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Exploring the Notion of Hazards for Health IT

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Abstract. Safety analysis is centred on identifying a set of hazards that form the basis of risk assessment. In healthcare, hazards are potential sources of harm to patients and as such the risk of these has to be assessed and managed. With the increased reliance on Health IT systems in health and social care settings, some of these hazards are associated with the development and use of these systems. In this paper we examine current practices in hazard identification, focusing on how clinicians and engineers approach this task within the Health IT safety assurance process. We highlight certain technical and organisational challenges and discuss approaches to improving current practices and promoting learning initiatives.

Keywords. Digital health, health IT, hazards, patient safety

1. Introduction

Health IT (HIT) has become a critical infrastructure in healthcare [1]. The connected use of information-intensive functions (e.g. electronic health records and ePrescribing) has revolutionised the provision of treatment and care. Recently, the HIT landscape has expanded by the use of health apps and social media, empowering patients to take a more active role in their own care [2]. For any technology used in the care pathway, the impact on patient safety is a fundamental concern [3]. HIT has the potential to improve patient safety but also introduce new hazards. For example, ePrescribing can help eliminate transcription errors in a paper-based process but also increase risk by inducing unsafe shortcuts and alert fatigue.

In order to address this challenge, different national reviews have encouraged the healthcare domain to consider and where appropriate adapt practices used in other high-risk sectors, particularly aviation [4], which adopt systematic approaches to safety assurance and management [5]. This typically includes the implementation of a proactive safety management system, generation of a Hazard Log and a safety case and institutionalisation of an open safety culture [6].

In England, the National Health Service (NHS) has been promoting and supporting such approaches for HIT, through a dedicated Clinical Safety Team at NHS Digital. NHS Digital is a public body that is responsible for providing data and IT systems for commissioners, analysts and clinicians in health and social care. Two HIT safety standards, targeting manufactures (SCCI0129 [7]) and health organisations (SCCI0160

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[8]), 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. Establishing a safety culture has been a primary objective, requiring evidence of commitment by senior management, e.g. providing the necessary resources and a clear chain of responsibility. This includes the appointment of Clinical Safety Officers (CSOs), who, in their capacity as experienced clinicians, are expected to lead the HIT risk management activities.

Similar to the majority of safety processes in other safety-critical sectors such as nuclear [9] and automotive [10], the SCCI0160 and SCCI0129 standards are centred on identifying the hazards posed by the HIT and assessing, mitigating and monitoring the risk associated with these hazards. In this context, a hazard is defined as "*potential source of harm to a patient*" [7], e.g. the patient receives more than the intended drug dose. A clinical risk is defined as the *"combination of the severity of harm to a patient and the likelihood of occurrence of that harm*" [7], e.g. the likelihood that the patient suffers a permanent life-changing incapacity as the result of the drug overdose.

In this paper, through a qualitative case study, we examine current practices in hazard identification, focusing on how clinicians and engineers approach this fundamental task within the HIT safety process, as defined by the SCCI0129 and SCCI0160 standards. We highlight certain technical and organisational challenges and discuss approaches to improving current practices and promoting learning initiatives.

2. Methods

2.1. Setting

This study concerns hazard identification practices for HIT in England, as scoped by the SCCI0129 and SCCI0160 standards. It focuses on the role of hazard identification within the overall risk management process (Figure 1). The standards follow the safety principles established for medical devices and are consistent with ISO14971 [11].

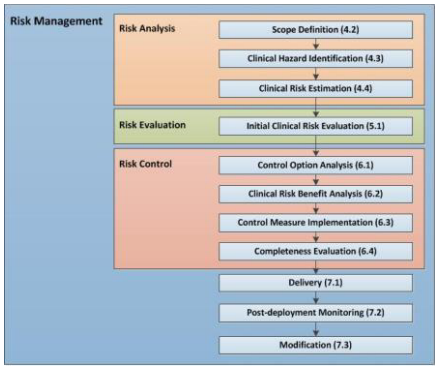

Figure 1. SCCI0129/SCCI0160 Risk Management Activities [7]

Two primary artefacts are generated from the risk management process that explicitly consider HIT hazards: Hazard Log (HL) and Clinical Safety Case Report (CSCR). The HL is a mechanism for recording the on-going identification, analysis and resolution of hazards associated with the HIT system. The CSCR documents an argument,

supported by evidence, for why the system is safe for a given application in a given environment.

2.2. Data Collection and Analysis

Three separate one-day workshops were organised in February/March 2016, involving 34 participants: 19 clinicians, 12 engineers, 2 researchers and 1 patient representative. The participants were selected due to their expertise in the development, deployment and/or assessment of HIT and their understanding of both the engineering and clinical perspectives of the technology. They represented the three main parties involved in HIT risk management: NHS Digital, health organisations and HIT manufacturers. Participants were split into groups of 5. Each group had a moderator who recorded a summary of the discussion. The discussion was led by the following question:

How is Hazard Identification performed so that the hazards identified are specific, relevant, clearly documented and "complete"?

The workshops were followed by detailed reviews of the CSCRs for 20 HIT systems, covering primary and secondly care, based on the above question. The CSCRs considered diverse functions (e.g. care records, prescription, bed management and emergency care) and were submitted by health organisations (for specific deployments), manufacturers (for type approval) and NHS Digital (for the national infrastructure). The CSCR reviews were used to corroborate and augment the workshop outputs.

