

A Structured Methodology for Systematically
Describing Health Informatics Hazards

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Abstract

Utilisation of Health IT to support care management and delivery is prevalent within the NHS but whilst it is safety related in nature it falls outside of scope of the medical device regulations.

Two national standards first published in 2009, addressing clinical risk management of Health IT in the NHS, establish a hazard centric approach to clinical risk management. However, it is considered that the concept of a hazard is not well understood and where it is used it rarely reflects or captures the patient safety consequences that could occur.

If the approach to clinical risk management as established in the standards is to be effective then there is a need, at the start of the risk management process, to be able to describe and communicate hazard descriptions that: reflect the harm-scenario, are relative to the care-pathway and focus on the credible patient harm outcome. There is also a need to recognise that Health IT cannot be considered in isolation; it forms a constituent element of a socio-technical system, forming a fundamental element of health informatics.

This research establishes a framework which uses simple language constructs, recognising the socio-technical context in which they exist to establish hazard descriptions that capture the characteristics discussed above.

The framework has been evaluated through a series of different activities: application to legacy hazards; review by clinical safety officers; conference presentation & workshop; pilot study in a secondary care setting and training course delivery and evaluation. The conclusions of the evaluations converge to indicate that the framework is effective in establishing meaningful hazard descriptions and that it is a practical tool that can be used.

Further work is on-going to establish the framework in NHS Digital's clinical risk management training programme, providing a nationally available "how to guide" and publishing complimentary implementation guidance to support the two clinical risk management standards.

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The following journal articles have been published during the course of this research:

- Habli, I., White, S., Harrison, S., & Pujara, M.
Exploring the Notion of Hazards for Health IT
Informatics for Health: Connected Citizen-Led Wellness and Population Health.
European Federation for Medical Informatics (EFMI) and IOS Press, 2017, pp. 554 - 558.
- Habli, I., White, S., Sujan, M., Harrison, S., & Ugarte, M.
What is the safety case for health IT? A study of assurance practices in England
Safety Science Volume 110 Part A Dec 2018 Pages 324 – 335
- Habli, I., Jia, Y., White, S., Gabriel, G., Lawton, T., Sujan, M., & Tomsett, C.
Development and piloting of a software tool to facilitate proactive hazard and risk analysis of Health Information Technology
Health Informatics Journal, June 2019

The following conference paper has been published during the course of this research:

- Habli, I., & White, S.
Hazard and Risk Analysis of Health Informatics: Fundamental Challenges and New Directions
SCSC-140, Proceedings of the Twenty-sixth Safety-Critical Systems Symposium, York, UK, Feb 2018

Declaration

This thesis is the result of my own work. Any reference to the work of others is clearly identified in the text and acknowledged in the bibliography. This thesis in whole or in part has not been submitted for any other award of degree or qualification at the University of York or at any other university.

1 Introduction

1.1 Research Motivation

Information Technology (IT) is embedded within health and social care delivery organisations throughout the world. Initiatives such as the National Programme for IT (NPfIT) (Hassey, 2005) launched by the Labour UK Government provided centrally funded health care systems and services to the NHS. Analysis of spending by American health care providers indicates \$7.1 billion was spent on Health IT services and systems during 2017 (Splitzer, 2018).

Healthcare providers are motivated to utilise Health IT to realise operational efficiencies and better patient outcomes. The move to electronic based medicine prescribing and administration was shown to reduce serious errors by at least 50% (Bates, 2000) and findings from literature review indicates that the benefits of using of Health IT is considered to have a positive outcome in 62% of cases (Beeuwkes Buntin, et al., 2011).

However, the use of Health IT has the potential to compromise patient safety outcomes. A recent inspection of a National Health Service (NHS) Trust by the Care Quality Commission (CQC)¹ identified the potential for harm to occur to patients due to incomplete or missing electronic patient health records (CQC, 2016). Independent research conducted following the implementation of a Health IT system within the NHS illustrates a perceived increase in risk of patient harm (Clarke, et al., 2016). In the US, the ECRI Institute² established that during 2016, IT was cited as a cause of 2 of the top 10 technology hazards (ECRI Institute, 2015).

A recent study of current safety assurance practice in the domain (Habli, et al., 2018) concluded that *'Significant effort is still needed to develop and evaluate practical techniques and tools ... that help clinicians and engineers generate and explain the HIT safety evidence to the required level of rigour, detail and clarity'*. This conclusion was established through qualitative observation and opinion expressed within the context of three workshops that were run by the authors. The workshops were attended by clinical and engineering risk management practitioners and their views on current practice were elicited by asking questions pertaining to key clinical risk management activities. This particular conclusion aligns with my own personal reflections working as a Safety Engineer within NHS Digital³, where I have formed an opinion that there is an opportunity to improve the state of best practice with respect to safety management of Health IT.

1.2 Research Scope

The general scope of this research and its practical application has been targeted at health and social care organisations, e.g. secondary care hospitals and General Practitioners (GP), that are funded by NHS England to manage and administer care. The rationale for this being that:

¹ CQC is the independent regulator of health and adult social care in England. They are responsible for ensuring that health and social care services provide people with safe, effective, compassionate, high-quality care and encourage care services to improve. <https://www.cqc.org.uk/about-us>

² ECRI Institute is a US based independent and trusted authority on healthcare practices and products that improve the safety, quality, and cost-effectiveness of patient care. <https://www.ecri.org/about/>

³ NHS Digital is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care. They work with partners across the health and social care system to ensure information flows efficiently and securely. <https://digital.nhs.uk/>

- a) The UK Government has declared to transform the NHS, making it paperless by 2020 (UK Government, 2014) and thereby committing to the wholesale adoption and implementation of digital and information technologies.
- b) Additionally, the UK Government has committed to integrate health and social care domains (UK Government, 2015) which will inarguably utilise digital and information technologies to achieve this.
- c) The Clinical Risk Management (CRM) standard, DCB 0160 (NHS Digital, 2018), mandates, under the Health and Social Care Act 2012, that organisations must conduct clinical risk management in support of the deployment and use of Health IT systems.
- d) Care delivery organisations are under financial pressures with an on-going trend of a significant numbers of Trusts being in deficit (The Kings Fund, 2018) so there is an incentive to provide innovation that will improve competency and effectiveness.
- e) Different countries operate different health delivery models⁴. It was considered that the breadth of different operational context and different governance frameworks could introduce a risk to the research in that a convergent research recommendation could not be made.

As is further discussed at Section 2.2, the NHS has established a clinical risk management system to support the safe development and use of Health IT in England. This has been achieved through the publication of two complimentary standards DCB 0129 and DCB 0160. The specific focus of this research has been targeted to support the activity of Clinical Hazard Identification which is managed through Requirement 4.3 of both standards and is depicted in Figure 1. Further, this focus aligns with a key participant recommendation made in (Habli, et al., 2018) to “Develop guidance on the necessary clinical and engineering expertise needed for hazard identification”.

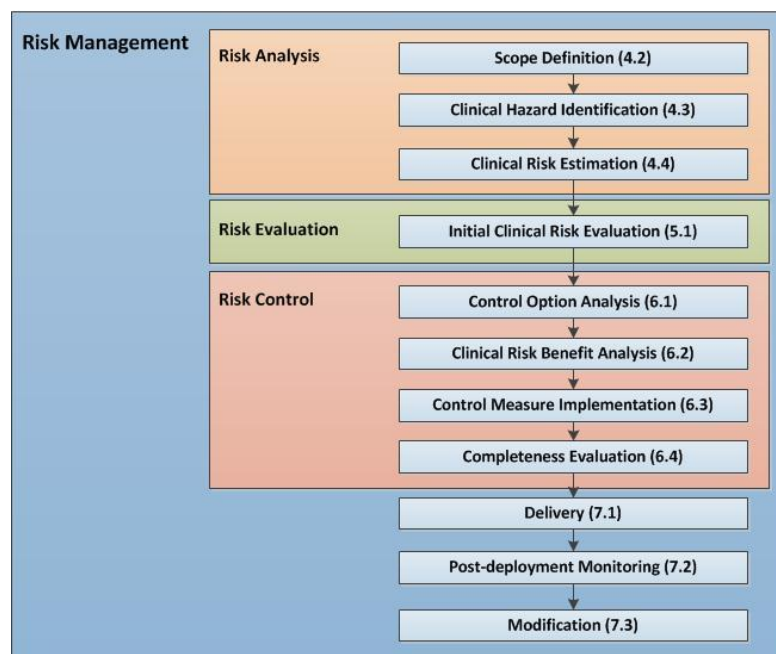


Figure 1 - Hazard Identification in Context (taken from DCB 0160)

⁴ Care delivery in NHS England is based on the Beveridge model where care is funded by central Government and is provided free of charge at the point of care. In Europe, care is based on the Bismarck model which is funded by a combination of central funding and private insurance whilst in USA care is almost always provided by private insurance.

It is important to recognise that the hazards associated with the use of Health IT cannot be identified and considered in isolation; the technology forms one element of a socio-technical system in which people, technology and information are inter-related and inter-dependant (Berg, 1999). Consequently, the term Health Informatics (HI) is used to reflect this eco-system and is used here-on-in within this thesis. The concept of HI is further discussed at Section 2.3.

The findings of this research have not been considered in the context of applicability to those technologies that are classed as Medical Devices (MD) i.e. those that are certificated under the Medical Device Directive (MDD) (EEC, 1993) or the replacement Medical Device Regulations (MDR) (EU, 2017). The MDD and MDR establish specific requirements that must be addressed by a manufacturer⁵ before a MD can be placed on market; it is feasible that the findings of this research may be of benefit in that process but that would be subject to further evaluation. The distinction between Health IT and MD is further discussed in Section 2.2

1.3 Research Objectives

There are two principal objectives associated with this research.

The first objective (1.3i) is, in the context of the observation drawn from (Habli, et al., 2018) and discussed above, to understand the challenges health organisations encounter in trying to comply with Requirement 4.3 of DCB 0160 i.e. the definition of HI related hazards.

The second objective (1.3ii) is to, building on this understanding, devise a methodology to assist organisations in addressing Requirement 4.3 of DCB 0160 which will support the meaningful definition of HI-related hazards.

Application of this methodology will ensure that hazards can be described in a systematic way such that the contextual significance of the hazard can be articulated and inform the subsequent risk analysis activities.

The methodology will also be expressed as a set of functional requirements to support the potential mechanisation of the methodology (i.e. tool support).

The research objectives will be achieved by fulfilling the following activities (note the related objective is identified in ()):

- a) Understanding and evaluating current practice with respect to hazard identification in the domain of HI (1.3i);
- b) Understanding and evaluating current practice with respect to hazard identification in other safety related and safety critical industries (1.3i);
- c) Deriving a methodology that addresses observed deficiencies in current hazard definition activities in the domain of HI (1.3ii);
- d) Applying and evaluating the methodology in the context of existing hazard definitions (1.3ii); and
- e) Applying and evaluating the methodology in support of new or imminent Health IT systems deployments (1.3ii).

⁵ Under medical device legislation (EU, 2017)] a manufacture is defined as “natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.”

1.4 Research Methodology

The research aim will be realised through the application of a four-stage research methodology:

1.4.1 Literature Review

A literature review will be conducted to establish an understanding of the state of current practice of hazard identification in both the health domain and in other safety related and safety critical domains. The review will further support an understanding of challenges organisations face and examine tools and processes that are used in hazard identification activities.

1.4.2 Domain Survey

A domain survey, targeted at health organisations, will be conducted to establish whether the findings of the literature review align with the views and thoughts of HCPs that are responsible for addressing the requirements of DCB 0160.

Work conducted in 1.4.1 & 1.4.2 will result in the development of a hazard identification methodology, specifically targeted to support the health domain.

1.4.3 Retrospective Application

The methodology will be applied to legacy and existing hazard logs and safety cases. A qualitative evaluation will be made as to whether the methodology improves the description and understanding of the hazards. This evaluation will be reviewed and appraised by Clinical Safety Officers⁶ (CSO).

1.4.4 Formative Application

The methodology will be applied to support the deployment of new or modified Health IT systems. A qualitative evaluation will be made as to whether the methodology improves the description and understanding of the hazards. This evaluation will be conducted by CSOs.

⁶ DCB 0160 establishes the role of a CSO. The CSO needs to be professionally qualified, registered and experienced and acts on behalf of the organisation to ensure the requirements of DCB 0160 are addressed.

1.5 Thesis Structure

The structure and organisation of this thesis is presented and summarised in Figure 2.

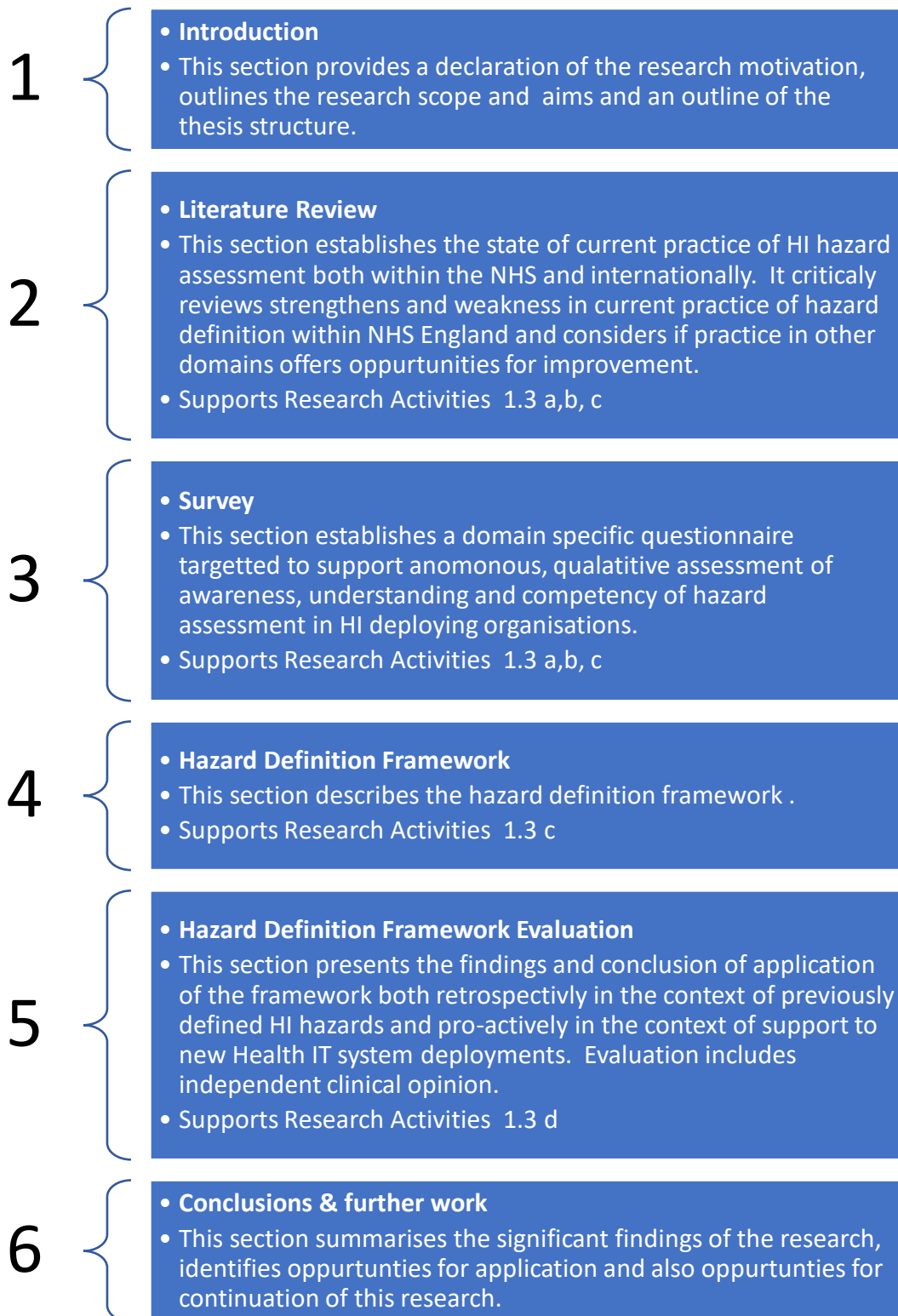


Figure 2 - Thesis Structure

2 Literature Review

2.1 Introduction

This literature review:

- establishes the different classification and regulatory frameworks that apply to software-based technologies that are developed for and used within the NHS;
- focuses on the emergent use of IT for health care purposes and establishes that it forms part of socio-technical ecosystem within the health domain;
- illustrates that Health IT is safety related and can credibly cause or contribute to patient harm
- provides an overview of generic safety management principles and discusses the approach to safety management within the health domain;
- focuses on hazard identification activities and reflects on the current state of practice within the NHS and compares this with practice in other domains.
- Formalise the specific research question that is addressed by this thesis.

2.2 Technology Classifications in the Health Domain

2.2.1 Medical Devices

In 1993 the Medical Device Directive (MDD) 93/42/EEC was established in statute and created a harmonised regulatory frameworkⁱ across the EU (European Union) through which products intended to be used in or on the human body had to be certificated by the manufacturer of the product. Such certificated products are formally classed as medical devices (MD) and are denoted by the CE⁷ mark. The MDD provides the following formal definition of a MD:

'an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which

-
- a) is intended by the manufacturer to be used for human beings for the purpose of*
- i. diagnosis, prevention, monitoring, treatment or alleviation of disease,*
 - ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
 - iii. investigation, replacement or modification of the anatomy or of a physiological process, or control of conception; and*
- b) Does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means'*

⁷ Derived from the French phrase *Conformite Europeene* which means European Conformity the CE mark is used by a manufacturer to declare that their product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. There are more than 20 directives setting out the product categories requiring CE marking. Conformity needs to be declared for products manufactured outside of the EU if they are to be sold within the EU. (Wellkang Tech Consulting, n.d.).

and defines a manufacturer of a MD as:

‘the person who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.’

Annex IX of the MDD establishes a classification scheme based on an increasing scale of risk of patient harm. A device is subsequently certificated at the classification level that aligns with the level of risk the device may introduce. The MDD defines the classifications as

Class I - Low risk

Class IIa - Medium risk

Class IIb - Medium risk

Class III - High risk

The scope of work a manufacturer must undertake and evidence increases with an increase in risk classification.

The MD classification dictates the route to certification and the authority to place the device on market. The UK arrangements for certification is as is depicted in Figure 3 and summarised below. (The same arrangements exist in other EU states, but the EU Representative, Regulatory Authority (RA) and Notified Body (NB) responsibilities are discharged by other organisations. UK manufacturers can apply to any NB in the EU and once they have the necessary certification their products can be sold anywhere in the EU).

Her Majesty’s Government is the UK’s representative in the EU and the Medicines and Healthcare products Regulatory Agency (MHRA), which is an executive agency sponsored by the Department of Health and Social Care, is the RA. The MHRA appoints NBs who are responsible for assessing whether a manufacturer and their MD(s) meet the requirements of the MDD in cases where that MD is not classified as Class 1. For Class 1 MDs, the manufacturers make a self-declaration of conformity to the MHRA.

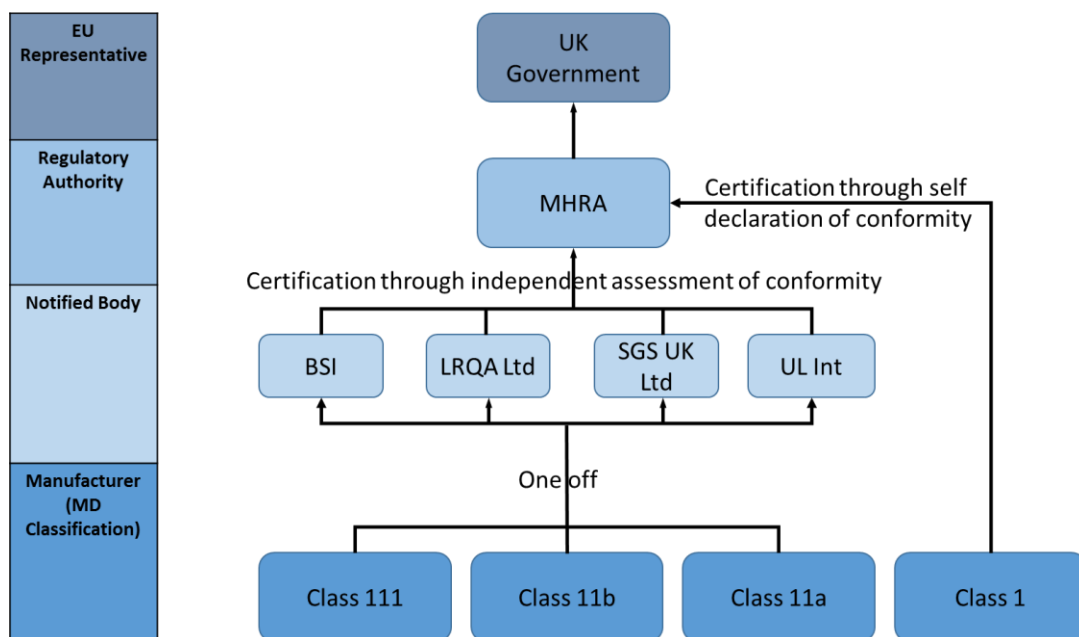


Figure 3 - UK Arrangements for MD Certification

In May 2017 the Medical Device Regulation (MDR) EU 2017/745 (EU, 2017) came into effect, replacing the MDD. There is a transitional period after which certificates issued under the MDD become void and the MD must be removed from market. The arrangements for certification under the MDR remain unchanged.

The increasing use of standalone software as a medical device, or the use of software as part of a medical device or the use of software for health purposes that do not constitute a medical device has been recognised in the MDR. Clause 19 states:

'It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.'

Further, the MDR provides definition regarding the classification of software through Rule 11:

'Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as Class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or*
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.*

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.'

In summary, a legislative framework exists to ensure that software is considered in the context of its use and its development is regulated and ultimately certificated, taking into consideration the degree of impact it may have on patient's health.

2.2.2 Health IT

Software technologies are used for health purposes that fall outside the definition of a MD and hence outside the regulation of the MDD/MDR. Consider the use of general-purpose IT and programming environments to provide an enterprise wide Electronic Health Record (EHR) System. An EHR is defined as (Institute of Medicine (US) Committee on Data Standards for Patient Safety, 2003):

Including: 1) longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the help of an individual or a healthcare provider to an individual; 2) immediate electronic access to person and population level information by authorised users; 3) provision of knowledge and decision support that enhances the quality, safety and efficiency of patient care; and 4) support for efficient processes for health care delivery

This definition clearly falls outside of the MDD's "diagnosis, prevention, monitoring, treatment" test yet it is easy to recognise that failure of the EHR or unintended use of the EHR could impact on the care of the patient and potentially cause harm.

This distinction between technology that clearly constitutes a MD and is subsequently managed through a regulatory framework and that which is not, but still has the potential to

cause or contribute to patient harm, was recognised by the international standards community in 2008. ISO/TC 215 Health Informatics (International Organization for Standardization / Technical Committee) in collaboration with Technical Committee CEN/TC 251, Health informatics (European Committee for Standardization/Technical Committee) worked to develop ISO/TS (Technical Specification) 29321:2008 "health Informatics — Application of clinical risk management to the manufacture of health software."

Additionally, the ISO community recognised that the MDD is focused on risk management in the context of product development and in support of placing safe products on market; the scope does not extend to address the potential risk of subsequent product deployment and use. To address this gap, a complementary specification, ISO/TR 29322:2008 Health informatics — Guidance on the management of clinical risk relating to the deployment and use of health software" was developed.

Although this work had significant support, both TRs failed to gain the minimum 75% of member body votes required for them to be published as international standards.

Despite the international decision not to publish, both were adopted in England by the NHS Information Standards Board (ISB) and published as CRM standards DSCN 14 (Data Set Change Notification) and DSCN 18 in 2009. Both standards have been revised and updated over time; the standard covering manufacture of Health IT is now published as DCB (Data Control Board) 0129 (NHS Digital, 2018) and the standard covering deployment and use is now published as DCB 0160 (NHS Digital, 2018). Both standards are in scope of the Health and Social Care Act 2012 under section 250.

Both standards were updated in June 2018, bringing MDs into scope. The motivation for this change in scope was to address the increasing implementation and use of calculators⁸ and clinical support algorithms in Health IT systems and for the need for CRM to be applied to the entire functionality of the Health IT system. This change in scope does not alter a manufacturer's legal responsibilities under the MDD/MDR and was made in agreement with the MHRA.

The scope and effectivity of this thesis and the supporting research is limited to those technologies described as Health IT.

2.3 Health IT, a Socio-technical Element

A key discriminating characteristic of Health IT, which can be derived from the discussions at sections 2.1 & 2.2, is that it has no direct control over the administration of care to an individual patient. The influence Health IT has on the care of a patient is achieved through direct action of Health Care Professionals (HCPs) where a HCP is defined as '*a person associated with either a specialty or a discipline and who is qualified and allowed by regulatory bodies to provide a healthcare service to a patient*' (Segan, 1992). The actions a HCP takes or the decisions that they make can be influenced by the information the Health IT provides but ultimately the final judgement is made by the HCP.

The concept of Health IT can be thought to be composed of two constituent components; the underlying technology of hardware and software and the information and data that is managed and communicated by the technology.

From a CRM point of view, it becomes difficult to consider Health IT as being an independent, standalone entity given its different constituent components and their dependency on HCP to

⁸Increasingly, paper-based calculators are being implemented within Health IT systems to automatically provide a score derived from parameters recorded within a patient's health record. In some cases the algorithms are sufficiently complex or the datasets are so extensive then they constitute medical devices as the HCP is unable to independently ascertain the validity of the result.

initiate a real-world, patient impacting action. Failure or malfunction of the technology can not directly result in harm to a patient whose care is being managed by the technology. The term *socio-technical system* has emerged and is used to describe these complex real-world scenarios where the combination of different entities combine and have a collective influence on the environment in which they exist. Berg (Berg, 1999) defines this concept as “*work practices to be made up of a number of interrelating networks, which are dependent on one another*”. This is a strong definition, as a patient’s care management and administration (in the context of Health IT) is achieved through work processes that HCP follow.

The term Health Informatics (HI) has recently emerged to capture the use of information to support healthcare. There does not appear to be universal definition. Coiera (Coiera, 2015) describes HI as being the ‘*study of information and communication processes and systems in healthcare*’ which is strong but does not necessarily take into consideration the contribution of technology. Hersh’s definition (Hersh, 2009) of ‘*optimal use of information, often aided by the use of technology, to improve individual health*’ extends to include the use of technology. This is represented pictorially at Figure 4.

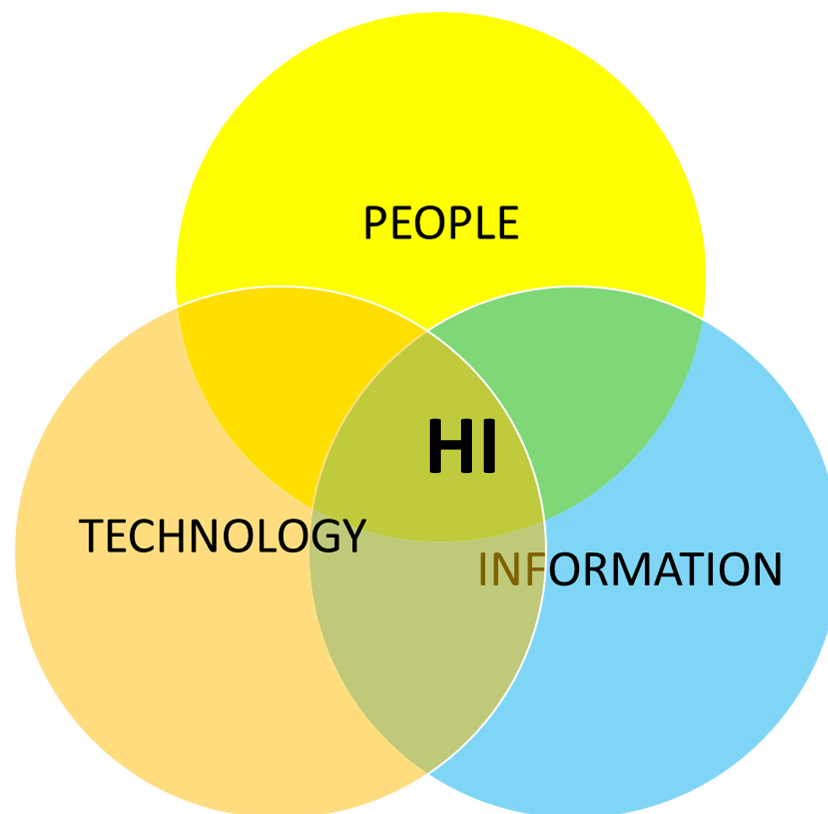


Figure 4 - HI as a Socio-technical System

The concept of HI being a socio-technical system established through the integration of people, technology and information is the model that is used in this thesis. This aligns with the views of Sittig and Singh (Sittig & Singh, 2010) and their development of ‘*an eight-dimensional model specifically designed to address the sociotechnical challenges involved in design, development, implementation, use and evaluation of Health IT within complex adaptive healthcare systems.*’

The simplified HI model at Fig 4 can be further refined by considering the explicit relationships that exist between the three elements. Regardless of the scale and complexity of the

technology, which may range from a health app⁹ running on a smart phone through to a nationally deployed primary care service¹⁰, there is an intrinsic link between the 3 components as illustrated in Figure 5.

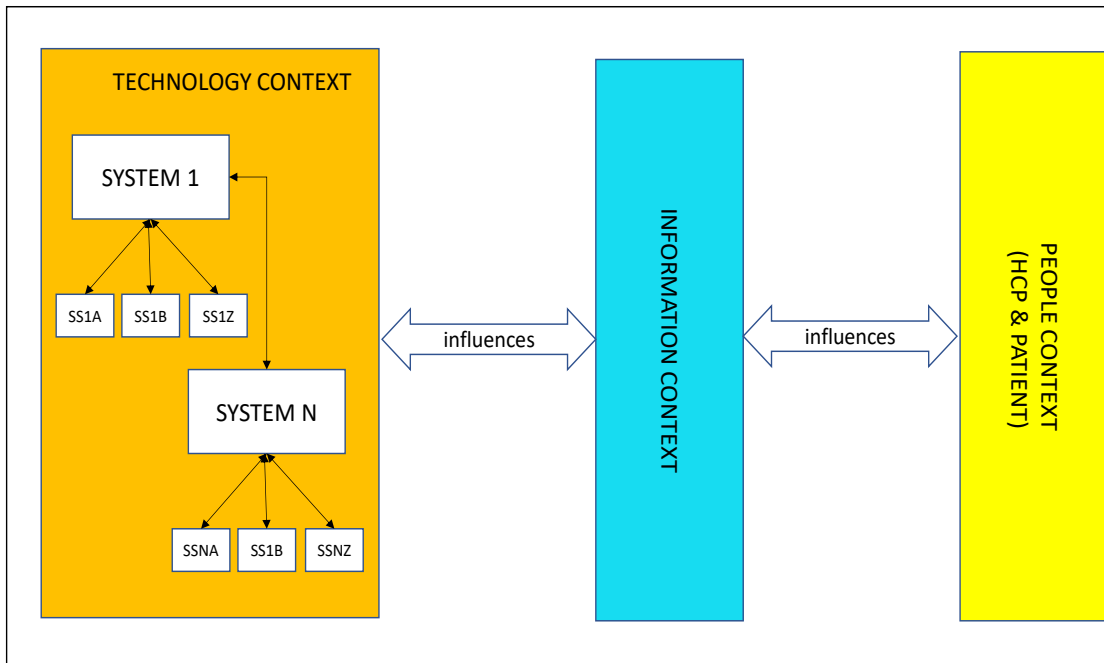


Figure 5 - Health IT in a Socio-technical Context

The relationships between components are shown as bi-directional as the influences may propagate from the technology, through the information it generates that influences the decisions and actions made by the HCP. Conversely, in response to the physiological and care needs of the patient, the HCP may manipulate information that has an impact on the technology. This can be better illustrated through specific examples.

In primary care¹¹ when assessing the cardiovascular health¹² of a patient, the General Practitioner (GP) is likely to run the QRISK¹³ calculator embedded within their desk-top system and their subsequent care management decisions will be influenced by the calculated risk factor. An error in the algorithm or its implementation or incorrect coding of risk factors within the health record are obvious failures that may result in a skewed or incorrect risk

⁹ Application programs that offer health-related services for smartphones and tablet PCs. Accessible to patients both at home and on-the-go, health apps are a part of the movement towards mobile health services in health care (TechTarget, 2011)

¹⁰ The Electronic Prescription Service enables prescriptions to be created and communicated electronically to the patient’s pharmacy of choice, eliminating the need for a paper prescription. (NHS, 2016)

¹¹ Primary care services are local points of contact in the NHS and include services such as general practice, community pharmacy, dentistry and optometry. (NHS England, n.d.)

¹² Those disease that affect the heart and/or blood vessels which include coronary heart disease, stroke, arterial disease and aortic disease. (NHS England, 2018)

¹³ The QRISK® algorithm calculates a person's risk of developing a heart attack or stroke over the next 10 years. It presents the average risk of people with the same risk factors as those entered for that person. (ClinRisk, 2018)

profile which in turn induces the GP to administer sub-optimal or inappropriate care to the patient.

If, during a primary care prescribing encounter, a patient suffers an allergic reaction to the medication prescribed, the GP will code this reaction into the patient's national Summary Care Record (SCR ¹⁴) via their Health IT system. If the patient then presents for care in another care setting e.g. at Accident and Emergency (A&E), the HCP can access the SCR, see that the patient is allergic to that medication and avoid prescribing it. A failure to encode the allergy or to mistakenly associate it with a different patient's health record are obvious errors that could result in this information not being saved in the patient's SCR and them potentially being administered sub-optimal or inappropriate care.

2.4 Health Informatics, a Safety Related Socio-technical System

Vincent (Vincent, 2010) describes patient safety as being the 'avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare.' The adoption and use of Health IT to support healthcare can improve patient safety outcomes but can, by introducing a change in the care-process, introduce new problems and associated risk.

The introduction of electronic prescribing has an obvious advantage over paper-based prescribing in eliminating transcription errors that occur when mis-reading a handwritten prescription (Bates, et al., 1998). However, without considered system design, hazards associated with alert fatigue and un-safe workarounds and short-cuts can be introduced (Kaushal, et al., 2003). The challenge of integrating technology into care-process is recognised by Black (Black, et al., 2011) who identified that the expectation of improved safety following the introduction of Health IT is not always realised because Health IT does not always integrate into existing care-process.

The Institute of Medicine (IOM) (Institute of Medicine., 2011) establishes that technology is a component part of a larger socio-technical system and that '*safety is an emergent property of that larger system*' and that by '*adopting a sociotechnical perspective acknowledges that safety emerges from the interaction among various factors.*' The work goes on to conclude that '*the current state of safety and health IT is not acceptable; specific actions are required to improve the safety of health IT*'.

