Hazard and Risk Analysis of Health Informatics: Fundamental Challenges and New Directions

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Abstract *There is an increasing focus on the importance of the availability and interchange of digital health information within health and care organisations as a means of improving patient care quality and outcomes. In England, this has recently been emphasised through the Government's vision for a 'paperless' National Health Service (NHS) by 2020. The scope of the technology supporting health informatics is expanding and is used to improve the integration between primary, secondary, community and social care settings. To promote patient-centred care, mobile apps, wearable devices and social media are used to actively involve patients in their own health and well-being management. Despite potential benefits, the new information-intensive capabilities pose a fundamental safety challenge: how should engineers and health and care professionals identify hazards and assess the risks posed by the technology in this large-scale, complex and dynamic socio-technical system? In this paper, we deconstruct this challenge and identify concrete safety problems, and opportunities for improvement, by examining current practice in hazard and risk analysis for health informatics. We then introduce the Safety Modelling, Assurance and Reporting Toolset (SMART), which has been developed collaboratively between The University of York and NHS Digital to help address these challenges and support clinicians and engineers to systematically assure the safety of health informatics.*

1 Introduction

It is now widely accepted that healthcare is a complex and adaptive sociotechnical system (Meeks et al. 2014). Within this system, there is a continuous need to manage and communicate the right information to the right people, at the right time and in the right format. This is increasingly being enabled through health informatics technologies. These technologies have therefore become a critical infrastructure in healthcare, e.g. in complex scenarios such as those involved in transferring and maintaining electronic health records and in ePrescribing. Recently, the healthcare landscape has expanded by the use of mobile health apps, empowering patients to take a more active role in their care.

Patient safety is a fundamental concern. These technologies can potentially improve patient safety but might also introduce new hazards. For example, ePrescribing can reduce transcription errors (due to doctors' famously challenging handwriting), but might also increase the risk of alert fatigue.

However, despite the major investments worldwide in health informatics, there remains "*a large gap between the postulated and empirically demonstrated benefits of*" these technologies (Black et al. 2011). Further, given the interactive nature of health informatics with its care setting, for the safety evidence to be credible, research studies have to explicitly and carefully capture the socio-technical factors associated with the implementation and use of health informatics (Sittig et al. 2010).

In this paper, we explore the challenges of performing hazard and risk analysis for health informatics by reviewing current safety assurance practices in England. We focus both on areas of strength and improvement. We then introduce the Safety Modelling, Assurance and Reporting Toolset (SMART), which has been developed to help address these challenges and support clinicians and engineers to systematically perform hazard and risk analysis and develop safety cases for health informatics.

2 Health informatics, a safety related domain?

The term *health informatics* is widely used within the National Health Service (NHS) and can be described as the "*optimal use of information, often aided by the use of technology, to improve individual health*" (Hersh 2009). Health Informatics is socio-technical in nature and relies on the effective interaction between the people providing and receiving care, the information they analyse in making

care decisions and the technology that provides the information and supports the care processes. These interrelationships are illustrated in Figure 1.

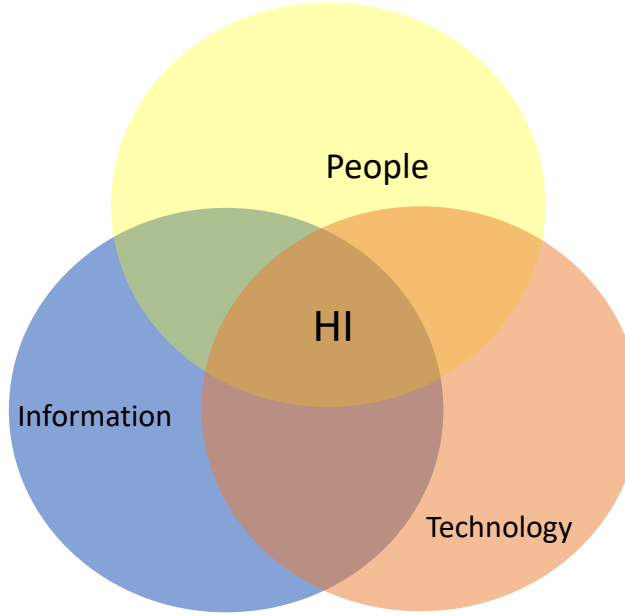


Fig. 1. Health Informatics (HI) in context

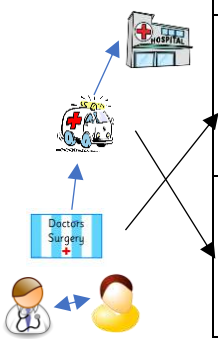
Health Information Technology (HIT) is a key enabler of health informatics and is now firmly embedded in modern health and social care delivery (NHS England). The ability of an organisation to deliver such care can be significantly compromised should the integrity of the supporting HIT be affected (Ash et al. 2004). Although it was a security rather than a safety event, in May 2017, a global ransomware attack infected the IT infrastructure in 48 NHS organisations resulting in HIT systems being shut-down and all but emergency care being suspended or cancelled (department of Health 2017

