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Research Highlights:

- Experience-based analysis of opportunities and challenges for using HRA in health
- Considers reliability, performance variability, regulator, and patient role
- HRA should have clinical engagement and patient participation
- HRA cost-effectiveness should be rigorously evaluated
- HRA can provide requisite imagination and build social safety infrastructure

On the Application of Human Reliability Analysis in Healthcare: Opportunities and Challenges

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Abstract: Safety in healthcare is a relatively recent field, but has received considerable attention over the past 15 years. Healthcare organisations have been encouraged to learn from safety management practices in other industries. In this paper we analyse opportunities and challenges for the application of Human Reliability Analysis (HRA) in healthcare. We consider the poor levels of reliability of many healthcare processes, performance variability, the absence of regulatory frameworks that incentivise proactive risk management, and the unique role of the patient. We conclude that HRA could provide a useful framework for the analysis and reduction of risk in healthcare, but techniques might have to be adapted and applied with due consideration of the specifics of the cultural and regulatory context of this domain. This includes clinical engagement with and ownership of the HRA process, greater focus on rigorous evaluation of cost-effectiveness of HRA techniques, and active involvement of patients.

Keywords: Healthcare; Human Reliability Analysis; Patient Safety; Risk Analysis; Human Factors; Safety-II

1. INTRODUCTION

Human Reliability Analysis (HRA) techniques are used widely as part of the safety management of safety-critical systems, such as nuclear installations, military operations, and aerospace [1]. However, in healthcare the use of HRA techniques is not common [2]. On the one hand this is surprising, because healthcare, more than other industries, relies on people rather than automation to deliver its services. On the other hand, safety management in healthcare is a relatively recent field, and the culture and drivers in this domain differ from those in other industries [3]. The paper discusses the potential positive contributions the application of HRA techniques in healthcare could bring to patient safety management, and analyses the challenges that have to be considered.

HRA techniques aim to determine the impact of human error on a system [1]. The techniques draw on systems engineering, and cognitive and behavioural science methods to understand and evaluate the human contribution to system reliability and safety [4]. HRA techniques can be used to inform system design (formative use) and to support decisions about licensing and adoption (summative use) [5]. The purpose for which the HRA is used also determines whether the analysis is qualitative or quantitative. For summative evaluation, the output of HRA needs to be quantitative, and typically feeds into probabilistic safety assessments (PSA) [6]. Common stages in the HRA process are problem definition and specification of the scope of the analysis, task analysis or task modelling, human error identification and analysis, human error quantification (if required), and error management recommendations [1, 4].

The adoption of systematic HRA techniques has its roots in the nuclear industry, with a strong emphasis on providing quantitative estimates of human error probabilities (HEP), which can feed into PSA calculations [7]. However, many HRA techniques also include a qualitative element, or provide qualitative assessments only. For example, the Human Factors Process Failure Mode & Effects Analysis (HF PFMEA) used by NASA provides a qualitative analysis of potential human errors and associated risks [4]. In 2009, a Health & Safety Executive review identified 79 HRA techniques [8], and it is very likely that this number has grown further since then. HRA methods are often categorised into generations, but the extent to which this is done consistently and whether it is helpful, is debatable [9]. First generation HRA techniques often include taxonomies of human tasks. These can be used to assign nominal HEPs to different types of human activity. The influence of the context is recognised in these techniques, albeit only in a secondary way, as a modifier of the base HEP. Lists of Performance Shaping Factors (PSF) can be used to determine the influence of the context, which can either increase or decrease the HEP. Examples of such techniques include Technique for Human Error Rate Prediction (THERP) [7] and Human Error Assessment and Reduction Technique (HEART) [10]. Second generation HRA techniques include models of human cognition in order to represent operator behaviour. For example, Cognitive Reliability and Error Analysis Method (CREAM) [11] is based on a contextual control model (COCOM). This model suggests that human performance is dependent on the context, and that patterns in human performance are due to regularities in the context rather than due to structural characteristics of human cognition. CREAM, therefore, proceeds from an analysis of the specific context (referred to as common performance conditions – CPCs), and determines from there likely patterns

of cognitive control (scrambled, opportunistic, tactical, strategic) with assigned probability ranges of unreliability. Boring suggests that the classification of HRA techniques into generations is not necessarily done consistently, sometimes based on whether they consider models of cognition or the influence of the context of human performance, their chronological novelty and their comprehensiveness [9]. With some of the more recent techniques, such as SPAR-H (Standardized Plant Analysis Risk – Human Reliability Analysis) [12], this classification becomes blurred, and the usefulness of this distinction can be questioned. Some older techniques, in particular THERP, continue to be used widely, where as many of the more recent techniques have very little evidence to support their application [13].

Various authors have provided critiques of individual HRA techniques or classes of techniques [5, 9, 11, 14-16]. The main criticisms include absence of, or poorly developed causal models of operator behaviour, inability to model dynamic behaviour, lack of a convincing foundation for assumed error probabilities, inadequate attention given to organisational factors, and significant inter-analyst variability.

Recent additions to the HRA portfolio are techniques, which use human performance simulation. Arguably the most mature of these is the Accident Dynamics Simulator paired with the information, decision and action in crew context dynamic operator behaviour model (ADS-IDAC) [15, 17, 18]. ADS-IDAC has been developed specifically for the assessment of nuclear emergency response scenarios. Simulation-based HRA techniques could provide a dynamic view of operator response and operational context [19], and they might be able to provide more reliable failure data for low probability scenarios [9], but to date few published applications exist.

The use of HRA techniques to analyse healthcare processes is considerably less common. The most frequently used prospective hazard analysis technique is Failure Mode and Effects Analysis (FMEA), for which a healthcare specific version (HFMEA) has been developed [20]. HFMEA shares some similarities with HF PFMEA, and it can be used to identify and analyse human errors. FMEA and its variants have been used, for example, to analyse organ procurement and transplantation, patient handover in emergency care, and intravenous drug infusions [21-23]. The use of FMEA in healthcare has been criticised for its inter-analyst variability and resource intensity [24, 25]. There are a small number of studies that describe the application of popular HRA techniques such as SHERPA (Systematic Human Error Reduction and Predication Approach) [26], HEART, SPAR-H and CREAM in healthcare. SHERPA has been used to identify human errors in anaesthesia [27], and to analyse drug prescription and administration in hospital, primary care and community settings [28-30]. While HRA techniques are usually used to predict performance of well-trained professionals, a study that sought to understand and improve the ability of stroke patients to deal with everyday tasks (e.g. making tea), demonstrated that SHERPA had good predictive validity for this patient group [31]. The Observational Clinical Human Reliability Analysis technique (OCHRA) is based on the action errors classification used in SHERPA, and has been applied for describing and classifying technical errors in surgery [32-34]. HEART was used to determine HEPs of data entry tasks in radiotherapy [35]. A study applying SPAR-H in order to quantify human error probabilities in a radiation therapy preparation task found that the predicted HEP values demonstrated good validity when compared to

actual observations [36]. In a retrospective analysis of adverse events, a study found that analysts using CREAM were able to identify more organisational and leadership PSFs than described in the originally undertaken Root Cause Analyses [37]. These studies were generally relatively small in scope, and taken together they provide a limited evidence base. However, the studies hint at the potential for the application of HRA in healthcare.

