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Impact of the Functional Resonance Analysis Method (FRAM) in safety management at healthcare organisations

Systematic Review

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Abstract

Patient safety events are likely to be one of the ten leading causes of death and disability in the world (World Health Organization, 2020). To manage safety, healthcare organisations have traditionally focused on identifying failures, performing analysis of events, and developing strategies to reduce the failures. Several thought leaders have argued that the traditional method is not adequate to manage safety in a complex environment. Their argument is that safety management should not solely focus on what went wrong, it should also include efforts which enable things to go right more often. If healthcare organisations want to broaden their approach towards managing safety, suitable methods must be investigated.

The Functional Resonance Analysis Method (FRAM) was developed by Hollnagel in 2004 and has been applied in high-risk industries such as railway, aviation, maritime and healthcare. FRAM investigates the interaction of the different functions within a complex, underspecified system, and improves the understanding of normal work and its variability (Hollnagel, 2012). This systematic review will assess the application of FRAM in healthcare settings to develop a rich understanding of the application of FRAM in healthcare as a complementary method to safety management. Firstly, understanding how FRAM was implemented within healthcare organisations and secondly understanding how healthcare organisations have perceived the value-add of FRAM in terms of safety management. The results are expected to provide healthcare organisations with guidance on applying the FRAM and demonstrate the value it potentially adds to safety management.

In the studies reviewed, FRAM was applied in a wide variety of settings and in different contexts. Thematic value-added aspects were identified and discussed. Shortcomings and prerequisites for the application of FRAM was also highlighted. This dissertation wishes to motivate healthcare organisations to investigate and apply alternative methods such as FRAM to enhance their ability to manage safety in a complex environment.

TABLE OF CONTENTS

List of Tables

List of Figures

List of Appendices

List of Abbreviations

BPMN	Business Process Model and Notation
FMEA	Failure Mode and Effects Analysis
FRAM	Functional Resonance Analysis Method
HRO	High-Reliability Organisations
LIIM	Leading Indicators Identification Method
NICU	Neonatal Intensive Care Unit
PICO	Patient Intervention Comparator and Outcome
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
RCA	Root Cause Analysis
RE	Resilience Engineering
SEIPS	Systems Engineering Initiative for Patient Safety
STAMP	System Theoretic Accident Model and Processes
VIM	Variability Impact Matrix
WAD	Work-as-Done
WAP	Work-as-Prescribed
WAI	Work-as-Imagined
ICU	Intensive Care Unit
LEAN	Leadership. Eliminate waste. Act now.

1. INTRODUCTION

1.1 Background

“Just as medicine understands more about disease than health, so the safety sciences know more about what causes adverse events than about how they can best be avoided.”

(Reason, 2000).

The World Health Organization (WHO) has indicated that adverse patient safety events are likely to be one of the ten leading causes of death and disability in the world (World Health Organization, 2020). In the attempt to prevent adverse patient outcomes, safety management in healthcare has traditionally relied on identifying adverse events, performing analyses to understand how and what went wrong and then developing strategies to reduce them. Despite safety management efforts in healthcare, the rates of adverse outcomes have remained unchanged and efforts to eradicate adverse outcomes have generally been unsuccessful (Kellogg et al., 2017) (Mannion & Braithwaite, 2017). There is a growing realisation that safetywill not improve by the sole application of traditional methods when managing adverse outcomes. Work processes in healthcare have become more integrated, complex, and demanding to the persons trying to manage the interaction between humans and technical systems that produces patient safety. In a study conducted by Clay-Williams, Hounsgaard, and Hollnagel (2015) their ability to understand complex safety matters and how to manage the variability in daily work, has improved with the application of the Functional Resonance Analysis Method (FRAM).

1.2 Aim and Objectives

This dissertation aims to explore the literature available on the implementation of FRAM in healthcare organisations. To the writer’s best knowledge, a systematic review on the application of FRAM with a specific focus on healthcare has not been published before. Published evidence and grey literature is used to answer the research question: “How does the application of Functional Resonance Analysis Method (FRAM) support healthcare organisations to enhance their ability to manage safety?” In an attempt to answer the research question, two objectives have been identified.

- Firstly, how FRAM can be implemented, in this section the author investigates where and how FRAM has been implemented, the types of applications are discussed as well as additions to FRAM.
- The second objective focusses on the value-add in terms of safety management for healthcare organisations. The outcomes which are realised due to the application of FRAM will be identified and discussed.

The results are expected to provide healthcare organisations with guidance on applying the FRAM and demonstrate the value it potentially adds to safety management. The Patient Intervention Comparator and Outcome (PICO) model (participants, interventions, comparators, and outcomes) has been used to frame the research question (Eriksen & Frandsen 2018). Participants are healthcare organisations; the intervention is the application of the Functional Resonance Analysis Method (FRAM) and the outcome is safety management. This systematic review will investigate how FRAM has been applied in various healthcare settings to form a rich understanding of its application and potential. The results are expected to provide healthcare organisations with guidance on applying the FRAM method and demonstrate the value it potentially adds to safety management.

1.3 Overview of dissertation

The dissertation comprised of four main sections. Firstly, the literature review will investigate what work entails in healthcare organisations, the FRAM method and how safety is managed and monitored. The second section of the dissertation describes the systematic methods used to search and select the primary studies, how the data will be extracted and in which way it can be analysed. The third part reports on the results which have been extracted from the literature after the application of FRAM, whereafter the findings are discussed and analysed. A discussion and conclusion follow which make up the remaining part of the dissertation.

2. LITERATURE REVIEW

The literature review explores the history and management of safety within healthcare organisations. It investigates the work that is done in healthcare organisations and the complexity it entails. Thereafter, a description of the FRAM model is provided and discussed focussing on the methods which healthcare organisations use to measure and monitor safety, and which aspects are needed to develop resilience potentials.

To investigate safety management, an understanding is needed of what the concept "safety" entails. Safety can be defined in several ways:

- Merriam-Webster dictionary (2020) define safety as "the condition of being safe from undergoing or causing hurt, injury, or loss; it is the act of protecting against failure, breakage, or accident".
- Safety is the avoidance of unexpected events (Li & Guldenmund, 2018).
- Hollnagel (2014) defines safety as a "dynamic non-event". In other words, "safety is present when nothing goes wrong".
- Vincent, Burnett & Carthey (2013) is of the opinion that safety is more than the avoidance of serious outcomes, it is the ability to foresee and respond to hazards and adverse outcomes.
- Hollnagel (2008) is of the opinion that the best way to ensure safety is to stop unwanted events from happening or to protect against the unwanted outcomes of events.
- Emanuel and colleagues (2008) describe patient safety as scientific methods being applied in healthcare, with the aim to increase the trustworthiness of the healthcare delivery system and its reliability in the face of high-risk therapeutic interventions.
- Wiig & Lindøe (2009) see safety as an emerging part of the socio-technical healthcare system; it cannot be attributed to specific persons, devices, or departments.

The definitions above of safety can be firstly seen in association with actual or potential adverse outcomes in individuals or patients. Secondly, safety is referred to as emerging from a system and not from single or individual factors. Healthcare systems can either contribute to or impede safety. A system cannot remain safe 'once and for all', resources are required, and a continuous investment in safety is necessary to enhance and maintain a safe system (Kleiner, Hettinger, DeJoy, Huang, & Love, 2015). Hollnagel (2017) echoes this by highlighting that a system cannot be deemed safe because it has a small number of reported adverse outcomes. The history of safety management in healthcare can shed light on the development of safety and the methods that have been used to manage safety over time.

2.1 History

Safety management has a 200-year history. In the 19th century work was not as complex, and processes occurred in a cause-and-effect sequence with a linear reliance on each other. In a linear thinking model X causes Y, which causes Z and a combination of X+Y = Z. Work was reasonably easy to understand, visualise and improve (Hollnagel, 2017). Adverse events were described as a series of events or circumstance that happened in a simple sequence or timeline (Li & Guldenmund, 2018). The methods that were used to investigate safety adverse outcomes at the time were developed for industrial and occupational safety. Methods included root cause analysis (RCA), accident reporting, failure assessment and risk management (Braithwaite et al., 2015).

Hollnagel and Speziali (2008) describe RCA as a 'single cause philosophy', that is the belief that if the single cause were removed, the outcome would have been prevented. In healthcare, RCA is the most frequently used method for investigating adverse outcomes. Card and colleagues (2012) reported in a systematic review that the quality of action plans instituted post-RCA was not high. In a study performed by Kellogg (2016) it was reported that solutions implemented over a period of 8 years following an RCA, were weak and did not prevent the recurrence of adverse outcomes. Kwok and colleagues (2020) had similar findings when after performing an RCA, only 2% of the 760 recommendations were strong, 15% medium and 82% weak. They used the action hierarchy of the United States of America's Veteran Affairs National Centre for Patient Safety (US Department of Veterans Affairs, 2015) as a method to evaluate the strength of the RCA recommendation:

- 'weak' indicating human behavioural changes,
- 'medium' indicate improvement actions which rely on human compliance e.g., completing a surgical safety checklist,
- 'strong' focus on system changes.

Peerally (2016) highlight those investigations consistently fail to deliver benefits and the quality that is needed as they are often focused on finding simple, linear solutions by using techniques such as "5 Why's" (asking "why" five times to find the root cause of the problem) and RCA. Mannion & Braithwaite (2017) argue that linear approaches are 'not matching the profound complexity of modern healthcare settings.' The RCA approach can be effective in linear systems, but it has limited applicability in complex systems. Salehi, Veitch & Smith (2020) are of the opinion that the conventional investigation tools do not have the ability to highlight risks which are related to performance variability. Traditional safety management is limited in its capability to understand a whole, complex system; therefore, methods such as FRAM was introduced to mitigate this shortcoming according to Kaya and Hocaoglu (2020).

Around the turn of the millennium, healthcare organisations started following a system approach in which a dysfunctional system, rather than the individual, was recognised to be causing adverse events. Approaches followed include LEAN techniques and Reason's multi-linear Swiss Cheese Model (Mannion & Braithwaite, 2017). Safety management focused on designing working environments to reduce the possibility of human error, reducing the active failures of staff, and eliminating upstream or latent failures within the wider system (Reason, 1997). Hollnagel (2017) highlights that implementing physical or functional barriers which stop or hinder an event from taking place in the Swiss Cheese Model can be an effective way to manage safety. Safety barriers such as improving decision-making, enhancing the ability to prioritise, or addressing the organisational culture, are however not as effective. Patriarca and colleagues (2017) highlight that safety adverse outcomes cannot be reduced by solely relying on a barrier-based approach within a complex system. Following Reason's model, the London Protocol was designed by Taylor-Adams and Vincent (2004) as an investigative and analysis tool to assist in investigating adverse events. It aims to uncover the deeper-rooted contributory factors to adverse events and highlight gaps or inadequacies within the healthcare system. It aims to create an open and fair culture within healthcare, by acknowledging system and individual accountability.

In the early 2000's healthcare organisations investigated how other High-Reliability Organisations (HRO) such as aviation, manage to achieve high levels of safety or reliability despite working in hazardous conditions (Pronovost et al., 2006). Sujan (2017) describes several attributes of a reliable organisation:

- it is preoccupied with failure and encourages staff to speak up about safety hazards,
- it has a reluctance to simplify and acknowledges complexity,
- it is sensitive to operations and acknowledges that frontline staff may need to adapt their functions at times,
- it is committed to resilience and
- it can delegate tasks to staff with the most relevant expertise, irrespective of hierarchy.

Nemeth and Cook (2007) are of the opinion that due to the variability, diversity, and pressures in healthcare, employing some features of high-reliability organisations in healthcare, may impede their performance, rather than improve it. Braithwaite and colleagues (2015) highlight that safety management cannot be improved by imposing more regulations, simplification, reducing the number of variances or by introducing standardisation. The argument is that the focus should be on being resilient and having the ability to adapt despite changing demands.

During the 20th century, healthcare work became increasingly automated with the addition of computers, telecommunication, and robotics. Leveson (2004) highlight that technology changes fast and consequently the nature of adverse events will also change. Work processes became more integrated, complex, and demanding. In addition, there is also the interaction between humans and technical systems that needs to be considered in ensuring safety. Healthcare is moving towards incorporating Resilience Engineering to enhance the system's ability to plan and prepare, absorb, recover, and adapt (Larkin et al., 2015). A system is resilient if it can adjust its functioning during and after an event and then continue to function in expected as well as unexpected conditions (Fairbanks et al., 2014). To investigate the variability and interaction of the different functions within a complex system, non-linear models like the Functional Resonance Analysis Method (FRAM) (Hollnagel, 2004) and the System Theoretic Accident Model and Processes (STAMP) (Leveson, 2004) were developed. STAMP positions safety as a control problem, using the principle that accidents occur when constraints which were set in place, was violated. STAMP is used for the analysis of system-related incidents and use control structures to enforce constraints (Leveson, 2004). According to Hollnagel and Speziali (2008) STAMP is not widely used, and the method is under development.

The application of the FRAM improves the understanding of normal work and its variability. It is suitable for complex systems, as it allows safety analyses to be done without having to split systems into various components and without reliance on a cause-and-effect relationship (Hollnagel, 2012). FRAM is based on a specific theory of functional resonance. The method can explain non-linear interactions since it focusses on system functions instead of system components, it is easily scalable. Several fields have applied FRAM extensively e.g., Aviation, Air Traffic Management, Critical Information Infrastructures, Emergency Management, Offshore and Healthcare (Hollnagel & Speziali, 2008). Salehi, Veitch and Smith (2020) have conducted a literature review on the use of FRAM in complex socio-technical systems. Fifty-two studies are identified of which sixteen (31%) are healthcare related. Salehi, Veitch and Smith (2020) reported a 'considerable growth' in the use of FRAM for safety management purposes.

It is therefore, in the interest of patient safety that the application of FRAM be explored to better understand what leads to or enables safety daily. We first need to understand how safety management is performed and how the thinking around safety management has evolved.

2.2 Safety management

Safety management in healthcare traditionally consists of identifying failures, performing analyses on failures, and developing strategies to reduce or prevent the identified failures. This is also called the *find and fix model* (Braithwaite, Wears & Hollnagel, 2015). Studying adverse outcomes for the purpose of preventing them from happening as seldom as possible, is known as Safety-I (Hollnagel et al., 2015). Li and Guldenmund (2018) highlight that organisations can derive ample information from researching adverse events, whereas Hollnagel (2012) argues that adverse outcome investigations (Safety I) only provide a "*snapshot of time*" when things go wrong. Braithwaite, Churruca and Ellis (2017) argue that insights derived from Safety-I can be useful, but that they are not adequate to comprehensively understand complex systems. Raben and colleagues (2018) is of the opinion that there is a gap in the way in which incidents are processed for improvement or learning. Meeuwis and colleagues (2020) acknowledge that an important part of any operational organisation is to form an understanding of why things went wrong and conduct safety investigations. Traditional incident reports and near miss data cannot be used to identify how internal factors e.g., stress, fatigue, nutritional levels influence variability in performance, and there is no process available to capture positive reports on successful systems and processes (Pickup, 2017).

Braithwaite and colleagues (2015) highlight that safety management must include Safety-II, which is characterised by rigorous efforts to enable things to go right on a continuous basis. Safety-II is rooted in Resilience Engineering, and they may be described as synonymous (Furniss, D., Nelson, D., Habli, I., White, S., Elliott, M., Reynolds, N., & Sujan, M., 2020). Meeuwis and colleagues (2020) also use the term *Safety Differently* investigations. The focus of Safety II thus changes the focus from preventing that things go wrong, to ensuring that as many things as possible go right. Organisations are thus enabled to improve everyday performance with a proactive approach, rather than having a reactive approach of only focusing on rare adverse outcomes.

In Safety II people are regarded as a valuable resource and not the problem that should be controlled via policies and procedures. This underlines the value of a Safety-II approach where the focus is to discover why things normally go right. To improve the quality of healthcare investigations, it is needed to experiment with a variety of theoretical and methodological approaches (Wiig, Braithwaite & Clay Williams, 2020). Patriarca and colleagues (2017) are of the opinion that a holistic view of the system is needed and that positive and negative events should be studied. To form a deep understanding of how a system functions, it should be studied in terms of how normal work is performed and what the interactions are between people. Studying normal work will shed light on performance variability, which is 'the real source of success as well of failures' (Patriarca et.al., 2017). To study normal work, we need to explore the types of work that are performed within organisations.

2.3 Work in healthcare organisations

An organisation is an association of people who perform certain tasks to reach a common goal (Hollnagel, 2017). Different roles and functions are assigned to people or groups of people within the organisation. The management of an organisation coordinates the tasks of staff and ensures that they have resources available to perform their work effectively (Hollnagel, 2012). In managing safety, healthcare organisations must ensure that certain safety functions or tasks are accomplished (Li & Guldenmund, 2018) and that daily processes happen reliably and continuously. Shorrock (2016) have identified four types of work that need to be considered to understand how work is done within an organisation: Work-as-Imagined, Work-as-Prescribed, Work-as-Disclosed and Work-as-Done.

In an organisation, managers and staff plan work for an intended outcome and have specific tasks in mind to reach the goal. The manager and staff assume that work will happen according to the plan they imagine (Hollnagel (2017). Work-as-Imagined (WAI) is used by management to design roles, allocate resources and tools and create the work environment that is needed to do the work (Iflaifel et al., 2020).

WAI is formalised by creating policies, regulations, job descriptions, and then translates into Work-as-Prescribed (WAP) (Shorrock, 2016). WAP is used by regulators for auditing purposes as it is assumed to be the correct way for tasks to be performed (Hollnagel 2017). The further a person is removed from actual work, the less accurate and simpler their understanding is of how the work is done (Iflaifel et al, 2020). Shorrock (2016) is of the opinion that the way in which we imagine the work of others is fundamentally incorrect and it is incomplete and grossly simplified. It is also impossible to prescribe all the work that staff perform, and tasks are usually performed in conjunction with other tasks. Furthermore, the conditions of work vary in terms of staffing, competency, time availability and other resources (Shorrock, 2016).

Work-as-Disclosed (WADi) is how staff will explain the work that they have done. In an open and fair culture, the work they disclose or explain will be very close to how they perform work, which is relevant in adverse incident investigations or understanding and optimising processes.

Work-as-Done (WAD) is the work that staff do at the frontline. It is always different to WAI, as staff need to adjust their work to fit with the local contexts and demands (Mannion & Braithwaite, 2017). It is therefore important that WAI is as realistic and as close as possible to WAD. Hollnagel (2012) highlights that a work system should be described by the functions it can perform and not in terms of how it is put together by components or by design. Understanding WAD creates safety outcomes and system resilience (or the lack thereof) according to Hollnagel (2012).

Braithwaite and colleagues (2016) are of the opinion that continuous realignment of WAI and WAD is necessary to ensure resilient health care. In practice, this means that in a complex environment frontline staff adapt WAD to ensure safe, effective clinical care while potentially deviating from WAI. The complex environment of healthcare is explored in the next section.

2.4 Complexity in healthcare

Current work environments are characterised by many interconnections between computerised systems and sub-systems (Kleiner et al., 2015), and Carayon and colleagues (2011) underline that complexity is inherent to healthcare. With the increased use of computerised systems in healthcare, the complexity increases even more, and this makes it more susceptible for failures and errors to happen (Kohn, Corrigan & Donaldson, 2000).

A healthcare system requires personal interaction between various individuals or groups and each person is part of the system from their own perspective. The interactions of people influence each other in unpredictable ways and interconnections create a complex adaptive system (Plsek & Greenhalgh, 2001).

Attributes of complex systems are that it has ambiguous boundaries and persons can leave and join the system or be part of various systems. The complex interaction or relationship between people, technology, organisation, and society is referred to as a complex dynamic socio-technical system (Falegnami, Costantino, Di Gravio & Patriarca, 2019). It is challenging to describe socio-technical systems, as these systems are dynamic and constantly changing (Hollnagel, 2012). Due to the unpredictability, problem solving becomes complicated. In complex systems, there are multiple interactions between components and if the functioning of one component fails, multiple failures can potentially be caused (Kohn, Corrigan & Donaldson, 2000).

Braithwaite and colleagues (2015) describe healthcare work as being unpredictable, operational principles are not entirely described, and work conditions are underspecified with many unknown relationships. As a result of a changed work environment, different challenges emerge and therefore the types of adverse outcomes can reflect it. Investigation methods should be suitable for the system in which they are applied and depending on the problem, one method may be more suitable than another. Carayon and colleagues (2011) are of the opinion that a systems approach should be followed to identify the multiple system elements and the way that the systems interact with and adapt to each other. In the review of Salehi, Veitch and Smith (2020) they used technological, human, and organisational functions to describe the multiple system elements within socio-technical systems.