Despite the prominence of HIT within the NHS, paper-based processes still exist at a large scale, especially in secondary care, and are used on a daily basis to support care management. The UK Government, has established a framework that will "*give care professionals and carers access to all the data, information and knowledge they need – real-time digital information on a person's health and care by 2020*" (Department of Health 2014). Similarly, the Government recognises the need for more effective integration between the health and social care domains and will "*create an electronic database that will provide information about what a person's care needs are and what treatment they are getting*" (Department of Health 2013).

The scale and complexity of HIT is wide ranging. There are *national services* such as the Electronic Prescription Service (EPS), which enables a General Practitioner (GP) to create a digital prescription in their desktop system and then authorise the prescription using a unique electronic signature before uploading it to national infrastructure. This will then relay the prescription to the patient's preferred pharmacy. On receipt, the Pharmacist can pull-down the electronic prescription into their desktop HIT system and prepare the medications in advance of the patient arriving at the pharmacy.

Another form of HIT is *Telehealth*, which enables the sharing of data between a patient and their carer at remote locations, potentially reducing the need for unnecessary face-to-face consultations, where appropriate. Typically, telehealth is used to monitor patients with long-term conditions such as chronic heart failure or those that have recently been discharged from hospital. Sensors and wearable devices provide real-time information, which can be communicated to the care practitioner.

But in what way is HIT a safety-related system? Figure 2 illustrates how health informatics can contribute to patient harm in a typical care journey.



HI Contribution	Hazard	Care Context	Harm
Drug mapping error in GP Prescribing system	Patient receives unintended medication	Patient is allergic to the prescribed medication	Patient suffers allergic reaction and requires specialist hospital treatment.
Ambulance dispatch system has wrong destination data	Patient experiences delay in care delivery	Patient has health condition that requires timely assessment	Patient health condition deteriorates, potentially to critical levels

Fig. 2. Health informatics hazard contribution

Care delivery differs in many respects to that of more widely recognised safety related domains. A care journey is dynamic in nature, influenced by the underlying patient conditions, variance in operating procedures, varied stakeholders, configurations of the supporting technology and the unpredictable day to day operation of a health or care organisation. Invariably the care journey, which is often long and complex, starts from an unsafe state and transitions to a safer state i.e. a patient will have a life impacting condition or complaint that is subsequently managed to point where it is eradicated or its impact reduced. Conversely, for example, an aircraft journey starts from a safe state and the aircraft is

subsequently managed to preserve that safe state or to safely manage any deviations from it.

3 Health informatics - current safety practice in the NHS

3.1 Current safety standards

In England, the NHS has been promoting and supporting risk-based approaches for HIT safety assurance through the Health and Social Care Act (2012) and by establishing a dedicated Clinical Safety Team at NHS Digital. NHS Digital is a public body within the Department of Health that is responsible for providing data and HIT systems for commissioners, analysts and clinicians in health and social care. Two safety standards, SCCI0129 (SCCI 2013) targeting HIT manufactures SCCI0160 (SCCI 2013) targeting care organisations have been issued by the Standardisation Committee for Care Information on behalf of NHS England. These standards specify normative requirements, supported by informative guidance, for the implementation of a risk management process and demonstration of organisational commitments. These standards mandate the appointment of Clinical Safety Officers (CSOs) who, in their capacity as experienced clinicians, are expected to lead the HIT risk management activities.

The SCCI0129 and SCCI0160 safety standards follow the risk management principles established for medical devices and are consistent with ISO14971 (ISO 2009). The overall risk management process is depicted Figure 3.

The risk management process commences with defining the HIT system and its clinical scope. This includes the intended system functionality, e.g. prescribing or patient identification, and the specific care setting within which the system is deployed, e.g. maternity unit. Once the scope is established, hazards are identified principally by considering how the HIT system could fail or be misused.