Whilst it's difficult to establish the real state of Health IT (Institute of Medicine., 2011) a review of 850 Health IT related patient safety events reported to NHS Digital between 2005 and 2011 was conducted by (Magrabi, et al., 2015) gives some real-world context. The review concluded that Health IT failures had been hazardous in 68% of the events including 3 events which had resulted in death.

¹⁴ Summary Care Records (SCR) are an electronic record of important patient information, created from GP medical records and saved on a national system (SPINE). They can be seen and used by authorised staff in other areas of the health and care system involved in the patient's direct care.

<https://digital.nhs.uk/services/summary-care-records-scr#using-scr>

2.5 Clinical Risk Management, General Principles

CRM, in the context of Health IT is defined (NHS Digital, 2018) within the NHS as the *systematic application of management policies, procedures and practices to the task of analysing, evaluating and controlling clinical risk* with clinical risk being defined as the *combination of the severity of harm to a patient and the likelihood of occurrence of that harm*. The inclusion of the term clinical is important as it serves to establish the focus of the risk management process and to exclude other risk themes such as costs and resources. This definition of CRM aligns with the concept of Safety I which applies management processes and practices *to make sure that the number of accidents and incident are kept as low as possible or as is as reasonably practicable* (Hollnagel, 2014).

The two CRM standards establish both a proactive and reactive approach to CRM. In a proactive approach *'adjustments are made before something happens'* whilst in a reactive approach *'adjustments are made when unacceptable outcomes have occurred'* (Hollnagel, 2012).

2.5.1 Proactive Clinical Risk Management

The proactive elements of risk management in DCB 0129 & DCB 0160 are depicted in Figure 1 by the activities of Risk Analysis, Risk Evaluation and Risk Control. These align with the generic 4 questions of proactive risk management as illustrated in Figure 6.

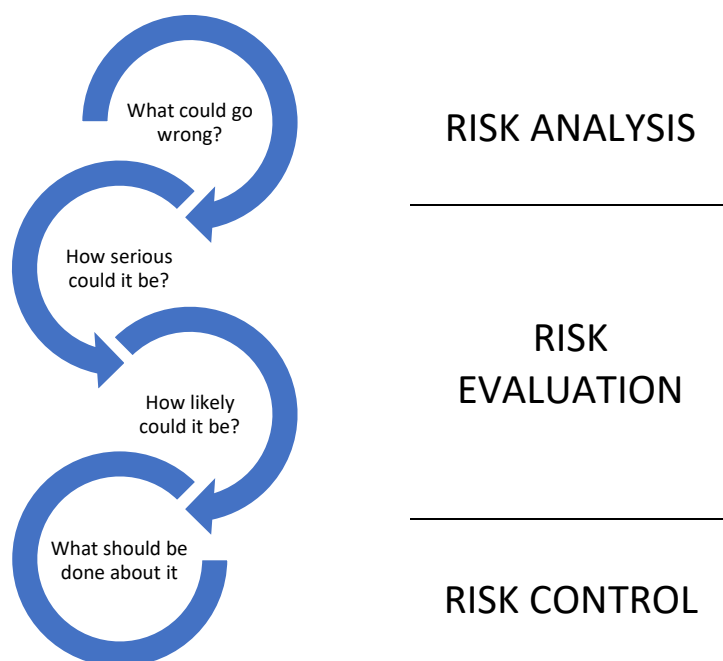


Figure 6 - Proactive Risk Management

The three phases are further elaborated at Figure 7 to describe the activities undertaken

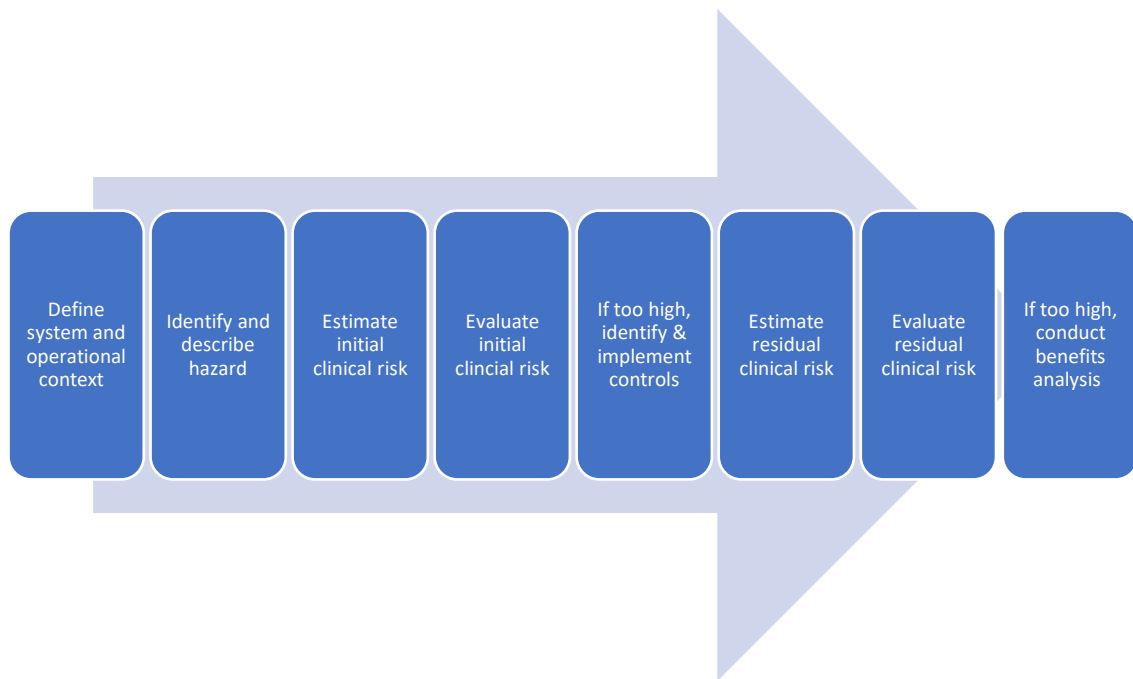


Figure 7 - Proactive Risk Management Key Activities

Define system & operation	Necessary to define the scope of the implementation and operational context in which the management process applies. Without doing so the ability to systematically consider how the system could fail or be used incorrectly and what the patient harm outcomes could be is compromised.
Identify and describe hazard	Use of deviation analysis techniques (SWIFT, FMEA or others) to explore what could credibly occur and result in patient harm. Definition of hazard.
Estimate initial clinical risk	Estimate the severity of harm outcome and likelihood of the harm outcome by considering what causes need to occur, which existing controls need to fail and/or what other conditions need to prevail for the hazard to occur. Risk is the combination of severity and likelihood and is derived from a pre-defined framework. Initial risk represents that level of risk that exists before any additional controls are introduced.
Evaluate initial clinical risk	Determine the acceptability of the initial risk against an acceptability framework. If it exceeds the level of acceptability further controls need to be considered.
Identify & implement controls	Identify and implement additional controls to reduce risk. This activity also needs to consider whether introduction of controls will introduce new hazards or have an impact on existing hazards. The controls can either be pre-emptive and eliminate or reduce the likelihood of the identified causes resulting in the hazard or re-active and reduce the likelihood of the hazard propagating into harm. (in general terms it is difficult to reduce the severity of a Health IT related hazard)
Estimate residual clinical risk	Estimate the severity of harm outcome and likelihood of the harm outcome after the additional controls have been introduced and been demonstrated to be effective.

Evaluate residual clinical risk Determine the acceptability of the residual risk against an acceptability framework. If it exceeds the level of acceptability and no further controls are practical a benefits analysis needs to be undertaken.

Conduct benefits analysis Analysis conducted to establish whether progressing with the system at an undesirable level of risk is outweighed by the clinical benefit that the system introduces.

A model of the implicit proactive CRM process established in DCB 0129 & DCB 0160 has been expressed (Habli, et al., 2018) using Goal Structured Notation (GSN)¹⁵ and is reproduced at Figure 8.

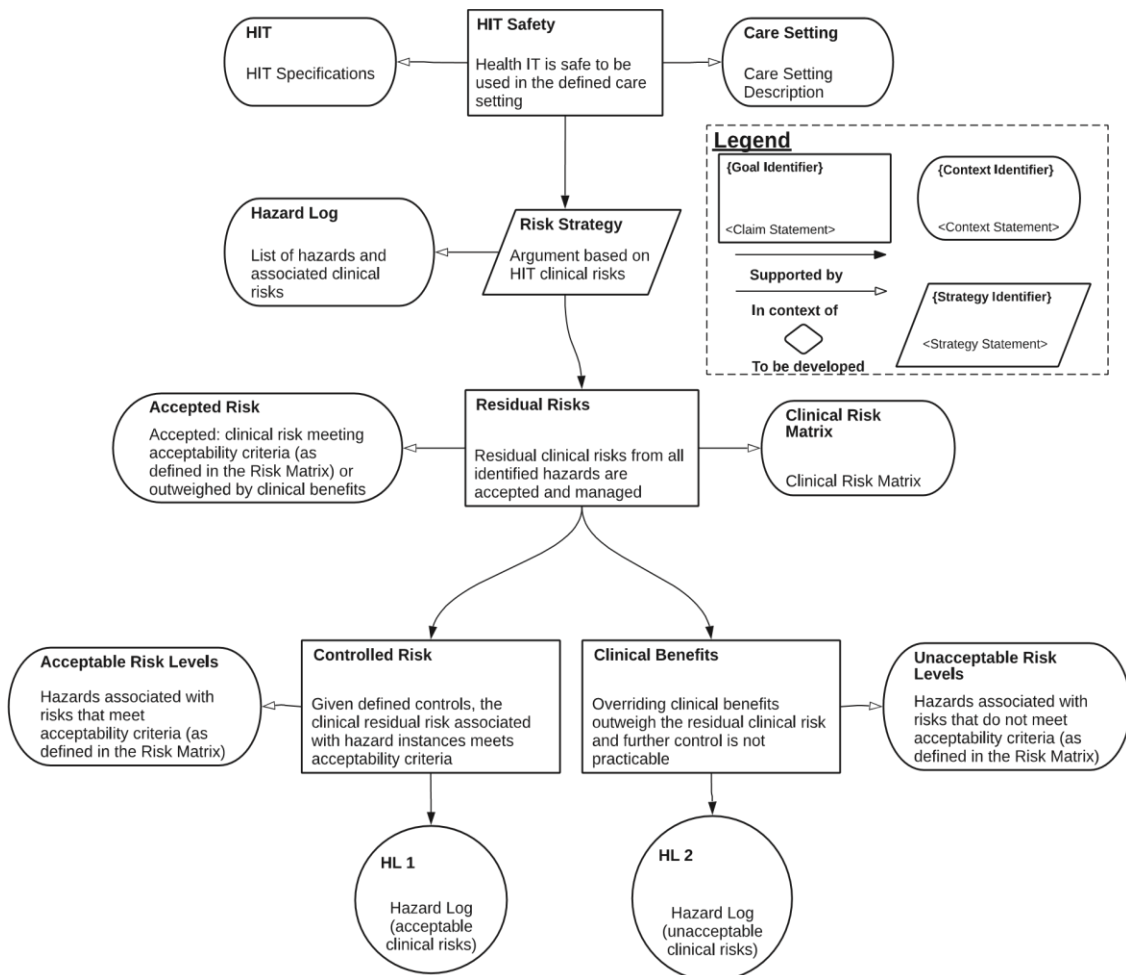


Figure 8 - GSN Representation of CRM Proactive Safety Process

This model clearly illustrates that the CRM standards take a hazard centric approach to CRM where a hazard is defined as a 'potential source of harm to a patient'. This approach is not unique and is one that is adopted in other safety related industries. For example, in the European rail industry Commission Regulation (EC) No. 352/2009 (EU, 2012) establishes a (revised) common safety method for risk evaluation and assessment and supporting guidance establishes that 'all reasonably foreseeable hazards are identified....' (Rail Safety and Standards Board, 2014)

¹⁵ GSN is a graphical notation that can be used to document the relationships between and the elements of a safety argument. <https://scsc.uk/r141B:1?t=1>

2.5.2 Reactive Clinical Risk Management

The concept of reactive CRM is addressed in DCB 0129 & DCB 0160 at Section 7.2, *Post-deployment monitoring*. Requirements establish the need for organisations to establish and implement a safety incident management process. The purpose of this management process is to ensure that when things go wrong, they are quickly identified, assessed, resolved and that their impact on the safety case for the system is understood.

A significant influence on the effectiveness of a reactive safety management process is the prevailing safety culture of the organisations. This has been addressed in the civil aerospace domain through promotion and introduction of “Just Culture” which is defined (EU, 2014) as ‘*a culture in which front-line operators or other persons are not punished for actions, omissions or decisions taken by them that are commensurate with their experience and training, but in which gross negligence, wilful violations and destructive acts are not tolerated*’. The need to establish an open and non-punitive culture within the NHS has been recognised with NHS Improvement launching A Just Culture Guide (NHS Improvement, 2018) following recommendations made by Professor Sir Norman Williams (Williams, 2018).

2.5.3 Hazard as a Concept

The concept and use of a hazard in proactive CRM is fundamentally established in DCB 0129 and DCB 0160 which define a hazard in a patient care context as a ‘*potential source of harm to a patient*’. In the engineering domain Leveson (Leveson, 2012) establishes that environmental conditions also need to exist with the hazard before an accident can occur. This engineering view can be considered in a healthcare context to establish that the care context needs to be considered in combination with the hazard to establish the patient harm outcome.

This philosophy is illustrated in Figure 9 where different contributions combine to realise patient harm

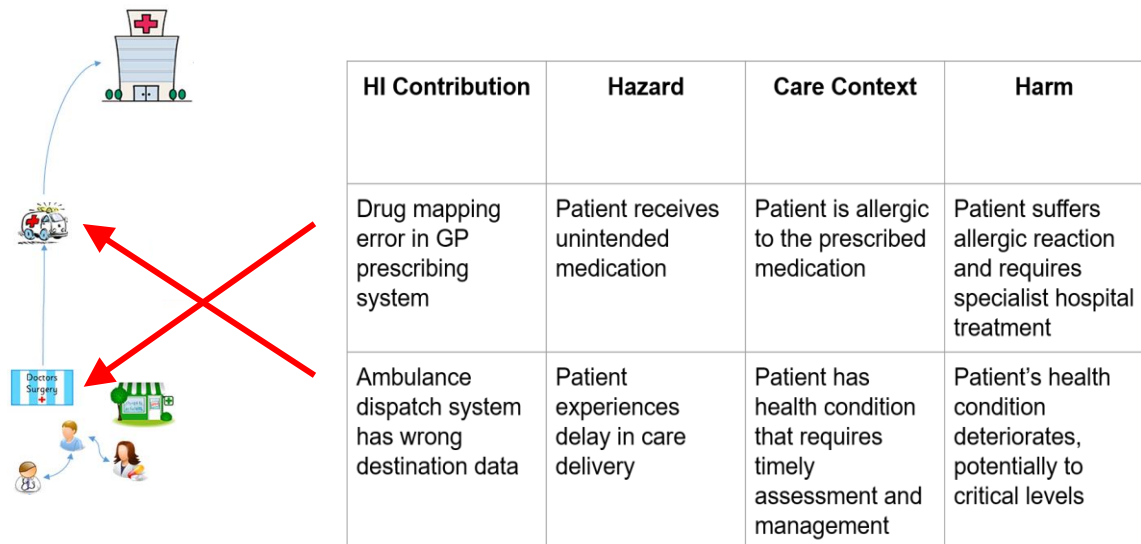


Figure 9 - Hazard as a Concept

2.6 Hazard Identification, State of Current Practice in the Health Domain

As discussed at Section 2.5, the concept of hazard is firmly embedded in the NHS CRM standards. However, having worked as a Safety Engineer in the NHS for 10 years I hold a view that the concept of hazard is not always understood and where it is used the description of the hazard rarely articulates or relates to the patient harm outcomes. Often, the term risk is used in place of hazard.

A similar observation is recorded by Habli (Habli, et al., 2017) where a participant in the workshop responded that *“the NHS has always worked in ‘risks’: I don’t know what a hazard is.”* Further, the thematic analysis conducted in that work indicated that there is *‘confusion about the terms hazard, risk, harm and quality and where hazards are defined, they are very generic and poorly linked to clinical environment.’*

This observation is evident in the literature: (Battles & Lilford, 2003) make a distinction between hazard and risk through definitions that align with those in the CRM safety standards but the terms are used interchangeably and together. Terms such as *‘identify fully the risks and hazards’* reinforce the position that they are the same thing rather than a hazard being a condition that could result in the harm and risk being a metric to inform the subsequent management of that condition. (Liberati, et al., 2018) also discuss *approaches to hazard and risk detection*.

The approach to CRM within the health domain has and continues to be largely reactive. Review of a NHS hazard identification and risk assessment management procedure (Nottingham University Hospitals NHS Trust, 2014) reveals that, *whilst the list is not exhaustive*, all potential sources of hazard are derived from an organisational response to an external factor e.g. following a patient safety conversation. No consideration is given to proactive hazard identification e.g. to support the introduction of a modification to the Health IT; in fact, technology or the use of technology was not considered within the scope of the procedure.

Whilst resources are being developed to foster a systematic approach to managing patient safety the viewpoint is largely one of reactive management e.g. NHS Improvement Patient Safety Alerts focus on communicating incidents and near misses. Whilst raising awareness and learning from these events is an important, there seems to be very few resources support proactive safety management.

There is a recognition (Sujan, et al., 2015) that *Healthcare organisations require support with the adoption of proactive and systematic safety management practices that are a key feature of safety-critical industries*. Where they have been used proactive techniques such as Failure Mode and Effects Analysis (FMEA) have been considered to be *a very useful procedure for proactively evaluating a defined healthcare process* (van Tilburg, et al., 2006). Similar studies (Potts, et al., 2014) recognise that proactive hazard identification is a *powerful way to increase understanding of risks in a system and implement changes before harm occurs* and concludes that *the collaborative discussion of risks by a healthcare team is powerful and it may be the case that raising awareness of risks in the system through these techniques (SWIFT and HFMEA) is as important a factor in increasing safety as the identification of hazards*.

Further work by Sujan (Sujan, et al., 2017) identified that participants in the study *‘from the health sector suggested that the concepts of risk (in relation to patient safety) and of risk management are poorly understood.’*

From a national perspective the NHS has the benefit of *‘having the longest standing and most well developed safety programs’* (Kushniruka, et al., 2013) although a national survey undertaken Connecting for Health (former name of NHS Digital) in 2013 (Connecting for

Health, 2013) concluded that care organisations within the NHS had little awareness of DSCN 18 (initial version of what is now designated DCB 0160).

2.6.1 Hazard Identification Techniques Tools

The following hazard identification techniques and tools have identified and reviewed from a perspective of applicability to HI and their ability to elicit a structured and patient harm centric description.

2.6.1.1 Structured What-IF Technique (SWIFT)

SWIFT is a well establish technique that is used to support hazard identification (Card, 2013). The technique is one of structured brainstorming where guidewords such as “what-if”, “how-could” are used to explore how deviations in the intended system operation could be induced. To be effective, SWIFT should be conducted by a multi-skilled group of people who are able to discuss different perspectives and opinions. As with all deviation analysis techniques an accurate and complete description or model of the system is required such that the technique can be applied in a systematic and repeatable way. The main disadvantages (Crawley & Tyler, 2003) of SWIFT are that the quality of the analysis is significantly influenced by the competency of the facilitator and if the workshop is unstructured a lot of time can be spent on trivial issues.

SWIFT is used in healthcare and is advocated by NHS Digital in their national CRM training programme.

Hazard descriptions established using SWIFT are unstructured and will be influenced by the experience team; there is an opportunity to compliment SWIFT by supporting the derivation of hazards that reflect the scenario explored through the analysis and the patient harm outcome.

2.6.1.2 Hazard Identification (HAZID)

This is derived from the technique of HAZOPS (Hazard Operations) which was developed in the process industry. HAZID is a deviation technique that uses guidewords to explore potential hazard conditions. Its conducted from a model of the system and uses guidewords related to the characteristic of the system. It is effective in information systems where guidewords such as wrong, late, no can be prefixed to the information in order to determine what the effect on the system could be. The output from HAZID is tabular and does not provide a framework to establish the hazard description.

2.6.1.3 Failure Modes and Effect Analysis (FMEA)

FMEA is conducted from a functional perspective and considers how failure of the implementation technology can result in a system level effect. It is often extended to include a criticality assessment (FMECA) of the effect of the failure (Federal Aviation Authority, 2000). FMEA is supported by a structured table and requires a representative model of the system and an understanding of the use of the system. It is very systematic in nature and can be undertaken by a single analyst or by a small team. The methodology can result in a lot of output so care is needed in its application.

FMEA has been adopted and adapted for use in the healthcare domain. Proactive hazard identification in the context of paediatric prescribing (Lago, et al., 2012) focused on failure of clinical processes and concluded that *FMEA enabled a prospective analysis of the process of*

drug delivery to review potential failure modes and their associated causes and to assess which risks have the greatest concern, stimulating the most urgent improvement effort in clinical practice to prevent errors before they occur.

FMEA does not provide a framework through which to describe the hazards, but its tabular nature means that a structured approach to describe the scenario could be integrated to and compliment the technique.

2.6.1.4 Functional Failure Analysis (FFA)

FFA is similar to FMEA in that it focuses on failures of the system in order to reveal potential hazards. Unlike FMEA, which is undertaken from a low-level component failure perspective, FFA considers failure of the function and as such can be undertaken much earlier in the lifecycle; it can be conducted in advance of the implementation being established. It is systematic in nature using a table and failure modes typically of no function, wrong function provided when not required to structure the analysis.

As with FMEA, it does not provide a framework through which to describe the resulting hazards.

2.7 Summary

Health IT is safety related but its contribution to patient harm outcomes cannot be established in isolation; they need to be considered as part of socio-technical system. CRM standards exist within the NHS to promote effective safety management from both a proactive and reactive perspective. As is common in other safety related and safety critical industries, the concept of hazard is used to establish focus in a proactive safety management process. However, current CRM practice in the health domain seems to be predominately reactive although there is some evidence to demonstrate that hazard identification tools and techniques routinely used in other industries are being adopted and are yielding positive outcomes. Although established tools exist, they do not enforce a structure in the hazard description that reflects the socio-technical context in which they occur.

Conclusions from the literature review re-enforce the research motivation that a mechanism needs to be established that aligns with the principles of proactive CRM management and enables safety practitioners to consistently and systematically establish hazard descriptions that convey meaning and understanding and support subsequent CRM activities. The mechanism needs to be complimentary to existing hazard identification techniques.

3 Hazard Survey

The original evidence base supporting the research motivation and objectives was effectively limited to the conclusions of the Habli study (Habli, et al., 2018) and personal observations working as a Safety Engineer in the NHS. The decision to conduct a survey was taken in order to establish a wider evidence base, principally from the organisations responsible for meeting the requirements of DCB 0160. It was anticipated that by designing a structured series of questions and circulating this to a large audience, a suitably large, qualitative dataset would be established that would be amenable to thematic analysis. This would then be supplemented by other research techniques.

3.1 Purpose

The principle purpose of designing and conducting a survey was to collate qualitative data that would create confidence (or otherwise) that the observations drawn from my own experience working as a Safety Engineer and from my literature review are representative in the context of health care provision within NHS England.

3.2 Design

The approach followed in designing and conducting the survey was derived from that described (Stone, 1993) as depicted in Figure 10.

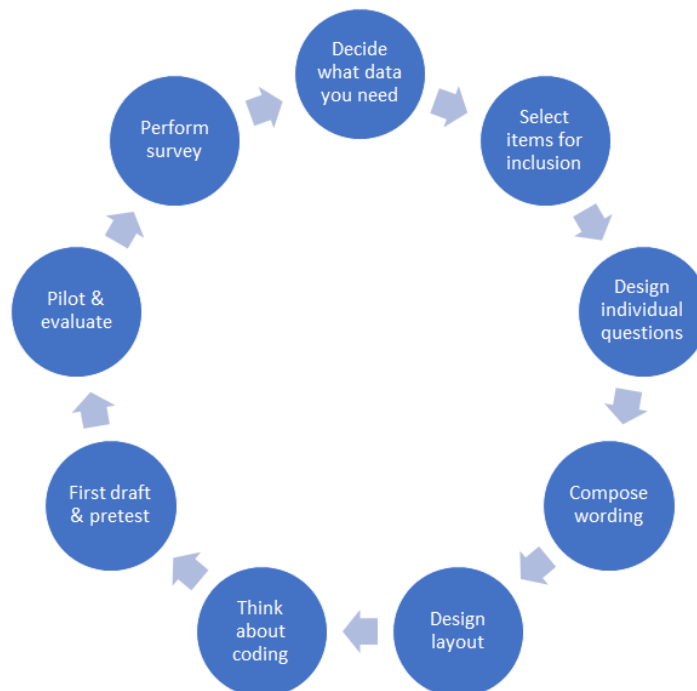


Figure 10 - D. H. Stone Questionnaire Design

This process was simplified as shown in Figure 11, taking into consideration the electronic nature of the survey and the availability of supporting survey management tools.

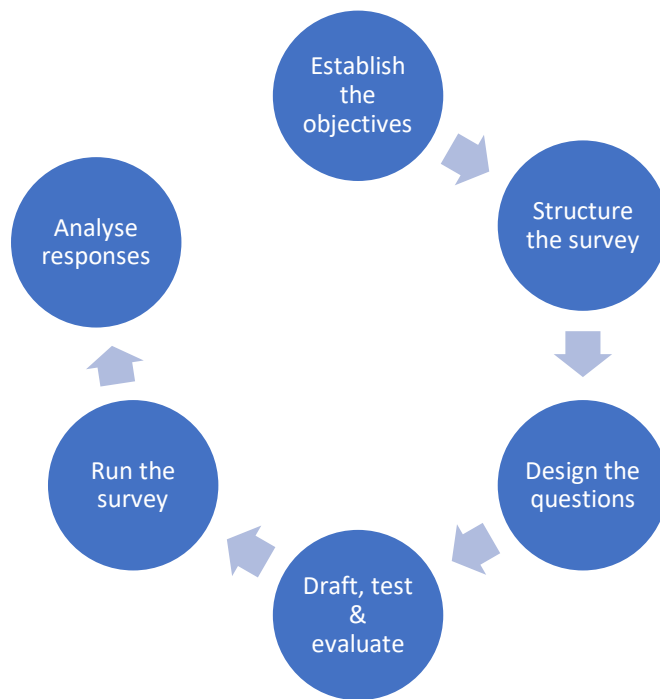


Figure 11 - Revised Questionnaire Design

3.2.1 Establish Objectives

The principal design objectives are as summarised below and further distilled into specific design requirements for the survey.

1. **Target Audience** - to establish the appropriate target audience i.e. that which is responsible for ensuring the requirements of DCB 0160 are addressed within NHS England.

DR1: Identify target audience of the survey.

Resolution: Section 3.2.6 Run

2. **Anonymity** - to preserve the anonymity of the individual respondents in order not to breach their rights under the General Data Protection Regulation (GDPR)¹⁶ (Regulation (EU) 2016/679, 2016). This needs to be addressed both in terms of the questions asked within the survey and in the mechanisation of the survey.

DR2: Ensure total anonymity of the respondents to the survey.

Resolution: Section 3.2.3 Design the questions
Section 3.2.4 Draft & test

¹⁶Regulation (EU) 2016/679 is European legislation that ensures data protection and privacy for all citizens of the EU. It gives control to individuals on how their personalised data is shared and used. Introduced as world-wide regulation on May 25th, 2018, GDPR serves to give more transparency to people about what data organisations collect about them and what those organisations use the data for. It also enables people to prevent unnecessary data collection. Additionally, it increases the potential fines organisations may face if they are found to be misusing the data they collect.

<https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr>
<https://publications.europa.eu/en/publication-detail/-/publication/3e485e15-11bd-11e6-ba9a-01aa75ed71a1/language-en>

3. **Role & Experience** - factors that may have an influence on correctness of respondent's answers to knowledge-based questions i.e. experienced clinical respondent could be expected to have more knowledge than a junior project manager.
 - DR3:** Elicit respondent's role & experience with respect to clinical risk management.
 - Resolution:** Section 3.2.3 Design the questions
Section 3.2.4 Draft & test

4. **Training** - a factor that may have an influence on correctness of respondent's answers to knowledge-based questions i.e. respondent who has been trained in risk management would be expected to have more knowledge than one that had not.
 - DR4:** Elicit respondent's degree of training in clinical risk management.
 - Resolution:** Section 3.2.3 Design the questions
Section 3.2.4 Draft & test

5. **Knowledge** - assimilate respondent's understanding of key concepts w.r.t hazard identification and risk assessment. No leading questions.
 - DR5:** Elicit respondent's level of knowledge with respect to hazard identification and risk assessment.
 - Resolution:** Section 3.2.3 Design the questions
Section 3.2.4 Draft & test

6. **Competence & Confidence** - assimilate respondent's perceived competence and confidence in conducting hazard identification and risk assessment activities. No leading questions
 - DR6:** Elicit respondent's level of competence and confidence with respect to hazard identification and risk assessment.
 - Resolution:** Section 3.2.3 Design the questions
Section 3.2.4 Draft & test

7. **Brevity** - minimise the number of questions and time to complete the survey without compromising its effectiveness.
 - DR7:** Design short and unambiguous questions
 - Resolution:** Section 3.2.3 Design the questions
Section 3.2.4 Draft & test

3.2.2 Structure

The structure of the survey is as depicted as shown in Figure 12. It progressively collects contextual information before exploring the respondent's knowledge, competence and confidence in undertaking the hazard identification and risk analysis activities.

There is a need to capture contextual information that may have an influence or impact on the knowledge response from a respondent. For example, a respondent working in a clinical role having had training in clinical risk management can reasonably be expected to have stronger knowledge and more competence and confidence in performing the activities than that of a respondent working in a management role without having had training.

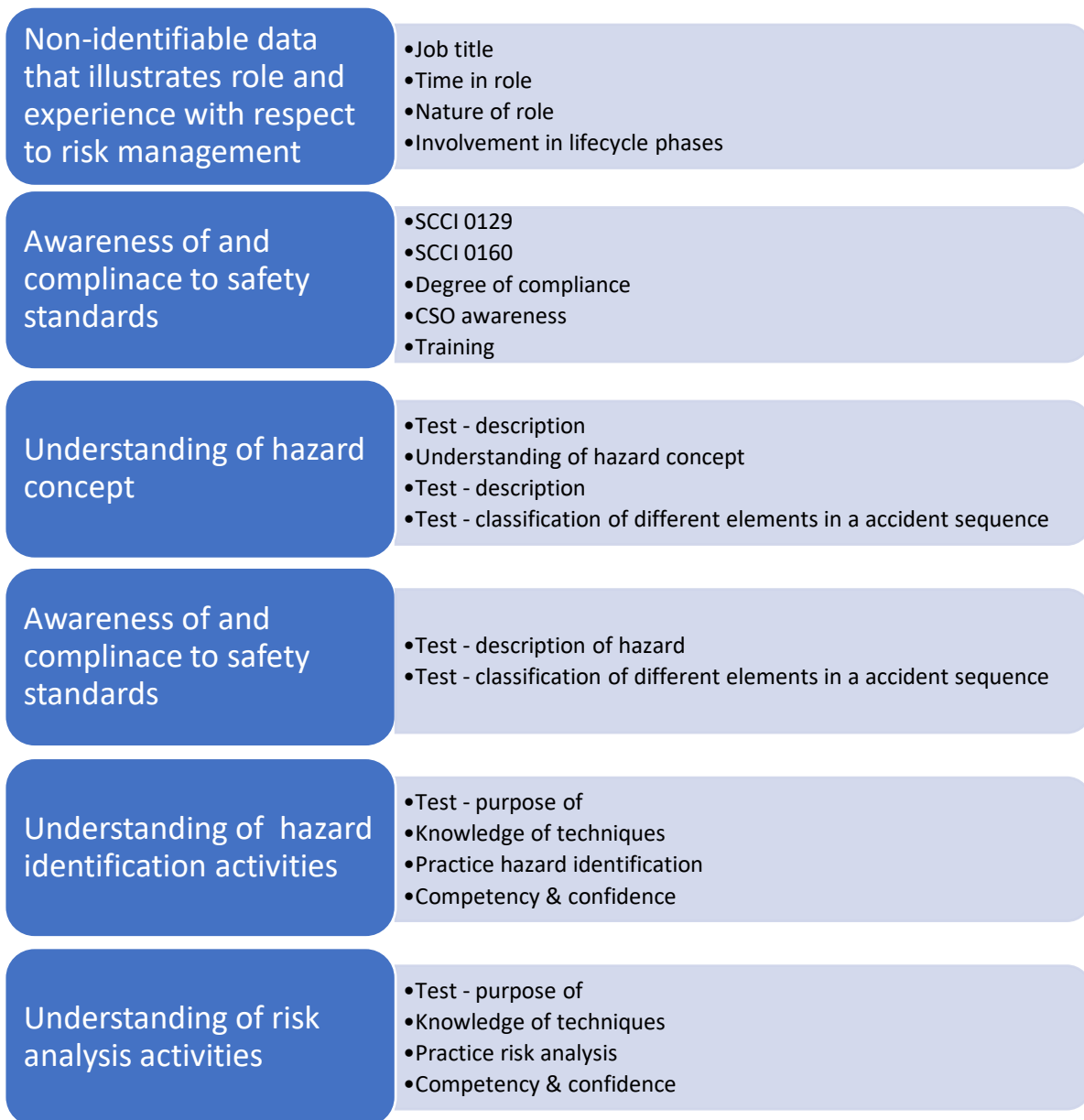


Figure 12 - Survey Structure

3.2.3 Design the Questions

The following design criteria were observed in designing the specific wording of the survey questions:

- Wherever practical closed questions were used in order to limit the number of responses and to reduce the amount of time taken to complete the questionnaire.
- Where closed questions were not appropriate, open response-option questions were used. These were used in the context of assessing knowledge where options of potential correct responses were provided.
- Open questions were used where it was beneficial for the respondent to provide qualifying information to support an answer.

The questionnaire design is presented at Appendix A and a specific question is discussed below:

Q3.1 Please select the statement which best defines a hazard

- An event or condition that results in harm (1)
- Combination of probability of harm occurring and the significance of that harm (2)
- An event or condition that has the potential to cause harm (3)

This question is designed to provide a knowledge check within the survey. The concept of hazard is central to the CRM process established in DCB 0160 so it follows that CRM practitioners must understand its definition. The question is closed in nature and purposefully provides three plausible answers to the question. Answer 2 is a definition taken from DCB 0160 that represents risk. Answers 1 and 3 are very similar with a key discrimination being made between a “definite” or “possible” harm outcome. A competent practitioner should recognise that in an accident scenario there may be an opportunity to apply reactive controls and prevent or reduce the harm outcome.