Hollnagel and Speziali (2008) studied different accident and investigation methods and evaluated their use in tractable and intractable systems. A system is tractable if its functioning is known, and it is easy to manage and explain. In an intractable system functioning is mostly unknown and it is difficult to control or explain. The solution for intractable problems may not be exact.

The connection and dependency of components within a system is called couplings. In loosely coupled systems, components function independently, and the impact on one area hardly affects other areas. Tightly coupled systems, on the other hand, are very interdependent and difficult to control, as a change in one area impacts other areas. To address safety management in these different systems, Hollnagel and Speziali (2008) recommend:

- **Loosely coupled and tractable systems:** RCA should be used to investigate,
- **Tightly coupled and tractable systems:** the Swiss Cheese Model and
- **Tightly coupled and intractable systems:** FRAM and STAMP.

Due to the complexity of healthcare, operational variation in organisations should be expected and is natural. Organisations can view variation as negative, which leads to the desire to control the system. If there is a general agreement on how specific actions should be performed to reach the desired outcome, then variation should be lower within the specific area. Organisations should however not aim to reduce all types of variation, as this may inhibit innovation (Plsek & Wilson, 2001).

As described above, several thought leaders are of the opinion that safety management is complex and there is not a single solution or focus that will enable healthcare to make systems safer. Resilience engineering in healthcare aim to assist safety management and to promote and measure resilience in organisations (Patriarca et al., 2017). One method used in Resilience Engineering, which will be discussed in more detail, is the Functional Resonance Analysis Method (FRAM).

2.5 Functional Resonance Analysis Method

The FRAM has been applied in high-risk industries (Salehi, Veitch & Smith, 2020) including healthcare. Shire and colleagues (2018) are of the opinion that the FRAM is most often used in the healthcare industry, as healthcare is a social system rather than an engineered system. FRAM is a systems analysis method and was developed by Hollnagel in 2004. The method identifies functions performed within a system and the interactions between functions. The three categories of functions which are mostly described, are technological, organisational, and human functions (Yu, Quddus, Kravaris & Mannan, 2020).

FRAM is a non-linear approach that can identify fixed and transient links within a complex socio-technical system (Hollnagel, 2012). The FRAM was developed to model WAD by identifying and describing system functions using six basic aspects - input, output, precondition, resource, control, time.

Hollnagel (2012) suggest that to understand a system and to be able to investigate adverse outcomes and assess risks, we need to know what 'goes on inside' the system. The method involves investigating and understanding the activities of all the different role-players within the system, including the patient and the family. FRAM was not developed as an accident analysis or a risk assessment method per se, but rather to investigate how functions in a system work together and can influence each other to cause an adverse outcome, or not (Hollnagel, 2012). In FRAM incident investigation, the aim is not to attempt to identify causes, but it seeks explanations (Hollnagel, 2012). FRAM describes system failure and incidents as the result of a functional resonance within normal performance variability (Hollnagel, 2013). FRAM can be applied either retrospectively or prospectively as it describesa system, instead of interpreting it.

Patriarca and colleagues (2017) describe two outcomes of a FRAM analysis. Firstly, it highlights performance variability in normal work and how this resonates throughout the system. This improves the understanding of normal work and allows identification of possible sensitive areas within the system that may require mitigating actions to manage variability. Variation of multiple functions may cause functional resonance to occur that can lead to unintended or unwanted outcomes. FRAM manages performance variability, by minimising the variability of unwanted outcomes and amplifying wanted outcomes.

Secondly, FRAM identifies critical connections between functions and situations in normal work that may get out of control, due to high performance variability. It can highlight when the system is more likely to function in a variable way and understand which conditions aggregate variability. By applying FRAM, a system can become more predictable, and work can be performed within safer margins (Hollnagel, 2012). FRAM allows for the description of complex, nonlinear interactions and tasks and has four principles according to which it approaches a problem:

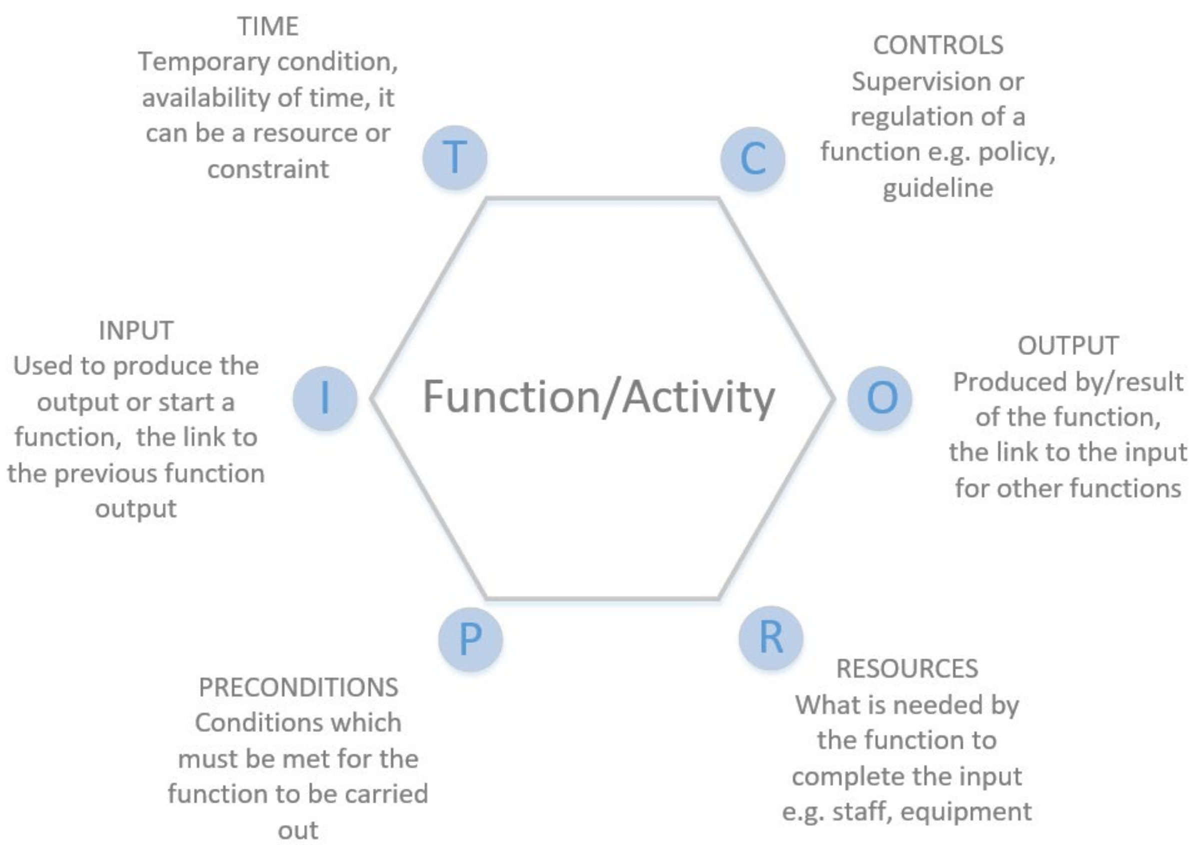
- **Principle describing successes** are the '*flip side of failures'* (Hollnagel, 2012). In everyday work, tasks are performed to obtain a favourable outcome. It is only with hindsight that one can observe if the tasks performed led to a favourable outcomeor a failure. The task itself was not necessarily performed incorrectly, but the task was wrong in relation to the situation. To improve the safety of the system, one needs to understand how tasks are normally performed and identify what wentwell, instead of only focusing on failures.

- **Principle of approximate adjustments.** In every system there is variation and tasks are adapted to allow for the variation. Humans working in complex socio-technical systems, can continuously adjust their tasks to cope with changes in internal and external conditions to ensure continued performance. Hollnagel (2012) is of the opinion that the ability of humans to adjust to circumstances is crucial for safety and that variation should be part of the system and not arbitrary and it is therefore predictable.
- **Principle of emergence**. Hollnagel (2012) explains that an outcome is resultant if it can be traced back to causal factors within the system. In an intractable system the outcome is emergent, it can often not be explained or traced back to the causes. The causes may be transient changes in conditions which are present at a specific point in time. In normal work there are regular conditions which can control, but in a complex system regular conditions do not always exist.
- **Principle of functional resonance.** Within a complex socio-technical system, individuals adapt their work to conditions, and this causes variability within the system. Work within a system is mostly interconnected and variation in one function can influence or interact with the work of another person. This can increase the variability of work.

The FRAM consists of the following steps

Step 1 in the FRAM model experts and staff working on the frontline identify and describe all functions, which is a description of WAD (Hounsgaard, 2016). They use their knowledge to describe the relevant aspects for every function, but it is however not necessary to describe all the aspects for all the functions. Functions are described in terms of the six aspects as explained in Figure 1 (Hollnagel, 2017), (Hollnagel, 2018).

Figure 1: FRAM Diagram



If there is interaction between two functions and they share the same aspect, they are coupled. Couplings can be described for specific events such as an incident investigation or it can be described as a potential scenario in the case of a prospective analysis (Hollnagel, 2017). One function can also impact another function at a later stage in the process and this is referred to as upstream-downstream coupling (Damen et al., 2018). Couplings can also be described as either loose or tight. In loose couplings, time delays between functions are possible and the sequence of elements in the system can vary without it compromising performance. In tight couplings the sequence of elements in the system cannot be altered and the system cannot be delayed (Hounsgaard, 2016). When functions are interdependent, they can allow variability to disseminate throughout the system (Damen et al., 2018).

Step 2 identifies actual and potential performance variables of functions and describes them qualitatively in terms of time (too early, on time, too late, or not at all) and precision (precise, acceptable, or imprecise). Variability can be impacted by internal and external conditions or upstream-downstream couplings. The variability of the output function is the most important to consider, as it impactsthe performance output.

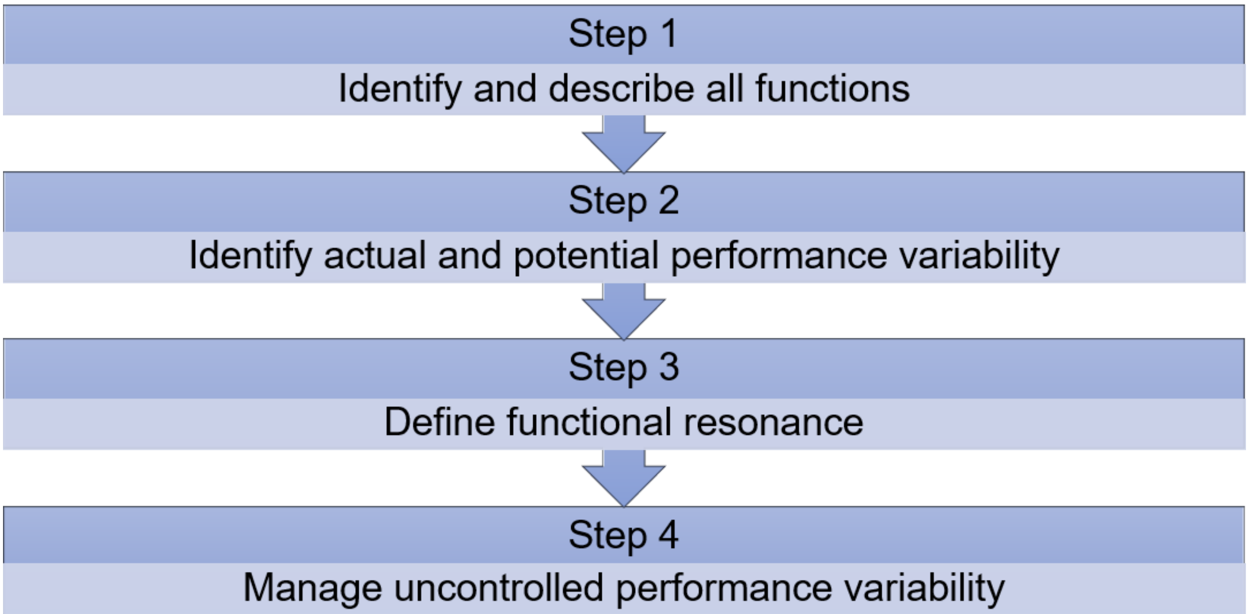
Functions can be grouped into human, organisational, and technological functions, with human functions being the most variable. When analysing variability, endogenous and exogenous factors should be considered in the investigation (Hollnagel, 2017).

Step 3 defines functional resonance, assess how performance outcomes are potentially or actually impacted by upstream and downstream functions and how variability can be decreased (dampened) or increased (functional resonance). Retrospective or prospective scenarios can be used to describe upstream and downstream couplings of functions and to identify where variability can be expected (Pereira, 2013). If there are multiple couplings to a function, this can indicate variability in the outcome and this variability may also affect other downstream functions (Hollnagel, 2017).

Step 4 manages uncontrolled performance variability, which may lead to positive (wanted) outcomes or negative (unwanted) outcomes. Unwanted outcomes can be controlled by identifying effective management and control strategies (Hounsgaard, 2016), by removing any threats, adding barriers or defences (Pereira, 2013). Positive or wanted outcomes can be amplified by doing things that goes well more frequent, or better.

A summary of the steps which are taken during a FRAM analysis, is displayed in Table 1.

Table 1: FRAM steps summary



There are known limitations to the application of FRAM and work has been done to improve the method, but all the limitations have not been overcome. Yu, Quddus, Kravaris and Mannan (2020) list the limitations as:

- being unable to describe performance viability in a quantitative manner,
- the method is applied to a single scenario, and
- experts are needed to perform the application.

To overcome the first limitation, Patriarca and colleagues (2017) have investigated a semi-quantitative approach in which to use the FRAM. To address the last two limitations, Zheng and Tian (2015) have applied model checking, an automated verification technique, to FRAM. The FRAM was also mapped to a multilayer network by Falegnami, Costantino, Di Gravio and Patriarca (2019). Discussing these advances in detail is beyond the scope of this literature review.

Patriarca and colleagues (2017) concluded their review by confirming that by adopting a resilience engineering approach in designing healthcare systems and activities, it has the potential to enhance patient safety. They suggested that researchers must develop methods which focus on exploring the benefits of Resilience Engineering methods like FRAM, while practically applying the method. The questions arise how to explore the potential benefits of FRAM in terms of safety management, and which methods should be used to measure and monitor safety?

2.6 Measuring and Monitoring Safety

Kleiner and colleagues (2015) propose that when safety is measured and described, organisations or systems should not describe it as safe or unsafe. It should be explained in terms of a continuum ranging from ‘relatively safe to relatively unsafe’ as the system is dependent on many dynamic socio-technical factors which can influence safety. Safety monitoring is seen as critical (Vincent, Burnett & Carthey, 2014), but it is problematic to measure safety when everything is working as expected; safety then becomes invisible. To make it easier to measure safety, it is measured by the presence of adverse outcomes, but Hollnagel (2014) critique this measure as the absence of adverse outcomes does not necessarily result in the presence of safety.

It is not sufficient to use a single method to measure patient safety, as it will not provide the knowledge and understanding that is required. Donabedian (1988) divides healthcare into structure, process, and outcomes for measurement purposes (Figure 2).

Figure 2: Donabedian quality assessment framework

Structure measures or input measures reflects the attributes of the service that the healthcare organisation provides. Process measures reflect the way that systems work together to reach the desired outcome; procedures are sometimes bundled together to reach a desired outcome. Outcome measures reflect the result of the outcome, or the impact on the patient. Outcome measurement is the '*ultimate validator*' according to Donabedian, but it may be difficult to define, and the outcome may be delayed in time.

Vincent, Burnett and Carthey (2013) highlight that there is no agreement on what a safe healthcare organisation entails, and how this safety is achieved. In an extensive report, they developed a framework to assist organisations to analyse and guide the management of safety. They propose that organisations can use five questions, which are embedded in different dimensions, to measure safety (Table 2).

Table 2: Five dimensions to measure safety.

Safety Measure Dimension	Question
Past harm	Has patient care been safe in the past? Past harm involves the measuring of harm-related outcomes within healthcare organisations via various means.
Reliability	Are our clinical systems and processes reliable? This describes the ability of the organisation to provide care in a reliable way.
Sensitivity to operations	Is care safe today? This involves having the ability tomeasure and monitor safety on a day-to-day basis.
Anticipation and preparedness	Will care be safe in the future? Safety is seen from a broader perspective of identifying potential hazards and risks and having the ability to anticipate how it may threat safety and perform preparations to reduce the risks.
Integration and learning	Are we responding and improving? This describes the ability of the organisation to detect potential hazards, to analyse and respond to the information and to transform it into meaningful improvement plans.

The measurement and monitoring of the safety framework developed by Vincent, Burnett and Carthey (2013) is used as a comparison to the application of the FRAM (Table 3). The framework was developed to assist organisations to analyse and guide the management of safety. By comparing the approach with FRAM, the possible understanding and value-add of the processes within the FRAM become more apparent.

Table 3: Comparison between Safety Framework and FRAM

Safety Framework (safety I approach)	FRAM (safety II approach)
Measure past harm such as incidents, errors, harmful patient outcomes.	Learning about what goes well and identify aspects which may lead to the probability of failure, make goal conflicts visible, acknowledge the complexity of the system.
Evaluating reliability in terms of the clinical systems and human behavioural factors.	Evaluate function output in terms of time and precision, identify adjustments made bystaff to ensure safety and efficiency and acknowledge variability as normal.
Sensitivity to day-to-day operations, being mindful and alert to risks and problems and	Understanding daily work, preconditions needed to perform functions, the impact of
evaluate timely interventions to address safety risks.	the output on other functions and couplings between functions.
Anticipation, planning and preparedness for tasks, risk registers for risk assessments, do FMEA to identify potential failures, conduct safety culture surveys.	Proactively identify performance variability and understand the potential impact of variability on the system, understand the upstream and downstream impact, know the conditions in which variability becomes problematic.
Integration of different safety data sources, analysing it meaningfully, share it for learning and implement sustainable solutions.	Identify how to amplify positive resonanceand reduce unwanted variability, identify, and use leading indicators, initiate improvements, use single and double loop learning.

Having an understanding how safety management is measured and having the ability to measure it, will not ensure that the organisation continuously performs in a safe manner under various conditions. To ensure safety under varied conditions, it is necessary for the organisation to develop the potential to be resilient (Hollnagel, 2017).

2.7 Developing resilience potentials.

Resilience is the ability of people to adapt their performance according to the conditions, to cope with everyday situations. Organisational resilience is the potential of an organisation to cope in expected as well as unexpected conditions (Hollnagel, 2017). Iflaifel, Lim, Ryan and Crowley (2020) conducted a systematic review to identify how resilience in healthcare is conceptualised and noticed that there is 'no gold standard' on how to develop and study resilient healthcare. They indicated that most studies used Hollnagel's (2017) four activities or potentials to identify if a system functions in a resilient manner – the potential to respond, monitor, learn, and anticipate.

Safety should be present in expected and unexpected situations, building resilience potentials is thus important when studying if and how FRAM can support healthcare organisations to enhance their ability to manage safety. Iflaifel and colleagues (2020) assessed healthcare related studies in which resilient methods and factors were applied. In the studies in which the FRAM was applied, various resilience capabilities were identified: monitor, respond, anticipate, and learn (Clay-Williams, Hounsgaard & Hollnagel, 2015); realignment between WAI and WAD (Raben, 2017); adjust to adapt to variability (Raben et al., 2018b), and trade-offs/using clinical assessment skills to resolve potential goal conflicts (Laugaland, 2014; Raben, 2017; Clay-Williams, Hounsgaard & Hollnagel, 2015).

This dissertation will use the four resilience potentials (potential to respond, monitor, learn and anticipate) of Hollnagel (2017) to investigate if there is a correlation between the four potentials and the application of FRAM.

The potential to respond relates to the ability to adapt to changing conditions and have the ability to respond to expected and unexpected circumstances. The way Hollnagel (2017) describe the potential to respond, is similar to the aspects used when building the FRAM model, e.g., responding entails knowing when the action/function should be initiated (input to function), what output is expected (with the correct timing and precision), what preconditions and resources are needed and what controls are in place.

The potential to monitor is having the ability to monitor what goes wrong and what goes right within the organisation and outside of the organisation, thus measuring performance.

Hollnagel (2017) describes monitoring as being proactive and making use of indicators and trends. Important aspects to consider when monitoring: the frequency in which it should be applied, knowing why and how a specific indicator is used and the acceptable threshold.

The potential to learn is described by Hollnagel (2017) as being knowledgeable about what goes right and wrong to learn from single experiences (single loop learning) and use the learning to bring about a change in goals (double loop learning). To learn, it is necessary to understand why something happened or why not. It is necessary to learn from the frequency of events and not focus solely on the few serious incidents. Learning should preferably happen on a continuous basis. For learning to be effective, it should result in action and organisations should also learn if the interventions they implemented were effective. Hollnagel (2017) list several things that are needed for learning: having competent staff and leaders who can collect and analyse information; having IT equipment/infrastructure; prioritisation of learning by making time and money available.