In this context, a hazard is defined as "potential source of harm to a patient" (SCCI 2013), e.g. the patient receives more than the intended drug dose. The risk of each hazard is then estimated. A risk is defined as the "combination of the severity of harm to a patient and the likelihood of occurrence of that harm" (SCCI 2013), e.g. the likelihood that the patient suffers a permanent life-changing incapacity as the result of the drug overdose. Each risk is then evaluated against predefined acceptability criteria, e.g. as defined in a risk matrix.

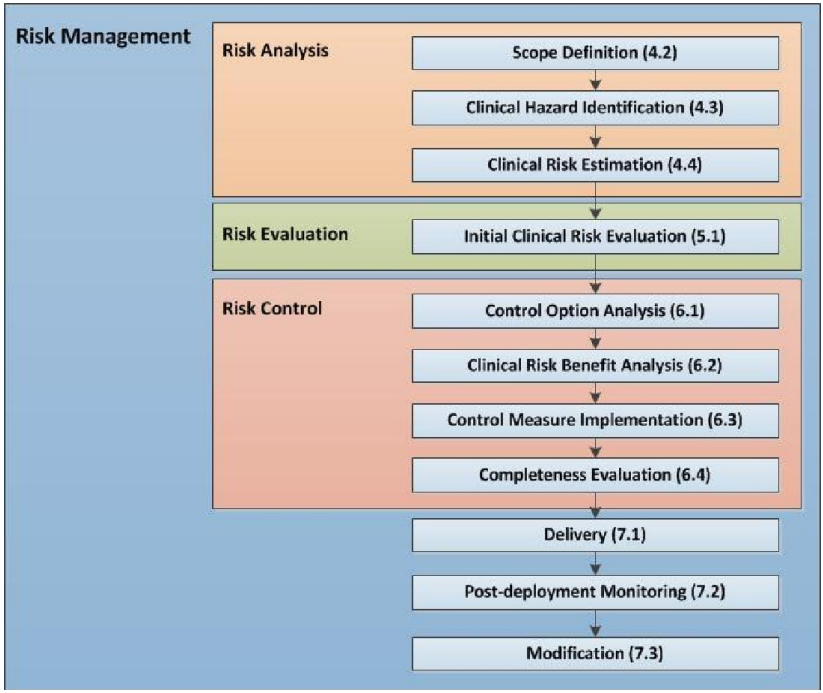


Fig. 3. SCCI0129/SCCI0160 Risk Management Process

Next, options are identified and analysed for controlling the risks that are deemed unacceptable, e.g. through redundancy, supervision or monitoring. In the rare case that a risk is deemed unacceptable and further control is not practicable, additional analyses are required to determine if the clinical benefits outweigh the residual clinical risk. Otherwise, the project has to be re-appraised. Following the implementation and verification of the risk control measures, the organisation has to evaluate the outcome of all subsequent activities, i.e. whether residual risks can be accepted.

The final three activities in the risk management emphasise the through-life nature of safety analysis and the importance of reviewing and updating the safety data during deployment, use, monitoring and maintenance. It is important to emphasise the importance of post-deployment monitoring, particularly in assessing the effectiveness of the risk control measures, based on use data, and the on-going identification of any new safety conditions, e.g. hazards that were missed in the initial hazard analysis.

3.2 An implicit safety argument

In addressing the risk management requirements of the SCCI0129 and SCCI0160 standards, organisations effectively comply with a core, implicit, risk-based argument that forms the essence of the clinical safety case.

This implicit argument is made explicit in Figure 4 using the Goal Structured Notation (GSN) (Kelly, Weaver 2004).