Considering the long tradition of the application of HRA techniques in safety-critical industries, and the wealth of experience that comes with it, are there opportunities for the more widespread application of HRA techniques to better understand the human contribution to patient safety? We believe so, but the adoption of HRA (or any technique from another industry) requires an appreciation of the specific norms, values and needs of stakeholders in healthcare, such as clinical and professional autonomy, the nature of what is accepted as scientific evidence, and the particular ways in which organisations need to demonstrate accountability [3, 38]. Healthcare is an incredibly diverse domain that requires frequent interaction across organisational boundaries, and that demands a significant tolerance for increased levels of uncertainty [2, 39]. Owing to these differences in the organisational, institutional and cultural context, methods and techniques from other industries have to be applied with caution and have to be adapted appropriately [40, 41]. We have to understand the purpose, theoretical underpinnings and the limitations of these techniques within their original context, in order to apply them meaningfully within healthcare [42]. Failure to do so might limit the benefits we can expect to get from the use of HRA in healthcare, and it might even contribute to increasing risks to patients [43].

In this paper we analyse some of the challenges that might need to be addressed in order to establish HRA as a useful framework for the analysis and reduction of risk in healthcare. The analysis is based on a critical reflection about our experiences with running a large, multi-centre patient safety improvement programme. Critical reflection is a frequently used technique to learn from experience and to improve practice [44, 45]. We discuss the implications for the application of HRA posed by the poor levels of reliability of many healthcare processes, performance variability, the absence of regulatory frameworks that incentivise proactive risk management, and the unique role of the patient.

The next section (Section 2) describes the context for our analysis. The following four sections are devoted to the analysis, where we discuss the reliability of clinical processes (Section 3), the notion of performance variability as an alternative frame to the success / failure dichotomy commonly used in PSA (Section 4), the role of the regulator (Section 5), and the role of the patient (Section 6). Concluding remarks are presented in Section 7.

2. THE CONTEXT – SAFER CLINICAL SYSTEMS

The healthcare industry is broad, and it includes diverse aspects such as drug development, the design of medical equipment, and the delivery of care in different settings. In this section, we provide some context on the scope of our analysis, which is concerned only with the delivery of care, for example hospital and emergency care services.

Patient safety as a field of significant scientific enquiry is a fairly young discipline. Even though medical errors and iatrogenic harm have been studied for a long time [46], many commentators regard the Institute of Medicine report “To err is human” published in 1999 as the beginning of the modern patient safety movement [47]. The report drew on findings of the seminal Harvard Medical Practice study [48], and claimed that as many as 98,000 Americans die each year as a result of medical error. Since then, the study design (retrospective case note review) of the Harvard Medical Practice study has been replicated many times in different countries [49-52]. An analysis published in the British Medical Journal extrapolated figures from a range of US studies, and estimated that medical errors cause 251,000 preventable deaths each year. This would place medical error as the third leading cause of death in the US [53]. Taken together, these studies suggest that around 9% of patients admitted to hospital will suffer an adverse event, and that about half of these might be preventable [54]. Adverse event rates have shown little improvements over time, even though significant research effort has been invested [53, 55, 56].

Healthcare providers have attempted to learn from safety management practices in other industries, but the lessons learned have often been narrow and selective [40]. The practice of patient safety management has been predominantly retrospective [57]. Much – some would argue too much [58] – effort has gone into counting the number of adverse events and incidents. Trackers of different types of patient harm, such as the NHS Patient Safety Thermometer [59], are reactive instruments. Root Cause Analysis (RCA) and incident reporting systems are used to collect and analyse data about past patient harms [60]. Without doubt, such retrospective learning from incidents is regarded as an important safety management strategy in safety-critical industries [61-63], but patient safety management has been very weak in complementing retrospective approaches with the use of proactive techniques, which are commonly used in safety-critical industries [41].

In our analysis, we draw on experiences with the Safer Clinical Systems programme (SCS). SCS was a five-year patient safety improvement programme funded by the Health Foundation, which ran in two phases from 2008 – 2013 [64]. SCS was designed as collaboration between twelve National Health Service (NHS) hospitals in the UK and a technical support team based at the University of Warwick. The aim of SCS was to adopt and trial in clinical settings proactive safety management techniques from safety-critical industries, such as task analysis, human reliability analysis and safety cases [65]. The clinical teams were multi-disciplinary, and included clinicians, managers, and quality improvement practitioners. None of the teams had significant prior patient safety management experiences. However, some of the teams were experienced in carrying out quality improvement projects. Phase 1 included four study sites, and the aim was to co-design the SCS approach. Phase 2 included eight study sites, where the approach was rolled out and refined further.

Patient safety projects are often framed as quality improvement initiatives. A widely used approach is the Model for Improvement developed and promoted by the Institute for Healthcare Improvement (IHI) [66]. The model combines statistical process control with rapid improvement cycles (Plan, Do, Study, Act). Looking at patient safety from a quality improvement perspective usually leads to a focus on increasing the

reliability of specific clinical processes through greater adherence to procedures. An example is the implementation of so-called clinical care bundles (a series of evidence-based steps), such as the care bundle recommended for reducing ventilator-acquired pneumonia [67]. However, there is an ongoing debate about whether such quality improvement initiatives have had a positive impact [68]. The SCS approach aimed to complement this quality improvement focus with a risk-informed perspective.

Projects within SCS addressed diverse issues around communication, handover and medicines management, such as improving the reliability of the medicines reconciliation process, and managing the risks of clinical handover for patients with acute renal failure. All of the projects involved clinical processes that crossed departmental and disciplinary boundaries, and which had not been designed (in the engineering sense) and for which no formal specification existed. An overview of the different projects is given in Table 1.

*****Insert Table 1*****

The SCS approach is structured into five steps [64], see Table 2. Steps 1 (pathway definition and context) and 2 (system diagnosis) were supported by a range of tools for system definition and risk analysis, including Safety Culture Index, process mapping, Hierarchical Task Analysis (HTA), Failure Mode and Effects Analysis and SHERPA. Steps 3 – 5 (option appraisal, planning, system improvement) were supported by rapid improvement cycles and statistical process control approaches, and involved also the re-application of methods from the previous two steps.

