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What kinds of insights do Safety-I and Safety-II approaches provide? A critical reflection on the use of SHERPA and FRAM in healthcare

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1. Introduction

Over the past decade, the field of healthcare has seen a significant shift in its approach to patient safety. Traditionally, safety efforts focused on understanding past harm and preventing errors, primarily through the use of standardisation and the introduction of barriers and safeguards, such as standardised communication protocols (e.g., SBAR (Haig et al., 2006)), checklists (e.g., WHO surgical safety checklist (Haynes et al., 2009)) and technology with safety features (e.g., smart infusion pumps (Taxis and Franklin, 2011)). This type of thinking about patient safety in terms of past harm and errors is also referred to as Safety-I (Hollnagel, 2014), even though this terminology has been criticised as it does not reflect adequately the diversity in safety science thinking (Leveson, 2020). However, the evidence for whether interventions based on this (Safety-I) thinking lead to improvements in patient safety is mixed at best (Kellogg et al., 2017, Wears and Sutcliffe, 2019), and critics have argued that the additional "safety clutter" produced as a result of such interventions might be counterproductive (Rae et al., 2018, Halligan et al., 2023).

The growing recognition of the intricate nature of healthcare systems has led to the development of systems approaches, which are thought to be better suited for improving the quality and safety of care. For example, the SEIPS model (Systems Engineering Initiative for Patient Safety) (Carayon et al., 2020, Holden et al., 2013) focuses on interactions between different elements of a work system, and the field of Resilient Health Care (Hollnagel et al., 2019) is built on principles of Resilience Engineering (RE) (Hollnagel et al., 2006). Resilience Engineering suggests that risks can arise not only from the potential failures of individual system elements but also from the structure and interconnectedness of the systems themselves. Resilience has been defined as the ability to succeed under varying conditions, with a focus on how people and organisations cope with complexity and uncertainty in dynamic environments (Woods and Hollnagel, 2006).

The concept of resilience evolved to encompass four fundamental aspects or cornerstones of Resilience Engineering (Hollnagel, 2010), also referred to as resilience abilities or resilience potentials (Hollnagel, 2018): monitoring, responding, anticipating and learning. In healthcare, this has also been interpreted as the ability to adapt to challenges and changes across different levels of a system in order to maintain high-quality care (Wiig et al., 2020). This perspective emphasises the focus on abilities rather than the more traditional focus on barriers and defences. The term Safety-II was introduced to clarify this distinction between the two perspectives on safety (i.e., Safety-I and Safety-II) along with their underlying assumptions (Hollnagel, 2014).

Resilient Health Care, along with the concept of Safety-II, appears to be embraced with significant enthusiasm and interest by those working in the field of patient safety, but the practical application remains challenging (Verhagen et al., 2022). Such practical problems include how to learn continuously and meaningfully from everyday work rather than from adverse events (Sujan et al., 2017), how to use the largely descriptive studies of everyday work to improve resilience and patient safety, and how to evidence and assess the effectiveness of any such improvements (Verhagen et al., 2022). In addition, practitioners need to consider how to reconcile existing Safety-I approaches (e.g., root cause analysis) with Safety-II thinking, whether these can coexist, or whether Safety-II provides a complementary approach, or whether safety management strategies require a complete overhaul.

Arguably, successful patient safety management requires requisite variety developed from a broad and diverse set of thinking, principles and approaches, which reflect the diversity of healthcare systems and their dynamic contexts (Amalberti and Vincent, 2020). However, it is important that the underlying principles of different approaches and their practical implications are understood in order to harness their potential (Sutcliffe et al., 2017, Sujan and Habli, 2021).

In this paper we explore the insights provided by Safety-I and Safety-II approaches by examining an example of the practical application of

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two frequently used methods: Systematic Human Error Reduction and Prediction Approach (SHERPA) (Embrey, 1986) and Functional Resonance Analysis Method (FRAM) (Hollnagel, 2012). Neither method should be uniquely labelled as a Safety-I or Safety-II approach, because analysts can use the methods coming from different perspectives or mindsets. However, SHERPA is traditionally used within a Safety-I context, and FRAM is frequently used within a Safety-II context (for the latter, see for example the overview of FRAM use provided by Patriarca and colleagues (Patriarca et al., 2020)). SHERPA is a Human Reliability Analysis technique developed in the 1980s, and it provides a structured approach to analysing and controlling the risk associated with human performance (Sujan et al., 2020). In this sense, SHERPA is closely aligned to Safety-I thinking. On the other hand, FRAM is a more recent method based on Resilience Engineering principles. FRAM supports a systems perspective through the analysis of dependencies and interactions, emphasising the importance of variability and adaptation (Hollnagel, 2012). FRAM can be used, therefore, to investigate systems from a Safety-II perspective. By examining the application of these two methods to the example of the management of post-surgical deterioration, we will critically reflect on the analysis logic embedded in each method and their potential contribution to improving patient safety.

This critical reflection adds to the body of literature, which has compared FRAM with other methods across a range of industries. Examples include methods such as Fault Trees, Root Cause Analysis and Systems-Theoretic Accident Model and Processes (STAMP) (Patriarca et al., 2020). Several studies have suggested integration of Safety-I and Safety-II based methods, e.g., for organisational learning (Martins et al., 2022, Verhagen et al., 2020, Sujan et al., 2011) and to understand procedural violations (Jones et al., 2018).

The next section (Section 2) provides background on SHERPA and FRAM. Then, the healthcare application scenario and the overall research approach are outlined (Section 3). The application of SHERPA and FRAM to this scenario is described in Section 4 and Section 5, respectively. In Section 6 a critical reflection on the application of the two methods is provided. Conclusions are offered in Section 7.

2. Background

2.1. Overview of SHERPA

SHERPA is a method that belongs to the class of Human Reliability Analysis (HRA) techniques. Such techniques gained popularity during the 1970s and 1980s, initially as a way of considering the human contribution to accidents in probabilistic risk assessments. HRA techniques have their roots in the nuclear sector, where the aim was to quantify human error probabilities (Swain and Guttmann, 1983). Since these early days, numerous HRA techniques have been developed and used across most safety–critical industries. A review by the Health & Safety Executive identified 79 HRA techniques (Bell and Holroyd, 2009). While initially the focus was on quantifying human error, over time many of the HRA approaches used in practice have given greater emphasis to the qualitative description and assessment of human error. This is largely due to the significant uncertainty often associated with human error quantification and the amount of effort involved.

HRA techniques are sometimes classified into chronological generations, but this approach has been contested (Boring, 2007). Some HRA techniques use taxonomies of human tasks, which have a nominal human error probability (HEP) assigned. This nominal HEP is then modified based on the quality of the context or so-called Performance Shaping Factors (PSFs) or Performance Influencing Factors (PIFs) (examples include (Swain and Guttmann, 1983, Williams, 1985)). Other HRA approaches include models of human cognition rather than nominal task specific HEPs. The precursor to FRAM, the Cognitive Reliability and Error Analysis Method (CREAM) is such an example (Hollnagel, 1998). More recently, HRA techniques using simulation models have been developed, which might improve quantitative approaches (Mosleh and Chang, 2004).

