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Safety Management in High-Risk Industries – Lessons for Patient Safety

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Introduction

This paper describes some of the key lessons from the management of safety in safety-critical industries, which might be applied in healthcare in order to improve the safety of care delivered to patients. Certain safety-critical industries, such as civil aviation and the nuclear industry, suffer very few accidents. Such domains are sometimes referred to as ultra-safe systems [1]. What do these industries do that enables them to remain near accident free for significant periods of time?

Arguably, many factors contribute to the success of ultra-safe systems. However, looking across safety-critical industries it is possible to identify a number of core safety management practices that are accepted and expected: the proactive identification and management of risk, the demonstration and critique of an organisation's safety position (i.e. why do we believe the organisation is safe?), and the commitment to continuous organisational learning.

The aim of this paper is to provide a brief overview of these safety management practices, and to describe lessons for the management of patient safety in healthcare organisations. The transfer of lessons from safety-critical industries to healthcare can often be challenging in practice [2-4]. When transferring and applying lessons from industry to healthcare it is important to understand the underlying theory, the benefits and the limitations of tools and methods within their original industrial context [5].

The next section looks at how safety-critical industries proactively seek out and manage risk. Then, the concept of safety cases is described. This concept is useful to make an organisation's risk position explicit. Subsequently, the importance of establishing strategies to promote organisational learning is discussed. A summary of the key lessons for healthcare concludes the paper.

Paper Objectives

- Provide an overview of successful safety management practices in safety-critical industries
- Introduce principles of proactive risk management
- Outline the use of safety cases to demonstrate and critique an organisation's safety position
- Discuss the role of organisational learning for sustaining progress with safety
- Describe lessons for managing patient safety in healthcare organisations

Proactive Risk Management

A defining characteristic of successful safety-critical industries is that organisations seek out and manage safety risks proactively [6]. It is useful to distinguish and discuss separately the

concept of risk, methods to assess risk, and the organisational strategies and processes for managing risk, as these are separate albeit interrelated issues.

The risk concept

Concepts of risk aim to model or to represent that an activity could in the future lead to some kind of consequences or outcomes that are not desired. The concept of risk has been discussed from different perspectives in the literature, and to date there is no agreed definition of risk [7]. Aven [7] and Althaus [8] give interesting overviews of the historical development of different conceptions of risk.

In healthcare it is common to talk about the risk of developing a specific type of disease or condition, e.g. diabetes risk, and to identify related risk factors that increase the risk. Risk in this interpretation represents a probability. From an engineering perspective, risk is often regarded as the combination of the probability of an event developing and the severity of the resulting consequences. Including consideration of the consequences is important because an event (e.g. failure of a brake) can have outcomes of different severity (e.g. negligible injury to fatality). The ISO 31000 standard on Risk Management defines risk as “effect of uncertainty on objectives”. This somewhat cryptic definition incorporates the notion of uncertainty, which in effect separates the risk concept from the measurement of risk. The earlier engineering perspective proposed probability and severity as both definition and measurement of risk. The ISO 31000 and other more recent definitions define risk through uncertainty related to activities and consequences, but leave the measurement open [9]. This is important because analysts typically make a number of assumptions or rely on background knowledge when assessing risk. These assumptions and background knowledge can be strong or not so strong, i.e. they have associated uncertainties. These uncertainties can have a significant impact on the assessment of risk, but are not usually

captured in the engineering perspective based on probabilities [9]. For example, consider a hazard involving the failure of an automatic train protection system (automatic braking system). Engineers might estimate the failure probability p and the severity of the consequences c . However, the train protection system might be a radically new design, and there might be only limited testing evidence available, which was collected under idealised conditions in a laboratory. Therefore, the existing knowledge to support the value of p would be weak. The failure probability p does not provide any indication of the uncertainty that is associated with its value. A possible way to deal with this problem is to articulate the assumptions and their relative strengths separately from the risk assessment, for example in the form of a safety case [10] (see below).

Other perspectives on risk emphasise the dynamic and social dimensions of risk [8, 11, 12]. Such approaches might be of particular relevance for healthcare, because the patient has a unique perspective on risk, which is shaped by their own history, experience, and expectations. It has been suggested that in a healthcare context, risk might be understood as something personal that is negotiated between the patient and healthcare professionals [13].

