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Paediatric Homecare Risk Management: An Application of Functional Resonance Analysis Method (FRAM)

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Abstract: Paediatric homecare is an advancing field of healthcare, bringing care direct to patients in their own homes. Risk management is an integral component of homecare services, including incident and risk assessment management. The objective of the study was to investigate risk management in homecare focusing on two aspects: incident reporting and risk assessments. A Grounded Theory approach was used to gather key functions of these aspects; these were then mapped using the Functional Resonance Analysis method (FRAM). Nineteen nurses working in paediatric homecare services were interviewed for the study. The interviews were semi-structured and focused on risk, quality, complaints, audit, care, and management. The interview data were transcribed and coded using Nvivo; the data were then converted into functions for utilization in the FRAM tool. The FRAM detailed the process of incident reporting and risk assessment management of the actual work carried out as viewed by the participants of the study. The information was then analysed and contrasted with the organizational policy to gain an understanding of the systems of incident reporting and risk assessments, which then led to the development of a refined process that could have less variability in function. Consequently, changes to policy and training in risk management were recommended to enhance the systems.

Keywords: homecare; risk management; incident reporting; risk assessment; nursing

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1. Introduction

Nursing children with complex healthcare needs in the community is a growing field in Ireland and, in a wider context, globally. The definition of complex healthcare needs varies throughout the world with the use of terminology such as life-limiting conditions, medically dependent children, and children with complex care needs [1]. Researchers have undertaken systemic concept analysis of the multidisciplinary language of children with complex care needs. The term "complex and integrated care needs" [1] is recommended for use in Ireland.

In Ireland, it is estimated that there were 3840 children living with life-limiting conditions in 2010 [2]. Five years prior data, using the prevalence rate of 12 per 10,000 population in the 2005 Irish census data, an estimated 1369 children were living with life-limiting conditions [3]. This is likely to be an underestimate, and recent data from the Laura Lynn Foundation put the estimated figure at 14.5 per 10,000 population [4]. The Health Service Executive (HSE) in Ireland's 2020 National Service Plan considered that 537 children with complex medical conditions would need to have home care packages meeting their requirements. The HSE has developed a framework for private and charitable organizations to manage these packages. Integral to the framework is the establishment of clinical governance processes [4]. The main risks that healthcare workers face in the home include lone working as well as a lack of training and supervision. In a scoping review of the literature, researchers found that adverse drug events as well as line-related, technology-related, infection, catheter, wound, and fall adverse events were all evident in-home setting [5]. The

complexity and diversity of paediatric home care can therefore be described as a complex sociotechnical system.

The management of risk is an integral part of the management of complex and integrated care needs. The initial phase of the assessment of risk in relation to homecare is the decisions made in acute care settings, with respect to the medical stability of the child to be cared for at home, by both parents and medical staff. This process is complex and multifaceted, ranging from the equipment to be used, to the operators, management, governance, training, and the suitability of the home setting. This process is undertaken with both acute care and primary care staff. The principles of the ISO 31000:2009 risk management standard is used by medical staff [6].

Incident reporting and management are critical for healthcare quality and improvements in patient safety [7]. Learning from incident reports, reported injuries, common trends, and themes is also a critical component of incident reporting [8]. Other forms of learning are associated with incident reporting by reviewing medic–legal litigation cases to establish procedures for reporting incidents and management [9].

FRAM is a tool for assessing resonance and variability of functions in complex systems [10]. The FRAM can be described in four principles:

1. Failures and success have the same origin; events can go right just as much as they go wrong.
2. Humans adjust to match the socio-technical systems.
3. The outcomes we see or do not see are emergent.
4. The interdependent relationships between the functions and the resonance can cause development in the systems.

The FRAM model is used to describe essential activities that build up a process based on functions. This can then be visualized using the tool permitting analysis of the system under examination. Each function has one or several aspects which are an input, output, precondition, resource, control, and time, with each function linking to another function in the process. Variability in relation to time and precision can then be assessed with each function. The FRAM has been used widely in the assessment of complex socio-technical systems since its development in 2012. In the literature, FRAM can be seen in fields like ground handling services in airports [11]. Studies have demonstrated the benefits of systemic as opposed to linear approaches to safety investigations, for instance, by looking at the socio-technical systems in flood defences in the Netherlands [12]. Comparing accident analysis methods of Sequential Timed Events Plotting (STEP) and FRAM, the FRAM identified the dynamic interactions of functions compared to illustrations of what happened, by whom, and when in the STEP [13].

