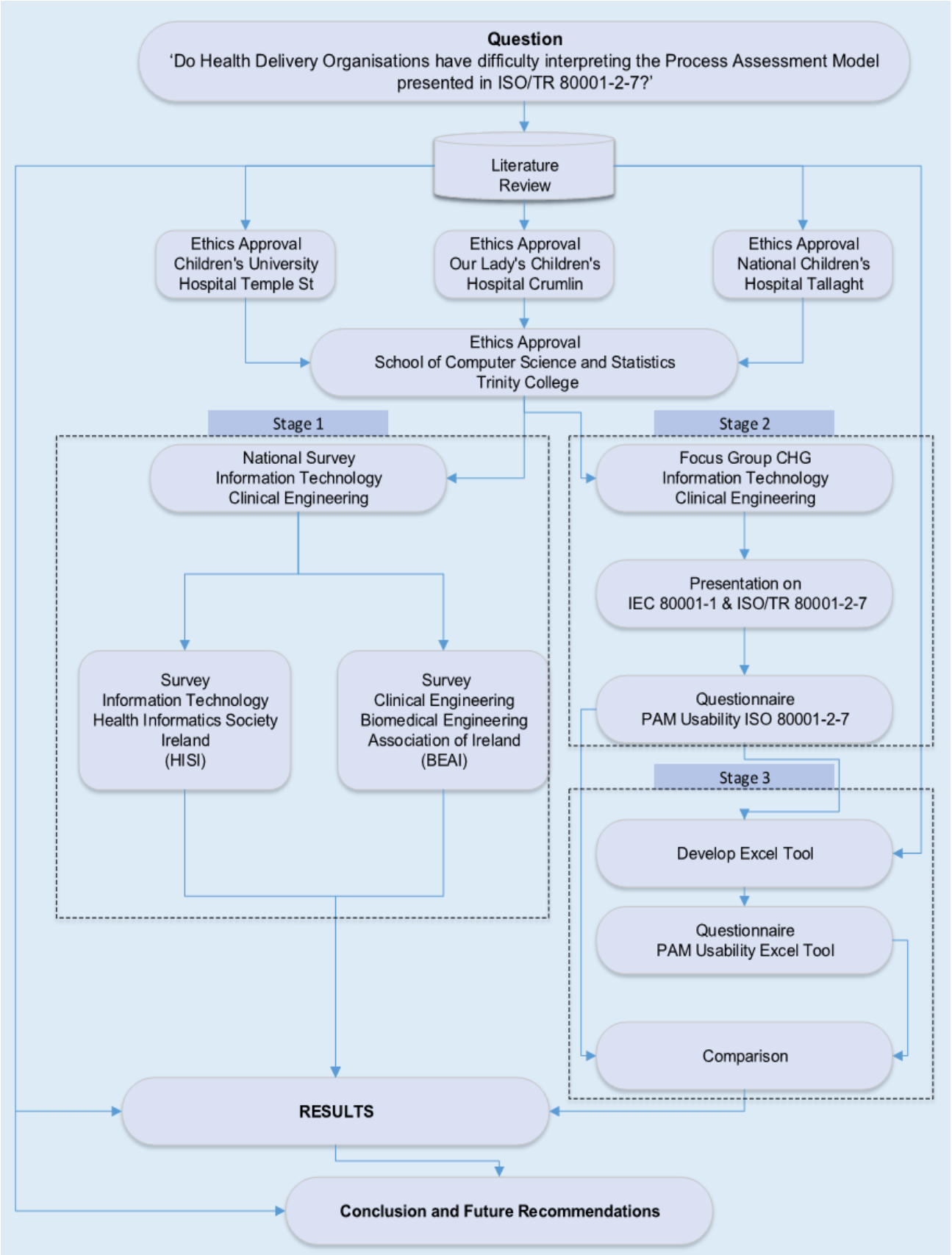

Figure 1-3 Overview of the Research Process

1.12 Overview of the Dissertation

Chapter one of the dissertation introduces the background to the research question and details the advancement in medical and IT technology which has resulted in HDOs incorporating medical devices onto heterogeneous networks. The associated risks and the ISO standard and technical report published to address these risks are presented. The research question and aims of the research are introduced.

Chapter two details the literature review and examines the challenges and associated risks faced by HDOs when placing a medical device onto a medical IT network. The literature highlighted the difficulties HDOs are experiencing in understanding and applying the requirements of this standard. The literature review also highlighted the lack of adoption of IEC 80001-1 which resulted in the publication of the technical report ISO/TR 80001-2-7. This technical report contains a process assessment model and method developed to assists HDOs self-assesses their conformance with IEC 80001-1. The lack of literature on the adoption and application of this technical report is identified. The literature review also highlights a commitment from senior management and investment in people, processes and the development of special tools as essential requirements for the successful adoption and implementation of standards.

Chapter three detailed the development of the excel tool. Following on from the literature review the researcher decided to present the PAM in ISO/TR 80001-2-7 in a more user friendly and accessible format. Excel pivot table and slicer functionality is used to present the information in a dashboard style format. The functionality of the excel tool is presented.

Chapter four introduces and outlines the research methodologies used and the rational for the selection of the research groups. The national survey and questionnaires with the three Children Hospitals personnel are presented and outlined. The ethical approval process which included the three Children's Hospitals and the School of Computer Science and Statistics in Trinity College all of which had different application procedures is presented.

Chapter five discusses the results of the three research studies and presents these in a graphical and tabular format along with analysis. These results confirm that there is not a widespread knowledge and application of IEC 80001-1 and ISO/TR 80001-2-7. The presentation of the PAM within a dashboard style format improves usability.

Chapter six reviews the research aim and objectives and how they were met. The chapter discusses the strengths and limitations of the study and makes recommendations for future research and concludes with the researchers reflections on the study. This concludes the report.

Chapter 2 - Literature Review

2.1 Introduction

This chapter lays out the process for the literature review, starting with the definition of a medical device and a description of a medical IT network. The risks to patient safety associated with placing medical devices onto IT networks are discussed. The chapter presents the IEC 80001-1 standard and its technical reports published to help HDOs identify and manage risks associated with the incorporation of medical devices onto IT networks. The chapter focuses on the Technical Report ISO/TR 80001-2-7 which gives guidance to HDOs on how to self-assess their conformance with IEC 80001-1, and the PAM within and concludes with a focus on the adoption and implementation of IEC 80001-1 and ISO/TR 80001-2-7.

2.2 Background

Traditionally, medical devices were designed as stand-alone devices and if they were required to be networked e.g. (Physiological Monitors in an ICU), they were placed onto a proprietary IT network provided and maintained by the manufacturer of the device (Gardner and Shabot, 2001) (Sampson Rod, 2016) Fig 1-1. A transformation in the IT architecture in health delivery organisations (HDO) is taking place which involves converging all the HDOs IT systems, applications and medical devices together on one single infrastructure utilising a common network Fig 1-2. This converged network can provide a number of benefits such a reduction in costs of care by ensure that the right information is available to the right person, where and when they need it (Sampson Rod, 2016). This results in a reduction in adverse events, leading to improved patient safety (McKinsey&Company, 2010) (West Health, 2013).

All medical devices are strictly regulated and tested however the incorporation of a medical device onto an IT network can introduce additional risks, compromising the safety, effectiveness and the data and system security of the IT network (Rakitin, 2006) (IEC, 2010).

In 2010 the IEC 80001-1 standard was developed to identify and address these risks. HDOs faced a number of challenges caused by the complexity of the different environments and diversity of stakeholders when trying to implement this standard (Cooper and Fuchs, 2013).

In 2015 ISO/TR 80001-2-7 application guidelines were published to help HDOs self-assess their conformance with IEC 80001-1. This includes a process assessment model (PAM) comprising 14 distinct process with their corresponding assessment questions and rating scales which help to identify the strengths and weaknesses of each process. The output from the PAM will help HDO improve risk management practices and conformance with IEC 80001-1 (ISO/IEC, 2015a).

2.3 Search Strategy

An extensive literature review was carried out in order to inform the subject matter of this thesis. Primarily electronic information searches where performed and these are listed in Table 2-1.

Table 2-1 Electronic Information Search Details

Electronic Information Search Details	
Databases	TCD library Stellar Search, PubMed, Science Direct, Scopus, Google, Google Scholar,
Type	Journals, Websites, Standards, Reports, White Papers, Government Publications, Academic Papers,
Key words "Terms" Searched	Medical Device, Physiological Monitor, Medical IT Network, Converged Network, Patient Safety and Risk, IEC/ISO Standards, IEC 80001-1, ISO/TR 80001-2-7,
Criteria	Language: English Years: All

2.4 Medical Devices

The World Health Organization (WHO) categories medical devices as devices for the diagnosis, prevention, rehabilitation and treatment of illness and disease and defines them as follows (WHO, 2013a):

" *any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of*:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury*
- *investigation, replacement, modification, or support of the anatomy or of a physiological process*
- *supporting or sustaining life*
- *control of conception,*
- *disinfection of medical devices*
- *providing information by means of in vitro examination of specimens derived from the human body*"

Within the European Union medical devices are strictly regulated and are governed by the Medical Device Directive MDD 93/42/EEC including Directive 2007/47/EC which outlines essential requirements on safety, performance and labelling that all medical devices must adhere to (European Council, 2007).

Medical devices have evolved from standalone analogue-computer technology to digitalised medical devices incorporating multiple microcomputers controlled by sophisticated software programs (Gardner and Shabot, 2001) (Rakitin, 2006).

2.5 Physiological Monitor

Gardner et al quoting Hudson [Hudson, 1985, p. 630] define physiological monitoring as *"repeated or continuous observations or measurements of the patient, his or her physiological function, and the function of life support equipment, for the purpose of guiding management decisions, including when to make therapeutic interventions, and assessment of those interventions*" (Gardner and Shabot, 2001).

The standard vital signs for routine physiological monitoring include non-invasive arterial blood pressure (sphygmomanometer), respiratory rate, pulse rate, temperature and arterial blood pressure (Major and d, 1954). These vital signs have been recorded in all hospital charts since 1912, and have become the primary basis to determine and measure the continuous physiological status of the critically ill patient. As medicine and technologies have advanced these physiological vital signs have progressed from just documenting the diagnosis or the demise of a patient to enabling physicians make life saving decisions for therapeutic intervention (Glaeser and Thomas, 1975).

Modern physiological monitors are sophisticated medical devices used to assess the physiologic parameters of a patient and detect changes in the patient's condition before they become clinically evident and significant. These medical devices contain multiple microcomputers which are capable of acquiring, displaying and managing all the clinical data from the patient. They can also incorporate and display data from external systems such as clinical laboratories, bedside point of care systems and medical devices e.g. ventilators, infusion pumps and specialised diagnostic equipment (Gardner and Shabot, 2001).

Historically patient monitors were designed as stand-alone devices and if they were required to be networked (e.g. Physiological Monitors in an ICU) they were placed onto a proprietary IT network provided and maintained by the manufacturer of the device (Sampson Rod, 2016). This also allowed clinicians to remotely view individual patient bedside monitors for vital signs, real time information and trend data using the hospitals intranet or the internet. The availability of this data resulted in the development of specialized information systems, which were then integrated into other hospital information systems e.g. laboratory information system (LIS), patient administration system (PAS) and picture archiving and communications systems (PACS). These systems support the continuum-of-care approach to patient care and have become widespread throughout HDOs (Gardner and Shabot, 2001)

2.6 Medical IT Network

Patient monitoring systems were initially installed on stand-alone networks with dedicated infrastructure isolating the monitors on their own network (Institute, 2013). These proprietary physiological monitoring networks were supported by hospital clinical engineering staff in conjunction with specialists from the vendor. Many of these monitoring applications have been installed over time in different departments within the HDO, each with its own dedicated infrastructure. Gateways have been introduced which allow data exchange between the monitoring systems and hospital administration systems (Sampson Rod, 2016). A McKinsey report in 2010 stated that the simplification of the IT architecture is necessary; if HDO want to integrate information from medical devices and computerized physician order entry systems into an electronic health record (EHR) (McKinsey&Company, 2010).

An IT network is defined as two or more computers connected together via a communications channel e.g. ethernet cable, phone lines or wirelessly and its function is to share files or information between the computers (Christensson P, 2006).

When a HDO, irrespective of its size connects at least one medical device onto a IT network that network then becomes a medical IT network (IEC, 2010). Increasingly, electronic medical devices such as physiological monitors are being connected to each other and to other technologies and information is exchanged and shared between these devices. The effective interconnectivity of various medical devices and systems is dependent on the secure transfer and use of information. Rakitin refers to this interconnectivity of medical devices and systems as *"interoperability*". This interoperability has the potential to promote innovation and facilitate new methods and models of healthcare delivery, resulting in increased efficiency and outcomes in patient care (Rakitin, 2009) (McKinsey&Company, 2010) (Administration and Drug, 2016). These shared networks facilitate the transfer of information between interoperable medical devices and their related systems while also allowing the transfer of video, telephone and data communication. The purpose of these heterogeneous networks is to ensure that the right information is available to the right person, where and when they need it (Sampson Rod, 2016). The interoperability of medical devices sharing a common network improves medical device capabilities and ease of use however it also adds complexity and therefore increases risk (Baker et al., 2013).

2.7 Patient Safety and Risk

The World Health Organisation (WHO) defines patient safety as the *"prevention of errors and adverse effects to patients associated with health care"* (WHO, 2017), and statistics from the WHO indicate that approx. 43 million patient safety incidences occur every year equating to 1 in every 10 patients being affected.

Communication failures between physicians, resulting in poor information relating to the clinical condition of a patient being communicated, is one of the most common factors contributing to adverse advents (Bates and Gawande 2003). The authors also suggests that the correct use of information technology can improve patient safety by improved communications and the availability of clinical decision support based on real time patient data from connected medical devices.

Whitehead et al suggests that the safe effective and efficient treatment of high acuity patients is achieved by the integration of individual medical devices into a networked infrastructure reducing healthcare costs and improving patient safety. This is achieved by the availability of real time patient information, early warning scores and clinical decision support systems based on that information and also includes medical device safety interlocks, compatibility and inventory management, closed loop medication delivery systems and availability of remote surveillance (S. Whitehead and J. Goldman, 2008). The Anaesthesia Patient Safety Foundation (APSF) stated that patient safety could be improved by the interoperability of medical devices and advocates the seamless intercommunication of these devices (S. Whitehead and J. Goldman, 2008).

There are multiple definitions of risk. In healthcare risk is defined *as "the probability that a specific adverse event will occur in a specific time period or as a result of a specific situation*" (NPSA, 2007). The International Electrotechnical Commission (IEC) defines risk in relation to medical networks as a *"combination of the probability of occurrence of harm and the severity of that harm"* (IEC, 2010).

The complexity of the integration of interoperable medical devices and systems onto heterogeneous network combined with their pivotal role in the delivery of care to the patient, introduces new unintended consequences which are outside of the control of the medical device manufacture and introduce risks that need to be identified and managed (Eagles, 2008) (Delvecchio, 2011).

An unintended consequence identified by the Food and Drug Administration (FDA) in 2013 was the potential for computer controlled medical devices being infected by viruses which can endanger patients. The FDA for the first time recommended that manufacturers of medical devices, when applying for FDA approval for their devices should include security measures to protect against cyber-attacks (Weaver, 2013). The same source also quoted the FDA warning HDOs to be more vigilant when it comes to cybersecurity and medical devices, citing statistics from the Department of Veterans Affairs from 2009--2013 indicating that malware affected 327 devices within the hospital group with more than 40 viruses infecting medical devices such as x-ray machines, laboratory equipment and physiological monitors (Weaver, 2013) (Talbot, 2012).

Sametinger et al, reported that as a result of this technological advancement and interconnectivity, medical devices have become vulnerable to international cyber threats allowing unauthorised access enabling change of settings and loss of data (Sametinger et al., 2015). Statistics from the Privacy Rights Clearinghouse (Privacy Rights, 2017) a non-profit corporation, whose mission is to engage educate and empower individuals to protect their privacy, show a sharp rise in the number of HDOs who have been hacked (Fig 2-1 configured from Privacy Rights Clearinghouse statistics). The total number of medical records affected is 16,736,544.

Number of Reported Hacks on HDO in the USA 2010-2016

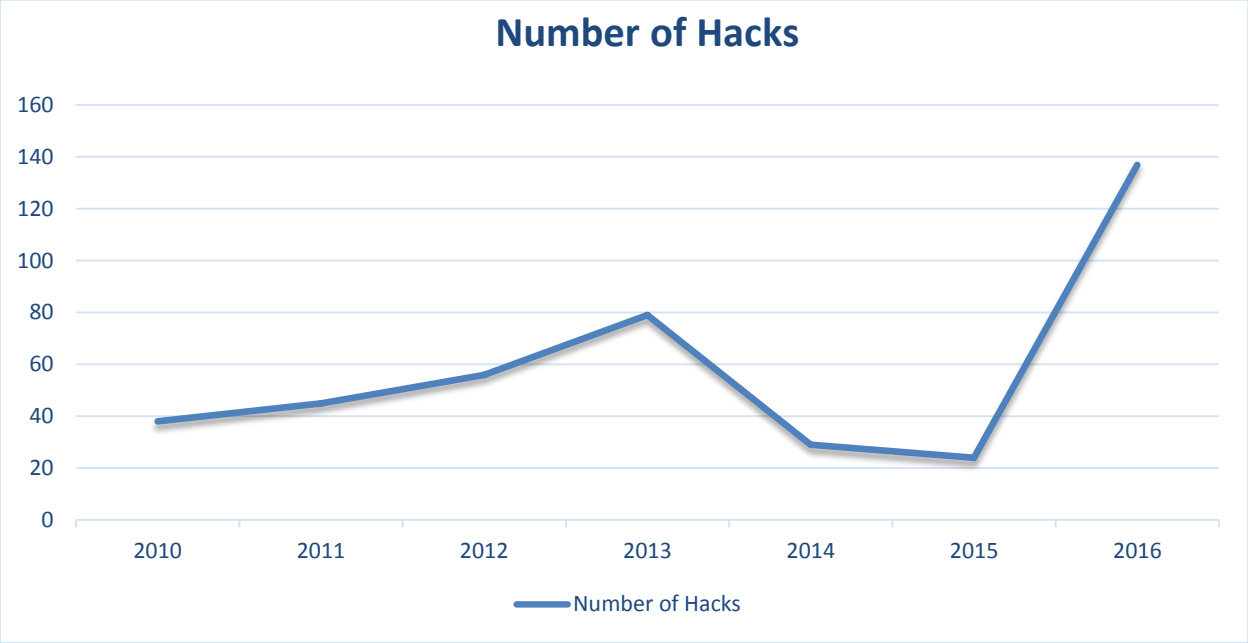

Figure 2-1 Number of Reported Hacks

As healthcare advances with the increased interoperability and connectivity of electronic medical devices there is an increased risk to HDOs by computer viruses and malicious attacks compromising data and systems security and patient safety. HDO need to put suitable counter measures in place to protect against these threats (Magrabi et al., 2013) (Sametinger et al., 2015).

2.8 IEC 80001-1

From 2000 onwards there was an increase in the integration of software into medical devices and implantable medical devices (IMD). This combined with the integration of medical device onto IT networks and a number of reported serious system failures involving networked medical devices (Cooper and Eagles, 2011) (A J Burns, 2016), prompted the FDA to convene a meeting with the relevant clinical engineering, healthcare provider and medical

device manufacturers. The purpose of this meeting was to discuss the lack of guidelines and explore methods to improve the safe use of networked medical devices (Administration and Drug, 2005). The outcome of this 2005 meeting resulted in a working group of international experts under the auspices of the ISO/IEC being established to develop guidelines that could be adopted by HDOs to help identify and manage risks associated with the incorporation of medical devices onto IT networks. This working group developed the Standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" which was published in 2010 (IEC, 2010). IEC 80001-1 states that any IT network within a HDO which has at least one medical device connected is categorised as a medical IT network. The goal of IEC 80001-1 is to prevent patient harm and three areas are identifies,

- Safety - to the patient and caregivers.
- Efficacy - of the medical device or medical system.
- Security - of the medical IT information infrastructure.

The standard requires that a comprehensive risk management policy be implemented to protect these (IEC, 2010).

The standard defines roles, responsibilities and activities in relation to the management of risk associated with placing a medical device onto an IT network for the following:

- Health Delivery Organisation.
- Medical Device Manufacturer.
- Other providers of IT equipment on the network.

The IEC 80001-1 standard recognises that overall responsibility for the medical IT network belongs with the HDO, who must work in conjunction with the manufacturer of any medical devices placed on the network and the suppliers of other products incorporated into the network, to ensure that all risks are identified and managed (IEC, 2010).

The standard uses a process approach by specifying the activities required by the HDOs, medical device manufacturer and IT vendors when medical devices are connected to an IT network. ISO define a process as a "*set of interrelated or interacting activities that use inputs to deliver an intended result*" and note that the inputs and outputs may range from materials and goods to software and knowledge (ISO, 2017a). This standard does not advise on the networking of medical devices or define the associated risks. Hong et al describes the IEC

80001-1 standards as technical instruction manuals for individuals within HDOs who are responsible for medical device integration (Hong Li, 2014).

2.9 IEC 80001-1 Technical Reports

Since the publication of IEC 80001-1, a number of technical reports have been published to address specific aspects and assist the individuals responsible for the different aspects of medical device integration into IT networks in the implementation of the standard. These are as shown in Table 2-2 below.

Table 2-2 IEC 80001-1 Technical Reports

Name	Description	Published
IEC/TR 80001-2-1	Application of risk management for IT-networks incorporating medical devices -- Part 2-1: Step by Step Risk Management (ISO/IEC, 2012a).	2012
IEC/TR 80001-2-2	Application of risk management for IT-networks incorporating medical devices -- Part 2-2: Guidance for the communication of medical device security needs, risks and controls (ISO/IEC, 2012b).	2012
IEC/TR 80001-2-3	Application of risk management for IT-networks incorporating medical devices -- Part 2-3: Guidance for wireless networks(ISO/IEC, 2012c).	2012
IEC/TR 80001-2-4	Application of risk management for IT-networks incorporating medical devices -- Part 2-4: General implementation guidance for Healthcare Delivery Organizations (ISO/IEC, 2013b).	2013
IEC/TR 80001-2-5	Application of risk management for IT-networks incorporating medical devices -- Part 2-5: Application guidance -Guidance for distributed alarm systems (ISO/IEC, 2014a).	2014
IEC/TR 80001-2-6	Application of risk management for IT-networks incorporating medical devices Part 2-6: Application guidance — Guidance for responsibility agreements (ISO/IEC, 2014b).	2014
ISO/TR 80001-2-7	Application of risk management for IT-networks incorporating medical devices Part 2-7: Application guidance -- Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1 (ISO/IEC, 2015a).	2015
IEC/TR 80001-2-8	Application of risk management for IT-networks incorporating medical devices -- Part 2-8: Application guidance -- Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2 (ISO/IEC, 2016).	2016

2.10 Adoption of IEC 80001-1

A review of the literature since the standard was published, primarily provides high level advice to HDOs on how to acquaint themselves with the requirements of the standard and its technical reports. In an interview with The Philip Trace Journal, one of the co-authors of IEC 80001-1 acknowledged that HDOs would require assistance in understanding and

implementing the requirements of the standard and its technical reports (Scharff, 2011). He also stated that one of the biggest challenges facing the adoption and implementation of the standard was the ability of the manufacture and the different stake holders within the HDOs to cooperate and collaborate. He specifically identified the Information Technology and Clinical Engineering departments whom have responsibility for IT infrastructure and medical devices and suggested that they would have to work together and make the necessary compromises to manage the risks (Scharff, 2011) (Rakitin, 2009).

The challenges presented to HDO trying to adopt and implement IEC 80001-1 are recognised by Cooper and Fuchs (Cooper and Fuchs, 2013). A Phased approach is recommended, starting with small manageable projects and learning from them and using that knowledge and experience to progress to larger projects. Cooper et al (Cooper and Eagles, 2011) also acknowledge that cooperation between the different stakeholders is essential if the standard is to be implemented observing that education within HDOs on the standard and its technical reports is crucial to its success. Schrenker et al (Schrenker and Hampton, 2011) observed that due to the size and complexity of HDOs no single approach would facilitate the implementation and application of the standard. Delvecchio (Delvecchio, 2011) suggests four recommendations that HDOs should implement to improve the adoption of IEC 80001-1,these are:

- Education in the requirements of IEC 80001-1 and its technical reports
- Establish a risk assessment process for medical IT networks
- Identify Stakeholders, internal and external and establish communications
- Start with small scale projects when implementing IEC 80001-1.

IEC 80001-1 adoption as a risk management assessment tool for assessing the integration of medical devices onto IT networks does not appear to be very widespread (Eckhardt et al., 2015). Eckhardt et al who, as a result of a patient safety incident applied IEC 80001-1 to the integration of a real time alarm communication and management system in a long term patient care facility in a Canadian hospital. They reported that the process approach outlined in IEC 80001-1 for identifying risks associated with incorporating a medical device on an IT network were very effective and identified multiple risks associated with their proposed networked technical solution and workflows. They found that while the process identified risks relating to the medical devices it also identified risks relating to usability, staffing duties

and operational costs and concluded that the Standards process approach resulted in substantial savings and risk reduction within the unit, while also improving best practice as new risks are continually identified (Eckhardt et al., 2015). Hegarty, et al, using IEC 80001-1 to self-assess a medical IT network in a large academic teaching hospital in Dublin found the process assessment very useful in informing the HDO of their responsibilities and the processes and resources required, however they found that the language used and the specific requirements detailed, difficult to interpret within a health care framework (Hegarty et al., 2014).

Ahlbrandt et al applied IEC 80001-1 process to risk assess a chain of medical devices in a test environment for an ICU bedside in a hospital in Germany and identified eleven risks which could potentially affect the patient safety. These risks were successfully addressed. They concluded that while the risk management process increased the work load, time and effort involved in placing a medical device onto an IT network, the ability to identify and mitigate potential risks outweighed this and suggested that HDO should start with small scale projects when implementing IEC 80001-1 (Ahlbrandt and Röhrig, 2013).

2.11 ISO/TR 80001-2-7

Previously stated, the adoption of IEC 80001-1 as a risk management assessment tool for assessing the integration of medical devices onto IT networks does not appear to be very widespread (Eckhardt et al., 2015) and the literature primarily provides high level advice to HDOs on how to acquaint themselves with the requirements of the standard and its technical reports.

HDOs faced a number of challenges caused by the complexity of the different environments and diversity of stakeholders when trying to implement the requirements of this standard making them confusing and difficult to implement. This combined with the lack of a process assessment model contribute to the lack of adoption and implementation of the standard (MacMahon et al., 2012) (Cooper and Fuchs, 2013).

In 2015 the IEC published a technical report entitled ISO/TR 80001-2-7:2015.

- Application of risk management for IT-networks incorporating medical devices - Application guidance - Part 2-7: “Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1”.

This includes a process assessment model (PAM) incorporating an assessment method comprising of 14 distinct process with their corresponding assessment questions and rating scales which help to identify the strengths and weaknesses of each process. The output from the PAM will help HDOs improve risk management practices and conformance with IEC 80001-1 (ISO/IEC, 2015a).

2.11.1 Process Assessment Model (PAM)

The exemplar process assessment model (PAM) presented in ISO/TR 80001-2-7 includes a set of indicators which can be used by a HDO to self-assess their performance of risk management of a Medical IT-Network incorporating a medical devices (ISO/IEC, 2015a).

The PAM shown in Table 2-3, includes 4 process groups incorporating 14 distinct processes. The process groups are:

- Medical IT Network Risk Management Process Group (MRM) Table 2-4
- Change Release Management & Configuration Management Process Group (CRCM)
- Live Network Risk Management Process Group (LNRM)
- Medical IT Network Documentation and Planning Process Group (MDP)

Table 2-3 PAM - Processes Assessment Model

Process Assessment Model (PAM) Process			
Medical IT Network Risk Management Process Group (MRM)		**Change Release Management & Configuration Management Process Group (CRCM)**	
MRM.1	Medical IT Network Risk Management Process	**CRCM.1**	Change Release and Configuration Management
MRM.1.1	Risk Analysis & Evaluation	**CRCM.2**	Decision on how to apply Risk Management
MRM.1.2	Risk Control	**CRCM.3**	Go Live
MRM.1.3	Residue Risk		
Live Network Risk Management Process Group (LNRM)			
LNRM.1	Monitoring		
LNRM.1.1	Event Management		
Medical IT Network Documentation and Planning Process Group (MDP)			
MDP.1	Medical IT Network Planning		
MDP.2	Medical IT Network Documentation		
MDP.3	Responsibility Agreements		
MDP.4	Risk Management Policy		
MDP.5	Organisational Risk Management Process		

Medical IT Network Risk Management Process Group (MRM) is the first process group relating to the Risk Management Process of a medical IT network and is represented in Table 2-4.