The data was then imported into NVivo11 for analysis. The text was coded following an iterative process and analysed using Thematic Analysis [12], determining and interpreting repeated patterns of meaning in the data set. The final phase involved combining the different codes into overarching themes using a thematic map, which was independently validated by a senior safety analyst against the original data set.

3. Results

The data indicates that the safety assurance framework established through the SCCI0129 and SCCI0160 standards has provided a systematic approach to identifying hazards within the overall HIT risk management process. When complying with these standards, it is now common practice to produce an explicit HL that is developed by a multidisciplinary team comprising clinicians and engineers. This HL forms the evidence basis for the CSCR. The data also highlighted specific challenges and areas for improvement that concern the technical and organizational aspects of hazard identification. These are summarised in **Table 1** and discussed in the rest of this section.

Firstly, the notion of hazard is not familiar in healthcare settings. The term risk is more recognisable by clinicians, as expressed by one participant: "*the NHS has always worked in the 'risks': don't know what a hazard is*". The overwhelming majority of hazards are care hazards, e.g. patient misidentification, which predate the deployment of HIT and to which the technology now contributes. Positioning the specific hazardous contributions of HIT within the care process is seen as a difficult task.

Secondly, deciding on the level of granularity for hazard identification is problematic. On the one hand, many of the identified HIT hazards are too detailed and correspond to technical failures (i.e. 'network unavailability'). As such, they do not reflect the potential harm to patients. On the other hand, other hazards are defined

generically, with little information about the context, to make them specific to the clinical environment (e.g. 'wrong prescription'). In part, this can be complicated by a poorly-defined clinical scope, as illustrated by one participant: "*an important distinction needed to be made between hazards caused by system and hazards caused by clinical activity. Can the system lead to patient harm or was the patient harm already there but the system perpetuates it?*"

Table 1. HIT Hazard Identification Themes and Recommendations

Summary of Themes
– Confusion about the terms hazard, risk, harm and quality; – 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 health organisations; – Lack of early engagement in, funding for, hazard identification; – Perception of hazard identification as a tick-box exercise.
Key Recommendations (made by participants)
– 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/engineering expertise needed for hazard identification.

Thirdly, it was observed that engineers were more comfortable than clinicians concerning thinking hypothetically about foreseeable hazards, i.e. proactive hazard identification during design stages. Clinicians placed more emphasis on actually experienced hazards and problems based on "*what they already know*". It was noted that many of the events flagged by engineers as hazards were treated as quality issues by clinicians, i.e. events that commonly occur and from which recovery is expected, e.g. 'delay in providing care'.

Fourthly, where do hazards come from? Ideally, the clinicians and engineers from both the manufactures and health organisations should identify the potential hazards collaboratively. A more common scenario has been to take the HL generated by the manufacturers and instantiate it to fit within the specific clinical context of the health organisations. The perception here is that the manufacturers are more competent and have the resources to produce the HL to the required quality. The potential consequence, however, is that many health organisations adopt the HL without the adaptation necessary to cater for the specific local clinical requirements. This is, in part, due to lack of early engagement: "*Poor quality is due to many reasons including doing the work last minute, 'as something that needs to be done', a tick box exercise. It is usually left to the clinician assigned rather than done in plenty of time with a multidisciplinary team. The hazards are generic, often lifted from other documents*". Some highlighted the lack of resources as the primary contributor: "*a continuing message is that there is no funding and resources provided to the NHS to deal with these issues*".

Finally, to increase confidence in the hazard identification results, evidence of the use of systematic techniques is typically provided. What-If Analysis, combined with "*user stories*", appears to be the most common approach. To ensure consistency and promote learning, participants emphasised the need to "*publish anonymised hazard logs for HIT and known hazards of care within the NHS*", combined with "*practical guidance on Hazard Identification workshops and techniques*". Initiatives within NHS Digital are currently focusing on compiling generic hazard logs for different types of HIT systems, including apps, combined with a tool-supported methodology and practical guidance, which will be publicly available for use by the wider community.

4. Discussion and Conclusions

Hazard identification challenges are not uncommon for novel, highly-configurable and context-sensitive technologies. For example, in the automotive industry, autonomous driving has raised concerns about the adequacy of the current approaches to hazard identification, highlighting gaps in our understanding of the relationship between the human driver and the autonomous vehicle functions [13]. For healthcare, ideally, safety analysis should be applied in a top-down and integrated manner, focusing on the potential patient harm and the hazards posed by the health services to which different technologies (including HIT), clinical practices and organisational processes contribute. Such a holistic approach, which is common in aviation and nuclear for instance, is rarely followed in healthcare for many complex reasons [14]. As such, labelling certain HIT failure conditions as hazards is a pragmatic choice and can be criticised as being IT-centric. After all, information, unlike human actions or implantable medical devices, cannot directly lead to harm. However, the sphere of influence for clinicians and engineers who are currently responsible for the development and deployment of HIT is often limited. This has led to treating critical HIT failures as hazards, rather than causes of higher care hazards.

Finally, the recent national review of HIT in the NHS, led by Robert Wachter, highlighted the principle that "*Health IT Entails Both Technical and Adaptive Change*" [15], focusing on clinical aims and practices and patient outcomes (not the mere act of digitisation). Meeting such a principle will help achieve an integrated approach to hazard identification that involves the right clinical and technical stakeholders, including patients and front-line users.

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