In healthcare, FRAM has been used in the analysis of falls and delirium in older inpatients, whereby a substantial gap between work as done and work as imagined was detected. This demonstrated the usefulness of the tool [14], e.g., in risk assessments within healthcare [15], and for understanding healthcare processes using FRAM in the early detection of sepsis, resulting in the FRAM identifying new processes previously not revealed in the referral process [16]. Adaptations of the FRAM were undertaken to capture qualitative and quantitative characteristics of the variability, called the DynaFRAM [17]. This was used in demonstrating healthcare-related case studies. In handover of patients in transitional care from multiple stakeholders, the FRAM identified the complexity of the transition from hospital to home care [18]. The analysis particularly focused on the upstream functions and reducing variability. Reviewing protocols of double-checking injectable medications administration using FRAM was undertaken by Schutijser; this was carried out through interviews with 27 nurses in an acute hospital and identified differences between work as done and work as imagined [19]. Aligning work as imagined with work as done in relation to clinical guidelines was studied by Clay-Williams. The aim was to reduce workarounds by clinicians and facilitate changes to guidelines based on the FRAM to mitigate the risk from workarounds [20].

2. Methodology

To be able to gain an understanding of the work as done in relation to incident reporting and risk assessment management, in-depth semi-structured interviews were conducted with 19 nurses working in paediatric home care in Ireland. All were qualified nurses, females of varying ages and all with over 3 years of experience in paediatric care. The study location was with Resilience Healthcare, a private healthcare company that has over 120 homecare packages across Ireland. The qualitative approach was underpinned by the constant comparative analysis, theoretical sampling, and memo writing of Grounded Theory [21]. The overall objective was to gain an understanding of the two systems: reporting incidents and risk assessments. The interviews were structured with open-ended questions to allow exploration into participants' views on incident reporting and risk assessment management. The aim of these interviews was to capture the work as done by the participants. The transcribed interview data were mapped into functions related to incident reporting and risk assessment processes. This was then developed further using the FRAM software (version 6.1) in mapping interactions of functions and the variability of each function of the work as done. A methodological approach using the FRAM principles was completed [10,22].

3. Results

The methodology used in the study enabled a comprehensive examination of the risk management procedures in paediatric home care. The study was divided into two parts, firstly that of incident reporting and secondly the risk assessment process used. The results are from the use of FRAM as an analysis tool for both parts.

3.1. Incident Reporting

Incident reporting in the services is derived from the policy within the organization. The policy clearly outlines the reasons for reporting, the process, and the analysis of incidents. The employees are inducted on the policy procedures and regular training is undertaken on incident management.

The FRAM details each function of the incident management process following the analysis of interview data of employees. The interview transcripts were analysed using NVivo to detail each function. This can be seen in Figure 1 in the FRAM diagram. The FRAM represents the work as done and not the process stated in the policy.

The starting point of the FRAM is the actual event (Event Function). During the interviews, participants described an actual event defined as an incident or a near miss that they had experienced during the care episodes, which meets the criteria stated in the organization's policy. The event is recorded as a function with a time aspect for reporting within 24 h of identification. Following the event, participants described the measures taken to maintain the safety of the client, which outlined a separate function for safety (Safety Function). Safety was described throughout the process, predominantly at the start of the event. Following the event, the nurse made a decision (Decision Function) about the next steps in the process. This decision was very individualized but fundamentally involved four functions. Participants have access to an emergency call bell, which alerts the parents (Inform Function) who would be asleep in an adjacent room. This call bell is designed for emergencies. Participants can use this to alert the parents of the incident, or the parent could be notified later, dependent on the event. The participants have the option of doing nothing, neither reporting or raising a concern to either the parents, nurse manager, or on-call staff, or recording the event in the progress records (Inhibitor Function). More often, as described by the participants, there would be a discussion with the nurse manager at a convenient time (Management A Function). This would happen the following day on most occasions or during the on-call arrangements. The participants could report the incident using the incident reporting procedures (Report Function). These procedures are in the form of an electronic reporting process available on the care management system. The

function of a decision had an associated pre-condition as stated in the Incident Management Policy of the organization, which stated what and how to report.