Table 2-4 Medical IT Network Risk Management Process Group (MRM)

Medical IT Network Risk Management Process Group (MRM)	
MRM.1	Medical IT Network Risk Management Process
MRM.1.1	Risk Analysis & Evaluation
MRM.1.2	Risk Control
MRM.1.3	Residue Risk

2.11.2 Process Assessment Method

The assessment method includes a set of assessment questions which can be customised by the HDO. These questions can then be used to perform a self-assessment of the HDOs conformance with the requirements of the ISO 80001-1 standard and also identify the capability levels of each process. The questions relate to specific process performance indicators called base practices within each process which are used to determine the capability level of the process. The capability level categorised by ISO/IEC 15504-2 defines six Capability levels (ISO/IEC, 2004), capability level zero (Incomplete Process) to capability level five (Optimizing Process) Fig 2-2.

The assessment method recommends assessment to capability level one (Performed Process) and is calculated on the average rating of the base practices related to that process (ISO/IEC, 2013a). The base practices are assigned a rating using objective evidence gathered during assessment using a four-point (N-P-L-F) rating scale

- Not achieved (0 - 15%)
- Partially achieved (>15% - 50%)
- Largely achieved (>50%- 85%)
- Fully achieved (>85% - 100%)

The aim of the assessment method is to use the assessment questions to identify areas within the risk management process which have not achieved capability level one (Performed Process) and give recommendations on how to achieve capability level one (ISO/IEC, 2015a).

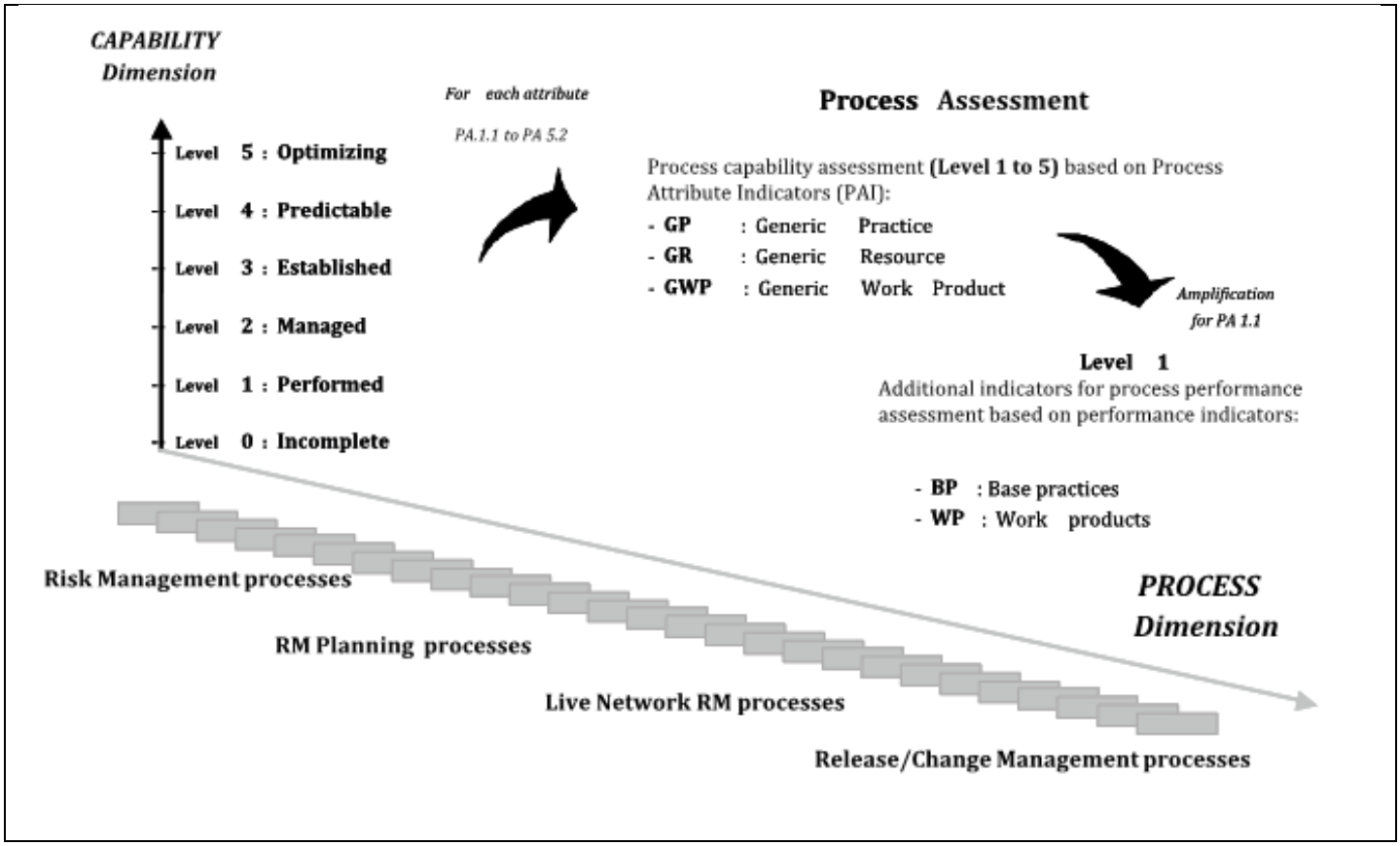

Figure 2-2 Process Assessment Indicators (ISO/IEC, 2015a)

The results of the assessment will highlight any weaknesses within current risk management processes and can be used as a basis for the improvement of these.

The Process Assessment Method for the first process group, Medical IT Network Risk Management Process Group (MRM) including the process indicators (base practices) and assessment questions has been extracted by the researcher from ISO/TR 80001-2-7 and presented in the Table 2-5 (ISO/IEC, 2015a).

Table 2-5 MRM.1-MRM.1.3 Base Practice and Questions

MRM.1	**Medical IT Network Risk Management Process**	
BP1	Establish a Medical IT-Network Risk Management File.	
	Q1	Do you have a Medical IT-Network Risk Management File?
	Q2	How is the file stored, accessed, and maintained
BP2	Assign Risk Management Resources.	
	Q1	Have risk management resources been assigned?
BP3	Identify Risk Management Stakeholders and inform of their responsibilities.	
	Q1	Are risk management stakeholders identified and aware of their responsibilities?
BP4	Manage the Medical IT-Network throughout the life cycle as per the Risk Management Plan and Process.	
	Q1	Is a life cycle approach taken to the management of the Medical IT-Network?
	Q2	Are risk management activities performed according to the risk Management Plan and process?
	Q3	Are the key properties of the network considered during the performance of risk management activities?
BP5	Document Risk Management activities	
	Q1	Are risk management activities documented?
BP6	Review Risk Management Activities at defined intervals	
	Q1	Are risk management activities reviewed at defined intervals?
MRM.1.1	**Risk Analysis and Evaluation Process**	
BP1	Identify likely hazards	
	Q1	How do you Identify likely hazards?
BP2	Estimate, Analyse, and Evaluate associated risks.	
	Q1	How do you estimate, analyse, and evaluate associated risk for each identified hazard throughout the life cycle?
BP3	List possible consequences of harm.	
	Q1	How do you identify possible consequences of harm?
BP4	Record results of Risk Analysis and Evaluation activities.	
	Q1	How are the results of risk analysis and evaluation activities recorded?

Table 2-5 MRM.1-MRM.1.3 Base Practice and Questions (continued)

MRM.1.2	**Risk Control Process**	
BP1	Identify proposed risk control measures for each identified risk.	
	Q1	Are proposed risk control measures identified for every risk?
	Q2	How are risk control measures considered in relation to the key properties and prioritised?
BP2	Manage Risk Control measures under the Change/Release Management process.	
	Q1	Are risk control measures managed under the Change/Release Management Process?
BP3	Record selected risk control measures in a Medical IT-Network Risk Management File.	
	Q1	Are the selected risk control measures documented in the risk Management file?
BP4	Conduct risk/benefit analysis and document results including residual risk.	
	Q1	Is risk/benefit analysis of residual risk conducted (when risk reduction measures have been determined not to be practical) and are the results documented?
BP5	Implement Risk Control measures.	
	Q1	Are selected risk control measures implemented?
	Q2	How are risk control measures implemented?
BP6	Verify and document the implementation and effectiveness of risk control measures.	
	Q1	Is the implementation and effectiveness of risk control measures verified and documented?
BP7	Review and evaluate risk control measures and operational system and document results.	
	Q1	Are risk control measures and the operational system reviewed and evaluated and are the results documented?
MRM.1.3	**Review Residue Risk**	
BP1	Review Residue Risk	
	Q1	Is residue risk reviewed and assessed for acceptability?
BP2	Evaluate Residue Risk	
	Q1	Is residue risk evaluated.
BP3	Apply additional risk control measures.	
	Q1	Are additional risk control measures applied for unacceptable individual/overall unacceptable risks?
BP4	Define and document residual risk summary.	
	Q1	Is residual risk summary defined and documented?
BP5	Document risk/benefit analysis.	
	Q1	Is risk/benefit analysis of individual or overall residual risk documented?
BP6	Make decision on residual risk.	
	Q1	Is the decision on whether or not to approve the residual risk, based on the documented risk/benefit analysis?

2.12 Application of ISO/TR 80001-2-7

Kielty, L.A., in her thesis "Development & Validation of an Assessment Method for the International Standard IEC 80001-1. 2014", assessed the incorporation of a point of care (POC) blood gas analyser onto a medical IT network in the intensive care unit and observed that the assessment method was fit for purpose and highlighted the risks and strengths in relation to the medical IT network project. Kielty noted that the involvement of health care personnel in the development and assessment of standards helps raise awareness and positively affects the implementation of these standards. This ultimately benefit the patient in terms of patient safety (Kielty L A, 2014).

This researcher could not find any literature on the application and use of the process assessment model presented in ISO/TR 80001-2-7 and proposes that this is probably due to the fact that the technical report was only published in 2015.

2.13 Implementation of Standards

The significance of standards within healthcare to facilitate the integration of systems and transferral of data and information are widely recognised (Chen et al., 2012). Peijl et al describes a collaborative research project in the Netherlands between a university hospital, a medical device company and two universities on the implementation of the IEC 62366 (medical device standard for ''Application of Usability Engineering to Medical Devices'') and ISO 14971 (standard for risk management). The author identifies senior management support, multi-disciplined participation and the management of the project by specialist personnel as essential requirements for a successful outcome (van der Peijl et al., 2012).

Standards adoption at the United States Department of Veterans Affairs (VA), are described by Bouhaddou et al. The VA operates one of the largest health care systems in the world which include 152 hospitals, 800 community-based outpatient clinics, 126 nursing home care unit (Department of Veterans Affairs, 2017) and has a long history and experience of adopting and implementing a wide range of standards (Bouhaddou et al., 2012). The author describes the processes within the VA for implementing standards and summarises by outlining a generalised framework for the adoption of standards which involves:

- People: The Support and commitment of senior management and the identification and participation of all stakeholders including IT, informatics, clinical and technical personnel. Standard adoption and implementation is facilitated by internal staff with expertise in this area.

- Process: Well defined and documented processes which provide guidance through all aspects of standard adoption and implementation. Education for all employees describing what standards are, the value of standards to the organization, where to find information about them, how they are currently used and evidence of their positive impact on the organisation.
- Tools: The adoption and use of standards within an organisation is greatly increased when the standards are readily available and easy to read and understand and this can be facilitated by specific designed toolsets.

The author concludes by highlighting the benefits of standard adoption which include reduced software development and maintenance costs, increased internal and external interoperability resulting in more comprehensive information. This translates into improvements in patient experience and clinical outcomes (Bouhaddou et al., 2012).

2.14 Conclusion

The literature review confirms the rapidly changing environment within HDOs as more and more medical devices are incorporated onto heterogeneous IT networks. The literature review also examined the challenges and associated risks faced by HDOs when placing a medical device onto a medical IT network. The IEC 80001-1 standard was developed to assist HDOs identify the risks in dealing with these challenges. The literature highlighted the difficulties HDOs are having in understanding and applying the requirements of this standard. The literature review also highlighted the lack of adoption of IEC 80001-1; however in the few instances where it has been adopted the benefits of identifying and mitigating risk are very evident. The literature review identifies the technical reports published by the IEC to assist HDO to conform to the standard. Focusing on the technical report ISO/TR 80001-2-7 which contains a process assessment model and method developed to assists HDO self-assess their conformance with IEC 80001-1. The lack of a process assessment model and method has been indicated by a number of authors as the possible reason for the lack of adoption of IEC 80001-1. The literature review presents the process assessment model and method as detailed in ISO/TR 80001-2-7 and identifies the lack of literature on its adoption and application. Where standards have been successfully adopted and implemented a commitment from senior management is essential and an investment is required in people, processes and the development of special tools. Based on these findings the researcher proposes to present the PAM in ISO/TR 80001-2-7 in a more useable format using a excel tool. The development of that excel tool is outlined in the next chapter.

Chapter 3 - Excel Tool Development

3.1 Introduction

This chapter focuses on the iterative development of the excel tool. The literature review indicated that one of the factors that greatly increased the adoption and use of standards within an organisation was when the standards were readily available and easy to read and understand (Bouhaddou et al., 2012). One of the contributing factors to the successful achievement of this within the VA was the use of specially designed toolsets. Informed by the research and feedback from the focus groups the researcher developed a excel tool with the purpose of presenting the exemplar PAM in a more useable format.

The PAM Table 2-3, includes 4 process groups incorporating 14 distinct processes.

The process groups are:

- Medical IT Network Risk Management Process Group (MRM)
- Change Release Management & Configuration Management Process Group (CRCM)
- Live Network Risk Management Process Group (LNRM)
- Medical IT Network Documentation and Planning Process Group (MDP)

The excel tool focused on the first process Group MRM (Medical IT Network Risk Management Process Group), within the PAM Table 2-4.

MRM Medical IT Network Risk Management Process, provides a sample process from the PAM and was used by the researcher to develop the excel tool. ISO/TR 80001-2-7 is a paper based system which outlines the scope, assessment method, rating scales and presents an exemplar assessment method, assessment model and reference model. The purpose of this is to provide a standardised basis for configuring the exemplar assessment method when required (ISO/IEC, 2015a).

3.2 Medical IT Network Risk Management Process Group (MRM)

This process group contains four processes which focus on the practices in relation to risk management. The first process details the processes and resources required within a HDO in relation to risk management of a medical IT network. The remaining three processes relate to risk analysis, risk control and evaluation of residue risk. This process group (Medical IT Network Risk Management Process Group) Table 3-1 incorporates:

- 4 Processes MRM.1-MRM.1.3
  - MRM.1 Medical IT Network Risk Management Process
  - MRM.1.1 Risk Analysis and Evaluation Process
  - MRM.1.2 Risk Control Process
  - MRM.1.3 Review Residue Risk
- 28 questions
- 32 Outcomes (observable results of the successful achievement of the proposed process).

Table 3-1 MRM.1-MRM.1.3 Base Practice and Outcomes

Medical IT Network Risk Management Process Group (MRM)			
	Base Practice	Questions	Outcomes
MRM.1 Medical IT Network Risk Management Process	BP1 BP2 BP3 BP4 BP5 BP6	2 1 1 3 1 1	Out 1 Out 2,4 Out 5,6,8 Out 7,9 Out 1,10 Out 3
MRM.1.1 Risk Analysis and Evaluation Process	BP1 BP2 BP3 BP4	1 1 1 1	Out 1 Out 2 Out 3 Out 4,5
MRM.1.2 Risk Control Process	BP1 BP2 BP3 BP4 BP5 BP6 BP7	2 1 1 1 2 1 1	Out 1,2,3 Out 5,8 Out 6 Out 4,9 Out 7 Out 10 Out 11
MRM.1.3 Review Residue Risk	BP1 BP2 BP3 BP4 BP5 BP6	1 1 1 1 1 1	Out 1,3 Out 2 Out 4 Out 5 Out 6 Out 6

Annex A, of ISO/TR 80001-2-7 provides the exemplar assessment questions for each of the processes.

Annex B, of ISO/TR 80001-2-7 provides a process reference model (PRM) which details the description of the process, the context and purpose for each process and the outcomes for each process. Outcomes are defined as *"observable results of the successful achievement of the proposed process and are measureable, tangible, technical or business results that are achieved by a process"*. They are observable and assessable and are based on the requirements of IEC 80001-1 (ISO/IEC, 2015a).

Annex C, of ISO/TR 80001-2-7 provides an exemplar process assessment model (PAM) based on ISO/IEC 15504-02 which defines the requirements for performing an Information Technology process assessment (ISO, 2003). This PAM provides a set of indicators for evaluating process performance and capability.

3.3 Assessment Method

The assessment method includes a set of assessment questions which can be customised by the HDO. These questions can then be used to perform a self-assessment of the HDOs conformance with the requirements of the IEC 80001-1 standard and also identify the capability levels of each process. The questions relate to specific process performance indicators called base practices (BP) within each process which are used to determine the capability level of the process. The capability level categorised by ISO/IEC 15504-2 defines six capability levels, capability level zero (Incomplete Process) to capability level five (Optimizing Process) Fig 2-2. For the basis of this research each process is assessed to capability level one (Performed Process) and is calculated on the average rating of the base practices related to that process (ISO/IEC, 2013a). The base practices are assigned a rating using objective evidence gathered during assessment using a four-point (N-P-L-F) rating scale:

- Not achieved (0 - 15%)
- Partially achieved (>15% - 50%)
- Largely achieved (>50%- 85%)
- Fully achieved (>85% - 100%).

The aim of the assessment method is to use the assessment questions to identify areas within the risk management process which have not achieved capability level one

(Performed Process) and give recommendations on how to achieve capability level one (ISO/IEC, 2015a).

The results of the assessment will highlight any weaknesses within current risk management processes and can be used as a basis for the improvement of these.

3.4 Excel Tool Development

Microsoft excel which is easy to use and is readily available was chosen for the analysis stage and also to develop a dashboard style tool to present the information in a more accessible format. MRM Medical IT Network Risk Management Process was chosen as a sample process from the PAM to validate the excel tool functionality and usability.

To develop the excel tool the researcher incorporated the questions for the Medical IT Network Risk Management Process Group from Annex A in ISO/TR 80001-2-7 with their corresponding outcomes from Annex B in ISO/TR 80001-2-7 into a single table (Table 3-2).

The narrative relating to the context and purpose of each process from Annex B as well as the description and guidance of each process from annex A was also extracted precisely from ISO/TR 80001-2-7 with the objective of presenting it on one view within the excel tool.

Table 3-2 MRM.1-MRM.1.3 Questions with corresponding Outcomes

Base Practice	Question	Outcome	
MRM.1	**Medical IT Network Risk Management Process**		
MRM.1-BP1-Q.1	Do you have a Medical IT-Network Risk Management File?	1	A Medical IT-Network Risk Management file is established and maintained containing all required documentation.
MRM.1-BP1-Q.2	How is the file stored, accessed, and maintained.	1	A Medical IT-Network Risk Management file is established and maintained containing all required documentation.
MRM.1-BP2-Q.1	Have risk management resources been assigned?	2	Adequate appropriately qualified resources for management, performance of work, and assessment activities are assigned.
		4	A qualified medical IT-network risk manager is appointed.
MRM.1-BP3-Q.1	Are risk management stakeholders identified and aware of their responsibilities?	5	People responsible for Risk Management activities and lifecycle management (including procurement and maintenance) of medical devices incorporated into IT networks, co-operate with the medical IT-network risk manager.
		6	Risk management process for medical IT-networks includes the participation of management responsible for life cycle management of Medical IT-Networks, general IT activities and the use of Medical Devices.
		8	All parties performing supervision, operation, installation, service, troubleshooting, and maintenance of Medical IT-Network(s) are adequately informed about their responsibility according to this standard, including their responsibility for maintaining the effectiveness of Risk Controls.
MRM.1-BP4-Q.1	Is a life cycle approach taken to the management of the Medical IT-Network?	9	The key properties of the medical IT-network are maintained throughout the life cycle.
MRM.1-BP4-Q.2	Are risk management activities performed according to the risk Management Plan and process?	7	All supervision, operation, installation, and maintenance of Medical IT-Network(s) throughout the life cycle are made according to the Risk Management plan and follow the results of the IT-Network Risk Management Process.

Table 3-2 MRM.1-MRM.1.3 Questions with corresponding Outcomes (Continued)

Base Practice	Question	Outcome	
MRM.1 Medical IT Network Risk Management Process			
MRM.1-BP4 Q.3	Are the key properties of the network considered during the performance of risk management activities?	7	All supervision, operation, installation, and maintenance of Medical IT-Network(s) throughout the life cycle are made according to the Risk Management plan and follow the results of the IT-Network Risk Management Process.
MRM.1-BP5 -Q.1	Are risk management activities documented?	1	A Medical IT-Network Risk Management file is established and maintained containing all required documentation.
		10	The risk management activities of risk analysis, risk evaluation, risk control, residual risk evaluation, and reporting and approval are documented.
MRM.1-BP6-Q.1	Are risk management activities reviewed at defined intervals?	3	The results of risk management activities, including event management, are reviewed at defined intervals.
MRM.1.1 Risk Analysis and Evaluation Process			
MRM.1.1-BP1-Q.1	How do you Identify likely hazards?	1	Hazards that are likely to arise from the medical IT–network are identified.
MRM.1.1-BP2-Q.1	How do you estimate, analyse, and evaluate associated risk for each identified hazard throughout the life cycle?	2	For each identified hazard, the associated risks are estimated, analysed and evaluated using available information or data throughout the lifecycle.
MRM.1.1-BP3-Q.1	How do you identify possible consequences of harm?	3	Possible consequences of harm (where probability of occurrence cannot be estimated) are listed for use in risk control.
MRM.1.1-BP4-Q.1	How are the results of risk analysis and evaluation activities recorded?	4	The results of these activities are recorded in the medical IT-network risk management file.
		5	Where the estimated risk(s) is so low that risk reduction need not to be pursued, the rationale for this decision is documented in the medical IT-network risk management file.

Table 3-2 MRM.1-MRM.1.3 Questions with corresponding Outcomes (Continued)

Base Practice	Question	Outcome	
MRM.1.2 Risk Control Process			
MRM.1.2-BP1-Q.1	Are proposed risk control measures identified for every risk?	1	Proposed risk control measures are identified and documented for each unacceptable risk.
MRM.1.2-BP1-Q.2	How are risk control measures considered in relation to the key properties and prioritised?	2	Risk control options are used in the following order: inherent control by design; protective measures; information for assurance.
		3	Key properties are considered in the following order of priority — safety, effectiveness, and data and systems security — when considering risk control options.
MRM.1.2-BP2-Q.1	Are risk control measures managed under the Change/Release Management Process?	5	Risk control measures that require a change to the medical IT-network are managed under the change-release management process.
		8	If a change is undertaken without documented consent of the medical device manufacturer, the manufacturer is notified and all necessary regulatory steps for putting such a modified medical device into service are followed. (Changes to a medical device without documented consent of the medical device manufacturer are NOT recommended).
MRM.1.2-BP3-Q.1	Are the selected risk control measures documented in the risk Management file?	6	Selected risk control measures are recorded in the medical IT-network risk management file.
MRM.1.2-BP4-Q.1	Is risk/benefit analysis of residual risk conducted (when risk reduction measures have been determined not to be practical) and are the results documented?	4	A risk/benefit analysis of the residual risk is conducted and documented when the required risk reduction has been determined not to be practical.
		9	Any residual risk is documented in the medical IT-network risk management file.
MRM.1.2-BP -Q.1	Are selected risk control measures implemented?	7	Where the estimated risk(s) are not acceptable, selected risk control measures are implemented according to risk control option analysis.
MRM.1.2-BP5-Q.2	How are risk control measures implemented?	7	Where the estimated risk(s) are not acceptable, selected risk control measures are implemented according to risk control option analysis.

Table 3-2 MRM.1-MRM.1.3 Questions with corresponding Outcomes (Continued)

Base Practice	Question	Outcome	
MRM.1.2 Risk Control Process			
MRM.1.2-BP6-Q.1	Is the implementation and effectiveness of risk control measures verified and documented?	10	Implementation and effectiveness of all risk control measures in the operational system are verified and documented in the medical IT-network risk management file.
MRM.1.2-BP7-Q.1	Are risk control measures and the operational system reviewed and evaluated and are the results documented?	11	The implemented risk control measures and the installed operational system are reviewed for new, unacceptable risks and the evaluation is documented in the Medical IT-Network risk management file.
MRM.1.3 Review Residue Risk			
MRM.1.3-BP1-Q.1	Is residual risk reviewed and assessed for acceptability?	1	Persons responsible for reviewing and accepting residual risk have co-operated with Medical IT-Network Risk Manager.
		3	Individual residual risks and the overall residual risk are assessed for acceptability.
MRM.1.3-BP2-Q.1	Is residual risk evaluated?	2	Residual risk is evaluated based on a pre-release assessment of the effectiveness of the implemented risk control measures.
MRM.1.3-BP3-Q.1	Are additional risk control measures applied for unacceptable individual/overall unacceptable risks?	4	Additional risk control measures are applied where an individual residual risk or the overall residual risk is not determined to be acceptable.
MRM.1.3-BP4-Q.1	Is residual risk summary designed and documented?	5	A residual risk summary is defined and documented.
MRM.1.3-BP5-Q.1	Is risk/benefit analysis of individual or overall residual risk documented?	6	The decision to approve the residual risk is made on the basis of a documented risk/benefit analysis of the individual or overall residual risk against the health benefit accrued (where the reduction of residual risk to an acceptable level is not practicable).
MRM.1.3-BP6-Q.1	Is the decision on whether or not to approve the residual risk based on the documented risk/benefit analysis?	6	The decision to approve the residual risk is made on the basis of a documented risk/benefit analysis of the individual or overall residual risk against the health benefit accrued (where the reduction of residual risk to an acceptable level is not practicable).

3.5 Excel Tool Functionality

The purpose of this tool was to equip users with an alternative way to determine their adherence to the PAM. The overarching principles were to provide a tool which presented the PAM in a more readily available, easier to read understand and usable format to the user. With these principles at the forefront the researcher decided that an excel based application would be best suited to the task at hand.

The strategy employed was to create a dashboard as shown in Fig 3-1, with all data and background workings hidden to the user. The dashboard contains all relevant information that the user required to complete the self-assessment process, this would enable the user to view everything in a concise and convenient fashion.

The tool was built using a table containing all data for MRM as the main fulcrum with pivot tables, slicers, formulae and visual basic coding all being dependant on this data table.

There are 6 key points of note on the dashboard which can be seen in Fig 3-1. The researcher will outline the functions and workings of each of these key points in more detail.

