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# Operationalising FRAM in Healthcare: A critical reflection on practice

M. Sujan [a,b,*], L. Pickup [c], M.S. de Vos [d], R. Patriarca [e], L. Konwinski [f], A. Ross [g], P. McCulloch [a]

[a] Nuffield Department of Surgical Sciences, University of Oxford, UK
[b] Human Factors Everywhere Ltd., UK
[c] LP Human Factors Ltd., UK
[d] Directorate of Quality and Patient Safety, Leiden University Medical Centre, Netherlands
[e] Department of Mechanical and Aerospace Engineering, La Sapienza University Rome, Italy
[f] Helen deVos Children's Hospital, USA
[g] Dental School, University of Glasgow, UK

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ABSTRACT

Resilience Engineering principles are becoming increasingly popular in healthcare to improve patient safety. FRAM is the best-known Resilience Engineering method with several examples of its application in healthcare available. However, the guidance on how to apply FRAM leaves gaps, and this can be a potential barrier to its adoption and potentially lead to misuse and disappointing results. The article provides a self-reflective analysis of FRAM use cases to provide further methodological guidance for successful application of FRAM to improve patient safety. Five FRAM use cases in a range of healthcare settings are described in a structured way including critical reflection by the original authors of those studies. Individual reflections are synthesised through group discussion to identify lessons for the operationalisation of FRAM in healthcare. Four themes are developed: (1) core characteristics of a FRAM study, (2) flexibility regarding the underlying epistemological paradigm, (3) diversity with respect to the development of interventions, and (4) model complexity. FRAM is a systems analysis method that offers considerable flexibility to accommodate different epistemological positions, ranging from realism to phenomenology. We refer to these as computational FRAM and reflexive FRAM, respectively. Practitioners need to be clear about their analysis aims and their analysis position. Further guidance is needed to support practitioners to tell a convincing and meaningful "system story" through the lens of FRAM.

## 1. Introduction

### 1.1. The need for systems approaches in patient safety

The publication of two key reports in the US and the UK in 1999 and 2000, respectively, highlighted the extent of widespread and potentially avoidable patient harm (Department of Health, 2000; Kohn et al., 2000). Especially the US report published by the Institute of Medicine had a significant and lasting impact on patient safety research and policy. However, this dominant influence has recently also been criticised (St. Pierre et al., 2022; Wears and Sutcliffe, 2019) as having contributed to a limited perspective on patient safety with a narrow focus on Reason's model of organisational accidents (Larouzee and le Coze, 2020; Reason, 2000) (i.e., the Swiss Cheese Model).

On the other hand, over recent years patient safety as a scientific discipline has increasingly looked beyond Reason's model towards systems approaches, which are thought to be better suited for understanding and improving modern complex healthcare systems. Examples include the increasingly popular SEIPS model (Systems Engineering Initiative for Patient Safety) (Carayon et al., 2020, Holden et al., 2013), which focuses on interactions between different elements of a work system, and the field of Resilient Health Care (Hollnagel et al., 2019), which is based on Resilience Engineering (RE) principles (Hollnagel et al., 2006). Resilience Engineering was developed to better understand and manage safety in complex systems. This is based on observations that: (a) complex systems cannot be decomposed in a meaningful way into their constituent components due to the importance of interactions that give rise to outcomes; (b) outcomes of functions are not bimodal, i.e., either correct or incorrect, but flexible and variable; (c) system outcomes are the result of context-conditioned performance variability, which is the source of both success and failure; and (d) some adverse outcomes might best be understood as the result of coupled performance

* Corresponding author at: Nuffield Department of Surgical Sciences, University of Oxford.
*E-mail address:* mark.sujan@nds.ox.ac.uk (M. Sujan).

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variability rather than being “caused” by component failures. In this thinking, resilience is 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). Complexity and uncertainty open up gaps, which practitioners have to anticipate, detect and bridge using their judgement and expertise (Cook et al., 2000). Such necessary performance adjustments are thought to contribute to organisational resilience (Fairbanks et al., 2014).

This initial description of resilience was further developed to encompass four cornerstones of Resilience Engineering (Hollnagel, 2010), subsequently also referred to as resilience abilities or resilience potentials (Hollnagel, 2018). These are the ability to monitor, to respond, to anticipate and to learn. What is critical here is the focus on abilities as opposed to, more traditionally, barriers and defences. The notion of Safety-II was introduced to draw out this distinction between the two perspectives on safety (i.e., Safety-I and Safety-II) more clearly along with their underlying assumptions (Hollnagel, 2014).

Resilient Health Care and the associated notion of Safety-II might be particularly well suited to the study of patient safety, because healthcare is characterised by many interactions, frequently across departmental and organisational boundaries, which are often underspecified (Verhagen et al., 2022). For example, an emergency department could be described more in terms of an open, self-regulating system rather than in terms of clearly defined and well-ordered tasks and processes. These properties make healthcare dynamic, non-linear and largely intractable, which limits the applicability of more traditional approaches (Hollnagel, 2016).

### *1.2. FRAM*

The Functional Resonance Analysis Method (FRAM) is one of the most significant and widely used methods based on Resilience Engineering thinking (Hollnagel, 2012). FRAM was initially developed as an accident model to help explain how accidents happen because of functional interconnectedness in terms of uncontrolled combination of everyday performance variability. In this sense, accidents are regarded as emergent properties of complex systems.

In the transformation from an accident model into an analysis method, FRAM puts 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 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.

### *1.3. Increasing interest in the application of FRAM in healthcare*

Early examples of the application of FRAM come predominantly from the aviation sector (Herrera and Woltjer, 2010, Martinie et al., 2013), but since the publication of the FRAM handbook (Hollnagel, 2012) in 2012 there has been a steadily increasing number of application examples across a range of sectors, and especially in healthcare (Patriarca et al., 2020). In part, this popularity in healthcare might be attributed to a strong international research community, which has produced six edited volumes on Resilient Health Care to date, as well as the potentially well-fitting alignment of FRAM with the intuitive appreciation of healthcare workers for the complexity of healthcare settings (Verhagen et al., 2022).

In addition to the cases we reflect on in this paper, FRAM has been used in healthcare across different settings and for the analysis of different activities, including several studies set in emergency care (Sujan and Felici, 2012, MacKinnon et al., 2021) and intensive care (Clay-Williams et al., 2015), analysis of intravenous infusion and medication administration (Furniss et al., 2020; Kaya et al., 2019; Schutijser et al., 2019; Sujan, 2021), modelling of the transition of care of older adults discharged from hospital (O’Hara et al., 2020), and for exploring the recognition and management of sepsis (Raben et al., 2018, McNab et al., 2018).

### *1.4. The need for further methodological development and guidance*

The studies referred to above demonstrate the diversity of applications of FRAM in healthcare, as well as the various extensions and modifications, which have been made to the method. As a result, it is hard to speak of “the” FRAM as if it were a clearly laid out methodology. Arguably, this flexibility, which allows people to use the method in different ways and with different emphasis, is a strength of FRAM.