The potential to anticipate is having the ability to forecast what to expect in the future. Hollnagel (2017) explains anticipation as planning ahead for future activities, anticipating new and innovative way on how to do things differently, performing risk assessments to identify possible threats or opportunities. To forecast probable future conditions, organisations can use the frequency of past events and trends of similar conditions in past events. They can alsodeliberately construct situations which may happen in the future, which informs users about possible variables within the system, and it allows them to anticipate adjustments which will be needed. Anticipation is not performed on a regular basis, but rather when there is a “distinct sense of unease” that situations have changed. Traditional risk assessments can be performed in tractable, stable conditions where there are not a lot of variables, but for intractable conditions, where changes happen faster than they can be described, the traditionalrisk assessment methods will not suffice (Hollnagel, 2017).

3. METHOD

This section will discuss the search strategy and screening methods and the elements contained in the PICO model. An explanation of how the data synthesis and extraction was done will then be discussed.

A systematic review of literature will be conducted on articles which has described the application of the FRAM within a healthcare setting or for healthcare-related purposes. This systematic review protocol will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis - Protocol (PRISMA - P) guidelines for reporting of systematic reviews. A protocol for the systematic review has been registered with PROSPERO (registration number: CRD42021225740), an international, prospective register for systematic review protocols (Shamseer, 2015). The PICO model (patient, intervention, comparison, outcome) was used as a search tool (Table 4). The purpose of the PICO model is that it keeps the researcher focused on the main issue, as key terms are used in a computerised search. Furthermore, the problem, intervention, and outcomes are clearly identified (Eriksen & Frandsen, 2018).

Table 4:The PICO Research Question

Research question	How does the application of Functional Resonance Analysis Method (FRAM) support healthcare organisations to enhance their ability to manage safety?
Participant	Healthcare organisations
Intervention	Application of the Functional Resonance Analysis Method (FRAM)
Comparator	Nil
Outcome	Safety management

3.1 Search Strategy and Screening

3.1.1 Databases

An electronic search was conducted, and eight data bases were included: Academic premier, CINAHL, Ei Compendex, Google Scholar, Healthsource Nursing/Academic, PubMed, Scopus, Web of Science. Sources used for grey literature: the ProQuest database was searched for conference abstracts and theses. A librarian supervised the searches of all the databases.

3.1.2 Search Methods

The websites https://www.functionalresonance.com/framily-meetings/index.html, https://www.researchgate.net/search.Search.html?type=publication&query=%22functional%20resonance%20analysis%20method%22 were hand searched and some records had to be requested from authors. Twitter was also used to hand search articles on FRAM. The electronic search included the dates January 1, 2004 - November 30, 2020, as FRAM was released in 2004 by Hollnagel.

3.1.3 Developing Search Syntax

The search terms included were: (Patient Safety OR Quality Improvement OR Medical Errors OR Safety Management OR Total Quality Management OR Task Performance and Analysis OR Systems Analysis OR Risk Management OR Quality of Health Care OR "Work as done" OR "Work as imagined" OR "Safety I" OR "Safety II" OR Resilience Engineering OR quality of health care OR Medical errors OR Safety management OR Quality management) AND ("Functional Resonance Analysis Method" OR FRAM) AND (Delivery of Health Care OR Health Services Administration OR Health Facilities OR health care OR health services OR health access OR medical care OR Delivery of health care OR health services administration OR health facilities).

Studies considered comprised of research articles, reviews, conference papers, theses, and book chapters. No language limits were used, and the application Deep L was used to translate the articles which were not available in English.

3.1.4 Eligibility criteria

A systematic review of literature has been conducted on articles that described the application of the FRAM in a healthcare setting or for healthcare-related purposes. Records were included if they contained evidence that they described or analysed the application of FRAM. Resources related to health and safety management and personal resilience were excluded.

3.2 Participants

FRAM as a model has been applied in various high-risk sectors (Damen et al., 2018) including healthcare. FRAM can be applied in a variety of contexts; thus, all sectors of healthcare were included in this dissertation. The participants described in this dissertation, is healthcare facilities in which the FRAM has been implemented. No geographical, gender, race and religion limitation were placed on the participants inclusionin this dissertation.

3.3 Intervention

The purpose of FRAM is to analyse any given system or situation, and then provide a representation of how things 'have been done', how it 'is done' and how it 'could be done' (Hollnagel, 2018).

Articles which demonstrated evidence that the intervention of FRAM was applied in a healthcare context, were included in this dissertation.

3.4 Outcome

The outcome of this dissertation is safety management. Safety management will be measured in this systematic review by evaluating the literature on the implementation of FRAM in healthcare organisations. The dissertation aims to explore the application of FRAM in healthcare and thereby develop a rich understanding of the capability that FRAM can offer healthcare to manage safety. The results are expected to provide healthcare organisations with guidance on applying the FRAM and demonstrate the value it potentially adds to safety management.

The objectives to the aim are firstly, to understand how FRAM has been implemented within healthcare organisations and secondly understanding how healthcare organisations have perceived the value-add of FRAM in terms of safety management. To answer the first objective, how FRAM has been implemented, the following aspects were explored:

a) aims, background and data gathering methods,
b) the types of applications are identified and discussed,
c) additions plus enhancements to FRAM are indicated.

The second objective focuses on the value-add in terms of safety management for healthcare organisations who implemented FRAM. The outcomes which are realised due to the application of FRAM will be identified and discussed.

3.5 Data Synthesis

The studies were read to ensure familiarity with the content. The data was coded for data extraction with the help of the Atlas coding tool. The coded data were grouped into themes and subthemes based on common attributes within the data. Once it was grouped, the coded data from the various studies were compared and summarised. Data in themes and subthemes were interpreted and grouped together to address the research question.

3.6 Data Extraction

Data extracted included: authors, year, aim of study, setting or background, data gathering methods, additions/enhancements to FRAM, uses of FRAM and the findings or results of the studies. The results include the aspects which studies reported to be positive or value adding as well as the negative aspects or trade-offs. The data is summarised in a narrative synthesis and quantifiable data is presented in a quantitative manner.

3.7 Ethical Review Approval

This study is exempt from ethics review approval as it is a systematic review which does not involve any human interaction, or disclosure of any privileged data/information.

3.8 Conclusion

The methodology described will provide a framework for the collection of data to answer the research question. This data is packaged in the results section following the PICO method.

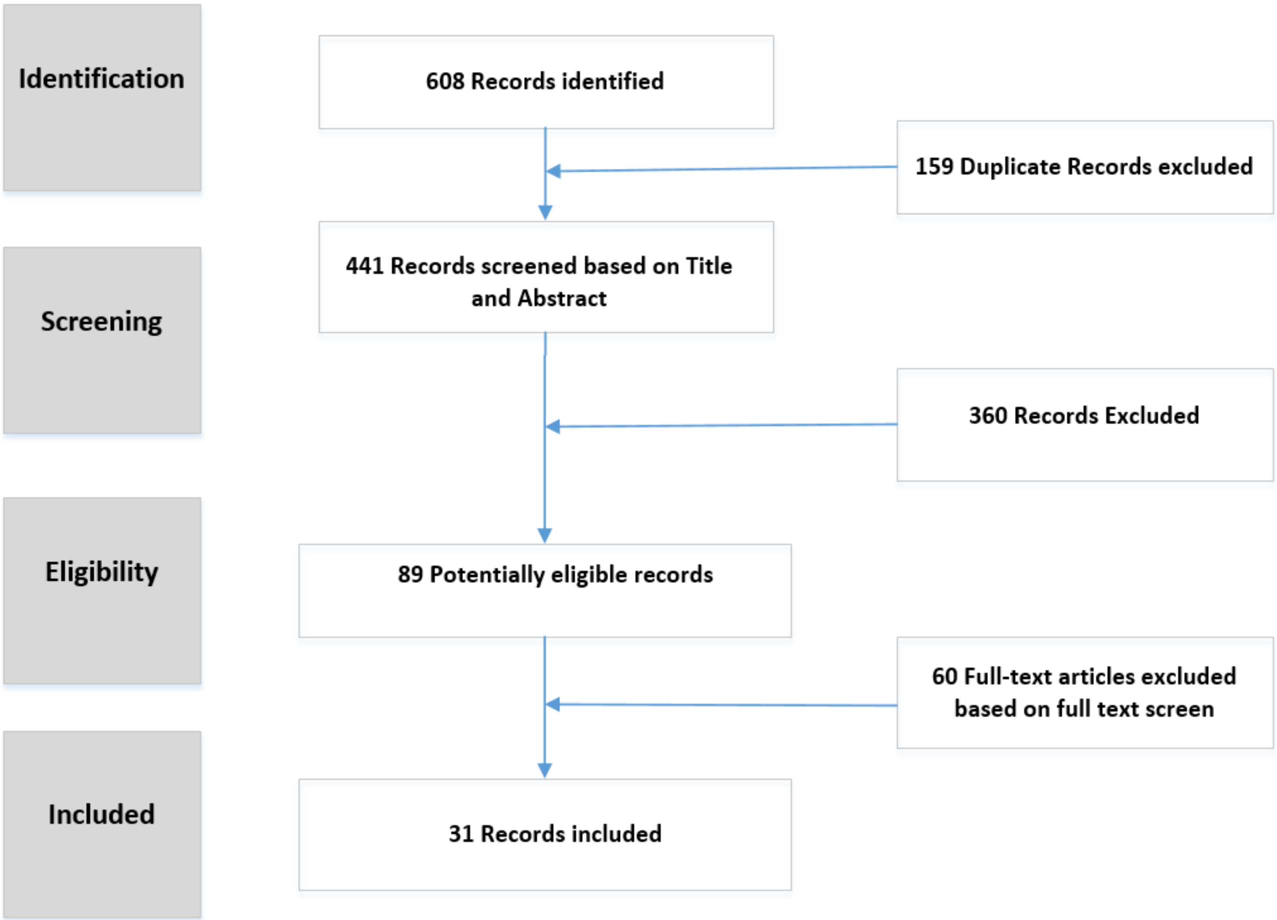
4. RESULTS

In this section, the outcome of the search results and a description of the participants in the studies reviewed will be discussed. A discussion of the results in terms of the objectives will follow. The first objective is to understand the implementation of FRAM and the second is to understand the value-add of FRAM.

4.1 Search and Screening

The search rendered 608 records: Academic premier (88), CINAHL (3), Ei Compendex (10), Google Scholar (197), Healthsource Nursing/Academic (0), PubMed (81), Scopus (175), Web of Science (21), ProQuest (25) and websites (8). With an electronic duplicate-search, 159 duplicate records were removed. The initial records were screened by means of title and abstract and 360 records were excluded. For the eighty-nine (89) potentially eligible records a full-text screen was used. Records which were excluded, was excluded for the following reasons: FRAM applied in non-healthcare context (5); The FRAM was not applied and described (34); Reviews (6); Duplicates (13); Commentary record (1); Proposal (1). Thirty-one records were included in the final review. The final records comprise of 1 Book chapter, 6 Conference papers, 23 Published articles and 1 Doctoral dissertation. The PRISMA chart (Figure 3) is used to visually explain the search and screening process which was followed. PRISMA guidelines, was created by international experts to improve the 'transparency, accuracy, completeness, and frequency of documented systematic review and meta-analysis protocols'(Shameer, 2015).

Figure 3: PRISMA chart



4.2 Participants

The types of healthcare services in which the model was applied can be summarised as primary, general hospital, intensive care, and other settings. Hounsgaard (2016) involved four studies in her dissertation, thus it covers more than one domain.

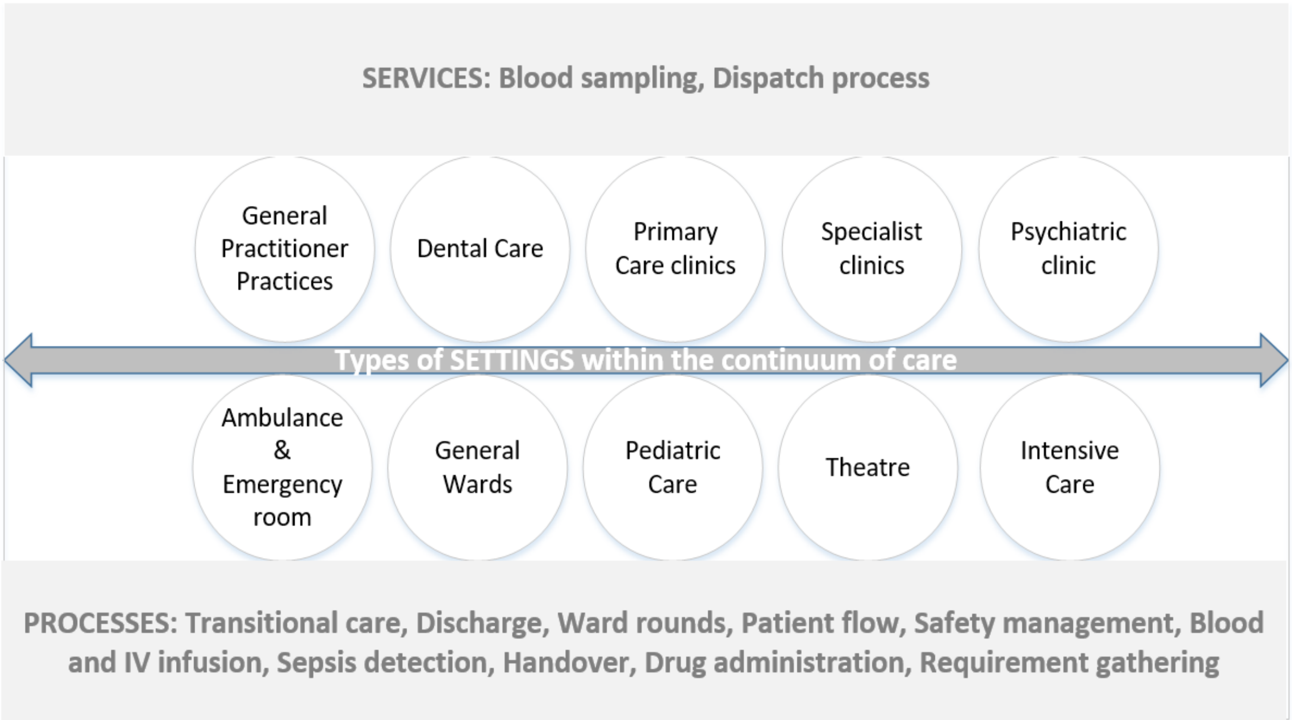
- Primary care settings comprised of eight studies: General Practitioner practices (Arcuria, 2020; De Carvalho et al., 2019; Hounsgaard, 2016; Magott & Wilkiera-Magott, 2019), a specialist spine centre clinic (Hounsgaard, 2016); Primary care clinics (McNab, 2018); Transitional care (O'Hara, Baxter & Hardicre, 2020) and Dental health (Ross, 2018).

  General hospital care settings included eighteen studies: Discharge process and planning (Buikstra, Strivens & Clay-Williams, 2020; Laugaland, 2014); Theatre (Alm & Woltjer, 2015); Paediatric care (Franklin, 2018); Ward rounds (Hounsgaard, 2016); Safety management (Kroeze, Wimmer & Hounsgaard, 2019); Patient flow emergency room to discharge (Mahmoudi, Mohamed & Timmoy, 2020); Medication administration in Emergency Department (Wachs & Saurin, 2018); Blood transfusion (Pickup, 2017); Blood sampling (Hounsgaard, 2016; Raben, 2017); Sepsis detection (Raben et al., 2018a; Raben et al., 2018b); General wards (Patriarca, 2018; Schutijser et al., 2019); Handover between ambulance, emergency service, ward (Sujan & Felici, 2012); Slack resource allocation in a maternity unit (Saurin & Werle, 2017) and COVID-19 pandemic (Tarakçı et al., 2020).

- Intensive care (ICU) settings involved six studies: Guideline development in ICU (Clay-Williams, Hounsgaard & Hollnagel, 2015); Anticoagulation in Cardiothoracic Surgery (Damen et al., 2018); Intravenous administration in an ICU (Furniss, 2020); Drug administration in Neonatal ICU (Kaya & Hocaoglu, 2020; Kaya, Ovalib & Ozturk, 2019).
- Three other studies include: Specialist psychiatric care (Dellepiane, 2018); Dispatch process of radiopharmaceuticals (Pereira, 2013); Requirement gathering for safety differently investigations (Meeuwis et al., 2020).

Apart from the types of settings, studies can also be grouped into two types of services (blood sampling and dispatch service) and various processes (transitional care, discharge, ward rounds, patient flow, safety management, blood transfusion and IV infusion, sepsis detection, handover, drug administration and requirement gathering). These services and processes are 'generic' to many types of settings within healthcare (Figure 4). Safety management includes the management of the COVID-19 pandemic, as well as a learning programme on Safety II.

Figure 4: Healthcare services, settings, and processes



4.3 The Implementation of FRAM

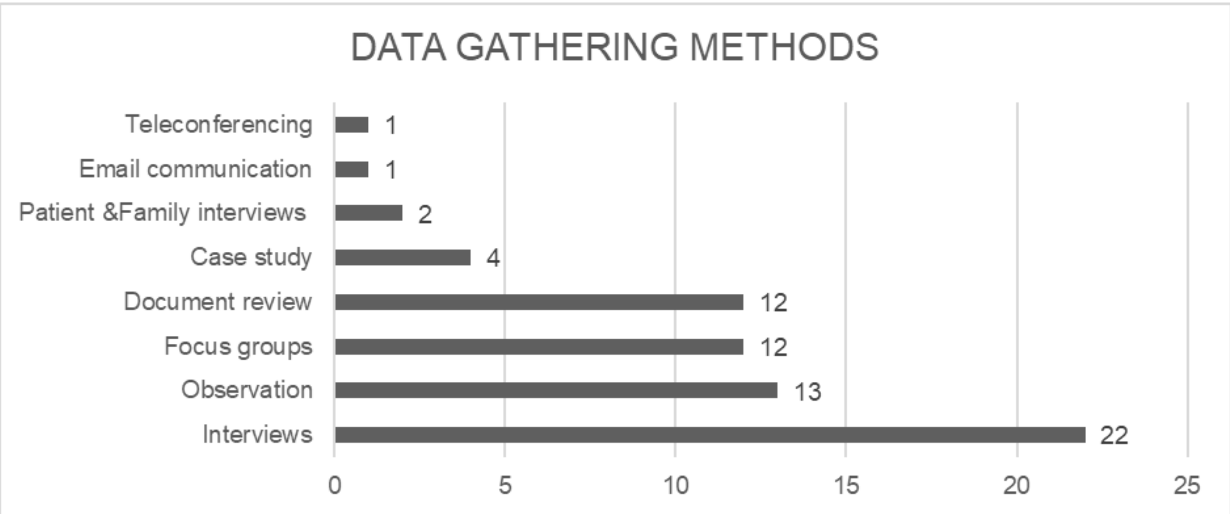
This dissertation investigates how FRAM has been applied in various healthcare settings to form a rich understanding of its application and potential. The results provide healthcare organisations with guidance on applying the FRAM and demonstrate the value it potentially adds to safety management. To answer the first objective, how FRAM has been implemented,the following aspects will be explored:

a) aims, background and data gathering methods,
b) the types of applications are identified and discussed,
c) additions plus enhancements to FRAM are indicated.

a) Aim, background and data gathering methods.