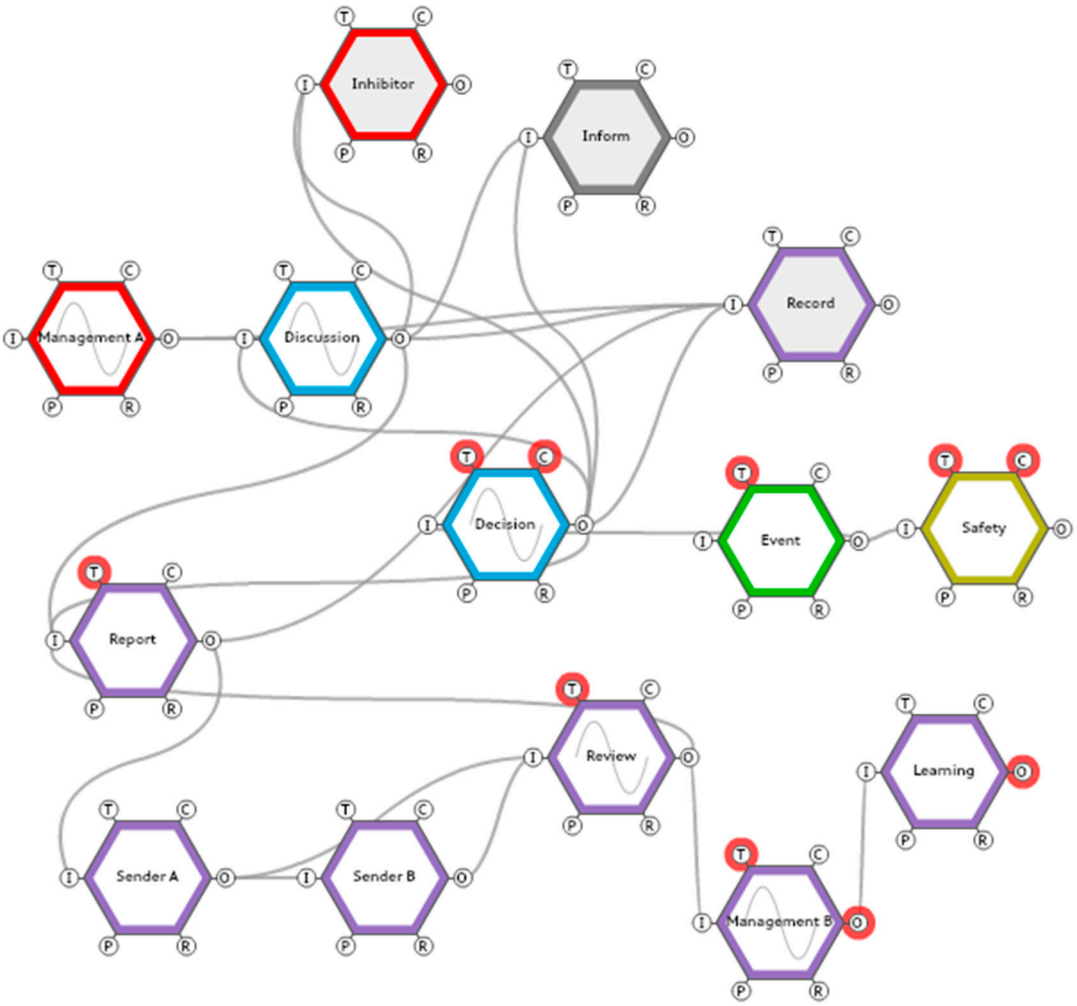

Figure 1. Incident-reporting FRAM.

The decision made by the participant communicating with the manager was identified in this study as the predominant approach following an event. This decision was evident dependent upon the actual severity of the event itself. As an example, if a client had a de-canulated endotracheal tube event, the parents would be called as well as on-call and the nurse manager informed later. If the event was of a minor nature, then a discussion with the nurse manager could occur later. The nurse manager discussion resulted in several outputs from the function. Reporting and managing the event through the incident management procedures and notifying of the event to the parents were recorded in most of the participants' events. The option recorded as a function of do nothing (Inhibitor Function) was recorded by the principal investigator, as this was an option available for participants. The final function was that of recording the event in the care record system (Record Function).

Following reporting of the event, there was an automated technological function whereby the incident form was notified, via an automated email, to the Risk Management Department and the Nurse Manager (Sender A&B Function). This then sets in motion the process of review, investigation, management, learning, and external reporting of the incident (Review, Management B & Learning Functions). The functions of reviewing the incident had a time aspect recorded of 14 days to review. The learning from an incident identified as a function was not essential to the analysis of the FRAM and incident reporting.