Risk assessment

The above discussion illustrated that the concept of risk and the process of assessing risk are two different things. How one assesses risk is influenced by the risk concept adopted, but which concept is the most appropriate will depend on the specific situation.

In UK safety-critical industries, the most common approach for risk assessment is to describe risk qualitatively and quantitatively (as required), and to document relevant uncertainties in a safety case. Risk assessment usually entails hazard analysis to identify

and to describe scenarios of interest, and risk analysis to describe and to evaluate the risks associated with the identified hazards. These steps can be supported by a large number of specific methods, such as Failure Mode & Effects Analysis (FMEA) and the extension Failure Mode, Effects and Criticality Analysis (FMECA) [14], Hazards and Operability Studies (Hazop) [15], Fault Tree Analysis (FTA) and Event Tree Analysis (ETA) [16], and more recent methods such as Functional Resonance Analysis Method (FRAM) [17] and System-Theoretic Process Analysis (STPA) [18].

Risks are often assessed qualitatively first, informed by engineering judgement and gut feelings. This type of qualitative analysis is considered sufficient in many cases [19]. In situations where this qualitative analysis suggests that risks might be high or the consequences severe, quantitative analysis might be carried out. Quantitative analysis is more common for engineering problems than for organisational changes, because such changes are more difficult to model and the uncertainties associated with quantitative estimates can be very high.

Common to all of the different approaches for risk assessment is the proactive search for threats and vulnerabilities. In proactive approaches the emphasis shifts from historic event and outcome data (i.e. adverse events) towards consideration of future events (i.e. risk). Regulatory requirements (e.g. [19]) act as a strong motivator, but there are also ethical and societal considerations. In addition, organisations are increasingly aware of the potentially negative impact of poor safety performance on the reputation of a business or company [6].

Risk management

Managing risk is more than describing and assessing risks. Managers have to make decisions about whether or not risks are acceptable, and whether to invest money in order to

reduce risk. Crucially, as the risk management process proceeds from risk analysis towards risk-informed decision-making, judgements about risk tend to be less based on purely factual evidence and more based on value assessments instead [20]. Value-based judgements might include considerations other than safety, such as production benefits and other business impacts, ethical concerns, issues of corporate responsibility, and whether or not a decision might hold up in court [6].

In the UK context, the Health & Safety Executive (HSE) has provided guidance about risk management, which is applied widely [19]. The guidance includes the requirement that operators of systems demonstrate that risks have been reduced as low as reasonably practicable (ALARP). This requirement is used to ensure that risks have been controlled effectively up to a point where further risk reduction would result in disproportionate cost. In practice, making such judgements can be difficult, and practical problems with this concept have been highlighted [21]. Even so, the guidance acts as a motivator to businesses to manage risks proactively and transparently.

Patient safety risk management

The management of risks to patient safety is still predominantly reactive [22]. Common tools for risk management include Root Cause Analysis (RCA) and incident reporting. These approaches look at adverse events and incidents, trying to identify factors that contributed specifically to these events, so that remedial action can be undertaken. While useful information can be generated in this way, the downside is that these approaches are reactive, i.e. they usually only look at events that have already caused harm.

Increasingly, organisations are encouraged to adopt proactive risk management approaches. FMEA has been proposed frequently as a potential tool for use in healthcare

contexts. In particular the Veterans' Affairs (VA) in the US has been promoting this approach, and a healthcare-specific version has been developed – Healthcare Failure Mode & Effects Analysis [23]. FMEA has been used in different settings [24-27]. Often participants have described the experiences of using FMEA positively, but there has been criticism of the approach [28, 29]. It has been suggested that FMEA is unduly time consuming, and that the risk assessments produced using FMEA were dependent on the participants and not necessarily replicable. One can add to these criticisms that knowledge of FMEA and other proactive methods for risk analysis is still limited in many healthcare organisations, and that such approaches are used only infrequently.

Safety Cases – Demonstrating and Critiquing the Safety Position

The concept of a safety case

The HSE in the UK requires that manufacturers and operators of safety-critical systems demonstrate that they have adopted a thorough and systematic process for understanding proactively the risks associated with their systems, and that these risks have been controlled appropriately. The regulator does not specify how risks should be dealt with specifically, but rather sets goals that have to be achieved (e.g. all risks have to be reduced ALARP). It is then left to the manufacturers and operators of systems to argue that they have met these goals.