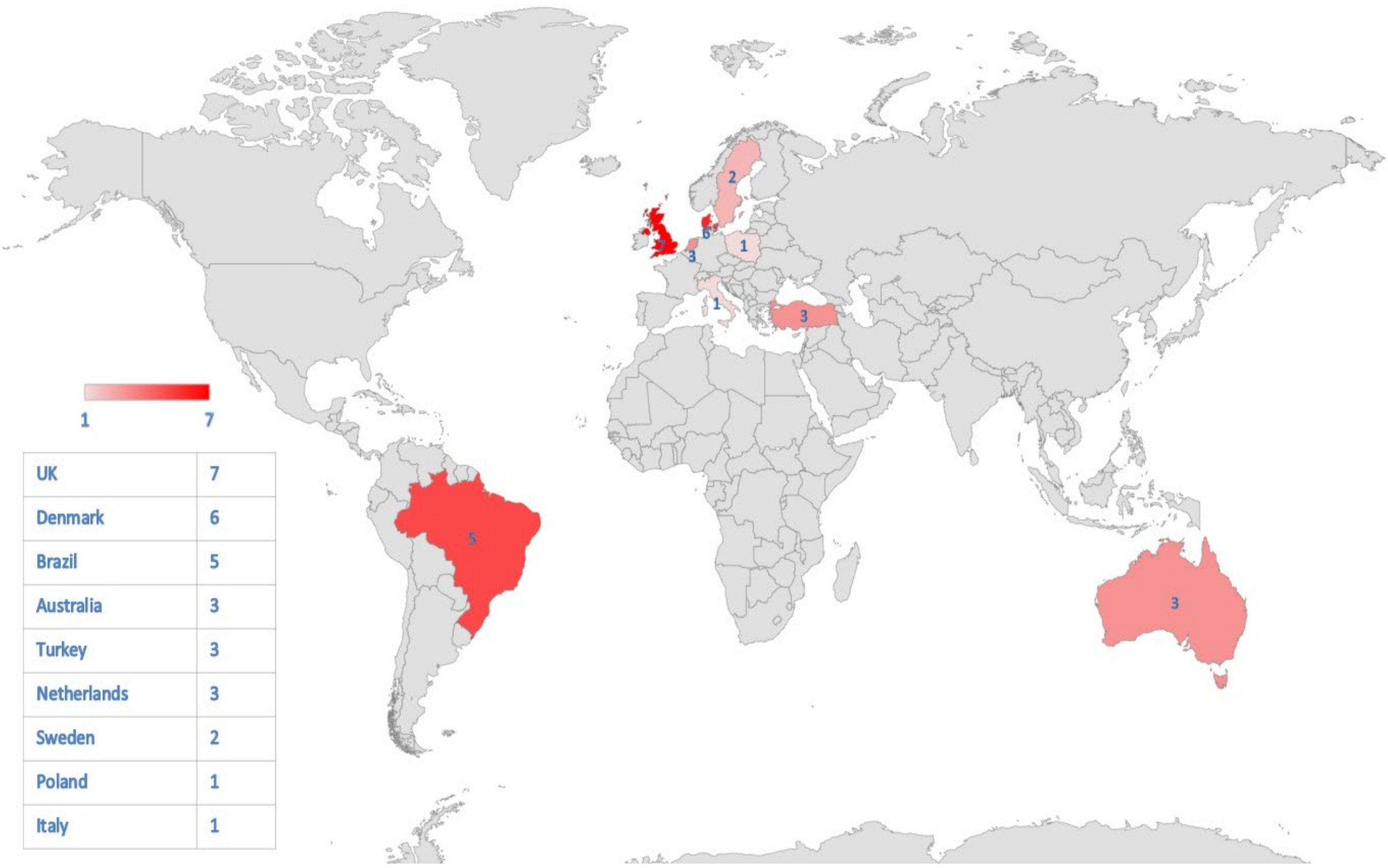
A compilation of the methods which were used to gather data in the studies, is displayed in Figure 5. All the studies used more than one method to gather their data. The most used method was 'Interviews' (22) which included mostly semi-structured interviews, but open-ended interviews were used in two instances. Interviews were conducted individually and/or in a group. 'Observation' (13) was conducted by means of direct observation and hospital ward observation was also mentioned in a study. 'Focus groups' (12) was also described as participation meetings, workshops, and meetings. 'Document reviewed'
(12) and analysed includes patient and other documentation, local plus international guidelines, and policies. 'Case studies' (4) or case-control studies was conducted in four instances. Conversations with patients and family (2) was conducted during visits and comprised of interviews, observations, and informal discussions. Email communication and Teleconference meetings were conducted once.

Figure 5: Methods used to gather data.



FRAM has been applied in various geographical locations as reflected in Table 5. The countries and the number of studies conducted in each country is depicted in Figure 6. Using colours to illustrate, a darker colour indicated that more studies were performed in comparison to the countries with a lighter colour where less studies were performed. There were three studies which were conducted in more than one country, which included Australia/Denmark, Australia/Netherlands, and Denmark/Netherlands. According to the United Nations (2020) classification of countries, 23 studies were conducted in developed countries while 8 were conducted in developing countries: Brazil (5) and Turkey (3). Although there were only two developing countries involved, 25,8% of the 31 studies were done in developing countries and almost three quarters (74,2%) in developed countries.

Figure 6: Geographical locations in which studies were conducted



To illustrate and understand where and how FRAM has been applied, a summary was made of the different studies in terms of the aims, background or setting and the data gathering methods in Table 5.

Table 5: Application of FRAM and data gathering methods.

Study	Aim of Study	Setting/Background	Data gathering methods
Alm and Woltjer (2015)	Apply FRAM to an incident investigation and examine if applicable to health care, comparison with current methods	A case study, surgical materials were left in a patient's abdomen during a surgical procedure	Interviews, observation, document review
Arcuria (2020)	To develop a theoretical model, improve daily work practices, understand how adjustments can lead to vulnerability or resilience (responding, monitoring, anticipation, and learning)	Improving a referral and prioritisation system run by family partitioners within Rio de Janeiro, the system allows the referral of more than 3 million patients to different levels of care	Interviews, guidelines and policy review, observation
Buikstra, Strivens and Clay-Williams (2020)	Understand variability in daily work, identify areas susceptible to resonance and highlight potential problems	Complex discharge planning process for the older person in a sub-acute geriatric inpatient ward in a 531-bed public hospital in regional Australia	Document review, focus groups, semi-structured interviews
Clay-Williams, Hounsgaard and Hollnagel (2015)	Use FRAM for guideline development, gain insight into the practical applicability of new procedures and a reconciliation between WAD and WAI	Intensive care guidelines were used within Australia and Denmark	Guidelines, meetings
Damen et al. (2018)	Assess preoperative anticoagulation management and explore the usability and value of the FRAM in the process	Australian and European Cardiothoracic Surgery Departments; anticoagulation therapy is used in surgical procedures and often require a trade-off in decision-making	Semi structured interviews, focus group, international guidelines
De Carvalho et al. (2019)	To discover if it is possible to do requirements gathering by using the FRAM model	Investigate the screening process/risk classification in a family clinic in Rio de Janeiro using FRAM and BPMN (Business Process Model and Notation)	Ethnography, a combination of observation, interviews, and participation

Study	Aim of Study	Setting/Background	Data gathering methods
Dellepiane (2018)	To use FRAM to analyse events such as suicide and to understand the care system, to observe if FRAM can support them to provide safe, quality care	Specialist psychiatric care centre in Sweden	Case-control study, patient documentation
Franklin (2018)	Use FRAM to reduce variability, understand workflow and design solutions	Children's surgical unit in a UK Trust	Interviews, observed practice, learning from excellence, workshops
Furniss (2020)	To explore performance variability and underlying systems contradictions in intravenous infusion administration	Intensive care unit in the UK; intravenous infusion administration is safety critical task which is commonly performed in intensive care units	Meetings, workshops, email communication
Hounsgaard (2016)	Four FRAM analyses were described: the investigation of a patient safety incident, to understand everyday performance, to assess the potential and actual effect of a change	Four studies in Denmark: Geriatric ward in a specific hospital, incident about the management of a patient with a spine fracture, pre- evaluation of patients at a Spine Centre, describing WAD in a blood sampling pathway	Semi-structured interviews individually or in groups
Kaya and Hocaoglu (2020)	To gain an in-depth understanding of the drug administration process, understand performance variability and support safety management, to apply the Monte Carlo method as a semi-quantitative approach to FRAM	Investigate the drug administration process in a neonatal intensive care unit (NICU) in Turkey	Data obtained from a previous study where meetings of over 41 man-hours was used, model reviewed by subject matter experts
Kaya, Ovalib and Ozturk (2019)	To understand performance variability under changing conditions, to understand how variability influences the system	Investigate the drug administration process in a neonatal intensive care unit (NICU) in Turkey	Observations, semi-structured interviews, and workshops

Study	Aim of Study	Setting/Background	Data gathering methods
Kroeze, Wimmer and Hounsgaard (2019)	Improving patient safety by using FRAM to learn from what goes right and what goes wrong (Safety II)	Collaborative learning programme between Dutch and Danish hospitals to apply FRAM, initiated by an insurance company which covers medical liability and focus on patient safety and medical risk management for 42 Dutch hospitals	No data available
Laugaland (2014)	To identify hospital discharge functions using FRAM, to analyse performance variability, to identify performance-shaping factors which can lead to improvement of the process	Understanding the hospital discharge process in Norwegian hospitals	90 hours' observations in hospital wards, conversations with patients, family, and staff
Magott and Wilkiera-Magott (2019)	FRAM is used to investigate an adverse outcome, explore variability, and develop proposals to avoid unwanted events	Investigating an adverse outcome in Poland, involving a General Practioner and a patient with lumbar pain	Case study
Mahmoudi, Mohamed and Timmoy (2020)	Investigate hospital surge procedures to improve functional performance (effectiveness and efficiency) by identifying WAD and comparing it with WAI	Analyse the flow of patients, from registration at the Emergency Department until discharge, in Queensland, Australia	Interviews, reviewing and analysing documents
McNab (2018)	To explore sepsis management in primary care and design a system-centred improvement intervention	Primary care setting within Scotland	Semi-structured interviews, group interviews and documentary analysis
Meeuwis et al. (2020)	A critical incident investigator group identified the requirements for a successful Safety Differently investigation	A University Medical Centre in North-western Europe	Critical incident investigators conducted a FRAM analysis

Study	Aim of Study	Setting/Background	Data gathering methods
O'Hara, Baxter and Hardicre (2020)	Model transitional care from multiple perspectives and develop a theory of change, thus identifying in a hypothetical manner how complex interventions will achieve desired outcomes	The data was obtained from two previously conducted research studies on the transitional care process for older adults, which was performed by the authors	Semi-structured interviews, patient-oriented field visits were conducted, comprising of interviews, observations, and informal discussions
Patriarca (2018)	Apply a semi-quantitative Monte Carlo framework to FRAM, do a risk analysis of a patient's pathway in neuro-anaesthesia treatment to better understand the application of FRAM for iatrogenic diseases	In a neuro-surgery ward of a European university hospital	Open-ended interviews, observations, semi-structured interviews, focus group
Pereira (2013)	To model and form an understanding of a radiopharmaceutical dispatch process using FRAM, to identify how performance variations can affect the effectiveness of system	Dispatch process of radiopharmaceuticals which contain radioactive substances, to nuclear clinics in Brazil	Two instantiations were applied to the radiopharmaceutical dispatch process
Pickup (2017)	To understand why variability in blood sampling performance in acute hospital settings can occur	NHS Scotland conducted a three-month study in clinical areas with a high proportion of incidents, 61 pre blood transfusion incidents were analysed	Open-ended interviews, observations, semi-structured interviews, focus group
Raben (2017)	To identify leading indicators for blood sampling and reflect on the feasibility of the leading indicator identification method (LIIM) and challenges in the process	A case of blood sampling in a Danish hospital has been described	Case study
Raben et al. (2018a)	To develop a systematic method for the identification of leading indicators for safety in healthcare based on a case study describing the early detection of sepsis	A case study that describes the early detection of sepsis in a Danish hospital ward	Document reviews, focus groups, direct observations, interviews

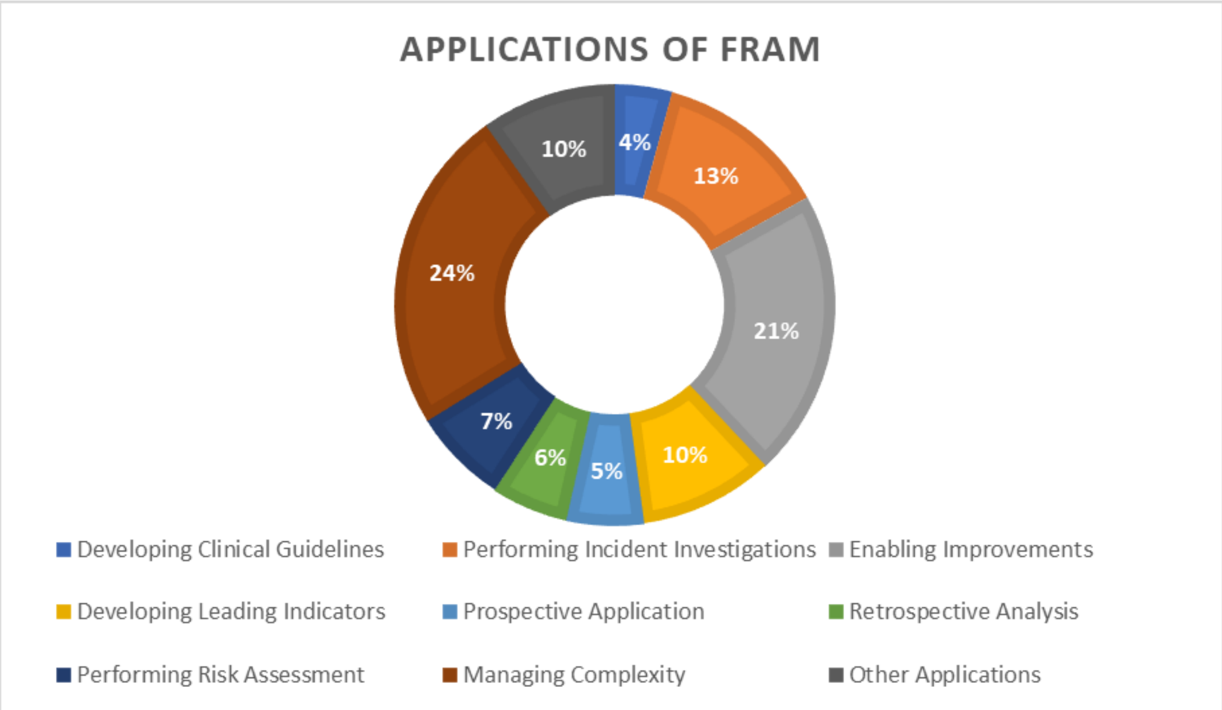
Study	Aim of Study	Setting/Background	Data gathering methods
Raben et al. (2018b)	Creating an understanding of complex processes and positive outcomes despite variability, using FRAM to describe the early detection of sepsis	A case study that describes the early detection of sepsis in a Danish hospital ward	Document reviews, focus groups, direct observations, interviews
Ross (2018)	Describe process of fluoride varnish application to children's teeth, identifying intervention opportunities to enable higher application rates	Oral health improvement programme (Childsmile) for Scottish children	Semi-structured interviews, workshop
Saurin and Werle (2017)	To introduce a framework for the analysis of slack resources, e.g., time, material, money. Slack resources can mitigate the variability in complex socio-technical systems and add to its resilience potential.	A maternity ward in a private hospital in Brazil, the ward comprises of inpatient beds, operating and recovery rooms, an obstetrics emergency department and neonatal ICU	Interviews, questionnaires, observation, documents, literature review
Schutijser et al. (2019)	To learn about process variation in the injectable medication administration process by determining the difference between WAD in practise and WAI per protocol	Internal medicine and surgical wards in Dutch hospitals	Semi-structured group interviews, observation
Sujan and Felici (2012)	Describes the application of FMEA in identifying vulnerabilities related to communication and handover within an emergency care pathway and discuss the application of FRAM as a complementary approach	Ambulance service, emergency department and hospital departments who received patients from the emergency department and a clinical decision/medical assessment unit in the UK	Case study
Tarakçı et al. (2020)	To understand the COVID-19 management process in health care facilities using FRAM	Investigate hospital processes related to COVID-19 patients in public and private hospitals in Turkey	Teleconference meetings over 34 hours

Study	Aim of Study	Setting/Background	Data gathering methods
Wachs and Saurin (2018)	To explore the interaction between procedures and the resilience skills of frontline workers in a complex environment	Preparation and administration of intravenous medications to patients in an Emergency Department in a Brazilian hospital	Observations, interviews, and document and data analysis

b) Types of Application

FRAM has been used by healthcare organisations for different reasons, the different uses of FRAM are summarised in Figure 7. The percentages indicating the prevalence of the uses as it appears in the studies reviewed. 'Managing Complexity' and 'Enabling Improvements' are the most prevalent, which is to be expected as the FRAM model is used in complex environments and studies are usually performed to better a situation or a process. 'Developing Clinical Guidelines' comprises only 4% as it is not a task performed very often with only a limited number of persons involved. 'Retrospective Analysis' and 'Performing Incident Investigations' may coincide in usage and 'Prospective Application' and 'Performing Risk Assessment' may coincide as these aspects are closely related but not exclusive. 'Performing Incident Investigations' (12%) is a commonly performed safety management safety management task in healthcare. 'Other Applications' (10%) comprises of studies which used FRAM in various ways: developing a primarily patient-facing intervention in transitional care (O'Hara, Baxter & Hardicre, 2020); investigate how hospitals deals with disruptive events (Mahmoudi, Mohamed & Timmoy, 2020); explore intravenous infusion administration in an ICU (Furniss, 2020); analyse the interaction between procedures and resilience skills (Wachs & Saurin, 2018); identify the requirements of a safety differently investigation (Meeuwis et al., 2020); analyse slack resources (Saurin & Werle, 2017); use FRAM and BPMN (Business Process Model and Notation) to do requirements gathering (De Carvalho et al., 2019).

Figure 7 : Applications of FRAM



The different ways in which studies used FRAM have been summarised in Table 6.

Table 6: A summary of FRAM application

Study	Application of FRAM								
	Developing Clinical Guidelines	Performing Incident Investigations	Enabling Improvements	Developing Leading Indicators	Prospective Application	Retrospective Analysis	Performing Risk Assessment	Managing Complexity	Other Applications
Alm and Woltjer (2015)		X	X					X	
Arcuria (2020)			X						
Buikstra, Strivens and Clay-Williams (2020)			X				X	X	
Clay-Williams, Hounsgaard and Hollnagel (2015)	X								
Damen et al. (2018)	X	X	X		X	X		X	
De Carvalho et al. (2019)									X
Dellepiane (2018)		X	X					X	
Franklin (2018)						X			
Furniss (2020)			X						X
Hounsgaard (2016)		X	X	X	X		X		
Kaya and Hocaoglu (2020)								X	
Kaya, Ovalib and Ozturk (2019)			X					X	
Kroeze, Wimmer and Hounsgaard (2019)			X		X				
Laugaland (2014)			X	X				X	
Magott and Wilkiera-Magott (2019)		X							
Mahmoudi, Mohamed and Timmoy (2020)	X		X	X				X	X
McNab (2018)			X			X		X	

Study	Application of FRAM								
	Developing Clinical Guidelines	Performing Incident Investigations	Enabling Improvements	Developing Leading Indicators	Prospective Application	Retrospective Analysis	Performing Risk Assessment	Managing Complexity	Other Applications
Meeuwis et al. (2020)		X							X
O'Hara, Baxter and Hardicre (2020)			X	X	X			X	X
Patriarca (2018)							X	X	
Pereira (2013)							X	X	
Pickup (2017)		X		X				X	
Raben (2017)				X					
Raben et al. (2018a)				X					
Raben et al. (2018b)		X	X					X	
Ross (2018)			X					X	
Saurin and Werle (2017)		X							X
Schutijser et al. (2019)								X	
Sujan and Felici (2012)						X			
Tarakçı et al. (2020)							X	X	
Wachs and Saurin (2018)									X

The author will delineate several applications from the table above, to illustrate andenable the reader to form a richer understanding of the application of FRAM.

Application 1: Developing Clinical Guidelines

Clinical guidelines are specific activities which are grouped together to ensure that a specific function or task is performed. In the study described by Clay-Williams, Hounsgaard and Hollnagel (2015) adherence to clinical guidelines in an intensive care unit is measured. It was reported that as few as 24 % of ICU patients receive complete, recommended care. Damen and colleagues (2018) are of the opinion that in the application of FRAM the redundancy of guidelines is highlighted when WAI and WAD are compared. Clay-Williams and colleagues

(2015) reported that FRAM offered a practical approach to bring synergy between procedure design and implementation. When applying FRAM, the practical aspects of how work is done is considered and dependencies between functions are identified. Clay- Williams, Hounsgaard and Hollnagel (2015) are of the opinion that FRAM can be used to determine if it is possible to follow a written procedure, and that FRAM can be used to find practical solutions to iterate and refine guidelines. Mahmoudi, Mohamed and Timmoy (2020) demonstrated similar findings in their study that insights gained by FRAM allow for implementing, and revising guidelines, protocols, and practices in a hospital system.

Application 2: Performing Incident Investigations

FRAM could be used as a tool for incident analyses as it studies how an incident emerged in relation to WAD and not by comparing incidents with protocols and guidelines, or WAI (Damen et al., 2018). Meeuwis (2020) has an alternate perspective regarding the process in which safety investigations should take place, it follows a system view and connects processes, people, and departments. Meeuwis (2020) research allows for various scenarios about the same incident, various aspects are highlighted such as goal conflicts, resource constraints and information about how normal work is performed.

Furniss (2020) argues that FRAM is useful in the following areas: investigating potential failures and its recovery and identifying underlying system contradictions and goal conflicts.

