

Combining Failure Mode and Functional Resonance Analyses in Healthcare Settings

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Abstract. Socio-technical systems rely on technological artefacts as well as human and professional practices in order to achieve organisational safety. From an organisational viewpoint of analysis, different safety barriers are often put in place in order to mitigate risks. The complexity of such systems poses challenges to safety assessment approaches that rely on simple, identifiable cause and effect links. Failure Mode and Effects Analysis (FMEA), for instance, is an established technique for the safety analysis of technical systems, but the assessment of the severity of consequences is difficult in socio-technical settings like healthcare. This paper argues that such limitations need to be addressed by combining diverse methodologies in order to assess vulnerabilities that might affect complex socio-technical settings. The paper describes the application of FMEA for the identification of vulnerabilities related to communication and handover within an emergency care pathway. It reviews and discusses the applicability of the Functional Resonance Analysis Method (FRAM) as a complementary approach. Finally, a discussion about different aspects of emerging technological risk argues that taking into account socio-technical hazards could be useful in order to overcome limitations of analytical approaches that tend to narrow the scope of analysis.

Keywords: Failure Mode and Effects Analysis (FMEA), Functional Resonance Analysis Method (FRAM), Healthcare.

1 Introduction

Since the publication of the Institute of Medicine report “*To err is human*” in 1999 [1], the safety of patients has received unprecedented attention. Researchers and healthcare organisations have turned to high-risk industries [27] such as commercial aviation for inspiration about appropriate theories and methods through which patient safety could be improved. For example, learning from past experience through incident reporting systems and Root Cause Analysis are now standard practices through-out the National Health Service (NHS) in the UK, triggered by the influential Department of Health Report, “*An organisation with*

a memory" [2]. The report led to the foundation of the National Patient Safety Agency (NPSA) and the development of the National Reporting and Learning System (NRLS), a national system to collect patient safety incidents and to share relevant learning throughout the NHS. In addition to such reactive approaches, healthcare policy makers have recognised the need for proactive assessments of threats to patient safety. In particular, the use of Failure Mode and Effects Analysis (FMEA) is now recommended widely in healthcare as an appropriate tool for proactive safety analysis. For example, the Joint Commission in the US — the organisation that accredits hospitals — requires from participating organisations evidence that they carry out at least one proactive assessment of a high-risk process every year [3], FMEA being the approach recommended. The US Department of Veterans Affairs (VA) has developed an FMEA version tailored to healthcare, Health Care Failure Mode and Effects Analysis (HFMEA) [4]. During the past few years FMEA has been used in healthcare to assess the risks associated with, for example, organ procurement and transplantation [5], intravenous drug infusions [6], and communication in emergency care [7].

As healthcare organisations are gaining experience in using FMEA, there starts to become available documented evidence of some of the problems that practitioners experience with the application of the method. Habraken and colleagues carried out a large evaluation of HFMEA in the Netherlands [8]. While they concluded that the method might be useful in Dutch healthcare, they remarked that practitioners commonly felt that the method was very time consuming, the identification of failure modes was poorly supported and the risk assessment part was very difficult to carry out. FMEA was also used as part of the Health Foundation's Safer Patient Initiative in the UK, and a study evaluating the perceptions of participating healthcare professionals found that participants felt that while the structured nature of the process was beneficial, there were negative aspects that may prevent the useful adoption of the method in the NHS, including the time required to perform the analysis and the subjective nature of the risk evaluation [9].

This paper addresses some of the difficulties related to the use of FMEA in healthcare settings by investigating the application of an alternative, complementary methodology in order to conduct a proactive safety analysis. It argues that some issues of adopting FMEA can be eased by combining diverse methodologies in order to assess vulnerabilities in complex socio-technical settings. This paper is organised as follows. Section 2 summarises some of the research findings around communication and handover failures in emergency care. Section 3 describes the application of FMEA for the identification of vulnerabilities related to communication and handover within a specific emergency care pathway. It then discusses the suitability of FMEA to assess risks in healthcare settings, and investigates its possible combination with an alternative approach, the Functional Resonance Analysis Method (FRAM). It also discusses and argues that taking into account socio-technical hazards could be useful in order to overcome limitations of analytical approaches that tend to narrow the scope of analysis. Section 4 draws some concluding remarks.