In the UK, these duties are often fulfilled through the use of safety cases [30]. The purpose of a safety case can be described as providing a structured argument, supported by a body of evidence that provides a compelling, comprehensible and valid case that a system is acceptably safe for a given application in a given context [31]. A key component of any safety case is a risk-based argument and corresponding evidence. This is intended to demonstrate that all risks associated with a particular system have been identified, that

appropriate risk controls have been put in place, and that there are appropriate processes in place to monitor the effectiveness of the risk controls and the safety performance of the system on an on-going basis. The argument and evidence in safety cases are then examined and challenged, typically by independent safety assessors, as part of the overall safety assessment or certification process.

As mentioned above, the safety case can usefully document assumptions and uncertainties. Increasingly, best practice is to include a “confidence argument” to complement the risk-based argument [32]. This confidence argument outlines the strength of the evidence, and the extent to which one can place confidence in the safety case. In practice, safety case assessors tend to challenge issues of qualitative nature (i.e. assumptions, boundaries of the system, excluded scenarios etc.) rather than specific numerical values.

Using safety cases in healthcare

There has been some recent interest in the application of safety cases in healthcare [10, 33]. However, this interest is limited at present to medical devices and to health informatics applications [34-36]. In the US, the FDA has issued guidance for assurance cases (a type of safety case) for infusion pumps that are certified via the 510(k) route. In the UK, NHS Digital has published standards for both manufacturers and users of health IT products, which include a requirement for the development of a clinical safety case. There is very limited empirical evidence available about the use of safety cases in healthcare, in particular at the system or the service level [22].

The regulatory environment acts as a key driver for the use of safety cases in UK industries [10]. In the NHS, and probably in healthcare more generally, there is no single body to provide centralised and coordinated oversight of patient safety [37]. There are around 20

regulatory bodies in health and social care in England, and this diversity has contributed to a lack of a coherent push for improving patient safety [38]. In addition, regulatory bodies require the necessary technical understanding and adequate resources in order to make a safety case approach work in practice.

In the absence of a regulatory push for safety cases, organisations might still consider using safety cases to make their risk position explicit. This requires adaptations to the safety case concept, moving it from a regulatory tool towards a tool for effective risk management. This is in line with observations and suggestions by both the Cullen inquiry (following the Piper Alpha oil platform explosion) [39] and the Haddon-Cave report (following the loss of a Royal Air Force aircraft in Afghanistan) [21]. Lord Cullen's report argues that safety cases should first and foremost provide assurance to companies themselves that they have followed a systematic and thorough approach to risk management to ensure that their systems are safe. Similarly, while the Haddon-Cave report criticises the Ministry of Defence and BAE Systems for their safety culture and attitudes, the report suggests that safety cases remain central to making an organisation's risk position explicit so that it can be reviewed and critiqued.

Organisational Learning

The third safety management practice, which successful organisations pursue, is organisational learning. Organisational learning can be characterised as a continuous cycle of action and reflection [40]. Organisations might be more successful at learning from past experience if they create and foster the capacity for deep reflection on whole system dynamics, which can lead to fundamental change [41]. On the other hand, insistence on past traditions, and quick fixes to existing strategies and procedures might inhibit more powerful forms of organisational learning. Organisations have a range of learning processes

at their disposal, which might be internal (for example audits and adverse event reviews) as well as external (for example feedback from the regulator) [42].

Many organisations are relying on incident reporting systems as a key process for reporting and organisational learning [43-45]. Ideally, effective learning from incidents triggers improvements in practice that enhance safety and productivity [46]. The analysis of incidents seeks to reveal contributory factors and underlying causes [43], which can then be addressed in order to reduce the likelihood of incidents recurring. Learning from past experiences does not have to be limited to the consideration of incidents, but can also include monitoring and analysis of leading indicators, or even weak signals [47]. However, there is increasing evidence in the literature that suggests that effective learning from past experiences in order to improve safety performance remains challenging even in traditional safety-critical industries [44, 46, 48].