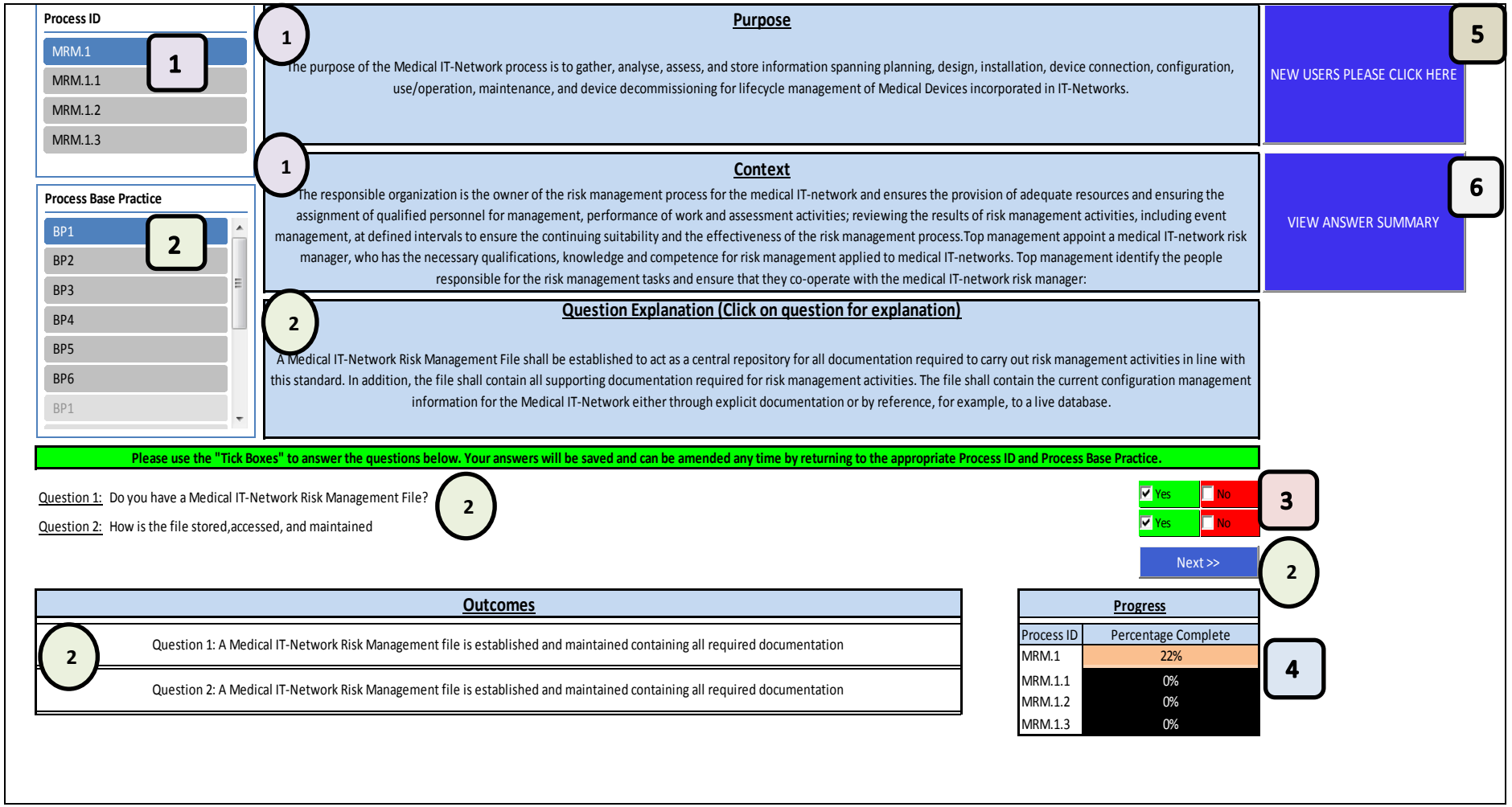

Figure 3-1 Excel Tool Dashboard

3.5.1 Process ID Slicer

This slicer (Number 1) is key, and is linked to all pivot tables in the engine of the tool. Once a Process ID is clicked on the slicer it amends all of the pivot tables to allow selection of the relevant Process Base Practice.

Having clicked on a Process ID, the Purpose and Context Pivot tables in the engine change to populate the “Purpose” and “Context” text boxes. These are distinct and specific to each Process ID and as such are not linked to the Process Base Practice Slicer.

Depending on which Process ID is selected the Process Base Practice slicer (Number 2) will change to show the relevant number of Base Practices. As indicated in Fig 3-2, each Process ID has a varying number of Base Practices (MRM.1 = 6, MRM.1.1 = 4, MRM.1.2 = 7, MRM.1.3 = 6).

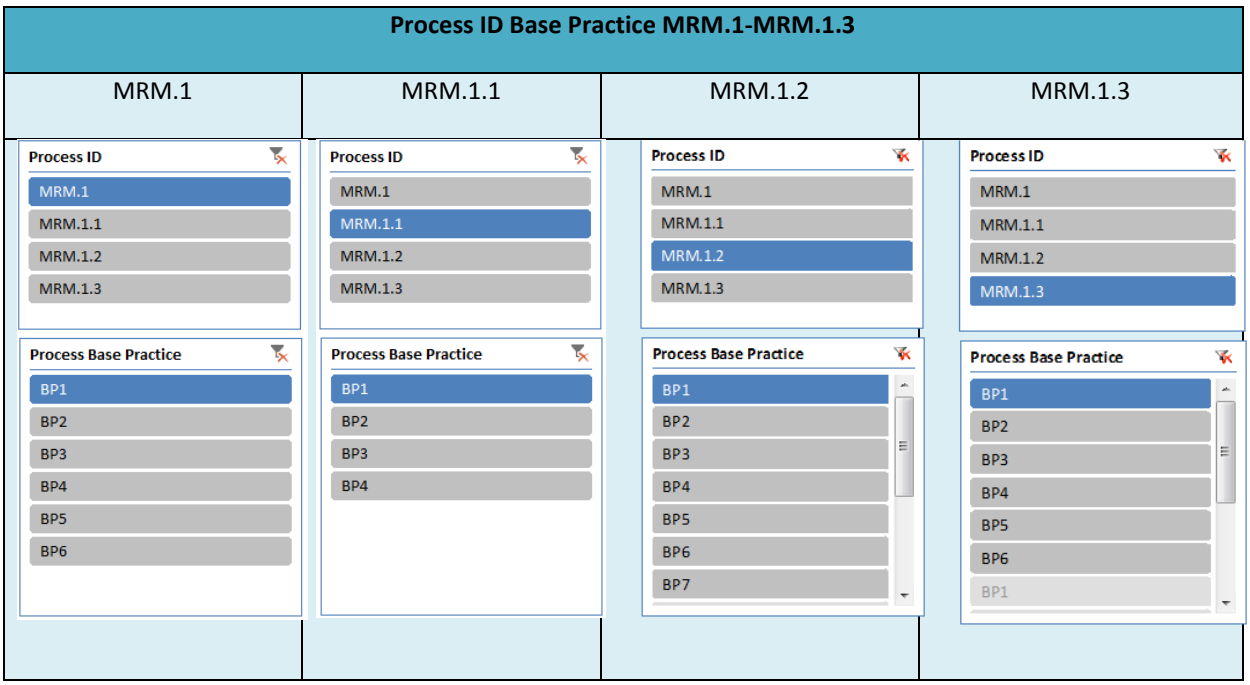

Figure 3-2 Base Practice Comparison

3.5.2 Process Base Practice Slicer

Once the Process ID (number 1) is chosen this slicer is used to select the Base Practice. Once a Base Practice is chosen (Number 2) the pivot tables are changed to reflect this selection and the questions relating to that process are drawn into the pivot tables. Having drawn the questions into the pivot tables the visual basic determines the numbers of questions there are (1, 2 or 3) and perform a calculation to hide or unhide rows on the dashboard, see Fig 3-3. This visual basic coding insures that only what is relevant appears for the user.

Selecting the Base Practice also populates the “Outcomes” section of the dashboard using visual basic. The code looks up the questions for the Base Practice and returns the corresponding outcomes for those questions. To get an explanation for each question the user must click on a question, once a question has been clicked the visual basic returns the correct explanation for that question.

Finally for the Process Base Practice Slicer there is a visual basic “Nest Button” which allows the user to cycle through the Base Practices in a liner fashion without having to press the slicer itself. Once the next button reaches the last Base Practice for a Process ID it moves to the next Process ID.

MRM.1 BP 4

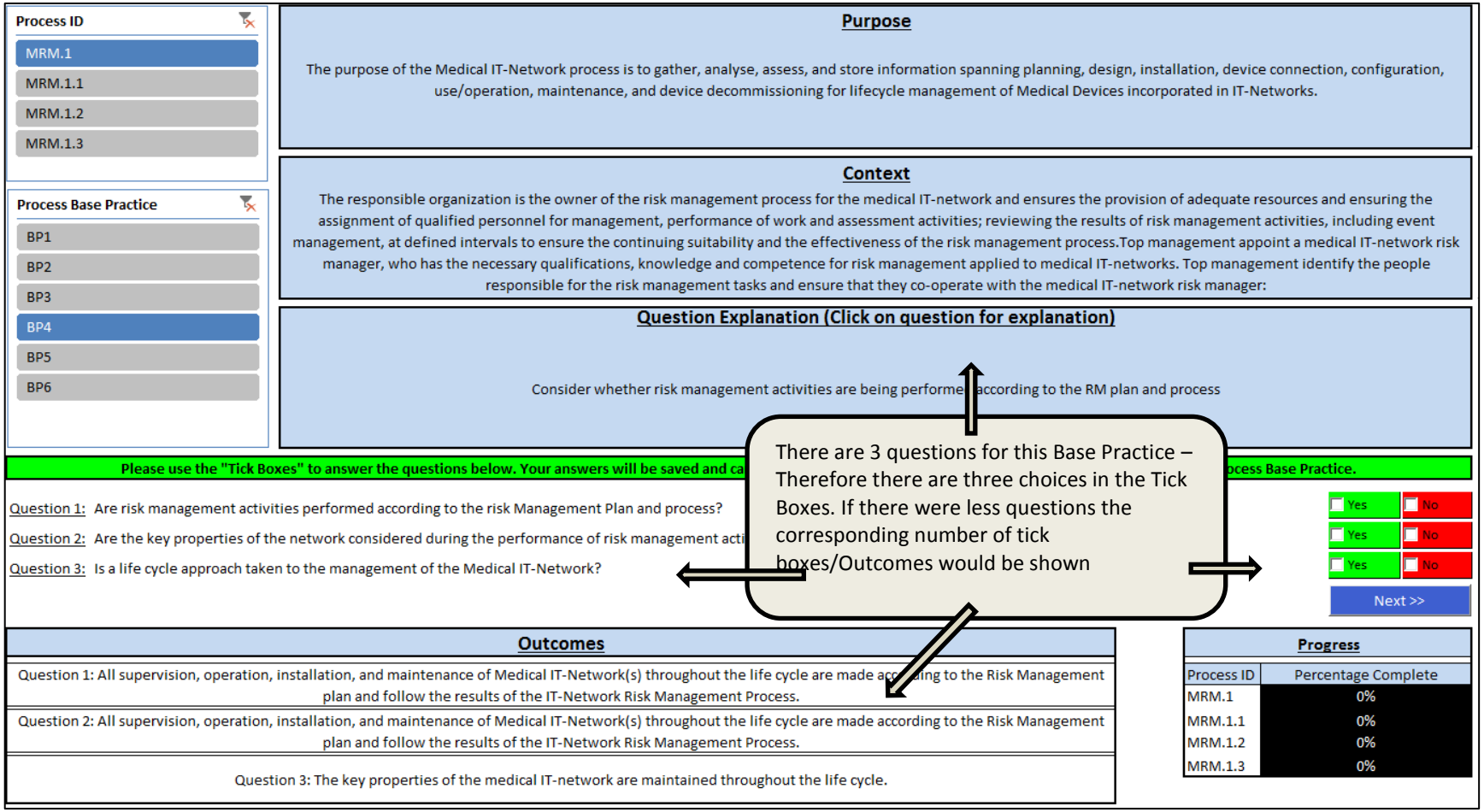

Figure 3-3 Base Practice Questions

3.5.3 Yes/No Tick Boxes

The tick boxes (Number 3) are the driver of the percent completed calculations and are the way that a user signifies whether a Base Practice has been adhered to. These are visual basic driven and once clicked the answer is inputted into the main data table in the background.

The answers are saved in the data table and can be returned at a later date if the user requires changing his/her answer (Fig 3-5).

The tick boxes only allow one answer to be selected i.e. a user cannot select both yes and no for a Base Practice (Fig 3-4).

Each question has two tick boxes. If either yes or no is not selected the toll assumes the answer to the question to be no and calculates the percentages accordingly.

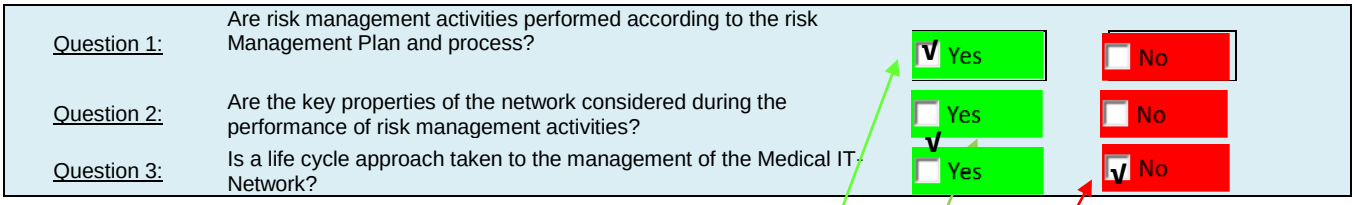

Figure 3-4 Base Practice Tick Boxes

Process ID	Process Base Practice	BP Guidance	BP Question No	BP Question	Answer
MRM.1	BP4	Consider whether risk management activities are being performed according to the RM plan and process	Q.1	Are risk management activities performed according to the risk Management Plan and process?	Yes
MRM.1	BP4	Consider the impact to the network in terms of safety, effectiveness, and data and system security throughout the life cycle.	Q.2	Are the key properties of the network considered during the performance of risk management activities?	Yes
MRM.1	BP4	Consider whether risk management activities are performed during the supervision, operation, installation, and maintenance of Medical IT-Network(s) throughout the life cycle.	Q.3	Is a life cycle approach taken to the management of the Medical IT-Network?	No

Figure 3-5 Tick Box Answers Saved into Main Data

3.5.4 Completions Percentages Table

The percentage completed table (Number 4) looks at the main data table and calculates the total number of questions for each Process ID and divides the number of “Yes” answers by this total. This calculates an average rating for the base practices related to that process which is assessed to Capability level one (Performed Process).

The table has conditional formatting to show the user how they have performed on the four points (N-P-L-F) rating scale, see Fig 3-6.

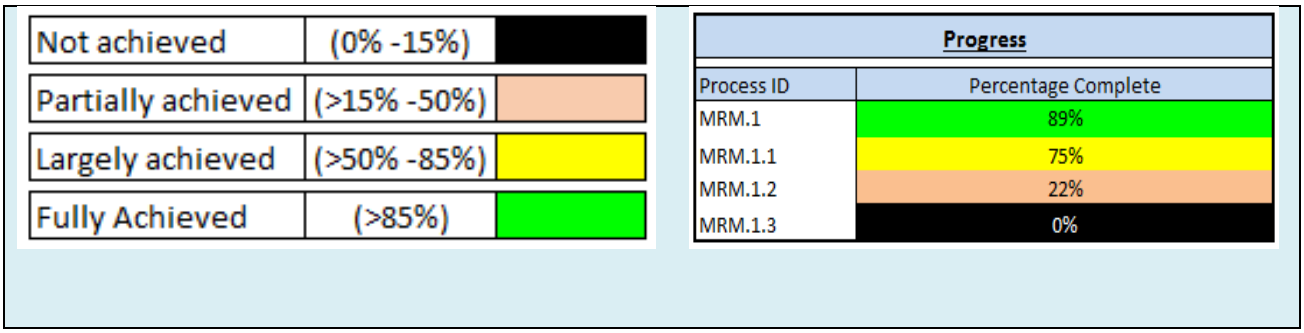

Figure 3-6 Percentage Completed Table

3.5.5 New User Button

This button (Number 5) is controlled by visual basic and is used by a new user when commencing their review of the PAM. Upon clicking this button all slicers and data are reset. This deletes all previous tick box answers and returns completed percentages back to 0%, see Fig 3-7.

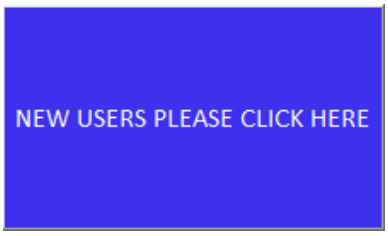

Figure 3-7 New User Button

3.5.6 Answer Summary Button

This button (Number 6) is run by visual basic and populates a summary sheet for the user upon clicking. The summary sheet contains all Base Practices where the tick box answer was "no". This summary sheet can be printed for review by the user, see Fig 3-8.

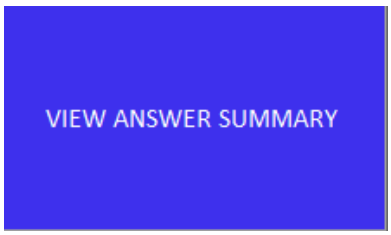

Figure 3-8 Summary Sheet Button

3.5.7 Summary Sheet

The summary sheet (Fig 3-10) contains a list of all the Base Practices where the tick box answer was "no" and also includes the corresponding outcomes. This list enables the user to identify any weaknesses within the current risk management processes and can be used as a basis for the improvement of the process. MRM.1 BP 4 questions 1, 2 & 3 are answered "no", see Fig 3-9.

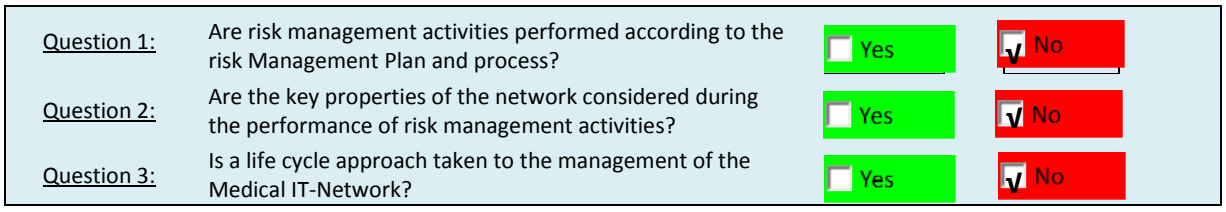

Figure 3-9 MRM.1 BP 4 Question 1, 2 & 3 answer = No

All the information relating to that base practice including question, description, and guidelines are then displayed in one location. This enables the HDO to identify what resources or processes need to be implemented as in this example, outcome number 7 and 9 as per Fig 3-10 should be implemented.

Process ID	Process Base Practice	BP Description	BP Guidance	BP Question No	BP Question	Outcome No	Outcome	Answer
MRM.1	BP4	Manage the Medical IT-Network throughout the life cycle as per the Risk Management Plan and Process.	Consider whether risk management activities are being performed according to the RM plan and process.	Q.1	Are risk management activities performed according to the risk Management Plan and process?	7	All supervision, operation, installation, and maintenance of Medical IT-Network(s) throughout the life cycle are made according to the Risk Management plan and follow the results of the IT-Network Risk Management Process.	No
MRM.1	BP4	Manage the Medical IT-Network throughout the life cycle as per the Risk Management Plan and Process.	Consider the impact to the network in terms of safety, effectiveness, and data and system security throughout the life cycle.	Q.2	Are the key properties of the network considered during the performance of risk management activities?	7	All supervision, operation, installation, and maintenance of Medical IT-Network(s) throughout the life cycle are made according to the Risk Management plan and follow the results of the IT-Network Risk Management Process.	No
MRM.1	BP4	Manage the Medical IT-Network throughout the life cycle as per the Risk Management Plan and Process.	Consider whether risk management activities are performed during the supervision, operation, installation, and maintenance of Medical IT-Network(s) throughout the life cycle.	Q.3	Is a life cycle approach taken to the management of the Medical IT-Network?	9	The key properties of the medical IT-network are maintained throughout the life cycle.	No

Figure 3-10 Summary Sheet

3.6 Verification of Excel Tool

The excel tool was designed to present the process assessment method which included questions, context and outcomes from MRM process group in ISO/TR 80001-2-7 in a dashboard style. This presented the relevant information and automatically calculated the conformance of each process to capability level one (Performed Process) and gives the user a list of the processes and actions that needed further attention. The tool was developed by comparing each step with the corresponding information in ISO/TR 80001-2-7. This process was an iterative process from an initial concept of displaying the questions and their context to incorporating the outcomes and calculating the capability level of each process.

3.7 Conclusion

This chapter detailed the rational for and development of the excel tool. Based on the literature review the researcher decided to present the information in ISO/TR 80001-2-7 in a more accessible format. Having no experience in app or software development the researcher chose the excel pivot table and slicer functionality to present the information. However as the tool developed the requirements to link the questions with their corresponding context and outcomes, and also the ability to calculate the capability level of each process became more evident.

The capacity to do this in excel became more complex with the researcher having to write some of the functions using visual basic increasing the researchers knowledge of excel and visual basic (VBA). Microsoft excel is a spreadsheet which present tables of values which can be mathematically manipulated (Webopedia, 2017). The information in ISO/TR 80001-2-7 is primarily descriptive, while excel was capable of presenting the first process group (MRM) it would not be capable of presenting all 4 process groups. The researcher did consider using a different application to present the data and downloaded Microsoft Visual Studio 2015 which is an integrated development environment (IDE) used to develop computer programs, websites, web apps and mobile apps (Wikipedia, 2017). However due to time limitations and the fact that the researcher would have to learn a new software package and programming language Microsoft excel was chosen. Building on the work already done the researcher proposes to further develop the tool within a different application and incorporate all four process groups and present it in a web or mobile app format.

Chapter 4 - Research Methodology

4.1 Introduction

This chapter outlines the different research studies conducted as part of this dissertation and details the rationale behind the choice of the research population, study groups and data collection methods. It then introduces the researches methodologies used which were qualitative, quantitative and mixed and concludes with ethical approval and chapter conclusion.

The literature review highlighted the lack of adoption of the standard IEC 80001-1 by HDOs which a number of authors suggested may have been due to the lack of an assessment model and method. This was addressed by the publication of ISO/TR 80001-2-7 by the IEC in 2015 which outlines a process assessment model and method. The literature highlighted the lack of adoption of the process assessment model. The motivation behind this study is to determine if the process assessment model presented in ISO/TR 80001-2-7 is accessible enough to allow a health delivery organisation with a medical IT network self-assess their conformance with IEC 80001-1.

Three different research stages were conducted as part of this study

Stage 1: The creation of an online questionnaire which was sent to selected National HDO managers to ascertain their knowledge, accessibility and adoption of IEC 80001-1 and its Technical Report ISO/TR 80001-2-7.

Stage 2: Focus groups were held with the target population, (Information Technology and Clinical Engineering Managers in the Children's Hospital Group). The purpose of the focus groups is to present the process assessment model (PAM) presented in ISO/TR 80001-2-7 and evaluate its accessibility and usability.

Stage 3: The PAM was presented in a dashboard style format within an Excel tool developed by the researcher to the target population. The target population were then asked to complete an online questionnaire re-evaluating the accessibility and usability of the PAM.

4.2 Research Populations

The research populations comprised of two groups involving the CE and IT managers nationally for the National Survey and within the CHG for the Focus Groups.

4.2.1 National Survey - Stage 1

Previously highlighted, the literature review identifies the lack of adoption of the standard IEC 80001-1 by HDOs. The researcher could only find one example within an Irish Healthcare context. The purpose of the survey is to determine the knowledge, accessibility and adoption amongst IT and CE professionals within an Irish healthcare context of IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO/TR 80001-2-7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1".

4.2.2 Children's Hospitals Focus Groups - Stages 2 & 3

The Health Service Executive (HSE) has indicated that that the Children's Hospital Group (CHG) will be the first implementation of a National Acute electronic medical record (EMR). They are currently progressing a national eHealth program which includes the delivery of an electronic medical record (EMR) solution for the whole of Irish healthcare (HSE, 2015). One single heterogeneous IT network is planned for the new children hospital and it is crucial that all associated resources, procedures and risks are identified and appropriate measures are put in place.

4.3 Research Methodology

The Oxford English online dictionary defines research as *"The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions"* (Dictionary, 2017b) in other words the quest for knowledge. Research methodology refers to the methods used to manage and conduct a particular area of study or activity (Dictionary, 2017a). A practical rather than theoretical approach was used by the researcher for this dissertation which focused on empirical evidence obtained through questionnaires, surveys and focus group interviews.

These primarily consisted of closed questions with a small number of open questions; therefore the research was mixed, both quantitative and qualitative in nature.

Qualitative Research, primarily exploratory research defined by Glesne as *"a type of research that focuses on qualities such as words or observations that are difficult to quantify and lend themselves to interpretation or deconstruction"* (Glesne, 2011), focusing on motivations, reasons and opinions which and can offer an understanding of a particular difficulty.

Quantitative research is focused on a measured value for example numeric data, information from a survey, questionnaire etc. and evaluates the problem by following a structured and rigid approach based on useable statistics from the measured data (Kumar, 2010).

4.4 Research - Stage 1 - Questionnaire Method

The purpose of this research is to determine if the standard IEC 80001-1 and its Technical Report ISO/TR 80001-2-7 are accessible within Irish HDOs.

A link to an online questionnaire was circulated to IT and CE professionals within acute healthcare delivery organisations nationally. These professionals were asked to provide feedback on their knowledge, accessibility and adoption of the IEC 80001-1 standard and its Technical Report ISO/TR 80001-2-7.

Participants were asked to do the following:

Complete an online questionnaire to determine their knowledge accessibility and adoption of:

- IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices",
- ISO/TR 80001-2-7 "Application guidance -- Part 2-7: Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1.

The questionnaire was developed using Qualtrics, which is an online software tool available to Trinity College, School of Computer Science and Statistics students. The introduction to the questionnaire contained an information page and consent form. The participants had to accept the consent form before progressing with the questionnaire. In keeping with Trinity

College ethical guidelines the participants were also given the opportunity at the final submission point to exit without submitting the questionnaire.

The link to the questionnaire was sent to the Chair of the Health Informatics Society of Ireland (HISI), IT managers group and the Secretary of the Biomedical & Clinical Engineering Association of Ireland (BEAI). They then emailed the questionnaire to IT and CE managers within the national HDOs.

The questionnaire primarily contained closed questions allowing for quantitative research with one qualitative open question included. See Appendix H: Questionnaire for National Study.

The questionnaire consisted of four sections:

- Introduction including background and informed consent,
- Roles and responsibilities pertaining to medical IT networks,
- Awareness and application of the Standard IEC 80001-1 and ISO/TR 80001-2-7,
- Restrictions to the adoption and implementation of IEC 80001-1.

The purpose of this feedback is to determine a baseline for the awareness and adoption of the standard nationally and identify possible barriers to its implementation.

4.5 Research - Stage 2 - Focus Group Method

The purpose of the focus groups is to present the process assessment model (PAM) presented in ISO/TR 80001-2-7 to the IT and CE managers within the Children's Hospital Group and evaluate its accessibility and usability.

The following points were explored:

- Are the questions within the PAM phrased in a way understandable to medical device and IT managers within the CHG?
- Determine if the assessment scoring methodology presented in the PAM is accessible to medical device and IT managers within the CHG.
- Determine if the output recommendations presented in the PAM are accessible to medical device and IT managers within the CHG.

This research focused on the first process Group MRM (Medical IT Network Risk Management Process Group) Table 2-5.

The assessment method can be used to perform a self-assessment to determine conformance against IEC 80001-1 and the results of the assessment will highlight any weaknesses within current risk management processes and can be used as a basis for the improvement of these.

The researcher conducted focus groups with selected IT and CE staff from the CHG which involved a presentation consisting of:

- A brief overview of IEC 80001-1.
- An overview of ISO/TR 80001-2-7.
    - Introduction to the PAM.
    - Introduction to the 14 processes within the PAM.
    - Introduction to the (process attributes rating values) level of achievement of each process.
    - Introduction to the capability levels for each process.
- Introduction and explanation of the first process group *Medical IT Network Risk Management Process (MRM)* Table 3-2, which includes:
    - 4 Processes MRM.1-MRM1.3
        - MRM.1 Medical IT Network Risk Management Process
        - MRM.1.1 Risk Analysis and Evaluation Process
        - MRM.1.2 Risk Control Process
        - MRM.1.3 Review Residue Risk
    - 28 questions.
    - 32 Outcomes which are observable results of the successful achievement of the proposed process.

After the presentation the participants were asked to use the paper based process assessment method for the first process group *Medical IT Network Risk Management Process (MRM)* as presented in the Technical report ISO/TR 80001-2-7 to:

- Perform a self-assessment of a medical IT network within their organisation.

Participants were then presented with an online questionnaire and asked to rate; from "Extremely Easy" to "Extremely Difficult" their experience in applying the paper based process assessment method to MRM within ISO/TR 80001-2-7 to self-assess their compliance with IEC 80001-1. The questionnaire which was also developed using Qualtrics incorporated the same principles that were used in the survey.

A link to the questionnaire was sent to the participants by the researcher. The questionnaire primarily contained closed questions allowing for quantitative research with one qualitative open question included. See Appendix J: Questionnaire for IT and CE Managers.

The questionnaire consisted of four sections:

- Introduction including background and informed consent.
- Usability of Process Assessment Method.
- Accessibility of the Process Assessment Method.
- Determining the outcomes and achievement level for each process.

The purpose of the interviews is to present the process assessment model (PAM) presented in ISO/TR 80001-2-7 and evaluate its accessibility and usability. The results of this assessment will inform the researcher when developing an excel tool which is envisioned to present the process assessment method, questions, assessment scoring methodology and output recommendations in a more accessible and useable format.