SHERPA was developed in the 1980s, initially for use in the nuclear industry (Embrey, 1986), but has subsequently been used widely across different industries. SHERPA has been shown to provide good reliability and validity across a number of studies (Kirwan, 1998), while also being reasonably straightforward to apply in practice. SHERPA is firmly rooted in traditional HRA and, hence, Safety-I thinking, but in current practice SHERPA is often used more broadly to reason systematically about human performance, the contextual conditions that impact human performance, and the improvements that can be put in place to improve overall system performance.

SHERPA is based on a simple, high-level taxonomy of human behaviours and associated errors, see Table 1.

A SHERPA analysis consists of two main phases: (1) task analysis using Hierarchical Task Analysis (HTA) and (2) Predictive Human Error Analysis (PHEA) using the taxonomy shown in Table 1. Task analysis techniques including HTA have been described extensively and comprehensively elsewhere (Kirwan and Ainsworth, 1992, Stanton, 2006). The typically graphical HTA is transferred into a tabular representation for PHEA. For each task step, the analyst considers:

- The potential failure mode / human error
- The potential consequences of the failure
- Relevant PIFs
- Suggestions for making the failure less likely and for reducing the severity of the consequences (i.e., for controlling the risk)

When considering suggestions for improvements, the analyst should consider first the hierarchy of control (in a UK context as required by the Health & Safety Executive (COMAH Competent Authority, 2016)) before moving on to improvements in the performance influencing factors, i.e., the intention is to reduce reliance on people before subsequently making it easier for people to do the right thing.

2.2. SHERPA in healthcare

While the use of HRA techniques is very common in many safety–critical industries, and is often a regulatory requirement (e.g., in the UK petrochemical industry regulated by the Health & Safety Executive), the use of such techniques in healthcare is less common (Sujan et al., 2020). However, there are now several published studies describing the

Table 1
SHERPA human behaviour and error taxonomy.

Behaviour Type	Code	Error Mode
Action	A01	Action too long / too short
	A02	Action mistimed
	A03	Action in wrong direction
	A04	Action too little / too much
	A05	Action too fast / too slow
	A06	Misalign
	A07	Right action on wrong object
	A08	Wrong action on right object
	A09	Action omitted
Checking	C01	Check omitted
	C02	Check incomplete
	C03	Right check on wrong object
	C04	Wrong check on right object
	C05	Check too early / too late
Information Retrieval	R01	Information not obtained
	R02	Wrong information obtained
	R03	Information retrieval incomplete
	R04	Information incorrectly interpreted
Communication	I01	Information not communicated
	I02	Wrong information communicated
	I03	Information communication incomplete
	I04	Information communication unclear
Selection	S01	Selection omitted
	S02	Wrong selection

application of SHERPA in healthcare, which might be indicative of a growing interest in this technique.

SHERPA has been used to identify human errors in anaesthesia (Phipps et al., 2008), and to analyse drug prescription and administration in hospital, primary care and community settings (Chana et al., 2017, Lane et al., 2006, Parand et al., 2017). In addition to these studies, which consider the performance of healthcare professionals, SHERPA has also been used in an innovative way to understand and improve the ability of stroke patients to deal with everyday tasks (Hughes et al., 2015). An adaptation of SHERPA called Observational Clinical Human Reliability Analysis technique (OCHRA) has been used to describe and classify errors in surgical technique (Foster et al., 2016, Joice et al., 1998, Tang et al., 2005).

2.3. Overview of FRAM

The Functional Resonance Analysis Method (FRAM) is one of the most widely used methods based on Resilience Engineering thinking (Hollnagel, 2012). FRAM was initially developed as an accident model, but has since been transformed into an analysis method with an emphasis on exploring work-as-done (WAD), i.e., everyday work as actually carried out, along with the normal variability resulting from trade-offs and adaptations (Hollnagel, 2009), and the numerous functional interactions within a system.

Using FRAM, a function (a purposeful activity in a system, which can be human, technological or organisational) is described with six aspects, which refer to the ways in which a function can be connected to other functions. These aspects are: (1) input, (2) output, (3) control, (4) resource, (5) precondition, and (6) time. Graphically, a function is represented as a hexagon, where the output of a function can be connected to another function via one of its aspects (other than output).

A FRAM analysis typically consists of four steps (Hollnagel, 2012):

1. Identification of functions
2. Description of performance variability of each function
3. Analysis of couplings between functions
4. Monitoring and control of variability

FRAM distinguishes between a model and an instantiation. The model describes the potential variability and couplings between functions, whereas instantiations look at the actual variability and couplings in the model representing a specific situation or scenario. In other words, a FRAM model can be regarded as the combination of multiple instantiations. When used for the investigation of accidents and adverse events, i.e., for events that have already happened, there is no potential variability. Hence, this analysis would be, in the first instance, an instantiation. However, there is value in building the FRAM model (with potential variability) because this enables the analyst to look beyond the specific accident (or event) to understand how the system normally functions.

FRAM offers flexibility to the analyst in terms of the underlying epistemological paradigm (Sujan et al., 2023). A FRAM analysis can be approached from a more realist (computational FRAM) as well as from a more phenomenological perspective (reflexive FRAM). What this means is that in the former case FRAM is used to model systems and variability in a reasonably objective and potentially quantifiable way (e.g., Patriarca et al., 2018). In the latter case, FRAM is used in an interpretative way by the analyst, who brings their own knowledge, background and experiences to bear on the analysis in order to develop insights about resilient performance (e.g., Furniss et al., 2020).

2.4. FRAM in healthcare

While FRAM was initially developed and applied in safety–critical industries, especially the aviation sector (Herrera and Woltjer, 2010, Martinie et al., 2013), there has been a rapidly growing number of publications describing the use of FRAM in healthcare settings (McGill et al., 2022, Salehi et al., 2021). There is also a strong international research community, now formally established as the Resilient Health Care Society, which has produced six edited volumes on Resilient Health Care to date.

Most of the papers describing the use of FRAM in healthcare have been published in safety science (e.g., Buikstra et al., 2020, Kaya et al., 2019, Schutijser et al., 2019), engineering (e.g., Patriarca et al., 2018, Raben et al., 2018a, Raben et al., 2018b) and ergonomics journals (e.g., Furniss et al., 2020, Pickup et al., 2017). FRAM studies are also starting to be published in healthcare journals, which is indicative of a tentative interest in FRAM beyond the more obvious communities mentioned above (Clay-Williams et al., 2015, MacKinnon et al., 2021, McNab et al., 2018).

3. Method

3.1. Research approach

Critical reflection is a frequently used process of learning from experience in order to improve professional practice (Fook, 2011). Critical reflection can be interpreted as a higher-level reflection-on-action (Schön, 1983). It goes beyond describing decision-making and choices in practice (referred to as reflection-in-action) and encourages an analytical approach that examines underlying assumptions that influence decision-making and actions.

The work described in this paper was part of a larger programme of research concerned with developing and evidencing interventions to improve the management of post-surgical deterioration. A particular focus of this research programme was the investigation of the applicability of Safety-II thinking in this context because Safety-II is becoming subject to enthusiasm-based adoption without rigorous evaluation (Sujan et al., 2022b), see also the critique by Cooper outside of healthcare (Cooper, 2022). A main objective for using SHERPA was the comparison with FRAM reported in this paper. The SHERPA analysis was undertaken in line with normal industry practice informed largely by practical experience in the petrochemical sector (Furniss et al., 2019).