However, with this flexibility also comes the risk that the method can be confusing to practitioners, that its concepts and principles are misinterpreted or misused, and that opportunities for improving patient safety remain unrealised. The FRAM handbook (published in 2012) is starting to become somewhat (out-)dated considering the wealth of activity and development since its publication. In addition, of the four steps for a FRAM analysis outlined in the handbook, the last step (step 4) now appears significantly underspecified, as it is, essentially, not going beyond the suggestion to monitor and control variability. Potentially, this could lead to problematic applications of FRAM, which then share many of the shortcomings of previously criticised concepts such as human error and human reliability analysis (Sujan et al., 2020). In this way, the focus of the recommendations for improvement generated by users of FRAM might be directed more towards control and containment of performance variability – concepts that are associated more with traditional safety thinking – rather than focus on strengthening the ability to succeed under varying conditions, i.e., resilience.

This manuscript aims to provide practical guidance for the application of FRAM in healthcare by reflecting on a number of application examples, which the authors have carried out in recent years. The next section describes the approach taken in this work (Section 2). Then, five previously published application examples of FRAM are described in a structured way, including reflections on each example individually (Section 3). Subsequently, lessons from the reflection across application examples are discussed (Section 4), and implications for research and practice are identified (Section 5).

## 2. Methods

The method used in this work is critical reflection, both individually and collectively. Critical reflection can be understood as a process of learning from experience in order to improve professional practice (Fook, 2011). From this perspective, critical reflection is aligned to Schön’s notion of reflection-on-action as distinguished from reflection-in-action. The latter refers to decision-making and choices in practice, whereas the former describes a retrospective analytical process that challenges the underlying assumptions for decision-making (Schön, 1983).

An overview of how critical reflection was applied is given in Table 1. Initially, informal discussions at professional meetings were held (including FRAM community of practice meetings as well as patient safety community of practice meetings), where a sense of confusion transpired about how FRAM could or should be applied in practice and how it might support the development of interventions to improve patient safety. Based on this, one author undertook six expert interviews with individuals who had experience with applying FRAM in healthcare. Following this, the experts were asked to provide a structured description each of one of their FRAM use cases including a short critical reflection (see Table 2) One use case was excluded, because it had not been previously published.

Individual case descriptions and (self-)reflections were shared among all authors, who then provided individually their interpretation and synthesis of the cases. These reflections were shared again and subsequently discussed in a group meeting to identify the main lessons, opportunities, and challenges for the successful application of FRAM in healthcare.

## 3. FRAM use cases and individual reflections

In this section, the five FRAM use cases are described, along with individual reflections from one of the respective study authors. For ease of reference, these are summarised in Table 3. All of the use cases have been published previously, and full details about the respective methods and results can be found in the corresponding references.

### *3.1. FRAM analysis of the management of deteriorating patients on a surgical emergency unit*

This case study was concerned with the management of deterioration in surgery. Complications and deterioration following surgery are a significant patient safety concern and have frequently been studied from the perspective of preventing "failure to rescue", i.e., how to prevent the failure to recognise and respond to acute deterioration (Burke et al., 2020). In this case study, a Resilience Engineering perspective was applied in order to understand how the management of deterioration usually succeeds (rather than fails) and how resilience could be strengthened (Sujan et al., 2022).

**Setting:** The study took place in a surgical emergency unit (SEU) of a university hospital in England. The SEU is large compared with other similar units. It has 54 beds, and it is divided into an area for triage, two wards, an ultrasound area, and a waiting room.

**Purpose:** FRAM was used to understand the management of surgical patients at risk of deterioration. The aim was to explore the adaptations and trade-offs staff make and to identify opportunities for systems-based interventions to strengthen resilience.

**Data collection / application of FRAM:** This study was undertaken during COVID-19 and, consequently, access to the clinical environment was restricted. Initial observations were undertaken, but subsequently data collection relied on semi-structured interviews with 31 participants and two workshops with 14 participants. Functions were identified from these data rather than from documentation, and they represent work-as-done. Every function was analysed for its potential for variability, and this was then described in a structured way in terms of: the manifestation of the variability (i.e., how participants described it), the underlying tensions and uncertain performance conditions (i.e., the reasons for the variability), and the functional coupling (i.e., the potential consequences of the variability). This was done from a non-normative perspective, i.e., variability was considered as normal part of work-as-done rather than classified as wanted / unwanted variability.

**Table 1**
Critical reflection on FRAM use cases.

| | | |
|---|---|---|
| Phase I | Community of Practice engagement | Informal discussions at community of practice meetings: FRAMily, Safety-II in practice, Resilient Health Care Net, UK SIREN<br>Six expert interviews |
| Phase II | Single cases reflection | Structured descriptions of five use cases of FRAM including reflections by the respective study author |
| Phase III | Cross-case reflection | |
| | A: Individually | Reflection across all 5 FRAM use cases by each co-author indvidually |
| | B: Group | Reflection across all 5 FRAM cases by all of the co-authors in group discussions |

**Table 2**
Structured template for the description of FRAM use cases.

| | |
|---|---|
| Setting | Description of the setting where the study was carried out. |
| Purpose | Description of the main aims of the study. |
| Data collection / application | Overview of how data were collected and how FRAM was applied in practice. |
| Design of interventions | Description of how the FRAM analysis informed the design of interventions. |
| Reflection | A self-reflection on key lessons from this case study, e.g., what stood out, what worked, what problems arose? |

**Design of interventions:** The final step in this study consisted of mapping explicitly the findings about variability in everyday work to the four resilience abilities, i.e., the ability to monitor, to respond, to anticipate and to learn. This mapping of the learning from everyday work was then presented to participants as input for discussion and suggestions for intervention development with a focus on strengthening resilience. Examples of suggestions for improvement included:

- Monitoring: encouraging sharing of concerns about a patient by designing opportunities for inter-professional communication into the workplace; machine learning solution that predicts likelihood of deterioration; having dynamic plans for patients, which involve inter-departmental collaboration from the outset.
- Responding: breaking down professional and hierarchical barriers; inclusion of roles that can be deployed flexibly; creating opportunities for discussions among colleagues; supporting cross-departmental communities of practice.
- Anticipating: IT solution to collect and aggregate relevant data longer-term; machine learning solution to predict busy periods in real-time to facilitate dynamic allocation of staff and resources.
- Learning: implementing organisational learning processes that capture everyday work; designing resilient escalation procedures that consider explicitly the need for trade-offs; creating opportunities for informal and inter-departmental learning.

These suggestions for improvement could be the starting point for interventions, but the study did not provide implementation details or indication of feasibility and effectiveness.

**Reflection:** In this application of FRAM, the intention was from the outset to learn from work-as-done in a detailed way (micro level) about the tensions and contradictions inherent in everyday work. Variability, in this sense, was regarded only as the starting point for the analysis to enable understanding of the underlying system dynamics. The study was never concerned with whether variability was desirable or unwanted, but instead linked observed behaviours back to resilience theory.

The suggestions for improvement derived in this way focus on strengthening resilience abilities. On the one hand, this makes them reasonably generic as suggestions for improvement across settings, such as the creation of opportunities for informal discussions and inter-departmental learning. This also provides people with the flexibility to implement and adapt these improvement suggestions to fit their needs. On the other hand, it might be argued that such suggestions are too generic and, hence, lack the specificity to be implemented as a direct result of the analysis.