*****Insert Table 2*****

HTA [69] is a structured approach used to analyse and to document tasks. Tasks are described in terms of goals, operations and plans. Higher-level goals are decomposed hierarchically into sub-goals and eventually into operations. Plans describe the sequence in which sub-goals or operations should be executed in order to achieve the higher-level goal. The output produced by HTA is useful by itself, for example for documenting an activity for teaching and dissemination purposes. It is also frequently used as a starting point for subsequent human error identification. SHERPA was originally developed as a methodology for qualitatively modelling human error in the context of nuclear power generation safety analyses [26]. SHERPA builds on HTA, and applies a taxonomy of human error types (see Table 3) to the elementary tasks described in the HTA (the bottom-level tasks) in order to identify potential error modes. Once credible errors have been identified, they are analysed further to determine their impact on the system performance, their likelihood of occurrence, and their potential for recovery. While SHERPA is based on the analyst's expertise and judgement, it has been shown to have relatively good levels of validity and reliability [6, 70].

This is the reference and frame for the analysis below. SCS has been subjected to rigorous, independent evaluation [38]. In this paper, we do not discuss the findings of the overall evaluation. Rather, within this context, we analyse more narrowly some of the potential positive contribution the use of HRA techniques could make, and we discuss the challenges that we anticipate.

3. RELIABILITY OF CLINICAL PROCESSES

A key learning point from the SCS programme is that clinical processes and tasks often have poor reliability. In an engineering sense, reliability may be defined as the “probability of a component, or system, functioning correctly over a given period of time under a given set of operating conditions” [71]. However, speaking about the reliability of care processes is not straightforward, because many processes and tasks have never been purposefully designed or specified. In these cases, it might be more appropriate to think about processes in terms of (poor) consistency. For example, one project team looked at the handover process between surgeons and nephrologists for patients with acute renal failure. These high-acuity patients are cared for under the direction of nephrologists, but might be housed on a surgical ward before or after surgery. Hence, efficient communication between the two clinical teams is safety-critical. The project team found that even though the handover process was a regularly occurring activity, it had never been designed or documented, but had become accepted through repeated use. As a result, it differed significantly depending on the individuals involved. The absence of properly designed processes is almost a given in situations where care crosses departmental and organisational boundaries.

There also exist a large number of clinical protocols and pathways that specify best practices to which the engineering definition of reliability might be more easily applicable. Failure to follow such guidance typically increases the risks to patients. For example, failure to implement the steps recommended in the Sepsis Six care bundle (high-flow oxygen, blood cultures, intravenous antibiotics, intravenous fluid resuscitation, lactate levels checking, hourly urine output monitoring) puts patients at increased risk of developing severe sepsis and is associated with increased mortality rates [72]. In this sense, the reliability of many care processes is very poor when compared with other safety-critical industries. A study of different clinical processes (clinical handover, prescribing, availability of clinical information, availability of surgical equipment) in seven NHS hospitals found that reliability was around 80% [73]. A US study found that only 55% of patients received care that was consistent with best practice, with reliability figures ranging from 79% (senile cataract) to as little as 10% (alcohol dependence) [74]. More recently, a large study investigating the quality of care provided to children in Australia found that across a range of conditions adherence to recommended quality indicators was only about 60% [75]. The authors caution that poor adherence to guidelines, for example asthma guidelines, may negatively affect patient outcomes. Patient safety interventions, such as the World Health Organisation (WHO) surgical checklist [76] are troubled by persistently high levels of non-adherence [77, 78].

The poor reliability of care processes and the frequent absence of documented tasks and process models pose a challenge for the application of HRA techniques. In safety-critical industries HRA techniques are usually used to determine the impact of human errors in situations that are well defined, and where the expected operator tasks and behaviours have been clearly specified, for example through the use of task analysis [16]. The assumed operator behaviour is constrained by emergency response procedures, standardisation and a high degree of training [15]. Such assumptions cannot always be made in healthcare contexts, and in the case of boundary-crossing processes that would most likely be wrong most of the time.

Can we meaningfully apply HRA techniques to understand the reliability of processes that have not been designed and that often demonstrate almost chaotic behaviour? One way of dealing with this challenge is to simply limit the application of HRA techniques to those clinical processes or tasks, which do not fall into this category. For example, Cook and colleagues performed a PSA to quantitatively assess the likelihood of unintentional ABO-incompatible (wrong blood type) thoracic organ transplant [79]. The blood type matching process is complicated, but a national standard exists. Similarly, the various documented applications of OCHRA focus on the identification of surgical action errors in well-defined surgical procedures [32-34]. Tackling the application of HRA techniques in healthcare by focusing on such reasonably well defined and stable processes and tasks might be a good starting point.

However, another way of approaching this challenge more broadly is to question whether the absence of process and task models is a desirable or necessary state. It clearly is not desirable, and most likely it is not necessary either in many cases. The systematic application of HRA techniques could contribute to raising awareness about the unsatisfactory status quo, and support clinicians and healthcare providers in attempts to define and standardise clinical processes. Within SCS clinical teams found that in their projects the use of task analysis within the SHERPA methodology supported them in gaining a better understanding of their processes, and of the different types of variations that existed. Clearly, this is a recognised strength of techniques such as HTA [69]. The use of HTA also provided team members from different backgrounds with the opportunity to build important relationships with each other, which in normal clinical practice they would not have. Creating opportunities to strengthen the social infrastructure of safety and enhancing staff engagement should be a key patient safety improvement strategy [80]. In order to achieve this, the use of HRA techniques should be participative, and ideally the clinical or multi-disciplinary improvement team should own it [81]. This represents a significant cultural shift from industrial practice, where it is more common for safety experts to undertake and own such analyses, and where subject matter experts are involved as appropriate. An example of such a participative approach to HRA was also demonstrated in a study that used a modified, team-based version of HEART to the analysis of human error in a radiotherapy task [35]. The authors point out that for this approach to work, healthcare professionals require suitably tailored training materials and experienced facilitators with a human factors and HRA background.

4. PERFORMANCE VARIABILITY

Another way of looking at the reliability shortfall of clinical tasks and processes is in terms of performance variability. Performance variability could be regarded as something negative, because it diminishes the reliability of well-designed systems. However, performance variability could also be regarded as useful and inevitable – as a mechanism that allows complex systems to deal successfully and safely with competing and conflicting priorities, tensions and contradictions in the work environment, and mismatches in demand and capacity [82-84]. This is essentially the argument developed within the Resilience Engineering (RE) and Resilient Health Care (RHC) communities [85, 86]. It is also referred to as the Safety-II perspective on complex systems [87].

HRA techniques that are intended to feed into the PSA framework usually consider only the simple dichotomy of successful and unsuccessful tasks. Zio discussed the problems that this dichotomy presents for reliability engineering in general, by alluding to the fact that many systems could be regarded as multi-state systems rather than binary systems [19]. Similarly, criticism has come from within the RE community with suggestions that modern socio-technical systems might best be regarded as complex adaptive systems (CAS), which have significant amounts of uncertainty about their technical, organisational and social structures [88-91].