Alm and Woltjer (2015) explain how FRAM and root cause analysis (RCA) are used to assess a negative incident in the theatre. The RCA method oversimplified the complex incident whereasFRAM could explain the scenario much better in terms of time and space. As stated earlier, FRAM is an important complement to traditional root cause analysis, as it raises more detailed findings, and it provides a valuable tool in patient safety (Dellepiane, 2018). The FRAM assesses how the variability of various functions coincide and spread for a function to have an unwanted output (Hounsgaard, 2016). Saurin and Werle (2017) used FRAM to analyse instances in which critical events occurred to understand the variability and couplings between functions and then gaps could be identified. Hounsgaard (2016) studies the application of FRAM in terms of the care pathway of spine patients. The study highlights functions which could potentially result in safety incidents; thus, FRAM allows staff to proactively make improvements to these functions before an incident could happen. Raben and colleagues (2018b) investigated incidents of sepsis in his study. Magott and Wikiera-Magott (2019) used FRAM to analyse an adverse incident concerning General Practitioners and a patient with lumbar pain. By utilising FRAM, the studies identified functional resonances and countermeasures to avoid incidents from happening.

Application 3: Enabling Improvements

Enabling improvements can also be seen as a result of the application of FRAM. The reason it is grouped under applications, is that users usually embark on an analysis or investigation process with the aim to improve a process or system.

The way in which FRAM aim to assist with identifying systemic improvements:

- Firstly, by dampening unwanted variability using methods such as application of barriers and improving performance conditions (Alm & Woltjer, 2015; Buikstra, Strivens & Clay-Williams, 2020; Hounsgaard, 2016; Furniss, 2020; McNab, 2018).
- Secondly, by using indicators to detect variability that is necessary but cannot be dampened (Alm & Woltjer, 2015).
- Lastly, by adapting the conditions of the aspects (Input, Output, Precondition, Resource, Control, Time) used to build the FRAM model (Alm & Woltjer, 2015; Kaya, Ovalib & Ozturk, 2019; Laugaland, 2014).

Hounsgaard (2016) is of the opinion that FRAM 'enable improvement' as it helps to indicate which modifications are needed to enhance positive outcomes. FRAM can highlight interdependency of function and how the variability between functions can amplify downstream outcomes in a positive or negative way (Alm & Woltjer, 2015; McNab, 2018; O'Hara, Baxter & Hardicre, 2020; Ross et al., 2018). Ross and colleagues (2018) used this information to identify where to intervene, and they then hypothesised how these interventions may lead to a desired outcome. The FRAM model allow its users to get a deep and detailed understanding of WAD as it is described under local conditions (Damen et al., 2018; Mahmoudi, Mohamed & Timmoy, 2020; O'Hara, Baxter & Hardicre, 2020; Raben et al., 2018b). Pickup (2017) plus Mahmoudi, Mohamed and Timmoy (2020) reported that FRAM provides a visual representation of WAD, and it highlights areas for improvement. Table 7 provide examples of improvements which was realised in the studies reviewed.

Table 7: Examples of improvement.

Arcuria (2020)	The study uncovered how family doctors can adapt and improve their performance within their daily work, to cope with the shortcomings in a decentralised referral system
Damen et al. (2018)	It was identified that patients had to rely on their memory to adhere to discharge prescriptions of anticoagulation therapy at home and an improvement solution could be suggested.

Dellepiane (2018)	They were able to identify six critical aspects in the psychiatric unit, and by increasing the focus on how to improve theses aspects, the safety of the psychiatric patients increased.
Furniss (2020)	They reported that staff adapt the way they perform double checking of in intravenous medication administration and uses trade-offs to prioritise their work. With the insights gained through the application of FRAM, they can now seek ways to enhance the way staff manage the variability and the adaptations they make. Examples are to support staff to recognise and develop strategies for making trade-offs, learn how to prioritise, and to know when to recognise when they need to ask for help.
Hounsgaard (2016)	Staff realised the way in which they write the heading of test result as it could result in patient safety incidents and the improvement implemented was to change the structure of the test result form
Laugaland (2014)	Despite known contributing factors, the progress in improving the processof hospital discharge of the elderly has been limited. FRAM was used to study the functions, variability and performance-shaping factors and model the complexity of hospital discharge process. FRAM allowed themto perform a detailed, systemic analysis and they could identify the impact of organisational factors related to specific discharge processes. As an outcome of the study, these factors were earmarked for investigation and improvement.
Mahmoudi, Mohamed and Timmoy (2020)	By using FRAM, a comprehensive insight into complex processes of surge procedures in hospitals was possible, it clarified the deviation between WAI and WAD, and it highlighted the hidden obstacles and opportunities in hospital system performance.
McNab (2018)	FRAM was used to model the primary care management of possible sepsis and explored interactions, resources, controls, and the influence oftime on outputs. Information was collated in a in a driver diagram and six improvement intervention themes were identified. The clinical teams could perform targeted improvement efforts, as they have a better understanding of the conditions and interactions that influence work and how this cause variable function output.
O'Hara, Baxter and Hardicre (2020)	While studying transitional care of patients, they could identify key interdependencies between functional activities, identify a critical 'pivot point' within the transitional care process, identify areas with unwanted

	variability and could identified where to focus interventions and improvement.
Ross et al. (2018)	FRAM was useful in that it could support the improvement of fluoride varnish application on children's teeth within dental practice.

Application 4: Developing Leading Indicators

Raben (2017) is of the opinion that the indicator method can improve the management of healthcare processes and understand the complexity and interrelations of the system. The method can be applied in different systems, and it is able to highlight aspects which are needed for a successful performance. Leading indicators helps to proactively identify factors which could influence performance (Pickup, 2017; Raben, 2017; Raben et al., 2018a). The aim of leading indicators is to build resilience into the system as it improves to ability to anticipate, monitor, and respond proactively. Staff on the frontline are then not required to absorb the variability within the system (Pickup, 2017).

Aspects used to develop efficiency and quality indicators were timing (Laugaland, 2014; Mahmoudi, Mohamed & Timmoy, 2020), precision (Laugaland, 2014), and a combination of variability and upstream–downstream couplings (Hounsgaard, 2016; Raben, 2017; Raben et al., 2018a).

Raben and colleagues (2018a) is of the opinion that their study presents an alternative method for safety indicators to be used, as the traditional methods does not highlight the most important factors that is needed for successful safety management, nor does it provide indicators. The study of Raben and colleagues (2018a) recommend that clearly defined processes should be used to identify leading indicators as it improves its usability and relevance.

The process which Raben and colleagues (2018a) used to develop leading indicators is:

a) Identify the relevant functions within the process and placed it into chronological order, this allows the process to be understood over time.
b) Cluster key functions into sets, a set consists of all the activities that is needed to fulfil the objective or task at hand.
c) Analyse the variability of each set of functions. Variability is considered if it is important for the process or if it impacts the process at a later stage. To understand how variability impact the process, variability of functions is analysed by considering internal factors (human or organisational) and external factors (working environment) and by investigating the couplings between functions.

d) Identify functions in each set that is subject to variability early within the process and can affect functions later in the process. Timing and precision are used to examine how variability affects functions later in the process and if a combination of functions leads to variability.
e) Identify leading indicators for each set of functions. Variable functions with no consequences later in the process is not identified as an indicator, but if there is interference to a time-dependency to reach to goal (e.g., detect sepsis), it is indicated as an indicator.
f) Confirm the selected indicators with experts and by comparing it with previous adverse events.

Application 5: Prospective Application

Damen and colleagues (2018) describe the prospective application of FRAM as a unique feature, as it is not needed to wait for an incident to happen; FRAM focus on 'what goes right'. Patriarca and colleagues (2020) describe FRAM as useful to perform a prospective analysis of socio-technical behaviours in complex work environments. According to Hounsgaard (2016) FRAM is useful to help predict the consequences of a change. In the study conducted by O'Hara, Baxter and Hardicre (2020) safety gaps are identified during handovers, this information can be used proactively to plan the delivery of safer handovers. Kroeze, Wimmer and Hounsgaard (2019) mentioned in their study that FRAM can help to broaden the situational awareness of staff, which will increase their ability to be proactive and aware of potential risks in their work, which will then improve the safety of care.

Application 6: Retrospective Analysis

Patriarca and colleagues (2020) are of the opinion that a retrospective analysis is usually done by auditing a series of events to understand how the adverse outcome came about. FRAM assist users to identify critical work elements. When WAD and WAI are compared, it identifies potential system failures (Patriarca et al., 2020), highlight the consequences of actions, and help to predict issues (Franklin, 2018). McNab (2018) uses the risks information realised to provide feedback to staff which facilitate reflective learning. Damen and colleagues (2018) stated in their study about anticoagulation management, that documentation is used to perform a retrospective FRAM analysis, and this reveals habitual risky behaviour, inaccuracies, and missing information. This reveals how junior staff must make treatment decisions and unhealthy workarounds.

Application 7: Performing Risk Assessments

Patriarca and colleagues (2020) apply FRAM and Failure Mode and Effects Analysis (FMEA) and compare the risk assessment approaches. FRAM has been found to be suitable to help visualise complex processes, and it helps to highlight variation that may impact the performance of the system. Patriarca and colleagues (2020) also show FRAM to be useful in modelling system behaviours, and to identify or manage system risks.

Buikstra, Strivens and Clay-Williams (2020) used the FRAM to do a risk assessment on the discharge process of older persons. FRAM enable them to identify risk factors and hazards in the process. They are also able to do an analysis on the hazards and they could identify controls to eliminate the risks.

Tarakçı and colleagues (2020) apply FRAM as a risk analysis method and conclude in their study that FRAM is a very suitable method to use in the analysis of complex cases such as the COVID-19 pandemic. Emergency situations evolve and there are limited decision-making data available when an early and effective emergency response is required. FRAM can assist to link all processes and components and thereby enable a better understanding and management of emergency processes.

Application 8: Managing Complexity

Visualising and capturing complexity: FRAM can assist its users to form a wider view of processes by capturing the complexity of situations (Alm & Woltjer, 2015; Dellepiane, 2018; Laugaland, 2014; Raben et al., 2018b). Schutijser and colleagues (2019) believe that FRAM is 'very useful' to visualise complex healthcare processes, e.g., double check process of injectable medication administration.

Insight and understanding of complex processes: A FRAM analysis assist in providing a comprehensive insight into complex processes (Laugaland, 2014; Mahmoudi, Mohamed & Timmoy, 2020; O'Hara, Baxter & Hardicre, 2020; Patriarca, 2019; Raben et al., 2018b). Kaya, Ovalib & Ozturk (2019) is of the opinion that FRAM assist in the understanding of a complex drug administration process in a Neonatal Intensive Care Unit.

FRAM provides its users with a systems perspective while focusing on WAD and identifying variability in performance (Alm & Woltjer, 2015; Laugaland, 2014). Damen at al. (2018) reported that FRAM provides insight into the complex WAD and WAI processes of preoperative anticoagulation management within international contexts. Damen and colleagues (2018) conclude that FRAM is valuable when studying complex processes within healthcare and that it assists in identifying functions and their interdependence as well as variability. Buikstra, Strivens and Clay-Williams (2020) report that FRAM can be used to highlight the problems that staff face in a complex environment.

Facilitation of implementing complex systems: McNab (2018) belief that FRAM is a method which can be used to facilitate the implementation of a complex systems approach. It can explain the interaction between functions, the potential performance variability in function outputs and the likely impact all of this on the complex system.

Application 9: Other Applications

Heterogeneous applications of FRAM were grouped under "Other" in Table 8.

Table 8: Other types of application grouped together.

De Carvalho et al. (2019)	FRAM and BPMN (Business Process Model and Notation) are used to do requirements gathering. Functional and non-functional requirements are gathered for each activity or function during the risk classification of patients in the clinic. The experiment prove that the FRAM model is capable of gathering usability requirements.
Furniss (2020)	A non-normative approach of FRAM is used to explore intravenousinfusion administration in an ICU. A normative approach entails amplification of positive variance or dampening of unwanted variance. A non-normative approach identifies the underlying sources of performance variance in the process first and then describe underlying system contradictions. These contradictions allow staff with 'margins of manoeuvre' and it needs to be managed effectively. Examples of underlying systems contradictions are conflicting rules and advice, goal conflicts, trade-offs and mismatches between demand and capacity and mismatches between competences and situational issues.
Mahmoudi, Mohamed and Timmoy (2020)	FRAM is used to investigate how a hospital deals with disruptive events,as different policies and practices are followed when there is a surge in the number of patients that are admitted.
Meeuwis et al. (2020)	FRAM is used by investigators to identify the requirements of a safety differently investigation by conducting a FRAM analysis of the requirements necessary to conduct a successful investigation. The FRAM was judged to be the 'best capable' method in which to map the requirements of safety differently investigations as it can identify institutional opportunities, constraints and analyse everyday performance.
O'Hara, Baxter and Hardicre (2020)	The FRAM analysis is used to develop a patient-facing intervention, in which patients and families are supported during their transitional care.

Saurin and Werle (2017)	The study proposes eleven steps to analyse slack, an available resource in times of need. In step 1 they use flowcharts and process maps to identify the boundaries of the system and interconnections between the different stages of the processes. In step 2 they identify the various sources of variability by using cognitive task analysis. In step 3 the risk of each variability source is calculated and in step 4 available slack is identified. In step 5 the effectiveness of slack is evaluated and in step 6 a matrix was developed to analyse the way in which slack can mitigate variability, by assigning effectiveness scores to each unit. Step 7 consists of categorising the units of slack and in step 8 the slack is compared against regulatory requirements and best practices. Step 9 variability sources areprioritised by identifying whether they are covered by slack or not. Critical eventsare then analysed with using FRAM to understand the variability and couplings between functions. The risk scores in step 3 are used to calculate if there are any gaps in the way in which variability is mitigated. In step 10 improvement opportunities are identified by focusing on gaps, reducing variability, re-allocation, or allocation of slack, and monitoring unintended consequences. Step 11 assess the recommendations.
Wachs and Saurin (2018)	The researchers propose a six-step framework whereby the interaction between procedures and resilience skills is analysed. In step 1 the team members develop a common understanding of the concepts which underwrites the framework. Step 2 focus on identifying a suitable application for the framework e.g., a high incidence of adverse events, a complex work environment. In step 3 the procedure is analysed to form an understanding of WAI while following pre-defined criteria. Step 4 focus on understanding WAD and identifying work constraints which requires resilience and supportive measures. In step 5 the FRAM is used to createa deeper understanding of WAD. The focus in step 6 is to redesign the interactions between procedures and resilience skills by using methods such as scenario-based-training. Scenario-based-training help to highlight gaps in procedures, as staff is exposed to the variability of real-life situations.

c) Additions and Enhancements to FRAM

Apart from the traditional FRAM approach, some studies have added additional ways to implement and/or enhance the application of FRAM, which is discussed in this section.

- Pickup (2017) explores if using the Systems Engineering Initiative for Patient Safety (SEIPS) model (Carayon et al., 2006) for incident data analysis contributed towards informing the FRAM model and if it is practical. They reported that it enables the team to have a better understanding of WAD and variability and they can identify reasons why variability exists.
- Kaya and Hocaoglu (2020) apply a semi-quantitative method to FRAM by translating the grammatical describe variables into numerical scores, the higher the score, the higher the variability. Subject matter experts then assign a probability score to variables. Kaya and Hocaoglu (2020) are of the opinion that this method helps them to create a 'simpler and more understandable' FRAM. It saved time, as they were able to focus on couplings with high variability that is deemed critical. Hollnagel (2012) questions the method as FRAM focus on variability itself and not the probability of variability.
- Kaya and Hocaoglu (2020) furthermore apply the Monte Carlo simulation method and use it to create various real-life scenarios. This addition provides the ability to measure the critical couplings at each scenario. They report that by applying this method they can do a more in-depth analysis of the FRAM and it help to increase situational awareness and enables a response to change.
- O'Hara, Baxter and Hardicre (2020) visualise the FRAM in a way that the functional activity at the start of the process is located at the left side of the diagram and the functional activity at the end of the at the right side of the diagram. They are of the opinion that this adaptation helps them to identify gaps between different functions.
- Magott and Wikiera-Magott (2020) calculate the number of upstream connections between functions and the aspects input, time, resources, preconditions, control, as well as the number of downstream connections to the output. If a function has many connections, the higher the probability will be that this function will enhance the functional resonance within the system.
- To enhance the traditional approach of FRAM, Patriarca (2018) use the Variability Impact Matrix (VIM) to combine semi-quantitative variability assessments and their resonance throughout the system. Patriarca (2018) conclude that these enhancements had a positive impact, as it could be used as a decision support tool to prioritise

remedial actions, it ‘support complex knowledge management’ and it helps to gather and manage semi-quantitative variability data. A need for an IT or Artificial Intelligence support tool was highlighted by this study.

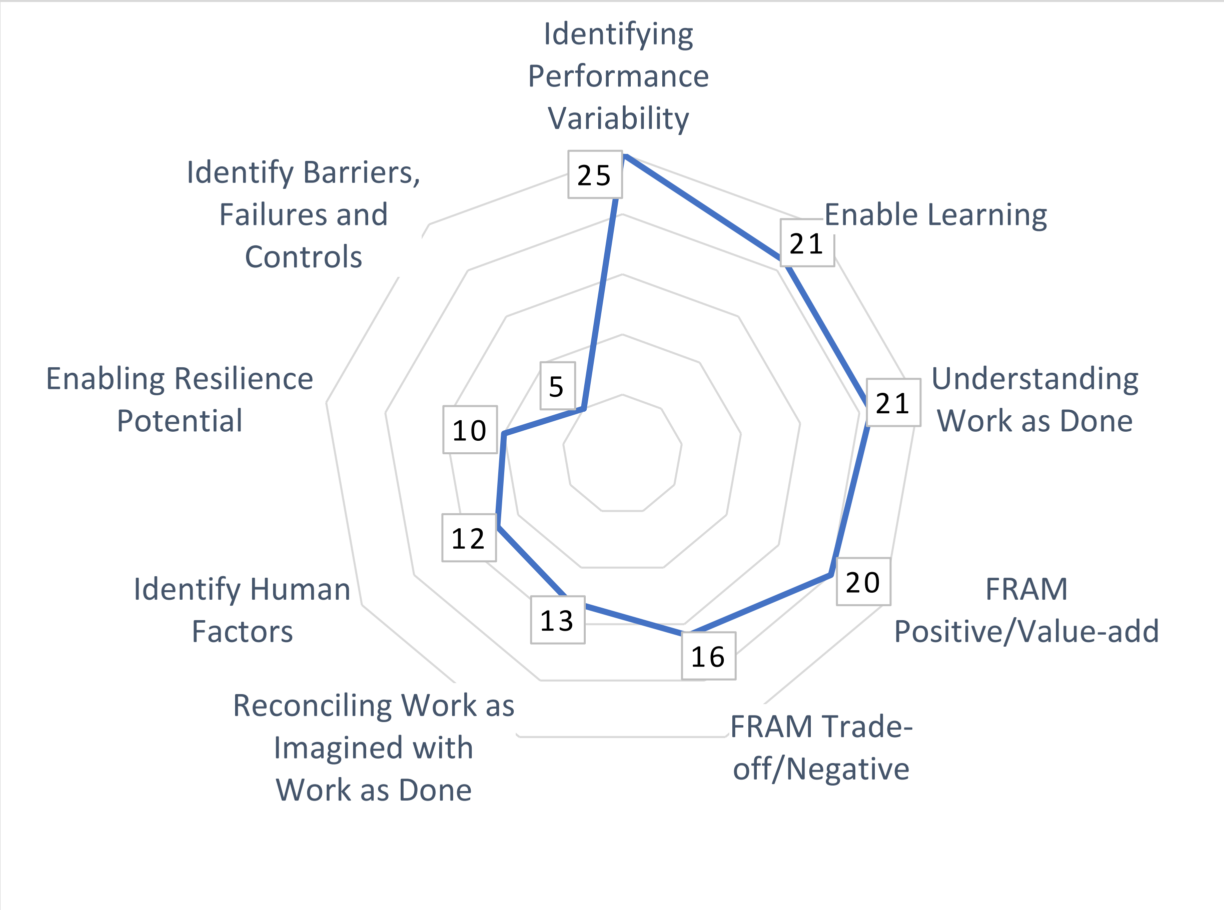
- If variability is detected in a function, Raben and colleagues (2018b) split it into more specific functions. The functions are also divided into subsets, each representing a different task. This addition enables users to easier identify functions which cause variability and may have the biggest impact.
- In the study of Meeuwis and colleagues (2020) the requirements necessary to conduct a safety differently investigation are not equally critical, so they added a ranking by using colour coding to the different aspects indicating which aspects are in place for traditional safety investigations and which requirements are not in place to do a safety differently investigation.

4.4 The value-add of FRAM.

The second objective of this study is to identify value-added aspects in terms of safety management for healthcare organisations that implemented FRAM.