**Table 3**
Summary of FRAM application examples.

| Study reference | Setting | Purpose | Data collection / application of FRAM | Design of interventions | Reflections |
|---|---|---|---|---|---|
| Sujan et al, 2022 | Surgical Emergency Unit in a university hospital, England | - Understand the management (work-as-done, WAD) of surgical patients at risk of deterioration.<br>- Explore adaptations and trade-offs to identify opportunities for systems-based interventions to strengthen resilience. | - Observations<br>- Semi-structured interviews<br>- Workshops / focus groups<br>- Development of WAD model<br>- Analysis of variability in a non-normative way | - Mapping of identified variability to resilience abilities<br>- Strengthening of resilience abilities based on stakeholder feedback | - Focus on using variability as a proxy for understanding resilience mechanisms<br>- Interventions aimed at strengthening resilience abilities<br>- Interventions are broadly applicable across contexts, but are not very specific<br>- No data on actual improvements |
| Pickup et al, 2017 | 4 acute hospitals, Scotland | - Develop shared understanding of dependencies and variability in the process<br>- Enhance resilience of the process | - Observations<br>- Semi-structured interviews<br>- Workshops / focus groups<br>- Development of WAD model<br>- Analysis of dependencies | - Education on systems resilience principles to support stakeholders in the design of interventions<br>- Co-design of interventions to strengthen resilience abilities<br>- Stakeholder evaluation of impact of interventions on resilience abilities | - Complementary perspective<br>- Co-design based on shared understanding of dependencies and variability<br>- Challenging to justify how interventions lead to improvement in resilience<br>- Interventions would require a broader set of stakeholders<br>- No data on actual improvements |
| Ross et al, 2018 | General Dental Service, Scotland | - Identify and describe the system context for applying Sodium Fluoride Varnish, a preventive measure for dental caries<br>- Identify opportunities for intervention to support dental teams in regular application | - Synthesis of routine monitoring and survey data<br>- In-depth, semi-structured interviews with practice staff and stakeholders in Government and management roles | - Key functions built into a "toolkit", co– designed with dentists applying high rates of varnish<br>- Embedding "resilience strategies" to reduce functional variability | - Feasibility testing has shown dentists feel the approach gives a little more depth to quality improvement work than standard clinical audit<br>- Considerable resource to gather data and build the model<br>-The world is dynamic, and post-pandemic changes to the service probably indicate further modelling is needed |
| Damen et al, 2018 | 2 cardiothoracic surgery departments, Australia and Netherlands | - Understand the difference in WAD / WAI (work-as-imagined) of the process<br>- Examine usability and utility of FRAM as a tool to reconcile WAD / WAI | - Document analysis<br>- Semi-structured interviews<br>- Workshops / focus groups<br>- Development of both WAI and WAD model<br>- Analysis of variability and dependencies | - Focus on significant differences between WAD / WAI<br>- Stakeholder input on ways in which WAD / WAI could be aligned | - Encourage stakeholders to reflect on WAD / WAI<br>- Reflection can be an intervention in itself<br>- Can support investigation of events<br>- No concrete interventions were developed<br>- No data on actual improvements |
| Patriarca et al, 2018b | Neurosurgical unit in a hospital, Southern Europe | - Identify functions and couplings with higher potential of adverse outcomes<br>- reconfigure operations or suggest design alternatives from a systems perspective | - Document analysis<br>- Observations<br>- Semi-structured interviews<br>- Open-ended interviews<br>- Surveys<br>- Development of WAD model-Development of semi-quantitative simulation model to generate an index of the impact (via couplings) of variability | - Prioritisation of topics based on variability impact assessment<br>- Stakeholder discussion of these topics | - FRAM models can become overwhelming, and prioritisation is useful (e.g., via the variability impact assessment)<br>- FRAM useful to create shared understanding among different stakeholders and perspectives-Interventions evaluated in subsequent studies using RAG (Resilience Analysis Grid) |

### 3.2. FRAM analysis of blood sampling practices

This case study investigated the variability in blood sampling practices in hospitals (Pickup et al., 2017). In acute hospital care the hazard of testing the wrong patient's blood, for example due to inaccuracies in sample labelling or patient identification, creates a risk of inefficient patient care, patient harm and even death. A wrong blood in tube (WBIT) incident will influence the likelihood that a patient efficiently and safely receives the required intervention e.g., the transfusion of the correct blood component (Bolton-Maggs and Watt, 2020). The study considered how to enhance the resilience of the blood sampling system by understanding how everyday work usually succeeded, but sometimes went wrong, and how best to ensure more things could go right.

**Setting:** The study was undertaken across four acute hospitals in Scotland. The data collected were obtained from both ward and outpatient settings within medium to large teaching hospitals.

**Purpose:** A FRAM model of blood sampling was developed with clinical practitioners to gain a shared understanding of the dependencies and likely variability in how blood sampling is completed. This was used to illustrate how and why unwanted outcomes may occur, in order to focus future safety improvement activities, which could enhance the resilience of the blood sampling process.

**Data collection / application of FRAM:** 50 sets of observations and 15 interviews were completed with staff representative of the main roles familiar with taking blood. The observations recorded the core functions involved in obtaining a blood sample and enabled a description of work-as-done. The interviews elicited information relating to variability in how and where blood sampling was completed, the equipment or resources relied upon, constraints either in terms of time or controls, and how these may influence the labelling of a blood sample. Each function was described to understand its role in achieving a correctly labelled blood sample and likely variability, either observed or described, which may influence the success or performance of each function. A FRAM model was co-created with advanced blood transfusion practitioners based on the data collected to provide insights into how work-as-done differed from work-as-imagined. The model provided a shared understanding of the dependencies between the functions and highlighted which functions had the greatest impact upon multiple functions, indicating where and why certain types of variability may have a wider impact than others.

**Design of interventions:** The FRAM model and the main sources of variability in everyday work were described to and verified with the Governance and Improvement Leads to ensure a shared understanding. Information about the concept of system resilience was also shared with the Governance and Improvement Leads to enable the co-design of improvement activities to enhance the resilience of the blood sampling system. These included activities to enhance the ability to monitor, anticipate and respond to increasing demands in blood sampling in order to reduce the variability affecting the most critical functions. Examples include: (1) the implementation of processes and resources for timely maintenance and repair of the printers, which are relied upon for labelling blood samples; (2) the development of systems to ensure availability and accessibility of equipment and patient information in all contexts; (3) closed loop reporting for staff (recognising rates of success and failure in samples); and (4) system-based learning to support the timeliness and breadth of learning to enable a more timely response targeted at factors within the system influencing the variability in the performance of blood sampling. These suggestions resulted in the proposition of seven discrete system improvements. Five key members of the governance and improvement team were asked to consider each of the improvements relative to each of the functions, and their dependencies, as described within the FRAM model. They were all provided with descriptors of the four resilience abilities to anticipate, monitor, respond and learn and asked to rate each improvement based on their perception of the potential to enhance the resilience of the blood sampling system. These interventions were then considered in terms of timeframe and resources necessary for effective implementation.