SHERPA and FRAM were applied by the same researcher, who has experience with both methods in different contexts. Therefore, the comparison of the two methods is not an independent exercise of assessing or evaluating the approaches, but rather a critical reflection on their use based on a deep understanding of their respective underlying principles and logic. It is neither possible nor desirable to close one's mind to prior experiences, and in this case, this means that even when using a Safety-I or Safety-II method, this was done not by blindly following a paradigm but from the broader perspective of an experienced professional, which would also be the case (ideally) in practice.

The author group met weekly during 2020 – 2023 for the overall research program and reflected individually and in discussion on the use of SHERPA and FRAM in the project. The critical reflection on the use of the two methods led to the development of three dimensions or broader topics for structuring the discussion. These were (1) representation of clinical work, i.e., how the methods describe clinical work, (2) assessment logic, i.e., how clinical work is analysed with each of the methods, and (3) the nature of recommendations and improvement suggestions developed with the two methods. These dimensions do not represent the only way in which the methods could have been compared. For example, FRAM has been compared to other methods for incident investigation based on model characteristics (e.g., component relationships, learning costs and structure), the analysis process and the nature of the results (Qiao et al., 2019). Similarly, Safety-I and Safety-II (along with Safety-III) have been compared along a set of eight aspects (Aven, 2022).

The research was undertaken with ethical approval by the Health Research Authority and IRAS approval from Cambridge East REC (IRAS project ID 270881, REC reference 20/EE/0259).

3.2. Management of postsurgical deterioration

The clinical scenario used in this paper is the management of post-surgical deterioration. The recognition of and adequate response to acute deterioration is a significant patient safety concern (Ghaferi and Dimick, 2015). Failure to manage deterioration can lead to patient death, referred to as "failure to rescue" (FTR) (Silber et al., 1992), and FTR rates have been found to range between 8 % − 18 % across surgical settings (Johnston et al., 2015b).

A large body of literature exists on FTR (Burke et al., 2020), yet the management of acute deterioration remains highly variable. Contributory factors identified in the literature include lack of clinical experience, high workload, overconfidence, communication problems, equipment and logistical bottlenecks, delayed referrals and transfers, and difficulties in locating senior doctors due to competing priorities (Peebles et al., 2012, Johnston et al., 2015b, Burke et al., 2020, Wakeam et al., 2014b, Callaghan et al., 2017, Donohue and Endacott, 2010). Strategies for reducing FTR include higher nurse staffing levels and a higher percentage of nurses educated to degree level (Blegen et al., 2013, Rafferty et al., 2007). Trigger tools such as the UK National Early Warning Score (NEWS2) are widely used (Royal College of Physicians, 2017), but not universally found to improve outcomes (Bedoya et al., 2019, Donohue and Endacott, 2010). Improvement efforts also include the use of clear standardised escalation and communication protocols, Rapid Response Teams (RRT), and a focus on safety culture (Ghaferi and Dimick, 2015, Johnston et al., 2015a, Johnston et al., 2014, Wakeam et al., 2014b, Wakeam et al., 2014a).

3.3. Setting

The study setting was a surgical emergency unit (SEU) within a National Health Service (NHS) teaching hospital in England. This setting was chosen because post-surgical deterioration is particularly likely following emergency surgery. The SEU is considered large with 54 beds. Daytime staffing levels are ca. 35 staff, including four consultant surgeons. In addition, there is a perioperative medicine team. During the night, medical staffing levels are reduced and include two junior doctors, two middle grade doctors and one consultant.

4. SHERPA

4.1. How SHERPA was used in the project

The SHERPA analysis was undertaken by an individual with experience in the use of the technique in other sectors (mainly the petrochemical industry). Participants (subject matter experts) were: an experienced nurse, a middle-grade doctor and a consultant surgeon working on SEU, as well as an experienced Advanced Clinical Practitioner external to the organisation. Such a relatively small number of participants is common in industrial practice. The analysis involved initial exploratory interviews and then a series of conversations and feedback on draft analysis outputs.

In the first phase an HTA for the high-level goal "Manage patient at risk of deterioration" was produced, see Figs. 1–4. The high-level goal was broken down into eight sub-goals, which are dependent on the trigger score (see the high-level plan). The trigger score can be normal, in which case care management proceeds as before; it can be elevated and, therefore, preliminary escalation actions need to be implemented; or it can be serious and require escalation to a senior doctor with a range of subsequent escalation options, such as transfer to intensive care or transfer to theatre for emergency surgery.

The graphical HTA was then converted into tabular format for the predictive human error analysis, see Table 2. The error analysis is at the heart of a SHERPA analysis. Participants were prompted to consider credible failures for each task step they were familiar with. The analyst prompted participants to consider "how might this step fail?" and then selectively encouraged consideration of some of the prompts depending on the discussion. Participants were asked to identify possible consequences of the failure, which in itself can be challenging (see e.g., (Pasquini et al., 2011) for a discussion). The analyst then prompted consideration of PIFs. Finally, participants were asked to make suggestions for possible improvements, which could reduce the likelihood of failure or mitigate the severity of the consequences. This step was an open conversation, and the analyst did not impose consideration of the hierarchy of control or similar concepts, because their applicability in healthcare has been contested, for example because "administrative" controls such as standardisation can potentially reduce risk effectively even though such controls are regarded as weak (Liberati et al., 2018).

4.2. The types of insights and interventions / recommendations generated from the SHERPA analysis

The HTA that was developed as the first part of SHERPA provided a helpful general overview of the management of patients at risk of deterioration in terms of the high-level breakdown of people's tasks. This was useful for focusing and structuring the analysis. At the same time, the hierarchical nature of HTA enabled very detailed analysis of specific task steps. For example, in Fig. 2 task step 3.2 describing the initial escalation was broken down further into three sub-goals, because participants felt it was important to include detail about how this was done, i.e., by looking up the patient's electronic notes (task step 3.2.2) and communicating the concern using a structured communication protocol (task step 3.2.3). The hierarchical breakdown was done pragmatically, depending on whether participants or the analyst felt that further detail might provide useful insight. For example, task step 2.2 (complete vital signs observations) was initially broken down further to

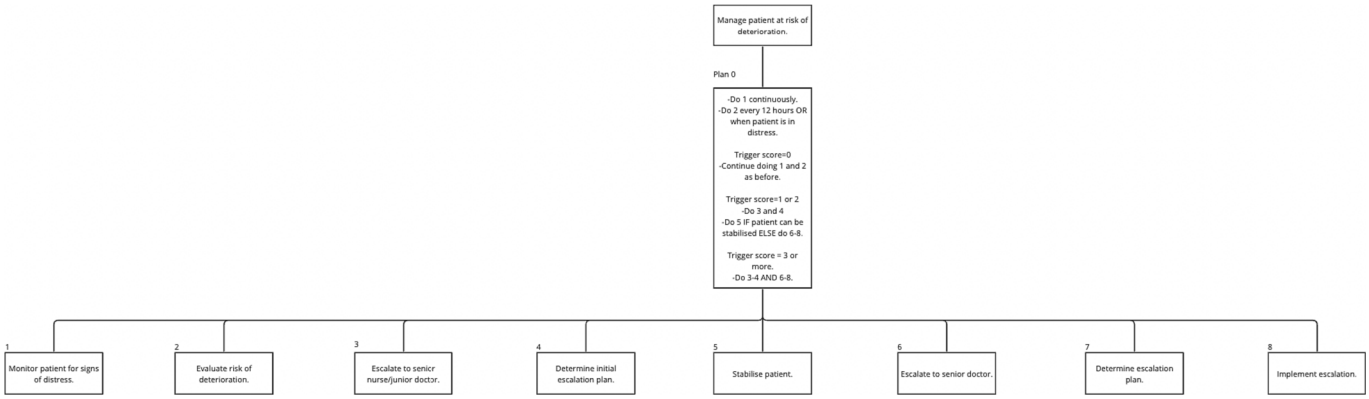


Fig. 1. HTA for the management of patient at risk of deterioration (high-level structure).