4.6 Research - Stage 3 - Excel Tool Evaluation Method

The purpose of this questionnaire is to present the process assessment model (PAM) from ISO/TR 80001-2-7 presented in a dashboard style format within the excel tool designed by the researcher, to the IT and CE managers within the CHG and evaluate its accessibility and usability.

The following points were explored:

- Are the questions within the PAM phrased in a way understandable to medical device and IT managers within the 3 children's hospitals?

- Determine if the assessment scoring methodology presented in the PAM is accessible to medical device and IT managers within the 3 children's hospitals.
- Determine if the output recommendations presented in the PAM are accessible to medical device and IT managers within the CHG.

This research focused on the first process group (Medical IT Network Risk Management Process Group) Table 2-5.

Participants were presented with an online questionnaire and asked to rate, from "Extremely Easy" to "Extremely Difficult" their experience using the excel tool in applying the process assessment method (MRM Medical IT Network Risk Management Process) within ISO/TR 80001-2-7 to self-assess their compliance with IEC 80001-1. The questionnaire was developed using Qualtrics and incorporated the same principles that were used in the survey.

A link to the questionnaire was sent to the participants by the researcher. The questionnaire primarily contained closed questions allowing for quantitative research with one qualitative open question included. See Appendix L: Questionnaire on Excel Tool

The questionnaire consisted of four sections:

- Introduction including background and informed consent.
- Usability of Process Assessment Method as presented in the excel tool.
- Accessibility of the Process Assessment Method as presented in the excel tool.
- Determining the outcomes and achievement level for each process as presented in the excel tool.

The results of this assessment will be compared with the results from the focus group questionnaire and this analysis will help to inform the researcher when further developing the excel tool.

4.7 Ethical Considerations

In order to conduct any research in a HDO, ethical approval is required. The researcher requested ethical approval from the three children's hospitals within the CHG, Our Lady's Children's Hospital Crumlin, Children's University Hospital Temple Street and The National Children's Hospital Tallaght. Ethical approval was also requested from the School of Computer Science, Trinity College Dublin to distribute the questionnaires and conduct the interviews, and this was granted. There is a potential conflict of interest in relation to conducting this research study as the author is a colleague of some participants. The ethical code of good practice for research was adhered to at all times. As per the Data Protection Acts 1988 and 2003 the data was anonymized and no disclosures of personal information were provided, and no consent was required from the data controller.

4.8 Conclusion

This chapter introduces the rational for the selection of the various research groups and outlines the research methodologies used. The national survey and focus groups with the Children Hospital Group personnel are presented and outlined. The results from the questionnaire to the CE and IT managers within the CHG (Stage 2) identified the need for the excel tool. The Ethics application and approval process which included the National Survey and focus groups, involved applications to the three Children's Hospitals, the School of Computer Science and Statistics Trinity College was complex and challenging due to the different application procedures. Chapter 5 presents the results and discussion on each of the research stages.

Chapter 5 - Results and Analysis

5.1 Introduction

Ethical approval was received from the ethics committee in Trinity College Dublin on the 6th April allowing the researcher to progress with the IEC 80001-1 National survey and ISO/TR 80001-2-7 PAM evaluation.

- An email was sent to the secretary of the BEAI to circulate a link to the online questionnaire amongst the National Clinical Engineering community.
- An email was sent to the chair of HISI, Health Care Information Technology managers group, to circulate a link to the online questionnaire amongst Information Technology managers.
- Focus groups took place with the CE and IT managers in the Children's Hospitals Group between Mon 10 April 2017 and Monday 8th May.

An analysis follows on each of the research studies, and the chapter concludes with a comparison on the excel tool.

5.2 IEC 80001-1 - National Survey - Stage 1

5.2.1 Method

The purpose of this research is to determine the knowledge, accessibility and adoption of the standard IEC 80001-1 and its Technical Report ISO/TR 80001-2-7 within Irish HDOs. A link to an online questionnaire was sent out to IT and CE professionals within acute healthcare delivery organisations nationally on Monday 10th April and the closing date was set for Monday 8th May. The questionnaire was hosted online by Qualtrics which generated two reports based on the inputted data. The researcher downloaded the raw data into excel and generated the following results using pivot tables and graphs. See appendix N for a detailed list of the results.

5.2.2 Results

A sample size of 90 was surveyed which returned a response rate of 27%. CE consisted of 65% of the responses with IT professionals comprising the remaining 35%.

The questionnaire consisted of four sections:

1. Introduction including background and informed consent.

2. Roles and responsibilities pertaining to medical IT networks.

3. Awareness and application of the Standard IEC 80001-1 and ISO/TR 80001-2-7.

4. Restrictions to the adoption and implementation of IEC 80001-1.

See appendix N for a detailed results from each section.

Section Two sought to determine the prevalence of medical devices connected to IT networks within HDOs and the awareness of the definition for a medical IT network. The results showed that while 96% of HDOs have medical devices connected to IT networks only 18% were aware of the definition of a medical IT network. It was found that 82% of respondents were aware of the definition of a medical device, 59% were aware of the definition of a business administration IT network (Fig 5-1).

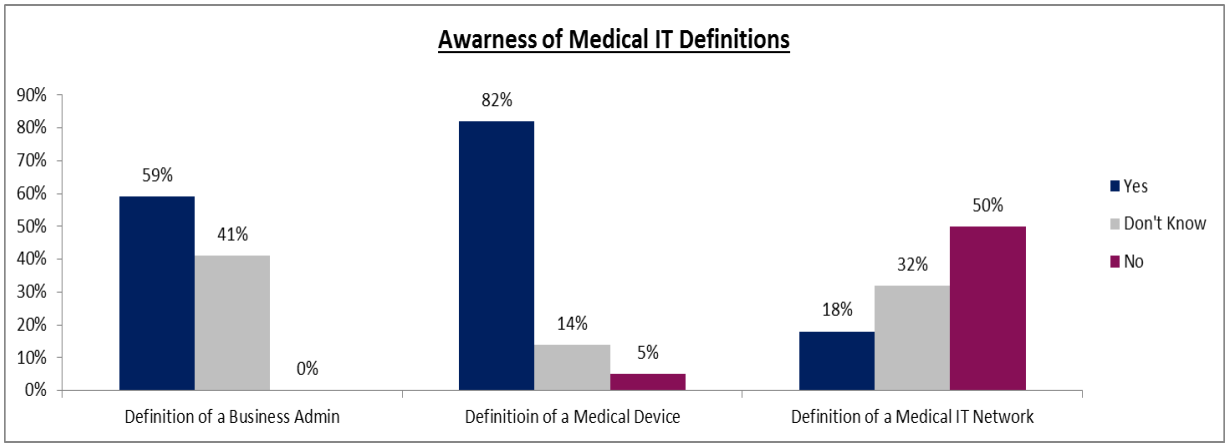

Figure 5-1 Awareness of Medical IT Network

In section three participants were asked a number of questions to determine their awareness and application of the Standard IEC 80001-1 and Technical Report ISO/TR 80001-2-7.

Participants were asked to indicate their knowledge, from extremely aware to not aware at all and the results are shown in Fig 5-2. In relation to IEC 80001-1 nobody was extremely aware with only 5% very aware and 32% not aware at all. There was nobody either extremely aware or very aware of ISO/TR 80001-2-7 with 50% of participants not aware at all.

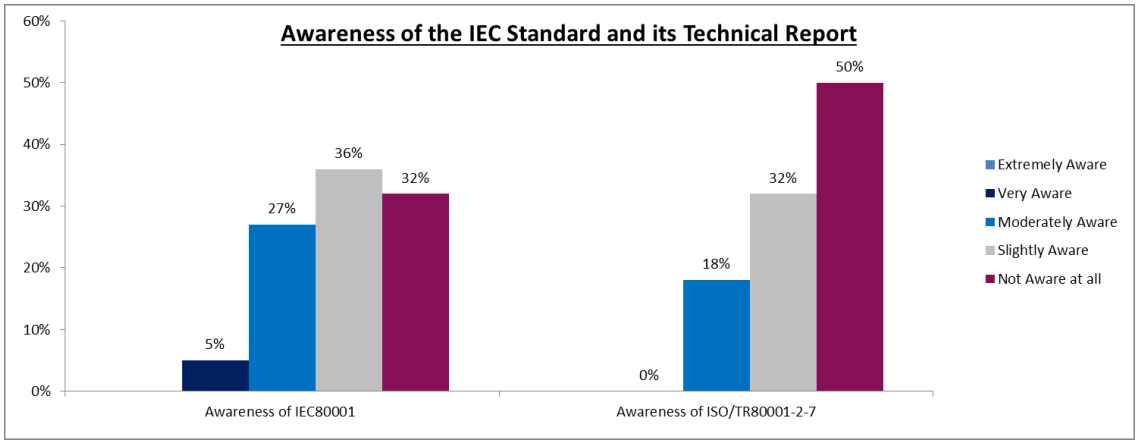

Figure 5-2 Awareness of IEC 80001-1 & ISO/TR 80001-2-7

When asked if a self-assessment of a medical IT network conformance with IEC 80001-1 had been undertaken 100% of respondents said No.

Section four sought to identify limitations to the adoption and implementation to the standard and participants were presented with 10 different types of limitations. The results are shown in Fig 5-3.

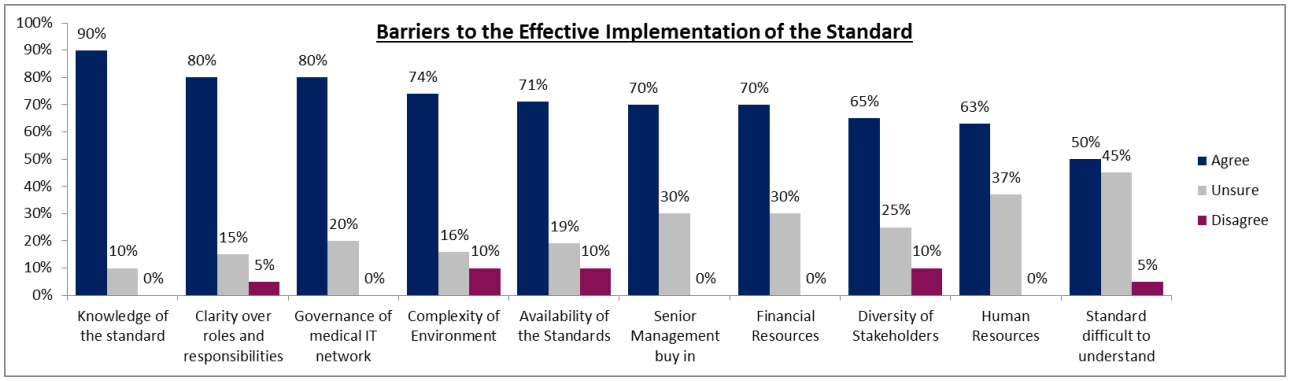

Figure 5-3 Restrictions to the Effective Implementation of IEC 80001-1

The top three limitations are:

- Knowledge of the standard.
- Clarity over roles and responsibilities.
- Governance of medical IT network.

In section four there were two questions (Q24, Q25) which gave participants the opportunity to comment on barriers which they felt were limiting the adoption of IEC 80001-1, and ISO/TR 80001-2-7. These comments reflect the results above and are available in appendix N. When asked if they would be interested in receiving more information on IEC 80001-1 and self-assessment guidelines presented in ISO/TR 80001-2-7, 95% of respondents said Yes.

5.3 Discussion

The literature review highlighted that the adoption of IEC 80001-1 as a risk management assessment tool for assessing the integration of medical devices onto IT networks does not appear to be very widespread (Eckhardt et al., 2015). The results from the national survey confirm this in an Irish health care context, as 0% of respondents had used IEC 80001-1. The results also highlighted the lack of awareness of the standard (Fig 5-2) which was identified by one of its authors who recognized that HDO would require assistance in understanding and implementing the requirements of the standard and its technical reports (Scharff, 2011). A number of authors also identified cooperation between stakeholders as crucial to the successful adoption and implementation of the standard and identified IT and CE as some of the main stakeholders. This was also confirmed by the national survey which identified 1 - Knowledge of the standard, 2 - Clarity over roles and responsibilities and 3 - Governance of medical IT network as the top 3 restrictions to its implementation. The individual comments also confirm this; see Table 5-1 below.

Table 5-1 Comments from IT & CE Professionals.

Q24 &25 Barriers you feel which may restrict the adoption and implementation of IEC 80001-1 within your organisation.
"Project led from top management that this is the way to proceed and overcome reluctance of existing stakeholders towards change".
"Principal barrier is where the responsibility rests i.e. ICT or clinical engineering".
"Not a very strong link between Clinical Engineering and IT departments. Seems very much a "Them and US" scenario where demarcation of responsibly is constantly debated. (From this cable onward is Clinical Engineering's responsibility etc)".
"The level of commitment to recognising the importance of the standards, along with having the skill set in-house to implement the standard".
"The knowledge and understanding of the standard".
"I would suggest there needs to be a specific discipline within clinical engineering to assume the responsibility of medical devices on the IT network as this will become a more increasing portfolio. This specific discipline will need to incorporate the skills/knowledge of both ICT and medical device management".
"The Standard is poorly written, and its implementation is very dependent on resourcing this project".
"VLANS used to separate medical networks from business networks. Never read the standards - not sure if VLANS are an acceptable method of separating networks".

The results from the survey including the comments above reinforce Delvecchio (Delvecchio, 2011) recommendations, that HDOs should adopt to improve the adoption of IEC 80001-1.These are:

- Education in the requirements of IEC 80001-1 and its technical reports.
- Identify Stakeholders, internal and external and establish communications and cooperation.
- Establish a risk assessment process for medical IT networks.

Delvecchio and a number of other authors also suggested that the HDO should start with a small scale project when implementing IEC 80001-1.

The literature also identified the lack of a process assessment model as an obstacle to lack of adoption and implementation of the standard (MacMahon et al., 2012) (Cooper and Fuchs, 2013). A process assessment model is presented in ISO/TR 80001-2-7 however the results from the survey indicate that there is very little awareness of this technical report with only 18% of respondents being moderately aware of it.

5.4 ISO TR 80001-2-7 Focus Groups - Questionnaire - Stage 2

The motivation behind this study is to determine if the process assessment model presented in ISO/TR 80001-2-7 is accessible and usable enough to allow a health delivery organisation with a medical IT network self-assess their conformance with IEC 80001-1.

5.4.1 Method

The target population chosen was the CE and IT managers in the Children's Hospital Group as the HSE has indicated that the New Children's Hospital will be the first implementation of a National acute medical record and the hospital will open as a digital hospital. The individuals identified consisted of 3 CE and 6 IT managers of which 7 responded and were willing to participate.

- Focus groups were carried out with these individuals, and consisted of a presentation on IEC 80001-1 and ISO/TR 80001-2-7 see appendix P. This was followed by an explanation of the PAM as presented in ISO/TR 80001-2-7.

- The participants were then asked to use the PAM within ISO/TR 80001-2-7 to perform a self-assessment of their organisations conformance with IEC 80001-1 focusing on the first process group (Medical IT Network Risk Management Process Group). They were then directed to an online questionnaire which consisted of a question to determine their profession, a multi choice question asking them to rate from extremely easy to extremely difficult their experience using the PAM and finally a text box inviting them to comment on the PAM.

5.4.2 Results

The sample size of 7 consisted of 3 CE and 4 IT managers and the results of the multiple choice question are shown in Fig 5-4. From a target population of 9 there was a response rate of approx. 78%. When asked to rate the usability of the PAM, 83% of participants found it extremely difficult to use with the remaining 17% finding it somewhat difficult. 83% found the language used extremely difficult to interpret and the questions used somewhat difficult to interpret with 67% finding the method to identify strengths and weaknesses of each process somewhat difficult.

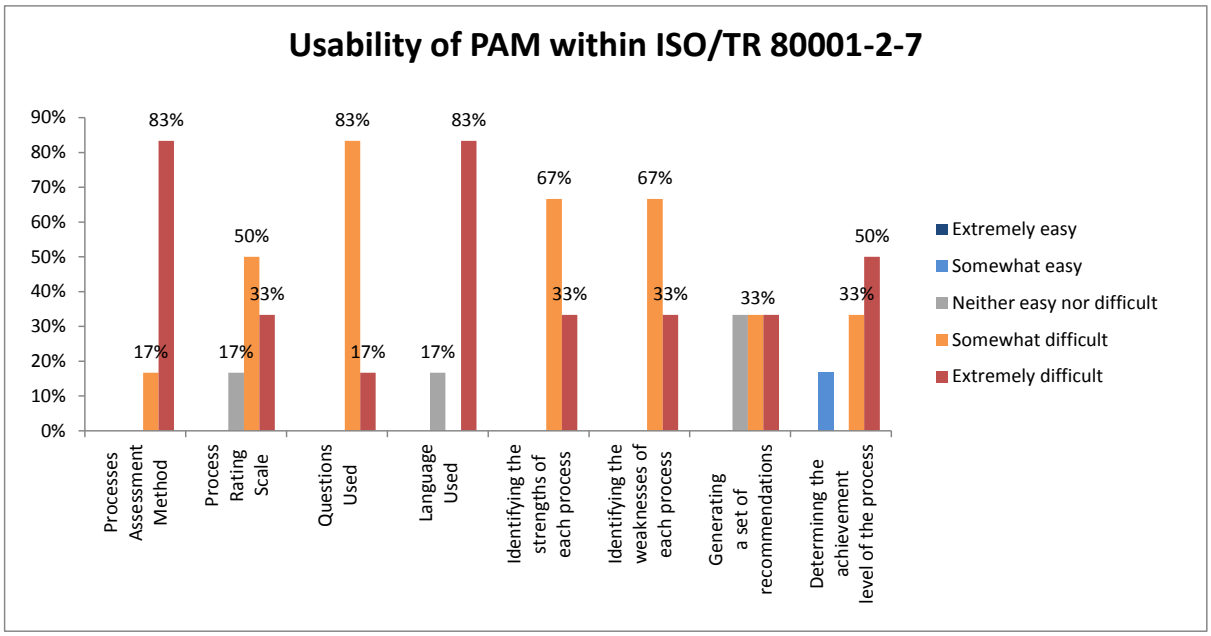

Figure 5-4 Usability of the PAM within ISO/TR 80001-2-7

The last question gave the participants the opportunity to comment on the PAM within ISO/TR 80001-2-7. These comments reflect the results above and are available in table 5-2.

Table 5-2 Comments from the Focus Groups on the PAM within ISO/TR 80001-2-7

Please record in the box below any other comments relating to the use of the PAM.
"Found the structure complex and difficult".
"Generally found the Process Assessment Process difficult to navigate. The flow of the document and language used was difficult follow and understand at times".

5.5 Excel tool Evaluation - Stage 3

The researcher then presented the PAM in a dashboard style using excel and asked the participants to repeat the self-assessment process and complete an separate online questionnaire relating to their experience using the PAM as presented in the excel tool.

5.5.1 Method

The purpose of this questionnaire is to present the process assessment model (PAM) from ISO/TR 80001-2-7 presented in dashboard type format using Microsoft excel designed by the researcher, to the IT and CE managers within the Children's Hospital Group and evaluate its accessibility and usability. The questionnaire was hosted online by Qualtrics which generated two reports based on the inputted data. These reports, one in excel and one in word were merged together by the researcher in a separate excel document where a table of results and graphs were created. See appendix O for a detailed results from each question.

5.5.2 Results

From a target population of 9 there was a response rate of approx. 78% consisting of 43% from CE and 57% from IT. The participants were asked the same questions relation to using the PAM and the results are shown in Fig 5-5.

When asked to rate the usability of the PAM, 83% of participants found it extremely easy to use with the remaining 17% finding it neither easy nor difficult. 67% found the language used extremely easy to interpret with 100% finding it extremely easy to generate a set of

recommendations with 83% finding it extremely easy to determine the achievement level of each process.

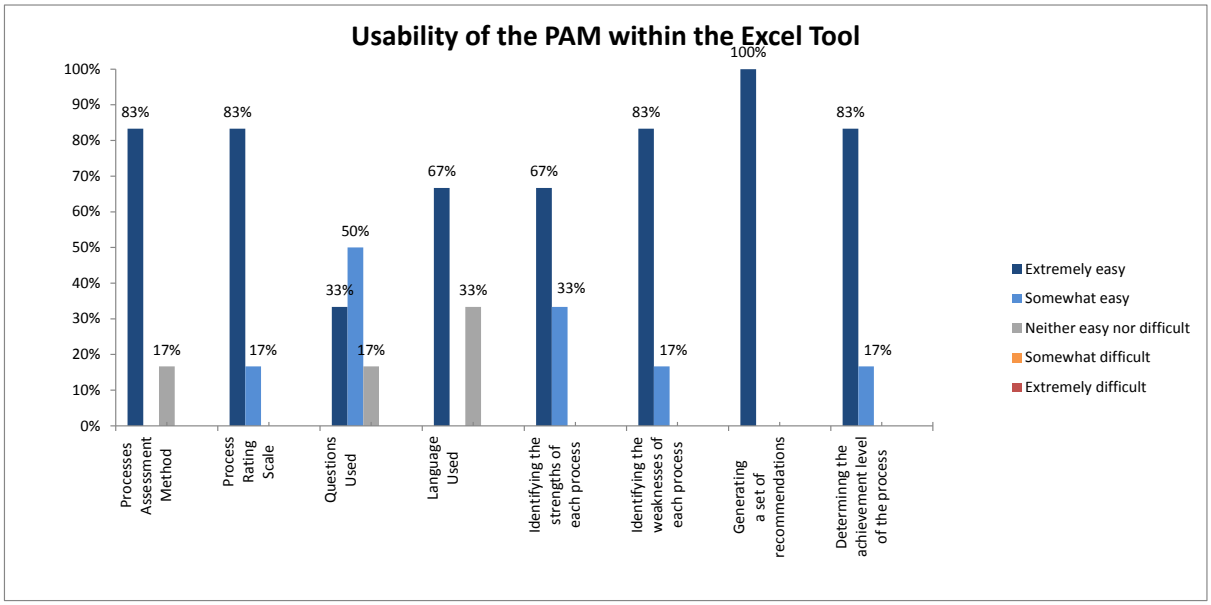

Figure 5-5 Usability of the PAM within the Excel Tool

The last question gave the participants the opportunity to comment on the PAM within ISO/TR 80001-2-7 as presented within the excel tool. These comments reflect the results above and are available in table 5-3.

Table 5-3 Comments from the Focus Groups on the PAM presented within the Excel Tool

Q7 Please record in the box below any other comments in relation to using the PAM within ISO/TR 80001-2-7 as presented within the excel tool.
"Extremely easy to use. Very intuitive. Takes the complexity out of the Assessment Method".
"This tool should and could be adapted to make difficult to understand documents more accessible".
"Excellent Worksheet. It makes the process so much easier and a lot less time consuming".

5.6 Comparison and Discussion

A linear comparison of the difference in difficulty using the PAM is represented in Fig 5-6 and indicates the increase in ease of use of all the functionality when presented in the excel tool.

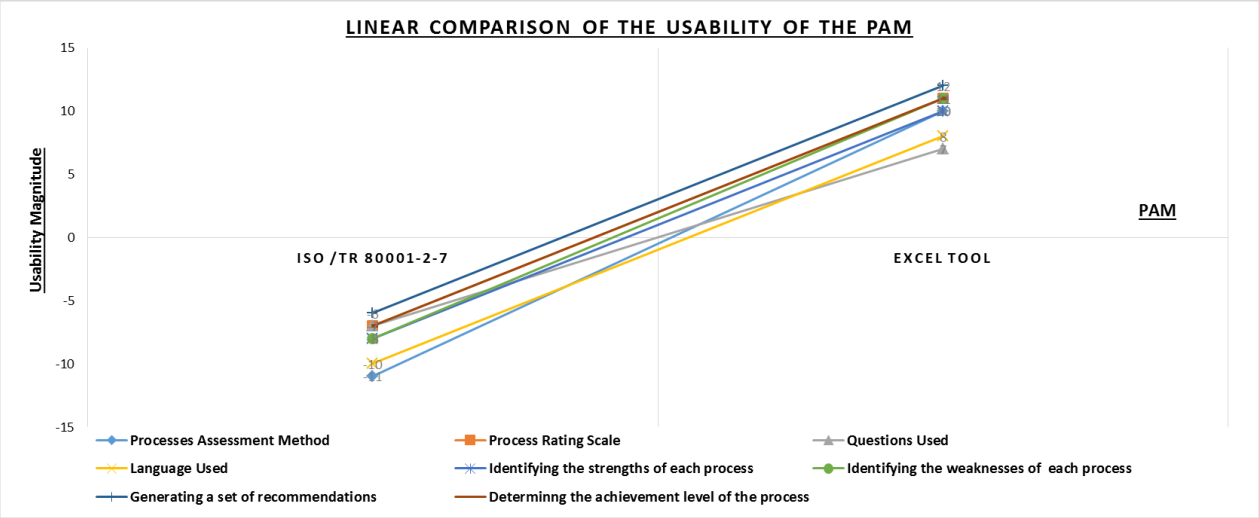

Figure 5-6 Linear comparison of the usability 0f the PAM

There was a significant increase in usability of all the categories within the PAM when presented in the excel tool and these results confirm the difficulty that HDOs have when interpreting the PAM within ISO/TR 80001-2-7. Of particular note was the increase in usability of the language and questions used, since the questions and language were not altered, however the researcher incorporated the questions with their corresponding description, context, purpose and guidance within the excel tool. All this information is available within the PAM however it is not easily accessed. The literature also identified the lack of a process assessment model as an obstacle to the lack of adoption and implementation of the standard (MacMahon et al., 2012) (Cooper and Fuchs, 2013). These results indicate that the process assessment model as presented in ISO/TR 80001-2-7 could be improved. Bouhaddou et al. (Bouhaddou et al., 2012) discussing standard adoption and implementation within the VA, recommends a general framework involving:

- People - The involvement of senior management within the National Standards Authority of Ireland (NASI) the HSE and HDOs is essential along with the availability of personnel with expertise in standards development and adoption who can work across disciplines.

- Processes - Documented and defined processes which provide guidance and assign responsibility throughout all aspects of standard adoption and implementation must be readily available along with an educational programme on the value of standards.

- Tools - The VA found that the adoption and use of standards within their organisation is greatly increased when the standards are readily available and easy to read and understand and this can be facilitated by specific tool (Bouhaddou et al., 2012). The results above confirm this.

5.7 Conclusion

This chapter commenced by outlaying the details of the National survey and the subsequent results. These results confirmed what was already outlined in the literature that the adoption and use of the standard IEC 80001-1 is not very widespread within an Irish Healthcare context and identified a number of obstacles which were restricting its implementation. To overcome these obstacles, the implementation of an education program in the requirements of IEC 80001-1 and its technical reports, the identification of internal and external stakeholders and establishment of communications between these stakeholders and the establishment of a risk assessment process for medical IT networks are recommended. One obstacle identified by literature was a lack of a Process Assessment Model which is presented in ISO/TR 80001-2-7, however the results from the survey indicate that there is very little awareness of this Technical Report.

The chapter then outlines the details of the focus groups held with CE and IT managers within the CHG to determine the accessibility and usability of the Process Assessment Model as presented in ISO/TR 80001-2-7. The results indicate that the participants found the Process Assessment Model and its methodology varying between difficult and extremely difficult to use. These results were then compared with an identical survey conducted with the same focus groups on the same Process Assessment Model, however this time presented in a dashboard type format within an excel tool developed by the researcher. These results are in stark contrast to the initial results and indicate that the participants found the Process Assessment Model and its methodology varying between easy and extremely easy to use. This chapter concludes with a comparison and discussion on these results.

Chapter 6 - Conclusion

6.1 Introduction

This chapter commences with a discussion on the strengths and limitations of the different aspects of the study and details the implications of the study. This is followed by an explanation of how the findings will be disseminated and a review of the research aims as outlined in chapter one. This chapter concludes with recommendations and potential future research will be suggested

6.2 Strengths and Limitations of the Study

The strengths and limitations of the study are discussed separately relating to each stage of the study and are outlined below.

6.2.1 Strengths

The researcher would like to acknowledge a number of strengths in relation to this study. Firstly the strengths in relation to the national survey of the IT and CE managers are identified followed by the strengths in relation to the excel tool development.