Overall, there were 14 functions identified using the FRAM for incident reporting. Of these 14 functions, 2 of them had time-related aspects associated with the functions. Each function has a type recorded against it; this could be human, technological, organizational, or unidentified. Two of the function types related to technology connected with the automated reporting process, and the remainder were all recorded as human.

The key aim of FRAM is the assessment of variability in a function and the resonance this could cause for the downstream functions. In the incident reporting FRAM, the variability was first detected in the decision function. This decision is made by one nurse, at the time of the event, and the related circumstances of the event and would have significant variability for all the downstream functions. If the decision was made not to report, then the event could go unnoticed and, consequently, there would have been very limited learning. The consequence of this could mean the event might occur again, potentially causing harm. The second variability was in the discussion function with the Nurse Manager. This is again linked to the potential consequences of not reporting. The likelihood of this variation in this function was less due to the experience and accountability of the Nurse Manager, who would have a professional and ethical duty to report. The final variability was identified in the management of the incident functions. As the functions are human in nature, variability could occur at this stage, possibly resulting in similar consequences as with the decision not to report an event. The functions that have variability are listed in (Table 1) together with the type, description, functional aspects, variability related to time, and variability related to precision.

Table 1. Functional variability in incident reporting.

Function	Type	Description	Aspects	Variability/ Time	Variability/ Precision
Decision	Human	Staff member on duty makes a decision relating to managing the event	Input: Reporting action Outputs: Report Discussion Inform parents Do nothing Record event Control: Incident Management Policy Time: 24 h to report	Not at all	Acceptable
Discussion	Human	Staff member decides to discuss the event with the line manager, either by phone, text, email, or in person	Input: Discussion Outputs: Reported Parents informed Manage event Do nothing Record	To late	Imprecise
Management A	Human	Nurse Manager and staff member manage the event, not reported	Input: Manage event Output: Record on Care Management System	Too early	Imprecise

Table 1. *Cont.*

Function	Type	Description	Aspects	Variability/ Time	Variability/ Precision
Review	Human	Review of the incident by managers	Input: Review Outputs: Update E-Form Root Cause Analysis Time: 14 days to review	Too late	Imprecise
Management B	Human	Managers responsible manage the event, review root cause, grade, categories, report externally, learn	Input: Root Cause Analysis Outputs: Learning External reporting Time: External reporting timeframes	On time	Acceptable

3.2. Risk Assessments

The organization has an established risk management policy which is embedded into the organization's internal structures. The policy reflects the process for undertaking a risk assessment, the management of risks, the risk registers and the reporting, escalation, and evaluation of risks. The policy is part of the induction for new employees and an ongoing teaching program for established staff with refresher training. The policy reflects the dynamic assessment and variations in risk across the business, from financial, health and safety, emergency planning, clinical, operational, strategic, and positive risk-taking. The risk management policy within the organization is based on the regulatory requirements and service-level agreements with clients.

The analysis of the risk system was undertaken in the semi-structured interviews with staff. Details about the specific functions of risk management were gained through the coding of transcripts following interviews.

The FRAM details the functions of risk management in paediatric homecare as seen from a nurse's perspective. The FRAM visual is presented in Figure 2.

The starting points for the risk management FRAM are detailed by the Hazard A to G Functions in Figure 2. These are in the form of the identification of risks. The study highlighted seven functions pertinent to the identification of risks. Information arises from the initial referral and communication with the public health nurse (Hazard A Function). These were mainly focused on the clinical nursing requirements to manage the service, such as details about the specific diagnosis, past medical history, and the clients' activities of daily living (Hazard B Function). On occasion, aspects such as social circumstances, family dynamics and previous commissioned service would be gained. The identification of known hazards predominately originates from the Nurse Manager (Hazard C Function). These are based on the experience of the nurse manager, often linked to other services provided, for example, the risk of fire, slips, trips, and falls, and infection, prevention, and control. Risks arising from incidents reported (Hazard D Function) predominantly focus on the process once the service has been established. An incident reported and reviewed by the nurse manager, in turn, can alter the risk assessment as the future risk of re-occurrence could be heightened or reduced. The nurse manager meets with the commissioners of the service and other stakeholders as deemed necessary and gains information relevant to known risks (Hazard E Function). Prior to commencing the service, the nurse manager will visit the client's home and undertake an environmental risk assessment of known risks (Hazard F Function). In numerous discussions with the parents, client information that would highlight any risks is gained and forms part of the assessments (Hazard G Function).