2 Communication and Handover Failures

Communication failures are a recognised threat to patient safety [10]. Handover denotes “*the transfer of professional responsibility and accountability for some or all aspects of care for a patient, or group of patients, to another person or professional group on a temporary or permanent basis*” [11]. Handover may occur between members of the same profession, for example during nursing shift change, or between individuals belonging to different medical professions or even different organisations, such as the Ambulance Service handover to the Emergency Department. Handover is a frequent and highly critical task in clinical practice as it ensures continuity of care and provides clinicians with an opportunity to share information and plan patient care [12]. Ideally, handover should be thought of as a dialogue that creates shared awareness and provides an opportunity for discussion and recovery as participants bring different perspectives and experiences to this interaction [13, 14]. There is now a large body of evidence and a number of systematic reviews that suggest that inadequate handover practices are putting patients at risk [15–19]. Inadequate handover can create gaps in the continuity of care and contribute to adverse events [20]. Some of the adverse events associated with inadequate handover include increased length of stay [21], treatment delays [13, 22], repetition of assessments and confusion regarding care [23]. In time-critical environments such as Emergency Departments, the additional burden put on already stretched resources due to inadequate handover poses a risk not only to the individual patients handed over, but also to other patients in need of urgent care [13].

3 Proactive Risk Analysis

As described in the previous section, communication and handover failures are a significant threat to patient safety. This has been recognised and organisations are experimenting with different solutions to the problem, including standardised communication protocols, electronic handovers and electronic documentation available on PDAs or tablets at the point of handover. In the research project that provides the background to this paper, it was decided to conduct a systematic risk assessment prior to the adoption of any technological or procedural solution in order to ensure that risks have been properly understood.

3.1 Description of the Emergency Care Pathway

For the purpose of our case study, the emergency care pathway consists of the Ambulance Service bringing a patient to hospital (typically two paramedics in an ambulance), the Emergency Department (ED), and hospital departments that receive patients from the ED – in the UK often a Clinical Decision Unit (CDU) or Medical Assessment Unit (MAU). As part of the FMEA process, staff working within the pathway were invited to participate in a process mapping session in order to describe the pathway for the subsequent risk analysis. Participants

included doctors, paramedics, ED and MAU nurses. Figure 1 shows the resulting process description for highly critical patients (resuscitation patients). Such simple, sequential process maps are commonly used in healthcare. The figure shows steps in the process and information that is produced or communicated (shown with background colour). The process in terms of communication and handover consists essentially of a pre-alert by the Ambulance Service that a patient is about to be brought in (for highly critical patients), preparatory activities within the ED, a handover between paramedic and the ED team, completion of documentation and the negotiation of the onward transfer of the patient out of the ED. A similar process description was produced for patients that have severe but less critical injuries (majors cases), the main differences being that there is no pre-alert and that the paramedics hand over to the triage nurse or nurse coordinator rather than to the resuscitation team.

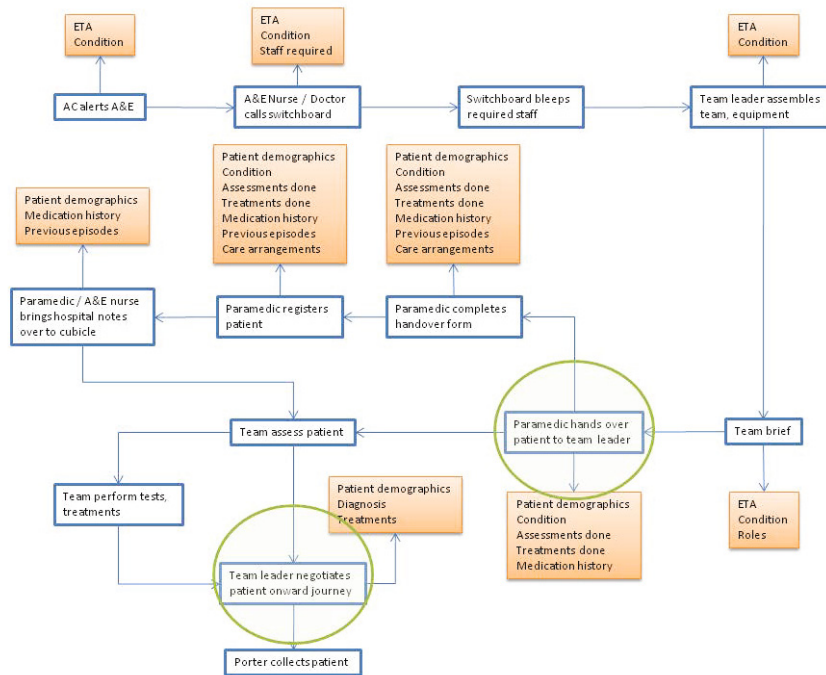


Fig. 1. Emergency Care pathway description

3.2 FMEA to Identify Major Vulnerabilities

Following the process mapping activity described above, two further meetings were organised to identify failure modes and to perform the risk analysis. As healthcare professionals tend to have limited time available to participate in such safety activities, the meetings started with a quick review of the process map and a discussion around which steps should be looked at in more detail based on

the experience of the participants (rather than an analysis of all process steps as would be the proper way to apply the method in technical settings). The groups identified the steps that required to be analysed in greater detail and that were perceived the most critical steps: (1) pre-alert, (2) handover between paramedic and team, and (3) onward negotiation. The groups also analysed major cases and included the handover between paramedic and triage nurse as a critical activity (4). Table 1 presents for illustration the results of this FMEA for Step (1): *Telephone pre-alert (ambulance crew or control centre to Nurse-in-Charge or ED staff closest to red phone)*.