6.2.2 National Survey - Stage 1

- The National Survey completed amongst CE and IT professionals in HDOs and confirmed the lack of adoption and implementation of IEC 80001-1 and its technical report ISO/TR 80001-2-7.
- A Greater Awareness of IEC 80001-1 and ISO/TR 80001-2-7 was generated by the national survey.
- Obstacles were identified to the adoption and implementation of the standard, the top three being: Knowledge of the standard, Clarity over roles and responsibilities and Governance of medical IT networks.

6.2.3 Excel Tool - Stage 2 & 3

Focus groups and questionnaires were completed which led to the development on an excel tool which presents the PAM in ISO/TR 80001-2-7 in one dashboard type view. This combined the questions for the Medical IT Network Risk Management Process Group with their corresponding outcomes and the narrative relating to the context and purpose of each

process, as well as the description, guidance and percentage completion of each process. The strengths are listed below.

- Identified the difficulty that HDOs have interpreting the PAM within ISO/TR 80001-2-7.
- Confirmed the literature which stated that the adoption and use of standards within an organisation is greatly increased when the standards are readily available and easy to read and understand.
- Confirmed the PAM in technical report ISO/TR 80001-2-7 could be presented in a more accessible format without changing any of its terminology or contents.

6.3 Limitations

The researcher would like to acknowledge a number of limitations in relation to this study. Firstly the limitations in relation to the national survey of the IT and CE managers are identified followed by the limitations in relation to the excel tool development.

6.3.1 National Survey - Stage 1

The National Survey only included the IT and CE managers who are primarily responsible within HDOs for looking after IT networks and medical devices. It would have been beneficial to include risk managers, Chief Information Officers (CIO) and Chief Executive Officers (CEO), however due to time and ethics limitations this was not possible.

6.3.2 Excel Tool - Stages 2 & 3

Regarding the excel tool development, the first process group (MRM1) containing four processes was selected to validate the process assessment model. This process group deals with the main risk management activities within the PAM.

The information in ISO TR 80001-2-7 is primarily descriptive while excel was capable of presenting the first Process group (MRM1) it would not be capable of presenting all four process groups.

The sample population of IT and CE managers within the CHG consisted of nine individuals. The researcher would have preferred a larger sample size.

6.4 Dissemination

The results of the survey and study will be disseminated through a number of different methods see Table 6-1. Firstly the results will be stored online in a folder on Microsoft OneDrive and will be emailed to participants who expressed an interest in reviewing them; the researcher has received a number of such requests. The researcher has also been invited to present the results to the IT project team for the Children's Hospital Group in the format of a power point presentation followed by a question and answer session. The researcher has also been invited to present a paper for publication in the Biomedical & Clinical Engineering Association of Ireland scientific journal (Spectrum) and present at their Annual Scientific Conference in September 2017. An invitation has also been received to present the findings to the recently formed National "Access to Information Steering Group

Table 6-1 Dissemination of Results

People	***Organisation***	***Action***
National Access To Information Group	HSE/HIQA/TCD	Invitation received to present findings.
Children's Hospital Group	CHG	Power point presentation followed by a question and answer session scheduled for September.
Clinical Engineering	BEAI	○ Results will be circulated by email. ○ Publication in Spectrum BEAI scientific Journal. ○ Presentation at the BEAI Annual Scientific Conference.
Information Technology	HISI	Results will be circulated by email.
National CEO Health Service	HSE	Research required identifying the appropriate body to request sending the findings to.
National Standards Association of Ireland	NASI	The researcher intends to make contact with the NASI through the SCSS in TCD.
Risk Managers Health Service	HSE	Research required identifying the appropriate body to request sending the findings to.
The Office of the Chief Information Officer (OCIO)	HSE	A meeting will be requested with the OCIO to present the findings and recommendations.

A number of other professional stakeholder groups were identified and further research is required to identify the correct method of informing them about the standard and results of this research.

6.5 Implications of the Study

The literature review highlighted the lack of adoption of IEC 80001-1, and the National Survey could serve as a benchmark as to the awareness of this standard within an Irish HDO context. Also highlighted by the National Survey was the lack of information about this standard with 100% of those surveyed requesting more information on the standard and its technical reports. The researcher found the PAM within ISO/TR 80001-2-7 very difficult to interpret. The feedback from the excel tool evaluation confirmed that if the information was presented in a more accessible format there would be a higher probability of the PAM being used.

Currently IEC 80001-1 is a voluntary standard however voluntary standards have a tendency to become mandatory especially after an adverse event or incident when a regulatory authority suggests them as a means to meet the requirements of that authority. In the likelihood that IEC 80001-1 becomes a mandatory standard, it is imperative that HDOs are aware and compliant with this standard.

6.6 Reflections on the study

Chapter one presents the title of this research proposal “Risk management process for physiological monitors on a medical IT network” and the research question “Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7?” Ten research aims are presented and have all been achieved successfully, see Table 6-2.

The researcher under estimated the quantum of time and work required to complete this study. Firstly the ethics application was very complex with ethics approval required from the three children’s hospitals and the department of Computer Science and Statistics in Trinity College. This involved adherence to the different ethical applications for each HDOs and included an interview by the ethics committee in one of the HDOs who requested that the application include the proposed National Survey of the Information Technology and Clinical Engineering personnel. This gave the researcher invaluable insight into the importance of the ethics process.

Table 6-2 Research Aims Status

Research Aims	Status
Stage 1	
Investigate the knowledge, accessibility and adoption of IEC 80001-1 and its technical report ISO/TR 80001-2-7 within Irish National healthcare delivery organisations.	Achieved
Stage 2	
Evaluate the current PAM presented in ISO/TR 80001-2-7 with CE and IT managers within HDO by:	Achieved
Determining if the PAM as presented in ISO/TR 80001-2-7 is accessible and useable to CE and IT managers within HDO.	Achieved
Determining if the assessment scoring methodology presented in the PAM is accessible and useable to CE and IT managers within HDO.	Achieved
Determining if the output recommendations presented in the PAM are accessible to CE and IT managers within HDO.	Achieved
Stage 3	
Develop an excel tool based on the PAM which will assist the HDO in self-assessing conformance with IEC 80001-1.	Achieved
Present the process scoring mechanism within the excel tool based on the PAM which will assist the HDO in self-assessing conformance with IEC 80001-1.	Achieved
Present the terminology from the PAM, within the excel tool in a more accessible, useable form to medical device and IT managers within HDO.	Achieved
Evaluate if the excel tool can assist medical device and IT managers within HDO to self-assess compliance with IEC 80001-1.	Achieved
Evaluate if the excel tool can assist medical device and IT managers within HDO to identify where resources and processes are required.	Achieved

Secondly the researcher developed three different online questionnaires using Qualtrics which increased the researcher's knowledge in quantitate, qualitative and mixed methodologies research.

Thirdly the focus groups involved a presentation and the participants filling out the online questionnaires. The questions were primarily closed however the researcher underestimated the time involved and the availability of the participants. This experience

was very rewarding from a personal development perspective and also in highlighting the IEC 80001-1 standard and the PAM within ISO/TR 80001-2-7.

Fourthly the excel tool development initially started using the slicer and pivot table functions in excel however as the tool developed the process became more complex with the researcher having to write some of the functions using visual basic increasing the researchers knowledge of excel and visual basic. It was very rewarding to see the positive reaction to the tool.

Finally the researchers knowledge of IEC 80001-1 standard and the process assessment model presented in ISO/TR 80001-2-7 have been greatly increased.

6.7 Recommendations and Future Research

The results highlight that adoption and use of standards within an organisation is greatly increased when the standards are readily available and easy to read and understand. This is consistent with other findings repeated in the literature which also identifies an investment in the following at a National and HDO level:

- People - The involvement of senior management within the NASI, HSE and HDOs is essential along with the availability of personnel with expertise in standards development and adoption who can work across disciplines. This includes the Identifications of stakeholders, internal and external and establishment of communications between these parties (Delvecchio, 2011) . (Bouhaddou et al., 2012) (van der Peijl et al., 2012).

- Processes - Documented and defined processes which provide guidance and governance throughout all aspects of standard adoption and implementation must be readily available. This combined with an educational programme on the value of standards should be available across disciplines within HDOs (Delvecchio, 2011) (Bouhaddou et al., 2012) .

- Tools – The adoption and use of standards within an organisation is greatly increased when the standards are readily available and easy to read and understand and this can be facilitated by specific tool. These tools could facilitate HDOs in implementing

standards on a small scale project before implementing larger scale projects (Bouhaddou et al., 2012) (Cooper and Fuchs, 2013) (Ahlbrandt and Röhrig, 2013).

It is envisaged that the excel tool will be further developed using a different software package like Visual studio and will incorporate all four process groups and will be presented in web or mobile app format. This should be an iterative process combining the limitations of the software with the requirements of the standard and the expectations of the end-users. Close collaboration between stakeholders within HDOs and the standards community is essential for a successful outcome.

6.8 Conclusion

The interoperability of medical devices and the incorporation of these medical devices onto IT networks are becoming ubiquitous. This coupled with the increase in cyber-attacks on HDOs, increases the risks to patient safety and data and system security. IEC 80001-1 which was published to help HDOs assess these risks is currently a voluntary standard. ISO/TR 80001-2-7 was published to assist HDO assess their conformance with IEC 80001-1. This research highlights the difficulties HDOs have interpreting and using this standards and technical report. The excel tool developed by the researcher certainly presents the technical report in a much more user friendly format however additional work is required to progress this tool to an optimum product.

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Appendices

Appendix A: Ethics Approval and Application Our Lady's Children's Hospital Crumlin

Ethics Approval Our Lady's Children's Hospital Crumlin

Not for prescription purposes

Ospidéal Mhuire na Leanaí, Cromghlinn
Our Lady's Children's Hospital, Crumlin

NPHDB
14 MAR 2017
RECEIVED

ETHICS (MEDICAL RESEARCH) COMMITTEE OFFICE

Tel: + 353 (01) 409 6307/6243

Mr Tony Fitzgerald
National Paediatric Hospital Development Board
Hospital 7
St James's Hospital Campus
James's Street
Dublin 8

1st March 2017

REC Ref: GEN/536/17

Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7
Principal Investigator: Mr. Tony Fitzgerald

Dear Mr Fitzgerald

The Ethics (Medical Research) Committee, at a meeting which took place on, 28th February 2017, reviewed and approved the above study.

The Committee requested that the Application Form be amended to state that permission has been granted from BAI to send the Questionnaire.

The Committee requested a copy of the updated Application Form and a copy of the Informed Consent Form.

The requested documentation which you subsequently submitted was reviewed and approved by the Chairperson.

The Committee would like to thank you for being present at the meeting and for speaking to this item and wish you every success with the study.

Yours sincerely

Claire Rice
Secretary
Ethics (Medical Research) Committee

Ethics Application
Our Lady's Children's Hospital Crumlin

STANDARD APPLICATION FORM

For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: _ "Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7

_____

Application Version No: _Version 1_____

Application Date: __23-January 2017

_____

For Official Use Only – Date Stamp of Receipt by REC:

TABLE OF CONTENTS	MANDATORY /OPTIONAL

SECTION A GENERAL INFORMATION	MANDATORY*
SECTION B STUDY DESCRIPTORS	MANDATORY*
SECTION C STUDY PARTICIPANTS	MANDATORY*
SECTION D RESEARCH PROCEDURES	MANDATORY*
SECTION E DATA PROTECTION	MANDATORY*
SECTION F HUMAN BIOLOGICAL MATERIAL	(OPTIONAL)
SECTION G RADIATION	(OPTIONAL)
SECTION H MEDICAL DEVICES	(OPTIONAL)
SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS	(OPTIONAL)
SECTION J INDEMNITY AND INSURANCE	MANDATORY*
SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS	MANDATORY*
SECTION L ADDITIONAL ETHICAL ISSUES	(OPTIONAL)

This Application Form is divided into Sections.

*Sections A, B, C, D, E, J and K are **Mandatory.**

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

IMPORTANT NOTE: Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL WHEN COMPLETING THIS APPLICATION FORM.

SECTION A GENERAL INFORMATION

SECTION A IS MANDATORY

A1 Title of the Research Study:

"Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7"

A2 (a) Is this a multi-site study? Yes

If you chose 'yes' please delete questions A2 (e) and (f), If you chose 'no' please delete Questions A2 (b) (c) and (d)

A2 (b) If yes, please name the principal investigator with overall responsibility for the conduct of this multi-site study.

Title: Mr **Name:** Tony Fitzgerald
Qualifications: Post Grad Diploma studying for MSc
Position: Principle Clinical Engineer
Dept: Clinical Engineering, currently on secondment to New Children's Hospital Project
Organisation: OLCHC, NPH
Address: Crumlin-St James
Tel: 0863815897 **E-mail:** tony.fitzgerald@nph.ie

A2 (c) For multi-site studies, please name each site where this study is proposed to take place, state the lead co-investigator for each of these sites and state if you have got an outcome from the relevant research ethics committee(s).

Site:	Lead Co-Investigator for each site:	Research Ethics Committee Outcome
OLCHC	TONY FITZGERALD	PENDING
CHILDREN'S UNIVERSITY HOSPITAL TEMPLE ST	TONY FITZGERALD	YES
TALLAGHT HOSPITAL	TONY FITZGERALD	YES
HOSPITAL CLINICAL ENGINEERING MANAGERS NATIONWIDE (CONTACTED THROUGH THE BEAI)	TONY FITZGERALD	YES
HOSPITAL INFORMATION TECHNOLOGY MANAGERS NATIONWIDE CONTACTED THROUGH HISI)	TONY FITZGERALD	YES

A2 (d) For multi-site studies, please provide details of the Lead Co-Investigators at each site.

Title: Mr **Name:** Tony Fitzgerald
Qualifications: Post Grad Diploma studying for MSc
Position: Principle Clinical Engineer
Dept : Clinical Engineering, currently on secondment to New Children's Hospital Project
Organisation: OLCHC, NPH
Address: Crumlin-St James
Tel : 0863815897 **E-mail:** tony.fitzgerald@nph.ie

A3. Details of Co-investigators: None

Name of site (if applicable): Non-applicable
Title: Dr. / Ms. / Mr. / Prof. **Name:** Answer
Qualifications: Answer
Position: Answer
Dept : Answer
Organisation: Answer
Address: Answer
Tel: Answer **E-mail:** Answer
Role in Research e.g. statistical / data / laboratory analysis: None

A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Name: Tony Fitzgerald
Position: Principle Clinical Engineer
Organisation: OLCHC, NPH
Address for Correspondence:
Tel (work): Answer **Tel (mob.):** 0863815897 **E-mail:** tony.fitzgerald@nph.ie

A5 (a) Is this study being undertaken as part of an academic qualification? Yes

If answer is No, please delete remaining questions in Section A

A5 (b) If yes, please complete the following:
Student Name(s): Tony Fitzgerald
Academic Course: MSc Health Informatics
Academic Institution: Trinity College Dublin

A5 (c) Academic Supervisor(s):

Title: Prof. **Name:** Gaye Stephens
Qualifications: Professor
Position: Lecturer
Dept: School of Computer Science and Statistics (SCSS)
Organisation: Trinity College Dublin
Address: Dublin 1
Tel: 01-6083692 **E-mail:** gaye.stephens@tcd.ie

SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. What is the anticipated start date of this study?

April 1st 2017 or sooner if possible

B2. What is the anticipated duration of this study?

2 Months April- May 2017

B3. Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.

The purpose of this project is to conduct research to determine if the Standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible within the three Children's Hospitals and determine the awareness and conformance with these standards in an attempt to identify and remove barriers to their implementation

B4. Provide brief information on the study background.

Traditionally, medical devices were designed as stand-alone devices and if they were required to be networked e.g. (Physiological Monitors in an ICU) they were placed onto a proprietary IT network provided and maintained by the manufacturer of the device. A transformation in the IT architecture in health delivery organisations (HDO) is taking place which involves converging all the HDO IT systems, applications and medical devices together on one single infrastructure utilising a common network. This converged network can provide a number of benefits such a reduction in costs of care, reduction in adverse events, leading to improved patient safety.
All medical devices are strictly regulated and tested however the incorporation of a medical device into an IT network can introduce additional risks, compromising the safety, effectiveness and the security of the IT network.
In 2010 the IEC 80001-1 standard was developed to address these risks. HDO faced a number of challenges caused by the complexity of the different environments and diversity of stakeholders when trying to implementing the requirements of this standard making them confusing and difficult to implement.
In 2015 The ISO TR 80001-2-7 Application guidelines was published to help HDO self-assess their conformance with IEC 80001-1.This includes a process assessment method (PAM) comprising 14 distinct process with their corresponding assessment questions and rating scales which help to identify the strengths and weaknesses of each process. The output from the PAM will help HDO improve risk management practices and conformance with IEC 80001-1.

B5. List the study aims and objectives.

The aims and objectives of this research is to determine if the process assessment method as presented in ISO TR 80001-2-7 is

- Accessible to medical device and IT managers within the 3 children's hospitals.
- Are the questions within the PAM phrased in a way understandable to medical device and IT managers within HDO
- Determine if the assessment scoring methodology presented in the PAM is accessible to medical device and IT managers within HDO
- Determine if the output recommendations presented in the PAM are accessible to medical device and IT managers within HDO

B6. List the study endpoints / measurable outcomes (if applicable).

The results of this assessment will inform the researcher when developing an excel tool which is envisioned to present the process assessment method, questions, assessment scoring methodology and output recommendations in a more accessible manner.

B7. Provide information on the study design.

This research is primarily quantitate, and will consist of semi-structured individual interviews with selected staff from the Information Technology and Clinical engineering departments. The interviewees to fill out a pre and post questionnaire. (Draft Attached)

B8. Provide information on the study methodology.

1.
The researcher proposes to carry out a semi structured interviews with selected staff (IT and Clinical Engineering) from the 3 children's hospitals which will involve

- A brief overview of ISO 80001-1

- An overview of ISO TR 80001-2-7
  - Introduction to the PAM
  - Introduction to the 14 processes within the PAM
  - Introduction to the (process attributes rating values) level of achievement of each process.
  - Introduction to the capability levels for each process.

- Explanation of the first process group Medical IT Network Risk Management Process (MRM) Fig 2, which includes
  - 4 Processes MRM.1-MRM1.3
    - ☐ MRM.1 Medical IT Network Risk Management Process
    - ☐ MRM.1.1 Risk Analysis and Evaluation Process
    - ☐ MRM.1.2 Risk Control Process
    - ☐ MRM.1.3 Review Residue Risk
  - 28 questions
  - 32 Outcomes which are observable results of the successful achievement of the proposed process.

- Using the first process group Medical IT Network Risk Management Process (MRM)
  - Perform a self-assessment of a medical it network within their organization.

- Fill in a questionnaire as to the usability of the process assessment method,

2.
The researcher propose to email an excel tool developed as a result of the interview and questionnaire with selected staff from the 3 children's hospitals and ask the staff to use the tool which will focus on the first process group Medical IT Network Risk Management Process (MRM) and perform a self-assessment of a medical it network within their organization.

- Medical IT Network Risk Management Process (MRM) Fig 2, which includes
  - 4 Processes MRM.1-MRM1.3
    - ☐ MRM.1 Medical IT Network Risk Management Process
    - ☐ MRM.1.1 Risk Analysis and Evaluation Process
    - ☐ MRM.1.2 Risk Control Process
    - ☐ MRM.1.3 Review Residue Risk
  - 28 questions
  - 32 Outcomes which are observable results of the successful achievement of the proposed process.

- Using the first process group Medical IT Network Risk Management Process (MRM)
  - Perform a self-assessment of a medical it network within their organization using the Excel tool

- Fill in a questionnaire as to the usability of the process assessment method, as presented in the excel tool.

2 A link to an on-line questionnaire will be sent out to Information Technology (IT) professionals and Clinical Engineering professionals within acute healthcare delivery organisations .These professionals will be asked to provide feedback on their knowledge, implementation and adoption of the IEC 80001-1 standard and ISO TR 80001-2-7.
The purpose of this feedback is to determine a baseline for the adoption of the standard and identify possible barriers to its implementation.
URL: https://scsstcd.qualtrics.com/SE/?SID=SV_a41yUwD8OjFJIzj

All participants selected will be Information Technology and Clinical Engineering professionals working within an acute healthcare delivery organization. All participants will be over 18 years of age.

The Information Technology Professionals will be sent an email containing a background description of the research project and a link to an online questionnaire. They will be sent this through their professional group within Health Informatics Society of Ireland (HISI)
The Clinical Engineering Professionals will be sent an email containing a background description of the research project and a link to an online questionnaire. They will be sent this through their professional group within Biomedical Engineering Association of Ireland (BEAI).

B9. Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.

Not Appropriate

B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

Answer see below

B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

It is proposed to interview individuals in IT and clinical engineering with experience and responsibility managing medical IT networks within Children's Hospitals. These individuals represent the total population within this area.

B11. How many research participants are to be recruited in total?

The IT and Clinical engineering individuals with this experience will be low in number and not expected to exceed 2-3

B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable).

Name of Study Group:	**Name of Study Group:**	**Name of Study Group:**	**Name of Study Group:**	**Name of Study Group:**
Answer	Answer	Answer	Answer	Answer
Number of Participants in this Study Group:	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**
Answer	Answer	Answer	Answer	Answer

B12 (b) Please provide details on the method of randomisation (where applicable).

No applicable

B13. How many research participants are to be recruited at each study site (where applicable)? Please complete the following table.

Site:	**Number of Research Participants at this site:**
OLCHC	2-3
CUH TEMPLE ST	2-3
TALLAGHT	2-3
NATIONAL IT AND CLINICAL ENGINEERING MANAGERS	30-40

SECTION C STUDY PARTICIPANTS

SECTION C IS MANDATORY

C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1.1 How will the participants in the study be selected?

Voluntary- members of IT and clinical engineering with experience and responsibility managing medical IT networks within Children's Hospitals

C1.2 How will the participants in the study be recruited?

Voluntary- through personal contact with members of IT and clinical engineering with experience and responsibility managing medical IT networks within Children's Hospitals

C1.3 What are the inclusion criteria for research participants? (Please justify, where necessary)

They must have experience and responsibility managing medical IT networks within Children's Hospitals i.e. networks that incorporate medical devices.

C1.4 What are the exclusion criteria for research participants? (Please justify, where necessary)

Not necessary

C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project? Not to my knowledge

C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes

C2.1 (b) If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained.

Not Applicable

C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)

Prior to any interviews a study information sheet and consent form will be given by the researcher to the participants.
Informed consent form

BACKGROUND OF RESEARCH: The purpose of this project is to conduct research to determine if the standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible with Irish HDO and determine the awareness and conformance with these standards in an attempt to identify barriers to their implementation while also identifying the appropriate resources and procedures are in place for CHG

PROCEDURES OF THIS STUDY:

Participants are asked to do the following:

- Fill an on-line questionnaire to determine your knowledge and accessibility of
  - IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices"
  - ISO TR 80001-2-7 "Application guidance -- Part 2-7: Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1

It will take approximately 10 minutes to answer the questionnaire.
There are no anticipated risks to the participants taking part in this questionnaire.

PUBLICATION: This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications.

Individual results may be aggregated anonymously and research reported on aggregate results.

DECLARATION:
- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I agree not to mention any third parties directly.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I have received a copy of this agreement.

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.
RESEARCHERS CONTACT DETAILS: fitzgea6@tcd.ie 086-3815897

URL: https://scsstcd.qualtrics.com/SE/?SID=SV_a41yUwD8OjFJIzj

2) Interview Process
Information Sheet for Prospective Participants
Project Title: "Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7"
Name of Lead Researcher: Tony Fitzgerald
Name of Supervisor: Professor Gave Stevens
Lead Researcher's email: fitzgea6@tcd.ie
Lead Researcher's Contact Tel No.: 086-3815897
Course Name and Code: MSc Health Informatics Estimated start date of survey/research: April 2014

Background of Information:
The purpose of this research is to determine if the process assessment method as presented in ISO TR 80001-2-7 is

- Accessible to Clinical Engineering and IT managers within the 3 children's hospitals.
- Are the questions within the PAM phrased in a way understandable to Clinical Engineering and IT managers within HDO
- Determine if the assessment scoring methodology presented in the PAM is accessible to Clinical Engineering and IT managers within HDO
- Determine if the output recommendations presented in the PAM are accessible to Clinical Engineering and IT managers within HDO

You have been selected to participate in this research as you are an Clinical Engineering and IT professional working within the Children's Hospital Group and therefore have experience in managing and maintaining IT infrastructure which contains medical devices within these health delivery organisations.

Procedures of this study:
You will be asked to participate in a semi structured interviews which will involve the following.
- A brief presentation on ISO 80001-1

- A presentation on ISO TR 80001-2-7 which will include
  - Introduction to the PAM
  - Introduction to the 14 processes within the PAM
  - Introduction to the (process attributes rating values) level of achievement of each process.
  - Introduction to the capability levels for each process.

- Explanation of the first process group Medical IT Network Risk Management Process (MRM) Fig 2, which includes
  - 4 Processes MRM.1-MRM1.3
  - ☐ MRM.1 Medical IT Network Risk Management Process
  - ☐ MRM.1.1 Risk Analysis and Evaluation Process
  - ☐ MRM.1.2 Risk Control Process
  - ☐ MRM.1.3 Review Residue Risk
  - 28 questions
  - 32 Outcomes which are observable results of the successful achievement of the proposed process.

- Using the first process group Medical IT Network Risk Management Process (MRM)
  - Perform a self-assessment of a medical it network within their organization.

- Fill in an online questionnaire as to the usability of the process assessment method presented in ISO TR 80001-2-7

- Your involvement in this study will take approximately 1 hour for the introduction and presentation on IEC 80001-1 and ISO TR 80001-2-7.

- The online questionnaire should take approx. 5 minutes to complete once the self-assessment using the first process group of a medical IT network is performed.

Additional Information:
- Your participation in this study is voluntary.
- You may withdraw from the study at any point for any reason without any penalty.
- You do not have to answer each of the questions.
- The data will be anonymized. There will be preservation of your and third-party anonymity in analysis, publication and presentation of resulting data and findings. Please do not refer to any third parties directly.
- I do not anticipate any risks to you in this study. The benefits of participating in the study is that your feedback will allow the researcher to determine a base line as to the adoption and implementation of ISO 80001-1 and identify barriers to its use and implementation and also raise awareness of this standard.
- A copy of the research will be provided to you if requested.
- If you require any further information on the study, please feel free to ask me.
- You may only participate in this study if you are 18 years of age or older and are competent to supply consent to participate in this study.
- In the very unlikely event that an illicit activity is reported to me during the study I will be obliged to report it to the appropriate authorities.
- In my dissertation I may use direct quotations when they are contextually appropriate, but you will still remain anonymous.
- I will act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Informed consent form
Interview Process

BACKGROUND OF RESEARCH:

The purpose of this research is to determine if the process assessment method as presented in ISO TR 80001-2-7 is

- Accessible to Clinical Engineering and IT managers within the 3 children's hospitals.

- Are the questions within the PAM phrased in a way understandable to Clinical Engineering and
  IT managers within HDO

- Determine if the assessment scoring methodology presented in the PAM is accessible to Clinical Engineering and IT managers within HDO

- Determine if the output recommendations presented in the PAM are accessible to Clinical Engineering and IT managers within HDO

Participants are asked to do the following:

You will be asked to participate in a semi structured interviews which will involve the following.

- A brief presentation on ISO 80001-1

- A presentation on ISO TR 80001-2-7

- Explanation of the first process group Medical IT Network Risk Management Process (MRM) Using the first process group Medical IT Network Risk Management Process (MRM)
  - Perform a self-assessment of a medical it network within their organization.

  - Fill in an online questionnaire as to the usability of the process assessment method presented in ISO TR 80001-2-7

Your involvement in this study will take approximately 1 hour for the introduction and presentation on IEC 80001-1 and ISO TR 80001-2-7.

The online questionnaire should take approx. 5 minutes to complete once the self-assessment using the first process group of a medical IT network is performed.

There are no anticipated risks to the participants taking part in this questionnaire.

PUBLICATION: This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications.

Individual results may be aggregated anonymously and research reported on aggregate results.

DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I agree not to mention any third parties directly.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I have received a copy of this agreement.

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.
RESEARCHERS CONTACT DETAILS: fitzgea6@tcd.ie 086-3815897

C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Yes

C2.2 (b) If no, please justify.

Not applicable

C2.3 (a) Will there be a time interval between giving information and seeking consent? No

C2.3 (b) If yes, please elaborate.

Not applicaple

C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.

It is proposed to present the study information sheet and consent form at the beginning of the semi-structured interviews. These interviews will take approx. 1 hour and will need to be arranged in advance with the selected individuals.