**Reflection:** FRAM was used in this study to consider a problem that is well recognised in healthcare, and where traditional approaches to increasing safety, mainly involving training staff and developing procedures to address safety concerns, have not led to sustainable improvement. FRAM offered an alternative approach to visualise why and how variability in everyday work of taking a blood sample may occur and can sometimes lead to a WBIT. The visualisation of the findings supported the co-design of improvements through a shared understanding across the team. The approach revealed why the intervention of training and requesting staff to follow policies may not have succeeded. This enabled a shift in thinking to recognise how safety was usually achieved by the adjustments made by staff to accommodate high demands for blood samples and contexts where resources were not always as required.

The concept of increasing system resilience was well received as an alternative to traditional patient safety approaches. However, the challenge came in developing improvements with justified confidence that they could enhance resilience. The improvements were co-designed, however, the team acknowledged they would involve a wider number of stakeholders within the organisation than typically considered to be relevant or responsible for the reliability of blood sampling.

The interventions were also not fully implemented nor evaluated due to changes in staffing and changing priorities for the senior team. These are contextual and operational realities with which many practitioners are confronted.

### *3.3. FRAM analysis of fluoride varnish application*

This case study investigated variability in the application of sodium fluoride varnish (FV) to prevent childhood caries in General Dental Service in Scotland (Ross et al., 2018). This preventive measure is recommended twice-yearly for all children, but only about 20 % of children aged 2–5 registered with an NHS dentist receive two or more varnishes. Application is remunerated through the dental contract and can be carried out either by a dentist, a dental therapist, hygienist, or Extended Duty Dental Nurse.

This study aimed to model the FV application system to identify opportunities for intervention to support dental teams in applying varnish more consistently during child appointments.

**Setting:** General Dental Practices delivering NHS dental services in Scotland.

**Purpose:** A FRAM model was developed to illuminate key functions in everyday work linked to fluoride varnish application.

**Data collection / application of FRAM:** Data from mixed sources were extracted and synthesised using the FRAM methodology. These included routine monitoring data on application rates and surveys with General Dental Practitioners, where regression analysis had shown important aspects in intended application. Forty-three in-depth, semi-structured interviews were then carried out with dentists, nurses and policy leads; key activities and variabilities were synthesised, and these were fed into a workshop with NHS clinical directors, specialists in dental public health, and child oral health managers for discussion.

Two researchers independently coded functions extracted from the data (text excerpts, questionnaire results, workshop notes) to the model and achieved 84 % coding reliability (disagreements were resolved by discussion and revisions made where appropriate). The formal analytics steps and results were also discussed internally with child oral health programme leads, and externally at the 10th Workshop on the Functional Resonance Analysis Method (FRAMily) in Lisbon, Portugal in June 2016.

The model of work-as-done contained 33 linked functions closely associated with FV application. Application emerges (or otherwise) through many interacting patient management and practice-based activities such as interpreting guidelines and appraising evidence, assessing children for risk, managing child behaviour, managing time and space, maintaining business models, and educating professionals.

**Design of interventions:** Following from the original model, a set of key variabilities were identified. An instantiation of FRAM was produced, depicting a projected future state that could be expected to follow an intervention. In effect, this describes the aims of the intervention in terms of reduced FRAM function variability (e.g., time and space found for application, child less unsettled, dental team utilised, current guidance disseminated, feedback on application given). The next stage of the work tested the feasibility and acceptability of Human Factors and "Resilient Systems" approaches and methods for Quality Improvement in general practice, focused on preventive care. A toolkit was produced, which contained: an introduction to Human Factors and Resilience Engineering / systems thinking; the FV worked example drawing on the FRAM model; worksheets to apply "systems thinking" to an area of preventive care of the participant's choice. Forty-five dentists worked through the material and exercise and completed a survey; 14 were interviewed. Results are being prepared for publication but show high acceptability and perceived utility of the approach for enhancing QI. There are implementation barriers to be overcome in terms of time and resource, ensuring terminology is tailored for non-specialists, and involving whole teams, which can be difficult in the general dental service setting.

**Reflection:** This project focused on an issue of reliability and consistency of a preventive intervention. The FRAM model helped illuminate the system and reflected work-as-done. However, conducting the original FRAM study, then building the findings into a toolkit for dissemination and allowing dentists to work through their preventive system took considerable effort. It is not clear, in the absence of a controlled trial design, whether simply interviewing dentists about the barriers to applying fluoride varnish might have resulted in similar recommendations for improving application rates. Further, the study took place during the pandemic with a) a heavily disrupted service and b) remuneration for dentists undertaking the project. The issue of finding time and space to study systems in this way in normal high-street practice was a theme in responses. However, most participants felt it was worthwhile and a way of enhancing the value of conventional QI activity like clinical audits.

### 3.4. FRAM analysis of preoperative anticoagulation management

This case study focused on management of anticoagulation therapy in patients planned for cardiothoracic surgery (Damen et al., 2018). Depending on the individual patient and associated surgical risks, anticoagulants can be continued, temporarily interrupted, or temporarily replaced by another type of anticoagulant. These decisions and plans need to be coordinated by a team of healthcare professionals, and they need to be communicated to patients in a clear and timely manner. Prior research focused on communication and coordination issues that are linked to adverse outcomes. Alternatively, this study sought to understand how this process usually goes right at the frontline in everyday practice.

**Setting:** The study was conducted at the cardiothoracic surgery departments of two university hospitals in Australia and the Netherlands. These sites were selected for their high incidence of complex surgeries with many patients on anticoagulation therapy regimes.

**Purpose:** The study aims included obtaining a deeper understanding of how preoperative anticoagulation management is carried out in everyday practice (work-as-done, WAD), and how this relates to predefined procedures (work-as-imagined, WAI). In addition, this study sought to examine the usability and utility of FRAM as a tool to reconcile WAI and WAD in healthcare.

**Data collection / application of FRAM:** An initial model of WAI was constructed based on relevant guidelines. Semi-structured interviews were conducted with 18 healthcare professionals involved in preoperative anticoagulation management to develop a model of WAD, which was updated after each interview in an iterative manner. Interviews were carried out until data saturation was reached for the model, defined as three consecutive interviews during which no new functions were identified. In both hospitals a discussion meeting was organised to present and validate the final models, and to elaborate on potential clinical implications and recommendations for improvement. Variability and interdependence were assessed for foreground functions. Effort required in hours was estimated per step of the analysis process.

**Design of interventions:** The study results illustrated how, for both centres, WAD at the frontline differed from WAI. This could be explained by practical reasons, such as different disciplines playing a central role in patient care on the ward. In both teams, staff had developed personal control mechanisms to ensure success and to enhance efficiency or thoroughness as appropriate (e.g., critical review of colleagues' decisions and documents), but these mechanisms were often unknown to colleagues. Finally, perceptions on roles and responsibilities appeared to differ among clinicians: one discipline felt responsible for a task, but others reported that this was often omitted and carried out by others. When staff discussed the differences between WAI and WAD evidenced by the FRAM analyses several opportunities for improvement were suggested based on these reflections, such as:

- An input was lacking for the FRAM function that represented the patient adhering to the adjusted medication strategy (e.g., stop the medication a given number of days before surgery). Modern information technology may provide solutions to become less dependent on patients having to remember to change their medication regime, for example by sending an automated text message.
- Staff had developed personal control mechanisms, such as a checklist or notebook. Although these mechanisms may support the ability to provide safe, high-quality, and efficient care, colleagues were unfamiliar with many of these personal methods, hampering their use when key individuals are absent or being replaced, and consequently these potentially valuable control mechanisms were "hidden" in the organisation.