Table 1. FMEA of communication and handover in the emergency care pathway

Step (1) Pre-alert				
Failure Mode	Likelihood	Severity	Causes	Mitigation
a. Not pre-alert	4	5: delay in getting the right people, bed (trauma / airway patients)	Poor mobile phone connection; ED phone not working; possibly inexperienced staff	Improved radio link; reduction in ED overcrowding
b. Misinterpreting information, numbers, abbreviations	4	2-3: ED is prepared but may require different / additional resources when patient arrives	Inexperienced staff; communication comes from control centre who cannot answer clinical questions	Cautious ED planning; communication coming from ambulance crews
c. Fragmented information	4	2-3: similar to (b)	Similar to (b)	Cautious ED planning
d. Failure to notify of deteriorating patient condition	3	4-5: ED is prepared but patient may be a lot sicker than expected and right people may not be around	Too little time; failure to recognise deterioration	
e. Failure to notify of improving patient condition	4	2: Resuscitation team / room needlessly prepared and not available for other patients	Failure to recognise improvement; lack of understanding of impact on ED	Increase awareness among ambulance crews

Table 2 explains the categories for assessing the likelihood of occurrence and the severity of the consequences that were used.

Table 2. Scores for likelihood of occurrence and severity of the consequences

Value	Likelihood	Severity
1	Less than once a year	No harm, no increased length of stay
2	Less than once a month	Non-permanent minor harm or increased length of stay
3	Less than once a week	Non-permanent major harm or permanent minor harm
4	Less than once a day	Permanent major harm
5	Once a day or greater	Death

A major risk identified relates to the failure of the pre-alert when the ambulance crew is unable to establish a communication link with the ED, for example because they are in an area where there is no mobile phone reception or – in very rare cases – due to unreliability of the ED communication equipment. Participants felt that this happened fairly regularly and that patients may die if upon arrival critical team members such as airway management specialists were unavailable. Another major risk relates to the failure of the handover between the paramedic and the resuscitation team, when the team are starting to treat the patient before the para-medical has had the chance to complete the handover. This is a frequent occurrence, since ED staff are keen to start treatment of critically ill patients as quickly as possible. However, in some cases this may lead to a situation where medication is given that has already been given by the paramedic on scene or in the ambulance. Factors that contribute to this failure include the perceived need to act quickly, a sense of hierarchy that may prevent the paramedic from challenging the senior ED doctor, and high levels of stress.

3.3 Establishing the Worst Credible Consequences

The aim of approaches such as FMEA is the identification of single failures that carry high risk. This is reasonable and the method has been applied successfully in industrial settings for decades. FMEA requires assessment of the worst credible consequences of any particular failure. This is difficult in most but very simple systems, but it is even more complicated in healthcare, typically a complex socio-technical system with a lot of uncertainty arising from contextual factors and the patient condition. There is a risk of overlooking the limitations of FMEA by over-relying on it, while excluding other possible complementary approaches. When asked about assessing the severity of the consequences of a particular failure mode as part of an FMEA exercise, participants will usually reply that this depends on the condition of the patient and other contextual factors. If the condition of the patient is sufficiently critical, even minor failures may lead to death. The problem with FMEA in such settings is that it assumes fairly

immediate cause and effect links and does not by itself encourage consideration and differentiation of contextual factors. In the FMEA example above, clinicians often contextualised the consequences of a particular failure mode by adding statements such as “*if we have a trauma patient*”, or “*when a patient comes in and their airway is difficult to manage*”. But even with this additional patient-related information, it was difficult to establish the worst credible effect, since single failures rarely kill patients, but usually have the potential to do so in conjunction with other circumstances.

FMEA works well for technical systems and there is also scope for its application in healthcare. However, the particular way of looking at a system and of representing risk that is inherent in the method needs to be properly understood by people applying it in healthcare. The method can be applied usefully when these characteristics are taken into account, and when the method is complemented by other approaches. This highlights some of the problems of using FMEA in healthcare. The complexity and richness of the domain expose the limitations of FMEA. Combining FMEA with complementary methodologies that extend technical approaches could address such limitations. The next section uses FRAM to identify vulnerabilities that may result from the propagation of variation rather than from single failures.