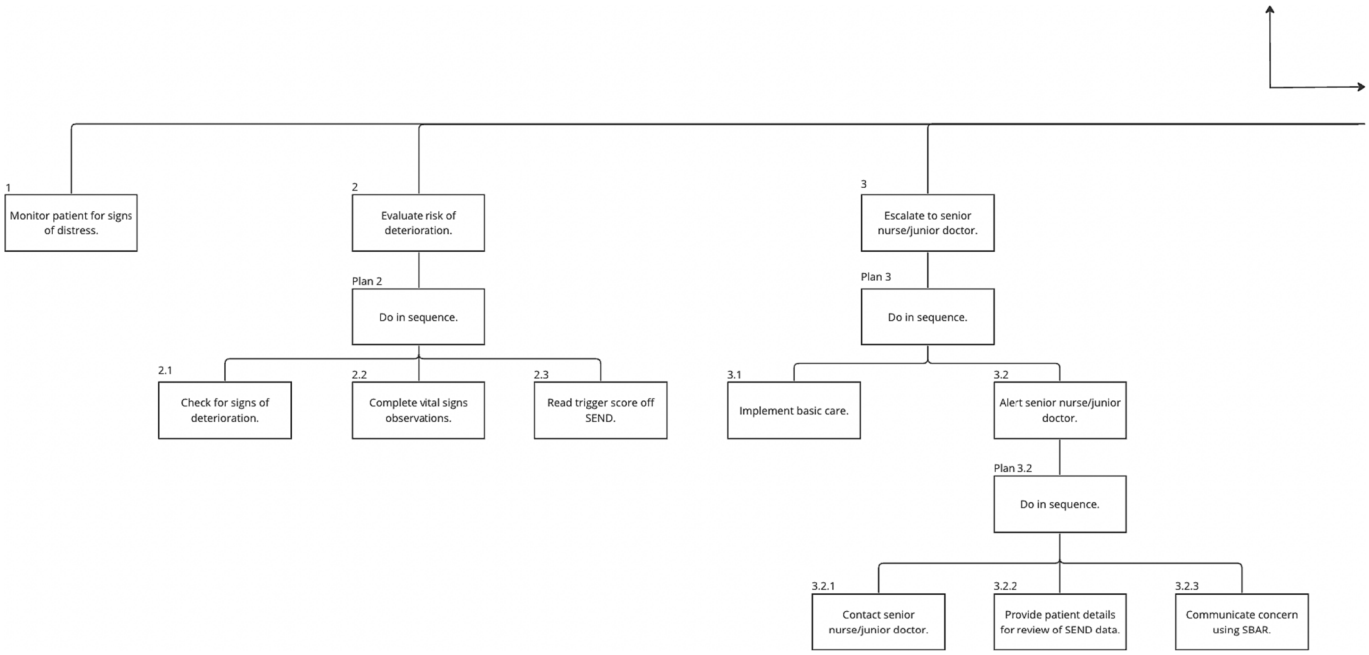


Fig. 2. HTA for the management of patient at risk of deterioration (sub-goals 1——3) (SEND: System for Electronic Notification and Documentation; SBAR: Situation, Background, Assessment, Recommendation).

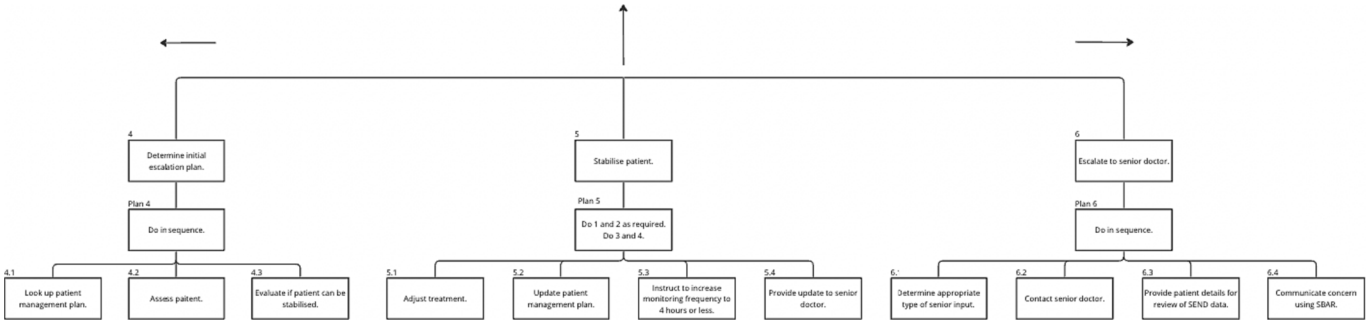


Fig. 3. HTA for the management of patient at risk of deterioration (sub-goals 4——6) (SEND: System for Electronic Notification and Documentation; SBAR: Situation, Background, Assessment, Recommendation).

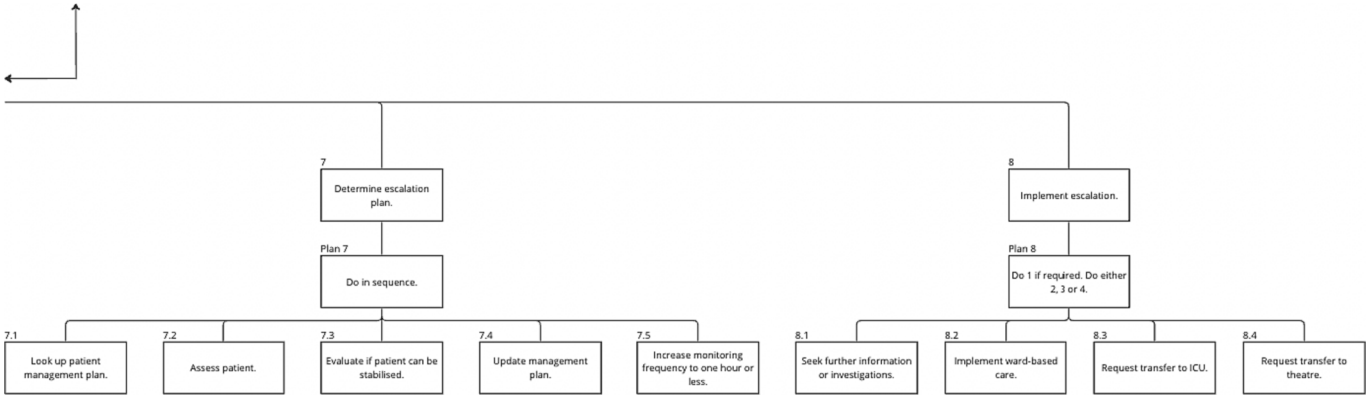


Fig. 4. HTA for the management of patient at risk of deterioration (sub-goals 7——8).

include detail about the technology used (SEND – System for Electronic Notification and Documentation), but was subsequently analysed at the higher level, because it was felt that this provided sufficient insight for the purpose of the analysis.