As with other examples, the study did not include implementation or evaluation of interventions.

**Reflection:** This study used FRAM to obtain insights into both WAI and WAD, and subsequently used both models to discuss the gaps between these two with the healthcare professionals involved. This was beautifully visualised using FRAM. For example, the department had recently implemented a process improvement around the organisation of the preoperative workup in the clinic, allowing the patient to visit all relevant disciplines at once ("one-stop shop"), but they had not considered how the patient could be supported to adhere to adjustments in medications, relying solely on their memory.

One could argue that the team discussion might be an intervention in itself, because it can stimulate reflection on everyday work processes, increase insight into how one's own work relates to that of others and vice versa, reveal gaps or duplicate work, and trigger discussion about roles and responsibilities. Just discussing a FRAM model (or instantiations) can already have a positive effect on the team because they become more aware of interactions and upstream - downstream effects. The reflection on one's everyday work and how this is dependent on, and connected to, activities carried out by others, can help to become aware of the potential impact of disturbances and changing circumstances on one's work as well as on that of the wider system.

What this study lacked is follow-up on whether these discussions triggered local improvement initiatives or how this analysis was used to reconcile WAI and WAD. The reason for this is that the study was funded externally as research rather than internally as quality improvement, and the timeframe required for evaluation would have extended beyond the limited duration of the project.

Nonetheless, this study's model of WAD can potentially provide a future reference for local investigations of incidents or sentinel events because it offers a more accurate picture of how work is carried out in everyday practice compared to guidelines or protocols (i.e., WAI). The FRAM model shows the actual variability in practice, e.g., guidelines that are not applicable or followed in both successful as well as unsuccessful instances, and hence with FRAM this can be represented in a non-normative way, which does not require judgemental terminology (such as human error).

### 3.5. FRAM analysis of perioperative neurosurgery pathway

This case study focused on the management of the patient pathway during neurosurgery. The study embraced a systems perspective to model normal operations and to understand the strengths and weaknesses of the system in relation to iatrogenic disease. Following a RE perspective, strengths refer to situations where adaptive practices combine to carry out a surgery successfully despite daily variability in the context. On the other hand, weaknesses refer to situations that escalate - or have the potential to escalate - into any unwanted or adverse patient outcome (Patriarca et al., 2018b).

**Setting:** The study took place in a neurosurgical unit of a hospital in Southern Europe. This unit is located in a dedicated building directly connected to the hospital emergency department. The unit has 33 beds, 9 of which are ventilated beds for critical care, and 4 beds are for neuro-maxillo-facial surgery. The unit includes equipment for traditional Radiology, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and a neuro-angiography suite.

**Purpose:** FRAM was used to understand how neurosurgeries were conducted under normal circumstances. The aims of the study were to: (i) identify functions and couplings with higher potential to generate iatrogenic disease, and consequently (ii) reconfigure operations or suggest design alternatives from a socio-technical perspective.

**Data collection / application of FRAM:** The study used data triangulation, integrating the output of documentary studies, open-ended interviews, naturalistic observations, semi-structured interviews, and surveys. First, a thematic analysis of procedures, standards, and checklists allowed eliciting normative functions, i.e., functions describing how the process should have been conducted (work-as-imagined). This analysis facilitated dialogue with operators about operational practices. Then, ten 1-hour open-ended individual interviews (five anaesthetists, two surgeons, two nurses, one neurophysiopathologist) were conducted to capture normal practices and to design the work-as-done FRAM model from multiple perspectives. This model was enlarged and revised via data elicited from naturalistic observations (ten hours) and finalised through semi-structured interviews with two groups of participants (three anaesthetists and one nurse per group). A 3-hour focus group was conducted to check model completeness and significance. The complexity of the resulting model was investigated through a multi-layer approach (Patriarca et al., 2017), taking inspiration from (Rasmussen, 1985). The FRAM model accounted for 64 functions at the lower level of granularity, grouped into 20 generalised functions, in turn collapsed into 7 functional purposes functions. All functions were unevenly distributed among 7 agents. A survey was shared with 15 participants (seven anaesthetists, five surgeons, three nurses) to get snapshot data on functional variability for each individual function. Data collection lasted for about two months involving a total of 320 person-hours and included 23 participants.

**Design of interventions:** The data on variability of functions collected through surveys were converted into discrete probability distribution functions intended to map the different operating states. These distributions were used to feed the relationships of the FRAM work-as-done model and thus obtain a semi-quantitative simulation model. The output of the simulation allowed categorising each coupling into a Variability Impact Matrix (VIM) built around two dimensions: criticality (quantified probability of a function being resonant), and reverberation (number of a function's downstream connections). The couplings in VIM were then prioritised for discussions in a focus group with stakeholders. Couplings scoring the highest values in both dimensions were related to communication issues. Some of the recommendations identified in discussion during the focus group were:

- Definition and analysis of indicators related to staff concurrence time (i.e., time spent by two or more staff members in the surgery room, briefing and debriefing time) logged by the head nurse, who was responsible for one intervention at a time. This indicator was used as a leading metric (i.e., lower values could anticipate potentially insufficient coordination) to suggest a higher need for explicit co-ordination checks between surgeons and anaesthetists, at the request of the nurse.
- Proposition of "sequential briefings" to allow for peer-review on some of the functions being affected by higher levels of inconsistency and misunderstanding (e.g., functions < Position the patient > and < Induce anaesthesia > ).
- Identification of "Team time outs" for variable, yet highly connected functions. Rather than prescriptive sequential activities, the surgery team agreed on the need for time-out calls to allow flexibility and, at the same time, ensure proper coordination. Four critical moments for time-outs were identified: (i) before entering the operative block, (ii) before accessing the operating room, (iii) before initiating the surgery, (iv) after the surgery.

**Reflection:** In this application of FRAM, operations were studied at the micro level and then extended at different degrees of abstraction. The model allowed capturing trade-offs and tensions for each function as performed by different people.

The resulting FRAM model soon became overwhelming in terms of functions and their connections, requiring computational support to facilitate interpretation. The design of a simulation model supported a systematic analysis of variability values. In this sense, FRAM was used as the foundational engine for simulations, and stayed mostly at the back-end of the actual analyses presented to stakeholders. Simplified extracts of the model were used to document specific concerns and to facilitate discussions.

The efforts to reconcile different perspectives into a single model (anaesthetist, surgeon, nurse, neurophysiopathologist) were considered necessary and instrumental to gain an overall understanding, which was otherwise largely hidden to each actor.

Discussions among different types of staff were undertaken at a level of detail considered sufficient to take actionable decisions. The FRAM study was part of a larger exploration of system resilience, and it was combined with other macro-scale studies based on the Resilience Analysis Grid (RAG) to map performance over time, especially following the implementation of the suggested changes (Patriarca et al., 2018a).