3.4 From Failure Modes to Functional Resonance

An alternative approach has been described by Hollnagel [28] based on the concept of functional resonance. Functional resonance is defined as the detectable signal that emerges from the unintended interaction of the everyday variability of multiple signals. The variability is mainly due to the approximate adjustments of people, individually and collectively, and of organisations that are the basis of everyday functioning. Each system function has a normal, weak variability. The other functions constitute the environment for this particular function, and their variability can be represented as random noise. However, on occasion the pooled variability of the environment may lead to a situation of resonance, i.e. to a detectable signal that emerges from the unintended interaction of the normal variability of many signals. The Functional Resonance Analysis Method (FRAM) proposes to model the functions of a system with six aspects, namely input, output, time, resources, control and preconditions (I: Input, O: Output, T: Time, R: Resources, C: Control, P: Precondition). The application of FRAM then tries to establish the variability of the output of functions and the propagation of this variability. System failures may emerge not necessarily as a result of failures, but due to the propagation and resonance of variability. We have modelled for simplicity only five steps of the above emergency care pathway as functions: (1) Provide pre-alert to emergency department, (2) Prepare emergency department, (3) Bring patient to the emergency department, (4) Hand over relevant information to emergency department team, (5) Treat patient. FRAM prompts the analyst to consider the effect of variability on the output of a function. Figure 2 shows a very simple example of FRAM resulting model of analysis.

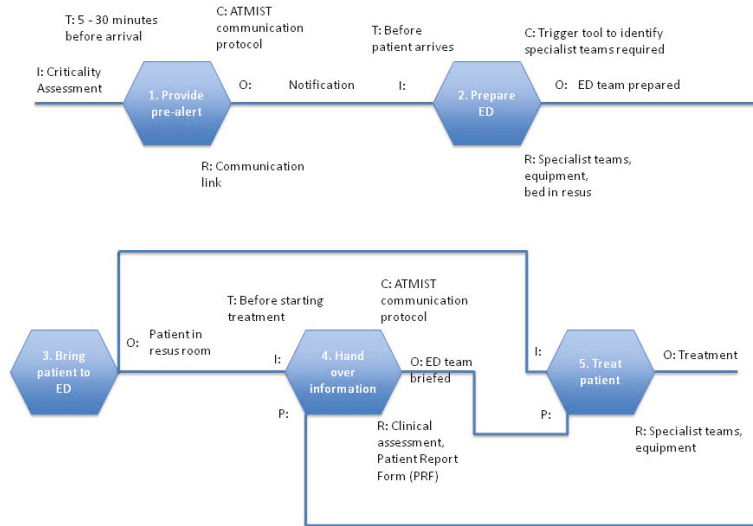


Fig. 2. FRAM representation

Table 3, for example, describes the possible effect of variability on function 2 (prepare emergency department).

Table 3. Possible effect on the variability of the output of function 2

Type of variability		Aspect and its effect on output variability			
		Input	Resource	Control	Time
Timing	On time	Dampening	Dampening	Dampening	Dampening
	Too early	Dampening	Increase	-	Increase
	Too late	Increase	Increase	Increase	Increase
	Never	Increase	Increase	Increase	Increase
Precision	Optimal	Dampening	Dampening	Dampening	-
	Acceptable	No effect	No effect	No effect	-
	Imprecise	Increase	Increase	Increase	-

In this case, if the output of function 1 (pre-alert) is late or does not take place, this may lead to an increase in the variability of the output of function 2. Likewise, if team members arrive late or are unavailable (resource), then variability may increase. If on the other hand, team members arrive on time and the function is completed before the patient arrives, then variability may be dampened. In this way, a more complex model allows the analyst to consider the propagation and the possible dampening or reinforcing effect of variability without the need to relate the observed effect causally to failures of any kind.