HRA techniques often include consideration and rating of PSFs to determine their effect on human reliability (or on a nominal HEP). This poses a problem in many healthcare scenarios, because the conditions under which healthcare professionals work are almost always suboptimal. Applying the PFSSs proposed in techniques such as SPAR-H would result frequently in unreliability probabilities close to 1. For argument's sake, consider the frequent scenario of a junior doctor on night shift in an emergency department (ED). Ambulances are queuing outside of the ED, patients are waiting to be seen, time is short, stress levels are high, some patients have complex presentations that make diagnosis difficult, experience of the junior is inadequate, procedures are available but frequently outdated and overly lengthy, the technology lacks interoperability, the junior doctor lacks sleep, and work processes have not been designed properly. This (hypothetical) scenario will sound all too familiar to any healthcare professional who has ever worked in the ED. And yet – somehow the junior doctor manages to get through the night, to succeed in the face of PSF adversity, and to provide good quality care to patients. From a Safety-II perspective, this is due to their ability to adapt, to make appropriate trade-offs and to bridge the gaps in the work processes [92].

The challenge for the application of HRA techniques is how to approach conceptually the poor reliability and relatively high performance variability of clinical processes and tasks – from a Safety-I or Safety-II perspective? Aimed at predicting and reducing human error or aimed at understanding and improving human performance?

Hollnagel developed the Functional Resonance Analysis Method (FRAM) in order to analyse and understand performance variability [93]. FRAM takes a functional view, and can therefore be used to analyse variability of technical, human, organisational and combined functions. In a first step, the analyst identifies and describes functions along six aspects independently of other functions. The six aspects relate to input, time, control, output, resources and preconditions. The analyst can consider for each function the potential variability. Then, the analyst can analyse the coupling between functions by creating FRAM instantiations, i.e. by linking functions through their aspects (e.g. one function's output might be the input for another function, and it might be a precondition for a third function). FRAM emphasises the dynamic nature of these couplings, i.e. certain links might be present at one time, but be absent on other occasions. This is reflected in the choice of terminology of FRAM instantiations rather than a single FRAM model. In this way, FRAM supports the analyst in identifying and characterising variability, and in tracing the propagation of variability throughout the system. The application of FRAM in healthcare has been described, for example in [94, 95].

The extent to which FRAM is a method or rather a lens through which the analyst can look at human performance is debatable. However, anecdotal evidence suggests that the application of FRAM can support clinicians in thinking differently about their processes and activities (J. Houndsgaard, personal communication). This can provide the requisite imagination, which is crucial in understanding the safety of complex systems [96].

Boring suggests that traditional HRA techniques and RE share many conceptual underpinnings [97]. Based on our experiences we support this view in situations where HRA techniques are used to inform system design and improvement (rather than for summative evaluation). It might even be possible to combine traditional HRA techniques with techniques such as FRAM to gain additional insights. For example, in a study on clinical handover, FMEA was used to identify potential failure modes, and FRAM was used to complement this analysis by exploring the impact on clinical processes and on the patient (i.e. the severity of the consequences) [98]. This was useful because practitioners found it difficult to think in terms of success or failure of certain activities, and the concept of variability proved to be more aligned with clinical practice.

On a more formal level, Steen and Aven argue that the RE perspective and risk-based analysis can be reconciled when adopting a definition of risk based on uncertainty rather than on probability [99]. Further research is needed to determine how this risk definition can be practically integrated with human performance analysis techniques (i.e. HRA techniques based on RE concepts) such as FRAM.

5. ROLE OF THE REGULATOR

The regulatory landscape in healthcare is problematic. In the NHS in England, there are currently more than 20 different regulatory bodies in health and social care. This has contributed to confusing signals around patient safety, and to an absence of a coherent framework for improving patient safety [100]. There is no consistent, overarching patient safety regulatory framework, with some bodies formulating targets for certain types of harm (so-called Never Events [101]) and others specifying performance and outcome measures. A common feature of these diverse regulatory frameworks is their reactive nature. There is a lack of regulatory guidance and an absence of institutional drivers for systematically and proactively reducing risk [40].

This is in stark contrast to the regulatory approach in most other safety-critical industries in the UK. Regulatory regimes in the nuclear industry, in the petrochemical industry and in the rail sector are risk-based, and they all entail an expression of the ALARP (As low as reasonably practicable) principle in some form [102]. The ALARP principle requires operators of safety-critical systems to demonstrate that risks have been identified and reduced to a level where further risk reduction would result in grossly disproportionate cost.

The development and use of HRA techniques has been tightly linked to such strong, proactive regulatory regimes [4]. It is highly unlikely that the regulatory regime in healthcare will look anything like those in other safety-critical industries in the short to medium term. The question then arises how HRA techniques should be introduced in the healthcare context, where the PSA framework is largely unknown and

completely missing from the regulatory approaches. Healthcare providers have no regulatory incentives for investing time and resource in the use of HRA techniques, and – more importantly – there is a critical lack of awareness of and familiarity with the application of HRA techniques among healthcare providers and healthcare professionals.

Drawing again on the experiences with the SCS programme, it is fair to suggest that it is difficult, but possible to introduce HRA techniques. It requires careful attention to the norms, values and needs of the different stakeholders by addressing, for example, issues around the existing knowledge base, the role of scientific evidence in healthcare, and the need of healthcare providers to demonstrate accountability in prescribed ways to regulators, commissioners and patients [38]. As described in Section 2, the predominant frame for patient safety is quality improvement. The introduction of a risk-based approach requires a different mindset, which can be met with scepticism. The techniques can be perceived as overly technical, too resource intensive, and too variable in their outputs [24, 25]. In addition, at present there is a lack of rigorous evaluation of the application of HRA techniques in terms of their impact on patient safety. This is crucial, because healthcare is governed by strong credence in the principle of evidence-based medicine. The burden of unsafe care to health systems worldwide has been documented in a recent report by the OECD [103], and the more widespread and rigorous application of HRA techniques could provide financial incentives. However, the effort that goes into the application of HRA techniques needs to be justified, and the cost-effectiveness of HRA techniques would need to be compared with that of other techniques, such as standard quality improvement approaches. The gold standard of providing evidence through Randomised Controlled Trial designs (RCT) most likely would not be appropriate for the evaluation of such interventions, but more recent trial designs such as stepped wedge study designs (a form of cluster randomised controlled trial) [104] or evaluation approaches rooted in realism [105] might provide useful insights into the applicability and utility of HRA techniques.

Rigorous evaluation of the application of HRA techniques is also an opportunity to advance the understanding of whether and how the use of these techniques contributes to safety improvements. This might be valuable beyond the patient safety context, and the institutional drivers and the necessary evaluation expertise are present in healthcare.