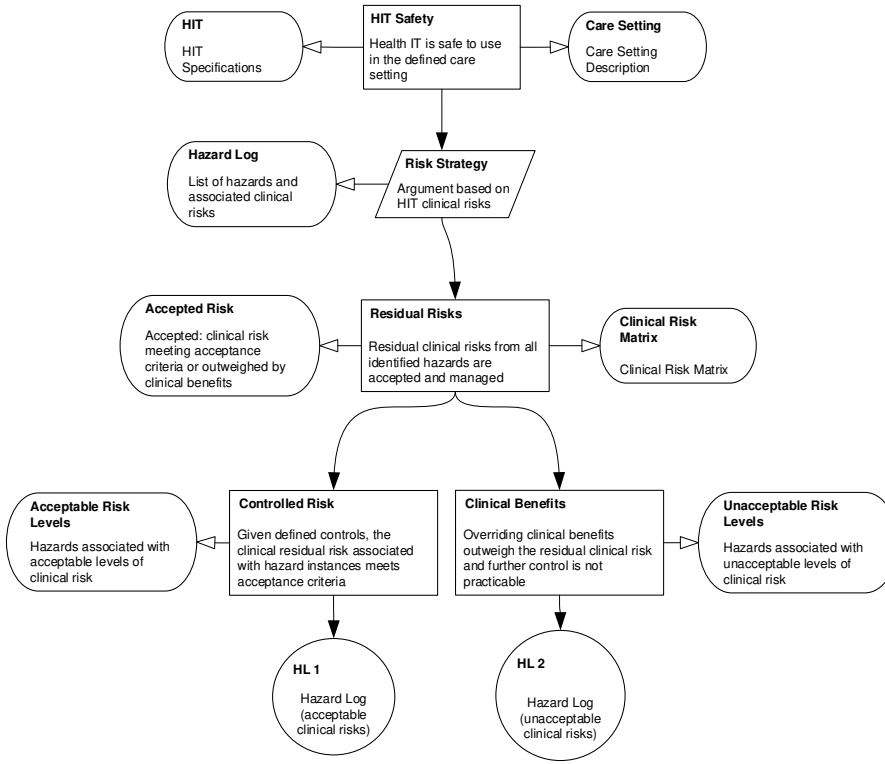


Fig. **4**. SCCI0129/SCCI0160 Safety Argument

Briefly, the chain of reasoning within the above argument is as follows: a HIT system is safe to use in a defined care setting if the residual risks associated with the identified hazards are accepted and managed. A residual risk is accepted if either it is within a predefined target (e.g. low/medium in a Clinical Risk Matrix) or the clinical benefits of the intended use outweigh the clinical risk.

Further claims about risk-benefit analysis, severity and likelihood are substantiated by specific evidence, captured in the Hazard Log, considering current and future risk controls.

Although this argument seems generic, i.e. covering overarching principles in risk management regardless of a specific domain, it can be seen as offering confidence that safety assurance practices implemented elsewhere in the *traditional* safety-related engineering domains are incorporated into NHS standards.

3.3 Review of current safety assurance practices in England

During 2016, The University of York and NHS Digital undertook a review of current clinical risk management practice within HIT manufacturers and deploying health organisations. The review was achieved through three structured workshops (involving 34 clinicians and engineers) and a review of a sample of clinical safety case reports for 20 different local and national systems.

During the workshops, facilitators encouraged the delegates to discuss and reflect on how they addressed the key requirement established in the SCCI standards. The workshops covered the core risk management activities in the SCCI0129 and SCCI0160 safety standards, mainly:

- **Scope Definition:** do we understand the HIT system, both its design and use, within the intended health and/or social care setting?
- **Hazard Identification:** what are the potential sources of harm?
- **Risk Estimation:** what are the likelihood and severity of the harm associated with the identified hazards?
- **Risk Control:** if residual risks are not acceptable, how are these managed?
- **Risk Acceptability:** how are decisions made, and by whom, concerning risk acceptability?

Positive and negative feedback was recorded and thematically analysed. The conclusions are summarised in Table 1.

Table 1. Summary of Safety Assurance Factors

Summary of Findings	Recommendations of Participants
Scope Definition	
• Great variation in the level of detail and clarity for specifying the HIT system and its clinical environment; • No consensus on key terms: 'clinical scope', 'intended use' and 'operational environment'; • Good engagement by clinicians though often depends on availability rather than expertise; • Authorship bias: clinicians (contextual) vs engineers (technical); • Insufficient consideration of variation in practice in clinical environment and impact of local HIT configurations; • Lack of detailed information on integration and interfaces with external systems.	• Modelling notations are needed for integrating clinical and engineering perspectives; • Clear definitions to be included in the standards; • More coverage required for different configurations and clinical settings; • More emphasis on interoperability requirements.
Hazard Identification	
• Confusion about the terms hazard, risk, harm and quality issues; • Difficulty of positioning hazardous failures of HIT within care processes; • Hazards too detailed to reflect potential harm to patients; • Hazards very generic and poorly linked to clinical environment; • Hazards identified by manufactures lacking validation for their relevance by deploying health organisations; • Lack of early engagement in, and funding for, hazard identification; • Perception of hazard identification as a tick box exercise.	• Publish anonymised Hazard Logs for HIT and known hazards of care within the NHS; • Develop practical guidance on hazard identification workshops and techniques; • Develop guidance on the necessary clinical and engineering expertise needed for hazard identification.
Risk Estimation	
• Two main risk matrices used: NHS National Patient Safety Agency (NPSA) and NHS Digital, with medium range leading to most confusion; • Too much customisation leading to complication in risk communication, rating and comparison; • Insufficient historical data to generate empirical estimate of severity and likelihood; • Risk parameters estimated qualitatively and subjectively, e.g. expert judgement; • Expert judgement should be provided with clear justification; • Hazards biased based on clinical representation (of different specialities);	• Implementation of a consensus risk estimation framework is needed to ensure consistency and promote learning; • Stressing the importance of customising standard risk matrices to suit local environments; • Greater explanation and justification needed for severity and likelihood parameters.