During the data synthesis process, coded data has been grouped together in themes and outcomes have been identified in the process. The outcomes are depicted in a radar graph to indicate the number of times the outcome has been realised in the different studies. The graph indicates that ‘Performance Variability’, ‘Enable Learning’ and ‘Understanding Work as Done’ were the most prevalent outcomes. Twenty (20) studies indicated that they found the application of FRAM valuable and sixteen (16) studies mentioned that there were negative aspects or trade-offs they had to make while implementing FRAM. The outcomes of ‘Reconciling Work as Imagined with Work as Done’, ‘Identifying Human Factors’ and ‘Enabling Resilience Potential’ were almost 50% less prevalent than the top three outcomes. These outcomes can be seen as secondary or partly dependant on the top three outcomes, as an organisation first has to identify how daily work is performed and learn where performance variability is most prevalent, before some of the other outcomes can be realised. Only five (5) studies indicated spesifically that FRAM assisted them to identify barriers, failures and controls.

Figure 8: Prevelance of outcomes



The themes and outcomes were summarised per study in Table 9.

Table 9: Outcomes realised with the implementation of FRAM.

Study	Results								
	Understanding Work as Done	Reconciling Work as Imagined with Work as Done	Identifying Performance Variability	Identify Human Factors	Enabling Resilience Potential	Identify Barriers, Failures and Controls	Enable Learning	FRAM Positive/Value-add	FRAM Trade-off/Negative
Alm and Woltjer (2015)	X		X					X	X
Arcuria (2020)	X	X	X		X	X	X		
Buikstra, Strivens and Clay-Williams (2020)	X	X	X						
Clay-Williams, Hounsgaard and Hollnagel (2015)	X	X		X			X	X	
Damen et al. (2018)	X	X	X	X		X	X	X	X
De Carvalho et al. (2019)			X					X	
Dellepiane (2018)							X		
Franklin (2018)			X						X
Furniss (2020)	X		X		X		X		
Hounsgaard (2016)	X		X	X			X	X	X
Kaya and Hocaoglu (2020)	X	X	X	X	X		X	X	X

Study	Results								
	Understanding Work as Done	Reconciling Work as Imagined with Work as Done	Identifying Performance Variability	Identify Human Factors	Enabling Resilience Potential	Identify Barriers, Failures and Controls	Enable Learning	FRAM Positive/Value-add	FRAM Trade-off/Negative
Kaya, Ovalib and Ozturk (2019)	X	X	X	X	X		X	X	X
Kroeze, Wimmer and Hounsgaard (2019)			X					X	X
Laugaland (2014)	X	X	X	X	X		X	X	X
Magott and Wilkiera-Magott (2019)	X		X	X			X	X	
Mahmoudi, Mohamed & Timmoy (2020)	X	X	X		X	X	X	X	
McNab (2018)	X	X	X	X			X	X	X
Meeuwis et al. (2020)				X			X	X	X
O'Hara, Baxter and Hardicre (2020)	X		X		X		X	X	X
Patriarca (2018)					X		X	X	X
Pereira (2013)	X		X				X	X	X
Pickup (2017)	X	X	X	X	X		X	X	X
Raben (2017)			X				X		

Study	Results								
	Understanding Work as Done	Reconciling Work as Imagined with Work as Done	Identifying Performance Variability	Identify Human Factors	Enabling Resilience Potential	Identify Barriers, Failures and Controls	Enable Learning	FRAM Positive/Value-add	FRAM Trade-off/Negative
Raben et al. (2018a)	X		X						
Raben et al. (2018b)	X	X	X	X			X		
Ross (2018)	X	X	X	X	X		X	X	X
Saurin and Werle (2017)					X			X	
Schutijser et al. (2019)	X	X	X			X	X	X	X
Sujan and Felici (2012)			X					X	
Tarakçı et al. (2020)	X		X			X			
Wachs and Saurin (2018)									

The author will demarcate several outcomes from the summary above, to illustrate andallow the reader to form a deeper knowledge on the outcomes of applying FRAM.

Outcome 1: Understanding Work as Done

Provides insight into daily work: Hounsgaard (2016) is of the opinion that the FRAM model provides a ‘detailed description’ and a ‘shared insight’ into WAD. Kaya, Ovalib and Ozturk (2019) and Raben and colleagues (2018b) can identify the functions that are related todaily work. FRAM enables the users to investigate the process in a systematic way and therebygain an understanding of how the process works. Laugaland (2014) learns that FRAM help to identify specific factors related to hospital discharge and clarifies how functions are connected and affects one another.

Illustrates the interaction between functions: Raben and colleagues (2018b) conclude that the application of FRAM has shown it to be ‘a useful and powerful method’ which illustrates dynamic interactions between functions and helps to understand the ‘how and why aspects’ within the process. Damen and colleagues (2018) report that essential functions, their interdependence, variability and how these aspects relate with guidelines are revealed in the application of FRAM. Hounsgaard (2016) can form an understanding of the workflow and interdependency between functions as well as the conditions necessary to complete daily work successfully. Arcuria (2020) is of the opinion that investigating WAD enable practitioners to reflect on the different ways in which the system operates. By applying the FRAM model Tarakçı and colleagues (2020) report that it assists them to identify the functions which are performed (WAD) and they can connect functions within the process of COVID-19 in the hospital.

Highlights vital safety aspects: Hounsgaard (2016) reports that critical aspects necessary to ensure safe patient care are highlighted, e.g., there is not a standard way in which physicians categorised patients as ‘Urgent’. The consequence is that medical secretaries end up doing the final prioritisation and booking of patients in the best possible way. O’Hara, Baxter and Hardicre (2020) are of the opinion that exploring WAD via FRAM and incorporating the perspectives of all role-players are crucial to understand the significant aspects necessary to provide safe transitional care, and to guide improvement interventions.

Highlights, adaptations, or trade-offs: The FRAM assists Hounsgaard (2016) to identify adaptations that staff does in their daily work (WAD). Plotting the adjustments that staff make (WAD) in the FRAM, describe how the adjustments can at times emerge into an unwanted outcome for the patient. Users are enabled to form a realistic visual representation of daily work and understand the adjustments staff make and the associated trade-offs (McNab, 2018; Pickup, 2017; Schutijser et al., 2019). Raben and colleagues (2018b) observe that there can be a lack of information transfer from nurses to doctors due to multiple interruptions to tasks which are performed, and this results in time pressure and potential safety issues. Damen andcolleagues (2018) learn that the FRAM analysis provide insight for frontline clinicians into themanagement of preoperative anticoagulation. While plotting WAD within the FRAM, it is highlighted that staff performed workarounds to maintain efficiency.

Outcome 2: Reconciling Work-as-Imagined with Work-as-Done

The application of the FRAM clarifies the deviation between WAI and WAD (Clay-Williams, Hounsgaard and Hollnagel, 2015; Buikstra, Strivens and Clay-Williams, 2020; Mahmoudi, Mohamed and Timmoy, 2020; Schutijser et al., 2019). The FRAM assists Damen at al. (2018) to bring together the world of guidelines (WAI) and the world of everyday clinical practice (WAD) and it provides insight into the complex processes of WAD and WAI. Pickup (2017) concludes that the FRAM represents what actually or potentially happens in daily work (WAD), rather than performing an analysis on what is perceived to happen as it is reflects in protocols and guidelines (WAI). McNab (2018) reports that WAD includes workarounds and trade-offs to ensure safe patient care. They identify conditions of work which lead to deviation between WAI and WAD, for example when patients are being assessed. Clinicians imagine work being done in a specific way, while it is done differently by administrative staff. Clay-Williams, Hounsgaard and Hollnagel (2015) are of the opinion that guidelines written according to WAI without taking WAD into account, is often incompatible with the provision of effective patient care, as staff then uses workarounds and adjust their performance, which may be 'detrimental to both safety and quality.' Clay-Williams, Hounsgaard and Hollnagel (2015) can pinpoint items which are missing from the original guideline and items which do not make sense in clinical practice. They can align the guideline closer to WAD and develop a more usable guideline. They report FRAM to be 'an excellent tool' which is useful to start team discussions.

Outcome 3: Identifying Performance Variability

In FRAM, variability is seen as a normal part of daily work, but uncontrolled performance variability, which is outside of safety margins, must be identified and addressed (Raben et al., 2018a).

Ways in which variability is identified:

- Pereira (2013) and Damen and colleagues (2018) classify output functions into technological, human, and organisational system functions. They determine and investigate the potential variability of output functions by investigating internal and external conditions plus influences from upstream functions.
- Performance variability can affect downstream functions and output can be measured in terms of time - early, on time, or late (Mahmoudi, Mohamed & Timmoy, 2020; Raben et al., 2018b)

- Output of functions are measured in terms of time and precision - precise, acceptable, or imprecise (Damen et al., 2018; Kaya & Hocaoglu, 2020; Kaya, Ovalib & Ozturk, 2019; Laugaland, 2014; McNab, 2018; Pereira, 2013; Tarakçı et al., 2020).
- Raben and colleagues (2018b) identify that variability occur as a result of resource availability, human factors and in upstream–downstream couplings.
- Pickup (2017) use the core functions as codes and then thematically analyse the data to find sources of variability for every function. For example, 'Labelling the blood sample' is identified as a 'vulnerable' function, as it is influenced by seven different functions that have a potential of being variable in terms of time or precision.
- Hounsgaard (2016) identify trade-offs between efficiency and thoroughness to result in performance variability.
- Alm and Woltjer (2015) use eleven common performance conditions, which are described by Hollnagel (2012), to identify potential or actual variability: 1. availability of personnel and equipment, 2. training, preparation, and competence, 3. communication and quality 4. human-machine interaction and operational support 5. availability of procedures 6. working conditions 7. number of goals and goal conflict 8. available time 9. circadian rhythm and stress 10. team collaboration 11. organisational quality. They described and assessed how the output of functions vary and identify common performance conditions which contribute to the variability.

Usefulness of identifying variation:

- Buikstra, Strivens and Clay-Williams (2020) reports that FRAM is useful for mapping variability in the workplace. Areas of high risk combined with variability was identified. This information was used to make recommendations to reduce or eliminate the risks for patients and to prioritise action plans.
- Ross (2018) reports that they can identify which applications are variable in practice and how it links up with inputs, outputs, and resources.
- Furniss (2020) uses FRAM to explore sources of performance variability in intravenous infusion administration in the ICU and reports three main areas associated with high performance variability: medication order, medication administration and double checking.
- Schutijser and colleagues (2019) also identify high variability in the double check process of medication.
- Furniss (2020) chose to take a non-normative approach, in which variability is not judged as wanted or unwanted. Variability is seen as part of the system with either positive outcomes or unwanted outcomes at times. Furniss (2020) is of the opinion that

FRAM is useful in the following areas: focusing on positive variance in successful systems, identifying wanted and unwanted variance.

- Franklin (2018) identify variability in the way in which the theatre list is marked off.
- In the study of Wachs and Saurin (2018) FRAM highlights variability sources which was not anticipated.

Outcome 4: Identify Human Factors

People are a valuable resource to improve the quality, safety, and resilience of systems (Magott & Wilkiera-Magott, 2019; Pickup, 2017), as frontline staff must adapt their work to conditions which are not ideal and where resources are limited (Hounsgaard, 2016).

Pickup (2017) reports that a 'mismatch' between resources and demands can influence human performance and that current incident report and near miss data does not consider internal human factors such as stress, fatigue, or nutritional levels, which may influence variability. Pickup (2017) agrees that variability in human performance is normal and that the aims should be to promote the positive performance variability and dampen negative variability.

Raben and colleagues (2018b) and Magott and Wilkiera-Magott (2019) are of the opinion that human factors such as the ability to conduct clinical judgements, previous experience and knowledge are the main sources of performance variability. The expertise of a practitioner is instrumental in decision-making and successful performance (Hounsgaard, 2016; Pickup, 2017; Raben et al., 2018b).

Examples of human factors identified in studies:

- The application of FRAM highlights how system performance relies on human interaction to compensate for a system e.g., a receptionist can identify patients who are not able to follow the electronic screen, which facilitates patient flow. If conditions within the system changes and human interaction is not possible or not available, a negative outcome can be expected (Hounsgaard, 2016).
- In the study of Ross (2018) the practitioners have difficulty to complete the 'Childsmile' forms and describe them as 'double Dutch'. This has a direct impact on monitoring if the varnish is applied to the children's teeth; the procedure is performed but not captured.
- In the study of Wachs and Saurin (2018) 70% of the functions being identified during the administration of medication process, required human intervention.
- Laugaland (2014) report that there is a variation in how nurses contribute to a decision-making process. Human factors such as the relationship with the doctor, the

personality of the doctor and familiarity with the patients are reported to influence the decision-making process and thus influenced variation. Patient related human factors e.g., mental ability, influenced communication between practitioners and patients, and influence the ability of the patient to be involved in the discharge process, which leads to variation, and it influences the performance of discharge processes.

- Clay-Williams, Hounsgaard and Hollnagel (2015) acknowledges that while FRAM may be useful to identify what changes needs to be implemented, clinician behaviour may also need change in some respects.
- In the study of Damen and colleagues (2018) they realise that healthcare centres are supplying patients with information, but that they are relying on the patient's memory to adhere to preoperative anticoagulation management while at home. This reliance on human factors can impact performance outcomes.

Outcome 5: Enabling Resilience Potential

Arcuria (2020) categorise data according to Hollnagel's (2017) resilience potentials – learning, anticipation, monitoring, and responding and reports it useful to identify and analyse resilient performance.

Potential to respond: Hounsgaard (2016) can form an understanding of the workflow and interdependencies between functions as well as the conditions necessary to perform daily work. Patriarca and colleagues (2017) and O'Hara, Baxter and Hardicre (2020) are of the opinion that studying and understanding daily work can assist in building resilience potentials and safety outcomes.

In using FRAM to analyse WAD, the adaptations that staff makes to maintain efficiency becomes apparent (Damen et al., 2018; McNab, 2018; Pickup, 2017). A collaboration of functions is being modelled in FRAM and this then highlights areas in which the system can improve its efficiency and resilience potential (Mahmoudi, Mohamed & Timmoy (2020).

Potential to monitor: In the study of Arcuri, and colleagues (2020) practitioners can reflect on how the system operates and what goes right by looking at frequent events. Developing leading indicators is covered in the studies of Clay-Williams and colleagues (2015); Damen and colleagues (2018) and Mahmoudi, Mohamed and Timmoy (2020). There is consensus between the studies that the application of FRAM can be useful to find practical solutions to iterate and refine guidelines.

Clay-Williams and colleagues (2015) and Damen and colleagues (2018) are of the opinion that FRAM offer a solution to resolve the ambiguities reported between guideline design (WAI) and practical implementation (WAD).

Potential to learn: this potential is discussed in Outcome 7: Enable Learning.

Potential to anticipate: Mahmoudi, Mohamed and Timmoy (2020) are of the view that by applying FRAM, policymakers can get a realistic understanding on WAD. This highlights the inherit risks within the system and allow policymakers the ability to anticipate future risks.

In the study of Ross and colleagues (2018), they can identify where to intervene to initiate improvement and they can hypothesise or anticipate how these interventions may lead to the desired outcomes.

In building FRAM, Arcuri and colleagues (2020) use the resilient potentials of Hollnagel (2017) as themes to understand the resilience abilities of the system. They can identify adjustments that is made to counteract for shortcomings in the system. They conclude that it is a valuable approach, as it increases their understanding of the elements which affects the resilient performance of the system.

Saurin and Werle (2017) indicates that FRAM assists them to anticipate by identifying the gaps between the availability of slack resources and the risks which are identified. It is necessary to have the ability to anticipate when decisions are being made on the allocation of slack resources.

Outcome 6: Identify Barriers, Failures and Controls

Barriers: In the study of Schutijser and colleagues (2019) several barriers in conducting a physical double check for every injectable medication are identified. The barriers result in process workarounds and nurses not following WAI. The lack of time and availability of a second nurse to conduct the physical double check for all injectable medication administrations, is reported to be a major barrier. Nurses are conducting their own risk assessment based on their experience. They assess if double checks are necessary or possible, e.g., high-risk medication will always be double checked, but not necessarily medication that they regard as having a lower risk.

FRAM assists to highlight obstacles and opportunities which is hidden in the performance of the hospital system (Mahmoudi, Mohamed & Timmoy, 2020).

Failures: Arcuria (2020) identify failures within the patient referral system due to a misalignment between capacity and demand. In the study of McNab (2018) every patient's full set of vital signs is not taken, as primary care physicians are relying on their experience to decide whether patients can be discharged or not. Some patients with sepsis are not referred from primary to secondary services, which results in better patient outcomes.

By applying FRAM, Mahmoudi, Mohamed and Timmoy (2020) identify that in the case of surge or disruptive events, the cooperation and communication between the hospital and external stakeholders is not efficient.

Controls: Tarakçı and colleagues (2020) are of the opinion that by using FRAM the necessary process controls for managing the COVID-19 pandemic is defined. FRAM enable hospital management to know which issues to control to ensure safe conditions.

Magott and Wikiera-Magott (2019) reports that by modelling the work of General Practitioners, they can identify functional resonances and identify controls to prevent unwanted events.

Outcome 7: Enable Learning

In the McNab (2018) study, professionals indicate that they want feedback to learn from their practices and a ‘system-based reflective tool’ is developed which individuals and teams could use for repeated reflection. The tool encourages teams to repeatedly reflect on their performance and they can learn which conditions and interactions are influencing their performance and output. The tool is useful when a sepsis case is investigated, and it can also be used to share learning with other teams.

In the study by Patriarca and colleagues (2017) scenario-based training assists staff to learn how to adapt their work to possible scenarios and system constraints. They are thus equippedand can anticipate how to better respond in similar real-life scenarios.

Dellepiane (2018) and Hounsgaard (2016) are of the opinion that by modelling FRAM, staff learn which functions can potentially result in safety incidents and this enable them to make specific improvements. Laugaland (2014) is of the viewpoint that by studying functions, variability, and performance-shaping factors they were able to learn which functions and associated aspects were critical within the discharge process.

Furniss (2020) reported that individuals were able to reflect on the resilience strategies that they use daily by using methods such as storytelling. In this way they could share knowledge amongst team members and enable learning. When applying FRAM, the staff ‘learned many lessons’ and they consider it to use FRAM to train staff (Kaya, Ovalib& Ozturk, 2019). Magott and Wilkiera-Magott (2019) identify that FRAM can be used in the education of doctors.

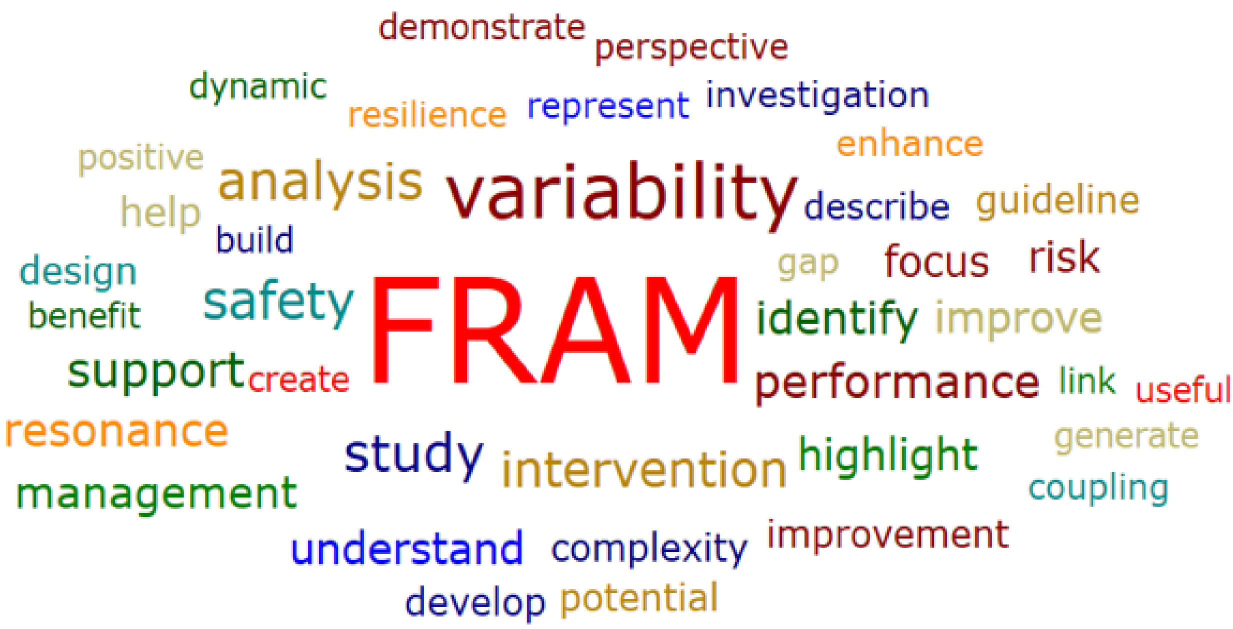
Meeuwis and colleagues (2020) are of the opinion that safety differently investigations allow richness in reports, and it opens up the opportunity for ‘deep learning and quality improvement.’