6. ROLE OF THE PATIENT

Patients have an active part in their own care. This is in contrast to traditional safety-critical industries, where the public are assumed to be passive consumers. Healthcare services have been described as being co-produced by patients and healthcare providers [106]. However, if healthcare professionals and patients are working as partners in a joint team to deliver care, how should HRA techniques consider the role of the patient in error prevention and reduction?

There have been considerable efforts to open up patient safety research and practical safety improvement interventions to patient participation. The WHO World Health Alliance for Patient Safety runs a programme on Patients for Patient Safety, with the aim of enhancing patient engagement in patient safety initiatives.

The Health Foundation undertook a literature review on the evidence base for patient involvement in patient safety, and concluded that patients could contribute to identifying adverse events, play an active role in their own safety, and support the planning of change [107].

Within the SCS programme one project actively involved patients in modelling the medicines reconciliation process. The resulting HTA formed the basis for a predictive human error analysis. Medicines reconciliation lends itself very well to patient participation because patients have a very good understanding of the different types of drugs they have been told to take by different healthcare providers. Healthcare professionals, on the other hand, have to rely on letters and handovers, which can be error-prone. As part of the safety improvement interventions, patients were encouraged to bring to hospital their own medications (awareness raising), and special bags were provided for patients to store their medications. The project provided an example of how patients could be meaningfully involved in assessing risks and planning improvements, and be a part of the safety improvement solution.

However, questions remain about whether and how patients should be modelled and analysed within HRA. Patients usually have a much better understanding of their history than healthcare professionals, and they are physically present at every encounter. Healthcare professionals have to rely on frequently incomplete medical records. In addition, patients have a strong self-interest and intrinsic motivation. It might make sense, therefore, to regard the patient as an active participant and part of the patient safety solution. Patient safety interventions, such as empowering patients to challenge healthcare professionals about hand hygiene, and involvement of patients in the medicines reconciliation process are built on this assumption. On the other hand, patients can also contribute to errors, and caution needs to be exercised about the effectiveness of such safety barriers. Lyons suggests that from an engineering perspective patients should not be included as active participants because of the diversity of the patient population (e.g. some patients might suffer from dementia, others might have language barriers etc.) and the problems with barriers that rely on human redundancy [108]. This view is supported by research that suggests that patients might feel uncomfortable challenging healthcare professionals and that it might erode trust between patients and healthcare professionals [109]. There is a lack of conclusive research evidence about the effectiveness of involving patients in error prevention [110, 111].

It is clear that the role of the patient is unique and requires consideration in some form. There is a real opportunity to engage patients in patient safety, and to enhance the knowledge base and requisite imagination that HRA techniques can draw upon by including patients as active participants. However, patient behaviour is not bounded and constrained by professional cultures, procedures and training like that of healthcare professionals. Another challenge HRA techniques face in modelling and analysing the behaviour of patients is the difficulty of eliciting adequate data about patient decision-making and relevant contextual factors, which would be required for estimating patient error probabilities. Further research is needed about how HRA techniques should model the contribution of patients.

7. LIMITATIONS

The analysis presented in this paper is based on the authors' critical reflection of their personal experience of being involved in the design and implementation of SCS. As such, it is subject to potential bias. The authors might have given greater consideration to topics that affected them more deeply, and less consideration to topics that might not have come up during SCS, but which might still be relevant to the application of HRA in healthcare. The strength of critical reflection lies in the deep analysis of experience and the understanding of practice.

8. CONCLUSION

There is a real opportunity to contribute to making healthcare safer through the use of HRA techniques. The use of HRA techniques can support healthcare providers and healthcare professionals to gain a deeper understanding of the ways in which they deliver care, and it can contribute to building relationships and the social infrastructure that will be crucial for implementing change. The application of HRA techniques, in particular when combining the traditional and resilience engineering perspectives, can provide requisite imagination, which allows teams to think differently about what they do, and the vulnerabilities that they face. This can be further strengthened by actively involving patients in the analysis process. The application in healthcare also offers the opportunity to rigorously evaluate the effectiveness and cost-effectiveness of HRA techniques, because there is a strong evidence-based culture in healthcare along with the institutional drivers and the necessary expertise in evaluating complex interventions.

Will it be easy? Experience suggests that a good deal of practical flexibility is required when introducing approaches from other industries, such as HRA techniques. HRA techniques will have to be adapted and applied with due consideration of the specifics of the norms, values and needs of healthcare stakeholders.

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REFERENCES

- [1] Kirwan B. A guide to practical human reliability assessment. London: CRC press; 1994.
- [2] Lyons M, Adams S, Woloshynowych M, Vincent C. Human reliability analysis in healthcare: a review of techniques. *International Journal of Risk & Safety in Medicine*. 2004;16:223-37.
- [3] Kapur N, Parand A, Soukup T, Reader T, Sevdalis N. Aviation and healthcare: a comparative review with implications for patient safety. *JRSM open*. 2016;7:2054270415616548.
- [4] Chandler F, Chang Y, Mosleh A, Marble J, Boring R, Gertman D. Human Reliability Analysis Methods: Selection Guidance for NASA. NASA / Office of Safety and Mission Assurance Technical Report. Washington, DC: NASA; 2006.
- [5] French S, Bedford T, Pollard SJT, Soane E. Human reliability analysis: A critique and review for managers. *Safety Science*. 2011;49:753-63.
- [6] Kirwan B. Human error identification techniques for risk assessment of high risk systems—Part 1: review and evaluation of techniques. *Applied Ergonomics*. 1998;29:157-77.
- [7] Swain AD, Guttman HE. Handbook of human-reliability analysis with emphasis on nuclear power plant applications. Final report. Sandia National Labs., Albuquerque, NM (USA); 1983.
- [8] Bell J, Holroyd J. Review of Human Reliability Assessment Methods. Norwich: HSE; 2009.
- [9] Boring R. Dynamic human reliability analysis: Benefits and challenges of simulating human performance. In: Aven T, Vinnem JE, editors. *ESREL*. Stavanger, Norway: CRC Press; 2007. p. 859-64.