Summary of Findings	Recommendations of Participants
• Risk overestimation as a result of confusing likelihood of hazard and likelihood of resulting patient harm; • Risk classification sometimes performed retrospectively; • Insufficient consideration of demographics and patient variation.	
Risk Control	
• System re-design most desirable (removing source of hazard or carefully implementing alerts); • Training and appealing to clinical expertise most common; • Training generally regarded as a weak (and too generic) risk control; • Choice of control depends on phase: redesign during development and workarounds after deployment; • Alert fatigue regarded as a source of concern; • Concerns about lack of documentation, traceability and assessment of changes in risk controls; • Lack of explicit evidence and feedback about the effectiveness and suitability of risk controls; •	• Importance of diversity and balance in risk control types; • Appealing to vigilance by clinicians should depend on detectability; • Training to be specific, justified and on-going; • Proactive monitoring of, and feedback on, workarounds and design changes.
Risk Acceptance	
• Lack of documented clinical justification and technical explanation for risk acceptance; • Rare use of the 'As Low As Reasonably Practicable' (ALARP) principle; • No clearly established accountability and responsibilities of the stakeholders involved in risk acceptance decisions (senior management and CSOs); • Clear emphasis on professional registration and judgement of clinicians.	• Define more clearly the roles, responsibilities, authority and resources within both manufacturers and health organisations; • Greater emphasis on interpretation and justification of acceptance decisions.

Four themes that cut across the different HIT risk management activities were identified, representing two areas of strength: establishment of a systematic approach to risk management and close engagement by clinicians; and two areas for improvement: greater depth and clarity in hazard and risk analysis practices and more organisational support for assuring safety. These themes are summarised in Table 2.

The data indicates that the assurance framework established through the SCCI0129 and SCCI0160 standards has provided a principled approach to risk

management, building on best practice in system safety (e.g. the use of Hazard Logs and Safety Cases). The role of the clinicians, particularly the CSOs, has been recognised by the different organisations. Most of the safety analyses are clinically-led, with representation from multidisciplinary teams.

However, concerns exist about the rigour, detail and clarity of the HIT risk analysis evidence. The identified HIT hazards, and their associated risks and controls, are rarely specific to the system and the clinical environment, or justified in sufficient detail, in order to enable the stakeholders to evaluate and, where necessary, challenge the safety beliefs about the system. This issue cannot be addressed in isolation of common organisational barriers, particularly with regard to making sufficient resources available for implementing the HIT risk management process. Unfortunately, these resources are seldom provided. Where they exist, such resources are typically used to confirm, rather than assess, the acceptability of the risk posed by the system. Risk analysis is also commonly performed late in the lifecycle. This often weakens the credibility of the evidence and its ability to influence the deployment of the system.

Table 2. Evaluation Themes

Theme	Examples
Strengths	
Risk-based: current approach provides a systematic process and a common language for identifying and analysing the risks of hazardous HIT failures, combined with the requirements for organisational commitment.	Wide-scale use of Hazard Logs (HLs) and Clinical Safety Case Reports (CSCRs) CSCRs cover HIT-related hazards, risk estimation, available controls and acceptance statements.
Clinical engagement: there has been a recognition of the significant role of clinicians, particularly CSOs, during HIT risk analysis and approval.	CSOs taking a leading role within health organisations, manufacturers and NHS Digital; CSO advice regarded as necessary for HIT approval.
Improvements	
Depth of risk analysis: safety evidence tends to be generic and requires more explicit clinical and engineering justification in the context of the deploying health organisations.	Risk estimation lacking empirical data, relevant to the clinical environment; Insufficient clarity about the effectiveness of risk controls.
Organisational support: level of organisational funding and commitment does not seem to be proportionate to the safety criticality of HIT, particularly within health organisations.	Risk analysis performed as a late activity, purely for compliance reasons, as a tick-box exercise; Lack of clarity about responsibilities and authorities.