3.5 Learning Generated by FRAM

The application of FRAM as part of this project was experimental in order to investigate whether there is some potential for alternative methods to complement FMEA during proactive risk analysis in healthcare. The way the method was used, was first of all to model the functions with their aspects, then to determine their potential variability (see above), and in a final step to mentally simulate with practitioners how variation could propagate and lead to situations of resonance. Practitioners were able to reflect on common situations and how they deal with variability and how this may affect patient safety. For example, it is common that the pre-alert received from the ambulance service is either at short notice or does not reflect perfectly the patient's condition (variation in the output of function 1 in terms of timing and precision). Neither of these are considered failures by practitioners. This has a knock-on effect on the preparatory activities (function 2), because there is less time to alert the specialist teams required and not all specialists may be contacted. This function may further vary due to the fact that no resuscitation bed is available (resource aspect), and hence a patient needs to be moved out of this area quickly prior to the arrival of the pre-alerted patient. The output of this function can, therefore, vary in terms of timing and precision because the bed may not be available by the time the patient arrives and specialists may arrive late. Once the patient arrives, the handover between paramedic and ED staff may be affected due to this previous variation, for example because specialists have not yet arrived (precondition) and the handover takes place without them. Further variation can be introduced through incomplete clinical assessments by the paramedics (resource) or incomplete or imprecise communication (control — the ATMIST communication protocol). Finally, the assessment and treatment of the patient should start only once the handover has been completed (precondition), but variability could be introduced here as the ED starts attending to the patient straightaway. Likewise, imprecise handover may affect the assessment and treatment.

When practitioners compared the application of FRAM with FMEA, they noted essentially two differences. First, FRAM forces consideration of the different contextual aspects that are usually not included in such a systematic way in the simple sequential process maps that form the basis for the application of FMEA in healthcare. Second, FRAM felt more intuitive because it does not require consideration of failures and absolute consequences. Practitioners felt more comfortable reasoning qualitatively about possible sources of variation. This way of reasoning could provide some further insights into the severity classification derived by the application of FMEA. For example, the application of FMEA to the pre-alert provided estimates that not receiving a pre-alert could lead to the death of the patient. However, using FRAM, practitioners were able to structure their reasoning about what happens when the pre-alert is not perfect and provide insights of how the dynamic of the system may be affected. This is, of course, different and complementary to the assessment of the worst credible outcome.

3.6 Socio-technical Classification of Hazards

The proactive risk analysis obtained by combining FMEA and FRAM analyses identified vulnerabilities in the emergency care pathway and provided an assessment of their potential impact. This section investigates the nature of such vulnerabilities, and whether it could provide useful insights for deploying technological artefacts in the future. Drawing on research collaborations in dependability, it was possible to identify classes of socio-technical hazards that are usually overlooked, or misinterpreted, by narrow, technology based assessments, rather than involving wider social-organisational perspectives [24, 25]. It is possible to extend technological risk analyses by taking into account three main classes of socio-technical hazards [24, 25]: *Boundary Hazards*, *Evolutionary Hazards* and *Performativity Hazards*. Boundary Hazards characterise technology that supports different communities of practice. Technological integration strategies often undermine differences between communities of practice giving rise to tensions resulting into ‘failures’. Evolutionary Hazards characterise a lack of understanding of the evolutionary nature of technology. Technology innovation involves an extent of evolving work practice. Assessing technology and its impact involves dealing with knowledge uncertainty. Unfortunately, engineering methodologies often struggle to cope with uncertainty. Performativity Hazards, finally, characterise the interplay between technology and social behaviour. This section uses such classes to classify the vulnerabilities and impacts identified by combining FMEA and FRAM analyses. A similar classification analysis has been useful to to analyse the findings drawn from clinical trials [26].

The feedback collected during clinical trials of telemetry-enabled healthcare systems, was classified according to such classes of socio-technical hazards. The medical trials summarise findings according to different categories of users: Patient and Care Personnel. Some feedback collected by pilot trials related directly to the classes of socio-technical hazards. Taking these classes of socio-technical hazards as a starting point can provide an analysis of potential vulnerabilities affecting technology deployments and work practice in healthcare organisations [24–26]. The proactive risk analysis combining FMEA and FRAM analyses highlights specific failure modes and vulnerabilities. All of them fall into the class of Boundary Hazards [25]: *“highlight the vulnerabilities of organisational boundaries. Technology often exposes organisations to the propagation of hazards across organisational boundaries. Moreover, the risk lays also in the shift of responsibilities across organisational boundaries and in the raising of mistrust across divisions of labour.”*

4 Conclusions

The application of FMEA in healthcare is useful in order to understand some of the potential vulnerabilities of healthcare processes, but in practice it is difficult to determine the consequences of failures as these depend on the context and the patient’s condition. The combination of FMEA with other methods could be a promising way of analysing risk in socio-technical systems. In this paper we have

described the additional application of FRAM to analyse a healthcare process. FRAM focuses on variability and possible situations of resonance rather than on failures and cause-effect links. FRAM provided insights into how the system dynamic is affected by small variations in system functions. While practitioners felt that FRAM added useful new insights, further work is required to determine how the findings generated by diverse methods should be integrated in a systematic way for proactive risks analysis.

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