The question is purposefully sequenced in the survey so that it appears after questions that qualitatively explore the respondent’s experience, clinical experience, competence and confidence in CRM. High scores in these areas should correlate with a correct answer to this question.

3.2.4 Draft, Test and Evaluate

The survey was constructed, hosted and communicated using Qualtrics. The iterative design of the survey was tested and revisions made to a point where it could be evaluated independently.

Independent evaluation of the survey was conducted by an experienced NHS Clinical Safety Officer and by a Principal Safety Engineer working in the aerospace domain. Both participants were able to access the survey, provide answers to the questions asked and complete it within the target time of under 5 minutes.

Feedback was provided which predominately related to the need to emphasis key elements:

- *‘highlight the words “competence” & “confidence” in the questions somehow to ensure the user is reading the question correctly’*

and to provide more opportunity to substantiate an answer through the addition of supporting narrative:

- *‘It would be nice to have a bigger text box to be able to view/read back what I had written’*
- *‘A comments box might be useful here to able to explain/quantify answer’*

Changes were made to the survey to address these comments.

3.2.5 Run

The focus of my research is health delivery organisations in both primary and secondary care within NHS England. Consequently, the target audience for this survey was identified as being the Clinical Commissioning Groups (CCGs).

This is justified on the rationale that CCGs are *clinically led statutory NHS bodies responsible for the planning and commissioning of health care services for their local area* (NHS England, 2018) Commissioning is defined as *the process of assessing needs, planning and prioritising,*

purchasing and monitoring health services, to get the best health outcomes (NHS England, 2018) and extends to include consideration of technology in support of care provision.

The CCGs accountability with respect to Health IT and specifically the risk management associated with deployment and use of such is further established in the addendum to the GP IT Operating Model (NHS England, 2018) which, under *Clinical Safety Assurance Service* states that the CCGs *Provides the clinical safety and assurance service required to comply with SCCI0160 for all contractors (GPs) providing primary care essential services to a registered patient list.* (The statutory status of DCB 0160 is discussed at Section 2)

A mailing list, targeting all 211 CCGs, as published by NHS England at <https://www.england.nhs.uk/ccg-details/> was created.

The survey was developed and hosted using Qualtrics and distributed using an anonymous link preserving the anonymity of respondents, Figure 13.

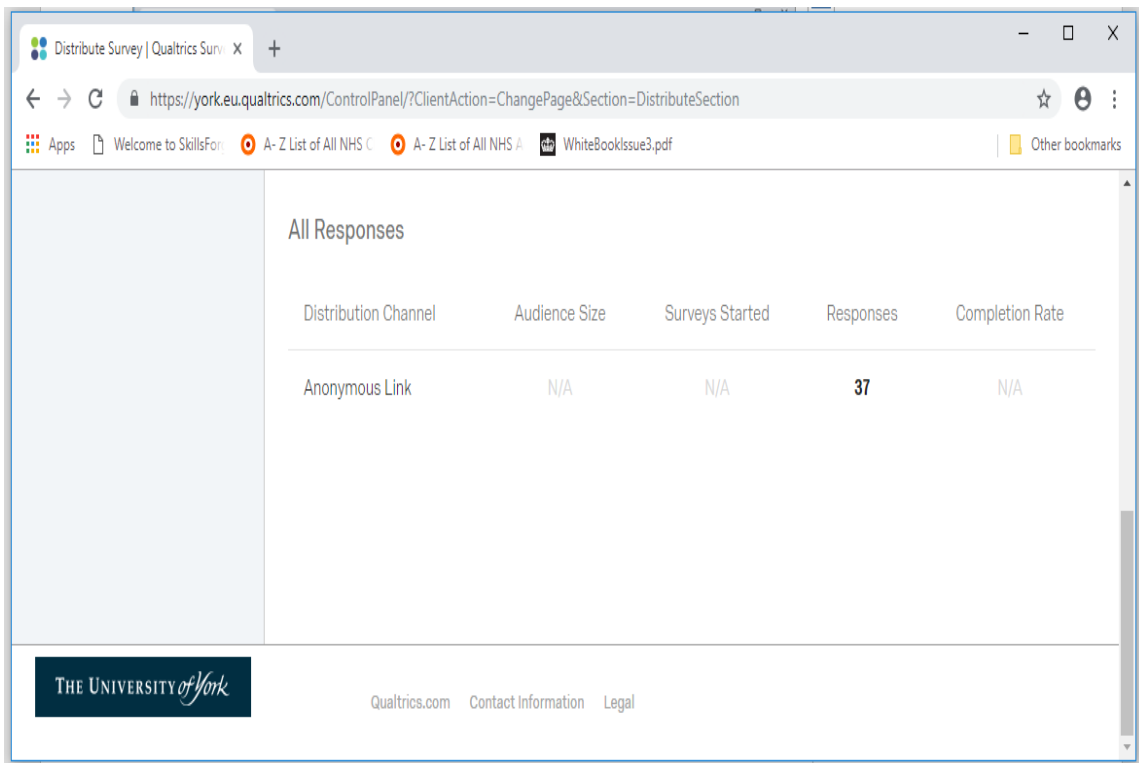


Figure 13 - Preserving Anonymity

Further consideration was given to a heightened awareness within organisations with respect to preserving the confidentiality of personal and sensitive data in light of the recent introduction of the GDPR. A supporting email made it clear that no personal data would be asked for or recorded; Figure 14.

Dear Sir / Madam

I'm a Safety Engineer and am currently studying on a Masters by Research programme at the University of York. To support my research, I would like to understand the approach health and care organisations take with respect to safety management of technology systems that they specify, procure, deploy and maintain to support provision and delivery of care processes.

To this end, I would be grateful if your organisation could complete a short questionnaire, it should take no longer than five minutes. Your Clinical Lead is probably the best person to do so.

All responses are totally anonymous; no organisational or personal data is asked for nor recorded. The questionnaire has been approved for use by the University of York's Ethics Committee.

Questionnaire Link:

https://york.qualtrics.com/jfe/form/SV_eyBCWVX4qUycr41

Many thanks

Sean

Figure 14 - Supporting email

3.2.6 Analysis

Table 1 summarises the responses to the survey and clearly illustrates that the response rate was very low.

Table 1 - Survey Response Summary

Category	Number
Number of organisations contacted	221
Number of organisations that accessed the link	37
Number of organisations that answered some questions	7
Number of organisations that answered all questions	4

This low response rate means that no meaningful statistical analysis or trend analysis can be conducted.

3.2.6.1. Thematic Analysis

From the onset of the survey design, there had been an intention to conduct thematic analysis (Braun & Clarke, 2006) of the returned data-sets in order to establish any qualitative relationships and themes between the role characteristics of the respondents and their knowledge and test responses.

Themes of interest and their value in re-enforcing the literature review findings are as summarised below in Table 2.

Table 2 - Influencing Factors and Themes

	Influencing Factors	Anticipated Resulting Theme
1	Work experience ↑ (Q3.2) & Clinical role (Q1.3) & Clinical Safety Officer (Q2.6) & Knowledge of standards (Q2.1 & Q2.2) & Trained in CRM (Q2.6)	Competency and confidence in Hazard Identification & Risk Assessment ↑ (Q4.4, Q4.5, Q5.4 & Q5.5)
2	Organisational compliance with standards ↑ (Q2.3)	Competency and confidence in Hazard Identification & Risk Assessment ↑ (Q4.4, Q4.5, Q5.4 & Q5.5)
3	Trained in CRM (Q2.6) & Correct definition of hazard (Q3.1)	Ability to identify different elements of an accident chain ↑ (Q3.2)
4	Competency and confidence in Hazard Identification & Risk Assessment ↓ (Q4.4, 4.5, 5.4 & 5.5)	Lack of awareness to do it (Q4.6 & Q5.6) or Lack of skill to do it (Q4.6 & Q5.6) or Lack of time to do it (Q4.6 & Q5.6) or Another reason (Q4.6 & Q5.6)

	Influencing Factors	Anticipated Resulting Theme
5	Understanding of the purpose of hazard identification ↑ (Q4.1) & Use of techniques ↑ (Q4.2)	Competency and confidence in Hazard Identification ↑ (Q4.4, Q4.5)
6	Understanding of the purpose of risk analysis (Q5.1) & Use of techniques ↑ (Q5.2)	Competency and confidence in Risk Assessment ↑ (Q5.4 & Q5.5)
7	Knowledge of standards (Q2.1 & Q2.2)	Ability to identify different elements of an accident chain ↑ (Q3.2)

Note: ↑ and ↓ depict *increasing* and *decreasing* strength of the factor or theme. For example, at 2 it is reasonable to conclude that someone who works in an organisation that has a long history of having work processes that comply with the CRM standard will have greater competency and confidence in the hazard identification and risk assessment that they conduct.

Unfortunately, only a small number of datasets were returned, of which some were incomplete, which meant that thematic analysis was not practical. Limited qualitative assessment that could be made is discussed at Section 3.2.6.2

3.2.6.2. Qualitative Observations

In the absence of any credible analysis, a small number of qualitative observations have been made

Hazard Identification

Question 3.1 asked respondents to identify the statement that best describes a hazard from a list of 3 alternative definitions:

- An event or condition that results in harm
- Combination of probability of harm occurring and the significance of that harm
- An event or condition that has the potential to cause harm

As illustrated in Table 3, all 7 respondents identified the correct definition of a hazard as being *an event or condition that has the potential to cause harm*. Given the subtle difference in wording between the 1st definition (of a harm event) and the 3rd definition (of a hazard) and that the 2nd definition describes risk (a concept widely used in health organisations) then this would suggest that the concept of a hazard is recognised and understood. However, analysis of the responses to Question 3.2 indicates that this understanding is lost when respondents were asked to consider the difference between elements in an accident sequence.

Figure 15 illustrates a simple harm-scenario in which an incorrect coding term within a Health IT system potentially results in patients being administered medications which are not required.

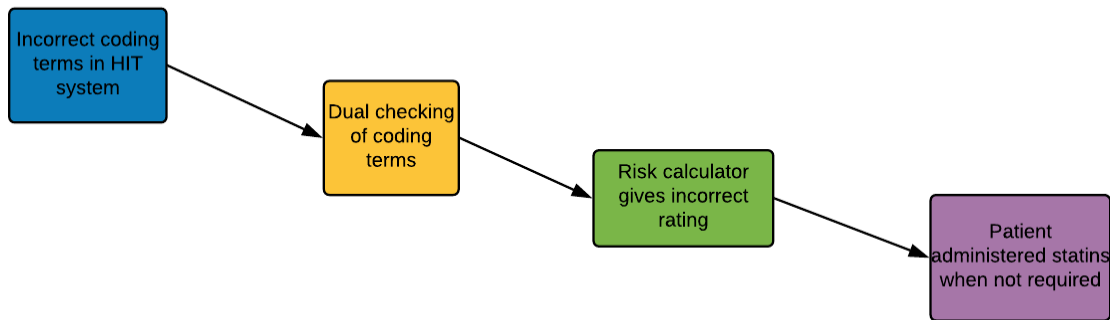


Figure 15 - Harm-scenario

Respondents were asked to classify each element as a hazard cause, a hazard control, a hazard or an accident.

As illustrated in Table 3 only 2 respondents (4 and 7) correctly identified the associated hazard as being *Risk calculator gives incorrect rating*. However, inspection of their responses to the definition of the other 3 elements would indicate that their understanding is not strong.

Respondent 7, (care professional) classified all the other 3 elements as also being hazards. This would indicate that they are unable to make a distinction between the different elements within a typical accident sequence. Interestingly, their responses to Q4.3, Q4.4 and Q4.5 indicate that they undertake hazard identification activities and that they consider that they have *good competence* and *some confidence* in undertaking these activities.

Respondent 4, (management) correctly identified *Patient administered statins when not required* as being an accident but incorrectly identified the other 2 elements as also being hazards. Their response to Q4.4 and Q4.5 indicate that have *some competence* and *some confidence* in undertaking hazard identification activities.

None of the 7 respondents were able to correctly classify all four elements; in all cases respondents misclassified or did not classify at least 2 elements.

The strongest observation that can be drawn from the responses to Question 3.2 relates to the classification of the hazard cause element; *Incorrect coding terms in HIT system*. Only respondent 2 (management) classified this correctly. However, they also (incorrectly) classified *Risk calculator gives incorrect rating* and *Patient administered statins when not required* as being hazard causes. This would indicate a weakness in their associated understanding. All other respondents either failed to make a classification (2 off) or (incorrectly) classified it as a hazard. This observation aligns with conclusions drawn from my literature review (Section 2) and analysis of hazard logs (Section 5.1) that there is a tendency within health organisations to define hazards at a low level of abstraction, focusing on known software bugs and system issues and losing the relationship to potential patient harm events.

Table 3 - Hazard and Accident Response (Green: correct, Red: incorrect; NR: No response)

	Q1.3 Role	Q3.1 Please select the statement which best defines a hazard	Q3.2 Risk calculator gives incorrect rating	Q3.2 Dual checking of coding terms	Q3.2 Patient administered statins when not required	Q3.2 Incorrect coding terms in HIT system
1	Management	An event or condition that has the potential to cause harm	NR	NR	NR	NR
2	Management	An event or condition that has the potential to cause harm	Hazard Cause	Hazard Control	Hazard Cause	Hazard Cause
3	Management	An event or condition that has the potential to cause harm	Hazard Cause	Hazard Control	Accident	Hazard
4	Management	An event or condition that has the potential to cause harm	Hazard	Hazard	Accident	Hazard
5	Care professional	An event or condition that has the potential to cause harm	Hazard Cause	Hazard Control	Accident	Hazard
6	Care professional	An event or condition that has the potential to cause harm	NR	NR	NR	NR
7	Care professional	An event or condition that has the potential to cause harm	Hazard	Hazard	Hazard	Hazard

Clinical Risk Management Training

DCB 0160 establishes the role of a Clinical Safety Officer (CSO) in deploying organisations. Individuals fulfilling this role need to be registered with a professional body and be suitably knowledgeable and experienced in clinical risk management. They are responsible for ensuring that appropriate clinical risk management is undertaken in support of the deployment and use of health IT systems within their organisation. Training is recognised as a mechanism for gaining the pre-requisite knowledge; NHS Digital and other, commercial, organisations run national training programmes.

Respondents 5 and 6 (Care professionals) are fulfilling the role of Clinical Safety Officer within their organisations and both have undertaken training in the principles of clinical risk management (Q2.6). As a consequence, it would be reasonable to expect a strong correlation between their responses and the correct classification of the accident sequence elements. Whilst Respondent 5 correctly identified the hazard control and accident elements, they incorrectly identified the hazard and hazard cause elements. Unfortunately, Respondent 6 did not return any answers to Q3.2 (nor to any subsequent questions).

3.3 Summary

Organising this survey took a significant amount of time. The ability to run it electronically was also complicated by the fact that no single contact list for the national CCG's seems to exist. An email address for each CCG had to be found before a distribution list could be constructed. The low response rate to the survey was extremely disappointing. Potentially the WannaCry cyber-attack (NHS England, 2018) that occurred in May 2017 that affected the NHS (and other organisations) has resulted in a heightened awareness and a more cautious attitude to responding to unsolicited emails and website links.

Acknowledging that the data-set sample is very small, and that no meaningful thematic analysis could be performed, the responses to the survey did not counter my underlying perception that health organisations don't understand the concept of a hazard.

4 Hazard Definition Framework & Methodology

4.1 Introduction

Through the literature review, the analysis of legacy hazards at Section 5.1 and my own personal experience it is established that in the domain of HI, practitioners struggle with the concept of a hazard and as a consequence hazard definitions can become unstructured and don't necessarily capture the patient harm effect; predominantly they are described in causal terms e.g. "loss of N3¹⁷ connection". (More examples illustrating the state of art of current practice are presented at Section 5.1).

This element of the thesis is intended to address research objective 1.3(ii) i.e. the derivation of a linguistic framework and a methodology that can be used by CRM HCPs to define hazards that are patient centric and reflect the credible scenario from which patient harm may result. It is intended that the framework will provide a sequence of linguistic constructs that relate to the socio-technical contexts of HI as discussed at Section 2.3 and foster a systematic expression of the scenario.

4.2 Care-pathway and Harm-scenario

Hazard identification cannot be meaningfully undertaken without a definition of the system having been established. This is established in DCB 0129 and DCB 0160 through requirements 4.2.1 & 4.2.2 and also in other domains. ESSI¹⁸ (European Strategic Safety Initiative, 2009) establish that "*hazard identification techniques require a definition of the System / Operation, its environment of operation and its interactions to have been completed prior to undertaking the task.*"

In this thesis the following terms are used to support the definition and expression of care and patient harm in a HI context.

- Care-pathway: The organisation of care processes, care management decisions and resources need to support the care needs for a defined group of patients.
- Harm-scenario: a representation of those events that could occur in the care-pathway (either intentionally or unintentionally) that could credibly result in harm to a patient who is being managed on the care-pathway.

4.3 Hazard Definition

Considering the concept of a hazard definition, it can be broken down into two properties:

Hazard Definition = Hazard Name + Hazard Description

The problem can be simplified if the Hazard Name property is simply thought of as means to establish a unique identifier for a specific hazard e.g. "Haz 001" or "patient administered wrong medication". The format and style of the hazard name are not too important if they are used consistently, if there is only one instance of them in safety management system and, if a descriptive name is used, it relates to the harm-scenario.

¹⁷ N3 (which has recently been replaced by HSCN Health & Social Care Network) was the secure national broadband network provided for and used by the NHS

¹⁸ ESSI closed in 2016 and its functions and deliverables transferred to the Safety Risk Management system administered by European Union Aviation Safety Agency (EASA).

The Hazard Description is the key property. It needs to describe the prevailing scenario from which credible harm could materialise, making a distinction between those events that are occurring in the scenario and how they may result in patient harm.

So, the overarching objective of this research is to devise a linguistic framework that provides constructs which will support the expression of meaningful and context relevant Health IT related hazards.

4.4 Harm as a (dis)Benefit

4.4.1 Business Management Benefits

Best practice in the discipline of benefits management within the NHS (Baker, 2017) promotes the use of English language constructs to articulate the business objective and describe the benefit(s) that will be realised by the recipient of the service.

Four key linguistic constructs are used which are concatenated to form a meaningful expression of the benefit scenario:

Action: that which is done to initiate a change in the real-world state

Change: that which is new following the action

Outcome: the result of the change

Benefit: the advantage that the recipient gains

The use of colour to distinguish between the constructs further emphasises the distinction between the individual constructs and the combined effect they have in articulating a HI related scenario:

Action, Change, Outcome, Benefit

Replacing the multiple systems that are currently in use with a single system will mean that health care staff will only need to log onto 1 system to find all the information they need. The log-on process will be quicker, releasing enough time for staff to see an additional patient during the course of a clinic thereby reducing patient waiting times.

From this description it is easy to understand how an initiating event can propagate through a work process and result in an advantage being gained by the recipient of that work process.

There is an obvious diametric correlation between benefit being an intended positive and beneficial advantage and harm being an unintended negative and detrimental disadvantage. It follows that harm-scenarios can be constructed and described in the same way. Table 4 establishes diametric safety constructs for those constructs used in benefits management:

Table 4 - Description constructs

Management Benefit Construct	Harm Construct
<p>Action that which is done to initiate a change in the real-world state</p>	<p>Cause An event or action that occurs in the care-pathway that by itself or in combination with other causes can result in the occurrence of harm. A cause may reflect an intentional event/action or an unintended event/action.</p>
<p>Change that which is new following the action</p>	<p>Effect The variation or deviation that is introduced into the care-pathway from what should be conducted to that which is conducted.</p>

Outcome the result of the change	Hazard The condition that is created in the care-pathway as a result of the effect that has the potential to cause harm
Benefit the advantage that the recipient gains	Harm Realisation of harm to the patient who is on the care-pathway.

A framework can be developed using this sequence of harm constructs to build hazard descriptions:



Figure 16 - Hazard description framework

4.4.2 Socio-technical Integration of the Framework

The framework can be transposed onto the HI socio-technical model developed at Section 2.3 to illustrate the context in which the identified constructs exist. This is shown at Figure 17.

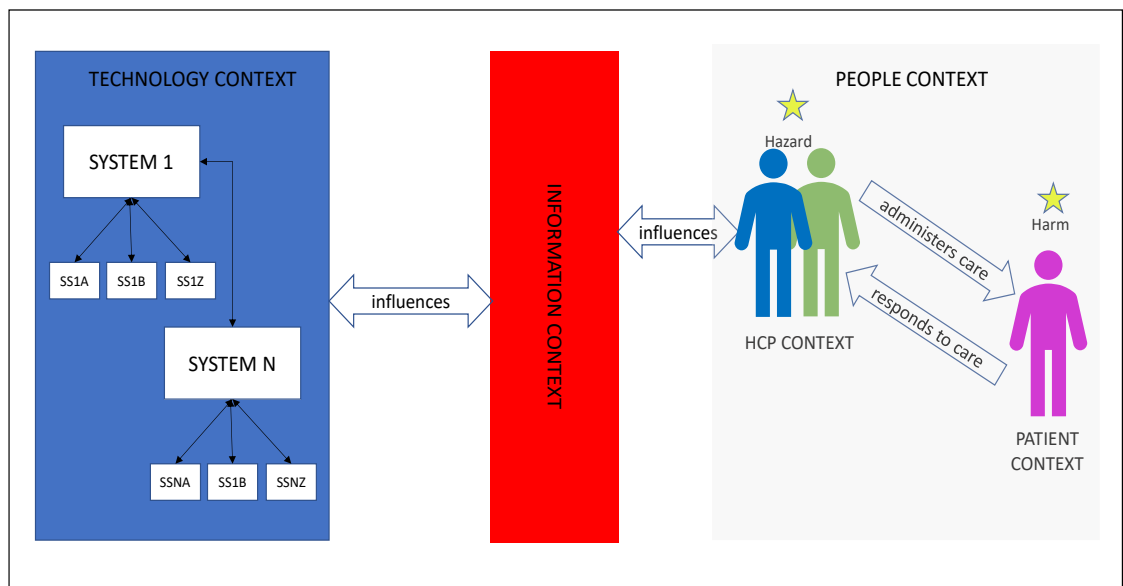


Figure 17 - Framework in HI Context

The rationale for the transposition is as follows:

- Harm:** By definition of the prevailing CRM standards (DCB 0129& DCB 0160) harm occurs to patients. Consequently, harm must be expressed in the context of the patient who is being managed on the care-pathway.
- Hazard:** From the definition of different health technologies discussed at Section 2.2.1 & 2.2.1 it can be established that Health IT has no direct “integration” with the patient; any “*diagnosis, prevention, monitoring, treatment or alleviation*” is undertaken by the HCP (otherwise it would be classified as a MD). By definition of the prevailing CRM standards (DCB 0129& DCB 0160) a hazard “*is an event or condition that that has the potential to cause harm*”. It therefor follows that incorrect, inappropriate or unintended actions of the HCP can represent hazards.
- Effect:** Care management and delivery is achieved through adherence to a care-pathway which in turn is supported by the provision (and collection) of information. Actions undertaken and decisions made are influenced by the information; incorrect, misleading or confusing information can have a disturbance effect in the care-pathway causing actions to be taken or decisions to be made that represent a deviation from that which should be conducted. An assessment can be made as to whether this new and unexpected change in information in the care-pathway can result in a hazard being created.
- Cause:** Information is generated by and consumed by technology. Technology failures or maloperation can cause a loss of, corruption or skewing of the information that is used to support the care-pathway. Similarly, information is influenced by the actions of the HCP and they may act as a cause, initiating or propagating a change in the information. It should be noted that a cause may not always be a failure; for example, a HCP may perform the correct action in the context of unknowingly being presented with mis-information and continue to propagate the disturbance effect within the care-pathway. This is discussed further at Section 4.4.3.

4.4.3 Humans as a Cause

During the second phase of evaluation of this framework (Section 5.2, CSO review) a respondent raised a concern that by identifying hazards at the point of interaction between the HCP and the patient a view could be induced that the HCP is the hazard or is the source of the hazard. Through the subsequent discussions it was established that the original model (as presented in Appendix C) required further elaboration to include the contribution a human can make acting as a cause in the harm scenario.

In following a Health IT enabled care-pathway, it is probable that the HCP will create data and change information through the course of their actions e.g. update a patient’s records to reflect the conclusion of their triage.

As with other causes in the care-pathway the action of the HCP may represent a failure e.g. an erroneous action or a correct action which is taken unwittingly e.g. without knowledge of a previous change in the care-pathway.

Human failures can be categorised into different types as summarised by (HSE, 2012) and illustrated at Table 5.

Table 5 - Human Failure Types

Human Error	Skill Based Error	Slip: not doing what is meant to be done e.g. recording weight in wrong part of the chart. Lapse: Forgetting to do something e.g. missing out a step in a work procedure.
	Mistake	Rule-based: following the wrong procedure for the work to be done
		Knowledge-based: not having sufficient knowledge or experience to undertake the work to be done
Violations		Deliberately doing the wrong thing

The scenario at Figure 18 illustrates how a HCP can act as a cause in a care-pathway, propagating an effect in the care pathway by doing the “right thing” unwittingly not knowing that the deviation effect has occurred.

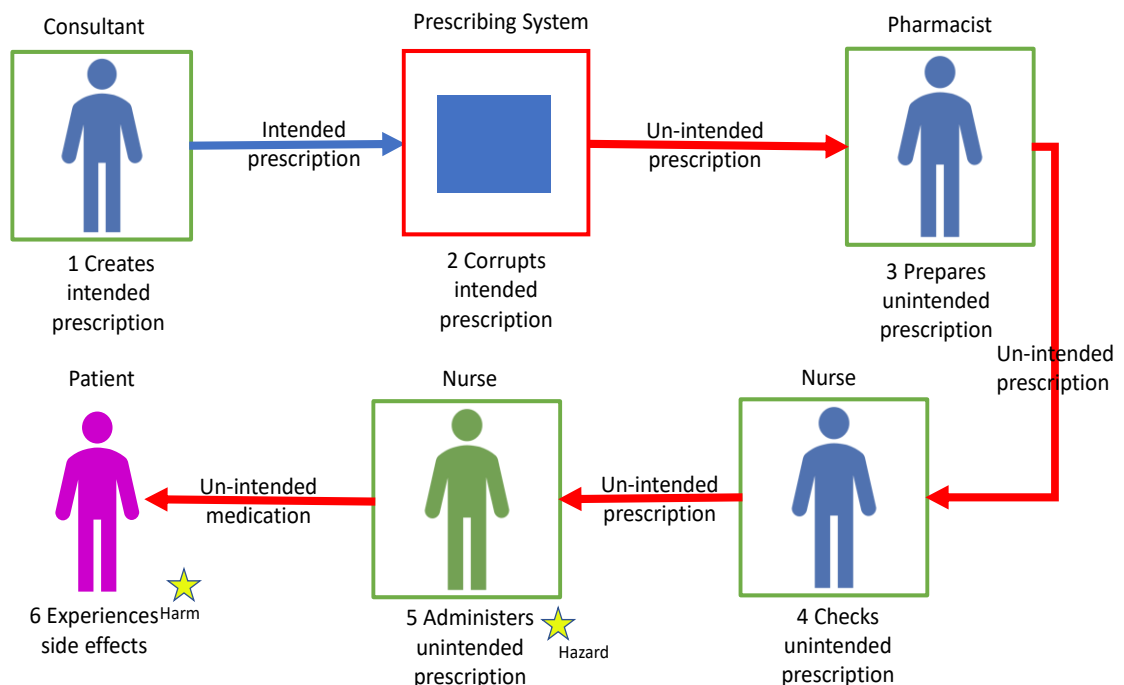


Figure 18 - Humans as causes

Key

- Green box: correct action being undertaken
- Red box: incorrect action being undertaken
- Coloured icon: framework construct type

Process step

- 1 Consultant creates *intended prescription* that addresses the care needs of patient and commits the prescription to the Health IT system.
- 2 There is a drug mapping error in the Health IT system which results in a different *un-intended prescription* being established. A disturbance effect has been created in the care-pathway.
- 3 Pharmacist receives *un-intended prescription* and with no knowledge of original prescribing intent follows correct work process and prepares the medication in accordance with *un-intended prescription*. Disturbance effect is propagated through the care-pathway.
- 4 1st Nurse, with no knowledge of original prescribing intent, follows correct work process and checks medications against *un-intended prescription*. Disruption effect is propagated through the care-pathway.
- 5 2nd Nurse, with no knowledge of original prescribing intent, follows correct work process and checks medications against *un-intended prescription*. A hazard is introduced into the care-pathway at this point of administration of medication.
- 6 Harm occurs because patient suffers side-effects on taking *unintended medication*.

4.4.4 The Framework as an Ontology

By definition (Gruber, 2009) an ontology in the context of computer and information sciences is “a set of representational primitives with which to model a domain of knowledge or discourse.” A simple ontology for the framework is presented at Figure 19 which further illustrates the relationships between the linguistic constructs and the socio-technical context in which they are relevant.

High level cause primitives are further detailed to provide thematic cues to support consideration of the harm-scenario. However, it must be remembered that the purpose of the framework is not to support hazard analysis and a balance needs to be drawn between *describing* the harm-scenario and *analysing* the harm-scenario. One cause primitive reflects the guidance written by the Safety Critical System Club¹⁹ (SCSC Data Safety Initiative Working Group, 2019) which considers how data should be managed in the context of safety related systems. A second cause primitive considers the SEIPS 2 Framework²⁰ (Holden, et al., 2013) which will assist in establishing human factor considerations that can influence the actions of HCP as causes in the harm-scenario.

In recognising 4 key linguistic concepts, the sequential relationship between them and the socio-technical context in which there are relevant it is concluded that meaningful hazard description can be developed to elaborate harm-scenarios in the HI domain.

¹⁹Data Safety Guidance (SCSC Data Safety Initiative Working Group, 2019) reflects best practice as to how data should be managed in a safety-related context.

²⁰ SEIPS2 (Holden, et al., 2013) establishes a human factors framework through which healthcare outcomes can be improved by considering and improving the work done by people in the socio-technical healthcare system.

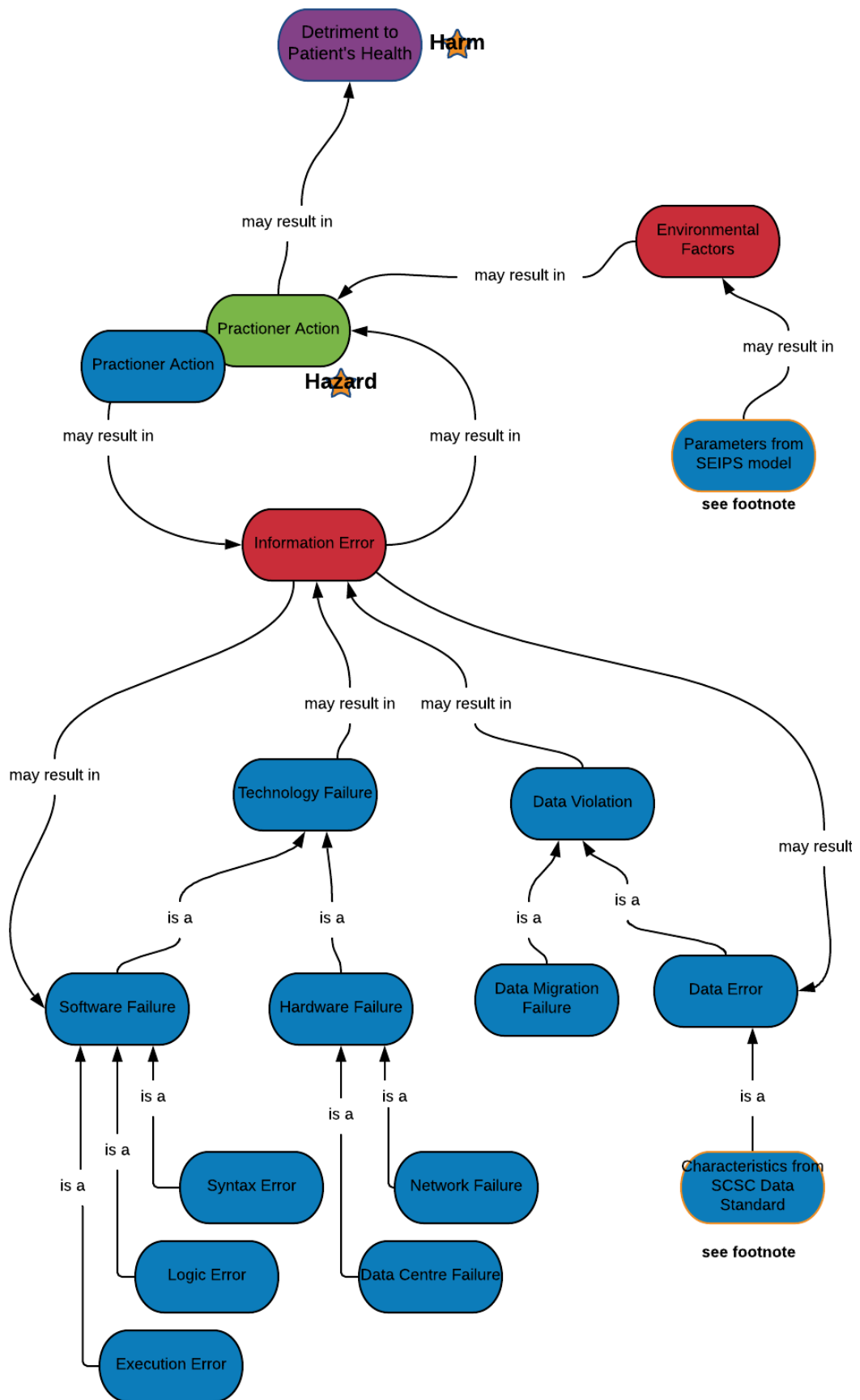


Figure 19 - Framework as an Ontology

4.5 Applying the Framework

The ontology at Figure 19 has been applied to the Q-RISK scenario described at Section 2.3 and is shown below at Figure 20

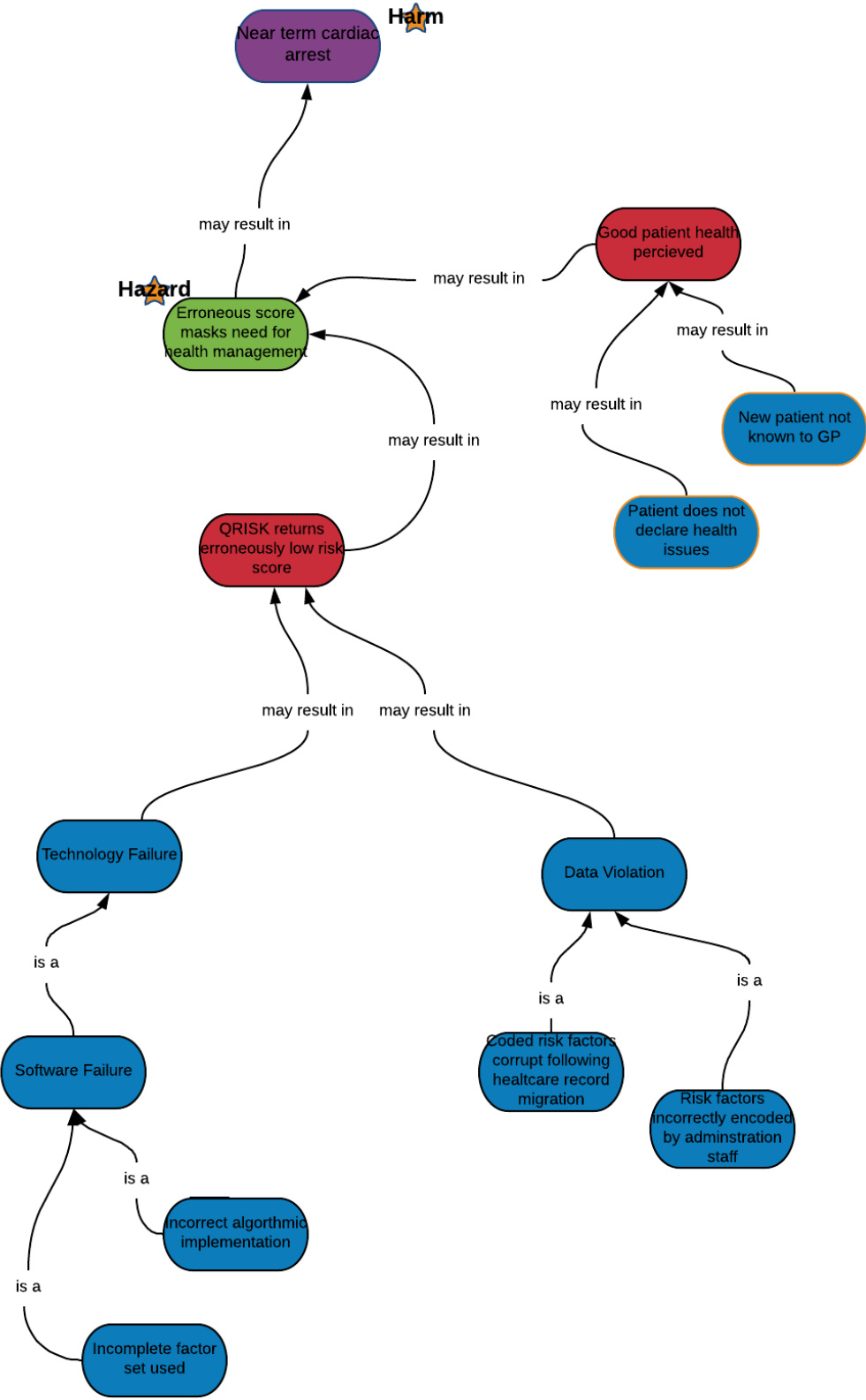
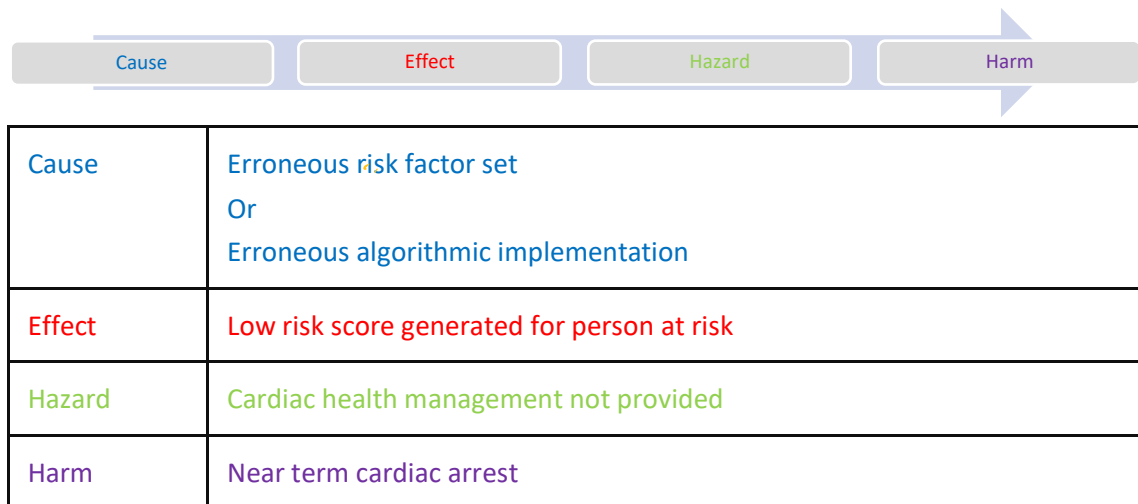


Figure 20 - Q-RISK Ontology

The hazard description can then be established by observing the sequence of constructs



Erroneous risk factor set used or error in algorithm implementation results in a low risk score for patient at risk. Cardiac care management is not administered, and the patient suffers near term cardiac arrest.