The recommendations of the participations can be considered in the context of the often-implicit safety argument as illustrated at Figure 5 (i.e. the argument is annotated with areas for improvement that are needed in order to improve clarity, depth and rigour).

In addressing these recommendations, the safety argument and consequential safety cases established based on it could be strengthened both in terms of depth and specificity of the justification evidence. This goes some way in addressing the first improvement area (depth of analysis) but its success is dependent on an organisation being committed to supporting and funding safety activities.

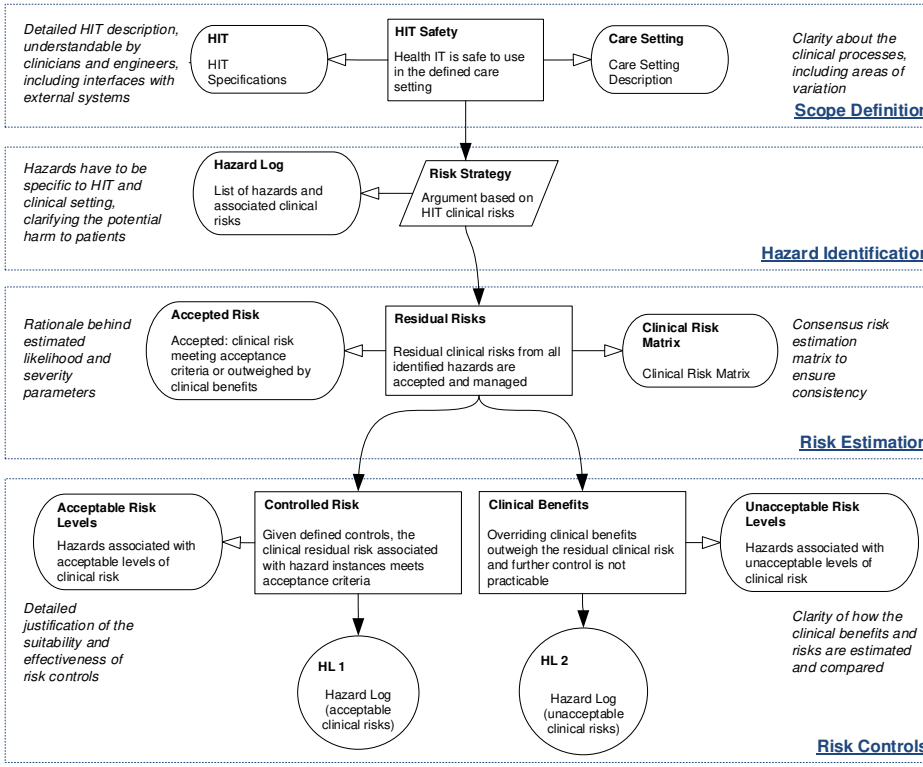


Fig. 5. Improved Safety Argument

4 Safety Modelling, Assurance and Reporting Toolset (SMART)

4.1 Overview

Developed as a proof of concept in order to address key hazard and risk analysis challenges identified in the review, SMART provides a self-contained and partially-automated assurance environment that integrates the design of the HIT system, the modelling of the care setting and the safety analysis and supporting evidence. It implements a data model, based on the safety argument expressed in Figure 4, and leads the analyst through an end-to-end process in a systematic way, ensuring the rationale used to make safety assurance details is explicitly captured. Further, SMART helps manage traceability between the constituent elements of the safety case.

Figure 6 shows a snapshot of the SMART user interface, which provides the editors used for defining the HIT solution, its care setting and Hazard Log. The different HIT design, clinical and safety data sources captured through these editors are integrated via the risk-based argument shown explicitly on the right side. The pictorial safety argument is interactive and can be used to navigate between different elements of the argument. It is automatically updated as the safety argument is developed to give a high-level view of progress made.