Arcuri and colleagues (2020) uses external-learning loops to provide feedback to policymakers who are responsible for a referral prioritisation system. Feedback includes the need to develop new practices and improvements to enhance the resilience potential of the referral system.

Outcome 8: Value-adds

The word-cloud application of the Atlas coding tool was applied to the coded information which pertain to value-added outcomes in the studies under review. Figure 9 is a visual representation of the frequency and the value of the text; bigger and bold words appear more often.

Figure 9: Visual representation of value-added text



Blame free and comforting: As FRAM does not focus on finding failures or see variability as a failure, staff are able to freely discuss performance variability without fearing blame (Kaya, Ovalib & Ozturk, 2019; Kroeze, Wimmer & Hounsgaard, 2019; Sujan & Felici, 2012). Participants in the Kaya, Ovalib and Ozturk (2019) study describe the FRAM as ‘more comforting’ as FRAM does not focus on failure if compared to traditional safety management tools. The FRAM assists participants to understand how to manage performance and participants felt ‘more confident’ to implement improvements.

Insightful: Damen and colleagues (2018) comment that reflective meetings with staff are ‘insightful’ and it highlights interdependencies between the staff functions. McNab (2018) is of the opinion that a benefit of FRAM is that it allows a synthesis between qualitative and quantitative data, improves understanding of the whole system, identify aspects which cause output variability and FRAM supports clinical teams to identify the areas in which improvement is needed.

Pereira (2013) report that the focus of FRAM on performance variability instead of human error, allow leadership to form a 'global understanding of safety' within a complex system.

Extensive: Alm and Woltjer (2015) reports FRAM advantageous because of its ability to expose the complexity of healthcare. FRAM allows investigations to be 'more extensive' and when compared to other methods, and users can find complex interdependencies. Kaya, Ovalib and Ozturk (2019) study describe the FRAM as 'comprehensive and accurate'.

Identify variability: FRAM assist users to identify the impact of small variations on the system (Hounsgaard, 2016; Kaya, Ovalib & Ozturk, 2019; Sujan & Felici, 2012). Hounsgaard (2016) is of the view that having the ability to identify variability in daily work and the subsequent adaptations by junior staff to compensate for the variation, assist in identifying potential high-risk areas and improvement opportunities. This in turn ensures proactive safety management.

O'Hara, Baxter and Hardicre (2020) and McNab (2018) are of the opinion that the FRAM could provide healthcare staff with a 'roadmap' to identify unwanted or positive variability. Staff become aware of the consequences of variability to patients and the impact on the system.

Laugaland (2014) comments that being able to identify performance variability, is not generally being recognised as an asset. Laugaland (2014) further describe FRAM is an 'innovative method' that is used to analyse performance variability within a complex system.

Identify system inefficiencies: Hounsgaard (2016) report that FRAM assist by highlighting the system inefficiencies which result in unwanted outcomes and staff becomes aware of the downstream impact that their behaviour may have on safety outcomes.

Effective: Meeuwis and colleagues (2020) reports that uptake of FRAM as an analysis method was 'swift and effective' whereas clinicians in the study of Damen and colleagues (2018) finds it easy to see the relevance and understand the background and design of the FRAM. In an experiment done by De Carvalho and colleagues (2019) they report that more usability-related requirements are gathered by using the FRAM when compared to BPMN (Business Process Model and Notation) model and the FRAM manages to gather requirements which is not identified by BPMN. Participants report a higher satisfaction rate after using the FRAM.

Structurally simple: Kaya and Hocaoglu (2020) consider the FRAM to be 'structurally simple' and that it allows for the description of the various phases of an incident investigation. The FRAM leads the investigator to collect the necessary information and the analysis reveals functions that are dependent on each other, which is a dimension usually missed in incident investigations. When implementing FRAM, Clay-Williams, Hounsgaard and Hollnagel (2015) reports that clinicians are easily able to understand FRAM and a clinician have reported that it is the first time he has come across an analysis method that can describe work as it happens.

Visual representation: Pickup (2017) reports that the FRAM provides a visual representation of WAD, enable a greater understanding about variability within the system, highlight areas where staff adapt their practices and indicate where resilience can be improved. In the study of O'Hara, Baxter and Hardicre (2020) it was observed that FRAM assisted to visualise the whole system of primary care, secondary care, and community care whilst including the perspective of patients and families. Healthcare staff perceive FRAM to be a 'useful tool' as it gives them visibility on the complexity of the medication administration process (Wachs & Saurin, 2018). Raben and colleagues (2018b) are of the opinion that FRAM assist in illustrating what, how and why a process happens, as it provides an illustration of the interactions within the process.

Identify safety gaps: O'Hara, Baxter and Hardicre (2020) can identify safety gaps which was unknown to healthcare staff before. Healthcare leadership can also identifyvariability in the system as well as the consequences of variability for patients, families, and the system. The study of Saurin and Werle (2017) conducts a qualitatively analysis of variability sources as well as a FRAM analysis to understand variability and coupling between functions. They indicate that by using FRAM they can form a 'more complete picture' of positive and negative gaps.

Decision-making aid: Clay-Williams and colleagues (2015) and Raben (2017) reports that FRAM helps to extract the functions which staff use to make decisions, this is especially true when they identify the variability of functions and upstream–downstream couplings. Patriarca (2018) is of the opinion that FRAM, in a semi-quantitative version, can potentially support decision-making to improve healthcare safety, efficiency and resilience.

Detailed analysis: Laugaland (2014) reported that the FRAM provided a detailed and systemic analyses of the discharge process. In the unit in which the study was performed, the outcome measures of satisfaction, decision-making and the quality of the information transferred, was influenced.

Driving improvement: Kroeze, Wimmer & Hounsgaard (2019) highlights positive aspects of FRAM: improvement can be done without having to wait for an accident to happen, improvement is supportive of operational work, discussions with staff about FRAM is perceived as valuable, the model improve situational awareness and FRAM can be useful in several ways and situations. Mahmoudi, Mohamed and Timmoy (2020) FRAM is described as 'an insightful technique' which assist its users to identify areas of improvement and it enhances resilience.

Outcome 9: Negative Aspects/Trade-offs

The word-cloud application of the Atlas coding tool was applied to the coded information which pertained to negative aspects in the studies under review. Figure 10 is a visual representation of the prominent words found within the text after common filler words were removed.

Figure 10: Visual representation of text pertaining to Negative Aspects

Time consuming: Several studies have reported FRAM to be time consuming (Kaya, Ovalib & Ozturk, 2019; McNab, 2018; Meeuwis et al., 2020; Patriarca, 2018; Pereira, 2013).

Resource intense: FRAM is described as resource intense (Meeuwis et al., 2020; Patriarca and colleagues 2020).

Requires an experienced team: FRAM requires an experienced team (Hounsgaard, 2016; McNab, 2018; Meeuwis et al., 2020). Alm and Woltjer (2015) are of the opinion that staff with 'significant' experience and knowledge of both the context and of the organisation should be used to propose improvement recommendations. Pereira (2013) is of the view that the identification and description of FRAM functions are the most important stage within the method and that the input from a working team is needed to ensure that the functions are portrayed reliably. O'Hara, Baxter and Hardicre (2020) describe the process of identification and description of functions as iterative with multiple revisions that may be needed. McNab (2018) argues that by using facilitated group discussions, more participants can be included at once, which is a more time efficient alternative.

Access to frontline staff: Patriarca and colleagues (2020) believe that having access to frontline staff and their working environment is a prerequisite, as they are needed to gather information regarding the various functions, understanding the couplings between functions, and identifying potential variability.

This ensures that the model is valid and reliable, so this aspect can also be seen as a strength. Laugaland (2014) warns that if only one set of stakeholders participates in the information gathering, it may skew the outcome to suit the expectation of the stakeholder involved.

Training required: Alm and Woltjer (2015) is of the opinion that FRAM has a ‘different theoretical grounding’, and users will need to undergo training on the method and users also need experience in the domain of human and organisational factors.

Unknown scope of analysis: FRAM does not have a ‘boundary’, and users must decide what the scope should be of the analysis they want to conduct and use the method accordingly (Ross,2018). There is always a trade-off when boundaries are drawn and this must be done by experts in the field and of the FRAM (Patriarca et al., 2020). O’Hara, Baxter and Hardicre (2020) included many stakeholder groups and had to do the modelling at a higher level of granularity, which means that they lost some of the variability related to functions in the process.

Young, developing model: FRAM is a young model, still undergoing development (Alm & Woltjer, 2015).

Changing work environment requires re-work: Patriarca (2018) comments that a limitation of FRAM is that the model needs to be re-assessed if there are changes within a work domain.

Complexity: Kaya and Hocaoglu (2020) reports that it is visually difficult to generate scenarios from FRAM, due to its complexity and many interactive functions. Pickup (2017) questions if any methodological approach will be able to describe work processes within a complex socio-technical system. O’Hara, Baxter and Hardicre (2020) propose that FRAM should be converted into a ‘simpler’ model. Patriarca (2018) is of the opinion that FRAM needs IT or Artificial Intelligence support to help combine different perspectives.

Mandates of regulatory bodies: There is a need for leadership and regulatory bodies to provide a mandate to do safety differently investigations (Kroeze, Wimmer & Hounsgaard, 2019). Meeuwis and colleagues (2020) grapple with the same uncertainty, whether regulatory bodies will agree that healthcare organisations may use other methods than RCA.

Stakeholders buy-in: Franklin (2018) is unsure how to present the FRAM to non-experts and O’Hara, Baxter and Hardicre (2020) are of the opinion that it is unlikely that the complex information within the FRAM is quickly to share with stakeholders.

5. DISCUSSION

The applicability of using traditional safety management methods for complex environments, is questioned by several thought leaders. As healthcare has become even more complex with the introduction of computerised systems and sub-systems, there is a need to broaden the approach towards managing safety. Reasons why the author chose to investigate FRAM as an approach:

- is that it has been successfully applied in several high-risk industries,
- FRAM is a modelling method which models everyday work which is most of the time “hidden” for the investigator,
- it is a systems analysis method and investigates the interaction of functions,
- it can be applied in complex, underspecified systems, the author has found traditional methods lacking in this area,
- FRAM has been applied to a wide variety of safety management aspects, for example incident investigation, risk management, and improvement applications
- FRAM has been applied in developed as well as developing countries.

In this dissertation the author aims to investigate how the application of FRAM can support healthcare organisations to enhance their ability to manage safety. The results are expected to provide healthcare organisations with guidance on applying the FRAM and demonstrate the value it adds to safety management. The investigation comprised of a systematic review of thirty-one studies which contains evidence that the FRAM was applied in a healthcare or healthcare-related setting.

Where FRAM has been implemented

FRAM has been implemented in primary care, general hospitals, intensive care, and other settings. The FRAM has implemented in services such as blood sampling and dispatch services. The application is spread over various processes, such as transitional care, discharge, ward rounds, patient flow, safetymanagement, blood transfusion and IV infusion, sepsis detection, handover, drug administration and requirement gathering. The wide number of services, settings, and processes in which FRAM was applied, confirm that the model is not restricted in its application.

In the dissertation there were 31 studies, FRAM was widely applied in developed countries (74,2%) whilst only a small percentage of uptake occurred in developing countries (25.8%). When investigating the prevalence of inpatient harm between developed versus developing countries, the World Health Organization (2011) indicate that ten percent (10%) of patients in developed countries are harmed, whilst eighteen percent (18%) of patients in Eastern

Mediterranean and African Regions experienced adverse events. In this study, fourteen percent (14%) of patients were permanently disabled and thirty percent (30%) died, associated with adverse events. Eighty-three percent (83%) of these adverse events were deemed preventable (Wilson et al., 2012).

Wilson et al. (2012) is of the opinion that the prevention of these adverse events is complex and that further studies in the context and systems in which care is provided is necessary; simply adding more resources will not solve all problems. The World Health Organization (2011) indicate that we need better knowledge on how to prevent the 'epidemic of unsafe care'. Elmontsri, Banarsee and Majeed (2018) indicate that developing countries should use research which will enable them to gather data and information on their systemic safety problems. This dissertation indicate that the FRAM model was applied in developed as well as developing countries with equal success. The scale in which FRAM was applied, range between single case studies, medium size application and large-scale applications. In Brazil, the successful application of FRAM was done on a very large scale, the GP referral system of Rio de Janeiro involved 3 million patients (Arcuria, 2020). Spreading the application of FRAM to more developing countries can assist them to gain knowledge on their systemic safety problems and enable them to improve their safety management.

How FRAM has been implemented

Various types of applications have been extracted fromthe various studies: developing clinical guidelines, performing incident investigations, enabling improvements, developing leading indicators, prospective application, retrospective application, performing risk assessment managing complexity and other applications. The applications which are identified as the most prevalent, are managing complexity and enabling improvements. Each application was discussed and practical examples of how it was applied enable the reader to form a deeper understanding of the application of FRAM in the different contexts. The studies which indicate additions or enhancements to the application of FRAM, have been discussed separately.

Salehi, Veitch and Smith (2020) have conducted a literature review on the use of FRAM in complex socio-technical systems and sixteen (31%) of the 52 studies were healthcare related. In the literature review they identify applications and value-added aspects similar to what was identified in this dissertation: incident investigation, hazard identification and risk management, complexity management, factors which influence system performance, investigation of system design, identifying the difference between WAD and WAI, improving clinical processes and safety management. Kroeze, Wimmer and Hounsgaard (2019) also reported that FRAM can be useful in several ways and situations.

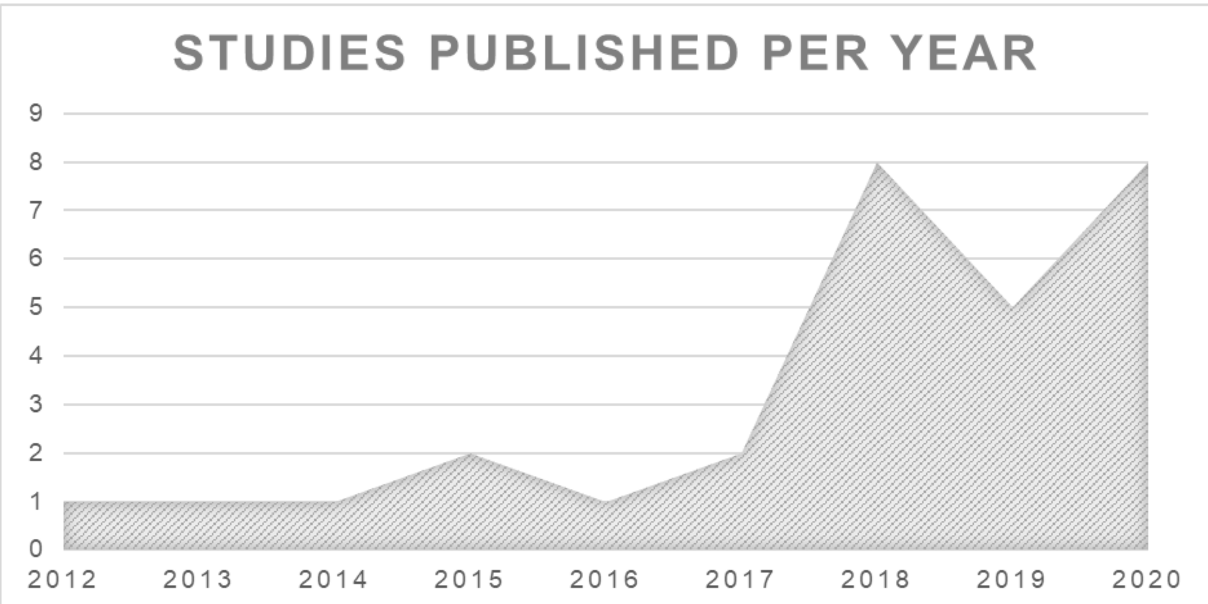
Value-add in terms of safety management

To demonstrate the value FRAM adds to safety management in healthcare organisations, themes have been identified in the studies, and several outcomes are realised: understanding work as done, reconciling WAI with WAD, identifying performance variability, identify human factors, enabling resilience potential, identify barriers, failures, and control, enable learning, and also value-added aspects plus trade-offs or negative aspects of FRAM. Other reviews that have been done on the applicationof FRAM in a healthcare context, will be incorporated in the discussion that follows on the value-adds of FRAM in terms of safety management.

The scoping review of Patriarca and colleagues (2017) on the relevance of using a Resilience Engineering (RE) approach in a complex healthcare environment, demonstrate that a RE approach has the potential to be used to enable a 'paradigm shift' in the management of safety within current and of future healthcare systems. This 'paradigm shift' is needed to enhance the safety of patients in healthcare (Patriarca et al., 2017). Their review conclude that future studies should explore the use of RE in safety management in more depth, while following a complexity management perspective. Pickup and colleagues (2017) concluded that safety management must consider system resilience going forward. According to Ross (2018), the FRAM as used by Pickup and colleagues (2017), has shown potential in guiding safety management efforts.

Salehi, Veitch and Smith (2020) reported a 'considerable growth' in the use of FRAM for safety management purposes. Figure 10 provides a breakdown of the various years in which the studies in this dissertation were published. It thus supports the finding, as there is a considerable growth in the application of FRAM from a healthcare perspective since 2017.

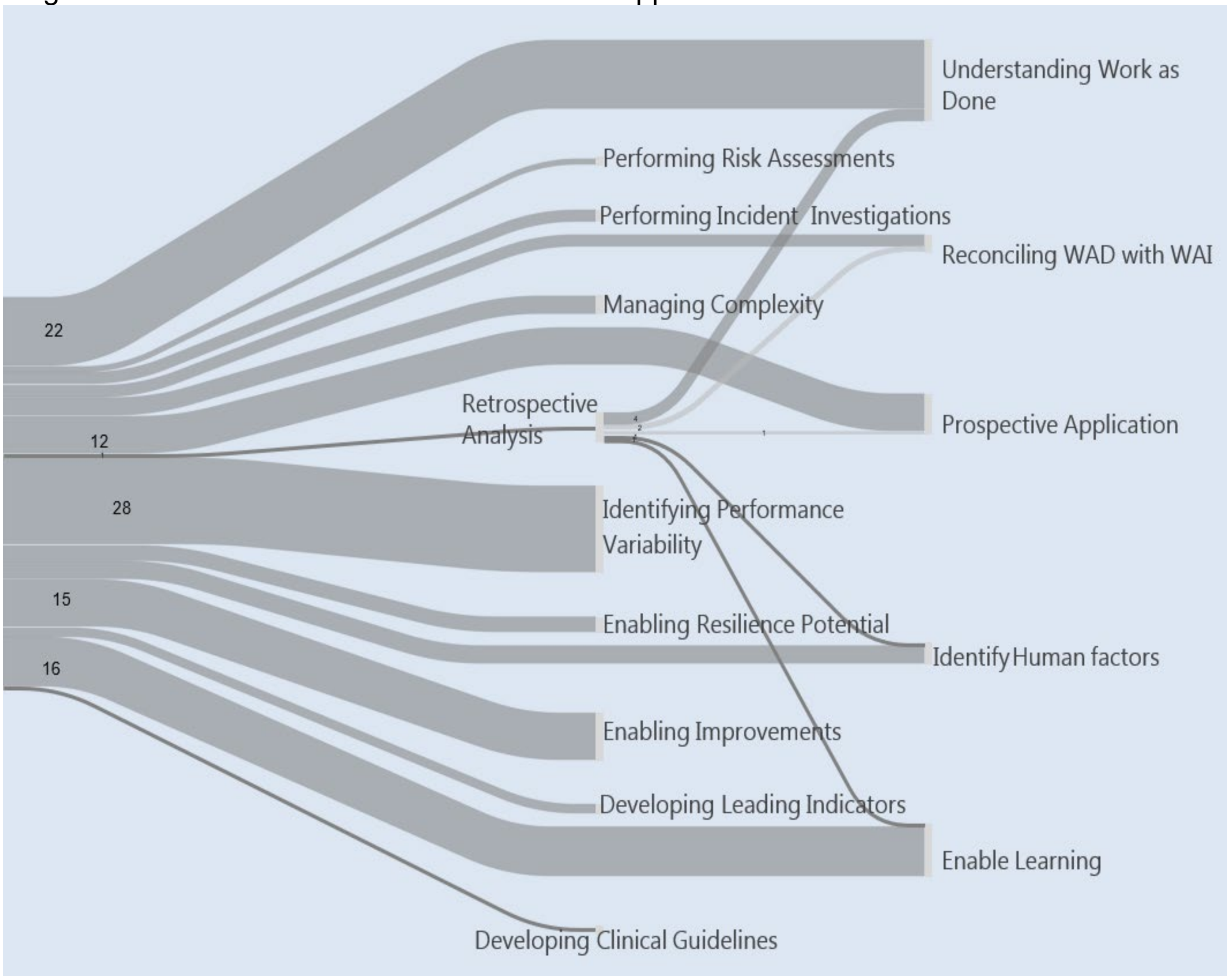
Figure 10: Studies per year



Applications and outcomes

The applications and outcomes which is realised in this dissertation, has been grouped in a co-occurrence diagram (Figure 12), together with the value-added results which is extracted from the studies assessed.