C3 ADULT PARTICIPANTS (AGED 18 OR OVER) - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent? Yes

If answer is Yes, please delete remaining questions in Section C3

C4 PARTICIPANTS UNDER THE AGE OF 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children? No

If answer is No, please delete remaining questions in Section C4

C5 PARTICIPANTS - CHECKLIST

C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE's National Consent Policy, particularly Part 3, Section 5.

Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.

(a) Healthy Volunteers No

(b) Patients No

- **Unconscious patients** No
- **Current psychiatric in-patients** No
- **Patients in an emergency medical setting** No

(c) Relatives / Carers of patients No

(d) Persons in dependent or unequal relationships No

- **Students** No
- **Employees / staff members** Yes
- **Persons in residential care** No
- **Persons highly dependent on medical care** No

(e) Intellectually impaired persons No

(f) Persons with a life-limiting condition No
(Please refer to guidance manual for definition)

(g) Persons with an acquired brain injury No

C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).

The researcher will speak to selected individuals in the Information Technology and Clinical Engineering departments. Their participation will be on a voluntary basis.

C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.

Non Applicable

SECTION D RESEARCH PROCEDURES

SECTION D IS MANDATORY

D1 (a) What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?

Participate in a semi structured interview,
Complete a pre and post questionnaire.

D1 (b) What other activities (if any) are taking place for the <u>purposes of this research study</u> e.g. chart review, sample analysis etc?

Review excel tool developed by the researcher

D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.

None

D3. What is the potential benefit that may occur as a result of this study?

1 Increase awareness of Standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1"

2 The results of this assessment will inform the researcher when developing an excel tool which is envisioned to present the process assessment method, questions, assessment scoring methodology and output recommendations in a more accessible and useable manner.
3 The output from the PAM will help HDO improve risk management practices and conformance with IEC 80001-1.

D4 (a) Will the study involve the withholding of treatment?
Non-applicable

D4 (b) Will there be any harms that could result from withholding treatment?
Non-applicable

D4 (c) If yes, please elaborate.

Non-applicable

D5 (a) How will the health of participants be monitored <u>during</u> the study, and who will be responsible for this?

Non-applicable

D5 (b) How will the health of participants be monitored <u>after</u> the study, and who will be responsible for this?

Non-applicable

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study? Non-applicable

D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?

Non-applicable

D7. Please comment on how individual results will be managed.

Non-applicable

D8. Please comment on how aggregated study results will be made available.

This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfillment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications.

D9. Will the research participant's general practitioner be informed that the research participant is taking part in the study (if appropriate)? Non-applicable

D10. Will the research participant's hospital consultant be informed that the research participant is taking part in the study (if appropriate)? Yes / Non-applicable

SECTION E DATA PROTECTION

SECTION E IS MANDATORY

E1 DATA PROCESSING - CONSENT

E1.1 (a) Will consent be sought for the processing of data? Yes

E1.1 (b) If no, please elaborate.

Answer

E2 DATA PROCESSING - GENERAL

E2.1 Who will have access to the data which is collected?

Mainly only the researcher and the project supervisor in TCD for verification purposes. All data will be anonymised.

E2.2 What media of data will be collected?

Online questionnaire using Qualtrics.

E2.3 (a) Would you <u>class</u> the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?

Questionnaire will be anonymous.

E2.3 (b) If 'coded', please confirm who will retain the 'key' to re-identify the data?

Will not be coded

E2.4 Where will data which is collected be stored?

The data will be stored in a password excel file on an encrypted laptop.

E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.

The questionnaire is hosted by Qualtrics. The option to *'Anonymize Response. Do NOT record any personal information and remove panel association'* has been selected and set to true, so that no personal information is automatically recorded

When the questionnaires have been completed, the data will be exported out to the software product Microsoft Excel for analysis. There should be no identifiable information in the results. If a name has been added in by a participant, this will be removed from the data in the Excel sheet by the author.

The data will be stored in a password protected excel file on an encrypted laptop.

E2.6 (a) Will data collected be at any stage leaving the site(s) of origin?

No

E2.6 (b) If yes, please elaborate.

Answer

E2.7 Where will data analysis take place and who will perform data analysis (if known)?

Data Analysis will take place on the researcher's encrypted laptop in the Trinity Library by the researcher.

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?

Data will only be retained for as long as necessary by Trinity College after which it will be destroyed/deleted.

E2.8 (b) Please elaborate.

All data files will be deleted by the researcher.

E2.8 (c) If destroyed, how, when and by whom will it be destroyed?

All data files will be deleted by the researcher.

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?

Data will only be retained for as long as necessary by Trinity College after which it will be destroyed.
Data files will be deleted.

E2.9 Please comment on the confidentiality of collected data.

No personal information will be automatically recorded and all data will be totally confidential and anonymous, only collated results will be issued.

E2.10 (a) Will any of the interview data collected consist of audio recordings / video recordings? No

E2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?

Non-applicable

E2.11 (a) Will any of the study data collected consist of photographs/ video recordings? No

E2.11 (b) If yes, please elaborate.

Non-applicable

E3 ACCESS TO HEALTHCARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)? YNo

If answer is No, please delete remaining questions in Section E3

SECTION F HUMAN BIOLOGICAL MATERIAL

F1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

F1 1 (a) Does this study involve human biological material? No

If the answer is No, please delete Section F

SECTION G RADIATION

G1 RADIATION – GENERAL

G1.1 (a) Does this study/trial involve exposure to radiation? No

If answer is No, please delete remaining questions in Section G

SECTION H MEDICAL DEVICES

H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device? No

If answer is No, please delete remaining questions in Section H.

SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

I.1 NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I1.1 (a) Does this study involve a medicinal product? No

If the answer is No, please delete remaining questions in subsection I1

I.2 COSMETICS

I2.1 (a) Does this study involve a cosmetic? No

If the answer is No, please delete remaining questions in subsection I2

I.3 FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? No

If the answer is No, please delete remaining questions in subsection I3

SECTION J INDEMNITY AND INSURANCE

SECTION J IS MANDATORY

J1 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study <u>at each site.</u>

The researcher (Tony Fitzgerald) is a staff member of the Clinical Engineering Dept. of OLCHC, the interviews with the IT and Clinical engineering staff of OLCHC will take place in OLCHC. It is not envisioned that insurance/indemnity is required.

J2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study <u>for each investigator.</u>

The researcher (Tony Fitzgerald) is a staff member of OLCHC, The interviewees are also staff members of OLCHC. It is not believed that Insurance/indemnity is required.

J3.1 Please give the name and address of the organisation / or individual legally responsible for this research study?

This study is part of a dissertation which is a requirement for an MSc on Health Informatics in Trinity College Dublin

J3.2 Where an organisation is legally responsible, please specify if this organisation is:

A pharmaceutical company Yes / No
A medical device company Yes / No
A university Yes / No
A registered charity Yes / No
Other Yes / No **If yes, please specify:** Answer

J3.3 Please confirm and provide evidence of any specific <u>additional</u> insurance / indemnity arrangements which have been put in place, if any, <u>by this organisation / or individual</u> for this research study?

Not-applicable

SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS

SECTION K IS MANDATORY

K1 COST AND RESOURCE IMPLICATIONS

K1.1 Please provide details of all cost / resource implications related to this study (e.g. staff time, office use, telephone / printing costs etc.)

No costs involved

K2 FUNDING

K2.1 (a) Is funding in place to conduct this study?

Funding not required

K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.

Not-applicable

K2.1 (c) If yes, please state the source of funding (industry, grant or other), the name of the funder, the amount of funding and duration of funding.

Source of funding (industry, grant or other):
Answer
Name of Funder:
Answer
Amount of Funding:
Answer
Duration of Funding
Answer

K2.1(d) Please provide additional details in relation to management of funds.

Not-applicable

K2.1(e) Is the study funded by a 'for profit' organisation? Yes / No

K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding? Not-applicable

K2.2 (b) If yes, please elaborate.

Answer

K3 PAYMENTS TO INVESTIGATORS

K3.1 (a) Will any payments (monetary or otherwise) be made to investigators? No

K3.1 (b) If yes, please provide details of payments (including amount).

Answer

K4 PAYMENTS TO PARTICIPANTS

K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants? No

K4.1 (b) If yes, please provide details of payments / reimbursements (including amount).

Answer

SECTION L ADDITIONAL ETHICAL ISSUES

L1 (a) Does this project raise any additional ethical issues? No

If answer is No, please delete remaining questions in Section L.

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.

Appendix B: Ethics Approval and Application Children's University Hospital Temple St

Ethics Approval

Children's University Hospital Temple Street

Children's University Hospital
TEMPLE STREET, DUBLIN

DEPARTMENT OF RESEARCH
Children's University Hospital
Temple Street, Dublin 1
Tel: +353 1 892 1787
Email: research@cuh.ie Web: www.cuh.ie

Mr Tony Fitzgerald
19 Doonsalla Drive
Dunlaoghaire
Co Dublin

22nd February 2017

Re: 17.009 Internal Research Proposal

Dear Mr Fitzgerald,

Your research proposal entitled "Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7" reference number 17.009 has been reviewed by the Medical Secretary of the Ethics and Research Committee and no concerns have been identified. Approval has been granted to your proposal.

Approval from the Information Governance Committee is incorporated within this approval.

We wish you every success with your research.

Best wishes,

Michael Riordan
checked and signed electronically

Dr Michael Riordan
Medical Secretary Ethics Research Committee
MCRN: 281464

Ethics Application

Children's University Hospital Temple St

AUDIT & RESEARCH PROFORMA 2016

Name	Tony Fitzgerald	**Hospital**	New Childrens Hospital
Position	Principle Clinical Engineer	**Contact details**	tony.fitzgerald@nph.ie 086-3815897
Date of submission	8-Feb-2017	**Start and finish dates**	1st March 2017— 1st May 2017
Supervisor	Prof Gaye Stephens	**Hospital and Dept**	Trinity College Dublin SCSS Dept

Title:				
Is this is a Clinical Audit? (Auditing against a standard)	Yes	☐	No	✓
Is this is a Chart Review? (Health Care Record Review)	Yes	☐	No	✓
Is this is a Review of non-chart based patient data? (ICT Systems)	Yes	☐	No	✓
Is this a low risk research study requiring administrative review?	Yes	✓	No	☐

Please provide a brief outline of this study

The health service executive (HSE) has indicated that that the Children's Hospital Group (CGH) will be the first implementation of a National Acute electronic medical record (EMR) and are currently progressing a national eHealth program which includes the delivery of an electronic medical record (EMR) solution for the whole of Irish healthcare . One single heterogeneous IT network is planned for the new children hospital and it is crucial that all associated resources, procedures and risks are identified and appropriate measures are put in place.

I am a clinical engineer working on the new children's hospital project. I am currently studying for an MSc in Health Informatics in Trinity College and as part of my thesis I want to survey the clinical engineering and Information technology managers to ascertain their knowledge of an IEC Standard. The Standard is called IEC 80001-1 ": Application of risk management for IT-networks incorporating medical devices " and defines roles, responsibilities and activities in relation to the management of risk associated with placing a medical device onto an IT network.
The purpose of my project is to conduct research to determine if the standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible within the 3 children's hospitals and determine the awareness and conformance with these standards in an attempt to identify and remove barriers to their implementati

Is there an agreed standard you will be auditing against? (Applicable to all Clinical Audits)

Yes ☐ No ☐ N/A ✓ Remember to attach a copy of the relevant standard(s) to the submission

How you will collect the data? Please attach a copy of the audit/research tool to the submission.
An online questionnaire is hosted by Qualtrics (see attached document outlining questionnaire)
Interview (see attached document outlining process)
Has a literature search been undertaken? Yes ✓ No ☐
What is the approximate sample size? Approx. 6, 2 per hospital (This is the full sample of pead IT & CE Managers)

Please tick additional reasons (if any) for carrying out this Audit/Research			
Service improvement	✓	Professional development	☐
High volume activity	☐	Re-audit	☐
High risk activity	☐	External audit (HSE/HIQA etc)	☐
High cost activity	☐	Clinical research	☐

Please highlight any ethical or research issues related to this study
of some participants. However, it is my intention to adhere to the ethical code of good practice for research at all times.

Data Protection
1. Who will have access to the data which is collected?
Only the researcher has access to this laptop, and the laptop is encrypted. All research and analysis documents relating to the dissertation will also be individually password protected.
2. What media of data will be collected?
The research and analysis documents include • dissertation (Microsoft Word) • results from the ISO 80001-1 Evaluation Questionnaire (Microsoft Excel) • answers collected from the Interviews (Microsoft Word) • results from the Excel Tool Evaluation Questionnaire (Microsoft Excel) o The questionnaire is hosted by Qualtrics. The option to 'Anonymize Response. Do NOT record any personal information and remove panel association' has been selected and set to true, so that no personal information is automatically recorded. o When the questionnaires have been completed, the data will be exported out to the software product Microsoft Excel for analysis. There should be no identifiable information in the results. If a name has been added in by a participant, this will be removed from the data in the excel sheet by the author. Once the dissertation has been submitted, all relating research and analysis documents and surveys will be deleted.
3. Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?
As per the Data Protection Acts 1988 and 2003 the data will be anonymized and no disclosures of personal information will be provided, and no consent is required from the data controller
4. If 'coded', please confirm who will retain the 'key' to re-identify the data?
N/A
5. Where will data which is collected be stored?
All research and analysis documents used for this dissertation will be stored on the researchers personal laptop.
6. Will data collected be at any stage leaving the TSCUH site? Yes ✓ No ☐
If yes, please elaborate.
This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research

may also be published in scientific publications.
7. Who will destroy data after 5 years and how?
Once the dissertation has been submitted, all relating research and analysis documents and surveys will be deleted by the researcher.

I confirm that all data collection/storage will comply with TSCUH ICT policies	Yes ✓

Dissemination of results:		
Report:	Yes ☐	No ✓
Presentation:	Yes ✓	No ☐
Publication:	Yes ✓	No ☐

Signed	**Audit/Research lead:**	**Signed**	**Audit/Research supervisor:**
Date 8-2-17	Tony Fitzgerald	Date 8-2-17	Prof Gaye Stephens TCD

Approval (Office use only)
Only the Chair of the Clinical Audit Review Committee for Clinical Audit or the medical secretary of the Research Ethics Committee may approve this application
Application number
Approver
Signature
Date

Checklist for Audit/Chart Review Proforma

1. Audit & Research proforma should be completed electronically and submitted to research@cuh.ie
2. Please also provide any appropriate Supporting documents for clinical audits (standards, guidelines, literature review)

Contact Dr Tara Raftery for any further assistance at research@cuh.ie or Tara.Raftery@cuh.ie

Appendix C: Ethics Approval and Application National Children's Hospital Tallaght

Ethics Approval Tallaght Hospital

From: Claire Hartin <Claire.Hartin@amnch.ie>
Sent: 25 January 2017 10:31
To: Tony Fitzgerald
Subject: RE: Information about ethics approval for survey

Dear Tony,

Thank you for your email. Your proposed research is something that SJH/AMNCH REC would consider peer research and is something which we would not review or deduce any further ethical issues with as you correctly identified on our website. With regard to accessing clinical engineering and Information technology managers in Tallaght Hospital which I presume you are querying, I would advise you seek permission from the Head of ICT, Mr. David Wall and the Head of Facilities, Mr. Ciaran Faughan. I am not familiar with who manages these functions in the other children's hospitals but you could enquire with their HR Departments.

This email should be sufficient if there are any queries regarding you seeking the opinion of an ethics committee with regard to any publication you may seek in regard to your proposed research.

Kind regards

Claire

Claire Hartin, MSc.
Research and Ethics Administrator| Medical Board Secretariat
Research and Ethics Dept. | Tallaght Hospital | Tallaght | Dublin 24
T. 353 1 4142199 |E. claire.hartin@amnch.ie
W. http://www.tallaghthospital.ie/About-us/

Ethics Application Tallaght Hospital

From: Tony Fitzgerald [mailto:Tony.fitzgerald@nph.ie]
Sent: 23 January 2017 20:29
To: Claire Hartin <Claire.Hartin@amnch.ie>
Subject: Information about ethics approval for survey

Hi Claire
My name is Tony Fitzgerald and I am a clinical engineer working on the new children's hospital project. I am currently studying for an MSc in Health Informatics in Trinity College and as part of my thesis I want to survey the clinical engineering and Information technology managers to ascertain their knowledge of an IEC Standard. The Standard is called IEC 80001-1 ": Application of risk management for IT-networks incorporating medical devices " and defines roles, responsibilities and activities in relation to the management of risk associated with placing a medical device onto an IT network.

The purpose of my project is to conduct research to determine if the standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-

7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible within the 3 children's hospitals and determine the awareness and conformance with these standards in an attempt to identify and remove barriers to their implementation

Your website stated that I do not need to submit an application to the ethics committee however I may need approval from hospital management.
Could you please give me guidance on who I need to contact in the hospital management.
I have attached summary of the research that I intend to do.

Regards

Tony Fitzgerald

Appendix D: Ethics Approval and Application Trinity College Dublin

rec-app-help@tchpc.tcd.ie <rec-app-help@tchpc.tcd.ie> 6 April 2017 at 15:51
To: fitzgea6@tcd.ie

The status of 'Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7?' has been updated by the Committee.

Title: 'Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7?'
Applicant Name: Anthony Fitzgerald
Submitted by: Anthony Fitzgerald
Academic Supervisor: Gaye Stephens
Application Number: 20170304

Result of the REC Meeting: Approved

The Feedback from the Committee is as follows:
The committee notes that the proposal has been externally approved by several hospital ethics commitees, and so as per our policy we make note of these approvals. The application is well prepared and we wish you success with your study.
While in such cases we do not require revisions to be made, there are two observations regarding the study which it would be better to adress if possible, when submitting the hard copy of your application to the Research Unit.
1. Data retention. College guidelines suggest that primary research data be retained for 10 years. We do not insist on this, but data for work contributing to a dissertation should be retained at least until the relevant exam board (not upon submission of the dissertation).
2. Anonymisation impacts on the ability to withdraw, so it would be better if statements on consent forms regarding the right to withdraw at any time have a clause stating that once data is submitted anonymously, it is no longer possible to remove the data.

The application can be viewed here:

https://webhost.tchpc.tcd.ie/research_ethics/?q=node/240

If amendments are required, please use the following link to edit the application and upload the changes:

https://webhost.tchpc.tcd.ie/research_ethics/?q=node/240/edit

School of Computer Science & Statistics
Research Ethics Application

Part A

Project Title: Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7

Name of Lead Researcher (student in case of project work): Anthony Fitzgerald

Name of Supervisor: .....Prof Gaye Stephens

TCD E-mail: fitzgea6@tcd.ie Contact Tel No.: 0863815897

Course Name and Code (if applicable): MSc in Health Informatics .....

Estimated start date of survey/research: .....April 2007

I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- If the study involves participants viewing video displays then I will verify that they understand that if they or anyone in their family has a history of epilepsy then the participant is proceeding at their own risk
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Signed: Tony Fitzgerald Date: 3-3-17.

Lead Researcher/student in case of project work

Part B

Please answer the following questions.		*Yes/No*
Has this research application or any application of a similar nature connected to this research project been refused ethical approval by another review committee of the College (or at the institutions of any collaborators)?		No
Will your project involve photographing participants or electronic audio or video recordings?		No
Will your project deliberately involve misleading participants in any way?		No
Does this study contain commercially sensitive material?		No
Is there a risk of participants experiencing either physical or psychological distress or discomfort? If yes, give details on a separate sheet and state what you will tell them to do if they should experience any such problems (e.g. who they can contact for help).		No
Does your study involve any of the following?	Children (under 18 years of age)	No
	People with intellectual or communication difficulties	No
	Patients	No

School of Computer Science and Statistics
Research Ethical Application Form

Details of the Research Project Proposal must be submitted as a separate document to include the following information:

1. Title of project
2. Purpose of project including academic rationale
3. Brief description of methods and measurements to be used
4. Participants - recruitment methods, number, age, gender, exclusion/inclusion criteria, including statistical justification for numbers of participants
5. Debriefing arrangements
6. A clear concise statement of the ethical considerations raised by the project and how you intend to deal with them
7. Cite any relevant legislation relevant to the project with the method of compliance e.g. Data Protection Act etc.

Part C

I confirm that the materials I have submitted provided a complete and accurate account of the research I propose to conduct in this context, including my assessment of the ethical ramifications.

Signed: Tony Fitzgerald Date: 3/3/17
Lead Researcher/student in case of project work

There is an obligation on the lead researcher to bring to the attention of the SCSS Research Ethics Committee any issues with ethical implications not clearly covered above.

Part D

If external or other TCD Ethics Committee approval has been received, please complete below.

External/TCD ethical approval has been received and no further ethical approval is required from the School's Research Ethical Committee. I have attached a copy of the external ethical approval for the School's Research Unit.

Signed: Tony Fitzgerald Date: 3/3/17.
Lead Researcher/student in case of project work

Part E

If the research is proposed by an undergraduate or postgraduate student, please have the below section completed.

I confirm, as an academic supervisor of this proposed research that the documents at hand are complete (i.e. each item on the submission checklist is accounted for) and are in a form that is suitable for review by the SCSS Research Ethics Committ

Signed: G. Stapleton Date: 3/3/2017
Supervisor

Completed application forms together with supporting documentation should be submitted electronically to the online ethics system - https://webhost.tchpc.tcd.ie/research_ethics/ When your application has been reviewed and approved by the Ethics committee, hardcopies with original signatures should be submitted to the School of Computer Science & Statistics, Room 104, Lloyd Building, Trinity College, Dublin 2.

CHECKLIST

Please ensure that you have submitted the following documents with your application:

1.	• SCSS Ethical **Application Form**	
2.	• **Participant's Information Sheet** must include the following: a) Declarations from Part A of the application form; b) Details provided to participants about how they were selected to participate; c) Declaration of all conflicts of interest.	
3.	• **Participant's Consent Form** must include the following: a) Declarations from Part A of the application form; **b)** Researchers contact details provided for counter-signature (your participant will keep one copy of the signed consent form and return a copy to you).	
4.	• **Research Project Proposal** must include the following: a) You must inform the Ethics Committee **who** your intended participants are i.e. are they your work colleagues, class mates etc. b) How will you recruit the participants i.e. **how** do you intend asking people to take part in your research? For example, will you stand on Pearse Street asking passers-by? c) If your participants are under the age of 18, you must seek both parental/guardian AND child consent.	
5.	• Intended **questionnaire**/survey/interview protocol/screen shots/representative materials (as appropriate)	
6.	• **URL** to intended on-line survey (as appropriate)	

Notes on Conflict of Interest

1. If your intended participants are work colleagues, you must declare a potential conflict of
   interest: you are taking advantage of your existing relationships in order to make progress in your research. It is best to acknowledge this in your invitation to participants.
2. If your research is also intended to direct commercial or other exploitation, this must be declared. For example, *"Please be advised that this research is being conducted by an employee of the company that supplies the product or service which form an object of study within the research."*

Notes for questionnaires and interviews

1. If your questionnaire is **paper based**, you must have the following **opt-out** clause on the top of
   each page of the questionnaire: *"Each question is optional. Feel free to omit a response to any question; however the researcher would be grateful if all questions are responded to."*
2. If you questionnaire is **on-line**, the first page of your questionnaire must repeat the content of the information sheet. This must be followed by the consent form. If the participant does not agree to the consent, they must automatically be exited from the questionnaire.
3. Each question must be **optional**.
4. The participant must have the option to **'not submit, exit without submitting'** at the final submission point on your questionnaire.
5. If you have open-ended questions on your questionnaire you must warn the participant against naming **third parties**: *"Please do not name third parties in any open text field of the questionnaire. Any such replies will be anonymised."*
6. You must inform your participants regarding **illicit activity**: *"In the extremely unlikely event that illicit activity is reported I will be obliged to report it to appropriate authorities."*

Ethical Approval

Research Project Proposal

- **PROJECT TITLE**

"Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7"

PROJECT PURPOSE

Traditionally, medical devices were designed as stand-alone devices and if they were required to be networked e.g. (Physiological Monitors in an ICU) they were placed onto a proprietary IT network provided and maintained by the manufacturer of the device. A transformation in the IT architecture in health delivery organisations (HDO) is taking place which involves converging all the HDO IT systems, applications and medical devices together on one single infrastructure utilising a common network. This converged network can provide a number of benefits such a reduction in costs of care, reduction in adverse events, leading to improved patient safety.
All medical devices are strictly regulated and tested however the incorporation of a medical device into an IT network can introduce additional risks, compromising the safety, effectiveness and the security of the IT network.
In 2010 the IEC 80001-1 standard was developed to address these risks.

HDO faced a number of challenges caused by the complexity of the different environments and diversity of stakeholders when trying to implementing the requirements of this standard making them confusing and difficult to implement.
In 2015 The ISO TR 80001-2-7 Application guidelines was published to help HDO self-assess their conformance with IEC 80001-1.This includes a process assessment method (PAM) comprising 14 distinct process with their corresponding assessment questions and rating scales which help to identify the strengths and weaknesses of each process. The output from the PAM will help HDO improve risk management practices and conformance with IEC 80001-1.

The health service executive (HSE) has indicated that that the Children's Hospital Group (CHG) will be the first implementation of a National Acute electronic medical record (EMR) and are currently progressing a national eHealth program which includes the delivery of an electronic medical record (EMR) solution for the whole of Irish healthcare . One single heterogeneous IT network is planned for the new children hospital and it is crucial that all associated resources, procedures and risks are identified and appropriate measures are put in place

The purpose of this project is to conduct research to determine if the standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible with Irish HDO and determine the awareness and conformance with these standards in an attempt to identify barriers to their implementation while also identifying the appropriate resources and procedures are in place for CHG.

This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfillment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications.

- **RESEARCH METHODS**

1) *Questionnaire*

A link to an on-line questionnaire will be sent out to Information Technology (IT) and Clinical Engineering (CE) professionals within acute healthcare delivery organisations .These professionals will be asked to provide feedback on their knowledge, implementation and adoption of the IEC 80001-1 standard and its technical report ISO TR 80001-2-7.
The purpose of this feedback is to determine a baseline for the adoption of the standard and identify possible barriers to its implementation.

2) Interviews

Interviews will be conducted with the IT & CE professionals within the existing 3 children's hospitals and the HSE lead responsible for the IT strategy for the new children's hospital. The purpose of the interviews is to present the process assessment model (PAM) presented in ISO TR 80001-2-7 and evaluate its functionality

3) Excel Tool Evaluation

A select population composing of the IT & CE professionals within the children's hospitals will be asked to download an excel tool, developed by the researcher which is based on the PAM within ISO TR 80001-2-7 and answer a number on online questions to determine how useable and applicable the process assessment model is when presented in this excel format.

PARTICIPANT SELECTION

All participants selected will be Information Technology and Clinical Engineering professionals working within an acute healthcare delivery organization. All participants will be over 18 years of age.

The Information Technology Professionals will be sent an email containing a background description of the research project and a link to an online questionnaire. They will be sent this through their professional group within Health Informatics Society of Ireland (HISI)
The Clinical Engineering Professionals will be sent an email containing a background description of the research project and a link to an online questionnaire. They will be sent this through their professional group within Biomedical Engineering Association of Ireland (BEAI).
.

1. **Online Questionnaire**
   A link to an on-line questionnaire will be sent out to IT and Clinical Engineering professionals through their membership of HISI and the BEAI. This online questionnaire should take approx. 10 minutes to complete.

2. **Interviews**
   I will ask the select population of the IT & CE managers within the Children's Hospitals to participate in interviews. I will contact these managers through their respective HDOs. These will be individual semi-structured interviews and should take about 1 hour.

3. **Excel Tool Evaluation**
   I will ask the select population of the IT managers within the Children's Hospitals to test the excel tool and participate in an online questionnaire and provide feedback on its functionality and suitability. This online questionnaire should take about 10 minutes to complete.

DEBRIEFING ARRANGEMENTS

I will inform all participants of the purpose of the research. If participants request to the see the results of any of the studies I will send on the final results in pdf format to their email address. If

participants request to view the final thesis I will send on a pdf copy when the dissertation has been completed.

ETHICAL CONSIDERATIONS

There is a potential conflict of interest in relation to conducting this research study as I am a colleague of some participants. However, it is my intention to adhere to the ethical code of good practice for research at all times.

DATA CONFIDENTIALITY

As per the Data Protection Acts 1988 and 2003 the data will be anonymized and no disclosures of personal information will be provided, and no consent is required from the data controller.