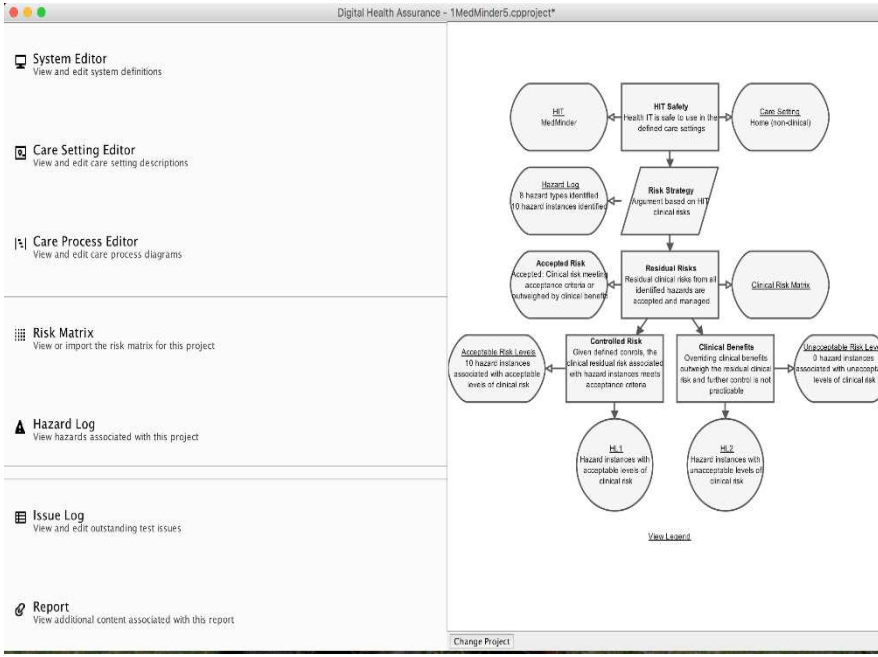


Fig. 6. SMART Interface

SMART provides the following core components:

System Editor: A text-based template that enables the analyst to record pertinent information that defines the system under assessment, e.g. name, version and description. The system can be hierarchically decomposed through the specification of system functions. One or more systems can be defined within the scope of a (safety case) project.

Care Setting Editor: A text-based template that enables the analyst to define a given care setting within which the HIT system is used. Again, it is structured to encourage the analyst to record all relevant information that will help in describing and understanding the clinical scope of the safety assessment. One or more care settings can be defined.

Care Process Editor: A graphical editor, supported by context-specific text templates, that uses a very small set of constructs to enable the analyst to define the particular care process or patient journey under assessment.

Risk Matrix: A predefined risk assessment and evaluation framework, derived from the one published under SCCI0129 and SCCI0160. This enables a risk assessment for all identified hazards to be conducted and automatically managed in the toolset.

Hazard Log: Within SMART, the concept of a hazard is specified based on two related aspects. Firstly, the analyst may create "Hazard Definitions" describing general types of hazard, with no reference to the context within which they occur. Secondly, the analyst can create a "Hazard Instance" and associate it with a "Hazard Definition". A "Hazard Instance" is a specific occurrence of the hazard defined by the associated "Hazard Definition". A "Hazard Instance" is established in a specific care process and is related to a particular Activity and its associated HIT functions. This approach ensures that hazards are only discussed in a specific context, reducing disagreements about the relative risk, likelihood and severity of a hazard that may be caused by ambiguous context. This can be illustrated by an example: Prescribing of medications in an acute hospital is undertaken in many different "Care Settings", e.g. Maternity and Emergency Care. A "Hazard Definition" of "Incorrect Quantity of Medication Prescribed" would be created with separate "Hazard Instances" of "Incorrect Quantity of Adrenaline Prescribed" (Accident and Emergency) and "Incorrect Quantity of Pethidine" (Maternity). These two "Hazard Instances" can then be used to manage the different risk profiles of those hazards in their particular care settings. Further, the Hazard Log editor is structured such that it ensures the analyst captures the relational logic between a hazard cause(s), hazard control(s) and hazard cause(s). It provides a bowtie editor and enables both an initial risk assessment (taking into consideration any existing mitigations) and residual risk assessment (after incorporation of further mitigations) to be made. The Hazard Log editor is available from within the Care Process Editor which provides the analyst with a rich view of the care process and in-scope hazards. Figure 7 shows an example care process, modelling a *Medication Setup*, and sample hazard instances associated with one HIT function (*Receive an Alarm*).