Figure 12: The value-add of FRAM in terms of application and outcome.



A discussion of the most prevalent value-added aspects derived from the co-occurrence diagram, will illustrate how the application of FRAM can support healthcare organisations to enhance their ability to manage safety. The two aspects which are identified as adding the most value, 'Identifying Performance Variability' followed by 'Understanding Work as Done', are also the first two steps in building the FRAM.

- **Identifying performance variability** is identified as adding the most value-added by the studies assessed. This verifies the notion of Laugaland (2014) that having the ability to identify performance variables, is as an asset to organisations. Salehi, Veitch and Smith (2020) are ofthe opinion that being able to recognise the sources of variability is crucial for safety management. The FRAM provides staff with the ability to identify unwanted or positive variability and recognise the consequences of variability to patients and the impact on the system (Kaya, Ovalib & Ozturk, 2019; O'Hara, Baxter &

Hardicre, 2020; McNab, 2018). Hounsgaard (2016) observes that while using the FRAM, system inefficiencies are highlighted which can result in unwanted outcomes. Staff become aware of the downstream impact that their behaviour may have on safety outcomes.

- **Understanding Work as Done** as discussed earlier in this dissertation, the complexity of healthcare makes it difficult to form an understanding of how work is performed and to know what the impact of various conditions are on performing the work. This dissertation highlights that users find the application of FRAM valuable as it enables them to form a deep and detailed understanding of how work is performed, and they can visualise how work is done. To improve the safety of the system, one needs to understand how tasks are normally performed and identify what went well, instead of only focusing on failures (Hollnagel, 2012).

- **Enable learning** is identified to be the third most value-added aspect. With the application of FRAM, individuals and teams learn about the way in which they perform their daily work (McNab, 2018). Several studies confirmed that FRAM opens the opportunity for deep learning. O'Hara, Baxter and Hardicre (2020) can identify safety gaps which has been unknown to healthcare staff before. The safety framework developed by Vincent, Burnett and Carthey (2013) highlights the ability to integrate and learn as important aspects. An organisation must be able to use information to analyse, respond and transform it into meaningful learning and improvement plans.
- **Enabling improvements** are realised to be the fourth most value-added aspect. The FRAM is described by Reason (2016) as a promising way forward in the improvement of safety within complex systems. In the dissertation there are various examples of how FRAM was applied to enable improvement within the organisation and Roland (2018) confirm this by describing FRAM as 'especially useful' in driving improvement. Recommendations for improvement interventions to be successful in complex systems, include defining the problem in detail, use co-design and involve frontline staff in improvementinterventions and consider social and the technical aspects (Marshall et al. 2017). Frontline staff participate in creating the FRAM (Buikstra, Strivens & Clay-Williams, 2020; Damen et al., 2018; Kroeze, Wimmer & Hounsgaard, 2019; O'Hara, Baxter & Hardicre, 2020). O'Hara, Baxter and Hardicre (2020) also argue that patients and families ought to be involved to co- design solutions. Damen and colleagues (2018) describe the involvement of staff in improvement as 'vital for success' and by involving staff, it reveals the naturally developed systems which staff developed to deal with daily work.

- **Prospective application** is regarded as the fifth most value-adding aspect. In the safety framework of Vincent, Burnett and Carthey (2013) anticipation and preparedness is seen asa vital aspect of safety, as it provides the ability to anticipate and prepare for potential hazardsand risks. Damen and colleagues (2018) describe the prospective application of FRAM as a unique feature. Saurin & Werle (2017) indicated that FRAM assisted them to anticipate by identifying gaps.

- **Identify human factors** is the sixth most value-added aspect. It can be seen as a subset of 'identify performance variability' but it was coded separately as healthcare heavily relies on person-centred interactions. Shire and colleagues (2018) are of the opinion that the FRAM ismost often used in the healthcare industry, as healthcare is a social system rather than an engineered system. Functions are usually grouped into human, organisational, and technological functions, with human functions being the most variable (Hollnagel, 2017). People are however regarded as a valuable resource to improve the quality, safety, and resilience of systems in terms of Safety II thinking.

- **Managing complexity** is perceived as the seventh value-added aspect. Complexity is inherent to healthcare (Carayon et al., 2011). In this dissertation several studies indicate thatthe FRAM clarifies and managing the complexities of work. Salehi, Veitch and Smith (2020) concluded that by applying the FRAM, organisations benefit as it can improve their ability to perform safety management in complex socio-technical systems. Patriarca and colleagues (2020) describe FRAM as useful to perform an analysis of socio- technical behaviours in complex work environments. Buikstra and colleagues (2020) and O'Hara and colleagues (2020) highlight that by managing functional resonance in complex systems, FRAM can improve the health and safety of patients.

- **Reconciling WAD and WAI** is the eighth aspect and can be linked to 'Understanding Work as Done', as one needs to understand how work is performed currently in relation to how it is described in policies, before reconsolidation can happen. There is consensus between studies in this dissertation that the application of FRAM can be used to find practical solutions to iterate and refine guidelines.

- **Performing incident investigations** is a specific type of application of FRAM. This aspect isalso mentioned in the safety framework developed by Vincent, Burnett and Carthey (2013). Having the ability to know if patient care has been safe in the past, can be measured by meansof harm-related outcomes to patients. It has been reported that FRAM is a useful model to collect the necessary information for incident investigations and that the analysis reveals functions that are dependent on each other, which is a dimension usually missed in incident investigations.

6. CONCLUSION

In this section the author will endeavour to integrate all the information.

The aim of this dissertation was to explore the application of FRAM in healthcare and thereby develop a rich understanding of the capability that FRAM can offer healthcare to manage safety. The results are expected to provide healthcare organisations with guidance on applying the FRAM and demonstrate the value it potentially adds to safety management.

The first objective was to understand where and how FRAM has been implemented within healthcare organisations. The results indicated that FRAM has been applied in multiple settings and it can be widely applied in many contexts within healthcare. This dissertation thus confirms the notion of other studies in this regard. The wide applicability can add value, as quality and safety teams can be taught one model which can be used in conjunction with others or by itself for many types of application. The applications are done in big settings, for example the GP referral system in Brazil, as well as on single cases such as an incident investigation. The model is also applied in developed as well as developing countries with equal success.

The dissertation highlights some real-world applications, which may resonate with healthcare staff and may provide them with practical guidance on how to implement the FRAM. Guidance on how to implement FRAM may not have been fully realised in all the aspects, as FRAM was applied in a very wide spectrum which does not allow for a detailed analysis of each circumstance. The author is nevertheless confident that potential new users of FRAM will benefit from the knowledge gathered on the application of FRAM.

The second objective focus on forming an understanding on how healthcare organisations have perceived the value-add of FRAM in terms of safety management. The result of this objective is the identification of various thematic outcomes which was realised when applying FRAM. The dissertation indicates various examples of how FRAM can add value to the ability of healthcare organisations to manage safety. The application and outcomes of the FRAM was grouped together to identify the most value-added aspects. These aspects have been discussed in term of their value in managing safety by using information gathered during this review, combined with information extracted from reviews by other authors. The scoping review of Patriarca and colleagues (2017) on the relevance of using a Resilience Engineering (RE) approach in a complex healthcare environment, demonstrates that a RE approach has the potential to be used to enable a ‘paradigm shift’ in the management of safety within current and future healthcare systems. This ‘paradigm shift’ is needed to enhance the safety ofpatients in healthcare. This dissertation can confirm that the application of FRAM is able to support healthcare organisations to manage safety in various ways.

Organisations can improve their performance with a proactive approach, rather than having a reactive approach, which only focuses on investigating rare incidents. By applying FRAM, healthcare organisations can form a deep understanding of how their systems functions and a Safety-II approach becomes possible, where the focus is to discover why things normally go right. In studying WAD, light is shed on performance variability, which Patriarca and colleagues (2017) refer to as the real source of success as well as of failures. This dissertation confirms the value of having the ability to identify performance variability, as this was identified as the most value-adding aspect by all studies.

The negative aspects and/or requirements to implement FRAM are clearly highlighted for organisations, should they wish to consider the application of FRAM. Patriarca and colleagues (2020) is of the opinion that implementing FRAM is not an easy solution, as 'modern tightly interconnected systems' are subject to resource constraints and have pressures to provide solutions that are quality and safety conscious, while being effective. This dissertation acknowledges that FRAM is a young model still undergoing development (Alm & Woltjer, 2015; Salehi, Veitch & Smith, 2020). The author however believes that the value-added aspects are of greater significance and hope that this dissertation will serve as motivation for organisations to explore the use of REs methods, such as FRAM, to manage safety.

6.1 Limitations

Despite the increased application of FRAM in the healthcare environment, it needs to mature within the healthcare setting. There is a limited amount of peer reviewed articles published and no controlled trials. The results or impact of the application of FRAM has not been investigated for an extended period in healthcare organisations. The scope of this review is limited to healthcare, and it is not doing a comparison between different industries to support its applicability across the board. A meta-analysis was not conducted as part of the study objectives, a recommendation for future studies would be to conduct a quantitative synthesis. The review is not specifically applying the methodology in a specific setting, but rather reviewing how others have applied FRAM.

6.2 Recommendations

Successful applications of FRAM and improvement efforts have been noted in the various studies. There is however a lack of literature describing the sustainability of FRAM interventions. It is therefore recommended that healthcare organisations who have been applying FRAM, do follow-up investigations to determine the long-term impact of the application of FRAM.

The author also recommends that healthcare organisations that is currently following traditional safety management methods, should consider the application of FRAM, as the application of FRAM is able to support healthcare organisations when managing safety. The application of FRAM can be incorporated in the safety management practises of developing countries. Developed and developing countries can do a combined application of FRAM.

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Appendix 1: Protocol

Division of Biomedical Engineering

Department of Human Biology

University of Cape Town

Impact of the Functional Resonance Analysis Method (FRAM) in safety management at healthcare organisations

Executive Summary of Research Proposal

in partial fulfilment of the requirements for the degree:

MPhil in Health Innovation

Maatje Wessels (VWYMAA001)

Supervisor: Dr Jill Fortuin

Co-supervisors: Prof. Tania Douglas

September 2020

Introduction

'Just as medicine understands more about disease than health, so the safety sciences know more about what causes adverse events than about how they can best be avoided.' (Reason, 2000).

The World Health Organisation has indicated that adverse patient safety events are likely to be one of the 10 leading causes of death and disability in the world (Patient Safety, 2020). Safety is the avoidance of unexpected events such as adverse outcomes, whereas safety management is the process to ensure that certain safety functions are accomplished (Li & Guldenmund, 2018). The aim of safety management is to consistently ensure that adverse outcomes occur as rarely as possible (Hollnagel, 2017) and to purposefully make it possible for things to go right.

Safety management in various high-risk industries such as aviation, nuclear, rail and healthcare entails performing investigations to learn from adverse outcomes. Li and Guldenmund (2018) highlight that organisations can derive ample information from researching accidents, whereas Hollnagel (2004) reason that adverse outcome investigations only provide insight into a 'snapshot of time' when things go wrong. In healthcare, the traditional focus of safety management is to identify failures, perform an analysis and develop strategies to reduce the failures. This approach is known as Safety-I (Hollnagel et al, 2015) or a 'find and fix model' (Braithwaite, Wears & Hollnagel, 2015). Braithwaite, Churruca & Ellis (2017) argue that insights derived from Safety-I can be useful, but that they are barely adequate to form a comprehensive understanding of safety in complex systems. Braithwaite and colleagues (2015) highlight that safety management must include Safety-II, which is characterised by rigorous efforts to enable things to go right repeatedly. This should include a proactive approach in which organisations are enabled to improve everyday performance, rather than a reactive approach only focussing on rare adverse outcomes. A system is not safe, just because it reports a low number of adverse outcomes (Hollnagel 2017). Despite attempts to improve safety management in healthcare, efforts to prevent adverse outcomes have been unsuccessful (Kellogg, 2016; Mannion & Braithwaite 2017). There is a realisation that solely focusing on the elimination of adverse outcomes will not improve safety, and there is a growing dissatisfaction with progress in patient safety (Thompson et al., 2016; Mannion & Braithwaite, 2017). Work processes in healthcare have become more integrated, complex, and demanding to the persons trying to manage the interaction between humans and technical systems that produces safety (Hollnagel, 2017). In other words, health care work is unpredictable, operational principles are not entirely described, and work conditions are underspecified and have many unknown relationships (Braithwaite et al., 2015).

Safety management is complex and there is not a single solution or focus that will enable healthcare to make systems safer. If healthcare organisations want to broaden their approach towards managing safety, they must investigate suitable methods.

The Functional Resonance Analysis Method (FRAM) was developed by Hollnagel in 2004 and has been applied in other high-risk industries including healthcare. FRAM investigates the interaction of the different functions within a complex, underspecified system, and improves the understanding of normal work and its variability (Hollnagel, 2012). FRAM can identify where variability in a system occurs and how this variability contributed to an adverse outcome, or not (Hollnagel, 2012). FRAM can be applied either retrospectively or prospectively. It provides the basis for adverse outcome investigation and risk analysis, as well as redesigning or designing a system. This systematic review will evaluate the literature on the implementation of FRAM in healthcare organisations. It will explore the application of FRAM in healthcare and thereby develop a rich understanding of the capability that FRAM can offer healthcare to manage safety.

1. Research Question

The study will answer the following research question: “How does the application of **Functional Resonance Analysis Method (FRAM)** support **healthcare organisations** to enhance their ability to **manage safety**?”

Table 1: The Patient Intervention Comparator and Outcome (PICO) of the study

Participant	Healthcare organisations
Intervention	Application of the Functional Resonance Analysis Method (FRAM)
Comparator	
Outcome	Safety management

2. Proposed Methodology

A systematic review of literature will be conducted on articles that have described the application of FRAM in a healthcare setting. We will review both scholarly peer-reviewed journal articles and studies published in books as well as grey literature which includes conference papers and published dissertation material which describe the application of FRAM in any healthcare setting.

3. Inclusion and Exclusion criteria

Inclusion of studies

- Scholarly peer-reviewed journal articles and studies published in books, written in English.
- Grey literature of conference papers and dissertations published describing the application of FRAM in any healthcare setting.
- Time period of 2004 -2020 (FRAM framework was developed in 2004)
- Healthcare and Humans, the use of FRAM in the context of healthcare provided to humans.

Exclusion of studies related to

- FRAM in non-health disciplines
- Occupational health and safety
- Personal resilience

4. Search Strategy

We will identify both published and unpublished studies and grey literature from 2004 - 2020. The databases to be searched will include EBSCOhost, Ei Compendex, Google Scholar, Medline, Ovid, ProQuest, PubMed, Science Direct, Springer Link and Web of Science. Google will be used for grey literature. So far, a scoping search in PubMed has yielded 18 potential articles which are to be screened.

Table 2: Preliminary search

Search No	Search Term	Results
#1	Functional Resonance Analysis Method OR FRAM	18
#2	Health system OR Healthcare systems OR Health services OR Healthcare organization OR Hospital shared services OR Delivery of healthcare OR Delivery of healthcare standards* OR Humans OR Hospitals* OR Workplace OR organisation OR health administration OR Health Services Research	20,733,690
#3	Work as done OR Work as imagined OR Safety-I OR Safety-II OR Resilience Engineering OR safety differently OR socio-technical system OR Continuous Quality Improvement OR Assessment OR Methods OR Resilience OR Resilient health care OR Safety resilien* OR Ergonomics OR Patient safety* OR Systems analysis* OR PatientSafety/standards* OR Safety management/organisation & administration* OR Quality Improvement/organization & administration*	11,620,438
#1 and #2 and #3		18

The author and an additional researcher will independently review the titles and abstracts of identified articles for eligibility for the study. Any discrepancies will be resolved through discussion, and should consensus not be reached, a third researcher will adjudicate. The author will then read the full text of the identified articles to make a final assessment for inclusion and will consult the second and third researchers in ambiguous cases.

5. Data Extraction and Data Synthesis

A data extraction form will be created. Data to be extracted will include, type of study, authors, year, country, type of application, the setting or context and the findings or results of the studies. The data will be summarised in a narrative synthesis. Quantifiable data will be presented in a quantitative manner (e.g., geographical distribution of health facilities).

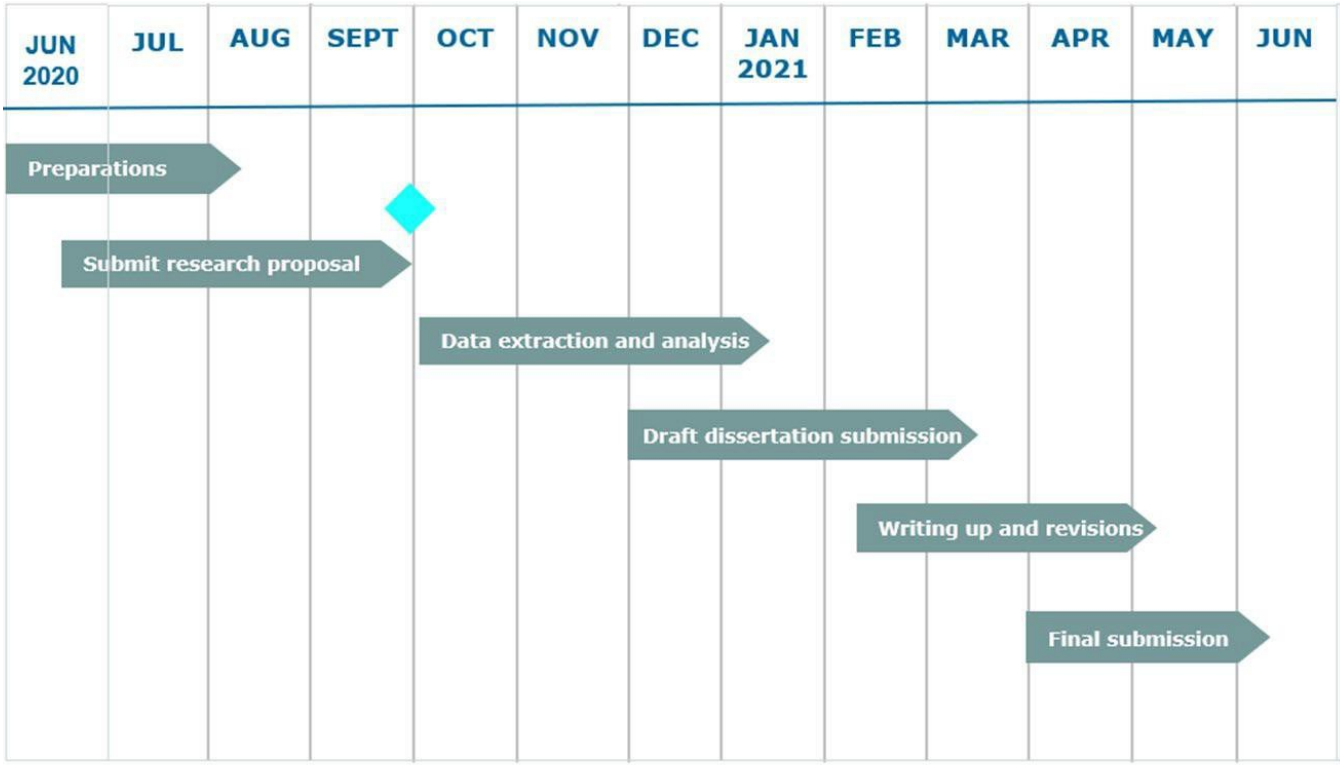
6. Conclusion

This systematic review will review the application of FRAM in healthcare settings to develop a rich understanding of the application of FRAM in healthcare as a complementary method to safety management; firstly, understanding how FRAM was implemented within healthcare organisations and secondly understanding how healthcare organisations have perceived the value-add of FRAM in terms of safety management. The results are expected to provide healthcare organisations with guidance on applying the FRAM and demonstrate the value it potentially adds to safety management.

7. Expected Output

- Publication in a peer reviewed journal.
- Understanding how FRAM was implemented within healthcare organisations.
- Understanding how healthcare organisations have perceived the value-add of FRAM in terms of safety management.
- The results are expected to provide healthcare organisations with guidance on applying the FRAM and demonstrate the value it potentially adds to safety management.

8. Project Schedule



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