The predictive human error analysis supported detailed assessment of the different ways in which the discrete task steps and the overall task as a whole can fail. Credible failures or vulnerabilities were identified for all task steps, and many of these were thought to have the potential to cause patient harm if left unaddressed. Table 2 provides a structured summary. Examples include checks done too late or incompletely, and

Table 2
Summary of SHERPA output for management of patient deterioration (SEND: System for Electronic Notification and Documentation; SBAR: Situation, Background, Assessment, Recommendation).

ID	Description	Failure Mode	Error description	Consequences	PIFs	Improvements
1	Monitor patient for signs of distress	C05 – Check too late	Nurse detects patient distress too late	Delay to escalation	Workload (nurse away from patient bedside) Organisation: staffing levels	Enable patients to raise concerns Ensure adequate staffing levels are met
2	Evaluate risk of deterioration					
2.1	Check for signs of deterioration	C02 – Check incomplete	Nurse does not perform a thorough assessment	Delay to escalation	Workload (nurse needs to complete check quickly) Person: experience (nurse does not know what assessments to perform)	Ensure adequate staffing levels are met Reduce reliance on agency staff / only use experienced agency staff
2.2	Complete vital signs observations	R01 – Information not obtained	Nurse does not do vital signs observations or with significant delay	Delay to escalation	Workload (nurse away from patient bedside) Staffing levels Equipment: availability (measurement equipment unavailable)	Ensure adequate staffing levels Ensure adequate equipment availability
		R04 – Information incorrectly interpreted	Nurse makes error in measurement or interpretation of vital signs information	Delay to escalation	Equipment: usability (reading of measurements difficult) Procedure: clarity (nurse unclear about how to interpret vital signs data)	Ensure procedure up to date and staff competent
2.3	Read trigger score off SEND	R04 – Information incorrectly interpreted	Nurse fails to recognise importance of trigger score	Delay to escalation	Person: experience (inexperienced nurse)	Ensure procedure up to date and staff competent
3	Escalate to senior nurse or junior doctor					
3.1	Implement basic care	A09 – Action omitted	Nurse does not implement an aspect of basic care (e.g., pain relief)	Patient discomfort		Staff training
3.2	Alert senior nurse or junior doctor					
3.2.1	Contact senior nurse or junior doctor	A09 – Action omitted	Nurse does not contact senior nurse or junior doctor or with significant delay	Delay to escalation, serious patient harm	Workload (senior nurse / junior doctor busy) Organisation: staffing level	
3.2.2	Provide patient details for review of SEND data	I02 – Wrong information communicated	Nurse provides details of wrong patient	Wrong patient record looked up	Tools & equipment: nurse having to rely on memory	This should be picked up and corrected when junior doctor looks up the record and discussed details with nurse.
3.2.3	Communicate concern using SBAR	I03 – Information communication incomplete	SBAR not used	Severity of deterioration not recognised immediately	Procedure: usability, applicability (perceived lack of value of procedure)	Staff training (SBAR) Teamwork training
4	Determine initial escalation plan					
4.1	Look up patient management plan	S02 – Wrong selection	Junior doctor looks up wrong patient	Delay to escalation, serious patient harm	Technology: usability (selection error on IT system)	Procurement of usable technology and software systems
		R01 – Information not obtained	Patient does not have a management plan	Delay to escalation		Ensure all patients have a management plan done on admission
4.2	Assess patient	A09 – Action omitted	Junior doctor does not assess patient in a timely fashion	Delay to escalation, serious patient harm	Workload (junior doctors having to deal with several patients concurrently, need to prioritise) Organisation: staffing levels	
4.3	Evaluate if patient can be stabilised	R04 – Information incorrectly interpreted	Junior doctor does not recognise signs of deterioration (e.g., internal bleeding in young and healthy looking patient)	Delay to escalation, serious patient harm	Person: experience (junior doctors are inexperienced)	Teamwork training (bringing in experienced nurse input)
5	Stabilise patient					
5.1	Adjust treatment	R04 – Information incorrectly interpreted	Junior doctor fails to adjust treatment correctly	Patient deterioration, need for subsequent escalation	See 4.3	See 4.3 Enable access to senior input and timely review
5.2	Update patient management plan	A09 – Action omitted	Junior doctor fails to update patient management plan	Delay to treatment	Workload Technology: availability (no access to IT at the patient's bedside)	See 4.1

(*continued on next page*)

Table 2 (*continued*)

ID	Description	Failure Mode	Error description	Consequences	PIFs	Improvements
5.3	Increase monitoring frequency to 4 h or less	A09 – Action omitted	Junior doctor fails to adjust monitoring frequency	Patient deterioration, need for subsequent escalation	See 4.3	See 4.3 See 5.1
5.4	Provide update to senior doctor	I01 – Information not communicated	Senior doctor is not informed of patient deterioration (patient stabilised)	Delay to updating patient management plan	Person: experience (junior doctor does not recognise importance of updating senior doctor) Organisation: staffing levels (senior doctor unavailable)	Ensure escalation procedure up to date and staff competent
6	Escalate to senior doctor					
6.1	Determine appropriate type of senior input	R04 – Information incorrectly interpreted	Junior doctor misinterprets patient's condition and contacts wrong type of senior clinician	Delay to escalation	See 4.3	See 4.3
6.2	Contact senior doctor	I01 – Information not communicated	Senior doctor is not informed of serious patient deterioration	Delay to escalation, serious patient harm	Person: experience (junior doctor with little experience) Organisation: no senior cover during the night Organisation: senior doctor unavailable (in theatre)	See 4.3 Ensure senior doctor availability on ward during night time
6.3	Provide patient details for review on SEND	I02 – Wrong information communicated	Junior doctor provides details of wrong patient	See 3.2.2	See 3.2.2	This should be picked up in the discussion
6.4	Communicate concern using SBAR	I03 – Information communication incomplete	See 3.2.3	See 3.2.3	See 3.2.3	See 3.2.3
7	Determine escalation plan					
7.1	Look up patient management plan	S02 – Wrong selection	Senior doctor looks up wrong patient	See 4.1	See 4.1	See 4.1
		R01 – Information not obtained	See 4.1	See 4.1		See 4.1
7.2	Assess patient	A09 – Action omitted	Senior doctor does not assess patient in a timely fashion.	See 4.2	See 4.2 (senior doctor workload)	
7.3	Evaluate if patient can be stabilised	R04 – Information incorrectly interpreted	See 4.3 (senior doctor)	See 4.3	Person: experience (in this instance, high level of experience of senior doctor makes failure less likely)	
7.4	Update management plan	A09 – Action omitted	See 5.2 (senior doctor)	See 5.2	See 5.2	See 4.1
7.5	Increase monitoring frequency to one hour or less	A09 – Action omitted	See 5.3 (senior doctor)	See 5.3	Person: experience (high level of experience makes failure less likely)	
8	Implement escalation					
8.1	Seek further information or investigations	I01 – Information not communicated	Investigations not requested	Wrong diagnosis, serious patient harm	Organisation: staffing levels (specialist not available or not able to prioritise request)	Ensure escalation procedure up to date and specialists signed up to it
8.2	Implement ward-based care	A09 – Action omitted	An aspect of ward-based care not delivered	Patient deterioration, serious patient harm	Tools & Technology: availability of equipment (specialist equipment not available on ward)	Procurement of adequate numbers of specialist equipment on ward
8.3	Request transfer to ICU	I01 – Information not communicated	Transfer to ICU not requested	Patient deterioration, serious patient harm	Organisation: ICU availability (no ICU bed available)	
8.4	Request transfer to theatre	I01 – Information not communicated	Transfer to theatre not requested	Patient deterioration, serious patient harm	Organisation: Theatre availability (not theatre available) Organisation: staffing levels (OR staff unavailable)	

misinterpreting information at the early stages of identifying deterioration, which can lead to delayed escalation. During the escalation stages, escalation might not be initiated in a timely fashion or information might not be communicated appropriately, which can cause delays to escalation and implementation of updated care plans. Implementation of escalation actions can fail largely due to unavailability of resources and people (i.e., not necessarily a human error).