- [10] Williams JC. HEART - A proposed method for achieving high reliability in process operation by means of human factors engineering technology. Symposium on the Achievement of Reliability in Operating Plant. NEC, Birmingham: Safety and Reliability Society (SARS); 1985.
- [11] Hollnagel E. Cognitive Reliability and Error Analysis Method (CREAM). Oxford: Elsevier; 1998.
- [12] Gertman D, Blackman H, Byers J, Haney L, Smith C, Marble J. The Spar-H method. NUREG/CR-6883, Washington, DC: US Nuclear Regulatory Commission; 2005.
- [13] Boring RL. Fifty Years of THERP and Human Reliability Analysis. Probabilistic Safety Assessment and Management Conference (PSAM 11). Helsinki, Finland: Curran Associates; 2012. p. 3523-31.
- [14] Alvarenga MAB, Frutuoso e Melo PF, Fonseca RA. A critical review of methods and models for evaluating organizational factors in Human Reliability Analysis. *Progress in Nuclear Energy*. 2014;75:25-41.
- [15] Mosleh A, Chang YH. Model-based human reliability analysis: prospects and requirements. *Reliability Engineering & System Safety*. 2004;83:241-53.
- [16] Hirschberg S. Human reliability analysis in probabilistic safety assessment for nuclear power plants. *Safety and Reliability*. 2005;25:13-20.
- [17] Chang YHJ, Mosleh A. Cognitive modeling and dynamic probabilistic simulation of operating crew response to complex system accidents. *Reliability Engineering & System Safety*. 2007;92:997-1013.
- [18] Li Y, Mosleh A. Modeling and simulation of crew to crew response variability due to problem-solving styles. *Reliability Engineering & System Safety*. 2017.
- [19] Zio E. Reliability engineering: Old problems and new challenges. *Reliability Engineering & System Safety*. 2009;94:125-41.
- [20] DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system. *The Joint Commission journal on quality improvement*. 2002;28:248-67, 09.
- [21] Apkon M, Leonard J, Probst L, DeLizio L, Vitale R. Design of a safer approach to intravenous drug infusions: failure mode effects analysis. *Quality & safety in health care*. 2004;13:265-71.
- [22] Steinberger DM, Douglas SV, Kirschbaum MS. Use of failure mode and effects analysis for proactive identification of communication and handoff failures from organ procurement to transplantation. *Progress in transplantation* (Aliso Viejo, Calif). 2009;19:208-14; quiz 15.
- [23] Sujan M, Spurgeon P, Inada-kim M, Rudd M, Fitton L, Hornblow S, et al. Clinical handover within the emergency care pathway and the potential risks of clinical handover failure (ECHO): primary research. *Health Serv Deliv Res*. 2014;2.
- [24] Dean Franklin B, Shebl NA, Barber N. Failure mode and effects analysis: too little for too much? *BMJ quality & safety*. 2012;21:607-11.
- [25] Shebl NA, Franklin BD, Barber N. Is failure mode and effect analysis reliable? *J Patient Saf*. 2009;5.
- [26] Embrey D. SHERPA: A systematic human error reduction and prediction approach. Proceedings of the International Topical Meeting on Advances in Human Factors in Nuclear Power Systems. Knoxville, Tennessee: American Nuclear Society; 1986. p. 184-93.
- [27] Phipps D, Meakin GH, Beatty PC, Nsoedo C, Parker D. Human factors in anaesthetic practice: insights from a task analysis. *British journal of anaesthesia*. 2008;100:333-43.
- [28] Chana N, Porat T, Whittlesea C, Delaney B. Improving specialist drug prescribing in primary care using task and error analysis: an observational study. *The British journal of general practice : the journal of the Royal College of General Practitioners*. 2017;67:e157-e67.
- [29] Parand A, Faiella G, Franklin BD, Johnston M, Clemente F, Stanton NA, et al. A prospective risk assessment of informal carers' medication administration errors within the domiciliary setting. *Ergonomics*. 2017:1-18.
- [30] Lane R, Stanton NA, Harrison D. Applying hierarchical task analysis to medication administration errors. *Appl Ergon*. 2006;37:669-79.
- [31] Hughes CML, Baber C, Bienkiewicz M, Worthington A, Hazell A, Hermsdörfer J. The application of SHERPA (Systematic Human Error Reduction and Prediction Approach) in the development of compensatory cognitive rehabilitation strategies for stroke patients with left and right brain damage. *Ergonomics*. 2015;58:75-95.
- [32] Foster JD, Miskovic D, Allison AS, Conti JA, Ockrim J, Cooper EJ, et al. Application of objective clinical human reliability analysis (OCHRA) in assessment of technical performance in laparoscopic rectal cancer surgery. *Techniques in Coloproctology*. 2016;20:361-7.
- [33] Joice P, Hanna GB, Cuschieri A. Errors enacted during endoscopic surgery—a human reliability analysis. *Applied Ergonomics*. 1998;29:409-14.
- [34] Tang B, Hanna GB, Cuschieri A. Analysis of errors enacted by surgical trainees during skills training courses. *Surgery*. 2005;138:14-20.
- [35] Chadwick L, Fallon EF. Human reliability assessment of a critical nursing task in a radiotherapy treatment process. *Applied Ergonomics*. 2012;43:89-97.
- [36] Sands G, Fallon EF, van der Putten WJ. The Utilisation of Probabilistic Risk Assessment in Radiation Oncology. *Procedia Manufacturing*. 2015;3:250-7.
- [37] Deeter J, Rantanen E. Human reliability analysis in healthcare. Proceedings of Symposium on Human Factors and Ergonomics in Health Care. Baltimore, Maryland: Human Factors and Ergonomics Society; 2012. p. 45-51.