Here the cause description has been generalised to capture the 3 specific causes that can result in the risk factor set not being representative. Similarly, the effect considers those causes that would mask the fact that the patient has a pre-disposition to cardio-vascular disease.

Alternatively, the framework can be superimposed on a model of the care-pathway. In Figure 21 the SCR scenario described at Section 2.3 has been modelled as a care-pathway in SMART²¹

Blue boxes represent activities undertaken and yellow diamonds represent decisions made. Human roles e.g. “Nurse” or system functions e.g. “Record Allergy Status” can be mapped to the activities or decisions.

The method for applying the framework to a model is to identify within the care-pathway the point of interaction with the patient as it is at this interface that the potential for harm occurs i.e. where the hazard exists. It is then a process of stepping back through the care-pathway considering if the activity or decision could represent a change or disturbance i.e. an effect. Having identified an effect, the process of stepping back continues to identify related effects or causes.

²¹ SMART: Safety Modelling, Analysis and Reporting Tool is a software modelling environment that enables users to conduct safety analysis and generate safety case reports that adhere to the requirements of DCB 0129 & DCB 0160. It has been developed in collaboration with The University of York and NHS Digital.

<https://www.cs.york.ac.uk/safedh/SMART.html>

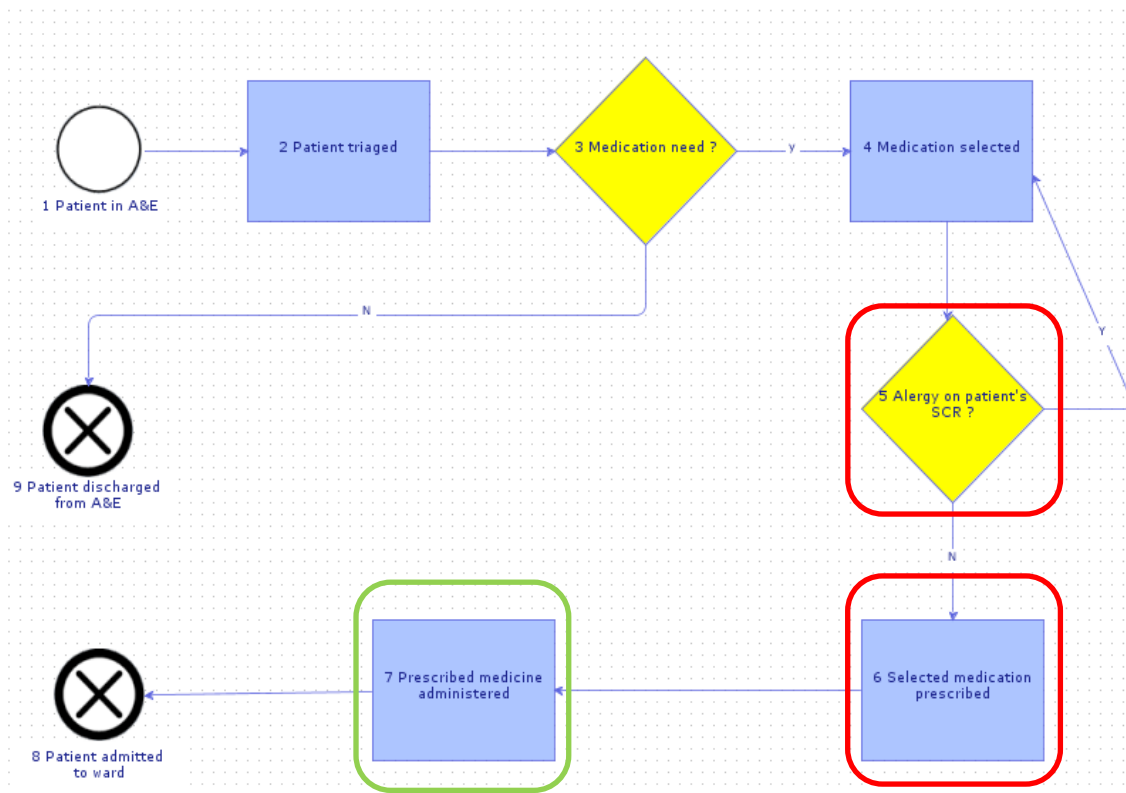


Figure 21 - Framework on a Model

The rationale applied in this scenario for categorising particular elements in the scenario is as summarised in Table 6:

Table 6 - SCR Analysis

Model component	Framework construct & rationale
7 Prescribed medicine administered	Hazard Point of care delivery so exists in the people context. Activity is discharged by a Nurse. Potential for harm to occur if the patient is allergic to the medication.
6 Selected medication prescribed	Effect Not a hazard as activity does not occur at point of care delivery although the activity occurs in the people context i.e. conducted by a prescriber. Represents a deviation from the intended care-pathway which safeguards against prescribing of drugs to which the patient is allergic. Although the prescribing activity is conducted in accordance with the prescriber's knowledge, the (mis)information is inducing an unwanted effect in the care-pathway.

Model component	Framework construct & rationale
5 Allergy on patient's SCR?	<p>Effect</p> <p>Misinformation at this decision point i.e. an allergy to the medication not being recorded on the patient's SCR.</p> <p>Not categorised as a Cause as it reflects the effect of (failure) causes i.e. misinformation in the patient's record.</p>

It has not been able to identify specific causes in this model of the care-pathway partly due to its purposeful simplification and the fact that viewpoint of the model is from one of care management and associated work processes.

To identify possible causes to the effect of incorrect allergy information in the patient's SCR, its necessary to look at the underlying data model to understand what system functions support this decision point. An extract from the system definition within SMART shows that Record Allergy Status is mapped to this decision.

Name	Description
Record Allergy Status	Patient's drug allergy status written to patient's SCR.
Care Process	Care Process Step
Used in Care Process: EMERGENCY PRESCRIBIING	Used in Care ProcessStep: ((Decision) 5 Allergy on patient's SCR?).

A hazard description can be developed:



Cause	Patient's allergy status not written to SCR
Effect	Patient's allergy status masked at point of medicine prescription
Hazard	Patient administered medicine to which they are allergic
Harm	Toxic shock

Patient's allergy status is not recorded in SCR so is masked at point of prescription. Patient is administered medicine to which they are allergic, and subsequently suffers a toxic shock.

4.6 Informing Risk Analysis

As previously established, the focus of this research is not aimed at hazard analysis. However, during the workshop evaluation (Section 5.4) it was realised that by applying rigour in the derivation and construction of a patient centric, hazard description there is an opportunity to inform and initiate subsequent hazard analysis activities.

The bow-tie methodology (de Ruijter & Guldenmund, 2016) so described as it represents a man’s bowtie, uses simple graphical notation to represent the relationship between hazards, their causes, consequences and controls. It is widely used in safety related industries and is promoted by NHS Digital in their CRM training. The methodology is embedded within SMART.

The hazard description established by applying the research methodology can be readily transposed to establish the basis of a bow-tie model. This is illustrated in Figure 22 in the context of the SCR harm-scenario using the bow-tie editor in SMART.

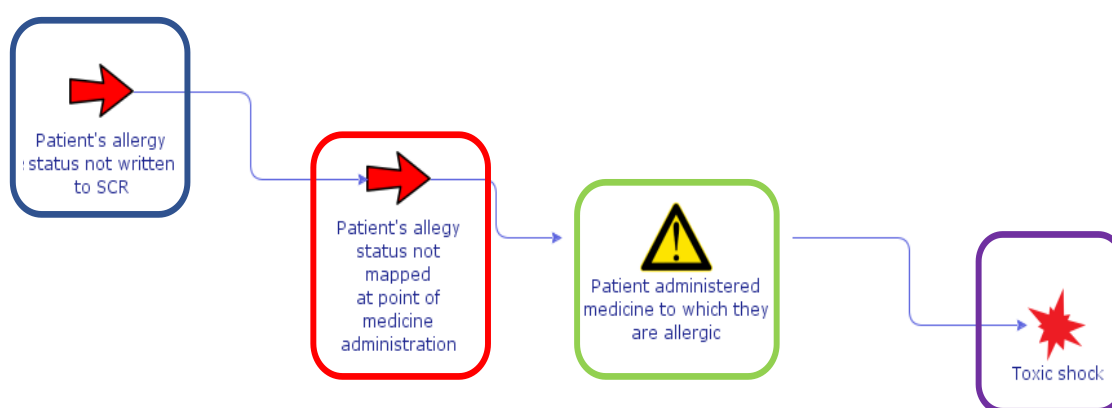


Figure 22 - Supporting Hazard Analysis Using SMART

(Note, the coloured boxes have been superimposed to reflect the linguistic constructs.)

Clearly, this initial model does not represent the full analysis but adds value to the process by establishing an initial model that should support focused development.

4.7 SMART Requirements

Table 7 details requirements that have been derived from Section 4.6 for consideration in the on-going development of SMART:

Table 7 - Derived SMART Functional Requirements

Req	Description	Rationale
S1	When a “Role” is linked to an Activity/Decision in a Care Process the Activity/Decision shall become green.	Hazards exist at the point of interaction with the patient. By automatically annotating those points in the Care Process model the user of SMART is prompted towards activities/decisions that could be hazardous.
S2	The user of SMART shall have the ability to revert green Activity/Decision steps back to their default colour.	Not all points of interaction with the patient will be hazardous.

Req	Description	Rationale
S3	When a “Function” is linked to an Activity/Decision in a Care Process the Activity/Decision shall become blue.	Functions of the Health IT have the potential to be causes of a hazard. By automatically annotating those points in the Care Process model the user of SMART is prompted to consider whether those functions could be causes to identified hazardous.
S4	The user of SMART shall have the ability to revert blue Activity/Decision steps back to their default colour.	Not all functions of the Health IT will be causes of a hazard.
S5	The user of SMART shall have the ability to manually change the colour of an Activity/Decision to blue, red, green or purple to reflect a particular linguistic construct.	The user needs the ability to overlay the framework independently.
S6	The user of SMART shall have the ability to revert a coloured Activity/Decision step back to its default colour.	The user needs the ability to undo any changes.
S7	Where elements of the framework have been annotated in the Care Process SMART shall automatically generate the hazard description.	This will save the user of SAMRT time and will ensure traceability between the Care Process model and the hazard description.
S8	Where elements of the framework have been annotated in the Care Process SMART shall automatically use these to establish the basis of the bow-tie model.	This will save the user of SAMRT time and will ensure traceability between the Care Process model, the hazard description and the hazard analysis.

4.8 Summary

The framework described here is derived from the benefits management domain. The use of four simple constructs, their sequential relationship and an understanding of the context in which they exist in a socio-technical system has the potential to introduce a systematic and consistent approach to hazard description in the HI domain. The framework can be applied by using the ontology developed herein or by transposing the framework constructs onto a model of the care-pathway. There is additional benefit in that the structured description can be used to establish an initial bow-tie representation of the harm-scenario and so direct subsequent risk analysis activities.

5 Hazard Description Evaluation

The purpose of the evaluation is to gain confidence that the research conducted and the hazard description methodology that has been developed addresses the 2 original research objectives which in turn have been further refined into 4 subobjectives as summarised in Table 8:

Table 8 - Research Objectives

Research Objective	Sub-objective	Principal Evaluation Method (see Figure 23)
(1.3i) to understand the challenges health organisations encounter in trying to comply with Requirement 4.3 of DCB 0160 i.e. the definition of HI related hazards.	1. To affirm the research observation that the concept of HI is one that is not well understood and often described without reference to patient harm outcomes.	1 Application to legacy hazards will identify (or otherwise) a lack of patient harm outcome in existing hazard descriptions. 2 Targeted CSO review and evaluation will establish (or otherwise) that practitioners of CRM within the NHS share the same view. 3 Conference presentation and evaluation will provide a consensus of opinion within the target audience that the research observation is accurate (or otherwise).
(1.3ii) to devise a methodology to assist organisations in addressing Requirement 4.3 of DCB 0160 which will support the meaningful definition of HI-related hazards.	2. To affirm that the methodology ensures that hazards are expressed in the context of care delivery and management and that they remained focused to the point of impact on the health of a patient.	1 Application to legacy hazards will enable the hazard descriptions to be re-expressed and qualitatively evaluated by an experienced CSO 4 Application in a pilot study will enable real-world hazard scenarios to be described by and qualitatively evaluated by CRM practitioners.
(1.3iii) to devise a methodology to assist organisations in addressing Requirement 4.3 of DCB 0160 which will support the meaningful definition of HI-related hazards.	3. To affirm that the methodology can be applied in practice.	3 Conference presentation and evaluation will expose the methodology to a wider audience and provide a large-scale qualitative evaluation by CRM practitioners in the context of a specific case study. 4 Application in a pilot study will demonstrate (or otherwise) that the methodology can be applied

		in an existing CRM system. 5 Training course module and evaluation will expose the methodology to a wider audience and demonstrate (or otherwise) that the methodology can be applied in the context of a specific case study.
(1.3ii) to devise a methodology to assist organisations in addressing Requirement 4.3 of DCB 0160 which will support the meaningful definition of HI-related hazards.	4. To affirm that the methodology supports communication and understanding of the harm scenario.	2 Targeted CSO review and evaluation will provide expert opinion to substantiate the claim (or otherwise). 3 Conference presentation and evaluation will provide a wider sample set of opinion to substantiate the claim (or otherwise). 4 Application in a pilot study will provide opportunity to observe the characteristics of communication and understanding amongst different stakeholders. 5 Training course module and evaluation will provide a wider sample set of opinion to substantiate the claim (or otherwise).

Evaluation of the framework and the method of application has been evaluated through five separate and different approaches with the feedback being appraised and, if necessary, the framework revised before conducting the subsequent evaluation activity.

The following nomenclature is used to uniquely identify the specific actions raised through the analysis of the evaluation feedback:

Action Na.b.c

Where

N = E; address in subsequent evaluation or

N = T; address in toolkit

a.b. = 2nd subsection number e.g. 5.2

c = incremental integer starting from 1.

So **Action T5.3.2** means 2nd toolkit requirement associated with “Workshop presentation and evaluation”

The evaluation methodology is depicted in Figure 23 and each activity is documented in subsequent sub-sections.

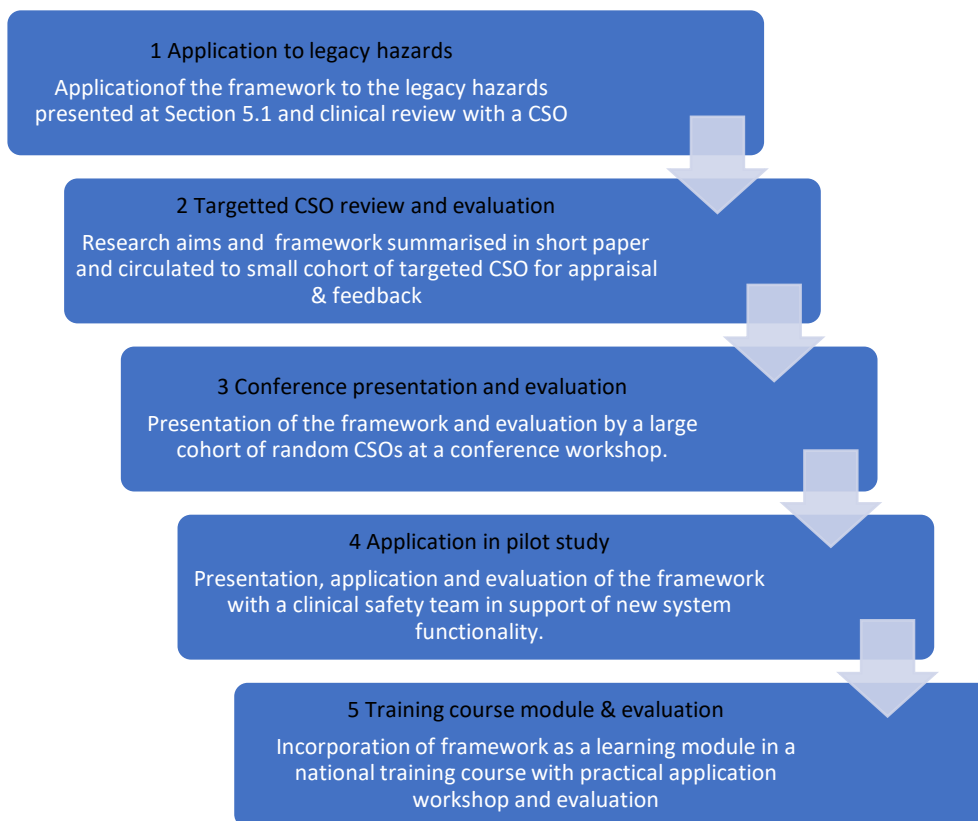


Figure 23 - Research Evaluation Strategy

5.1 Application of Framework to Legacy Hazards

5.1.1 Hazard Selection

The hazard descriptions were selected using the following criteria to ensure diversity in the sample set and to avoid the introduction of any bias:

1. Care setting: examples from different care settings were selected representing primary care and secondary care settings to represent different HI environments.
2. Care services: example from different care services were selected e.g. prescribing and new birth registration to yield different harm scenarios.
3. Standards: examples from both manufacturers and care delivery organisations were selected to represent different lifecycle phases.
4. Date: examples were selected over a date range of 8 years from current date to ensure no maturity bias.

A total of 54 hazard descriptions fulfilling the above criteria were selected for review from hazard logs submitted to NHS Digital.

5.1.2 Hazard Review and Appraisal

Each hazard description was reviewed in isolation from its supporting Clinical Safety Case Report (CSCR). This was done to avoid any subsequent knowledge that would be gained from reading the CSCR influencing the appraisal of the hazard description. It could be argued that this is a flawed approach as in practice the hazard description would constitute part of the CSCR and would be appraised in that context. Whilst this is true, the hazard definition should be established early in the lifecycle, in advance of the creation of a CSCR, forming a constituent element of the Hazard Log (HL). Given the purpose of the HL is to support and communicate the ongoing management of hazards through a project lifecycle it follows that the hazard definition must be expressed to achieve this.

The Hazard Description of each hazard was reviewed to assess if it articulated any of the four linguistic constructs; cause, effect, hazard or harm.

Of 54 hazards:

- 20 hazard descriptions related to causes
- 27 hazard descriptions related to effects
- 2 hazard descriptions related to cause and effect
- 0 hazard descriptions related to a hazard
- 0 hazard descriptions related to harm

The scope of the review was expanded to take into consideration the 'Hazard Name' and 'Potential Clinical Impact' elements of the HL (where populated) to establish if collectively the three elements provided a more representative hazard description.

The findings of this analysis are provided at Appendix B.

Whilst the number constructs increased it was largely related to the 'Potential Clinical Impact' element being populated as an effect concept not as a hazard concept as would be expected. The most significant observation is that patient harm was only expressed in 2 of the 54 hazards.

5.1.3 Hazard Re-expression Using Framework

All 54 hazards were re-expressed using the ontology to identify and describe the 4 sequential constructs. As stated above, with the exception of 2 hazards, the legacy descriptions did not describe the patient harm outcomes. As a consequence, without this context, it was difficult to articulate the harm construct. To address this, the supporting safety cases were examined to establish if they provided the harm context. A random dip check illustrated that they did not so a decision was made to simply record a generic harm consequence. In practice, when analysing the care-pathway, application of the framework in the care context will ensure the harm consequence is captured.

The re-expressed hazard descriptions are at Appendix B.

5.1.4 CSO Review and Appraisal

This was conducted in two phases.

In phase 1 the CSO was asked to review the original legacy hazard descriptions and articulate their thoughts. To ensure their review remained aligned with the objectives of this thesis the CSO was briefed to consider if they could understand the care scenario and whether the patient harm outcome was evident. The CSO was not promoted at any time nor where they asked any questions. At the end of this phase the CSO was asked to summarise their conclusions.

In phase 2 the objectives of the research and the derivation and application of the framework was explained to the CSO. The CSO was then asked to appraise the hazard descriptions established having applied the linguistic framework, with a focus as per phase 1.

5.1.4.1 CSO Review – Phase 1

The comments made by the CSO during the review of the legacy hazard descriptions have been grouped into themes which are summarised in Table 9

Table 9 - Legacy hazards themes

Hazard descriptions are confusing and clinical conclusions cannot be made.
Causes to hazards are expressed as hazards with no reference to patient harm.
Difficult to derive an understanding of the scenario although in some cases patient harm is discussed.
Hazard descriptions are complex and include multiple causes and associated controls. Analysis is being documented in the description.
Hazard descriptions do not capture patient harm.
No correlation between hazard name and the hazard description.
Multiple care scenarios expressed in the description.
Hazard descriptions are vague and general.
Hazard descriptions do not capture care/clinical context.

The concluding observations made by the CSO following review of the legacy hazards are summarised in Table 10 along with the feedback provided to the CSO.

Table 10 - Legacy hazards observations

CSO Observation	Author Comment
“We need to change current practice!”	Aligns with the findings of this research and my own personal observations. It is the intention of this research that the framework developed and the methods for its application will be embedded into NHS resources (CRM training, best practice guide, Standards implementation guidance) in order to promote and establish a robust approach to hazard definition.
“There isn’t a consistent approach to describing hazards”	Whilst an attempt has been made within the framework of the two CRM standards to provide a mechanism to drive consistency i.e. by establishing specific entries in the HL template, this review evidence establishes that there is a great deal of variance in how these particular entries are populated and that they are proving to be rather ineffective in communicating the harm scenario. Adoption of the framework will address this as it establishes a sequence of inter-related constructs that when concatenated describes the harm scenario from initiating event to harm outcome.

CSO Observation	Author Comment
“There is not a strong correlation with the patient”	The patient is often overlooked and the emphasis and focus of the description often centres around the causes. The reasons for this have not been investigated within the scope of this research but it’s not unreasonable to assume that the absence of any existing methodology to support the expression of a harm scenario is a contributory factor.
“No clinical context provided but can it be given?”	The answer must be a “yes” otherwise confidence in the effectiveness and relevance of subsequent clinical risk analysis and evaluation activities will be low. Hazard identification is the starting point of the CRM process so if the clinical context cannot be communicated it will be difficult to understand or accept any subsequent risk assessment. A constituent element of risk is the severity of the consequence; without understanding and communicating the clinical context then it becomes difficult to make a meaningful risk assessment. The “effect” construct addresses this point as it serves to capture and analyse the disturbance that may occur in the care pathway due to the occurrence of the “cause”. From this knowledge point an assessment can be made as to whether a “harm” outcome is credible through the realisation of a “hazard”.

5.1.4.2 CSO Review – Phase 2

No specific themes emerged from the review of the revised hazard descriptions, but the concluding observations are summarised in Table 11 along with the feedback provided to the CSO. Note, these are presented in the order in which they were raised and reflect a growing understanding and endorsement of the framework as the number of hazard descriptions reviewed increased.

Table 11 - Revised hazards observations

CSO Observation	Author Comment
“Do the revised description offer any benefit?”	This was an initial thought raised after reviewing the first description. However, after reviewing a further 2 descriptions, by their own admission, the penny dropped and the CSO subsequently raised positive observations as summarised below. There had been a limited amount of time to explain the methodology in advance of the review and this initial comment probably reflects that.

CSO Observation	Author Comment
<p>“Different to what we are accustomed to; there is a lot of text in the box.”</p>	<p>This was expressed in the context of the CSO fulfilling their role, reviewing the work of others in support of approving clinical deployment of Health IT.</p> <p>Whilst the description may appear to be lengthy it is no longer expressed over three HL entries. In many cases the word count is actually less. Further, the description is structured and provides a sequenced narrative of the patient’s journey through the care pathway.</p>
<p>“Including causes in the description could be problematic.”</p>	<p>The purpose of the framework is to set the scene; it is not intended to constitute the risk analysis. To this end, the description should be expressed at a high level of abstraction and causes generalised wherever practical. If the description is starting to include a set of specific causes this should be taken as a cue to re-focus.</p>
<p>“The effect concept is useful as it prompts you to think of a hazard in the context of the care that is being administered to the patient.”</p>	<p>Exactly, the focus of CRM effort has to be in the context of credible harm that could occur to the patient where their care is being supported by Health IT.</p>
<p>“Easier to express the real-world scenario from which hazards can be derived.”</p>	<p>Exactly, there is a need to be able to describe credible scenarios in the care pathway from which the patient may suffer harm. If this cannot be articulated, then it is not feasible to conduct meaningful risk analysis or make informed and reasoned safety management decisions.</p>
<p>“Sequence of knock-on events easier to understand.”</p>	<p>Exactly, by structuring the description to reflect the relationship between different events in the harm scenario aids communication and understanding of the patient harm concern that credibly exists in the care pathway.</p>
<p>“Easier to read and understand and even if you are not an expert you are in a better position to comprehend or challenge.”</p>	<p>In essence, this is the objective of the research.</p>

5.1.5 Summary

This phase of evaluation supports substantiation of objective 1, particularly the research observation that hazards are often described without reference to patient outcomes. This was observed through my own review and through that of the independent CSO.

It also supports substantiation of objective 2 which is to affirm that the framework establishes that hazard descriptions are focused on the impact of care delivery in the context of patient harm outcomes. There was recognition by the CSO that application of the framework results in hazard descriptions that are patient harm centric and convey an understanding of the chain of events that can lead to harm.

5.2 Targeted CSO review

5.2.1 Cohort Selection

The cohort was specifically chosen from a network of CSOs known to me (through my engagements working in my role of Senior Safety Engineer at NHS Digital) to ensure a high degree of diversity in the sample set as is detailed in Table 12 below:

Table 12 - Clinical Safety Officer Cohort

CSO Role Identifier	Operational Context
1.	CSOs working for NHS Digital, both in an independent assurance role and in a programme CSO role. Experienced in evaluating the clinical risk management activities of Health IT system manufactures providing systems into primary and acute care within the NHS. Experienced in conducting clinical risk management in the context of a national authority developing services and systems for widespread use in the NHS.
2.	CSOs working for Health IT system manufacturers, providing technology into different care settings within the NHS. Experienced in conducting clinical risk management to address the requirements of DCB 0129, national and customer requirements in support of the development and sale of commercial products.
3.	CSO working for a health organisation that develops its own Health IT systems. Experienced in conducting clinical risk management to address the requirements of both DCB 0129 and DCB 0160 in support of the development, deployment and use of bespoke Health IT systems to address local requirements.
4.	CSOs working for clinical and mental health organisations within the NHS. Experienced in conducting clinical risk management to address the requirements of DCB 0160 in support of the procurement and deployment of Health IT systems procured from commercial organisations into specific care settings.
5.	CSO working as an independent consultant providing clinical risk management services to Health IT manufacturers and the NHS. Experienced in conducting clinical risk management in support and deployment of different Health IT systems across a broad section of care settings.

Further, the cohort was selected based on the competence and experience of the CSOs. Through my previous interactions with the CSOs I am of the opinion that they all have a strong understanding of clinical risk management processes and have extensive experience of implementing effective clinical risk management within their organisations. Clearly, these are important characteristics and are necessary to establish a knowledge base from which objective and critical appraisal could be made. A deliberate decision was made not to include new in role or less experienced CSOs within the scope of the survey. I was concerned that feedback or questions relating to their lack of knowledge could be raised and skew their appraisal of the methodology. For example, if they only had limited experience of identifying and describing hazards it could be difficult for them to offer opinion as to whether the framework helps or hinders (Question 2 Table 13).

There is an inherent risk in the above strategy:

- Competencies of the respondents could mask shortcomings in the methodology. For example, drawing on their previous experience and knowledge they understand the transition between a “cause” and an “effect”; this may not be obvious to a less experienced CSO.

The potential bias introduced by purposefully selecting experienced CSOs is considered to be mitigated through the 3rd evaluation method; workshop presentation and feedback. Whilst the delegates attending the workshop were targeted on the basis of them actively working in the HI domain, they represented a broad cross section of roles with a varying degree of and experience. This was established by reviewing the delegates role details submitted when registering for the workshop.

5.2.2 Cohort Briefing

The research challenge and derived methodology was summarised in a 5-page paper (Appendix C) which was circulated by email to the cohort.

To support the CSO review, and in recognition of the considerable resource pressures clinical staff experience discharging their clinical roles, a short questionnaire (Appendix C) was also circulated. The questionnaire posed 3 questions with a Y/N answer with the opportunity to add any qualifying comments as summarised in Table 13 below:

Table 13 - Clinical Safety Officer Review Questions

Question #	Question
1.	Is the research observation regarding hazard definition in the domain of health informatics representative?
2.	Does the linguistic framework proposed aid meaningful hazard definition?
3.	Are there any flaws or weakness in the proposed framework?

The cohort were also encouraged to provide feedback outside of the specific questions.

5.2.3 Cohort Feedback and Analysis

Of the 11 CSOs approached, 9 provided responses representing all roles as described in Table 12 above.

The returned responses²² are summarised below in Tables 14 to 17. The responses to each question are grouped by themes and subsequently analysed. In some cases, analysis of the comments has resulted in specific requirements to be raised and uniquely identified as discussed at Section 5.

1 of the 9 respondents provided feedback via email rather than via the question sheet and their views are included within the scope of Table 17.

Whilst 1 of the targeted CSOs did not provide documented feedback, they invited me to run a pilot evaluation of the framework with their clinical safety team in support of the implementation of safety related functionality. This is fully discussed at Section 5.4

²² Permission to reproduce comments was obtained from the respondents.