## 4. Cross-case reflection and discussion

The previous section provided individual reflections on five examples of the application of FRAM in healthcare by one of the respective study authors. Building on these individual reflections, lessons were identified by reflecting collectively across the examples including the set of individual reflections. Four themes were developed: (1) core characteristics of a FRAM study, (2) flexibility regarding the underlying epistemological paradigm, (3) diversity with respect to the development of interventions, and (4) model complexity.

### 4.1. Core characteristics of a FRAM study

FRAM can be used for different purposes and in different ways. However, despite the diversity of examples regarding purpose and setting, several core characteristics were identified across the examples. When selecting FRAM as the analysis method, the application should be consistent with these characteristics.

**Provide a different perspective**

All the examples described in this paper investigated issues that had been studied previously but which had proved to be stubborn problems, e.g., the management of the deteriorating patient, blood sampling, and anticoagulation management. This is consistent with other studies using FRAM, which aimed to provide a different perspective on such problems, e.g., transfer of patients from intensive care to a hospital ward (Clay-Williams et al., 2015), handover in emergency care (Sujan and Felici, 2012), or drug administration in neonatal intensive care (Kaya et al., 2019). This aim links back to the underlying thinking in Resilience Engineering and Safety-II, which frames safety as the ability to succeed under varying conditions (Woods and Hollnagel, 2006), and which thereby brings a different perspective.

**Illuminate systems dynamics and work-as-done**

An aim shared across the different FRAM examples in this paper was the aspiration to understand the system dynamics and to investigate work-as-done as the basis for subsequent development of systems-based interventions. FRAM is an analysis method to achieve this as it supports analysts to capture the non-linear, complex work of healthcare professionals. The functioning of the system can be studied and represented considering resulting amplifying or dampening feedback loops.

**Reflect on the gap between work-as-imagined and work-as-done**

Based on the analysis of work-as-done, a FRAM analysis typically involves reflection on the gap between work-as-imagined and work-as-done. In some instances, this reflection can be the main purpose of the analysis and function as an intervention itself by enabling different stakeholders to develop a shared understanding of their collaborative work.

**Engage stakeholders**

In all cases engagement of stakeholders at different levels of the analysis was a key consideration. Data collection typically includes observations, interviews, and focus groups with a diverse set of stakeholders. Development of interventions also relies to a significant extent on the involvement of stakeholders as co-producers of improvements. In this respect, FRAM shares common assumptions and values with other approaches, such as Safety Differently (Dekker, 2014), co-production of healthcare services (Batalden et al., 2016), Quality Improvement (Berwick, 1996), and User-Centred Design (Bødker, 2000).

### 4.2. Epistemological paradigm

FRAM is a tool for the analyst. As such, the way FRAM is used depends on the mindset of the analyst and on the specific paradigm of how knowledge is produced, i.e., the underlying epistemology. FRAM is a flexible method that can accommodate different mindsets. Detailed descriptions of epistemological foundations are beyond the scope of the paper and can be found elsewhere (Corbin and Strauss, 2015; de Vaus, 2001; Edwards et al., 2014). FRAM is typically used, usually implicitly, along the continuum of realism and phenomenology. There is no single best way of using FRAM, but the analyst needs to be clear about their underlying assumptions, and these should fit with the purpose of the analysis. This includes reflection on the nature of the data used for designing the model, resolution of the analysis (i.e., establishing a consistent macro, *meso* or micro scale), and actual model boundaries (i.e., setting explicit background functions) (Patriarca et al., 2021). To distinguish between different approaches of using FRAM, we refer to these as computational FRAM and reflexive FRAM, respectively.

**Realist paradigm – Computational FRAM**

When doing a FRAM analysis from the perspective of realism, the analyst assumes that it is possible to provide a reasonably objective account of the system, the functions, their couplings, and the variability to the extent that this can even be quantified (or semi-quantified) and the propagation of variability can be assessed to identify the potential for functional resonance (the example by (Patriarca et al., 2018b) could be regarded as an instance of this perspective). The aim is to describe accurately (to a reasonable extent) how the system works and to document this in a - sometimes computational - model. From this perspective it makes sense to expect that different analysts produce largely similar models. Research in this sense is aimed at ensuring model consistency and providing instruments to facilitate and strengthen model development, e.g., via taxonomies, ontologies, and model checkers.

**Phenomenological paradigm – Reflexive FRAM**

The phenomenological application of FRAM emphasises the situated nature of knowledge. The analyst does not aim to provide an objective system model (or graphical / computational representation), but rather acknowledges and seeks to convey that the "system" is actively constructed and reconstructed through human activity and dynamic interactions. Every study participant discloses their perspective on the system, but these accounts only provide a snapshot and are highly context dependent (the example by (Sujan et al., 2022) falls into this category). FRAM provides the analyst with a guiding framework to explore participants' accounts of their working realities. The analyst interprets these accounts to provide insights into system variability and the underlying tensions and contradictions (Engestrom, 1987; Sujan et al., 2015). With such an interpretative approach, there are different "stories" one could tell about the system, and there is no attempt at quantifying an objective reality of the system and its variability. Different analysts can reasonably come up with different accounts of the system, which does not necessarily undermine the quality or validity of the FRAM analysis. It is important, however, that the analyst reflects on their active part in the analysis and on their assumptions and values, and how these impact on the focus of the analysis and the type of "story" that is being developed (Braun and Clarke, 2006).

### 4.3. Development of interventions

Depending on the purpose of the analysis and the epistemological position, recommendations (e.g., suggestions for interventions) can be developed in different ways. The realist paradigm can help identify recommendations that are directed at monitoring and controlling variability (i.e., close to what step 4 of the FRAM handbook suggests). Examples might include reducing the number of couplings of a function, introducing redundancy, or reducing variability by reconciling work-as-imagined and work-as-done (e.g., (Clay-Williams et al., 2015). Other forms of recommendations might be in the form of suggestions for safety indicators (or "variability" indicators) that can provide leading safety intelligence (Raben et al., 2018, Sujan et al., 2021). Care needs to be taken that such recommendations do not degenerate into simplistic barrier thinking (i.e., fall back into Safety-I type of thinking), as it is unlikely that this would lead to improvements in situations where established methods have already struggled.

The phenomenological paradigm might focus more on recommendations that are co-produced with stakeholders through reflections on work-as-done as illuminated through FRAM. This approach might encourage dialogue and reflection on competing demands and priorities, and on how more abstract resilience abilities could be strengthened in specific situations (e.g., (Furniss et al., 2020)).

There is no hard division between the two, and the realist paradigm can include elements of the phenomenological paradigm and vice versa.

### 4.4. Model complexity

A practical challenge of developing and communicating the FRAM model, which arose in all of the use cases, related to model complexity. We characterised healthcare systems as complex sociotechnical systems and, as such, the analysis needs to involve many different actors with different roles and responsibilities. The number of functions and their couplings can quickly become overwhelming, and it is increasingly challenging to use the graphical representation of FRAM models (or instantiations) meaningfully for analytical purposes and for communication with stakeholders. Related to this, there are further practical challenges of gaining sufficient access to the different parts of the system and people.