All research and analysis documents used for this dissertation are/will be stored on the researcher's personal laptop. Only the researcher has access to this laptop, and the laptop is encrypted. All research and analysis documents relating to the dissertation will also be individually password protected.

The research and analysis documents include

- dissertation (Microsoft Word)
- results from the ISO 80001-1 Evaluation Questionnaire (Microsoft Excel)
- answers collected from the Interviews (Microsoft Word)
- results from the Excel Tool Evaluation Questionnaire (Microsoft Excel)

Once the dissertation has been submitted, all relating research and analysis documents and surveys will be deleted.

1. ISO 8001-1 Evaluation Questionnaire
    - The questionnaire is hosted by Qualtrics. The option to 'Anonymize Response. Do NOT record any personal information and remove panel association' has been selected and set to true, so that no personal information is automatically recorded.
    - When the questionnaires have been completed, the data will be exported out to the software product Microsoft Excel for analysis. There should be no identifiable information in the results. If a name has been added in by a participant, this will be removed from the data in the Excel sheet by the author.

2. Interview Questions
    - The names of the interviewees will not be recorded.

3. Excel Tool Evaluation Questionnaire
    - The questionnaire is hosted by Qualtrics. The option to 'Anonymize Response. Do NOT record any personal information and remove panel association' has been selected and set to true, so that no personal information is automatically recorded.
    - When the questionnaires have been completed, the data will be exported out to the software product Microsoft Excel for analysis. There should be no identifiable information in the results. If a name has been added in by a participant, this will be removed from the data in the excel sheet by the author.

Appendix E: Application and Approval to contact Information Technology Managers

Application to Contact IT Managers through HISI (Health Informatics Society of Ireland)

From: Fitzgerald Anthony [mailto:fitzgea6@tcd.ie]
Sent: Sunday 26 February 2017 20:11
To: O Hare, Neil (IMS) <NOHare@STJAMES.IE>
Cc: Gaye <gaye.stephens@tcd.ie>
Subject: Assistance in contacting IT managers within the Health Service

Hi Neil
My name is Tony Fitzgerald and I am a clinical engineer working on the new children's hospital project. I am currently studying for an MSc in Health Informatics in Trinity College and as part of my thesis I want to survey the clinical engineering and Information technology managers within health delivery organisations to ascertain their knowledge of an IEC Standard. The Standard is called IEC 80001-l." Application of risk management for IT-networks incorporating medical devices " and defines roles, responsibilities and activities in relation to the management of risk associated with placing a medical device onto an IT network.

The purpose of this project is to conduct research to determine if the Standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organisations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible within Irish HDO and determine the awareness and conformance with these standards in an attempt to identify barriers to their implementation.
Prof Gaye Stevens has suggested that I contact you in relation to sending an online survey to IT professionals within the Health Services through the HISI IT forum. Would it be possible to contact the IT professionals through the HISI forum.
My intention is to send an online questionnaire via email to IT professionals within the healthcare industry to determine the awareness of the IEC 80001-1 standard and its technical report ISO TR 80001-2-7.
The purpose of this is to determine a baseline to the adoption and implementation of the Standard within the Irish context and also raise awareness of this standard.
Link to questionnaire
https://scsstcd.qualtrics.com/SE/?SID=SV_a41yUwD8OjFJIzj
I have also attached a summary of the research that I intend to do.
I am currently finalising my ethics application to Trinity College and intend to commence the survey at the beginning of April.

Regards Tony Fitzgerald

Approval to Contact IT Managers through HISI (Health Informatics Society of Ireland)

From: **O Hare, Neil (IMS)** <NOHare@stjames.ie>
Date: 3 March 2017 at 08:33
Subject: RE: Assistance in contacting IT managers within the Health Service
To: Fitzgerald Anthony <fitzgea6@tcd.ie>

Hi Tony

I am happy to send a note to the IT managers re your survey.

Can you draft me a paragraph for the e-mail setting out what the survey is about, etc and I will forward on to the group.

Kind regards

Neil

Appendix F: Application and Approval to contact Clinical Engineering Managers

Application to contact Clinical Engineering Managers through the BEAI (Biomedical Engineering Association of Ireland)

From: Fitzgerald Anthony [mailto:fitzgea6@tcd.ie]
Sent: 27 February 2017 10:42
To: Brian Kearney

Cc: Gaye
Subject: Contact Clinical Engineering Managers in relation to a survey on IEC80001 Standard

Hi Brian

My name is Tony Fitzgerald and I am a clinical engineer originally from Our Lady's Children's Hospital Crumlin but now working on the new children's hospital project. I am currently studying for an MSc in Health Informatics in Trinity College and as part of my thesis I want to survey the clinical engineering and Information technology managers within health delivery organisations to ascertain their knowledge of an IEC Standard. The Standard is called IEC 80001-1." Application of risk management for IT-networks incorporating medical devices " and defines roles, responsibilities and activities in relation to the management of risk associated with placing a medical device onto an IT network.

The purpose of this project is to conduct research to determine if the Standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organisations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible within Irish HDO and determine the awareness and conformance with these standards in an attempt to identify barriers to their implementation.

I am contacting contact you relation to sending an online survey to Clinical Engineering Managers within the Health Services through the BEAI forum. Would it be possible to contact the Clinical Engineering Managers through the BEAI forum.

My intention is to send an online questionnaire via email to Clinical Engineering managers within the healthcare industry to determine the awareness of the IEC 80001-1 standard and its technical report ISO TR 80001-2-7.

The purpose of this is to determine a baseline to the adoption and implementation of the Standard within the Irish context and also raise awareness of this standard.

Link to questionnaire

https://scsstcd.qualtrics.com/SE/?SID=SV_a41yUwD8OjFJIzj

I have also attached a summary of the research that I intend to do.

I am currently finalising my ethics application to Trinity College and intend to commence the survey at the beginning of April.

Regards Tony Fitzgerald

Approval to contact Clinical Engineering Managers through the BEAI (Biomedical Engineering Association of Ireland)

From: **Brian Kearney** <brian.kearney@hse.ie>
Date: 27 February 2017 at 11:15
Subject: RE: Contact Clinical Engineering Managers in relation to a survey on IEC80001 Standard
To: Fitzgerald Anthony <fitzgea6@tcd.ie>
Cc: Gaye <gaye.stephens@tcd.ie>, "Secretary, BEAI (secretary@beai.ie)" <secretary@beai.ie>, "Spectrum, BEAI (spectrum@beai.ie)" <spectrum@beai.ie>, "Communications, BEAI (comms@beai.ie)" <comms@beai.ie>

Hi Tony

Good to hear from you.

The BEAI would be more than willing to help you with this research. I am not sure about being able to segregate to CE Management only as this is a dynamic listing and subjective in many wayIf you send me your mobile number, I'll give you a shout about it sometime this week.

PS – as an aside, it would be good to consider publishing an article for the Spectrum Journal on your research. If you would like to know more about this, please email Frank Kelly on spectrum@beai.ie

Kind Regards,

Brian Kearney Chairperson, Biomedical / Clinical Engineering Association of Ireland (BEAI)

Web: www.beai.ie Email: chairperson@beai.ie

Appendix G: Information Sheet and Consent for National Survey

Project Title: "Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7"
Name of Lead Researcher: Tony Fitzgerald
Name of Supervisor: Professor Gave Stevens
Lead Researcher's email: fitzgea6@tcd.ie
Lead Researcher's Contact Tel No.: 086-3815897
Course Name and Code: MSc Health Informatics
Estimated start date of survey/research: April 2014

Background of Information:
The purpose of this project is to conduct research to determine if the standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible within Irish HDOs. I would like to determine the awareness of and conformance with these standards in an attempt to identify barriers to their implementation while also identifying the appropriate resources and procedures are in place for Children's Hospital Group.
You have been selected to participate in this research as you are an IT/CE professional working within the health care industry and therefore have experience in managing and maintaining IT infrastructure within a health delivery organisations.

Procedures of this study:

- *You will be asked to fill an on-line questionnaire to determine your knowledge and accessibility of*
    - *IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices"*
    - *ISO TR 80001-2-7 "Application guidance -- Part 2-7: Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1"*

- *Your involvement in this study will take approximately 10 minutes.*

Additional Information:

- Your participation in this study is voluntary.
- You may withdraw from the study at any point for any reason without any penalty.
- You do not have to answer each of the questions.
- The data will be anonymized. There will be preservation of your and third-party anonymity in analysis, publication and presentation of resulting data and findings. Please do not refer to any third parties directly.
- I do not anticipate any risks to you in this study. The benefits of participating in the study is that your feedback will allow the researcher to determine a base line as to the adoption and implementation of ISO 80001-1 and identify barriers to its use and implementation and also raise awareness of this standard.
- A copy of the research will be provided to you if requested.
- If you require any further information on the study, please feel free to ask me.
- You may only participate in this study if you are 18 years of age or older and are competent to supply consent to participate in this study.
- In the very unlikely event that an illicit activity is reported to me during the study I will be obliged to report it to the appropriate authorities.
- In my dissertation I may use direct quotations when they are contextually appropriate, but you will still remain anonymous.
- I will act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Informed consent form

BACKGROUND OF RESEARCH: The purpose of this project is to conduct research to determine if the standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices" and its Technical Report ISO TR 80001-2-7 "Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" are accessible with Irish HDO and determine the awareness and conformance with these standards in an attempt to identify barriers to their implementation while also identifying the appropriate resources and procedures are in place for CHG

PROCEDURES OF THIS STUDY:

Participants are asked to do the following:

- Fill an on-line questionnaire to determine your knowledge and accessibility of
  - IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices"
  - ISO TR 80001-2-7 "Application guidance -- Part 2-7: Guidance for health care delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1

It will take approximately 10 minutes to answer the questionnaire.
There are no anticipated risks to the participants taking part in this questionnaire.

PUBLICATION: This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications.

Individual results may be aggregated anonymously and research reported on aggregate results.
DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I agree not to mention any third parties directly.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I have received a copy of this agreement.

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.
RESEARCHERS CONTACT DETAILS: fitzgea6@tcd.ie 086-3815897

URL: https://scsstcd.qualtrics.com/SE/?SID=SV_a41yUwD8OjFJIzj

Appendix H: Questionnaire for National Study

Questionnaire

I have read the information details form and the informed consent form and I consent to participate in this study by filling in this questionnaire.

- ❍ Yes
- ❍ No

Q1 Which best describes your current position.

- ❍ IT Manager
- ❍ IT Professional
- ❍ Clinical/Biomedical Engineer

Q2 Are there medical devices incorporated into IT networks within your Organisation

- ❍ Yes
- ❍ No
- ❍ Don't Know

Q3 Please indicate who is responsible for maintaining these networks

- ❑ IT Department
- ❑ CE Department
- ❑ Medical Device Company
- ❑ All of the above
- ❑ Other

Q4 I have used standards in a professional capacity

- ❍ Strongly agree
- ❍ Somewhat agree
- ❍ Neither agree nor disagree
- ❍ Somewhat disagree
- ❍ Strongly disagree

Q5 Please indicate your level of awareness of the standard IEC 80001-1
"Application of risk management for IT-networks incorporating medical devices"

- ❍ Extremely Aware
- ❍ Very Aware
- ❍ Moderately Aware
- ❍ Slightly Aware
- ❍ Not Aware at all

Q6 Please indicate your level of awareness of the technical report ISO TR 80001-2-7 “Guidance for health-care delivery organizations on how to self-assess their conformance with IEC 80001-1"

- ❍ Extremely Aware
- ❍ Very Aware
- ❍ Moderately Aware
- ❍ Slightly Aware
- ❍ Not Aware at all

Q 7 How accessible are these standards within your organisation

- ❍ Extremely accessible
- ❍ Very accessible
- ❍ Moderately accessible
- ❍ Slightly accessible
- ❍ Not accessible at all

Q 8 Has a self-assessment of your organisations conformance with IEC 80001-1 been undertaken.

- ❍ Yes
- ❍ Don't Know
- ❍ No

Q 9 Has a self-assessment of a medical IT network within your organisation, conformance with IEC 80001-1 been undertaken.

- ❍ Yes
- ❍ Don't Know
- ❍ No

Q 10 Have you used ISO TR 80001-2-7 to self-assess your organisations conformance with IEC 80001 1

- ❍ Yes
- ❍ No

Display This Question:

If you have used ISO 80001-2-7 to self-assess your organisations conformance with ISO 80001-1 Yes Is Selected

Q 11 Please Indicate how easy-difficult it was to use ISO TR 80001-2-7 to self-assess your compliance with IEC 80001-1.

	Extremely easy	Somewhat easy	Neither easy nor difficult	Somewhat difficult	Extremely difficult
Processes Assessment Method	❍	❍	❍	❍	❍
Process Rating Scale	❍	❍	❍	❍	❍
Questions Used	❍	❍	❍	❍	❍
Language Used	❍	❍	❍	❍	❍
Identifying the strengths of each process	❍	❍	❍	❍	❍
Identifying the weaknesses of each process	❍	❍	❍	❍	❍
Generating a set of recommendations	❍	❍	❍	❍	❍

Q 12 In the text box below please write any other comments that you feel are applicable to the use of ISO TR 80001-2-7.

Q 13 Which of the barriers below do you feel restricts the adoption and implementation of IEC 80001-1 within your organization.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
Knowledge of the standard	❍	❍	❍	❍	❍
Availability of the Standards	❍	❍	❍	❍	❍
Standard difficult to understand	❍	❍	❍	❍	❍
Clarity over roles and responsibilities	❍	❍	❍	❍	❍
Diversity of Stakeholders	❍	❍	❍	❍	❍
Complexity of Environment	❍	❍	❍	❍	❍
Financial Resources	❍	❍	❍	❍	❍
Human Resources	❍	❍	❍	❍	❍

Q 14 Please comment in the box below any other barriers you feel which may restrict the adoption and implementation of IEC 80001-1 within your organisation

Q 15 How Interested would you be in receiving more information on IEC 80001-1 and self-assessment guidelines presented in ISO TR 80001-2-7.

- ❍ Extremely Interested
- ❍ Very Interested
- ❍ Moderately Interested
- ❍ Slightly Interested
- ❍ Not Interested at all

Q16 Each question in this questionnaire is optional. Please feel free to omit answers but the researcher would be grateful if all questions are responded to. . Are you happy to submit this questionnaire? Please note if you select No, all your answers will be lost.

- ❍ Yes
- ❍ No exit without submitting

Thank you for completing this questionnaire. Your feedback is much appreciated. If you would like a copy of the overall results please send an email to fitzgea6@tcd.ie requesting such. Many Thanks, Tony Fitzgerald

Appendix I: Information Sheet and Consent for IT and CE Managers

Information sheet for IT/CE Management in the 3 Children's Hospitals

Introduction

The exemplar process assessment method presented in ISO/TR 80001-2-7 includes a set of questions which can be used by a Healthcare Delivery Organization (HDO) to self- assess the performance of risk management of a Medical IT-Network incorporating a medical devices.

The process assessment model (PAM) Fig 1, includes 4 process groups incorporating 14 processes.

- Medical IT Network Risk Management Process Group (MRM)
- Change Release Management & Configuration Management Process Group (CRCM)
- Live Network Risk Management Process Group (LNRM)
- Medical IT Network Documentation and Planning Process Group (MDP)

This research will focus on the first process Group (Medical IT Network Risk Management Process Group) which incorporates

- 4 Processes MRM.1-MRM.1.3
  - MRM.1 Medical IT Network Risk Management Process
  - MRM.1.1 Risk Analysis and Evaluation Process
  - MRM.1.2 Risk Control Process
  - MRM.1.3 Review Residue Risk
- 28 questions
- 32 Outcomes which are observable results of the successful achievement of the proposed process.

The assessment method can be used to perform a self-assessment to determine conformance against IEC 80001-1 and the results of the assessment will highlight any weaknesses within current risk management processes and can be used as a basis for the improvement of these.

PAM Processes

Medical IT Network Risk Management Process Group (MRM)	
MRM.1	Medical IT Network Risk Management Process
MRM.1.1	Risk Analysis & Evaluation
MRM.1.2	Risk Control
MRM.1.3	Residual Risk

Change Release Management & Configuration Management Process Group (CRCM)	
CRCM.1	Change Release & Configuration Management
CRCM.2	Decision on how to apply Risk Management
CRCM.3	Go-Live

Live Network Risk Management Process Group (LNRM)	
LNRM.1	Monitoring
LNRM.2	Event Management

Medical IT Network Documentation and Planning Process Group (MDP)				
MDP.1	Medical IT Network Planning		MDP.4	Risk Management Policy
MDP.2	Medical IT Network Documentation		MDP.5	Organisational Risk Management Process
MDP.3	Responsibility Agreements			

Fig 1 PAM Processes –Assessment Method

Purpose of Research

The purpose of this research is to determine if the process assessment method as presented in ISO TR 80001-2-7 is

- Accessible to medical device and IT managers within the 3 children's hospitals.
- Are the questions within the PAM phrased in a way understandable to medical device and IT managers within HDO
- Determine if the assessment scoring methodology presented in the PAM is accessible to medical device and IT managers within HDO
- Determine if the output recommendations presented in the PAM are accessible to medical device and IT managers within HDO

The results of this assessment will inform the researcher when developing an excel tool which is envisioned to present the process assessment method, questions, assessment scoring methodology and output recommendations in a more accessible manner.

Objectives

The researcher proposes to carry out a semi structured interviews with selected IT and clinical engineering staff from the 3 children's hospitals which will involve

- A brief overview of ISO 80001-1
- An overview of ISO TR 80001-2-7
  - Introduction to the PAM
  - Introduction to the 14 processes within the PAM
  - Introduction to the (process attributes rating values) level of achievement of each process.
  - Introduction to the capability levels for each process.
- Explanation of the first process group **Medical IT Network Risk Management Process (MRM)** Fig 2**,** which includes
  - 4 Processes MRM.1-MRM1.3
    - MRM.1 Medical IT Network Risk Management Process
    - MRM.1.1 Risk Analysis and Evaluation Process
    - MRM.1.2 Risk Control Process
    - MRM.1.3 Review Residue Risk
  - 28 questions
  - 32 Outcomes which are observable results of the successful achievement of the proposed process.
- Using the first process group **Medical IT Network Risk Management Process (MRM)**
  - Perform a self-assessment of a medical it network within their organization.
- Fill in an online questionnaire as to the usability of the process assessment method presented in ISO TR 80001-2-7

Information Sheet for Prospective Participants

Project Title: *"Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7"*
Name of Lead Researcher: *Tony Fitzgerald*
Name of Supervisor: *Professor Gave Stevens*
Lead Researcher's email: *fitzgea6@tcd.ie*
Lead Researcher's Contact Tel No.: *086-3815897*
Course Name and Code: *MSc Health Informatics*
Estimated start date of survey/research: *April 2014*

Background of Information:
The purpose of this research is to determine if the process assessment method as presented in ISO TR 80001-2-7 is

- Accessible to Clinical Engineering and IT managers within the 3 children's hospitals.
- Are the questions within the PAM phrased in a way understandable to Clinical Engineering and IT managers within HDO
- Determine if the assessment scoring methodology presented in the PAM is accessible to Clinical Engineering and IT managers within HDO
- Determine if the output recommendations presented in the PAM are accessible to Clinical Engineering and IT managers within HDO

You have been selected to participate in this research as you are an Clinical Engineering and IT professional working within the Children's Hospital Group and therefore have experience in managing and maintaining IT infrastructure which contains medical devices within these health delivery organisations.

Procedures of this study:
You will be asked to participate in a semi structured interviews which will involve the following.

- A brief presentation on ISO 80001-1

- A presentation on ISO TR 80001-2-7 which will include
  - Introduction to the PAM
  - Introduction to the 14 processes within the PAM
  - Introduction to the (process attributes rating values) level of achievement of each process.
  - Introduction to the capability levels for each process.

- Explanation of the first process group **Medical IT Network Risk Management Process (MRM)** Fig 2**,** which includes
  - 4 Processes MRM.1-MRM1.3
    - MRM.1 Medical IT Network Risk Management Process
    - MRM.1.1 Risk Analysis and Evaluation Process
    - MRM.1.2 Risk Control Process
    - MRM.1.3 Review Residue Risk
  - 28 questions
  - 32 Outcomes which are observable results of the successful achievement of the proposed process.

- Using the first process group **Medical IT Network Risk Management Process (MRM)**
  - Perform a self-assessment of a medical it network within their organization.

- Fill in an online questionnaire as to the usability of the process assessment method presented in ISO TR 80001-2-7

- *Your involvement in this study will take approximately 1 hour for the introduction and presentation on IEC 80001-1 and ISO TR 80001-2-7.*

- *The online questionnaire should take approx. 5 minutes to complete once the self-assessment using the first process group of a medical IT network is performed.*

Additional Information:

- *Your participation in this study is voluntary.*
- *You may withdraw from the study at any point for any reason without any penalty.*
- *You do not have to answer each of the questions.*
- *The data will be anonymized. There will be preservation of your and third-party anonymity in analysis, publication and presentation of resulting data and findings. Please do not refer to any third parties directly.*
- *I do not anticipate any risks to you in this study. The benefits of participating in the study is that your feedback will allow the researcher to determine a base line as to the adoption and implementation of ISO 80001-1 and identify barriers to its use and implementation and also raise awareness of this standard.*
- *A copy of the research will be provided to you if requested.*
- *If you require any further information on the study, please feel free to ask me.*
- *You may only participate in this study if you are 18 years of age or older and are competent to supply consent to participate in this study.*
- *In the very unlikely event that an illicit activity is reported to me during the study I will be obliged to report it to the appropriate authorities.*
- *In my dissertation I may use direct quotations when they are contextually appropriate, but you will still remain anonymous.*
- *I will act in accordance with the information provided (i.e. if I tell participants I will not do something*, then *I will not do i*

Informed consent form Interview Process

BACKGROUND OF RESEARCH:

The purpose of this research is to determine if the process assessment method as presented in ISO TR 80001-2-7 is

- Accessible to Clinical Engineering and IT managers within the 3 children's hospitals.
- Are the questions within the PAM phrased in a way understandable to Clinical Engineering and IT managers within HDO
- Determine if the assessment scoring methodology presented in the PAM is accessible to Clinical Engineering and IT managers within HDO
- Determine if the output recommendations presented in the PAM are accessible to Clinical Engineering and IT managers within HDO

PROCEDURES OF THIS STUDY:

Participants are asked to do the following:

You will be asked to participate in a semi structured interviews which will involve the following.

- A brief presentation on ISO 80001-1
- A presentation on ISO TR 80001-2-7
- Explanation of the first process group **Medical IT Network Risk Management Process (MRM)**
  Using the first process group **Medical IT Network Risk Management Process (MRM)**
  - Perform a self-assessment of a medical it network within their organization.
  - Fill in an online questionnaire as to the usability of the process assessment method presented in ISO TR 80001-2-7

Your involvement in this study will take approximately 1 hour for the introduction and presentation on IEC 80001-1 and ISO TR 80001-2-7.

The online questionnaire should take approx. 5 minutes to complete once the self-assessment using the first process group of a medical IT network is performed.

There are no anticipated risks to the participants taking part in this questionnaire.

PUBLICATION: *This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications.*

Individual results may be aggregated anonymously and research reported on aggregate results.

DECLARATION:

- *I am 18 years or older and am competent to provide consent.*
- *I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.*
- *I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.*
- *I understand that if I make illicit activities known, these will be reported to appropriate authorities.*
- *I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.*
- *I agree not to mention any third parties directly.*
- *I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.*
- *I understand that my participation is fully anonymous and that no personal details about me will be recorded.*
- *I have received a copy of this agreement.*

Statement of investigator's responsibility: *I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.*
RESEARCHERS CONTACT DETAILS: *fitzgea6@tcd.ie 086-3815897*

URL: https://scsstcd.eu.qualtrics.com/jfe5/form/SV_bQ4swf2j832YDv7

Appendix J: Questionnaire IT and CE Managers

Questions

Please Indicate rating from easy-difficult your experience in using the process assessment method (MRM Medical IT Network Risk Management Process) within ISO TR 80001-2-7 to self-assess your compliance with IEC 80001-1.

I have read the information details form and the informed consent form and I consent to participate in this study by filling in this questionnaire.

❍ Yes
❍ No

Condition: No Is Selected. Skip To: End of Survey.

Which best describes your current position.

❍ Information Technology Manager/Professional
❍ Clinical/Biomedical Engineer

Please Indicate rating from easy-difficult your experience using the excel tool in applying the process assessment method (MRM Medical IT Network Risk Management Process) within ISO TR 80001-2-7 to self-assess your compliance with IEC 80001-1.

	Extremely easy	Somewhat easy	Neither easy nor difficult	Somewhat difficult	Extremely difficult
Processes Assessment Method	❍	❍	❍	❍	❍
Process Rating Scale	❍	❍	❍	❍	❍
Questions Used	❍	❍	❍	❍	❍
Language Used	❍	❍	❍	❍	❍
Identifying the strengths of each process	❍	❍	❍	❍	❍
Identifying the weaknesses of each process	❍	❍	❍	❍	❍
Generating a set of recommendations	❍	❍	❍	❍	❍
Determining the achievement level of the process	❍	❍	❍	❍	❍

Please record in the box below any other comments.

Q2 Each question in this questionnaire is optional. Please feel free to omit answers but the researcher would be grateful if all questions are responded to. . Are you happy to submit this questionnaire? Please note if you select No, all your answers will be lost.

- ❍ Yes
- ❍ No exit without submitting

Thank you for completing this questionnaire. Your feedback is much appreciated. If you would like a copy of the overall results please send an email to fitzgea6@tcd.ie requesting such. Many Thanks, Tony Fitzgerald

Outcome

The results of this assessment will inform the researcher when developing an excel tool which is envisioned to present the process assessment method, questions, assessment scoring methodology and output recommendations in a more accessible and useable manner.

Appendix K: Information sheet and consent form for Excel Tool assessment

Introduction

The exemplar process assessment method presented in ISO/TR 80001-2-7 includes a set of questions which can be used by a Healthcare Delivery Organization (HDO) to self- assess the performance of risk management of a Medical IT-Network incorporating a medical devices.

The process assessment model (PAM) Fig 1, includes 4 process groups incorporating 14 processes.

- Medical IT Network Risk Management Process Group (MRM)
- Change Release Management & Configuration Management Process Group (CRCM)
- Live Network Risk Management Process Group (LNRM)
- Medical IT Network Documentation and Planning Process Group (MDP)

This research will focus on the first process Group (Medical IT Network Risk Management Process Group) which incorporates

- 4 Processes MRM.1-MRM.1.3
  - MRM.1 Medical IT Network Risk Management Process
  - MRM.1.1 Risk Analysis and Evaluation Process
  - MRM.1.2 Risk Control Process
  - MRM.1.3 Review Residue Risk
- 28 questions
- 32 Outcomes which are observable results of the successful achievement of the proposed process.

The assessment method can be used to perform an assessment to determine conformance against IEC 80001-1 and the results of the assessment will highlight any weaknesses within current risk management processes and can be used as a basis for the improvement of these.