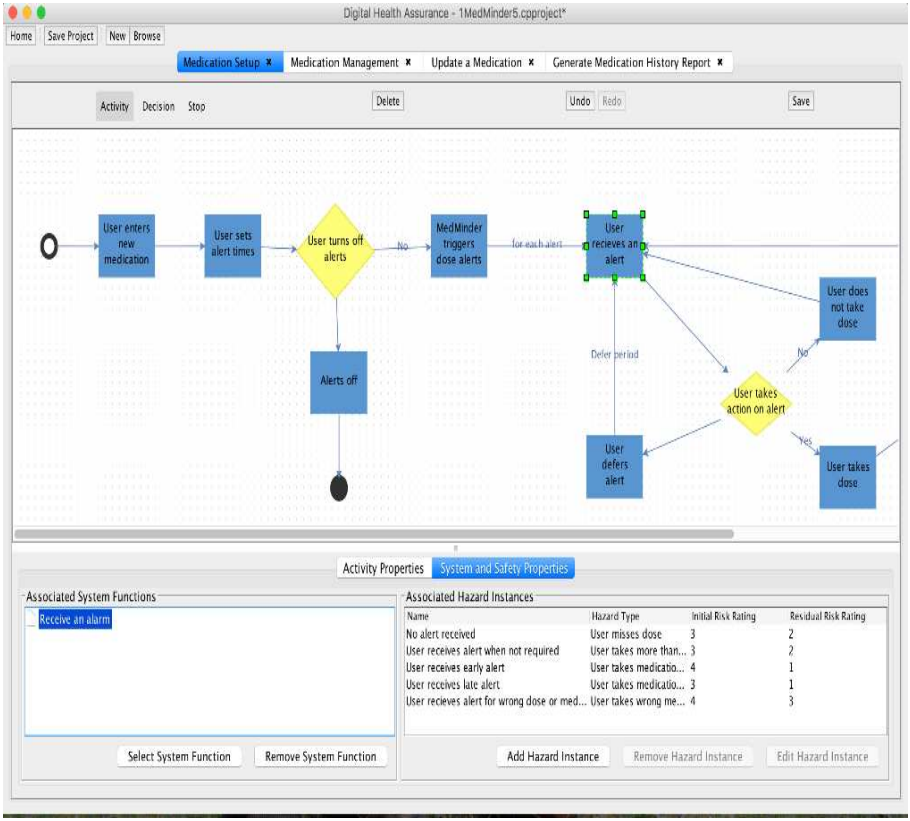


Fig. 7. Modelling a care setting, HIT function and associated hazards.

Issue Log: Enables test defects or live issues to be associated with particular system, setting or care activities.

Report Generator: Automatically creates a Word-based report that aligns with the structure of a Clinical Safety Case Report (CSCR) as expressed in SCCI 0129 and SCCI 0160.

4.2 Preliminary evaluation

SMART has been trialled on a number of HIT system programmes across a range of different care settings, involving participants from HIT system manufacturers, deploying care organisations and NHS Digital (more specifically: four secondary care originations, one national system, two manufacturers and three mobile/tele-health solutions). The feedback from these evaluations, although still

preliminary, has been positive and the toolset has largely addressed the original objectives. The evaluation has also identified a small number of limitations in the current proof of concept implementation and some suggestions for future development of the toolset (e.g. ability to import current care processes).

Based on the results achieved, NHS Digital is now committed to developing a "production" version that will be made available, free of charge, to the care community and supplier base.

4.3 SMART evolution

The vision is for SMART to be adopted by the HIT community and collaboratively developed to support that community. Some key areas for future development include:

- A graphical editor to express the relationship between a hazard, its causes, its effects and any controls;
- The ability to zoom in and out of any element of the model, enabling the analyst to see the specific detail or to present a high-level view;
- The use of different colours in the graphical editors to signify the ongoing status of the safety management of key activities;
- The ability to run queries and generate reports to support operational requirements e.g. provide a list of high-risk hazards;
- The ability to cut and paste elements between different care pathways;
- The provision of a library of "Hazard Definitions" which can be used and maintained by the community;
- The provision of a library of report templates which can be used and maintained by the community;
- An interface that will support the importing of previously created care process diagrams; and
- Mechanisms for dynamically updating the safety case based on real-time clinical data (Denny et al. 2015).

5 Summary

HIT that is used to support modern care delivery is safety related and becoming increasingly so with the emergence of new technologies, a transition to a paperless NHS and the greater involvement of patients in their own health and wellbeing management. Our recent review of current health informatics safety assurance practices has highlighted that whilst the national safety standards provide a

principled framework for risk management, the care domain faces challenges in key areas that are reducing the achieved effectiveness of the risk management activities. To help address these challenges, SMART was developed to provide an environment which leads the analyst through a structured process, supports the elicitation of pertinent justification and evidence whilst automatically managing the traceability between safety argument components and eliminating the burden of documentation.

Real world application and evaluation of SMART, as a proof of concept toolset, has produced positive feedback and supported a decision by NHS Digital to commit to the in-house development of an open, robust, scalable and customisable version that will be publicly made available to care organisations and their HIT system manufacturers.

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