Assessment of PIFs highlighted recurring contextual factors. These included: workload and staffing levels, lack of experience, issues with equipment (usability and availability), procedures, and lack of sufficient resources and infrastructure.

Accordingly, suggestions for improvements were based both on consideration of the specific task step and how it might fail, as well as an informal thematic analysis across the PIFs. Informal here means that participants simply looked at the frequency of PIFs and determined the extent to which these resonated with their experiences (i.e., no formal thematic analysis involving coding was done). Suggestions for improvements focused on patient involvement to enable patients to raise concerns (for themselves as well as for others) and addressing the contextual factors identified from the PIF analysis. This includes

suggestions to ensure staffing levels are adequate, reducing reliance on staff not familiar with the environment, focusing on procedure development and maintenance, training initiatives to ensure staff are familiar with procedures and competent in their use, and teamwork training to strengthen communication and team performance.

5. FRAM

5.1. How FRAM was used in the project

Full details of how FRAM was applied to this case have been published previously (Sujan et al., 2022a) and only a summary is provided here. Data were collected through semi-structured interviews (n = 31) and workshops (n = 14) with stakeholders working on or with SEU (including nurses, doctors, porters, managers, radiologists, anaesthetists).

Data were analysed based on the structure of FRAM. First, key functions were identified. Then, for each function couplings and variability were described. During the description of couplings, additional functions were identified and analysed accordingly. Functions that are carried out within SEU were analysed in greater depth as foreground functions. Functions outside of SEU were treated as background functions.

Performance variability was at the centre of the analysis. Participants were asked to describe areas where there is a lot of variability. This was done in a non-normative way, i.e., it was not suggested to participants that variability was necessarily bad or undesirable, the questioning was neutral, looking to gain insights into whether a function was always carried out in the same way or what kind of variability might be encountered in practice (Furniss et al., 2020). Once variability was described for specific instantiations (e.g., patient with a specific medical history), the analyst prompted participants to reflect on the reasons for the described variability, usually in terms of underlying tensions, trade-offs and uncertain performance conditions. Then, participants were asked to consider the impact of the variability in terms of functional coupling, i.e., what the effect on other functions might be.

In the interpretative stage of the analysis, the analyst linked the descriptions of performance variability explicitly to the four resilience abilities. In this way, the analyst constructed explanations of how performance variability can be an expression of resilient forms of behaviour. In the workshops, participants were then invited to reflect on this and to provide suggestions for how resilience (i.e., the resilience abilities) might be strengthened.

5.2. The types of insights and interventions / recommendations generated from the FRAM analysis

The use of FRAM provided insights into the variable nature of the work system underlying the management of patient deterioration. Variability was described for every function, and the analysis enabled examination of the adaptations and trade-offs people make, which in turn give rise to the variability. The analysis also explored the potential impact on other functions. This type of analysis represents a departure from the analysis described when FRAM was first formulated in as far as variability was not described in terms of timing and precision, but instead a non-normative approach was taken.

An example is provided in Box 1. The example concerns the function "do vital signs observations". This should be done at specific times according to a protocol. In practice, the timing of doing vital signs observations can vary significantly. Rather than describing this as a failure (and, hence, something negative), the analysis enabled a deeper understanding of the complexity of decision-making of people. For example, patients might be asleep, and the nurse does not want to wake the patient, or the nurse might need to attend to other patients whose condition is perceived higher priority. Analysis of functional coupling provided further insights into the system complexity, which illustrate how people adapt their behaviour. An instance of this is the proactive request by doctors to increase vital signs observation frequency and to lower the escalation threshold (i.e., not waiting for a patient's trigger score to warrant escalation) for patients where they might have intuitively greater concerns about potential deterioration. Such adaptations can provide resilience required for managing deterioration successfully under changing demands and competing priorities but can also sometimes contribute to deterioration.

Box 1*: Example of examination of performance variability.*

Function: Do vital signs observations
Variability: Timing
Tensions and uncertain performance conditions: Nurses trade off several variables to determine the timing for doing vital signs observations, including suggested observation time as per protocol, patient comfort, patient condition and their own workload.
Functional coupling: (1) The timeliness of vital signs observations can affect the functions "raise concern" and "determine escalation plan" both positively and negatively. Timely vital signs observations can facilitate prompt escalation, but if concerns based on vital signs observations are raised frequently and unnecessarily this can negatively affect downstream functions by ultimately resulting in diminished responses ("cry wolf syndrome"). (2) Doctors might create an additional function "assess likelihood of complications" to reflect their anticipation of an elevated risk of deterioration. This can change the way vital signs observations are used by (a) increasing the frequency and (b) lowering the escalation threshold for a given trigger score.

The analysis of the variability of everyday work can then feed into the development of suggestions for strengthening resilience. There is not necessarily a clear one-to-one mapping from learning about everyday work to specific suggestions for improvement. Learning from everyday work can provide inspiration and areas for exploration. For example, learning from everyday work about the resilience ability "monitoring" (i.e., knowing what is going on, knowing what to look for) suggested that, among others, participants try to build an awareness of the patients in the department even if they are not assigned to the patient. This is so that in case there is a need for escalation, and they need to help out, they are already informed about the patient to a certain extent. It also helps them to know what to look out for. Participants also provided examples of how they attempt to build shared awareness within the team. An instance of this was alluded to above, where a doctor might share their concern about a patient with the nurse, so that the nurse can monitor the patient more closely.

These insights from the analysis do not translate immediately into actionable improvements but were fed back to participants during workshops where they were prompted to consider how the ability to monitor (as well as the other resilience abilities) could be strengthened. Among the suggestions were, for example, the physical layout of the workspace including meeting rooms and common rooms to facilitate communication among team members about concerns and to share information. Another suggestion for the creation of shared awareness also addressed the issue of inter-departmental collaboration, which might be improved with the concept of dynamic plans for patient management. Such dynamic plans consider already upon admission potential alternative pathways and developments and include professionals from relevant specialties. Further examples are shown in Table 3 (Sujan et al., 2022a).

6. Discussion

The previous sections described separately the nature of insights and recommendations produced through the application of FRAM and SHERPA, respectively. In this section, we critically reflect on the practical experiences with the application of the two methods based on: (1) how they represent clinical work; (2) their (safety) assessment logic; (3) and the nature of the respective recommendations or improvement suggestions. A summary is provided in Table 4.

Table 3
Recommendations based on the FRAM analysis (based on (Sujan et al., 2022a)).