5.2.3.1 Cohort Feedback and Analysis – Q1

Table 14 - Review Question 1 Feedback & Analysis

Question	Y Response	N Response
Is the research observation regarding hazard definition in the domain of health informatics representative?	8	0
<p>Comments <i>“Agree completely with the context of the challenges of hazard definition as described.”</i> <i>“Agree – people generally ok with talking about risks but not too sure what a hazard is.”</i> <i>“The research purpose relates to the problem identified (i.e. ambiguity in the understanding and use of the term “hazard”).”</i> <i>“Yes, it is not uncommon to see a hazard which looks more like a cause, or in many cases they can be project risks rather than clinical hazards.”</i> <i>“The author correctly asserts that anecdotal evidence suggests within healthcare domain, hazards are associated with risks, and that the potential harm that occurs to a patient is rarely expressed.”</i></p>		
<p>Analysis This feedback reinforces the conclusions that I drew from the literature review and personal reflection that the concept of hazard is not widely understood and often describes a different element within a harm scenario e.g. the risk or a cause. It is apparent from the feedback that the concept of hazard needs to be promoted and “demystified” in the domain of health informatics. A distinction needs to be established between the hazard as being a condition that exists or is established in the care-pathway that could potentially result in harm and risk as being a measure or metric of the significance of that condition in a patient harm context.</p>		
<p>Resolution Action T5.2.1 The toolkit shall describe and re-enforce the concept of a hazard and introduce this framework into the domain. Action E5.2.1 The concept of a hazard shall be described in subsequent evaluation activities.</p>		
<p>Comments <i>“..will help CSO and Safety Engineers complete safety process in a consistent manner.”</i></p>		
<p>Analysis This feedback recognises that safety management is a collaborative process and that consistency in application and adherence to the management process is key.</p>		
<p>Resolution None required.</p>		
<p>Comments <i>“I would agree Sean, we talk a lot about risks in health care, and from a clinical perspective we understand and work with it daily, when IT gets involved there is a fear and lack of understanding about how this becomes a risk or could impact.”</i></p>		
<p>Analysis This feedback suggests that the use of technology in support of care management introduces “fear” and care HCPs struggle to comprehend the detrimental contribution technology can make in the context of safe care delivery. Again, this observation re-enforces the research position that clinical risk management must be considered from a health informatics viewpoint and not focused on the technology contribution in isolation. As is articulated within the scope of this thesis, hazards must be considered in the context of</p>		

deviation from the intended care-pathway and an informed and expert based opinion established as to whether the deviation could credibly result in patient harm outcomes.
<p>Resolution</p> <p>Action T5.2.2 The toolkit shall re-enforce the patient care centric context in which hazard identification and description should be undertaken and that technology should be considered in the context of it contributing to a socio-technical system.</p> <p>Action E5.2.2 The patient centric context in which of a hazard shall be described in subsequent evaluation activities.</p>
<p>Comments</p> <p><i>"I think the observation extends beyond just health informatics. It is more general amongst health care in my experience. Staff often quote hazards on a risk register as a "risk" and quote risks as a hazard on hazard logs. The linguistic expression as a phrase with a causal relationship can help identify the individual components correctly."</i></p>
<p>Analysis</p> <p>This feedback further re-enforces other comments regarding the comprehension of the concept of hazard in the health care domain. The fact that the terms risk and hazard are used interchangeably is concerning as it indicates a lack of consistency in the understanding and use of fundamental concepts in the clinical risk management process as established in the two CRM standards. Further, this issue has the potential to compromise communication and decision making between stakeholders in a care environment if they are using different concepts interchangeably.</p> <p>Encouragingly, the feedback acknowledges that the proposed methodology induces a causal relationship to be established and considered between the different elements that exist in a harm scenario.</p>
<p>Resolution</p> <p>None further beyond that established in Actions T5.2.1 & E5.2.1</p>

5.2.3.2 Cohort Feedback and Analysis – Q2

Table 15 - Review Question 2 Feedback & Analysis

Question	Y Response	N Response
Does the linguistic methodology proposed, aid meaningful hazard definition?	8	0
<p>Comments</p> <p><i>"Cause, effect, hazard and harm are better understood with the explanations provided; I particularly like the colour coding."</i></p> <p><i>"I like the colours and how the hazard can be described, just to throw out there the use of hazard is an alien one in health care"</i></p> <p><i>"I think it does, and the coloured text really helps that stand out."</i></p>		
<p>Analysis</p> <p>This feedback indicates that respondents consider that the framework can help to describe hazards and that the use of colours to identify individual concepts in a harm scenario aids understanding and provides emphasis.</p> <p>Again, the feedback re-iterates the research observation that the use of hazard as a concept in clinical risk management is unfamiliar.</p>		
<p>Resolution</p>		

None further beyond that established in Actions T5.2.1 & E5.2.1
Comments <i>"..people who will trial it need to spend quite a lot of time on making sure they understand the difference between the hazard and the risk."</i>
Analysis This is a valid comment but one that, in my view, pertains to the original research observation i.e. that as a domain we struggle with the concept of a hazard and where it is used, its use does not often align with its definition.
Resolution None further beyond that established in Actions T5.2.1 & E5.2.1
Comments <i>"I believe it does, but I would like to see it applied to more examples before being fully convinced."</i>
Analysis A valid observation and one that has been addressed by the progressive nature of the research evaluation. In total, this framework has been briefed to over 100 people, evaluated by 47 people and applied by 6 people who are all actively involved in the application of clinical risk management. As is reported within the scope of this thesis, the feedback from this evaluation has been very positive and constructive.
Resolution Non required.
Comments <i>"It does help to try and provide a structure / framework when describing hazards." "It provides a structured framework"</i>
Analysis This feedback is encouraging and gives confidence that the original research motivation and objective is being addressed
Resolution Non required
Comments <i>"The author makes a compelling case in the synergy between both the description of realising a benefit, linking into the key identifiers within a harm event occurring from the cause of a hazard to the potential of harm occurring to a patient."</i>
Analysis The feedback recognises that the inspiration for the framework was derived from considering other management techniques within the NHS where I recognised a diametric synergy between the achievement of a business benefit and the occurrence of patient harm. It is hoped that this synergy aids understanding of the framework, particularly with staff who have knowledge and experience in benefits management.
Resolution Non required

Table 16- Review Question 3 Feedback & Analysis

Question	Y Response	N Response
Are there any flaws or weakness in the proposed methodology?	0	8
Comments		
<i>"It can also be useful to state the type of hazard as part of a generic group; this can be done prior to describing the specific hazard or condition that can potential cause patient harm."</i>		
<p>Analysis</p> <p>This is an important observation. The concept of "hazard types" (Habli, et al., 2018) is being used to group and manage hazards that share a common theme. It is considered that the framework can still be applied in such scenarios. There is a potential challenge in that it may be difficult to articulate the causes within the harm scenario if it is being considered at a high level of abstraction. For example, its credible to describe at a high level a generic hazard of "incorrect medication prescribed". However, when that hazard type is analysed in specific care scenarios there are likely to be unique causes to that specific hazard instance that don't occur in other care scenarios: in paediatric care, dosage instructions are calculated based on the child's weight (Health Service Executive, 2013). Weight is generally not factored into adult dosing calculations. It would be difficult to express this variance using the framework. This is not considered to be a weakness in the framework, rather a consequence of the difficulty of trying to articulate detail from a perspective of generality. In such scenarios the best approach would be to apply the framework and either generalises the causes or omit them entirely from the hazard type description. The framework would still deliver value in terms of describing a generic harm scenario and in establishing the starting point from which a specific instance of the hazard type can be described.</p>		
Resolution		
Action T5.2.3 The toolkit needs to support application of the framework in the context of generic hazard types.		
Comments		
<p><i>".. I agree with the approach. How useful it will be in practice will be dependent on how pragmatic / practical the framework will be such that it can be easily understood and applied in practice e.g. by those populating hazard logs. This will depend on how the framework is ultimately described whether in academic / conceptual or pragmatic / practical language."</i></p> <p><i>"I understood it, but then I have some knowledge of clinical safety, those that don't and are working with the methodology may find it hard to understand, although I suppose they shouldn't be using it unless they are trained?"</i></p>		
<p>Analysis</p> <p>This feedback aligns with some of the responses to Question 1, pertaining to the understanding of a hazard in the health care domain and the competence and experience of those conducting `clinical risk management.</p> <p>The principle motivation for conducting this research was to take the opportunity to develop resources that would assist the health care domain in addressing an element of the clinical risk management process as established in DCB 0129 and DCB 0160. I agree entirely that for this to be achieved the framework needs to be unambiguous, defined in simple terms and supported by effective resources. The evaluation element of this research has been structured such that it seeks opinion from a wide range of</p>		

<p>stakeholders and that it is progressive in that feedback from one evaluation phase is addressed and implemented before commencing the next phase of evaluation.</p>
<p>Resolution No specific actions beyond that which has been addressed in the research evaluation design and other specific actions.</p>
<p>Comments <i>“the proposal needs to be clearly explained so that people grasp what it is trying to achieve. One area is in the description of the hazard equating to the practitioner context – could easily be misunderstood as the practitioner is the hazard.”</i></p>
<p>Analysis An important observation. The methodology presents a view that a hazard occurs in the context of the practitioner delivering care; this raises a concern that the practitioner could be viewed as being the hazard. There are 2 themes to be addressed here; 1) scenarios in health informatics where there is no direct interface between the care practitioner and patient and 2) the concern that the practitioner could be perceived to be the hazard.</p> <p>Addressing 1 There is a (deliberate) generalisation made in the framework (and in the concept description of health informatics) that a practitioner always participates in the harm scenario, that essentially, they act as the “actuator” between the information that is created by technology and the care a patient subsequently receives. Hazards subsequently occur at this point of integration. As with all generalisations there are exceptions; the Bowel Cancer Screening Programme (BCSP)²³ https://www.gov.uk/topic/population-screening-programmes/bowel, for example, automatically invites people aged over 55 onto the programme. The invitation is generated using date of birth information maintained on the National Health Application and Infrastructure Service (NHAIS) and is sent automatically to the patient without any clinical check. There is a potential hazard associated with an invitation not being sent when it should have been sent (i.e. patient aged 55 or over and not opted out). This can be described using the framework as such: Incorrect date of birth recorded on NHAIS results in a BCS invitation not being sent. Eligible patient is not enrolled on the bowl cancer screening programme and their cancer goes undetected and they suffer a catastrophic deterioration in their health.</p> <p>However, despite there being no HCP contribution in this scenario (either as a cause or control), the methodology still holds as the hazard occurs in the “people” context.</p> <p>Resolution The generalised model of hazard in the context of HI (Appendix C) has been further refined (Figure 17) to compensate for those scenarios where care management or delivery is not administered directly by a HCP. The generalisation still holds even in these scenarios; the hazard persists in the “people” context (i.e. at the interface between the information and patient) and not in the “technology” context.</p>

²³ Potentially, this functionality should be classified as a MD as it is essentially managing patient level healthcare without any check or intervention by a HCP.

<p>Action T5.2.4 The toolkit needs to be amended to emphasise that hazards persist in the “people” context which can be defined as: (Patient and HCP) or (Patient).</p> <p>Action E5.2.3 The concept of hazards existing in the “people” context will be emphasised in subsequent evaluation activities.</p> <p>Addressing 2</p> <p>To mitigate this concern, the framework needs to be supported by a richer definition and description of the hazard as a concept (i.e. as a condition that is established or exists within the care-pathway which has the potential to result in patient harm) and of the role of a practitioner (i.e. as an enabler of a patient’s care management and / or delivery). Further, there is a need to explain that a practitioner may also act as a cause of a hazard either through making an error or mistake (HSE, 2012)²⁴ or by doing the right thing but in the context of mis-information. This has been addressed and is documented at Section 4.4.3. It was also discussed at the Digital Health Conference (Section 5.3).</p> <p>Resolution</p> <p>Action T5.2.5 The toolkit needs to support the framework by describing key concepts.</p> <p>Action E5.2.4 The toolkit needs to support the framework by describing the contribution a practitioner can make in a harm scenario.</p>
<p>Comment</p> <p><i>“Minor comment: please, pay careful attention to the definitions of the steps and components of the framework”</i></p>
<p>Analysis</p> <p>This is a significant observation and one that must be addressed to ensure that the framework can be understood and applied successfully. Definition of the terms have been established and are summarised at Glossary of Terms.</p>
<p>Resolution</p> <p>Addressed in T5.2.5 & E5.2.4.</p>
<p>Comments</p> <p><i>“Not directly, although defining the hazard so close the event without allowing for anticipation of multiple preceding events loses the opportunity to develop a wider reaching control, or a common causality from multiple sources. However, the logic of the proposed notion seems sound.”</i></p>
<p>Analysis</p> <p>This is valid observation but extends beyond the purpose of the framework. The principle purpose of the framework is to provide a mechanism through which a meaningful hazard <i>description</i> can be established that explains the disturbance that is occurring in the intended care-pathway and how that could manifest as patient harm. It is not intended to fulfil the requirements associated with subsequent risk evaluation activities (Requirements 4.4 of DCB 0129 & DCB 0160) but does naturally provide a precursor to that, albeit at a higher level of abstraction.</p>

²⁴ Human failure can be categorised into two themes: Error and Violation. Errors can be further classified as skill-based errors i.e. slips of action or lapses in memory and mistakes i.e. rule-based and knowledge based. These failures are not intentional. Violations are intentional failures where a conscious decision is made not to do the right thing.

<http://www.hse.gov.uk/construction/lwit/assets/downloads/human-failure.pdf>

The linguist structure captured in the hazard description can be transformed to create the foundations of a bow-tie model of the harm scenario; key elements of cause, hazard and consequence having already been established. This is discussed at Section 4.6. Clearly this would not represent the complete hazard assessment but would form an initiating model which could subsequently be developed to include additional causes and associated controls.

Resolution

Action T5.2.6 The toolkit needs to describe how the framework can be transposed into an initial bow-tie model to support subsequent risk estimation activities.

Comments

Will this method still work for hazards related to human factors as well as technical?

Analysis

This comment needs to be considered in combination with the previous comment regarding the contribution of the HCP (and to a lesser extent the Patient e.g. giving misleading or inaccurate information to a HCP) in the harm scenario.

The framework does not impose any restriction over the nature or type of hazard cause and as discussed above, the actions of the HCP may act as causes in the harm scenario. Causes are not always failures and simply doing the right thing may propagate the disturbance effect that is occurring in the care pathway. In short, the framework can support description of human factor considerations which may reflect: the HCP doing the right thing at a given point in the care-pathway; the HCP be induced to do the wrong thing due to characteristics of the technology or the HCP doing the wrong thing due to a lack of knowledge or understanding.

This latter point had been pre-empted and discussed at the Digital Health Conference (Section 5.3).

Resolution

See Actions T5.2.5 & E5.2.4

Comment

“Although untested, compared with the inconsistent way hazards are described by healthcare organisations and system suppliers in the field, the model provides further clarity linking all the relevant aspects in a sequential way; which allows a user to see how elements are interrelated through to the harm that can potentially occur to a patient. In this way, a new standardised methodology would potentially improve the creation of, and aid healthcare colleagues understanding of hazards within clinical safety within the clinical field.

Analysis

This is extremely encouraging feedback and aligns very strongly with the intent of the research.

Subsequent evaluation activities (5.2.4 & 5.2.5) provide opportunity for the framework to be applied by staff working in clinical risk management on their own specific developments or deployments.

Resolution

None required.

5.2.3.3 Cohort Feedback and Analysis – Q2

Table 17 - General Feedback & Analysis

<p>Comments <i>Really interesting and useful MSc which I look forward to trying in practice. I completely agree with the challenges in describing hazards and I think this will help. I have often wondered if some of the difficulties has been that a hazard log only really includes 3 elements: Cause, Hazard and Consequence. To me it has always felt there's a missing element which makes it difficult to judge whether something should be described as a cause or a hazard (or a consequence). Seeing the 4 elements listed and then how they are combined in both the flowchart in fig 4 and the Hazard example through the colours, is insightful and may help with that problem.</i></p>
<p>Analysis Encouraging feedback which re-enforces the original research proposition.</p>
<p>Resolution None required.</p>
<p>Comments <i>I think that the project is workable and would help to improve the understanding around hazards. Very few comments but all-around same thing really and that is to ensure that people really do understand the differences between hazards, risks and issues.</i></p>
<p>Analysis Encouraging feedback that indicates that the framework is practicable and helps to address the original research proposition. I agree entirely with the observation regarding people needing to understand the difference between a hazard and its risk; preceding action points will address this in the toolkit.</p>
<p>Resolution None further beyond those actions already identified.</p>
<p>Comments <i>"It would provide strong support to demonstrate the validity of the methodology to use the framework for real world "hazards""</i></p>
<p>Analysis This is a valid observation which has been demonstrated through 2 key phases of the evaluation strategy:</p> <ol style="list-style-type: none"> 1. Section 5.1 discusses the application of the framework to a sample set of legacy hazards. The resulting hazard descriptions convey a far greater understanding of the harm scenario; this has been endorsed by an experienced CSO. 2. Section 5.4 discusses the application of the framework in a real-world hazard workshop which again demonstrated the effectiveness of the framework. Further it illustrated how the results of applying the framework can be used to inform subsequent hazard analysis activities.
<p>Resolution None further beyond those actions already identified.</p>
<p>Comments <i>"I think the concept is a great one in understanding differences and communicating</i></p>

effectively.

Pragmatically, I like to categorise my "hazards" into higher level/ upstream events or themes which isn't necessarily directly catered for in the model. Doing that helps me spot controls that can be more generally applied or prevent us getting to the event that triggers the hazardous situation. In essence I guess they're Pre-hazardous situations depending on your definition."

Analysis

Categorisation of "hazards" in this way essentially equates to the concept of "effect" in the framework. A disturbance is occurring in the intended care-pathway which may or may not result in a condition that could propagate and result in patient harm. Whilst the purpose of the framework was not intended to support hazard analysis, it emerged through the work that was conducted under Section 5.4, that the results of applying the framework can be transposed and used to construct an initial bow-tie model of the harm scenario. Controls can then be identified that manage the identified causes that are related to the "upstream events" or effects.

Resolution

None further beyond those actions already identified.

Comments

"The main points I would like to make are:

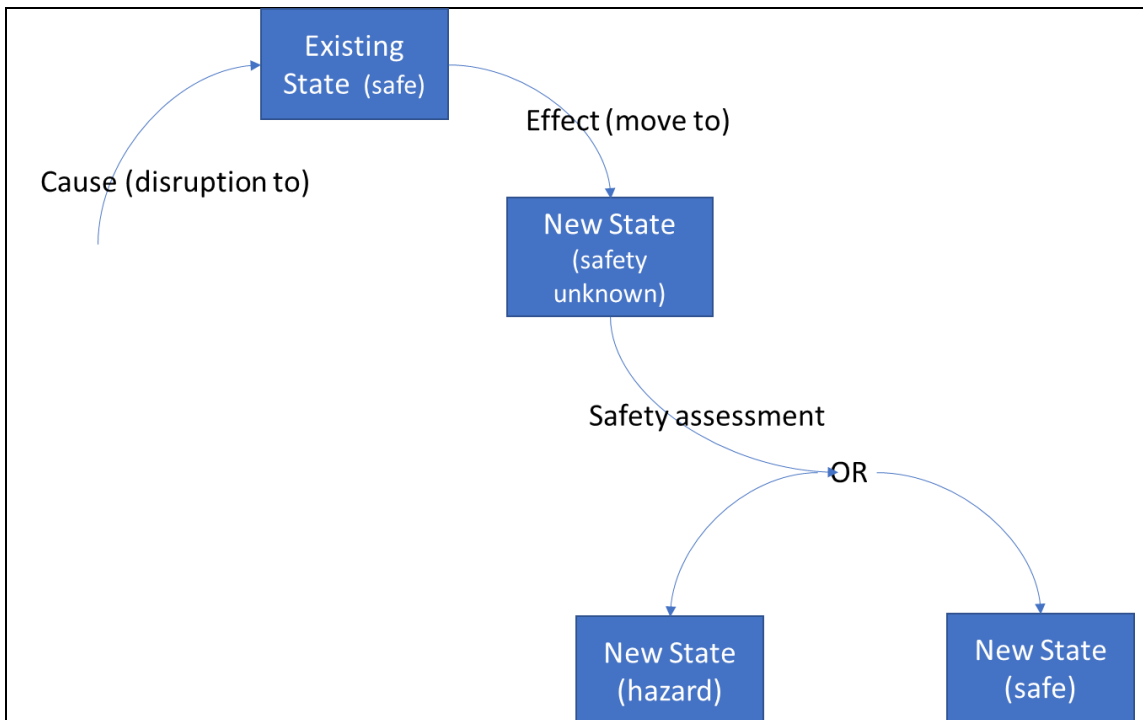
1-Terminology needs to be described very clearly as some of the terms and not used routinely in healthcare and there is ambiguity in the field.

2-In my opinion, the "hazard" would be the "change" rather than the "outcome". The way I see it is "the outcome of the hazard is the unwanted event"."

Analysis

I agree entirely with point 1 and one of the principle objectives of the toolkit is to provide a clear definition of terms in order to support consistent application, communication and understanding of the harm scenario.

With respect to point 2 "change" is a benefits management term (Baker, 2017) which equates to the concept of "effect" in the framework. I wouldn't necessarily agree that an effect, which is essentially a form of deviation from the intended process is always hazardous. An assessment has to be made as to whether that effect can result in the creation of a condition that has the potential to credibly result in harm i.e.:



If the term "unwanted event" is equated with harm then I would agree that is the outcome of the hazard. However, as explained by Reason (Reason, 2000) it must be recognised that there is not always an immediate relationship between hazard and harm and that in many harm scenarios other causes (whether they be failure of controls or presence of contributory factors) need to occur.

5.2.4 Summary

This was an effective evaluation activity with 9 out of 11 CSOs providing a response. The response rate is encouraging as it would suggest that there is an interest in the research topic.

This phase of evaluation supports substantiation of objective 1 (hazard concept), particularly the research observation that the concept of hazard in the health domain is not widely understood.

It also supports substantiation of objective 4 (communication) that application of the framework results in hazard descriptions that clearly articulate the harm-scenario.

Encouragingly, there was no feedback indicating that the research objective and outcome was flawed or misguided.

This evaluation phase provided constructive feedback in key areas that has resulted in consideration of other influences (e.g. practitioner being perceived as the hazard) and the need to elaborate terms and definitions.

5.3 Digital Health Conference Workshop March 2019

5.3.1 Conference Context

NHS Digital and the University of York co-hosted a 2-day digital health safety event over 27th & 28th March 2019²⁵. The event was specifically targeted at clinicians working within the NHS, social care organisations and system manufacturer organisations and was attended by in excess of 120 people. The majority of these delegates have attended training in clinical risk management and are acting as the CSO in their organisation. (The principle communication of this event was via the NHS Digital Clinical Risk Management Training webpage and CSO email distribution list).

I co-ran the 1st conference workshop addressing the use of safety cases in the health domain and took the opportunity to present the hazard definition methodology established through this research.

5.3.2 Workshop Objectives

The conference workshop was attended by 60 delegates representing a broad cross section of roles and levels of authority across the healthcare domain including health and care delivery organisations, care commissioning organisations and Health IT system manufacturers.

The presentation is at Appendix D and supported a 30-minute discussion which communicated the following learning points:

- The need to be able to define hazards in a meaningful, patient centric context in order to be able to subsequently conduct any credible hazard analysis and risk assessment. These activities are precursors to delivering a compelling safety case based on the implicit risk-based safety strategy established in the related CRM standards (DCB 0129 and DCB 0160).
- The need to think in terms of people harm context and the chain of events that can occur in the care-pathway that could credibly result in harm.
- The need to consider technology in combination with information and people, together all forming an integrated a sociotechnical system and avoid thinking of hazards just in a technology failure or misuse context.
- That harm can only occur in the context of people so hazards must also only exist in that context. That neither technology nor information can directly cause harm so technology must be a cause of a hazard.
- The need to think about the disturbance effect a cause has on the care-pathway that is being followed to manage the care of a patient
- That people can be hazard causes but not all causes are failures; people can do the right thing but in doing so, continue to propagate the disturbance effect in the care-pathway.

Delegates were asked, as part of conference workshop feedback to answer the following two questions relating to this element of the presentation:

- Do you think the hazard description technique supports meaningful description of Health IT related hazards? – please provide reasoning

²⁵ <https://digital.nhs.uk/news-and-events/events/2019-events/digital-health-safety-conference-2019>

- Do you think the hazard description technique will be practical to use in a hazard workshop? - please provide reasoning.

Feedback was collected via a web-based survey tool which delegates could access at the time of the workshop (each delegate was logged-on to a desk top computer during the workshop).

5.3.3 Conference Feedback and Analysis

Approximately 50% (28 out of 60) of delegates provided feedback. This is considered to be a sufficient sample size aligning with a typical response rate experienced by NHS Digital following delivery of other training events.

The amonished responses are at Appendix D and summarised below in Figures 24 & 25.

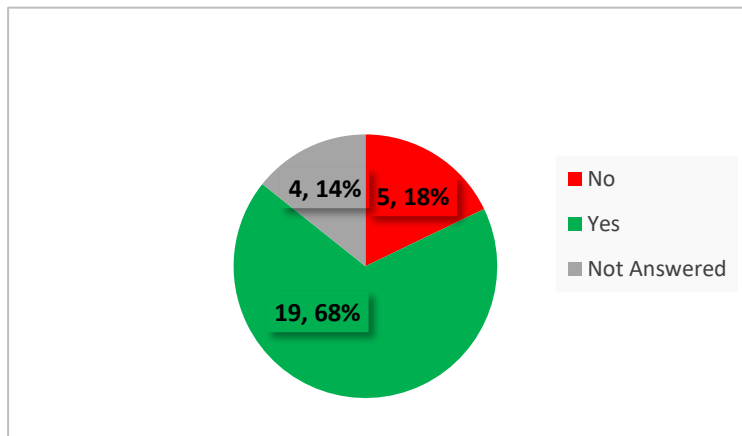


Figure 24 - Meaningful Definition

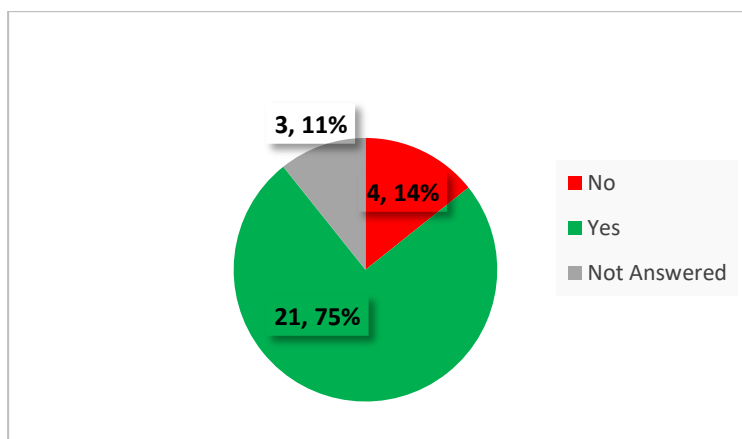


Figure 25 - Practical to Use

As would be expected there is high correlation between individual responses to “meaningful” and “practical”. Analysis of “No” and “Not Answered” response is summarised below in Table 18:

Table 18 - Conference Feedback Analysis

Respondent #	Meaningful	Practical	Comments
7	NA	NA	Neither response was qualified so its not possible to understand the perceived weaknesses.
9	NA	Y	The NA response was not qualified; the response to the Y response indicates that the respondent endorses the methodology. It is reasonable to assume the NA is an outlier and should have been recorded as Y.
13	N	N	Neither response was qualified so its not possible to understand the perceived weaknesses.
14	N	N	Neither response was qualified so its not possible to understand the perceived weaknesses.
16	N	N	Both responses were qualified with reference to the SMART tool ²⁶ and a expression of disappointment in the workshop. Reclassified as an outlier.
18	N/A	N/A	Both responses were qualified through a statement relating to a lack of opportunity to apply the methodology.
21	N	N	Neither response was qualified so its not possible to understand the perceived weaknesses.
22	NA	NA	Neither response was qualified so its not possible to understand the perceived weaknesses.
25	N	Y	Response to N was qualified with reference to the SMART tool but there was a positive response to practical application. It is reasonable to assume the N is an outlier and should have been recorded as Y.

Consolidating these observations gives a revised reflection on the considered effectiveness and practicality of the proposed methodology which is summarised in Figure 26:

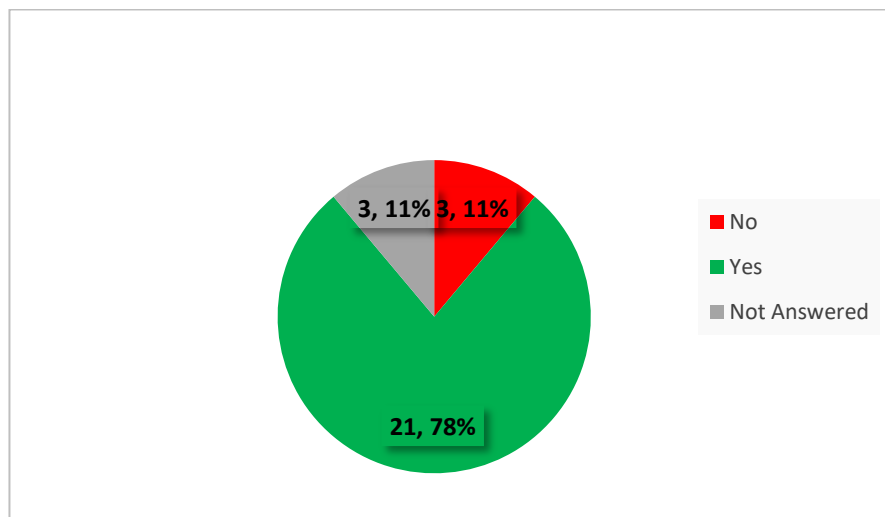


Figure 26 - Consolidated Feedback

²⁶ See section 4.5

5.3.4 Summary

This was an effective evaluation activity with 28 out of 60 delegates providing a response. This aligns with the response rate routinely experienced by NHS Digital in feedback to their CRM training courses.

This phase of evaluation supports substantiation of objective 1 (hazard concept) and objective 4 (communication). 75% of delegates considered that the methodology does support meaningful description of care centric, Health IT related hazards.

It also supports substantiation of objective 3 (practice). 75% of delegates considered that the methodology could be used in practice.

12 delegates provided qualitative feedback to support their Y/N answers. Of these, 5 made comments relating to other aspects of the workshop. All other feedback aligned with the themes raised and discussed in Section 5.2.

Given the limited time to communicate the methodology, the large number of delegates and the variance in their roles and experience of conducting CRM it is considered that this evaluation provides strong qualitative evidence that the framework addresses the research objectives and that it is considered practical to use within the health care domain. Importantly, no responses were raised that countered the objectives.

5.4 Application in a Pilot Study

The pilot study was conducted to support the implementation and subsequent use of the National Early Warning Score (NEWS)²⁷ in the context of acute care within the NHS.

It must be noted that descriptions and diagrams presented here have been purposefully simplified and generalised to maintain manufacturer confidentiality; the workshop was supported by more detailed resources. The generalisation presented herein does not distract from or undermine the workshop process and its conclusions.

5.4.1 Clinical Context

NEWS has been developed and by the Royal College of Physicians (RCP); Version 2 (Royal College of Physicians, 2017) has been endorsed by NHS England and NHS Improvement as the early warning system to be used for identifying acutely ill patients in hospitals within England.

NEWS uses a relatively simple algorithm based on an aggregated scoring system to generate an overall score. The score is derived from the measurement of the following 6 physiological parameters which are routinely measured and recorded as part of existing acute care management practice:

1. Respiration rate
2. Oxygen saturation
3. Systolic blood pressure
4. Pulse rate
5. Level of consciousness or new confusion
6. temperature

²⁷ NEWS has been developed by Royal College of Physicians and endorsed by NHS England and NHS Improvement as an early warning system to identify acutely ill patients.

<https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news-2>

Each parameter is allocated a score where the magnitude of the score reflects the extreme the parameter varies from the normal value. The total score for all parameters is then aggregated to create a NEWS.

5.4.2 Implementation Context

The NEWS algorithm is being implemented into an acute Electronic Patient Record (EPR) system that is widely used within the NHS. Values for the 6 parameters, which are recorded and stored in the individual patient record within the EPR as part of the routine care-pathway, are used by the implemented algorithm to create a patient's NEWS. If the NEWS exceeds a pre-defined value, an alert is generated to which nursing staff respond and triage the patient. A clinical decision is then made as to whether specialist care is needed. The alert can be suppressed in particular scenarios e.g. if the patient is in intensive care.

Figure 27 summarises NEWS in its clinical and implementation context.

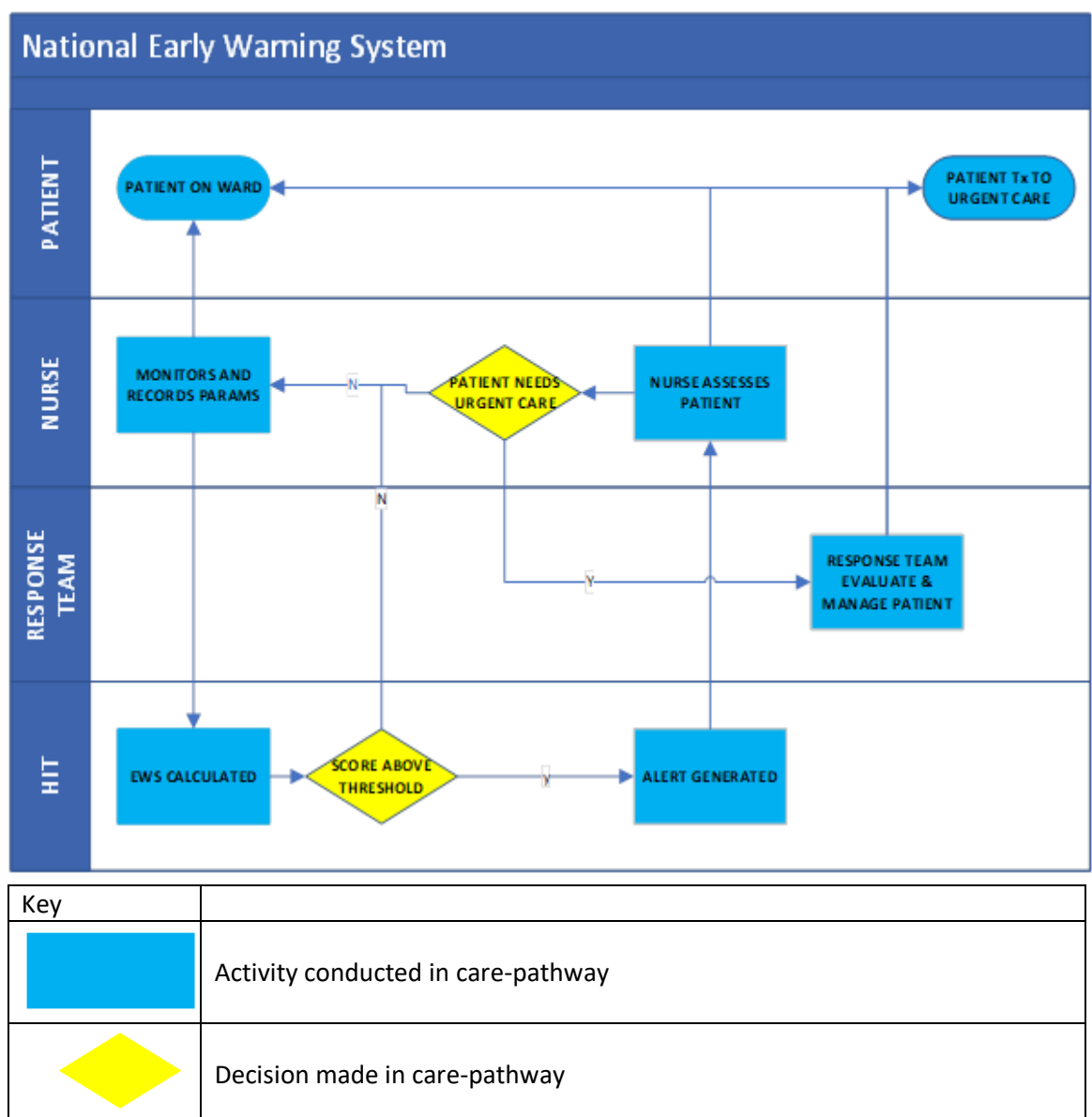


Figure 27 - NEWS Implementation Model

5.4.3 Hazard Workshop

The purpose of a hazard workshop is to identify hazards associated with the programme of work that is being undertaken. The scope of the workshop is related to the phase of the lifecycle the programme is at e.g. design, use or decommissioning. Successive hazard workshops are often conducted, especially so where the scope or nature of the work changes. To be most effective, a hazard workshop should be conducted early in the lifecycle phase in order to have an influence over subsequent activities.