- [38] Dixon-Woods M, Martin G, Tarrant C, Bion J, Goeschel C, Pronovost P, et al. *Safer Clinical Systems: Evaluation Findings*. London: Health Foundation; 2014.
- [39] Sujan MA, Chessum P, Rudd M, Fitton L, Inada-Kim M, Cooke MW, et al. Managing competing organizational priorities in clinical handover across organizational boundaries. *Journal of Health Services Research & Policy*. 2015;20:17-25.
- [40] Sujan MA, Habli I, Kelly TP, Gühnemann A, Pozzi S, Johnson CW. How can health care organisations make and justify decisions about risk reduction? Lessons from a cross-industry review and a health care stakeholder consensus development process. *Reliability Engineering & System Safety*. 2017;161:1-11.
- [41] Sujan MA, Habli I, Kelly TP, Pozzi S, Johnson CW. Should healthcare providers do safety cases? Lessons from a cross-industry review of safety case practices. *Safety Science*. 2016;84:181-9.
- [42] Sutcliffe KM, Paine L, Pronovost PJ. Re-examining high reliability: actively organising for safety. *BMJ quality & safety*. 2016.
- [43] Clay-Williams R, Colligan L. Back to basics: checklists in aviation and healthcare. *BMJ quality & safety*. 2015;24:428-31.
- [44] Fook J. Developing Critical Reflection as a Research Method. In: Higgs J, Titchen A, Horsfall D, Bridges D, editors. *Creative Spaces for Qualitative Researching: Living Research*. Rotterdam: SensePublishers; 2011. p. 55-64.
- [45] Jasper MA. Using reflective writing within research. *Journal of Research in Nursing*. 2005;10:247-60.
- [46] Vincent CA. *Patient Safety*. 2nd ed. Chichester: BMJ Books; 2010.
- [47] Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington: The National Academies Press; 2000.
- [48] Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of Adverse Events and Negligence in Hospitalized Patients. *New England Journal of Medicine*. 1991;324:370-6.
- [49] Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal*. 2004;170:1678-86.
- [50] Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals I: occurrence and impact. *The New Zealand medical journal*. 2002;115:U271.
- [51] Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Medical care*. 2000;38:261-71.
- [52] Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ (Clinical research ed)*. 2001;322:517-9.
- [53] Makary MA, Daniel M. Medical error-the third leading cause of death in the US. *BMJ: British Medical Journal (Online)*. 2016;353.
- [54] de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Quality & safety in health care*. 2008;17:216-23.
- [55] Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal Trends in Rates of Patient Harm Resulting from Medical Care. *New England Journal of Medicine*. 2010;363:2124-34.
- [56] Vincent C, Aylin P, Franklin BD, Holmes A, Iskander S, Jacklin A, et al. Is health care getting safer? *BMJ (Clinical research ed)*. 2008;337.
- [57] Sujan MA, Huang H, Braithwaite J. Learning from Incidents in Health Care: Critique from a Safety-II Perspective. *Safety Science*. 2017;99:115-21.
- [58] Cook R. Resilience, the Second Story, and progress on patient safety. In: Hollnagel E, Braithwaite J, Wears R, editors. *Resilient Health Care*. Farnham: Ashgate; 2013. p. 19-26.
- [59] Power M, Stewart K, Brotherton A. What is the NHS Safety Thermometer? *Clinical Risk*. 2012;18:163-9.
- [60] Department of Health. *An organisation with a memory*. London: The Stationery Office; 2000.
- [61] Drupsteen L, Guldenmund FW. What Is Learning? A Review of the Safety Literature to Define Learning from Incidents, Accidents and Disasters. *Journal of Contingencies and Crisis Management*. 2014;22:81-96.
- [62] Le Coze JC. What have we learned about learning from accidents? Post-disasters reflections. *Safety Science*. 2013;51:441-53.
- [63] Lukic D, Littlejohn A, Margaryan A. A framework for learning from incidents in the workplace. *Safety Science*. 2012;50:950-7.
- [64] Spurgeon P, Flanagan H, Cooke M, Sujan M, Cross S, Jarvis R. Creating Safer Health Systems: Lessons from other sectors and an account of an application in the Safer Clinical Systems Programme. *Health Services Management Research*. 2017;30:85-93.
- [65] Sujan M, Spurgeon P, Cooke M, Weale A, Debenham P, Cross S. The Development of Safety Cases for Healthcare Services: Practical Experiences, Opportunities and Challenges. *Reliability Engineering & System Safety*. 2015;140:200-7.
- [66] Berwick DM. A primer on leading the improvement of systems. *BMJ : British Medical Journal*. 1996;312:619-22.
- [67] Institute for Healthcare Improvement. *How-to guide: Prevent Ventilator-Associated Pneumonia*. Cambridge, MA: Institute for Healthcare Improvement; 2010.
- [68] Dixon-Woods M, Martin GP. Does quality improvement improve quality? *Future Hospital Journal*. 2016;3:191-4.
- [69] Stanton N. Hierarchical task analysis: Developments, applications, and extensions. *Appl Ergon*. 2006;37.

- [70] Stanton NA, Stevenage SV. Learning to predict human error: issues of acceptability, reliability and validity. *Ergonomics*. 1998;41:1737-56.
- [71] Storey N. Safety-critical computer systems. Harlow: Pearson Prentice Hall; 1996.
- [72] Daniels R, Nutbeam T, McNamara G, Galvin C. The sepsis six and the severe sepsis resuscitation bundle: a prospective observational cohort study. *Emergency Medicine Journal*. 2011;28:507-12.
- [73] Burnett S, Cooke M, Deelchand V, Dean Franklin B, Holmes A, Moorthy K, et al. Evidence: how safe are clinical systems? London: Health Foundation; 2011.
- [74] McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, et al. The quality of health care delivered to adults in the United States. *New England journal of medicine*. 2003;348:2635-45.
- [75] Braithwaite J, Hibbert PD, Jaffe A, et al. Quality of health care for children in australia, 2012-2013. *JAMA : the journal of the American Medical Association*. 2018;319:1113-24.
- [76] Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat A-HS, Dellinger EP, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. *New England Journal of Medicine*. 2009;360:491-9.
- [77] Vats A, Vincent CA, Nagpal K, Davies RW, Darzi A, Moorthy K. Practical challenges of introducing WHO surgical checklist: UK pilot experience. *BMJ (Clinical research ed)*. 2010;340.
- [78] Pickering SP, Robertson ER, Griffin D, Hadi M, Morgan LJ, Catchpole KC, et al. Compliance and use of the World Health Organization checklist in UK operating theatres. *British Journal of Surgery*. 2013;100:1664-70.
- [79] Cook RI, Wreathall J, Smith A, Cronin DC, Rivero O, Harland RC, et al. Probabilistic Risk Assessment of Accidental ABO-Incompatible Thoracic Organ Transplantation Before and After 2003. *Transplantation*. 2007;84:1602-9.
- [80] Sujan M. An organisation without a memory: A qualitative study of hospital staff perceptions on reporting and organisational learning for patient safety. *Reliability Engineering & System Safety*. 2015;144:45-52.
- [81] Sujan MA. A novel tool for organisational learning and its impact on safety culture in a hospital dispensary. *Reliability Engineering & System Safety*. 2012;101:21-34.
- [82] Sujan M, Spurgeon P, Cooke M. Translating tensions into safe practices through dynamic trade-offs: The secret second handover. In: Wears R, Hollnagel E, Braithwaite J, editors. *The Resilience of Everyday Clinical Work*. Farnham: Ashgate; 2015. p. 11-22.
- [83] Sujan M, Spurgeon P, Cooke M. The role of dynamic trade-offs in creating safety—A qualitative study of handover across care boundaries in emergency care. *Reliability Engineering & System Safety*. 2015;141:54-62.
- [84] Anderson JE, Ross AJ, Jaye P. Modelling resilience and researching the gap between Work-As-Imagined and Work-As-Done. In: Braithwaite J, Wears R, Hollnagel E, editors. *Resilient Health Care III: Reconciling work-as-imagined with work-as-done*. Farnham: Ashgate; 2016. p. 166-75.
- [85] Fairbanks RJ, Wears RL, Woods DD, Hollnagel E, Plsek P, Cook RI. Resilience and resilience engineering in health care. *Joint Commission journal on quality and patient safety / Joint Commission Resources*. 2014;40:376-83.
- [86] Hollnagel E, Woods DD, Leveson N. *Resilience Engineering: Concepts and Precepts*: Ashgate; 2006.
- [87] Hollnagel E. *Safety-I and Safety-II*. Farnham: Ashgate; 2014.
- [88] Braithwaite J, Clay-Williams R, Nugus P, Plumb J. Healthcare as a complex adaptive system. In: Hollnagel E, Braithwaite J, Wears R, editors. *Resilient Health Care*. Farnham: Ashgate; 2013. p. 57-73.
- [89] Marais K, Dulac N, Leveson N. Beyond normal accidents and high reliability organizations: The need for an alternative approach to safety in complex systems. *Engineering Systems Division Symposium 2004*. p. 1-16.
- [90] Leveson N, Dulac N, Marais K, Carroll J. Moving beyond normal accidents and high reliability organizations: a systems approach to safety in complex systems. *Organization Studies*. 2009;30:227-49.
- [91] Woods D, Branlat M. Basic patterns how adaptive systems fail. In: Hollnagel E, Paries J, Woods D, Wreathall J, editors. *Resilience Engineering in Practice: A Guidebook*. Farnham: Ashgate; 2011. p. 127-43.
- [92] Cook RI, Render M, Woods DD. Gaps in the continuity of care and progress on patient safety. *BMJ (Clinical research ed)*. 2000;320:791-4.
- [93] Hollnagel E. *FRAM, the functional resonance analysis method: modelling complex socio-technical systems*: Ashgate Publishing, Ltd.; 2012.
- [94] Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implementation Science*. 2015;10:125.
- [95] Nakajima K. Blood transfusion with health information technology in emergency settings from a Safety-II perspective. In: Wears R, Hollnagel E, Braithwaite J, editors. *Resilient Health Care Volume 2: The resilience of everyday clinical work*. Farnham: Ashgate; 2015. p. 99-114.
- [96] Westrum R. Cultures with Requisite Imagination. In: Wise JA, Hopkin VD, Stager P, editors. *Verification and Validation of Complex Systems: Human Factors Issues*. Berlin, Heidelberg: Springer Berlin Heidelberg; 1993. p. 401-16.
- [97] Boring RL. Human reliability analysis in cognitive engineering and system design. *Frontiers of Engineering: Reports on Leading-Edge Engineering from the 2008 Symposium: National Academy of Engineering Washington, DC*; 2009. p. 103-10.
- [98] Sujan MA, Felici M. Combining Failure Mode and Functional Resonance Analyses in Healthcare Settings. *Computer Safety, Reliability, and Security*. 2012:364-75.
- [99] Steen R, Aven T. A risk perspective suitable for resilience engineering. *Safety Science*. 2011;49:292-7.