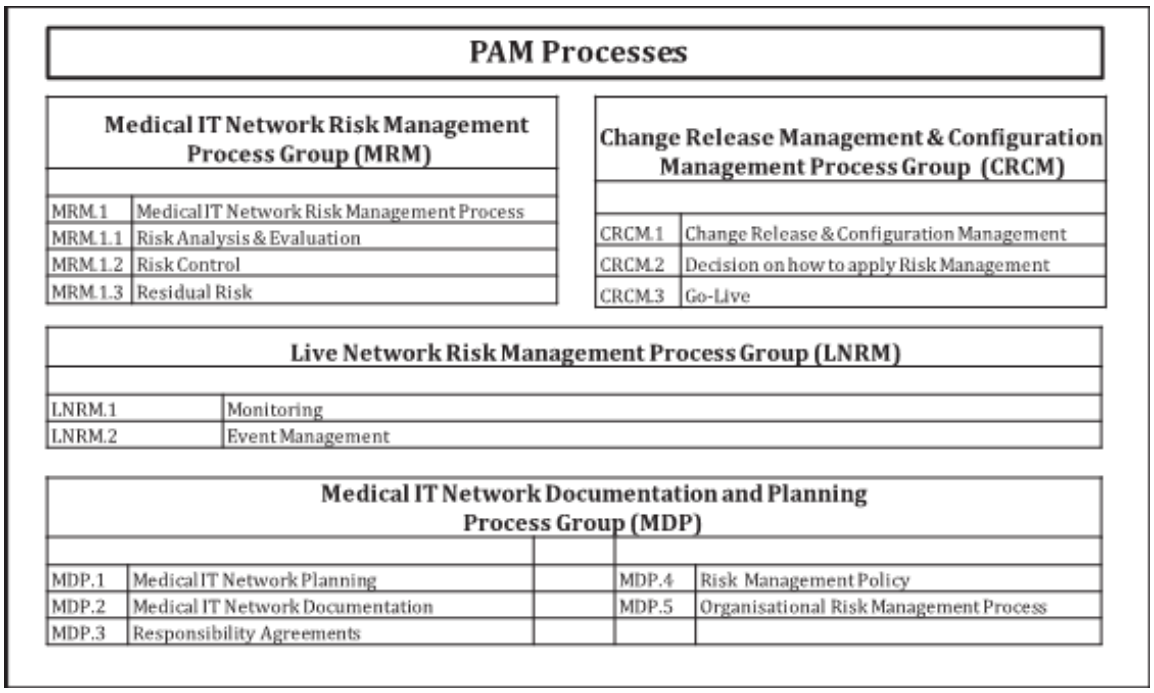


Fig 1 PAM Processes –Assessment Method

Purpose of Research

The purpose of this research is to determine if the process assessment method in ISO TR 80001-2-7 as

presented in the excel tool developed by the researcher

- Accessible to clinical engineering and IT managers within the 3 children's hospitals.
- Are the questions within the PAM presented in a way understandable to clinical engineering and IT managers within HDO?
- Determine if the assessment scoring methodology presented in the PAM is accessible to clinical engineering and IT managers within HDO
- Determine if the output recommendations presented in the PAM are accessible to clinical engineering and IT managers within HDO.

The results of this assessment will be compared with the results from the interview questionnaire and using gap analysis to inform the researcher when further developing the excel tool.

Objectives

The researcher proposes to email an excel tool developed as a result of the interview and questionnaire to clinical engineering and IT managers from the 3 children's hospitals and ask them to use the tool which will focus on the first process group Medical IT Network Risk Management Process (MRM) and perform a self-assessment of a medical IT network within their organization.

- **Medical IT Network Risk Management Process (MRM)** Fig 2**,** which includes
    - 4 Processes MRM.1-MRM1.3
        - MRM.1 Medical IT Network Risk Management Process
        - MRM.1.1 Risk Analysis and Evaluation Process
        - MRM.1.2 Risk Control Process
        - MRM.1.3 Review Residue Risk
    - 28 questions
    - 32 Outcomes which are observable results of the successful achievement of the proposed process.

- Using the first process group Medical IT Network Risk Management Process (MRM)
    - Perform a self-assessment of a medical it network within their organization using the Excel tool

- Fill in an online questionnaire as to the usability of the process assessment method, as presented in the excel tool.

Excel Tool Evaluation
Information Sheet for Prospective Participants

Project Title: *"Do Health Delivery Organisations have difficulty interpreting the Process Assessment Model presented in ISO/TR 80001-2-7"*
Name of Lead Researcher: *Tony Fitzgerald*
Name of Supervisor: *Professor Gave Stevens*
Lead Researcher's email: *fitzgea6@tcd.ie*
Lead Researcher's Contact Tel No.: *086-3815897*
Course Name and Code: *MSc Health Informatics*
Estimated start date of survey/research: *April 2014*

Background of Information:
The purpose of this research is to determine if the process assessment method in ISO TR 80001-2-7 as presented in the excel tool developed by the researcher

- Accessible to clinical engineering and IT managers within the 3 children's hospitals.
- Are the questions within the PAM presented in a way understandable to clinical engineering and IT managers within HDO?
- Determine if the assessment scoring methodology presented in the PAM is accessible to clinical engineering and IT managers within HDO
- Determine if the output recommendations presented in the PAM are accessible to clinical engineering and IT managers within HDO.

The results of this assessment will be compared with the results from the interview questionnaire and using gap analysis to inform the researcher when further developing the excel tool.

You have been selected to participate in this research as you are an Clinical Engineering / IT professional working within the Children's Hospital Group and therefore have experience in managing and maintaining IT infrastructure which contains medical devices within these health delivery organisations.

Procedures of this study:

The researcher proposes to email an excel tool developed as a result of the interview and questionnaire with selected staff from the 3 children's hospitals and ask the staff to use the tool which will focus on the first process group Medical IT Network Risk Management Process (MRM) and perform a self-assessment of a medical IT network within their organisation.

- *Fill in an online questionnaire as to the usability of the process assessment method, as presented in the excel tool.*

The online questionnaire should take approx. 5 minutes to complete once the self-assessment using the first process group of a medical IT network is performed.

Additional Information:

- *Your participation in this study is voluntary.*
- *You may withdraw from the study at any point for any reason without any penalty.*
- *You do not have to answer each of the questions.*
- *The data will be anonymized. There will be preservation of your and third-party anonymity in analysis, publication and presentation of resulting data and findings. Please do not refer to any third parties directly.*
- *I do not anticipate any risks to you in this study. The benefits of participating in the study is that your feedback will allow the researcher to determine a base line as to the adoption and implementation of ISO 80001-1 and identify barriers to its use and implementation and also raise awareness of this standard.*
- *A copy of the research will be provided to you if requested.*
- *If you require any further information on the study, please feel free to ask me.*
- *You may only participate in this study if you are 18 years of age or older and are competent to supply consent to participate in this study.*
- *In the very unlikely event that an illicit activity is reported to me during the study I will be obliged to report it to the appropriate authorities.*
- *In my dissertation I may use direct quotations when they are contextually appropriate, but you will still remain anonymous.*
- *I will act in accordance with the information provided (i.e. if I tell participants I will not do something*, then *I will not do it).*

Informed Consent form
Excel Tool Evaluation

BACKGROUND OF RESEARCH:

The purpose of this research is to determine if the process assessment method in ISO TR 80001-2-7 as presented in the excel tool developed by the researcher is

- Accessible to clinical engineering and IT managers within the 3 children's hospitals.
- Are the questions within the PAM presented in a way understandable to clinical engineering and IT managers within HDO?
- Determine if the assessment scoring methodology presented in the PAM is accessible to clinical engineering and IT managers within HDO
- Determine if the output recommendations presented in the PAM are accessible to clinical engineering and IT managers within HDO.

The results of this assessment will be compared with the results from the interview questionnaire and using gap analysis to inform the researcher when further developing the excel tool.

PROCEDURES OF THIS STUDY:

Participants are asked to do the following:

You will be asked to:

- Perform a self-assessment of a medical it network within their organization using the excel tool developed by the researcher. This self-assessment will focus on the first process group (MRM Medical IT Network Risk Management Process)

- Fill in an online questionnaire rating from easy-difficult your experience using the excel tool in applying the process assessment method (MRM Medical IT Network Risk Management Process) within ISO TR 80001-2-7 to self-assess your compliance with IEC 80001-1.

The online questionnaire should take approx. 5 minutes to complete once the self-assessment using the first process group of a medical IT network is performed.

There are no anticipated risks to the participants taking part in this questionnaire.

PUBLICATION: *This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications.*

Individual results may be aggregated anonymously and research reported on aggregate results.

DECLARATION:

- *I am 18 years or older and am competent to provide consent.*
- *I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.*
- *I agree that my data is used for scientific purposes and I have no objection that my data*

is published in scientific publications in a way that does not reveal my identity.

- *I understand that if I make illicit activities known, these will be reported to appropriate authorities.*
- *I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.*
- *I agree not to mention any third parties directly.*
- *I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.*
- *I understand that my participation is fully anonymous and that no personal details about me will be recorded.*
- *I have received a copy of this agreement.*

Statement of investigator's responsibility: *I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.*
RESEARCHERS CONTACT DETAILS: *fitzgea6@tcd.ie 086-3815897*

URL: https://scsstcd.qualtrics.com/SE/?SID=SV_3t0n3vXTeqVCCfH

Appendix L: Questionnaire on Excel Tool

Questions

Please Indicate rating from easy-difficult your experience using the excel tool in applying the process assessment method (MRM Medical IT Network Risk Management Process) within ISO TR 80001-2-7 to self-assess your compliance with IEC 80001-1.

	Extremely easy	Somewhat easy	Neither easy nor difficult	Somewhat difficult	Extremely difficult
Explanation of the Process Method.	❍	❍	❍	❍	❍
Language and terminology used.	❍	❍	❍	❍	❍
Questions Used	❍	❍	❍	❍	❍
Rating scales for the process	❍	❍	❍	❍	❍
Identifying the strengths of the process	❍	❍	❍	❍	❍
Identifying the weaknesses of the process	❍	❍	❍	❍	❍
Determining a completion level for the process	❍	❍	❍	❍	❍
Identifying the outcomes for the process					

Q 2 Each question in this questionnaire is optional. Please feel free to omit answers but the researcher would be grateful if all questions are responded to. . Are you happy to submit this questionnaire? Please note if you select No, all your answers will be lost.

- ❍ Yes
- ❍ No exit without submitting

Thank you for completing this questionnaire. Your feedback is much appreciated. If you would like a copy of the overall results please send an email to fitzgea6@tcd.ie requesting such. Many Thanks, Tony Fitzgerald

Outcome

The results of this assessment will inform the researcher when further developing the excel tool which is envisioned to present the process assessment method, questions, assessment scoring methodology and output recommendations in a more accessible manner.

Appendix M: IEC 80001-1, ISO/TR 80001-2-7

IEC 80001-1:2010

IEC 80001-1:2010: Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities.

This Standard is available from ISO. https://www.iso.org/standard/44863.html

ISO/TR 80001-2-7

ISO/TR 80001-2-7: Application of risk management for IT-networks incorporating medical devices – Application guidance – Part 2 – 7: Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1

This technical report is available from ISO. https://www.iso.org/standard/63509.html

Appendix N: National Survey Questions and Response.

Number	Question	Answer	%
Q5	I have read the information details form and the informed consent form and I consent to participate in this study by filling in this questionnaire.	Yes	100%
		No	0%
Q6	Please indicate whether you are employed in the public or private sector	Public	86%
		Private	14%
Q7	Please indicate what category of Health Delivery Organisation (HDO) you are employed in.	HSE regional hospitals, voluntary and joint board teaching hospitals	64%
		HSE county hospitals and voluntary non-teaching hospitals	5%
		HSE district hospitals	5%
		HSE Primary Care	0%
		HSE Information Technology	14%
		Private Hospital	14%
Q8	Which best describes your current position.	Information Technology Manager/Professional	36%
		Clinical/Biomedical Engineer	64%
Q9	Does your organisation have a clear definition of a Business/Admin IT network?	Yes	59%
		Don't Know	41%
		No	0%
Q10	Does your organisation have a clear definition of a Medical Device?	Yes	82%
		Don't Know	14%
		No	5%
Q11	Does your organisation have a clear definition of a Medical IT Network?	Yes	18%
		Don't Know	32%
		No	50%
Q12	Are there medical devices incorporated into IT networks within your organisation	Yes	95%
		Don't Know	0%
		No	5%

Q13	Please indicate who is responsible for managing IT networks incorporating medical devices within your organisation. You can select multiple departments	IT Department	91%
		Clinical Engineering Department	59%
		Medical Device Company	36%
		Clinical Department	0%
		Unknown	5%
Q14	Please indicate your level of awareness of Standards within a professional capacity.	Extremely Aware	18%
		Very Aware	45%
		Moderately Aware	27%
		Slightly Aware	9%
		Not Aware at all	0%
Q15	How accessible are Standards within your organisation.	Extremely accessible	5%
		Very accessible	27%
		Moderately accessible	41%
		Slightly accessible	27%
		Not accessible at all	0%
Q16	Please indicate your level of awareness of the Standard IEC 80001-1 "Application of risk management for IT-networks incorporating medical devices "published in 2010, defining roles, responsibilities and activities for the safety, effectiveness and the security of IT networks incorporating medical devices.	Extremely Aware	0%
		Very Aware	5%
		Moderately Aware	27%
		Slightly Aware	36%
		Not Aware at all	32%
Q17	Please indicate your level of awareness of the technical report "ISO TR 80001-2-7 "Guidance for health-care delivery organizations on how to self-assess their conformance with IEC 80001-1" Published in 2015 to help HDO self-assess their conformance with the Standard IEC 80001-1.	Extremely Aware	0%
		Very Aware	0%
		Moderately Aware	18%
		Slightly Aware	32%
		Not Aware at all	50%
Q18	Has a self-assessment of your organisations conformance with IEC 80001-1 been undertaken.	Yes	5%
		Don't Know	45%
		No	50%

Q19	Has a self-assessment of a medical IT network within your organisation, conformance with IEC 80001-1 been undertaken.	Yes	0%
		Don't Know	55%
		No	45%
Q20	Have you used ISO TR 80001-2-7 to self-assess your organisations conformance with IEC 80001-1.		
		Yes	0%
		No	100%
Q21-25	See next page for multiple choice questions and comments		
Q26	How Interested would you be in receiving more information on IEC 80001-1 and self-assessment guidelines presented in ISO TR 80001-2-7	Extremely Interested	27%
		Very Interested	41%
		Moderately Interested	23%
		Slightly Interested	5%
		Not Interested at all	5%

Q 21 Please Indicate how easy-difficult it was to use the process assessment method within ISO TR 80001-2-7 to self assess your compliance with IEC 80001-1.						
	Extremely easy	Somewhat easy	Neither easy nor difficult	Somewhat difficult	Extremely difficult	Total
Processes Assessment Method	0%	0%	0%	0%	0%	0
Process Rating Scale	0%	0%	0%	0%	0%	0
Questions Used	0%	0%	0%	0%	0%	0
Language Used	0%	0%	0%	0%	0%	0
Identifying the strengths of each process	0%	0%	0%	0%	0%	0
Identifying the weaknesses of each process	0%	0%	0%	0%	0%	0
Generating a set of recommendations	0%	0%	0%	0%	0%	0
Determining the achievement level of the process	0%	0%	0%	0%	0%	0

Q22 - In the text box below please write any other comments that you feel are applicable to the use of ISO TR 80001-2-7
No Comments

Multiple choice questions and comments

Q23 - Which of the barriers below do you feel restricts the adoption and implementation of IEC 80001-1within your organisation.						
	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	
Knowledge of the standard	52%	38%	10%	0%	0%	
Availability of the Standards	38%	33%	19%	10%	0%	
Standard difficult to understand	20%	30%	45%	5%	0%	
Clarity over roles and responsibilities	40%	40%	15%	0%	5%	
Diversity of Stakeholders	40%	25%	25%	5%	5%	
Complexity of Environment	42%	32%	16%	5%	5%	
Financial Resources	40%	30%	30%	0%	0%	
Human Resources	47%	16%	37%	0%	0%	
Senior Management buy in	45%	25%	30%	0%	0%	
Governance of medical IT network	40%	40%	20%	0%	0%	

Q24 - Please record in the box below any other barriers you feel which may restrict the adoption and implementation of IEC 80001-1 within your organisation.
Project led from top management that this is the way to proceed and overcome reluctance of existing stakeholders towards change
Principal barrier is where the responsibility rests i.e ICT or clinical engineering.
Not a very strong link between Clinical Engineering and IT departments. Seems very much a "Them and US" scenario where demarcation of responsibly is constantly debated. (From this cable onward is Clinical Engineering's responsibility etc.)
Th level of commitment to recognizing the importance of the standards, along with having the skill set in-house to implement the stanard
The knowledge and understanding of the standard

Q25 - Please record in the box below any other comments.
I would suggest there needs to be a specific discipline within clinical engineering to assume the responsability of medical devices on the IT network as this will become a more increasing portfolio. This specific discipline will need to incorporate the skills/knpwledge of both ICT and medical device management.
The Standard is poorly written, and its implementation is very dependent on resourcing this project.
VLANS used to separate medical networks from business networks. Never read the standards - not sure if VLANS are an acceptable method of separating networks.

Appendix O: Questions and results from Focus Groups.

Evaluation of the process assessment method presented in ISO TR 80001-2-7

Q6 - Which best describes your current position	
Information Technology Manager/Professional	57%
Clinical/Biomedical Engineer	43%

Q7 - Please Indicate rating from easy-difficult your experience using the process assessment method within ISO TR 80001-2-7 to self-assess your compliance with IEC 80001-1						
	Extremely easy	Somewhat easy	Neither easy nor difficult	Somewhat difficult	Extremely difficult	
Processes Assessment Method	0.00%	0.00%	0.00%	16.67%	83.33%	
Process Rating Scale	0.00%	0.00%	16.67%	50.00%	33.33%	
Questions Used	0.00%	0.00%	0.00%	83.33%	16.67%	
Language Used	0.00%	0.00%	16.67%	0.00%	83.33%	
Identifying the strengths of each process	0.00%	0.00%	0.00%	66.67%	33.33%	
Identifying the weaknesses of each process	0.00%	0.00%	0.00%	66.67%	33.33%	
Generating a set of recommendations	0.00%	0.00%	33.33%	33.33%	33.33%	
Determining the achievement level of the process	0.00%	16.67%	0.00%	33.33%	50.00%	

Q8 - Please record in the box below any other comments relating to the use of the PAM.
Found the structure complex and difficult
Generally found the Process Assessment Process difficult to navigate. The flow of the document and language used was difficult follow and understand at times.

Evaluation of the process assessment method in ISO TR 80001-2-7 as presented in the Excel tool.

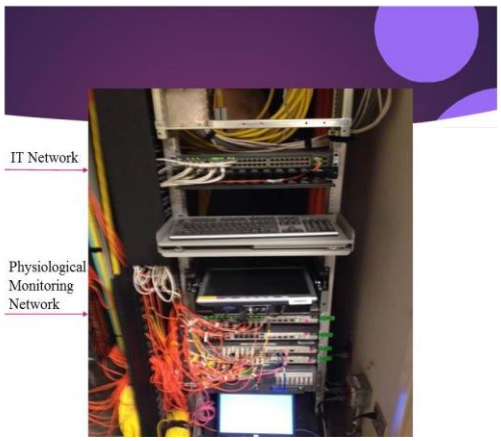
Q6 - Which best describes your current position	
Information Technology Manager/Professional	57%
Clinical/Biomedical Engineer	43%

Q7 - Please Indicate rating from easy-difficult your experience using the excel tool in applying the process assessment method within ISO TR 80001-2-7 to self-assess your compliance with IEC 80001-1.

	Extremely easy	Somewhat easy	Neither easy nor difficult	Somewhat difficult	Extremely difficult	
Processes Assessment Method	83.33%	0.00%	16.67%	0.00%	0.00%	
Process Rating Scale	83.33%	16.67%	0.00%	0.00%	0.00%	
Questions Used	33.33%	50.00%	16.67%	0.00%	0.00%	
Language Used	66.67%	0.00%	33.33%	0.00%	0.00%	
Identifying the strengths of each process	66.67%	33.33%	0.00%	0.00%	0.00%	
Identifying the weaknesses of each process	83.33%	16.67%	0.00%	0.00%	0.00%	
Generating a set of recommendations	100.00%	0.00%	0.00%	0.00%	0.00%	
Determining the achievement level of the process	83.33%	16.67%	0.00%	0.00%	0.00%	

Q 8 Please record in the box below any other comments in relation to using the PAM within ISO/TR 80001-2-7 as presented within the excel tool.
Extremely easy to use. Very intuitive. Takes the complexity out of the Assessment Method.
This tool should and could be adapted to make difficult to understand documents more accessible.
Excellent Worksheet. It makes the process so much easier and a lot less time consuming.

Appendix P: Power Point Presentation for Focus Groups.



IEC 80001-1

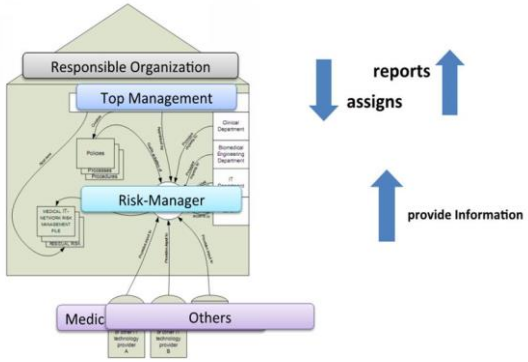
Application of risk management for IT-networks incorporating medical devices

The standard defines roles, responsibilities and activities in relation to the management of risk associated with placing a medical device onto an IT network for the following

- Health Delivery Organisation
- Medical Device Manufacturer
- Other providers of IT equipment on the network

Overall responsibility for the medical IT network belongs with the HDO

Important roles and responsibilities in IEC 80001-1



Risk-Management Plan – Key Properties

- Definition for each Medical IT-Network *(separately)*
- Key Properties for Risk-Management are:

Safety
- for Patient, User/Operator und Third Parties

Effectiveness
- for intended workflows supported by the IT-Network
  ability to produce the intended result for the PATIENT and the RESPONSIBLE ORGANIZATION

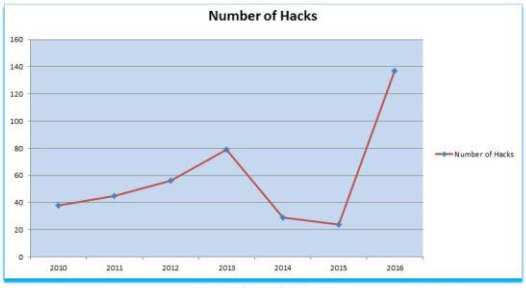
Data- & System Security
- reasonable protection from degradation of confidentiality, integrity and availability (of information assets)

Risk-Management

- Central Process of IEC 80001-1 for:
  - Identification of Hazards
  - Evaluation of corresponding Risks
  - Control of these Risks

  always in conjunction with the „Intended Use" of a network
- The Process „Risk-Management" shall be applied
  - Before putting a Medical IT-Network into service
  - When modifying an existing Medical IT- Network and/or its components

Number of Hacks on HDO in US



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- IEC/TR 80001-2-1 Application of risk management for IT-networks incorporating medical devices -- Part 2-1: Step by Step Risk Management (ISO/IEC, 2012a)
- IEC/TR 80001-2-2 Application of risk management for IT-networks incorporating medical devices -- Part 2-2: Guidance for the communication of medical device security needs, risks and controls (ISO/IEC, 2012b).
- IEC/TR 80001-2-3:2012 Application of risk management for IT-networks incorporating medical devices -- Part 2-3: Guidance for wireless networks(ISO/IEC, 2012c)
- IEC/TR 80001-2-4:2012 Application of risk management for IT-networks incorporating medical devices -- Part 2-4: General implementation guidance for Healthcare Delivery Organizations (ISO/IEC, 2013b).
- IEC/TR 80001-2-5:2014 Application of risk management for IT-networks incorporating medical devices -- Part 2-5: Application guidance -Guidance for distributed alarm systems (ISO/IEC, 2014a)
- IEC/TR 80001-2-6:2014 Application of risk management for IT-networks incorporating medical devices Part 2-6: Application guidance — Guidance for responsibility agreements (ISO/IEC, 2014b)
- ISO/TR 80001-2-7:2015 Application of risk management for IT-networks incorporating medical devices Part 2-7: Application guidance -- Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1 (ISO/IEC, 2015)
- IEC/TR 80001-2-8:2016 Application of risk management for IT-networks incorporating medical devices -- Part 2-8: Application guidance --Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2 (ISO/IEC, 2016).

ISO/TR 80001-2-7

Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1" (hereafter called ISO/TR 80001-2-7)

This contains

- 14 Processes
- 75 Questions
- Process assessment model

Its Complicated and non Clinical

Process Assessment Model

PAM Processes

Medical IT Network Risk Management Process Group (MRM)	
MRM.1	Medical IT Network Risk Management Process
MRM.1.1	Risk Analysis & Evaluation
MRM.1.2	Risk Control
MRM.1.3	Residual Risk

Change Release Management & Configuration Management Process Group (CRCM)	
CRCM.1	Change Release & Configuration Management
CRCM.2	Decision on how to apply Risk Management
CRCM.3	Go-Live

Live Network Risk Management Process Group (LNRM)	
LNRM.1	Monitoring
LNRM.2	Event Management

Medical IT Network Documentation and Planning Process Group (MDP)			
MDP.1	Medical IT Network Planning	MDP.4	Risk Management Policy
MDP.2	Medical IT Network Documentation	MDP.5	Organisational Risk Management Process
MDP.3	Responsibility Agreements		

Medical IT Network Risk Management Process Group (MRM)

		Base Practice	Questions	Outcomes
MRM.1	Medical IT Network Risk Management Process	BP1	2	Out 1
		BP2	1	Out 2,4
		BP3	1	Out 5,6,8
		BP4	3	Out 7,9
		BP5	1	Out 1,10
		BP6	1	Out 3
MRM.1.1	Risk Analysis and Evaluation Process	BP1	1	Out 1
		BP2	1	Out 2
		BP3	1	Out 3
		BP4	1	Out 4,5
MRM.1.2	Risk Control Process	BP1	2	Out 1,2,3
		BP2	1	Out 5,8
		BP3	1	Out 6
		BP4	1	Out 4,9
		BP5	2	Out 7
		BP6	1	Out 10
		BP7	1	Out 11
MRM.1.3	Review Residue Risk	BP1	1	Out 1,3
		BP2	1	Out 2
		BP3	1	Out 4
		BP4	1	Out 5
		BP5	1	Out 6
		BP6	1	Out 6

MRM.1	Medical IT Network Risk Management Process	
BP1	Establish a Medical IT-Network Risk Management File.	
	Q1	Do you have a Medical IT-Network Risk Management File?
	Q2	How is the file stored, accessed, and maintained
BP2	Assign Risk Management Resources.	
	Q1	Have risk management resources been assigned?
BP3	Identify Risk Management Stakeholders and inform of their responsibilities.	
	Q1	Are risk management stakeholders identified and aware of their responsibilities?
BP4	Manage the Medical IT-Network throughout the life cycle as per the Risk Management Plan and Process.	
	Q1	Is a life cycle approach taken to the management of the Medical IT-Network?
	Q2	Are risk management activities performed according to the risk Management Plan and process?
	Q3	Are the key properties of the network considered during the performance of risk management activities?
BP5	Document Risk Management activities.	
	Q1	Are risk management activities documented?
BP6	Review Risk Management Activities at defined intervals	
	Q1	Are risk management activities reviewed at defined intervals?

Medical IT Network Risk Management Process Group (MRM)

Medical IT Network Risk Management Process	
ce	Questions
-Q.1	Do you have a Medical IT-Network Risk Management File?
-Q.2	How is the file stored, accessed, and maintained
-Q.1	Have risk management resources been assigned?
-Q.1	Are risk management stakeholders identified and aware of their responsibilities?
-Q.1	Is a life cycle approach taken to the management of the Medical IT-Network?
-Q.2	Are risk management activities performed according to the risk Management Plan and process?
-Q.3	Are the key properties of the network considered during the performance of risk management activities?
-Q.1	Are risk management activities documented?
-Q.1	Are risk management activities reviewed at defined intervals?
ce	Outcomes
-Q.1	**1.** A Medical IT-Network Risk Management file is established and maintained containing all required documentation
-Q.2	**1.** A Medical IT-Network Risk Management file is established and maintained containing all required documentation
-Q.1	**2.** Adequate appropriately qualified resources for management, performance of work, and assessment activities are assigned. **4.** A qualified medical IT-network risk manager is appointed.
-Q.1	**5.** People responsible for Risk Management activities and lifecycle management (including procurement and maintenance) of medical devices incorporated into IT networks, co-operate with the medical IT-network risk manager. **6.** Risk management process for medical IT-networks includes the participation of management responsible for life cycle management of Medical IT-Networks, general IT activities and the use of Medical Devices. **8.** All parties performing supervision, operation, installation, service, troubleshooting, and maintenance of Medical IT-Network(s) are adequately informed about their responsibility according to this standard, including their responsibility for maintaining the effectiveness of Risk Controls.
-Q.1	**9.** The key properties of the medical IT-network are maintained throughout the life cycle.
-Q.2	**7.** All supervision, operation, installation, and maintenance of Medical IT-Network(s) throughout the life cycle are made according to the Risk Management plan and follow the results of the IT-Network Risk Management Process.
-Q.3	**7.** All supervision, operation, installation, and maintenance of Medical IT-Network(s) throughout the life cycle are made according to the Risk Management plan and follow the results of the IT-Network Risk Management Process.
-Q.1	**1.** A Medical IT-Network Risk Management file is established and maintained containing all required documentation **10.** The risk management activities of risk analysis, risk evaluation, risk control, residual risk evaluation, and reporting and approval are documented.
-Q.1	**3.** The results of risk management activities, including event management, are reviewed at defined intervals