The hazard workshop conducted in support of this thesis focused on the deployment and subsequent use phases of the project; initial development and implementation had already been undertaken.

The following roles participated in the hazard workshop:

- Clinical Consultant x3
- Solution Consultant x2
- Lead Regulatory Strategist

The purpose of the workshop was to:

- Explain the hazard description methodology to a cohort of clinical and technical staff actively involved in clinical risk activities in support of the development and deployment of Health IT
- Apply the methodology in order to establish meaningful, patient harm centric hazards
- Evaluate the merits of the methodology in the context of the research objectives.

The scope of the workshop was purposefully reduced to exclude the potential hazards associated with the activities conducted by the Response Team. The rationale for this being that the actions of the Response Team are not influenced by the NEWS and its implementation beyond the initial decision to engage them.

5.4.4 Hazard Workshop Activities

5.4.4.1 Methodology Briefing

In advance of the workshop, the original briefing paper used in support Targeted CSO Evaluation (Section 5.2) was circulated to all participants.

A presentation was delivered at the start of the workshop. The presentation was derived from that delivered at the Digital Health Conference (Section 5.3), addressing points of improvement actions identified through on-going evaluation.

5.4.4.2 Application of Methodology

The methodology was applied within the framework of SWIFT (see Section 2.6) which is practiced by the organisation. The organisation also use swim-lane diagrams to describe the care pathway, identifying roles (technology and people) the flow of information between the roles and the activities and decisions the roles perform. These diagrams provide a comprehensive and representative model of care delivery which is amenable to deviation analysis.

The following stepwise process was followed;

1. Identify human activities / decisions close to care delivery outcomes
Rationale: methodology establishes that hazards occur at the interface between the HCP and patient.
2. Apply SWIFT to appraise whether the identify activity / decision could credibly result in harm either through the intended activity / decision being made or an unintended activity being made at this point in the care-pathway.
Rationale: methodology establishes that hazards exist if there is a related and credible harm outcome.
3. If the activity / decision is considered to be hazardous then annotate as such in the model (green in the methodology schema). Capture the patient harm consequences that may occur as a result of the hazard
Rationale: The purpose of SWIFT is to identify hazards.
4. For those activities / decisions identified to be hazardous, systematically step through the care-pathway model and consider whether a disturbance at this point in the process has an effect on the care-pathway that may result in the identified hazard.
Rationale: methodology establishes that disturbance effects that cause deviation from what was intended to be done in the care-pathway can result in hazards.
5. If the activity / decision is considered to be an effect, then annotate as such in the model (red in the methodology schema)
6. For those activities / decisions identified to be effects, systematically step through the care-pathway model and consider whether the activity / decision is a cause of the previously identified effect
Rationale: methodology establishes that causes induce a disturbance effect in the care-pathway.
7. If the activity / decision is considered to be a cause, then annotate as such in the model (blue in the methodology schema)
8. From the model and using the colour coding, populate the worksheet to construct a hazard description.

5.4.5 Hazard workshop Results

5.4.5.1 Response Team Engaged When They Are Not Needed

This scenario considers the circumstances under which the Response Team are engaged when there is no clinical need.

Application of the methodology is depicted at Figure 28 and explained at Table 19

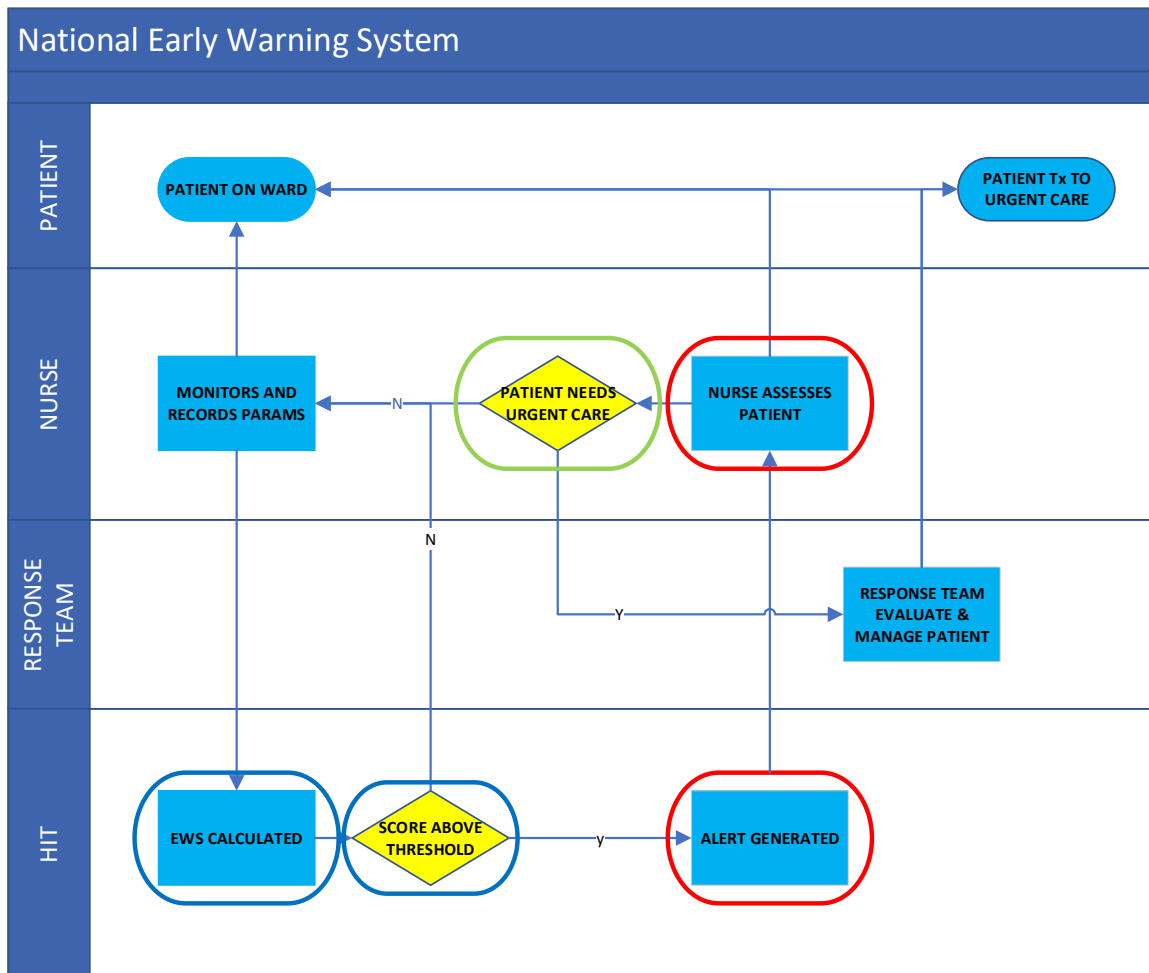


Figure 28 - Application of Framework to Care-pathway Model

Table 19 - Framework Application Rationale

Process Step	Classification & Rationale
PATIENT NEEDS URGENT CARE	<p>Potential point of hazard.</p> <p>The purpose of NEWS and subsequent alert is to make nursing staff aware of a specific patient’s deteriorating health and to prioritise and initiate a nursing assessment from which an informed decision can be made as to whether specialised response team need to be engaged.</p> <p>If the alert is erroneously generated and the Nurse subsequently makes an erroneous assessment, they could engage the Response Team in circumstances where they are not required. This may disturb the wellbeing²⁸ of the patient and may have a detrimental impact on the provision of Response Team service across the organisation.</p>

²⁸ DCB 0129 & DCB 0160 define harm as being “Death, physical injury, psychological trauma and/or damage to the health or well-being of a patient.”

Process Step	Classification & Rationale
NURSE ASSESSES PATIENT	Effect The nurse assesses the patient in response to the alert but draws the wrong conclusion on the health of the patient.
ALERT GENERATED	Effect The alert is generated in circumstances where it should not be which has a subsequent effect on the actions of the Nurse. Note In this scenario there is an assumption being made that the alert is operating correctly and that there are downstream causes which cause the alert to be generated
SCORE ABOVE THRESHOLD	Cause Incorrect design or implementation may result in an erroneously high NEWS.
EWS CALCULATED	Cause Incorrect design or implementation may result in a low NEWS causing an alert trigger.

From this mapping and rationale, the hazard description can be constructed as illustrated in Table 20:

Table 20 - Hazard Description Composition



Cause	Erroneously high EWS score is calculated by Health IT Or Health IT erroneously determines score is above alert threshold
Effect	EWS alert is generated when it should not be, and Nurse makes incorrect assessment of the patient
Hazard	Response Team are engaged when they should be
Harm	Patient becomes distressed.

Erroneously high EWS score or score deemed to be higher than threshold results in alert being generated and the Nurse subsequently makes an incorrect assessment of the patient. Response Team are engaged in circumstances where they are required which causes the patient to become distressed.

5.4.5.2 Hazard: Response Team Not Engaged When They Are Needed

This scenario considers the circumstances under which the Response team are not engaged when they should be i.e. when a patient’s condition is deteriorating to a point where their NEWS reaches the threshold value.

Application of the methodology is depicted at Figure 29 and explained at Table 21:

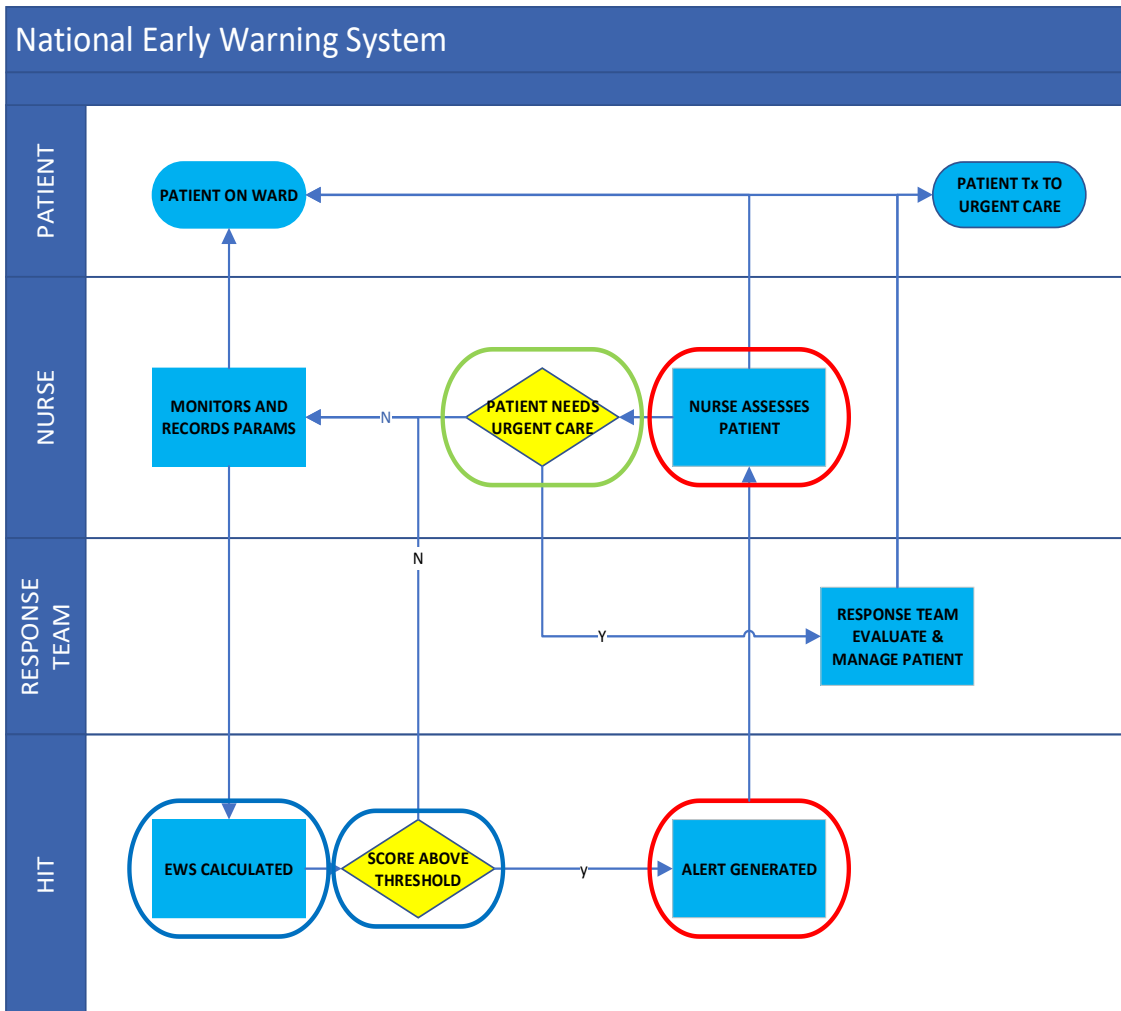


Figure 29 - Application of Framework to Care-pathway Model

Table 21 - Framework Application Rationale

Process Step	Classification & Rationale
PATIENT NEEDS URGENT CARE	<p>Potential point of hazard.</p> <p>The purpose of NEWS and subsequent alert is to make nursing staff aware of a specific patient’s deteriorating health and to prioritise and initiate a nursing assessment from which an informed decision can be made as to whether specialised response team need to be engaged.</p> <p>If the alert is not generated or is suppressed, then the likelihood of a deteriorating patient’s condition going unmanaged is likely to increase.</p>

Process Step	Classification & Rationale
NURSE ASSESSES PATIENT	Effect The nurse does not conduct an assessment of the patient despite their deteriorating condition.
ALERT GENERATED	Effect The alert is not generated in circumstances where it should which has a subsequent effect on the actions of the Nurse. Note In this scenario there is an assumption being made that the alert is operating correctly and that there are down-stream causes which mask the requirement for the alert to be generated. There is an alternative scenario in which the alert can be a cause i.e. it fails to generate the alert. It must be remembered that the purpose of this methodology is not to conduct hazard analysis but to construct a hazard description that articulates the harm scenario which in term begins to <i>inform</i> the hazard analysis.
SCORE ABOVE THRESHOLD	Cause Incorrect design or implementation may result in valid high NEWS being considered to be below the trigger threshold which has the effect of the alert not being generated.
EWS CALCULATED	Cause Incorrect design or implementation may result in an erroneously low NEWS which has the effect of the alert not being generated.

From this mapping and rationale, the hazard description can be constructed as illustrated in Table 22:

Table 22 - Hazard Description Composition



Cause	Erroneously low EWS score is calculated by Health IT Or Health IT erroneously determines score is below alert threshold
Effect	EWS alert is not generated when it should be so Nurse does not assess patient
Hazard	Response Team are not engaged when they should be
Harm	Deterioration in the patient's condition (onset of sepsis).

Erroneously low EWS score or score deemed to be lower than threshold results in alert not being generated when it should and subsequent and necessary patient assessment is not conducted by the nurse. Response Team are not engaged in circumstances where they are required which results in a deterioration in the patient's condition (onset of sepsis).

5.4.6 Hazard Workshop Feedback and Analysis

5.4.6.1 Hazard Workshop Outcomes

The time spent at the workshop in applying the methodology was limited to about 20 minutes (time was needed to explain the methodology to delegates, to discuss and understand the care pathway and to observe a demonstration of the development system). However, this was enough to be able to establish the description of the two harm scenarios discussed above. A significant contributing factor in achieving this outcome in a short period of time was the quality of the swim-lane models the organisation had developed.

The people roles provided a focus for identifying potential hazards and automatically prevented conversation and deliberation of lower level causes being established as hazards (without of any direct and obvious relationship to patient harm consequences).

The description constructs could be readily super-imposed over the model and as such directed the discussion and confirmation of the harm scenario. It was observed that conversation remained focused to the particular element of the model being analysed. One of the weaknesses of a SWIFT type approach to hazard identification is that if it is not carefully managed there is a danger that it can wander of track and focus is lost.

Subsequent to the workshop, the organisation has applied the methodology to other areas of the care-process, applied it to address some of the specificity which has been generalised in the thesis and are appraising its future use as a constituent element of their CRM process (see 5.4.6.2)

Two specific points were raised during the course; these and my responses are summarised in Table 23

Table 23 - Workshop Discussion Points

Comment	Response
Would applying this technique result in the creation of a large number of hazards.	My view is that application of the methodology in the workshop demonstrated that by focusing on the patient, hazards are in fact established at a higher level of abstraction. By working backwards from the point of the hazard through the care-pathway, we can readily identify causes and the effect they have on the ability to discharge the intended care-pathway. We can then start to think about controls and mitigation strategies and where best to apply them to greatest effect (as close to the source as possible).
Doesn't the methodology oversimplify the CRM work that needs to be conducted.	In applying this methodology, I'm not suggesting we are simplifying the work that needs to be done; obviously the necessary analysis and justification still needs to be undertaken, but by constructing a structured description of the hazard early in the process the harm context becomes apparent and it provides direction as to where to focus our resources to achieve optimum outcomes.

Feedback²⁹ was provided following the workshop and is summarised at Table 24:

Table 24 - Workshop Feedback

Question	Y/N	Comments
Is the research observation regarding hazard definition in the domain of health informatics representative?	Y	<i>“Talking about hazards in healthcare is still challenging as many institutions are very much risk averse. Having a methodology that brings the language of hazard close to the user will for sure be helpful when it comes to view clinical hazards as opportunities to improve practices and patient safety. “</i>
Does the linguistic methodology proposed aid meaningful hazard definition?	Y	<i>“It is a much more intuitive, easy to use tool when compared to a more traditional What if analysis. This methodology can bring up to speed even people with little experience identifying hazards as looks at the processes as a whole and not individual components. From a clinical perspective it relates to what clinicians would empirically identify as a hazard themselves and therefore makes the process more solution specific.”</i>
Do you think the methodology could be incorporated into your organisation’s clinical safety management system?	Y	<i>“This methodology has been presented to the Clinical Risk Management Committee for analysis and discussion and materials supplied by the author (Sean white) disseminated to members of the committee. “</i>

5.4.6.2 Informing Hazard Analysis

As discussed at Section 4.6, by applying rigour in the derivation and construction of a patient centric, hazard description there is an opportunity to inform and initiate subsequent hazard analysis activities.

The bow-tie methodology is widely used in safety related industries and is promoted by NHS Digital in their CRM training and the methodology is embedded within SMART. The methodology uses simple graphical notation to represent the relationship between hazards, their causes, consequences and controls.

The hazard description established by applying the research methodology can be readily transposed to establish the basis of a bow-tie model. This is illustrated in Figure 30 for the *hazard Response Team are not engaged when they should be*.

²⁹ Approval to reproduce the comments has been granted.

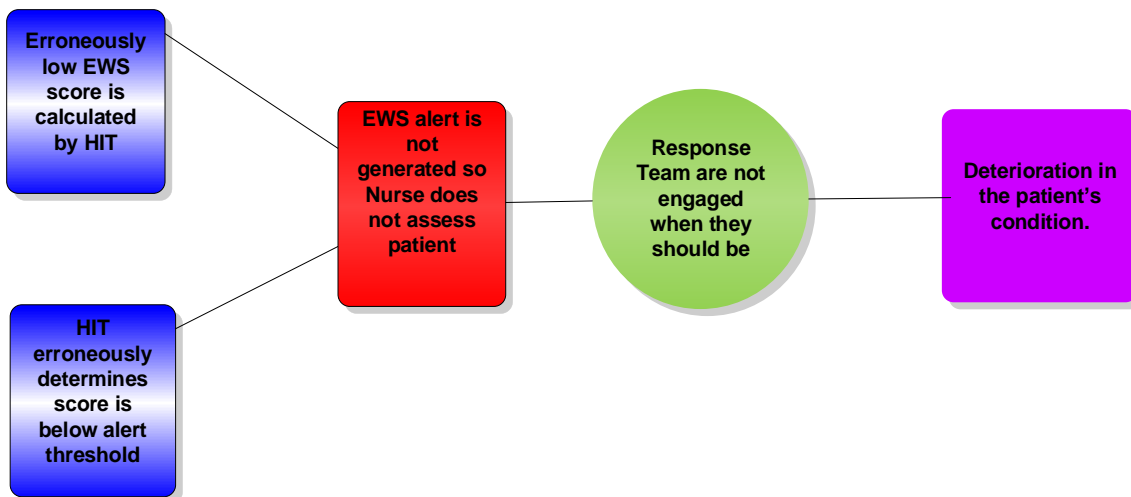


Figure 30 - Informing Hazard Analysis

Obviously, this is not a complete and exhaustive analysis; there are some obvious omissions such as:

- The nurse making an incorrect assessment
- The subsequent actions of Response Team

But importantly, in applying the hazard description methodology and transposing it into bow-tie establishes a systematic approach to the early phases and CRM building communication, traceability and rigour into the process and improving comprehension of the harm scenario by stakeholders.

5.4.6.3 Hazard Workshop Follow-up

A second meeting was convened with the organisation to review their independent application of the framework. Table 25 summarises the qualitative feedback that was provided and the discussion points that followed:

Table 25 - Follow-up Workshop Feedback

Observation	Discussion points
“Framework has been reviewed and applied in full NEWS care-pathway from a perspective of care delivery” (extending beyond initial limited scope of original workshop)	Noted; additional hazards that were identified and described are presented at Table 5.4.6-2.
“Hazard outcomes became generic”	This is to be expected if CRM is conducted in the context of patient centric care-pathways. NEWS has been developed to provide a single care benefit i.e. alert HCPs to the potential deterioration in a patient’s health and initiate a nursing intervention. From a harm perspective the outcomes are limited but there will be different harm-scenarios in which it may result.

Observation	Discussion points
<p>“Not time consuming but it seemed difficult to use initially.”</p> <p>“Applying the framework and establishing the constructs can be difficult, intuitively know what the hazard is”</p> <p>“Traditional approach of SWIFT takes longer”</p>	<p>An element of the “difficult” was associated with understanding the purpose and relationship of the different constructs. This did improve through further use of the framework.</p> <p>The intuition of clinicians is recognised and the two CRM standards harness this through the requirements for a CSO. The challenge is being able to capture, articulate and communicate this understanding into the CRM process. Without being able to do so, the effectiveness of the subsequent CRM activities and the confidence in the supporting safety case can be compromised. In being able to identify the point for potential harm in the care pathway meant that discussion could be managed around that viewpoint and it was observed that there was less digression as often can occur when using SWIFT.</p>
<p>“Not confident that it captures all the hazards.”</p>	<p>A fair point. It was suggested that being systematic and identifying and assessing all points of interaction between the HCP and the patient a claim of completeness could be made with a high degree of confidence. The challenge of demonstrating completeness becomes even more challenging when the approach to hazard identification and definition is undertaken in a random and unstructured way. It was further suggested that if it becomes difficult to identify additional patient harm outcomes then it is fair to claim that this initial phase of CRM has been addressed.</p>
<p>“Potential to use the structured description to simplify the hazard log e.g. by removing existing columns. This is something that is being evaluated.”</p>	<p>Indeed, by having consistent structure in the hazard description negates the need to capture and manage different elements of the hazard log. Reading and assimilating disparate chunks of information can be problematic.</p>
<p>“Positive response within the organisation when it was briefed during a recent CRM meeting.”</p>	<p>This is encouraging and an independent conversation with the Lead Regulatory Strategist indicates that the framework is to be embedded within the organisations CRMS.</p>

The host organisation has a mature and effective clinical risk management process in place with dedicated and knowledgeable staff who are responsible and accountable for ensuring the process is embedded into their programmes. Following the pilot study, the organisation has

recognised that their legacy hazard descriptions are not always expressed in the context of patient harm outcomes and have suggested that they will be reviewed.

Additionally, the organisation is planning to adopt the methodology to support future hazard identification activities and have initiated this by running internal communication events.

5.4.7 Summary

This phase of evaluation supports substantiation of objective 2 (care context) and objective 4 (communication). Participants in the workshop agreed that hazards described using the framework are expressed relative to the care-pathway and potential patient harm outcomes.

It also supports substantiation of objective 3 (practice). The organisation was able to apply the framework outside of the workshop and are of the view that it will save time. There is an overhead of learning but this is to be expected with the introduction of any new work process.

The strongest demonstration of the value of this research is the endorsement made by the organisation's Lead Regulatory Strategist who has promoted the framework internally to members of the Clinical Risk Management Group. Further there seems to be an appetite for the organisation to embed the framework within their CRMS and to review the efficacy of their existing hazard descriptions and the structure of their hazard log.

5.5 Training Course Module and Evaluation

5.5.1 Training Course Context

NHS Digital run a national programme of training in CRM³⁰ that aligns with the requirements of DCB 0129 & DCB 0160. The training comprises 3 elements; a foundational level of e-learning; a supplementary hands-on foundation course and a community of interest course.

To support further evaluation of the framework I have developed a training module (Appendix E) for delivery within the community of interest course. The purpose of this course is to deliver emergent themes in technology and CRM practice. It is aimed at knowledgeable and experienced delegates who are typically actively employed in the role of CSO within their organisations. It is intended that this training will be incorporated into the foundation training course and that the methodology will become the defacto way of defining hazards within the NHS and its supplier base.

I delivered the training module on 14th May 2019. 28 delegates attended the course of which 13 provided feedback. The profile of the respondents is summarised below in Table 26 and includes representatives from a wide range of stakeholders:

Table 26 - CSCOI Delegates

CSO Profile	Number of delegates
Manufacturer Providing technologies and systems, including Medical Devices, to the NHS and private health providers.	4
NHS Trust NHS funded organisation that provides acute and community care services.	5

³⁰<https://digital.nhs.uk/services/solution-assurance/the-clinical-safety-team/clinical-risk-management-training>

CSO Profile	Number of delegates
Medical Data Provider Providing drug databases for 3 rd party integration into Health IT systems.	1
Independent Consultant Providing consultancy services in CRM to a variety of organisations.	1
Regulatory Authority UK Government organisation responsible for licencing of Medical Devices.	1
General Practice NHS funded organisation that provides primary care services.	1

5.5.2 Training Course Analysis and Feedback

Feedback was collected as part of the training course evaluation process. Delegates were asked to answer the two questions summarised in Table 27 with the opportunity to add any qualifying comments.

Table 27 - Clinical Safety Officer Review Questions

Question #	Question
1.	Do you think the hazard description framework helps to establish meaningful hazard descriptions?
2.	Do you think the hazard description framework will be practical to use?

The returned responses³¹ are summarised below in Tables 28 & 29. The responses to each question are grouped by themes and subsequently analysed. Corrective actions are specified where deficiencies in the methodology are identified.

The module was timetabled at the end of the course and with hindsight it is apparent that this had an impact on delivery and possibly interpretation and understanding of the training as reflected in some of the comments. Two principle reasons have been identified:

- The course was over-running so the amount of time dedicated to this module was cut-short This meant that the material was delivered at pace with not sufficient time to fully explain the methodology and reflect on learning outcomes.
- The module was delivered at the end of the course which probably had an impact on the delegate's ability to absorb and understand the learning.

Table 28 - Review Question 1 Feedback & Analysis

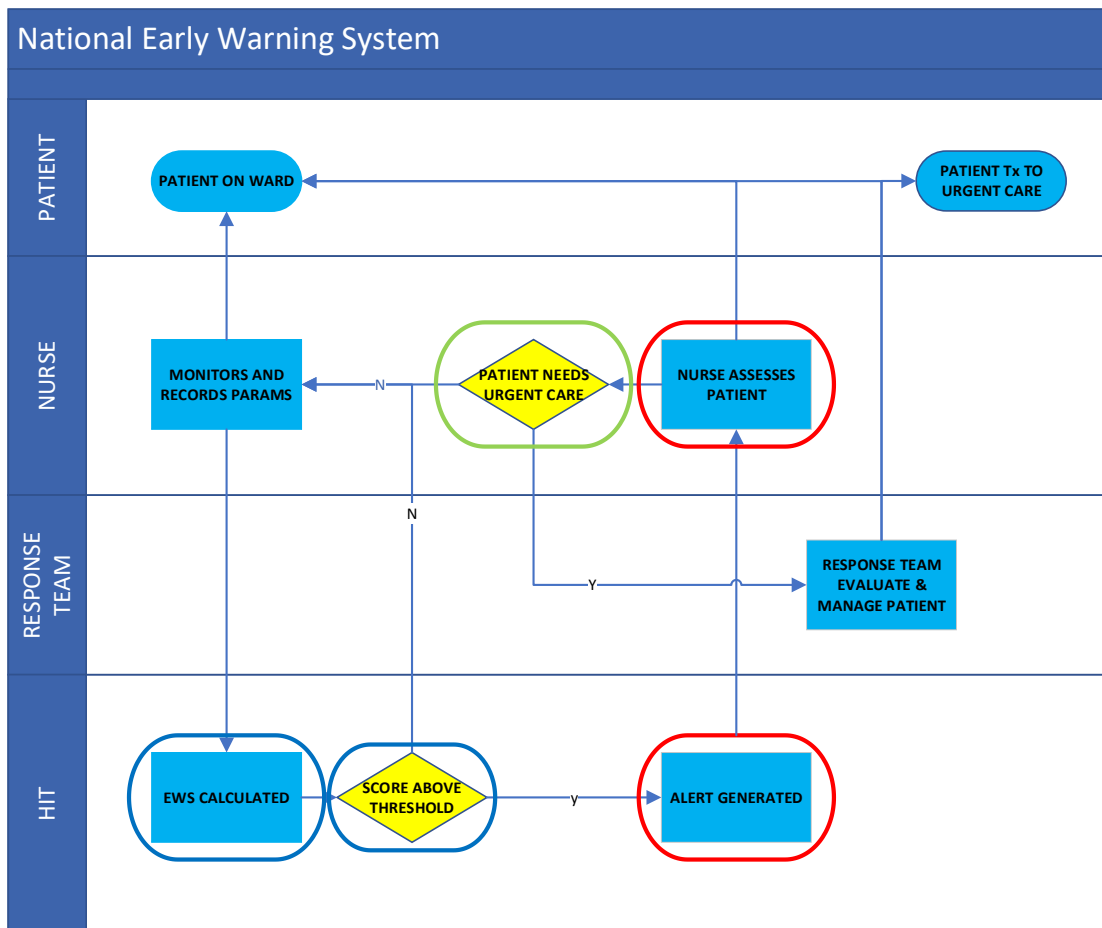
Question	Y Response	N Response
Do you think the hazard description framework helps to establish meaningful hazard descriptions?	13	0
Comments <i>"Interesting and helpful definition of a hazard - but a bit different from the Bow Tie concept - which is a potential harm to a patient. Both concepts have their strengths and I think the important thing is to have a clear definition which is then used consistently throughout the risk management work-flow."</i>		

³¹ Permission to reproduce comments was obtained from the respondent.

Analysis

This feedback possibly reflects the fact that delivery of the module was rushed. I did try and explain that the purpose of the methodology was to support a structured and patient centric description of the harm scenario and that its purpose was not that of hazard analysis. The module did explain that by using models to capture the care pathway, the methodology can be superimposed on that model and in turn an initial bow-tie diagram could be developed to form the basis of subsequent hazard analysis. The following abstracts from the training module illustrates this in the context of the National Early Warning Score (NEWS) functionality:

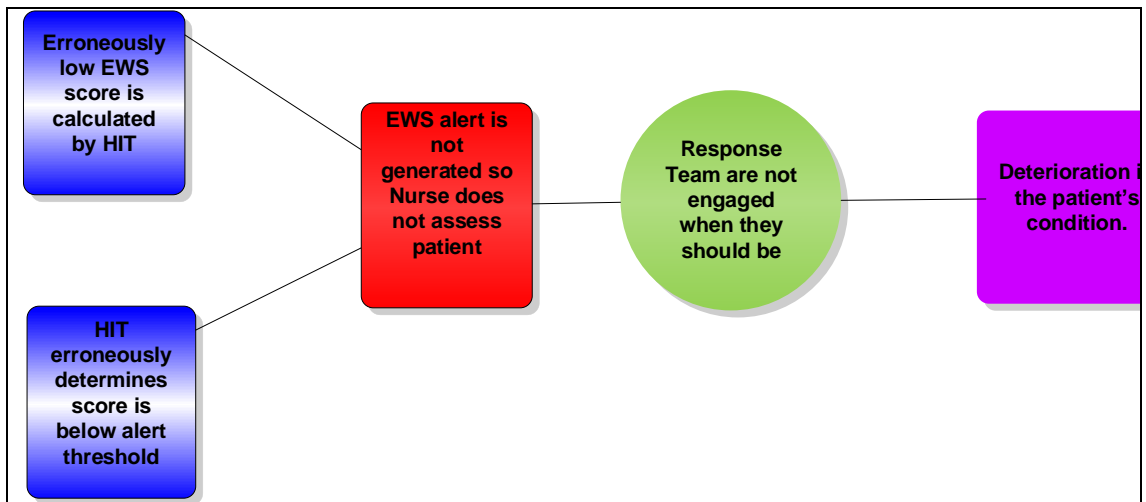
Simplified model of NEWS with elements of the methodology superimposed:



From which a hazard description can be established:

Low EWS score or score deemed to be lower than threshold results in alert not being generated when it should and subsequent and necessary patient assessment is not conducted by the nurse. Response Team are not engaged in circumstances where they are required which results in a deterioration in the patient's condition.

Which in turn can be transposed into an initial bow-tie diagram:



I would suggest that the methodology is complimentary and a pre-cursor to bow-tie analysis rather than being a different approach.

Resolution

Action T5.5.1 Ensure sufficient time for module delivery.

Action T5.5.2 Ensure that the purpose of the methodology and its applicability in the CRM process is clearly articulated in the training

Comments

“It helps to break it down in to understandable and practical steps as I think hazard and risk plus impact can be confusing.”

Yes, because so many people in project teams and front-line care still don't know the difference between Risk, issue, hazard, incident etc.”

Analysis

This feedback is encouraging and aligns with the research observations and objectives.

Resolution

None required.