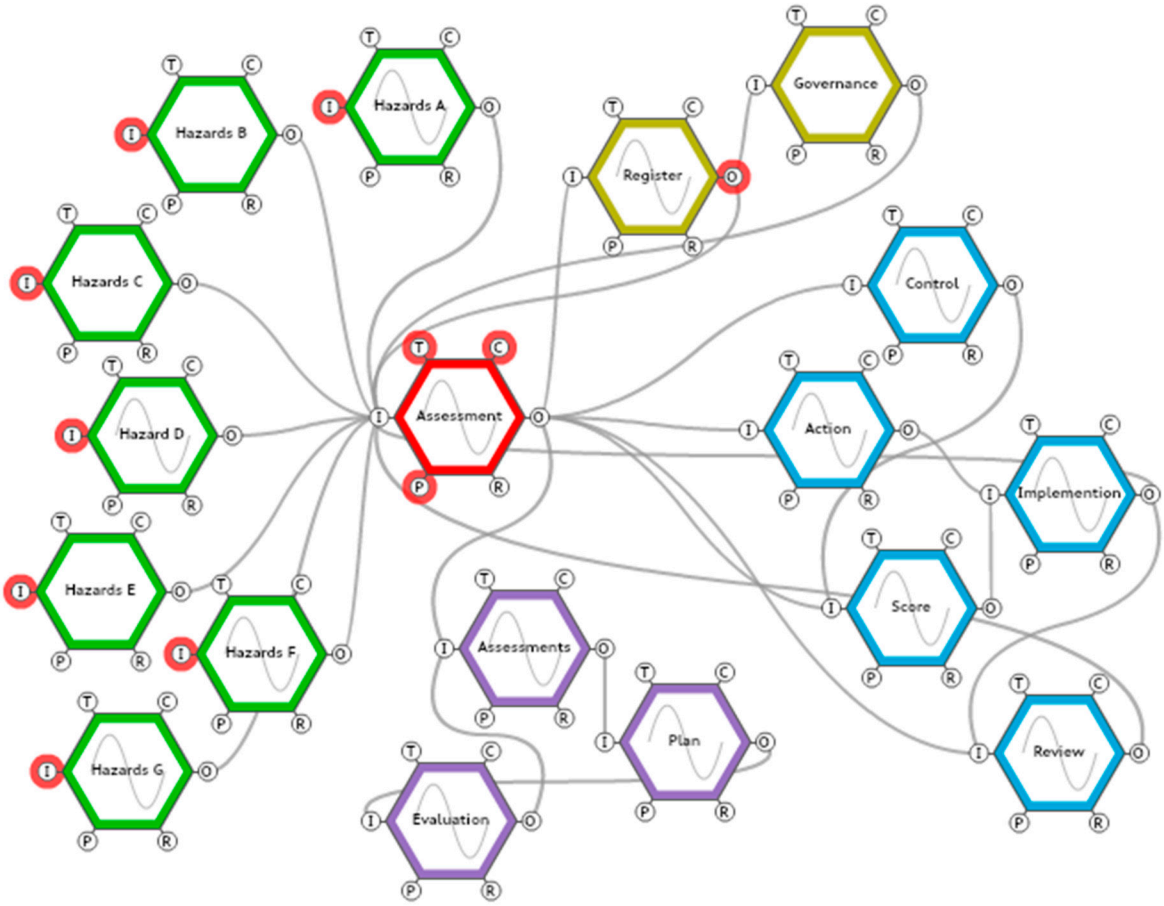

Figure 2. Risk assessment FRAM.

Comprehensive care plans are developed and tailored for each service; these include, as part of the nursing care, assessments using specific tools such as the *Waterlow* score, which gives an estimated risk rating for the development of a pressure sore, nutritional screening, and patient moving and handling. Whilst these are independent risk assessments, they form part of the overall risk management of the service. These are evaluated regularly, and the care plans change accordingly in the assessment, planning and evaluation functions.

The management of risk assessments follows a process of assessing the hazards associated with the risk, detailing the controls and subsequent actions needed to manage, mitigate, or reduce the risk. The process of scoring the risk involves their assessment, firstly the level of risk using a five-by-five matrix of the risk before controls. Following this, the risk is scored again following the controls, and, finally, a residual risk rating is calculated. Each risk assessment has actions arising from the assessment to reduce or monitor the risk (Action, Control, Score, Implementation and Review Functions).