- [100] Illingworth J. Continuous improvement of patient safety.: The case for change in the NHS. London, UK: The Health Foundation; 2015.
- [101] NHS England Patient Safety Domain. Revised Never Events Policy and Framework. London: NHS England; 2015.
- [102] Health and Safety Executive. Reducing Risk: Protecting People. 2001.
- [103] Slawomirski L, Aaraaen A, Klazinga NS. The economics of patient safety. Paris: OECD; 2017.
- [104] Burke RE, Shojania KG. Rigorous evaluations of evolving interventions: can we have our cake and eat it too? *BMJ Quality & Safety*. 2018;27:254-7.
- [105] Pawson R, Tilley N. Realistic Evaluation. London: Sage; 1997.
- [106] Batalden M, Batalden P, Margolis P, Seid M, Armstrong G, Opipari-Arrigan L, et al. Coproduction of healthcare service. *BMJ quality & safety*. 2016;25:509-17.
- [107] Health Foundation. Evidence Scan: Involving Patients in Patient Safety. London: Health Foundation; 2013.
- [108] Lyons M. Should patients have a role in patient safety? A safety engineering view. *Quality and Safety in Health Care*. 2007;16:140-2.
- [109] Davis RE, Jacklin R, Sevdalis N, Vincent CA. Patient involvement in patient safety: what factors influence patient participation and engagement? *Health Expectations*. 2007;10:259-67.
- [110] Lawton R, O'Hara JK, Sheard L, Armitage G, Cocks K, Buckley H, et al. Can patient involvement improve patient safety? A cluster randomised control trial of the Patient Reporting and Action for a Safe Environment (PRASE) intervention. *BMJ Quality & Safety*. 2017;26:622-31.
- [111] Wachter RM. Patient Safety At Ten: Unmistakable Progress, Troubling Gaps. *Health Affairs*. 2010;29:165-73.

Table 1: Projects within the SCS programme. Study sites 1 - 4 participated during Phase 1; study sites 5 - 12 participated during Phase 2.

Study site Project aim

1	Improve the reliability of handover within the neurology and the emergency departments.
2	Improve the reliability of in-hospital prescribing.
3	Improve the reliability of handover across the urgent care pathway.
4	Improve the reliability and accuracy of patient registration.
5	Improve the reliability of prescribing in an Emergency Admissions Unit at 24-hours post admission.
6	Improve the reliability of prescribing for patients with Parkinson's Disease admitted as an emergency to the hospital.
7	Improve the reliability of the Hospital at Night handover.
8	Improve the reliability of shared care communication between the urology and surgery departments for patients with acute renal failure.
9	Improve the reliability of prescribing in an Acute Medical Admissions Unit.
10	Improve the reliability of handover between hospital, primary and community care for frail and elderly patients.
11	Improve the reliability of handover for children with complex needs.
12	Improve the reliability of in-hospital prescribing.

Table 2: Overview of the SCS approach

SCS Step	Description
Step 1 – Pathway definition and context	<p>Scoping and definition of the pathway to be improved.</p> <p>Qualitative and quantitative description of organisational and safety culture.</p>
Step 2 – System diagnosis	<p>Proactive analysis of the patient pathway.</p> <p>Identification of hazards and risks.</p>
Step 3 – Option appraisal	<p>Development of shared understanding of risks to patients.</p> <p>Identification and development of options to reduce risks.</p>
Step 4 - Planning	<p>Definition of proposed patient safety improvement interventions.</p> <p>Planning of interventions through system redesign and design for safety.</p>
Step 5 – System improvement	<p>Rapid improvement cycles.</p> <p>Reassessment of hazards and risks.</p> <p>Support sustainability through organisational change management.</p>

Table 3: Task Activity Classification Taxonomy (TACT) used in SHERPA

Action failures	Checking failures	Communication failures
A1 Operation too long / short	C1 Check omitted	I1 Information not communicated
A2 Operation mistimed	C2 Check incomplete	I2 Wrong information communicated
A3 Operation in wrong direction	C3 Right check on wrong object	I3 Information communication incomplete
A4 Operation too little / too much	C4 Wrong check on right object	I4 Information communication unclear
A5 Operation too fast / too slow	C5 Check too early / late	
A6 Misalign		
A7 Right operation on wrong object	Information retrieval failures	Selection failures
A8 Wrong operation on right object	R1 Information not obtained	S1 Selection omitted
A9 Operation omitted	R2 Wrong information obtained	S2 Wrong selection