Comments

“Would need to apply it to my own examples to see if it adds any value.”

I will be spending some time trying to incorporate the framework into my assessment of hazards and risks.

Analysis

It would be interesting to follow-up this up.

Resolution

None required.

Comments

I found it easy to follow and the colour coded element simplified the process.

Analysis

This is encouraging feedback and aligns with similar comments made at Table 5.2.3-2

Resolution

Non required

Table 29 - Table Review Question 2 Feedback & Analysis

Question	Y Response	N Response
Do you think the hazard description framework will be practical to use?	13	0
Comments <i>"Only really for smaller projects."</i>		
Analysis It would have been useful if this feedback could have been further substantiated. I don't believe that application of the framework and its effectiveness will be constrained by the size of the project. It is considered that this framework promotes the consideration of constituent elements of a harm scenario in a systematic and relational way, retaining focus on the potential of patient harm. This view is substantiated in the context of the evaluation documented at Section 5.4 where the framework was applied to a large-scale project. There is an area of weakness in the framework in circumstances where a large number of causes are identified and the difficulty in expressing these in natural language. As previously discussed, the purpose of the framework is not to support hazard analysis and care should be taken when applying the framework that causes are expressed at a suitably high level; the detail of which would be detailed in the subsequent hazard analysis activities. A worksheet and an example of using it to develop the hazard description was presented in the training: From the previous NEWS model:		
Cause	Erroneously low EWS score is calculated by HIT Or HIT erroneously determines score is below alert threshold	
Effect	EWS alert is not generated when it should be so Nurse does not assess patient	
Hazard	Response Team are not engaged when they should be	
Harm	Deterioration in the patient's condition.	
Leads to Low EWS score or score deemed to be lower than threshold results in alert not being generated when it should and subsequent and necessary patient assessment is not conducted by the nurse. Response Team are not engaged in circumstances where they are required which results in a deterioration in the patient's condition.		
Resolution See Action T5.5.2		
Comments <i>"Might be difficult to get to this granular detail on bigger projects- but maybe that's where the Agile approach would help?"</i>		
Analysis This feedback is similar to the preceding comment and one made in the workshop evaluation (Section 5.3). I would counter the observation; the purpose of the framework is to establish a high-level description of the harm scenario and not document the subsequent hazard analysis where the granular detail of the harm scenario would be established e.g. low-level causes and their associated controls. Applying the framework and identifying the constituent concepts in their relational sequence establishes a chain of thought that		

naturally leads into more detailed analysis of the scenario.
Resolution None required.
Comments <i>“But be aware that people will ‘adjust’ it to fit their workflows and mindsets. However, keeping the basics in mind when writing up Safety Cases will help.”</i>
Analysis An important comment. This observation aligns with the overarching philosophy embedded within the practice of CRM in the NHS. The two CRM standards establish a framework of requirements, supported by implementation guidance, that lead an organisation through the process of CRM. It is not prescriptive and does not dictate how CRM must be conducted. This framework has been developed to align with this philosophy; obviously it can be adopted and used as described and established in this thesis; similarly, there may be a need to “localise” it to align with organisational terms and concepts. However, the “basics” do need to be adhered to i.e. recognising that there are different elements in a harm scenario and a sequential relationship between these elements.
Resolution None required.

5.6 Summary

This was an effective evaluation activity with 13 out of 28 delegates providing a response. This aligns with the response rate routinely experienced by NHS Digital in feedback to their CRM training courses.

This phase of evaluation supports substantiation of objective 3 (practice). 100% of delegates considered that the methodology could be used in practice.

It also supports substantiation of objective 4 (communication). 100% of delegates considered that the framework aids an understanding of the harm-scenario.

The intention is that this module will be incorporated into NHS Digital’s CRM training programme.

6 Research Conclusions

Safety management of Health IT in the NHS is a relatively new discipline with the related standards not becoming effective until 2009 and not being formalised under the Health & Social Care Act until 2013. The concept of hazard is a fundamental element of the standards but other research and personal experience would indicate that it is not universally understood nor used within the health domain. The initial objective of this research (1.3i Section 1.3) was to substantiate this observation and understand the reasons why.

Whilst the literature review did reveal some use of the hazard as a proactive risk management concept the predominate theme and approach to risk management in the domain was shown to be that of reactive management with a strong emphasis on incidents. The qualitative appraisal of legacy hazards revealed that hazards are largely expressed in terms of technical failures, defects, human error or mis-information and often the potential harm impact to the patient is not captured.

The conclusions of this element of the research supported the second research objective 1.3ii Section 1.3) of providing a methodology that would support the domain in defining hazards that reflected meaningful and credible harm scenarios.

The approach taken was to establish a framework that would promote a patient centric view of a scenario and instil a structured thought process derived from key concepts that collectively provide the environment in which health IT supports care management and delivery.

The framework that has been developed is derived from best practice that is applied in benefits management within the NHS. It provides a simple structure of sequential constructs which exist in a particular context of a health-related socio-technical system. An ontology has been developed which can be used to derive and establish the hazard description. Alternatively, the constructs can be superimposed on care-pathway models to achieve the same result. The structure and sequence that is instilled within the hazard description can be transposed into a bow-tie model, initiating the next phase of hazard analysis whilst ensuring traceability and continuity between CRM activities.

Application of the framework is not constrained or dependant on a particular hazard identification process and can be applied in combination with or independently of any.

The framework has been subjected to a diverse and extensive programme of evaluation, including practical application. Feedback and analysis have been positive and convergent and indicates that the framework does address the research objective and is practical to use.

My personal motivation for embarking on this programme of research was to gain an opportunity to address a challenge within the NHS and to devise a solution to address it. I am pleased with the outcome and even more so with the uptake of the work within an external organisation and its inclusion within the national CRM training programme. This provides a real opportunity to foster a systematic approach to describing hazards that are relevant to the care-pathway in which they exist and to the patient harm outcomes that may result.

The status of specific actions and requirements raised during this research are summarised in Table 30

Table 30 - Research Actions

Requirement	Description	Resolution
T5.2.1	The toolkit shall describe and re-enforce the concept of a hazard and introduce this framework into the domain	This has been addressed in the CRM Training Module and will be addressed in the other toolkit elements (see Future Work Section 7)
T5.2.2	The toolkit shall re-enforce the patient care centric context in which hazard identification and description should be undertaken and that technology should be considered in the context of it contributing to a socio-technical system.	This has been addressed in the CRM Training Module and will be addressed in the other toolkit elements (see Future Work Section 7)
T5.2.3	The toolkit needs to support application of the framework in the context of generic hazard types.	This has been addressed in the CRM Training Module and will be addressed in the other toolkit elements (see Future Work Section 7)
T5.2.4	The toolkit needs to be amended to emphasise that hazards persist in the “people” context which can be defined as: (Patient and HCP) or (Patient	This has been addressed as per Section 4.4.3 and incorporated into the CRM Training Module.
T5.2.5	The toolkit needs to support the framework by describing key concepts	This has been addressed as per Section 4.4.3 and incorporated into the CRM Training Module
T5.2.6	The toolkit needs to describe how the framework can be transposed into an initial bow-tie model to support subsequent risk estimation activities	This has been addressed in the CRM Training Module and will be addressed in the other toolkit elements (see Future Work Section 7)
T5.5.1	Ensure sufficient time for module delivery	Delivery of CRM Module will be practiced in advance of 1 st formal training course. Independent evaluation of content and timing will be conducted.
T5.5.2	Ensure that the purpose of the methodology and its applicability in the CRM process is clearly articulated in the training	This has been addressed in the CRM Training Module and will be addressed in the other toolkit elements (see Future Work Section 7)
E5.2.1	The concept of a hazard shall be described in subsequent evaluation activities	The concept of hazard was defined and discussed in subsequent evaluation activities.
E5.2.2	The patient centric context in which a hazard exists shall be described in subsequent evaluation activities.	This was addressed in subsequent evaluation activities.

Requirement	Description	Resolution
E5.2.3	The concept of hazards existing in the “people” context will be emphasised in subsequent evaluation activities	This was addressed in subsequent evaluation activities.
E5.2.3	The toolkit needs to support the framework by describing the contribution a practitioner can make in a harm scenario	This was addressed in subsequent evaluation activities.

7 Future Work

7.1 Toolkit

The original research objective identified the establishment of a “toolkit”; this needs to be completed and formalised. The toolkit will be made up of 4 tools, the status of which are discussed below:

NHS Digital CRM Foundation Module: This has been developed and is derived from that delivered and discussed at Section 5.5. It is currently with the NHS Digital TRG for formal incorporation into the national training course. Current forecast is that this will be delivered from September 2019.

CRM Learning Resources: A “hazard identification how to guide” is being compiled based on the findings of this research. A significant element of the narrative at Section 4 and Section 5.4 is being used and will be complemented by examples of application of the framework. This will be issued under NHS Digital configuration control and be hosted on the Clinical Safety website:

<https://digital.nhs.uk/services/solution-assurance/the-clinical-safety-team/clinical-safety-documentation>. Current forecast is that this will be completed by September 2019.

DCB 0129 & DCB 0160 Implementation Guidance: A variant of the “how to guide” will be published and will support interpretation of the hazard identification requirements in the 2 CRM standards. This will be hosted at the following websites:

<https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems> &

<https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems>

Academic Paper: Explore the possibility and merit of writing a paper for publication.

7.2 SMART Requirements

The requirements established at Section 4 to extend the capability of SMART to implement this framework need to be reviewed by the development team. The principle aim of SMART is to provide an environment that supports CRM that aligns with the requirements of DCB 0129 & DCB 0160, instils rigour and traceability into the clinical risk management activities whilst reducing the burden of administrative and clerical work processes. In this context, the hazard description framework adds rigour and establishes traceability between activities.

7.3 Independent Evaluation of the Ontology

The workshop evaluation (Section 5.4) demonstrated that the framework could be successfully applied in circumstances where the care-pathway is supported by a representative model and a SWIFT approach to hazard identification is followed. Further work is required, beyond that undertaken by the author at Section 4, to demonstrate that hazard descriptions can be

established by using the ontology in scenarios where there is no model to articulate the care-pathway and/or other hazard identification techniques are used.

7.4 Structured English Framework

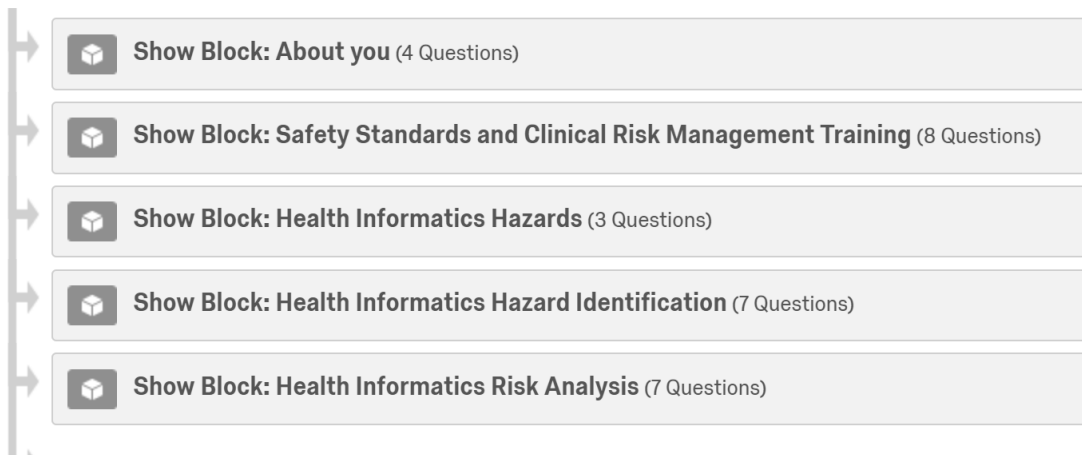
Consideration to be given to developing a formal framework with the use of structured language and a subset of descriptive terms. Whilst this would have benefit in improving consistency of practice and introducing uniformity into the domain, it would have to be considered in the context of the domain being relatively immature in safety management competency and operating outside of a regulatory framework (i.e. no mechanism to enforce it). There is a danger that too much prescription may disengage safety practitioners.

7.5 Application in Other Domains

Although the framework was specifically devised to support definition of health IT related hazards the potential to apply it in other safety related and safety critical domains should be explored. However, the domain of health IT differs from many others in one key area i.e. that the hazardous outcome (patient harm) occurs through the direct actions of people; there is no interaction or integration between the technology and the patient. Application of the framework to support risk management of MD seems to be a logical next step but, invariably, by definition MDs act as a point of actuation in the process of care management and delivery. Without pre-empting the outcome of such future work it is anticipated that some revision to the framework would be required.

Appendix A - Implemented Questionnaire

Survey Flow Hazard Identification and Risk Analysis in Health Informatics



Hazard Identification and Risk Analysis in Health Informatics

Part 1 About you (4 questions)

Q1.1 Please state your Job Title

Q3.2 Please state time in your current role

Q1.3 Please state the nature of your role

- Care professional (1)
- Management (2)
- Technical (3)
- Other, please specify (4) _____

Q1.4 Please indicate if you are involved in any of the following activities

- Specification of Health IT (1)
 - Procurement of Health IT (2)
 - Implementation & deployment Health IT (3)
 - Use of Health IT (4)
 - Maintenance of Health IT (5)
 - None of the above (6)
-

Part 2 Safety Standards and Clinical Risk Management Training (6 Questions)

Q2.1 Are you aware of the mandated safety standard SCCI 0129?

- Yes (1)
 - No (2)
-

Q2.2 Are you aware of the mandated safety standard SCCI 0160?

- Yes (1)
 - No (2)
-

Q2.3 To what degree do you think your organisation is compliant with the relevant SCCI standard? If possible, please explain why

- Fully compliant (1) _____
 - Partially compliant (2) _____
 - Not compliant (3) _____
 - Don't know (4) _____
-

Q2.4 Are you aware that the SCCI standards establish the need for a Clinical Safety Officer (CSO)?

- Yes (1)
 - No (2)
-

Q2.5 Do you know who fulfils the CSO role in your organisation?

Yes (1)

No (2)

Q2.6 Please only answer if you act as a CSO

Have you undertaken training in the principles of clinical risk management?

Yes (1)

No (2)

Part 3 Health Informatics Hazards (2 Questions)

Q3.1 Please select the statement which best defines a hazard

- An event or condition that results in harm (1)
 - Combination of probability of harm occurring and the significance of that harm (2)
 - An event or condition that has the potential to cause harm (3)
-

Q3.2 Please classify the following as either a hazard cause, a hazard control, a hazard or an accident

	Hazard Cause (1)	Hazard Control (2)	Hazard (3)	Accident (4)
Risk calculator gives incorrect rating (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dual checking of coding terms (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient administered statins when not required (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Incorrect coding terms in HIT system (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Part 4 Health Informatics Hazard Identification (6 Questions)

Q4.1 Please describe the purpose of hazard identification

Q4.2 Please list any hazard identification techniques that you use or have knowledge of

Q4.3 Do you or your organisation conduct hazard identification activities?

- Yes, please go to Q4.4 (1)
 - No, please go to Q4.6 (2)
-

Q4.4 How would you describe your degree of **competence** in conducting hazard identification activities

- Good competence (1)
 - Some competence (2)
 - No competence (3)
-

Q4.5 How would you describe your degree of **confidence** in conducting hazard identification activities

- Good confidence (1)
 - Some confidence (2)
 - No confidence (3)
-

Q4.6 If you answered No to Q4.3 above please can you state why

- Lack of awareness to do so (1)
- Lack of skill to do so (2)
- Lack of time to do so (3)
- Other Reason (4) _____

Q5.1 Please describe the purpose of risk analysis

Q5.2 Please list any risk analysis techniques that you use or have knowledge of

Q5.3 Do you or your organisation conduct risk analysis activities?

- Yes, please go to Q5.4 (1)
 - No, please go to Q5.6 (2)
-

Q5.4 How would you describe your degree of **competence** in conducting risk analysis activities

- Good competence (1)
 - Some competence (2)
 - No competence (3)
-

Q5.5 How would you describe your degree of **confidence** in conducting risk analysis

- Good confidence (1)
 - Some confidence (2)
 - No confidence (3)
-

Q5.6 If you answered No to Q5.3 above please can you state why

- Lack of awareness to do so (1)
- Lack of skill to do so (2)
- Lack of time to do so (3)
- Other Reason (4) _____

Appendix B – Legacy Hazard Review

Application of the framework to a set of legacy hazards is provided here:



Legacy hazard review.xlsx

Acute Care Setting Hazards

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT1-1	System failure	GP's unable to book due to system failure	Delay in patients agreeing appointments	Y	Y	Y	N	System failure results in practitioner not being able to review and subsequently book patient's preferred referral service (location, date and time). Patient may experience a delay in their care management and a subsequent deterioration in their condition.
ACT1-2	Delayed Messaging	Delayed MCCI message	Patient turns up on the day planned through Choose & Book but finds has no appointment.	Y	Y	Y	N	Delayed messaging results in secondary care appointment not being available at time the patient assumed. Patient may experience a delay in their care management whilst a alternative appointment is booked and a subsequent deterioration in their condition.
ACT1-3	Appointment slot issue (ASI)	If no slots are available (due to System Unavailability) in the patients chosen service they will be added to the Choose & Book ASI worklist.	Patient will not know immediately the date for their appointment.	Y	Y	Y	N	System failure results in practitioner not being able to review and subsequently book patient's preferred referral service (location, date and time). Patient may experience a delay in their care management and a subsequent deterioration in their condition.
ACT1-4	Certification expired	Failure to renew Provider Certificate.	Patients and GPs unable to book via the Choose & Book System. Potential delay in treatment though likely that alternative referral would be used for urgent cases.	Y	Y	Y	N	Expired certificate results in an inability to book a secondary care appointment. Patient may experience a delay in their care management and a subsequent deterioration in their condition.

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT1-5	System Unplanned Downtime	Unforeseen downtime of System	Patients and GPs unable to book via the Choose & Book System. Potential delay in treatment though likely that alternative referral would be used for urgent cases.	Y	Y	Y	N	Unplanned system down-time results in an inability to book a secondary care appointment. Patient may experience a delay in their care management and a subsequent deterioration in their condition.
ACT1-6	Potential for unknown impact on existing System functionality	Unforeseen effects on System linked to queue processes.	Effect across the totality of System	N	Y	N	N	
ACT1-7	Unable to obtain NHS Number for the mother's record	There is no antenatal record for the mother and unable to obtain NHS number	Can't complete baby registration	Y	Y	N	N	Mother's health record is not available which means baby's birth cannot be registered. Baby may miss subsequent screening and testing. Conditions such as cystic fibrosis may go undetected and baby's health subsequently deteriorates
ACT1-8	Birth Notification Data inaccurate	Birth Notification Data information within the maternity system inaccurate.	Inappropriate or missing care administered to the baby based on incorrect birth notification details.	N	Y	Y	N	
ACT1-9	Duplicate baby records created	Duplicate baby records created	If duplicate record exist for one baby, the HCP may provide treatment based on incomplete information	N	N	Y	N	Data migration process results in duplicate baby records being created. HCP may subsequently manage care based on incomplete medical record (other duplicate is more up to date). Baby's health could deteriorate.
ACT1-10	Confused record	NHS number manually entered incorrectly or entered against the wrong patient record	Subsequent care given to mother or baby could be inappropriate or missing e.g. Health visitor has wrong address details for baby or mother	Y	Y	Y	N	Data administration error results in a confused health record. Patient is administered care that is not appropriate to their condition and may experience a subsequent deterioration in their condition or an adverse reaction.
ACT1-11	Connectivity to spine failure - spine unavailable	HCP unable to use the system	Delay in obtaining NHS Number Delay in registering birth	Y	Y	N	N	Inability to communicate with Spine results in user being unable to a create a NHS number for the baby and register the birth. Routine screening programmes may be missed and the baby may subsequently suffer health conditions that would otherwise be detected.

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT1-12	Unplanned downtime of System	HCP unable to use the system	Delay in obtaining NHS Number Delay in registering birth	Y	Y	N	N	Unplanned downtime of system results in user being unable to create a NHS number for the baby and register the birth. Routine screening programmes may be missed and the baby may subsequently suffer health conditions that would otherwise be detected
ACT1-13	Certificate expired	Failure to renew Provider Certificate.	Delay in obtaining NHS Number	Y	Y	N	N	

Acute Care Setting Hazards

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT2-1		Unable to access the relevant prescription and/or medicine administration record.	Unable to manage care appropriately, there is potential delay in patient care.	N	Y	Y	N	System outage results in previous medical history not being available to support current prescribing activity. Patient is prescribed medication which they are allergic to and consequently suffer a reaction.
ACT2-2		Unable to view, enter or save clinical information into the Prescription and/or Medicine Administration solution.	Where information is not available for later consultation this may delay access to care.	N	Y	Y	N	
ACT2-3		Corrupt information is stored in the record.	Corrupted information in a prescription and/or administration can lead to delays in care in two ways: - Information is not available to support future activity - Corrupted information may be presented in a fashion that confuses or is ambiguous leading to a delay in care or inappropriate care being given.	N	Y	Y	N	High administrative workload results in erroneous patient data entry. HCP may subsequently manage care based on incomplete medical record. Patient's health could deteriorate.

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT2-4		Patient prescription and/or medicine administration details appear on incorrect patient record - confused prescription/medicine administration records created.	Data may be saved against an incorrect patient record. This results in clinicians working with incomplete or inaccurate information. This may lead to inappropriate care being given.	Y	Y	Y	N	Data administration error results in a confused health record. Patient is administered care that is not appropriate to their condition and may experience a subsequent deterioration in their condition or an adverse reaction.
ACT2-5		Demographic or administrative information is presented in a manner that is confusing or open to misinterpretation .	If the clinician is unable to positively identify the record, or an element of the record, as belonging to their patient it is possible that inappropriate care will be given to the patient.	N	Y	Y	N	
ACT2-6		Clinical information is presented in a manner that is confusing or open to misinterpretation .	The clinician may base care events upon information presented to them from the clinical record. Confusing or misleading information may result in inappropriate care being given. Where clinical information generates alerts or notifications the lack of these may result in actual harm. This may result in the misinterpretation of data and could lead to inappropriate care.	N	Y	Y	N	Use this as an example where hazard description is confused.
ACT2-7		Corrected/Additional data not displayed/recorded correctly.	The clinical record is the foundation of communication between clinical professionals. Inaccurate or missing information may result in inappropriate care being given e.g. patient may receive incorrect medicine, resulting harm to patient.	N	Y	Y	Y	

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT2-8		Hard or soft copy of the prescription for communication is not completed fully or accurately.	Incomplete or inaccurate clinical communication may lead to a delay in ongoing care or inappropriate care being given.	N	Y	Y	N	Failure to record prescription details correctly results in incomplete clinical communication between HCPs. The patient may experience a delay in care e.g. patient may receive incorrect medicine, resulting harm to patient.
ACT2-9		Unable to create, print or transmit a clinical communication.	Communication between care givers is vital if continuity of care is to be effective. The lack of ability to pass that information may result in a delay or loss of care activity.	N	Y	Y	N	
ACT2-10		Prescribing inaccurately calculates dose.	Patient/Child may receive toxic doses of drugs because of incorrect calculations or receive a non therapeutic dose if calculation is too low.	N	Y	N	Y	Erroneous dose calculator results in increased dosage instructions being presented which the prescriber adheres to and the patient is subsequently administered a toxic level of medication.
ACT2-11		The manner and frequency of presentation or failure to display an alert or consistency in icons, may result in high risk alerts being missed.	Patient treatment may be compromised by not noticing an alert.	Y	Y	Y	N	Poor system interface results in high risk alerts going un-noticed. Patient treatment is compromised and patient suffers side effect.
ACT2-12		Clinical Information validation ranges are inappropriate.	Where the clinical information validation range is inappropriate an inexperienced clinician may give inappropriate care on the basis of this information.	N	Y	Y	N	Drug dictionary errors result in incorrect validation ranges being established. An inexperienced clinician may administer inappropriate care and the patient's condition deteriorates.
ACT2-13		Fields with automatically precompleted entries could lead to incorrect clinical information being recorded.	Where incorrect clinical information is recorded it is possible that inappropriate care may be given.	N	Y	Y	N	Database design errors result in precompleted entries being populated with incorrect information. Incorrect care management decisions made and patient's condition deteriorates.
ACT2-14		Clinical Message Failure or error.	Messages that are faulty or do not arrive may cause a delay in care.	y	N	Y	N	
ACT2-15		System use is not as recommended.	Depends on what the inappropriate use consists of.	N	Y	N	N	

Acute Care Setting Hazards

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT3-1		Duplicate patient records are loaded into PAS when loading and converting patient record data from the organisation's legacy system.	If duplicate patient records exist in an organisation's implementation of PAS, then clinical information from one record might not be available in the second record.	Y	Y	N	N	Duplicate patient record is created which results in incomplete clinical history in record being used at the point of care. Individual patient's care maybe compromised or suboptimal resulting a deterioration in their health.
ACT3-2		A user does not enter sufficient search criteria in PAS to locate an existing patient record and creates a new, duplicate patient record.	If duplicate patient records exist in an organisation's implementation of PAS, then clinical information from one record might not be available in the second record.					This essentially is another cause to ACT3-1 ; this level of detailed should be addressed in the analysis of ACT3-1 rather than through the management of another hazard.
ACT3-3		A patient cannot be identified by healthcare staff and is unable to confirm their own identity (e.g., unconscious and lacking ID), and staff create a new, duplicate patient record.	If duplicate patient records exist in an organisation's implementation of PAS, then clinical information from one record might not be available in the second record.					As above
ACT3-4		A duplicate patient record could be created in PAS if an appointment is scheduled through a third-party scheduling system (e.g., CAB) and that system has a different NHS number associated with the patient's record than is associated with the patient's record in PAS.	If duplicate patient records exist in an organisation's implementation of PAS, then clinical information from one record might not be available in the second record.					As above

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT3-5		User error when registering a newborn or new patient: when performing a PDS trace, user selects the wrong patient from the options returned from the PDS.	<p>A key patient identifier (e.g., NHS number) that should be assigned to Patient "B" in PAS could instead be assigned to a different Patient "A."</p> <p>If Patient A's record is updated in PAS, those changes might result in unintended updates to Patient B's record in an interfaced third-party system that uses the patient identifier (e.g., demographics changes for Patient A in PAS might be associated with Patient B in PDS).</p> <p>If Patient B's record is updated in an interfaced third-party system that uses the patient identifier, those changes might result in unintended updates to Patient A's record in PAS. (e.g., CAB appointment placed for Patient B might be associated with Patient A in PAS).</p>	Y	Y	N	N	<p>Patient is mis-identified which results in another patient's record being updated. Incomplete or wrong patient record is used at the point of care. Individual patient's care maybe compromised or suboptimal resulting a deterioration in their health.</p>

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
ACT3-6		User error when registering a new-born or new patient: incorrect information is entered into PAS.	<p>A key patient identifier (e.g., NHS number) that should be assigned to Patient "B" in PAS could instead be assigned to a different Patient "A."</p> <p>If Patient A's record is updated in PAS, those changes might result in unintended updates to Patient B's record in an interfaced third-party system that uses the patient identifier (e.g., demographics changes for Patient A in PAS might be associated with Patient B in PDS).</p> <p>If Patient B's record is updated in an interfaced third-party system that uses the patient identifier, those changes might result in unintended updates to Patient A's record in PAS. (e.g., CAB appointment placed for Patient B might be associated with Patient A in PAS).</p>					See notes at ACT3-2; this is essentially another cause to ACT3-5

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Description	Hazard
ACT3-7		A user incorrectly merges two unique patient records in PAS.	<p>A key patient identifier (e.g., NHS number) that should be assigned to Patient "B" in PAS could instead be assigned to a different Patient "A."</p> <p>If Patient A's record is updated in PAS, those changes might result in unintended updates to Patient B's record in an interfaced third-party system that uses the patient identifier (e.g., demographics changes for Patient A in PAS might be associated with Patient B in PDS).</p> <p>If Patient B's record is updated in an interfaced third-party system that uses the patient identifier, those changes might result in unintended updates to Patient A's record in PAS. (e.g., CAB appointment placed for Patient B might be associated with Patient A in PAS).</p>					As above	

Patient Facing Services (Primary Care) Hazards

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Description	Hazard
APP1-1	PFS services unavailable	The patient cannot access Patient Facing Services	Unable to book appointment or order repeat prescriptions, especially true for deaf / mute patients	N	Y	Y	N	Patient Facing Services are not available which results in patients being unable to order repeat medications. Patient suffers a delay in receiving medications and their condition deteriorates.	

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
APP1-2	Information presented in confusing manner	The patient record may be presented to the patient in a confusing manner with such as text wrapping inappropriate, text truncation etc.	This would make could make information presented difficult to read and could lead to incorrect prescription being selected, appointments etc.	N	Y	Y	N	Poor App interface design results in patient's information being presented in a confusing manner. Patient subsequently makes a mistake (e.g. select wrong repeat medication) and their condition continues to deteriorate
APP1-3	Hidden information Displayed	Information recorded in the clinical system marked as hidden is visible to the patient or proxy	psychological trauma /upset	N	Y	N	Y	Flaw in app interface design results in data that is marked as hidden in clinical record not being masked. Hidden data becomes visible to patient who suffers psychological trauma /upset
APP1-4	Incorrect appointment booked	The patient selects an appointment but incorrect appointment or appointment type booked at practice	Possible delay to care /diagnosis where patient attend practice at wrong time and cannot be seen	N	Y	Y	N	App design results in a patient being unable to book appointment. Patient experiences a delay in accessing care and their existing condition worsens.
APP1-5	Appointment double booked	Multiple patients try to book the same appointment	Possible delay to care /diagnosis where patient attends practice but cannot be seen	N	Y	Y	N	This is a variant of AP1-4 and it is suggested that it could be managed under the same scenario
APP1-6	Appointment not booked	The Patient requests an appointment but it is not booked	Possible delay to care / diagnosis where patient attends practice but cannot be seen	N	Y	Y	N	As AP1-5
APP1-7	Prescription not available	The Patient requests a repeat prescription but not available for collection	Delay to prescription	N	Y	Y	N	App design results in a repeat prescription request not being actioned. Patient experiences a delay in getting their repeat medication and their existing condition worsens.

General observation: Review of this HL has highlighted that the manufacture of the app has not considered the causes of the hazards identified. Without understanding the causes, no meaningful risk assessment and evaluation can be undertaken. Inspection of the safety case (the formal review of which falls outside the scope of this research) illustrates that the manufacturer appeals to the availability of other business processes e.g. patient phoning GP surgery when app is not available as mitigation. This is disappointing as it illustrates that the manufacturer has not documented any consideration of potential failure modes of their technology and how these have been mitigated through development processes.)
PFS: Patient Facing Services:

Prescribing Hazards

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
PCP1	Repeat templates could result in erroneous mapping between dm+d and prescribing system	Repeat templates and changes to drug dictionary	Wrong drug / form / dose on the prescription. This relates to data migration problems, i.e. data on repeat template does not match what is on the message.	Y	Y	Y	N	
PCP2	Old data in PMR, not using dm+d	Repeat templates and changes to drug dictionary	Unable to send an electronic prescription	Y	Y	N	N	Data quality issues results in an inability to use electronic prescribing. Patient experiences a delay in receiving medication and existing condition worsens.
PCP3	PMR is using old dm+d data e.g. discontinued code, description etc	Repeat templates and changes to drug dictionary	Data on repeat template does not match what is in the message	Y	Y	N	N	It is unclear what the disruption would be to care process in this scenario.
PCP4	Incorrect historical data as a result of incorrect data migration during implementation.	Migration of existing data to dm+d could introduce errors	Wrong drug / form / dose on the prescription, particularly in relation to units of measure.	Y	Y	N	N	Transformation data errors introduced through data migration results in erroneous in prescription instructions. Patient is prescribed over/under dose and suffers unwanted side effects.
PCP5	Incorrect dm+d mapping between the prescribing system & the dm+d	Data provider incorrect Supplier use of third party data incorrect Errors due to deployment / configuration	Mismatch of prescriber's intention to electronic prescription. Patient may receive incorrect drug. Note dose and frequency covered in risk 5	Y	N	Y	N	Incorrect mapping of dm+d terms to proprietary terms results in erroneous in selection of medicine different to that intended. Patient is prescribed wrong medication and experiences unwanted side effects or reaction. Even in a HL hazards are referred to as risks
PCP6	Incorrect dm+d mapping between the prescribing system & the dm+d - drugs	Data provider incorrect Supplier use of third party data incorrect Errors due to deployment / configuration	Mismatch of prescriber's intention to electronic prescription. Patient may receive incorrect drug.					Duplication of PCP5
PCP7	Incorrect dm+d mapping between the prescribing system & the dm+d - forms	Data provider incorrect Supplier use of third party data incorrect Errors due to deployment / configuration	Mismatch of prescriber's intention to electronic prescription. Patient may receive incorrect form.					Duplication of PCP5

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	C	E	H	H	Re-expressed Hazard Description
PCP8	Incorrect dm+d mapping between the prescribing system & the dm+d - units/quantities	Data provider incorrect Supplier use of third party data incorrect Errors due to deployment / configuration	Mismatch of prescriber's intention to electronic prescription. Patient may receive incorrect dosage.					Duplication of PCP5
PCP9	Electronic prescription is incorrect & not as the Prescriber intended. This error is not identified by the Prescriber.	unfamiliarity/lack of knowledge of time pressure training workload system error prescriber error	Patient has wrong prescription (dose, frequency, drug) and is reliant on the Dispenser to identify the problem. That is to say, electronic prescription not as intended.	Y	Y	Y	N	
PCP10	Dose is free text based not code based	System design	Some of the automatic Electronic Prescription Service (EPS) checking that takes place cannot be carried out.	Y	Y	N	N	Free text dosage instructions means EPS safety checks cannot be undertaken Patient prescription has incorrect dosage instructions and patient suffers from under/overdosing.
PCP11	Cancellation request not sent/uploaded to the Spine.	technical error.	Consequences depend on the types of drug involved. Consequences could be worse if the GP thinks that a drug has been cancelled when there is a known allergy or contra-indication.	Y	N	Y	N	Cancellation request not sent to Spine which results in cancelled prescription reaching the pharmacy. Patient is dispensed medication that they should not have and experiences side effects or reaction
PCP12	An electronic cancellation message cannot be sent (e.g. system failure or prescription has already been dispensed) and Receptionist does not communicate cancellation information to Pharmacy or patient prior to dispensing	time pressure goal conflicts lack of clarity of roles and responsibilities	Drug dispensed and may be taken by the patient before they are notified about the cancellation.					This is a repeat of above but with a different low-level cause. This detail should emerge in the analysis of a common hazard to avoid duplication.

Appendix C - CSO Review

The research paper is provided here:



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Research context

The author's perception is that the concept of hazard is not widely used / understood in the healthcare domain; the concept of risk is predominately used. When considering the use of technology to support health care management and delivery, a risk often equates with a known issue, defect, bug or a dislike of the implementation.