From the risk assessments which are centrally controlled, different combinations of risk registers can be gained dependent upon the need. As an example, a specific register could be constructed for all health and safety risks or fire risks (Register and Governance Functions). These are detailed in the FRAM (Figure 1). The functions have been grouped by colour according to functional groups:

- Red is the assessment of risk
- Green is the identification of hazards
- Purple is the clinical care planning
- Yellow is the registers and overall governance
- Blue is the risk assessment actions

The construction and analysis of the risk assessment FRAM enabled the detection of variability in specific functions. Variability was not detected in the functions of clinical risk assessment and the governance committee.

The risk assessment process based on the functions in Table 2 is prone to variability and the possibility of downstream effects to other functions. As the process of identifying a hazard and assessment of the controls and actions relies on the human ability to know the risks and then record them, the resonance of such affects the ability to form comprehensive risk registers and have operational governance of the system.

Table 2. Functional variability in risk assessments.

Function	Type	Description	Aspects	Variability/ Time	Variability/ Precision
Assessment	Human	(Marked in red) Risk assessment on E-Form by Nurse Manager	Input: Identification of hazards Pre-condition: E-Form Control: Essential fields Time: Scheduled revies	Too late	Imprecise
Hazards (Grouped)	Human	(Marked in green) Public Health Identification of known hazards Incident Reporting Nurse Manager Assessment Home Visits parents	Inputs: Information pertaining to the function Output: Assessments made of the identification	Too late	Imprecise
Assessments, Plans and Evaluation	Human	(Marked in purple) Clinical Risk Assessments and Care plans plus Evaluations	Inputs: Clinical Risk assessments Re-evaluation Output: Care Plan	Too late	Acceptable
Registers	Organisational	(Marked in yellow) Specific risk registers	Input: Risk assessments Outputs: Registers Staff access Parent access Stakeholder access	On time	Imprecise
Assessment of risks	Human	(Marked in blue) Controls Scoring Actions Reviews Implementation	Input: Root Cause Analysis Output: Learning External reporting Time: External reporting timeframes	Too late	Imprecise

The overall analysis of the risk management systems in this study by reviewing the work as done, gave an insight into the actual risk management process used by staff. As these systems are defined in policies, what is called the imagined work, a comparison between the two systems can be made following step four of the FRAM process. The policy can therefore be amended in order to improve systems.

4. Study Limitations

A limitation of this study is that it was a small-scale and one-organization study.

5. Discussion

The process of incident reporting relies profoundly on the nurses' skills in knowing what to report, having the integrity to report, and being open and honest in reporting. The systems of incident reporting have been established in healthcare for some time now; all the nursing staff interviewed were aware of incident reporting. Essential in this process would be ease of access to reporting. This is not only about accessing the incident form but the complexity of the incident form. If the form is overly complex, then there is a further burden on the nurses to write all the necessary information.

During this research, the function of discussion of a potential incident was prominent with nursing staff. Discussing the potential incident with a colleague was identified in the FRAM and forms an essential part of the work as done, compared to that written in the policy. Policy and training should reflect the process of discussion and ensure less variability in this function.

The FRAM analysis identified that the system for risk assessment relies heavily on the input of known risks from the multi-disciplinary teams involved in the client's care. This then has a resonance on the whole risk management system if a risk is not identified. Therefore, the identification of risks is an essential component of the process. Assessments can be in multiple formats and sources and the risk management system could be an essential tool for the collation of this data in the form of assessments of risk.

The FRAM is a tool in the toolbox of risk management that enables the analysis of a socio-technical system in the form of functions, variability, and resonance. A very essential aspect of using FRAM is to ensure that the critical work as done is analysed from the perspective of the staff who undertake the work. Without this, the downstream effect of the FRAM would not be productive. The tool is easy to use and allows for the adaptation of the functions and the connections between functions.

6. Conclusions

The use of FRAM as a tool to understand the work as done, for complex socio-technical systems, has value in understanding aspects of these systems that work, do not work, or need improving. The tool, although initially challenging to work with, becomes more intuitive as you progress with the system under study. The FRAM visualizing component allows the study to be presented back to the participants of the study, which has value in understanding the work as done. Understanding the work as done can then facilitate changes in policy and training in risk management.

Whilst this study only reviewed two semi-complex systems of incident reporting and risk management, undertaking a review of a more complex healthcare system would take substantial time and resources, and those who do this should assess the time and cost benefits against the predicted outcome.

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