In the use cases these challenges were addressed pragmatically. Typically, the analysis was undertaken at one level only, either the micro level with a lot of detail about the trade-offs in everyday work and using the concept of background functions, which are then not analysed further (e.g., (Sujan et al., 2022)) or the macro level using more generalised functions (e.g., (Ross et al., 2018)). Ideally, however, one would want a mechanism that enables zooming in and zooming out as appropriate and as supported by the data collected (different levels of detail might be available for different aspects of the sociotechnical system) in a transparent and explicitly linked way. The use case analysing the perioperative neurosurgery pathway (Patriarca et al., 2018b) adopted a modified abstraction – decomposition space (Rasmussen, 1985) typically used for Work Domain Analysis (Vicente, 1999). This novel abstraction – agency space can be used to link FRAM models across different agents (which can be people, departments, organisations) and different levels of abstraction. However, this approach is not yet widely used, and further empirical evidence is required to establish the extent to which it supports communication with stakeholders.

### 4.5. Study limitations

This manuscript is the result of critical reflection and provides, therefore, an account of the authors' attempts to make sense of their respective experiences of applying FRAM in healthcare, both individually and as a group. Consequently, the findings are subjective and rooted in these personal experiences.

There is also a risk of selection bias, because the authors contributing to the manuscript had formed previous collaborations and professional relationships, and it could be argued that their experiences might be more aligned than what might have presented itself with a more heterogenous group of practitioners.

## 5. Conclusions

FRAM is a systems analysis method that offers considerable flexibility to accommodate different epistemological positions, ranging from realism to phenomenology. We have referred to these as computational FRAM and reflexive FRAM, respectively. Despite this flexibility, or because of it, practitioners need to be clear about their analysis aims and their analysis position.

FRAM enables the analyst to look at a system or an issue of interest from a different perspective and to ask different questions to gain additional insight into how a system works, rather than simply to investigate how a system sometimes fails. These insights can form the basis for subsequent interventions, but FRAM as an analysis method does not prescribe specific types of interventions.

Further guidance is needed to support practitioners to tell a convincing and meaningful "system story" through the lens of FRAM. This could potentially be in the form of a structured reporting guideline provided it allows for the flexibility that is characteristic for FRAM.

These lessons have been developed from reflections on the application of FRAM in healthcare, but should be applicable across analysis contexts, which are characterised by uncertainty and variability.

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## CRediT authorship contribution statement

**M. Sujan:** Methodology, Funding acquisition, Conceptualization, Writing - original draft, Writing - review & editing. **L. Pickup:** Funding acquisition, Conceptualization, Writing - review & editing. **M.S. de Vos:** Conceptualization, Writing – review & editing. **R. Patriarca:** Writing – review & editing, Conceptualization. **L. Konwinski:** Writing – review & editing, Conceptualization. **A. Ross:** Writing – review & editing, Conceptualization. **P. McCulloch:** Funding acquisition, Conceptualization, Writing - review & editing.

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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.

## References

Batalden, M., Batalden, P., Margolis, P., Seid, M., Armstrong, G., Opipari-Arrigan, L., Hartung, H., 2016. Coproduction of healthcare service. BMJ Quality & Safety 25, 509–517.
Berwick, D.M., 1996. A primer on leading the improvement of systems. BMJ : British Med. J. 312, 619–622.
Bødker, S., 2000. Scenarios in user-centred design—setting the stage for reflection and action. Interacting with Computers 13, 61–75.
Bolton-Maggs, P.H.B., Watt, A., 2020. Transfusion errors — can they be eliminated? British J. Haematol. 189, 9–20.
Braun, V., Clarke, V., 2006. Using thematic analysis in psychology. Qualitative Res. Psychol. 3, 77–101.
Burke, J.R., Downey, C., Almoudaris, A.M., 2020. Failure to rescue deteriorating patients: a systematic review of root causes and improvement strategies. J. Patient Safety.
Carayon, P., Wooldridge, A., Hoonakker, P., Hundt, A.S., Kelly, M., 2020. SEIPS 3.0: Human-centered design of the patient journey for patient safety. Appl. Ergonomics 84, 103033.
Clay-Williams, R., Hounsgaard, J., Hollnagel, E., 2015. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. Implementation Sci. 10, 125.
Cook, R.I., Render, M., Woods, D.D., 2000. Gaps in the continuity of care and progress on patient safety. BMJ 320, 791–794.
Corbin, J., Strauss, A., 2015. Basics of qualitative research: techniques and procedures for developing grounded theory. SAGE, London.
Damen, N.L., de Vos, Moesker, M.J., Braithwaite, J., de Lind van Wijngaarden, R., Kaplan, J., Hamming, J.F., Clay-Williams, R., 2018. Preoperative Anticoagulation Management in Everyday Clinical Practice: An International Comparative Analysis of Work-as-Done Using the Functional Resonance Analysis Method. Journal of patient safety.
de Vaus, D., 2001. Research design in social research. Sage.
Dekker, S., 2014. Safety Differently. CRC Press London.
Department of Health, 2000. An organisation with a memory. The Stationery Office, London.
Edwards, P.K., O`Mahoney, J., Vincent, S., 2014. Studying organizations using critical realism: a practical guide. OUP Oxford.
Engestrom, Y., 1987. Learning by Expanding. Orienta-Konsultit, Helsinki.
Fairbanks, R.J., Wears, R.L., Woods, D.D., Hollnagel, E., Plsek, P., Cook, R.I., 2014. Resilience and resilience engineering in health care. Jt Comm J Qual Patient Saf 40, 376–383.
Fook, J., 2011. Developing Critical Reflection as a Research Method. In: HIGGS, J., TITCHEN, A., HORSFALL, D. & BRIDGES, D., . (Ed.), Creative Spaces for Qualitative Researching: Living Research. SensePublishers, Rotterdam.
Furniss, D., Nelson, D., Habli, I., White, S., Elliott, M., Reynolds, N., Sujan, M., 2020. Using FRAM to explore sources of performance variability in intravenous infusion administration in ICU: A non-normative approach to systems contradictions. Appl. Ergonomics 86.
Herrera, I.A., Woltjer, R., 2010. Comparing a multi-linear (STEP) and systemic (FRAM) method for accident analysis. Reliability Eng. System Safety 95, 1269–1275.
Holden, R.J., Carayon, P., Gurses, A.P., Hoonakker, P., Hundt, A.S., Ozok, A.A., Rivera-Rodriguez, A.J., 2013. SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. Ergonomics 56, 1669–1686.
Hollnagel, E., Woods, D.D., Leveson, N., 2006. Resilience Engineering: Concepts and Precepts. Ashgate, Aldershot.
Hollnagel, E., 2018. Safety-II in practice: developing the resilience potentials. Routledge, Abingdon.
Hollnagel, E., Sujan, M., Braithwaite, J., 2019. Resilient Health Care - making steady progress. Safety Sci. 120, 781–782.
Hollnagel, E., 2009. The ETTO Principle: Efficiency-Thoroughness Trade-Off. Ashgate, Farnham.
Hollnagel, E., 2010. Prologue: The Scope of Resilience Engineering. In: HOLLNAGEL, E., PARIES, J., WOODS, D. D. & WREATHALL, J., . (Ed.), Resilience Engineering in Practice: A Guidebook. Ashgate, Farnham.
Hollnagel, E., 2012. FRAM, the functional resonance analysis method: modelling complex socio-technical systems. Ashgate Publishing Ltd.
Hollnagel, E., 2014. Safety-I and Safety-II. Ashgate, Farnham.
Hollnagel, E., 2016. Prologue: Why do our expectations of how work should be done never correspond exactly to how work is done. In: BRAITHWAITE, J., WEARS, R., HOLLNAGEL, E. (Eds.), Resilient Health Care III: Reconciling Work-As-Imagined and Work-As-Done. Ashgate, Farnham.
Kaya, G.K., Ovali, H.F., Ozturk, F., 2019. Using the functional resonance analysis method on the drug administration process to assess performance variability. Safety Science 118, 835–840.
Kohn, L.T., Corrigan, J.M., Donaldson, M.S., 2000. To Err Is Human: Building a Safer Health System. The National Academies Press, Washington.
Larouzee, J., le Coze, J.-C., 2020. Good and bad reasons: the Swiss cheese model and its critics. Safety Science 126, 104660.
Mackinnon, R.J., Pukk-Härenstam, K., Kennedy, C., Hollnagel, E., Slater, D., 2021. A novel approach to explore Safety-I and Safety-II perspectives in in situ simulations—the structured what if functional resonance analysis methodology. Advances in Simulation 6, 21.
Martinie, C., Palanque, P., Ragosta, M., Sujan, M. A., Navarre, D. & Pasquini, A. 2013. Understanding Functional Resonance through a Federation of Models: Preliminary Findings of an Avionics Case Study. *In:* BITSCH, F., GUIOCHET, J. & KAÂNICHE, M. (eds.) Computer Safety, Reliability, and Security: 32nd International Conference, SAFECOMP 2013, Toulouse, France, September 24-27, 2013. Proceedings. Berlin, Heidelberg: Springer Berlin Heidelberg.
McNab, D., Freestone, J., Black, C., Carson-Stevens, A., Bowie, P., 2018. Participatory design of an improvement intervention for the primary care management of possible sepsis using the Functional Resonance Analysis Method. BMC Medicine 16, 174.
O'Hara, J.K., Baxter, R., Hardicre, N., 2020. 'Handing over to the patient': A FRAM analysis of transitional care combining multiple stakeholder perspectives. Appl. Ergonomics 85, 103060.
Patriarca, R., Bergström, J., di Gravio, G., 2017. Defining the functional resonance analysis space: combining Abstraction Hierarchy and FRAM. Reliability Eng. System Safety 165, 34–46.
Patriarca, R., di Gravio, G., Costantino, F., Falegnami, A., Bilotta, F., 2018a. An Analytic Framework to Assess Organizational Resilience. Safety and Health at Work 9, 265–276.
Patriarca, R., Falegnami, A., Costantino, F., Bilotta, F., 2018b. Resilience engineering for socio-technical risk analysis: application in neuro-surgery. Reliability Eng. System Safety 180, 321–335.
Patriarca, R., di Gravio, G., Woltjer, R., Costantino, F., Praetorius, G., Ferreira, P., Hollnagel, E., 2020. Framing the FRAM: a literature review on the functional resonance analysis method. Safety Sci. 129, 104827.
Patriarca, R., Falegnami, A., Costantino, F., di Gravio, G., de Nicola, A., Villani, M.L., 2021. WAx: An integrated conceptual framework for the analysis of cyber-socio-technical systems. Safety Science 136, 105142.
Pickup, L., Atkinson, S., Hollnagel, E., Bowie, P., Gray, S., Rawlinson, S., Forrester, K., 2017. Blood sampling - Two sides to the story. Applied Ergonomics 59, 234–242.
Raben, D.C., Bogh, S.B., Viskum, B., Mikkelsen, K.L., Hollnagel, E., 2018. Learn from what goes right: a demonstration of a new systematic method for identification of leading indicators in healthcare. Reliability Eng. System Safety 169, 187–198.
Rasmussen, J., 1985. The role of hierarchical knowledge representation in decisionmaking and system management. IEEE Transactions on Systems, Man, and Cybernetics SMC-15, 234–243.