As a consequence, where used, hazard definitions can become unstructured and don't necessarily capture the patient harm effect; predominantly they are described in causal terms e.g. "loss of N3 connection"

The focus of the author's research is to devise a methodology that can be used to address these observations and support practitioners in being able to define hazards that are patient centric and reflect the credible scenario from which patient harm *may* result.

Considering the concept of a hazard definition, it can be broken down into two properties

- Hazard Definition = Hazard Name (Identifier) + Hazard Description

Hazard Name is not an important property if it is simply thought of as means to establish a unique identifier for a particular hazard e.g. Haz 001.

Hazard Description is the key property. It needs to describe the prevailing condition from which credible patient harm could materialise and what could cause or contribute to the prevailing condition

Research Proposal - Devise a linguistic framework that provides constructs which will support the expression of meaningful and context relevant hazards

Information, people and technology

The patient safety consequences of using health IT cannot be considered by simply focusing on the technology in isolation. There is a need to take a holistic view, considering patient harm effects in the context of health informatics (HI) failures or flaws. Figure 1 illustrates the concept of HI i.e. the integration and interdependency that exists between people, technology and information in the support of care management:

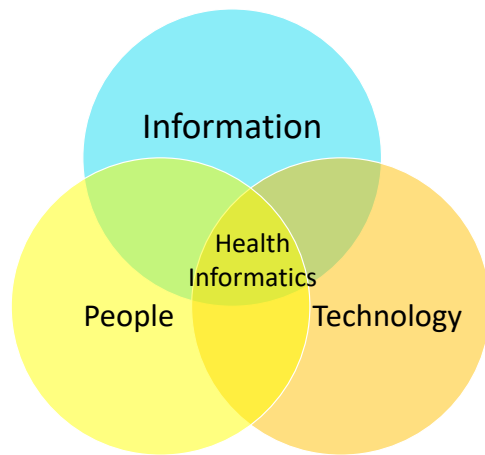


Figure 1 – Health informatics concept

The nature of this integration and the influence each component has on others in a generic healthcare environment is illustrated at Figure 2

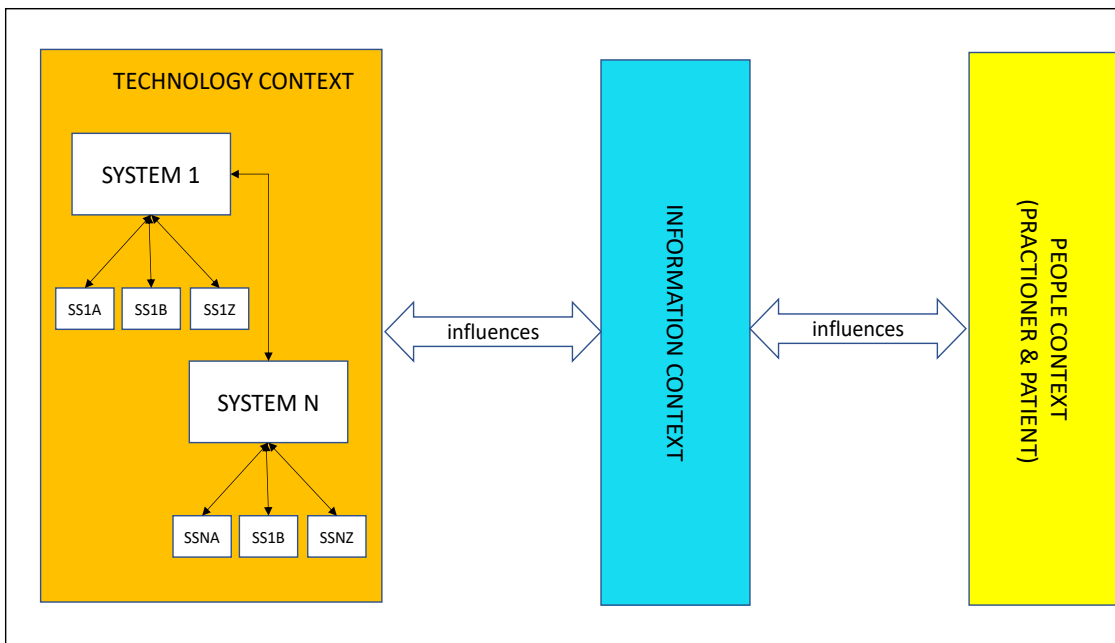


Figure 2 – HI Architecture

Hazards as (dis)benefits

Business management benefits

Benefits management principles establish key linguist constructs that are concatenated to form a meaningful expression of the benefit scenario:

Action: that which is done to initiate a change in real world state

Change: that which is new following the action

Outcome: the result of the change

Benefit: the advantage that the recipient gains

The effectiveness of this can be readily recognised in the following healthcare specific example:

Replacing the multiple systems that are currently in use with a single system will mean that health care staff will only need to log onto 1 system to find all the information they need. The log-on process will be quicker, releasing sufficient time for staff to see an additional patient during the course of clinic thereby reducing patient waiting times.

Benefits and harm events can be considered to be similar in that both have an impact on the user of the system or service and both occur following a change in the environment in which they exist. Whilst benefits are purposefully generated by initiating deliberate and specific actions, harm events occur as a consequence of some unwanted or unintended action being initiated.

By considering the definition of these four elements, an equivalence can be made to terms that are typically used to describe an accident sequence

- **Action** (n) The fact or process of doing something, typically to achieve an aim
 - Equates to a hazard cause
- **Change** (n) An act or process through which something becomes different
 - Equates to an effect in the hazard scenario
- **Outcome** (n): The way a thing turns out; a consequence
 - Equates to the hazard itself
- **Benefit** (n) An advantage or profit gained from something
 - Equates to the patient harm event

This framework can be integrated into the HI Architecture as depicted at Figure 2 to illustrate the context in which the linguistic elements exist, Figure 3. A key consideration in the domain of HI is the role of the practitioner. They are the “actuator” and administer care, taking into consideration the information they share with technology and the demands placed on them by the care environment. By using colours, it is clear in which particular context the linguist elements become relevant:

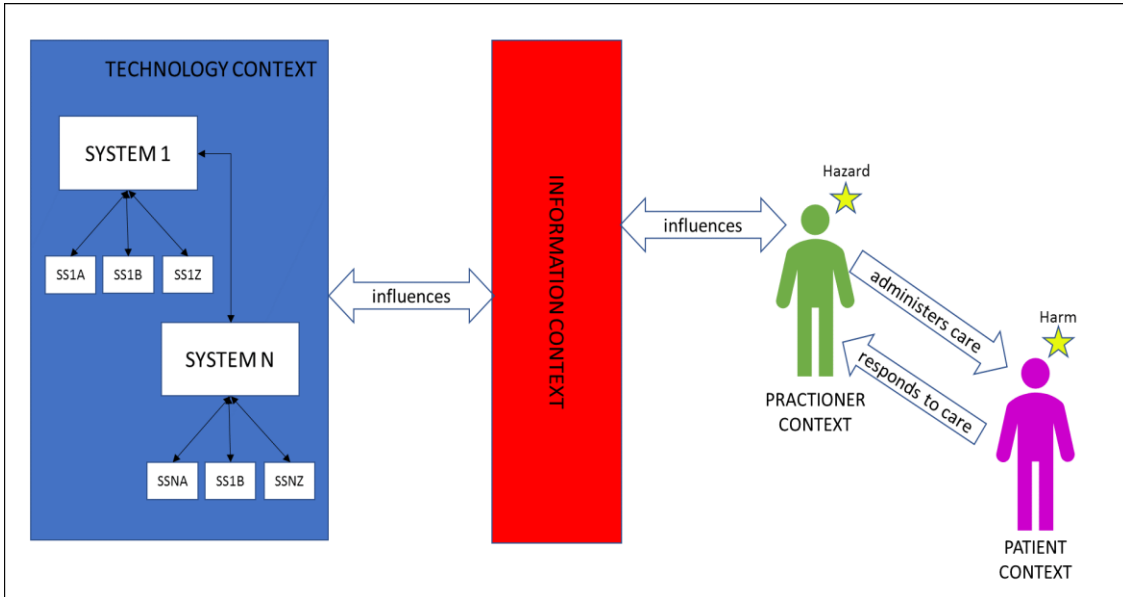
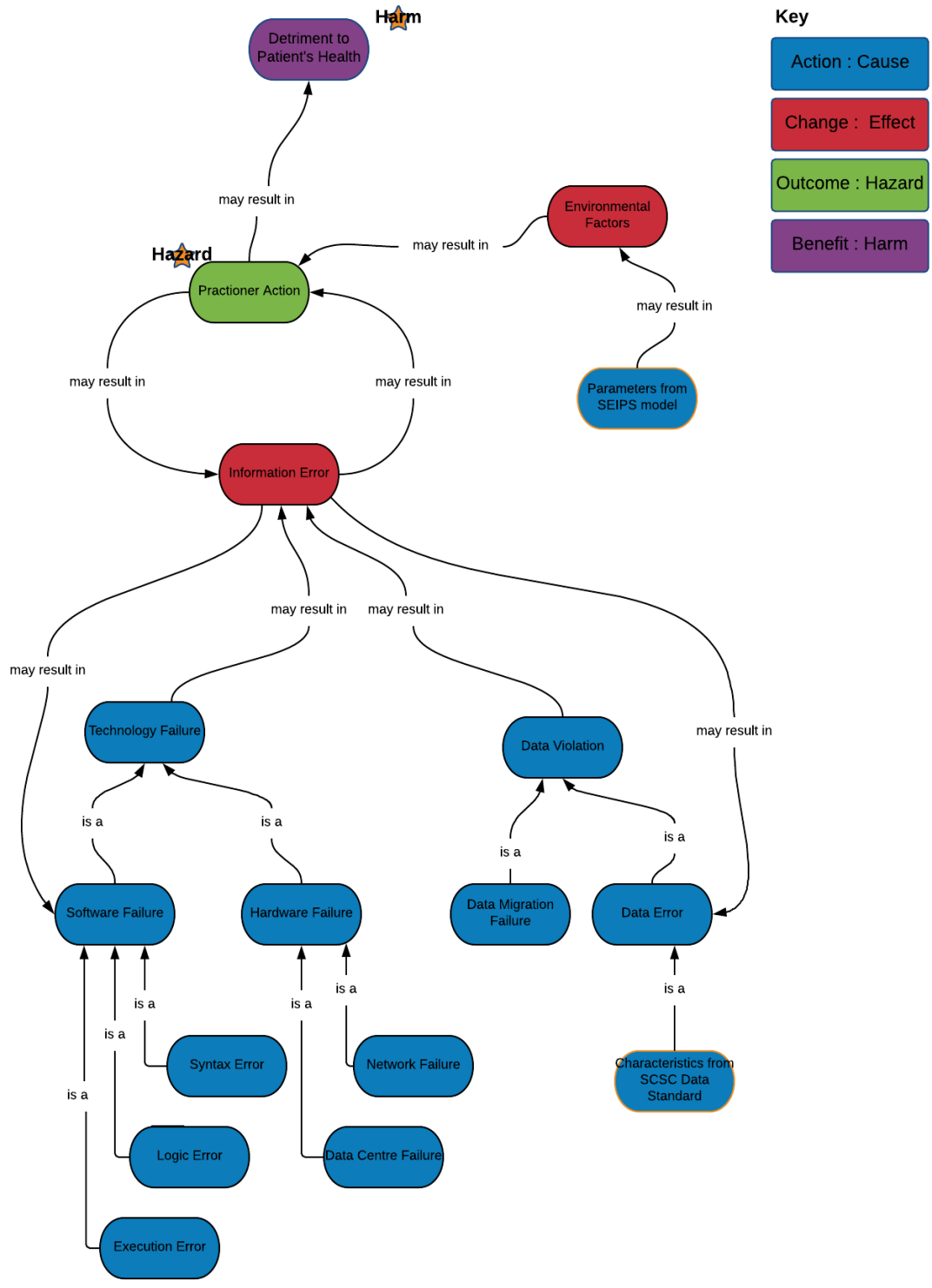


Figure 3 – Context of linguistic constructs

By considering and combining these constructs a harm event ontology can be established that identifies the key elements of an effective hazard description and the relationships between them. This is illustrated graphically at Figure 4.



OBJ

Figure 4 – Hazard description ontology

Example application

Hazard Id	Hazard Name (from HL)	Hazard Description (from HL)	Potential Clinical Impact (from HL)	Re-expressed Hazard Description
	Delayed Messaging	Delayed MCCI message	Patient turns up on the day planned through Choose & Book but finds has no appointment.	Delayed messaging results in secondary care appointment not being available at time the patient assumed. Patient may experience a delay in their care management and a subsequent deterioration in their condition.

In this example, the hazard is clearly described in causal terms and whilst the HL provides the opportunity to summarise the patient care impact it simply summarises a change effect in the patients care pathway.

Applying the framework enables a rich expression of the harm scenario to be articulated which in turn would support a more structured and justified risk assessment. In this example, the re-expressed hazard description still remains generic but could be readily amended to reflect the scenario in a specific care path way e.g. 2 week wait guidelines relating to cancer referrals.

The blank feedback form is provided here:



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Question	Y/N	Comments
Is the research observation regarding hazard definition in the domain of health informatics representative?		
Does the linguistic methodology proposed aid meaningful hazard definition?		
Are there any flaws or weakness in the proposed methodology?		
Please express any other views or comments.		
Do you give permission for your responses to be anomalously quoted within the scope of the thesis report?		

Appendix D – Safety Conference

Presentation

The presentation is provided here:



5.3

Presentation.pdf

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Health IT Safety Cases



Information and technology
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NHS Digital Clinical Safety Team

Agenda

Time	Activity	Presenter
9:30	The Case for Safety	SW
10:00	Effective Hazard Definition	SW
10:30	A SMART Overview	SL
10:45	Coffee	
11:00	Wearable Clinic – Safety Assessment	SL
12:30	Wearable Clinic – Safety Case Report	SL
12:45	Feedback	SW/SL
13:00	Lunch	

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Defining hazards

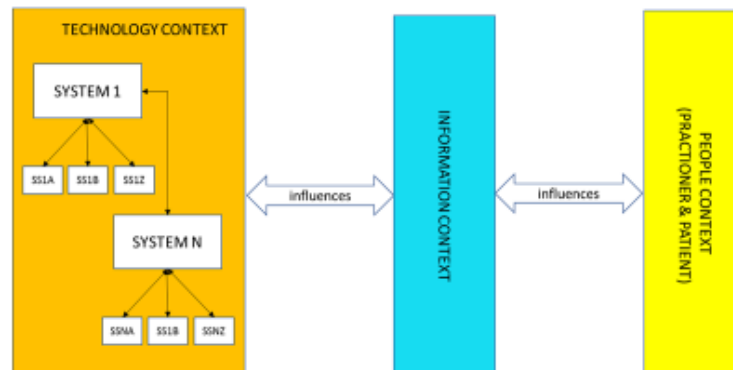
- If we don't understand our hazards we can't establish a safety case
- Not easy to do!
- Level of abstraction is a challenge
 - Cause, hazard or consequence
 - Cause: something that if unchecked can lead to a hazard
 - Hazard: condition that could result in harm
 - Consequence: occurrence of harm; realisation of the hazard

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Defining hazards

- Need to look at big picture: T I P



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Digital

Defining hazards

- From T I P we can establish that:
 - a “Consequence” can only happen in the “People Context”
 - Information cannot cause direct harm
 - But it can influence the decisions and actions of HCP
 - So “hazards” must occur in the “People Context”
 - Technology can't cause direct harm
 - But if it goes wrong or is misused it can influence information
 - So Technology must be a “cause” of a “hazard”

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NHS
Digital

Defining hazards

- But are we missing something?
 - What is the “effect” of the “cause” on what we are trying to do
 - and
 - Can the “effect” result in a “hazard” which may lead to a patient harm “consequence”

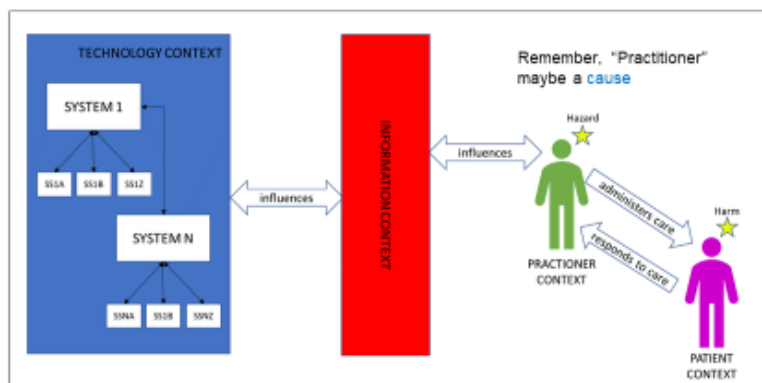


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NHS
Digital

Defining hazards

- In the bigger picture

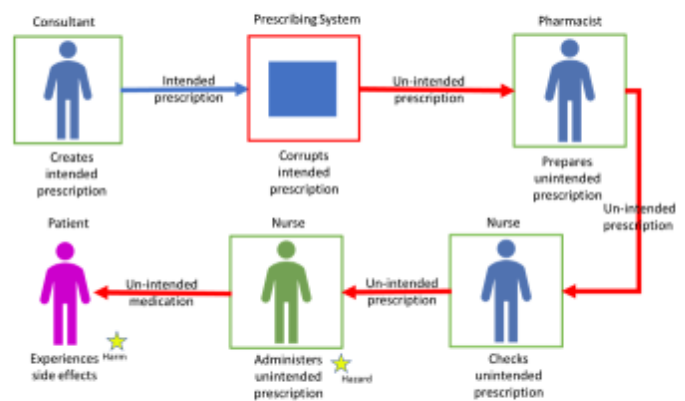


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Defining hazards

- Remember
 - Causes are not necessarily failures
 - People can do the right thing and propagate the problem



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Defining hazards

- Putting it into practice

There is no antenatal record for the mother and unable to obtain NHS number. Can't complete baby registration.

or

Mother's health record is not available which means baby's birth cannot be registered. Baby may miss subsequent screening and testing. Conditions such as cystic fibrosis go undetected and baby's health subsequently deteriorates.

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Delegate feedback is provided here:



5.3 Feedback.pdf

	Do you think the hazard definition technique supports meaningful description of Health IT related hazards?	Please provide reasoning	Do you think the hazard definition technique will be practical to use in a hazard workshop?	Please provide reasoning
1	Yes		Yes	
2	Yes		Yes	
3	Yes		Yes	
4	Yes		Yes	
5	Yes		Yes	
6	Not Answered		Not Answered	
7	Yes		Yes	Though may in effect slow down the process while users get used to using the tool!
8	Not Answered		Yes	defining needs to be simple... this was
9	Yes	in principle, but if it could be tied in with actual examples.	Yes	
10	Yes	Hazards, causes, effects are frequently confused but the use of the tool should prevent this.	Yes	I think so but today we worked individually.
11	Yes	Allows causes and controls to be visualised which helps to show how they feed into care process.	Yes	Helps to fit into care process.
12	No		No	
13	No		No	
14	Yes		Yes	

	Do you think the hazard definition technique supports meaningful description of Health IT related hazards?	Please provide reasoning	Do you think the hazard definition technique will be practical to use in a hazard workshop?	Please provide reasoning
15	No	do you mean the defining of the hazards within the tool? - if so, then i'd prefer to just use the hazard log	No	i was disapointed with this workshop - i had thought we would have spent more time on a safety case rather than on using a beta software not currently available to me that appears to take longer to formulate a hazard log entry than the current processes we use
16	Yes		Yes	Often hazards are not correctly identified
17	Not Answered	Don't know - haven't had a chance to properly try it yet.	Not Answered	Don't know - haven't had a chance to properly try it yet.
18	Yes		Yes	
19	Yes		Yes	
20	No		No	
21	Not Answered		Not Answered	
22	Yes	We discussed TIP?	Yes	
23	Yes		Yes	It will be helpful to help all involved to clarify hazards
24	No	No. It seems to be that it is mainly developed by IT employees. It think clinicians could have been involved in developing this SMART specially nurse clinicians.	Yes	
25	Yes		Yes	
26	Yes		Yes	

	Do you think the hazard definition technique supports meaningful description of Health IT related hazards?	Please provide reasoning	Do you think the hazard definition technique will be practical to use in a hazard workshop?	Please provide reasoning
27	Yes	Yes, with the knowledge around safety engineering and how this is being translated over to healthcare this is an unknown for health care and gives structure to this element of the digital healthcare, re day 1.	Yes	Know your audience, initially participants did not want to do this, once started i heard people say they liked it. What is in it for me, show them the report first maybe and then this is how we get there.....
28	Yes	Yes, but only in tightly defined care processes. Difficult for a supplier providing a generic form building capability to be used across healthcare. If a Healthcare Provider then had to assess each form they had built(using the form builder) it would be a big overhead.	Yes	It would be practical for a workshop assessing smaller systems which support specific care processes that are well bounded. Assessment of a larger system like an EPR that supports many different clinical processes in multiple care settings in a generic way would require MANY such workshops. This would be too large an overhead. It may be suitable for upgrades if they introduce a new tightly bounded feature.

Appendix E – Safety Training Module

The training module is provided here:



5.5 Training Module.pdf

Clinical Safety Community of Interest



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NHS Digital Clinical Safety Team

Agenda

Time	Activity	Presenter
9:00	Coffee and Registration	
9:30	Module 1: Welcome + Course Introduction	JW
10:00	Module 2: Developments in Health IT (1)	SW / JW
10:45	Module 3: Networking	All
11:15	Coffee	
11:30	Module 4: Presentation by Google - 30 min presentation 15 min QA	CA
12:15	Lunch	
13:00	Module 5 Incident Management	JW
13:30	Module 6: Developments in HIT (2)	JW
14:00	Module 7: Networking	All
14:30	Coffee	
14:45	Module 8: Presentation by Chelsea and Westminster Hospital - 30 min presentation 15 mins QA	GH
15:30	Module 9: Hazard Definition	SW
16:00	Module 10: Feedback & Course Close	SW
16:30	Finish	

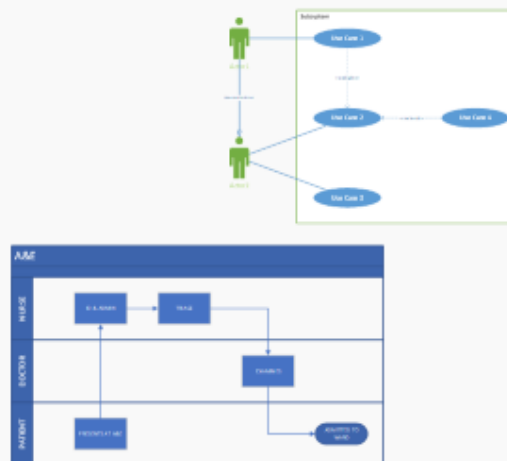
Why use hazards?

- Need to understand how deviations from what we intend to do can cause harm
- Need to be able to communicate and explain these scenarios
 - If we cant we cant establish a safety case
- Not easy to do!
- Biggest challenge seems to be level of abstraction
 - Faults, bugs, defects

3

Defining hazards

- Starting point is system definition and clinical use
 - Reqs 4.2.1 & 4.2.2
- Use models



4

Defining hazards

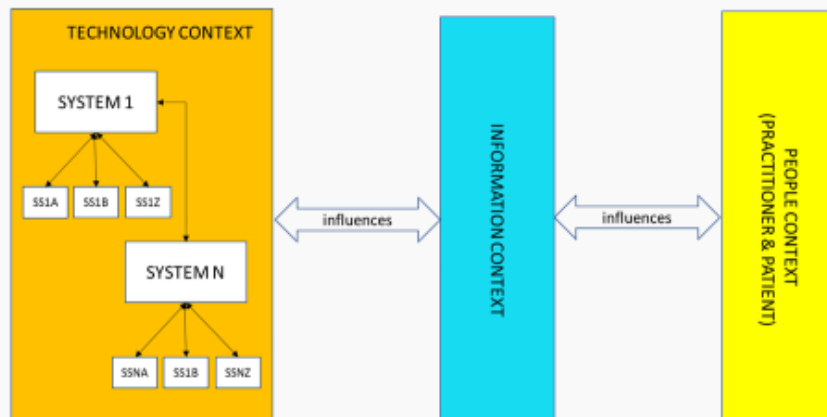
- Safety of HIT can't be considered in isolation
- Need to look at big picture
- Part of socio-technical system
- Hazards expressed in context of people



5

Defining hazards

- Need to look at big picture: Tech-Info-People (TIP)



6

Defining hazards

- From TIP we can establish that:
 - Harm can only happen in the “People Context”
 - So “hazards” must occur in the “People Context” also
 - Information cannot cause direct harm
 - But it can influence the decisions and actions of HCP and patients
 - Technology cant cause direct harm
 - But if it goes wrong or is misused it can influence information
 - So Technology must be a cause of a hazard

7

Defining hazards

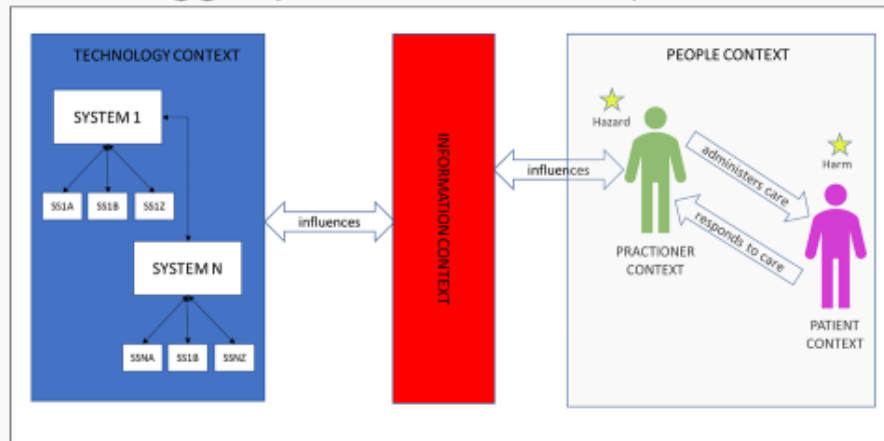
- But are we missing something?
 - What is the “effect” of the “cause” on what we are trying to do
 - and
 - Can the “effect” result in a “hazard” which may lead to a patient harm “consequence”



8

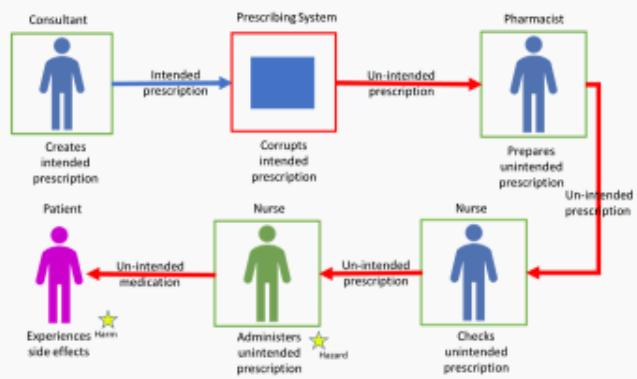
Defining hazards

- In the bigger picture



Defining hazards

- Remember
 - Causes are not necessarily failures
 - People can do the right thing and propagate the problem



10

Defining hazards – a linguistic framework



- Recognising the different hazard concepts
- Remembering the logical sequence between concepts
- Using colour to emphasis
 - Establish meaningful hazard descriptions

11

Defining hazards

- Putting it into practice

There is no antenatal record for the mother and unable to obtain NHS number. Can't complete baby registration.



Mother's health record is not available which means baby's birth cannot be registered. Baby may miss subsequent screening and testing. Conditions such as cystic fibrosis go undetected and baby's health subsequently deteriorates.

12

Defining hazards

- Putting it into practice

There is no antenatal record for the mother and unable to obtain NHS number. Can't complete baby registration.

or

Cause **Mother's health record is not available.**

Effect **Which means baby's birth cannot be registered.**

Hazard **Baby may miss subsequent screening and testing.**

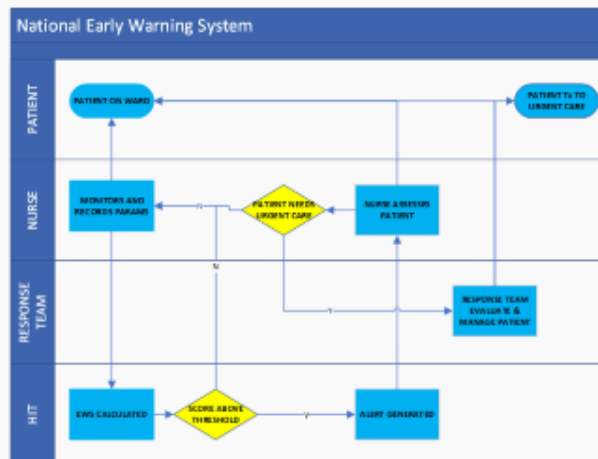
Harm **Conditions such as cystic fibrosis go undetected and baby's health subsequently deteriorates.**

13

Informing risk analysis

- NEWS

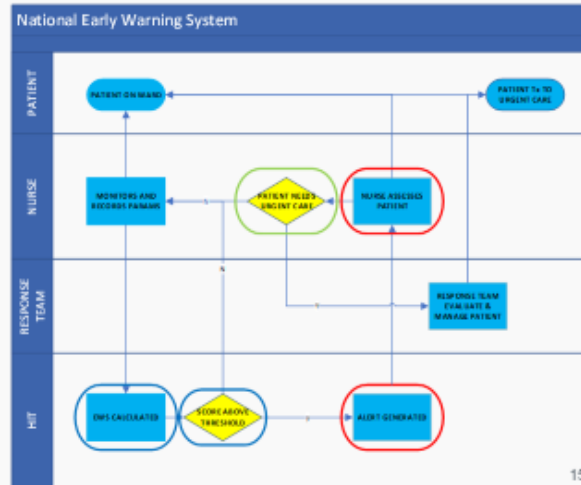
- Monitors 6 vital signs to improve detection of clinical deterioration
- Enables earlier intervention to support better outcomes
- Start with a simple model



14

Informing risk analysis

- Annotate using colours to identify hazard elements



Informing risk analysis

Cause	Effect	Hazard	Harm
Cause	Erroneously low EWS score is calculated by HIT Or HIT erroneously determines score is below alert threshold		
Effect	EWS alert is not generated when it should be so Nurse does not assess patient		
Hazard	Response Team are not engaged when they should be		
Harm	Deterioration in the patient's condition.		

Low EWS score or score deemed to be lower than threshold results in alert not being generated when it should and subsequent and necessary patient assessment is not conducted by the nurse. Response Team are not engaged in circumstances where they are required which results in a deterioration in the patient's condition.

16

Informing risk analysis

- Establishes basis of bow-tie model
- Yes it's a simplistic model
 - Nurse making incorrect assessment
 - Subsequent actions of Response Team
- But.....



17

Questions

?

18

Workshop

- Create a model of a simple care process
- Analyse the model and identify hazard elements



- Construct hazard description using worksheet
- Develop initial bow-tie model
- Be prepared to present your work!

19

Worksheet

Cause	
Effect	
Hazard	
Harm	

Hazard Description:

20

Delegate feedback is provided here:



5.5 Training
Feedback.pdf

	Do you think the hazard description framework helps to establish meaningful hazard descriptions?	Comments	Do you think the hazard description framework will be practical to use?	Comments
1	Yes	Interesting and helpful definition of a hazard but a bit different from the Bow Tie concept which is a potential harm to a patient. Both concepts have their strengths and I think the important thing is to have a clear definition which is then used consistently throughout the risk management work-flow	Yes	
2	Yes		Yes	Only really for smaller projects.
3	Yes		Yes	
4	Yes		Yes	
5	Yes		Yes	
6	Yes	It helps to break it down in to understandable and practical steps as I think hazard and risk plus impact can be confusing	Yes	
7	Not Answered	Possibly- would need to apply it to my own examples to see if it adds any value.	Not Answered	Might be difficult to get to this granular detail on bigger projects- but maybe that's where
8	Yes	We didn't really have a lot of time to discuss this as we were rushing at the end. I know that I sometimes have to spend time re-framing a hazard - I can see that	Yes	the Agile approach would help? But be aware that people will 'adjust' it to fit their workflows and mindsets. However, keeping the basics in mind when writing
9	Yes	I found it easy to follow and the colour coded element simplified the process.	Yes	
10	Not Answered		Not Answered	I had to leave as the session started later than planned so
11	Yes	Yes because so many people in project teams and front line care still don't know the difference between Risk, issue, hazard, incident etc	Yes	

	Do you think the hazard description framework helps to establish meaningful hazard descriptions?	Comments	Do you think the hazard description framework will be practical to use?	Comments
12	Yes		Yes	
13	Yes	Unfortunately, this presentation came at the end of the day and time was running out so felt a little rushed.	Yes	
14	Yes		Yes	I will be spending some time trying to incorporate the framework into my assessment of hazards and risks. I would appreciate receiving the

Abbreviations

A&E	Accident and Emergency
CRM	Clinical Risk Management
CSO	Clinical Safety Officer
DCB	Data Coordination Board
EPS	Electronic Prescription Service
EU	European Union
HCP	HealthCare Practitioner
HI	Health Informatics
HIT	Health Information Technology
IT	Information Technology
MD	Medical Device
MDD	Medical Device Directive
MDR	Medical Device Regulation
NEWS	National Early Warning Score
NHS	National Health Service
NPFiT	National Programme for IT
SCR	Summary Care Record

Glossary of terms

Term	Definition	Source of definition
Care-pathway	The organisation of care processes, care management decisions and resources need to support the care needs for a defined group of patients.	This research, derived from (Vanhaecht, 2010)
Cause	An event or action that occurs in the care-pathway that by itself or in combination with other causes can result in the occurrence of harm. A cause may reflect an intentional event/action or an unintended event/action.	This research
Clinical Risk Management	Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling clinical risk	DCB 0129 / DCB 0160
Clinical Safety Officer	Person in an organisation responsible for ensuring the safety of a Health IT System in that organisation through the application of clinical risk management.	DCB 0129 / DCB 0160
Effect	The variation or deviation that is introduced into the care-pathway from what should be conducted to that which is conducted.	This research
Harm	Death, physical injury, psychological trauma and/or damage to the health or well-being of a patient.	DCB 0129 / DCB 0160
Harm-scenario	A representation of those events that could occur in the care-pathway (either intentionally or unintentionally) that could credibly result in harm to a patient who is being managed on the care-pathway.	This research
Hazard	Potential source of harm to a patient.	DCB 0129 / DCB 0160

Term	Definition	Source of definition
Hazard Identification	Process of identifying and documenting known and foreseeable hazards to patients in both normal and fault conditions	DCB 0129 / DCB 0160
Risk	Combination of the severity of harm to a patient and the likelihood of occurrence of that harm.	DCB 0129 / DCB 0160
Risk Evaluation	Process of evaluating whether the hazard risk is acceptable.	Adapted from

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