The challenges of organisational learning in healthcare

Following the public inquiry into the failings at Mid Staffordshire NHS Foundation Trust, the subsequent Berwick report generated lessons and suggestions for change for the UK government and the National Health Service (NHS) in England [49]. The report recommends that the NHS should aim to become a system devoted to continuous learning and improvement of patient care. This is clearly a fundamental requirement for any healthcare organisation aspiring to improve the safety of care to higher levels.

Incident reporting as an instrument for organisational learning was introduced into the NHS about 2003, following a publication by the Department of Health [50]. This report recommended the development of a reporting system based on the model of incident reporting used in commercial aviation. Incident reporting is well established in the NHS, and

it is regarded as a key instrument for improving patient safety and the quality of services [51, 52].

In one respect, incident reporting in the NHS has been very successful. There are a staggering number of incidents reported every year. However, despite the large number of potential learning opportunities, questions have been raised about the effectiveness of incident reporting systems to contribute to improvements in patient safety [53-57]. There are now many studies that document barriers to effective incident reporting in health care. Such barriers include, for example, fear of blame and repercussions, poor usability of incident reporting systems, perceptions among doctors that incident reporting is a nursing process, lack of feedback to staff who report incidents, and lack of visible improvements to the local work environment as a result of reported incidents [55, 56, 58-61]. Among management staff in particular, there continues to be widespread misperception that incident reporting systems might be useful for monitoring incident frequencies, despite evidence that suggests that incident reporting data are poor indicators of actual incident frequencies [62]. It has been suggested that the focus of learning from incidents in health care has been too much on collecting and categorising data [56, 63], whereas successful learning from experience should inherently be a social and participative process [46, 56].

Learning from the ordinary

How can health care organisations enhance their ability to learn from past experience in order to set them on the path towards becoming ultra-safe organisations given the obstacles and practical difficulties with learning from incidents outlined above? One way might be to shift the focus from formal learning about extraordinary failures and incidents towards more de-centralised, local forms of learning about everyday clinical work [64].

An example of such a local form of learning is the Proactive Risk Monitoring in Healthcare (PRIMO) approach. This approach to organisational learning was developed in order to elicit a rich contextual picture of the local work environment, to move away from negative and threatening notions of errors and mistakes, and to encourage active participation and ownership with clear feedback for local work practices [60, 61]. The distinguishing feature of the PRIMO approach is that it focuses on learning from the ordinary, in this case the various hassles that practitioners experience in their everyday clinical work.

Hassle in this instance can be defined loosely as anything that causes people problems during their daily work. Examples of hassle include, for instance, unavailable equipment such as drip stands on a ward or supporting equipment for undertaking radiographic procedures. There are a number of important benefits of learning from everyday hassle. Among these the most important benefit is arguably that the focus on hassle supports building an understanding of the system dynamics, i.e., of the way performance adjustments are made, and the way work ordinarily unfolds. Reports of hassle typically contain not only descriptions of how the hassle manifested itself, but also how people coped – how they adapted their behaviour in order to continue to provide safe and good quality care [65]. Examples of typical adaptations made by health care professionals include the sharing of information and personal negotiation to create a shared awareness, prioritisation of goals and of activities, and offering and seeking help.

Other local and informal processes that organisations might consider supporting include regular staff meetings aimed at identifying ways to improve the delivery of care, informal discussions between staff and their managers, and discussions among peers, and informal lunchtime improvement groups. Such processes are perceived as locally owned, and they might be better suited to provide shared awareness, to make staff feel that they are being

listened to and that they can make a contribution to improving patient safety, and for generating ownership for improvement interventions [64].

Research suggests that where organisational effort is invested to support and include such processes, these can have a positive effect on staff engagement in reporting and learning activities [60] and on patient safety [66]. Utilising a range of processes that draw upon and strengthen different aspects of an organisation's culture might enable healthcare organisations to deliver more sustainable improvements in patient safety [67].

Summary

This paper discussed three key strategies that successful safety-critical industries adopt in order to achieve outstanding safety performance: the proactive management of risk, the explicit demonstration and critique of the organisation's safety position, and a commitment to continuous learning and improvement.

In principle, these strategies can work across different industries, and they have the potential to transform radically the safety record of healthcare organisations. However, healthcare is unlike other safety-critical industries in many aspects, and the different cultural and contextual background has to be considered. None the less, these lessons from industry should provide valuable input to patient safety management efforts in healthcare.

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