Reason, J., 2000. Human error: models and management. BMJ 320, 768–770.
Ross, A., Sherriff, A., Kidd, J., Gnich, W., Anderson, J., Deas, L., Macpherson, L., 2018. A systems approach using the functional resonance analysis method to support fluoride varnish application for children attending general dental practice. Appl. Ergonomics 68, 294–303.
Schön, D.A., 1983. The reflective practitioner: how professionals think in action. Basic Books, New York.
Schutijser, B.C.F.M., Jongerden, I.P., Klopotowska, J.E., Portegijs, S., de Bruijne, M.C., Wagner, C., 2019. Double checking injectable medication administration: Does the protocol fit clinical practice? Safety Science 118, 853–860.
Sujan, M., Spurgeon, P., Cooke, M., 2015. The role of dynamic trade-offs in creating safety—A qualitative study of handover across care boundaries in emergency care. Reliability Eng. System Safety 141, 54–62.
St.Pierre, M., Grawe, P., Bergstrom, J., Neuhaus, C., 2022. 20 years after To Err Is Human: a bibliometric analysis of 'the IOM report's' impact on research on patient safety. Safety Science 147, 105593.
Sujan, M., 2021. Muddling Through in the Intensive Care Unit. In: BRAITHWAITE, J., HOLLNAGEL, E., HUNTE, G. (Eds.), Resilient Health Care V6 - Muddling Through With Purpose. CRC Press, Boca Raton.
Sujan, M., Bilbro, N., Ross, A., Earl, L., Ibrahim, M., Bond-Smith, G., Ghaferi, A., Pickup, L., McCulloch, P., 2022. Failure to rescue following emergency surgery: a FRAM analysis of the management of the deteriorating patient. Appl. Ergonomics 98, 103608.
Sujan, M.A., Embrey, D., Huang, H., 2020. On the application of human reliability analysis in healthcare: opportunities and challenges. Reliability Engineering & System Safety 194.
Sujan, M., Watt, J., Patriarca, R., Costantino, F., Villani, M.L., De Nicola, A., 2021. Developing Leading Safety Indicators using the Functional Resonance Analysis Method. Safety-Critical Systems Club, Bristol, UK.
Sujan, M.A., Felici, M., 2012. Combining Failure Mode and Functional Resonance Analyses in Healthcare Settings. Computer Safety, Reliability, and Security 364–375.
Verhagen, M.J., de Vos, M.S., Sujan, M., Hamming, J.F., 2022. The problem with making Safety-II work in healthcare. BMJ Qual Saf 31, 402–408.
Vicente, K.J., 1999. Cognitive work analysis: Toward safe, productive, and healthy computer-based work. CRC Press.
Wears, R., Sutcliffe, K., 2019. Still Not Safe: Patient Safety and the Middle-Managing of American Medicine. Oxford University Press, Oxford.
Woods, D.D., Hollnagel, E., 2006. Prologue: Resilience Engineering Concepts. In: HOLLNAGEL, E., WOODS, D.D., LEVESON, N. (Eds.), *Resilience Engineering: Concepts and Precepts*. Ashgate, Aldershot.