Resilience Ability	Capturing what works	Improvement suggestions
Monitoring	Looking for red flags for patient deterioration. Understanding colleagues' capabilities and experience. Maintaining a broader departmental view. Actively communicating concerns and observations.	Enhance communication channels, e.g., shared workspaces. Leverage technology, e.g., clinical prediction tools using machine learning. Establish dedicated monitoring roles and responsibilities. Develop dynamic patient plans that anticipate potential developments and complications.
Responding	Collaborative decision-making, e.g., sharing tasks across professional groups. Flexible support, e.g., stepping up when colleagues are busy. Dynamic and proactive resource allocation, e.g., adjusting staffing levels in specific areas to meet changes in demand. Mutual trust and responsiveness, e.g., confidence in referring patients to colleagues.	Foster a collaborative culture, e.g., reduce hierarchical barriers and empower junior staff. Enhance preparedness and coordination, e.g., build on communities of practice and knowledge sharing across departments. Support communication and learning, e.g., create safe spaces for discussion and support.
Anticipating	Knowing when peaks are likely to arise in order to support workforce and skill-mix planning	Enhance data insights, e.g., data-driven forecasting models. Proactive resource management, e.g., implementation of data-driven flexible staffing models.
Learning	Appreciating gaps between work-as-imagined and work-as-done (trade-offs) Collaborative knowledge sharing Psychological safety and trust Role clarity and development	Embed learning into daily operations. Design for adaptability and learning, e.g., resilient procedures and work processes. Create opportunities for informal and inter-departmental learning. Develop proactive knowledge exchange.

Table 4
Summary of critical reflection on the use of FRAM and SHERPA (PIF: Performance Influencing Factor).

Method	Representation of clinical work	Assessment logic	Nature of recommendations
FRAM	• Functional breakdown • Variable • How functions interact (couplings)	• Performance variability • Contradictions and trade-offs • How do things to right?	• Resilience abilities • Systemic • How to strengthen the ability to succeed under varying conditions?
SHERPA	• Hierarchical breakdown • Static • What people do	• Failure modes • Risk • PIFs • What can go wrong?	• Risk controls • PIF improvements • Specific • How to prevent/ mitigate failures?

6.1. Representation of clinical work

Both SHERPA and FRAM aim to represent work-as-done rather than work-as-imagined, i.e., both methods incorporate the views and perceptions of people doing the work, and they do not simply map out procedures and guidelines. However, the way clinical work is represented in the two methods differs significantly.

SHERPA uses HTA. The HTA describes what people do, i.e., the tasks that people have to undertake in order to achieve a higher-level goal. In principle, HTA can be used to represent system goals and tasks (e.g., done by technology) (Stanton, 2006) from a functional rather than behavioural perspective (Annett, 2004), but the more common use of HTA in SHERPA (and more generally) is to focus on what people do. The hierarchical breakdown is an excellent approach to help the analyst represent work in a way that is easy to communicate (Annett, 2004). It also supports focusing the analysis on task steps that might require greater detail. While the HTA can capture alternative courses of action in the plan, it is a static and deterministic representation in as far as it does not typically consider any kind of trade-offs that might have to be made. An example from the above scenario is the high-level plan, which determines how the lower actions are to be carried out depending on the value of the trigger score. While potentially possible, it would be awkward in practice to map into the plan consideration of typical trade-off decisions, such as the decision not to escalate despite the trigger score if it is determined that this score is considered normal for this patient or if an escalation had already taken place. Plans would get very complicated, which is not something that is normally seen in HTAs nor desirable. HTA also does not easily consider interdependencies between different task steps across sub-goals. Lastly, HTA usually works best to represent reasonably discrete tasks, and interdependencies with other tasks or wider systems aspects are not normally included in the HTA itself but can be considered as part of the PIF assessment.

FRAM uses a functional representation, i.e., it maps what the system does. It is very easy to get started with FRAM to a certain extent, because the analyst can simply pick a function of interest and then continue to consider interactions with other functions and analyse these in turn, and so on (Hollnagel, 2012). However, this approach can quickly lead to an explosion in the complexity of the analysis (Patriarca et al., 2017). On the other hand, consideration of the various interactions (couplings) among functions is a key strength of FRAM. The analyst has a tool to identify and assess interactions and interdependencies explicitly. In addition, the distinction between a FRAM model and FRAM instantiations makes FRAM very flexible to represent variability. For example, it is easily possible to analyse and represent how in different situations functions might interact in different ways or even how new functions might be introduced (Furniss et al., 2020). Instances of the latter in the application scenario are, for example, when a doctor is worried about a patient a new function is introduced to lower the escalation threshold, or when a consultant decides to delay transfer to the operating theatre during the night time until the morning when there are higher staffing levels (acting as a safety net), a new function of monitoring and reassessing the patient's risk position is introduced in order to determine whether emergency surgery is warranted even in the absence of the safety net. This provides a richer picture of some elements of work-as-done compared with the HTA, and it also enables crossing departmental and organisational boundaries seamlessly (O'Hara et al., 2020, Ross et al., 2018). However, the HTA enables the analyst to consider some specific sub-tasks in much greater depth (e.g., interactions with a device interface) than would normally be done with FRAM.

An additional practical consideration is the tool support that is available to analysts. Many practitioners applying SHERPA use basic tool support and achieve satisfactory results, e.g., graphics software packages to represent the HTA and spreadsheet software to capture the failure analysis. There are commercial packages available, which can further improve the efficiency and the degree of standardisation of the analysis. The situation is different for FRAM. As mentioned above, a FRAM analysis frequently ends up with significant complexity and, therefore, many practitioners use specialised tool support. The availability of a free, dedicated FRAM software (FRAM Model Visualiser FMV available freely from Zerprize as a browser version) can make the FRAM analysis more manageable.

6.2. Assessment logic

Arguably, the most obvious aspect for comparing and contrasting SHERPA and FRAM is to examine their respective (safety) assessment logic, as this is where one would expect the differences between Safety-I and Safety-II to manifest themselves most prominently, see also the generic comparisons of Safety-I and Safety-II concepts described initially by Hollnagel and analysed subsequently by Aven from a risk science perspective (Hollnagel, 2014, Aven, 2022). SHERPA systematically analyses what could go wrong and examines the associated risk, contextual conditions (PIFs) that impact on the likelihood of failure and potential barriers that could either reduce the likelihood of the failure or mitigate the severity of the consequences (Furniss et al., 2019). The analysis of the clinical application scenarios demonstrated that failures and vulnerabilities could be identified for every task step.

FRAM, on the other hand, starts with the notion of performance variability as its central concept. Performance variability is regarded as inevitable and resulting from trade-offs and adaptations people have to make in order to manage complexity and uncertainty (Hollnagel, 2015). By understanding these trade-offs and adaptations, FRAM provides insights into the system's complexity, and about how things normally go right and how they sometimes fail (Hollnagel, 2012).

We can examine the practical implications by looking at the function "do vital signs observations", which is similar to sub-task 2 in the HTA ("Evaluate risk of deterioration"), see Fig. 2. The FRAM analysis provides detailed insights into how this function might vary and why, and what the impact on other functions might be using the couplings between the functions. From this, we learned about the need to consider patient comfort, the patient's and other patients' condition, and the nurse's workload; and we gained insights, among others, into how the escalation threshold might be lowered based on concerns of the doctor (which can be represented as control to this function). The failure analysis done as part of SHERPA places by its logic much greater emphasis on how individuals can fail, e.g., the nurse might not do a thorough assessment, might misinterpret vital signs readings, or fail to understand the trigger score. While this has the potential to set the analysis on a course that focuses on the individual as the weak link, consideration of contextual conditions is provided through the PIF analysis. The PIF analysis encourages consideration of systems issues, e.g., workload and staffing levels, but it does not explicitly go beyond that to understand trade-offs and competing priorities that need to be managed. In addition, the failure analysis is binary in as far as an action either fails or succeeds, but it does not enable consideration of degrees of task (or function) success (see also (Zio, 2009) for a discussion of the problems associated with quantification of multi-state systems), which is determined often by the context rather than by the task or function itself. Simplifying somewhat, one could argue that the systems considerations, which are explicitly represented in FRAM via functional dependencies, are being crammed into the PIF analysis in SHERPA, giving the analyst less explicit support.

6.3. Nature of recommendations and improvement suggestions

SHERPA is a risk-based approach, and, therefore, recommendations should first and foremost consider how risk can be controlled, typically by eliminating or reducing the likelihood of occurrence or by mitigating the severity of the consequences of a failure (see also (Aven, 2022)). In practice, this should be done following the hierarchy of control before any PIF improvements are considered (COMAH Competent Authority, 2016). In this project, the hierarchy of control was not used explicitly due to the lack of engineering controls and uncertainty about the applicability of the hierarchy in control in healthcare (Liberati et al., 2018). The recommendations that were suggested by participants were focused largely on improvements of PIFs, such as training and competence, processes for procedure development and maintenance, and teamwork training, which is in line with previous studies (Ashour et al., 2022). However, there is a clear link between these recommendations and the identified risks, and an argument can be created for how these interventions are supposed to reduce risk. In principle, such a clear argument should facilitate communication with decision-makers and executive sponsors of improvements.

This contrasts significantly with the nature of recommendations developed as part of the FRAM analysis. Rather than controlling risk, these recommendations are aimed at strengthening resilience abilities, i.e., the ability to monitor, respond, anticipate and learn in order to succeed under changing and uncertain conditions. This requires a different mindset of participants, moving outside of traditional, and potentially comforting, controls that rely on training and procedures, to gaze outward and upward in the system. While superficially these recommendations might share some similarities to the PIF improvements identified through SHERPA (e.g., teamwork training might help to break down hierarchical and cultural barriers), strengthening of resilience abilities involves much broader systems changes, including approaches for organisational learning, processes for data collection and data analysis to enable longer-term anticipation, and changes to the built environment to facilitate communication and building of shared awareness (Aven, 2022, Sujan, 2018). However, a practical problem is that the, albeit potentially simplistic, clear link between an identified risk and a recommendation is not as immediately obvious anymore. The systems recommendations coming out of the FRAM analysis tend to be broader and more generic. This might make their communication to decision-makers and executive sponsors and their implementation in practice more challenging.

6.4. The mindset of the analyst

SHERPA and FRAM were used as vehicles to examine what the practical application of Safety-I and Safety-II approaches looks like. However, in practice it is not possible to keep the mindset of the analyst separate from the characteristics of the method. Experienced analysts do not follow blindly algorithmic routines, but examine systems based on their existing knowledge, their mindset and with the help of specific methods. As a result, an analyst using SHERPA might well use the identification of PIFs, for example, to consider wider systems issues that go beyond the specific task and its failure modes being analysed. For example, if a task step is particularly vulnerable to unclear standard operating procedures (identified as PIF), then this might be used as starting point for a deeper investigation into how procedures are developed across the system, the extent to which staff are involved in procedure development, and the perceived role of procedures in delivering safe care. Arguably, these wider considerations go beyond what SHERPA by itself supports, and represents an integration of Safety-I and Safety-II thinking (see, for example, the discussion by Jones and colleagues (Jones et al., 2018)).

Similarly, an analyst using FRAM might choose to focus more narrowly on the identification of specific functions with a high degree of variability and consider how barriers might constrain and contain this variability, which might align more closely with traditional approaches. The mindset of the analyst determines, therefore, to a significant extent how the respective method is used. In other words, the precise delineation of Safety-I and Safety-II in practice is often difficult and probably not desirable.

6.5. Limitations

The research approach used in this study is critical reflection on practice. As such, it is inherently subjective because the researchers' experiences and values shape their (albeit critical) interpretation of their practice. It could be argued that critical reflection enables the researchers to understand more about themselves and their own practice than the study topic. However, making these insights visible and sharing them, should support others in the safety science community in

reflecting on their own practice.

The research design provides a qualitative examination of SHERPA and FRAM, but it is not an independent evaluation, and it is not intended to offer conclusions about whether one of the methods is superior to the other in any shape or form. Nor does it provide decision criteria about when to use which method.

SHERPA and FRAM are not the only methods that could have been chosen as representatives of Safety-I and Safety-II thinking. For argument's sake, among many others, one could have chosen Bow-tie analysis (McLeod and Bowie, 2018) or Failure Mode and Effects Analysis (DeRosier et al., 2002) from the Safety-I field, or the Resilience Analysis Grid (Hollnagel, 2011) as a method belonging to Safety-II. FRAM has previously been compared with a range of other methods, see the review provided by Patriarca and colleagues (Patriarca et al., 2020).

7. Conclusions

Safety-II is an increasingly popular perspective in healthcare, but the application of Safety-II in practice, and the actual and potential relationship to established approaches are less clear. We have critically examined the application of SHERPA and FRAM as representative methods of Safety-I and Safety-II thinking along the dimensions of how they represent clinical work, their safety assessment logic, and the nature of the recommendations, which they typically produce.

In practice, both methods and types of thinking about safety have a place, but there are significant differences in how they work and in their likely improvement recommendations. SHERPA and Safety-I thinking lead the analyst to focus on what people do, what can go wrong in their work, and how failures can be prevented or how the consequences of failure can be mitigated. FRAM and Safety-II thinking, on the other hand, encourage consideration of how functions interact, how work normally succeeds, and how a system's ability to succeed under varying conditions can be strengthened.

SHERPA and Safety-I provide a clear link between identified risks and suggested improvements, however this approach is likely to keep patient safety practice limited to improvements that are familiar but limited in achieving systemic change, and which, therefore, risks ignoring the complexity of healthcare systems. On the other hand, FRAM and Safety-II encourage wider systems change, but the recommendations might often go beyond the ability and authority of project teams to implement them.

The synergy of using both Safety-I and Safety-II methods together has practical value (Jones et al., 2018, Martins et al., 2022). However, it is important to integrate the findings of Safety-I methods, like SHERPA, which often examine more narrowly specific tasks and risks in a linear way, within an understanding of the wider, usually intractable system, which Safety-II methods, such as FRAM, can provide. From a healthcare perspective, we perceive a need for tailored educational frameworks to communicate such differences in patient safety mindset and the corresponding methods. These frameworks should equip patient safety specialists and other professionals involved in patient safety and quality improvement work and oversight functions with the necessary professional competencies in safety science. This educational approach should be complemented by the integration of embedded safety scientists and other professionals, such as ergonomists, to provide access to specialist expertise fostering a holistic approach to patient safety and quality improvement (Catchpole et al., 2021).

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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