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Should healthcare providers do safety cases? Lessons from a cross-industry review of safety case practices

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ABSTRACT

Healthcare organisations are often encouraged to learn from other industries in order to develop proactive and rigorous safety management practices. In the UK safety–critical industries safety cases have been used to provide justification that systems are acceptably safe. There has been growing interest in healthcare in the application of safety cases for medical devices and health information technology. However, the introduction of safety cases into general safety management and regulatory practices in healthcare is largely unexplored and unsupported. Should healthcare as an industry be encouraged to adopt safety cases more widely? This paper reviews safety case practices in six UK industries and identifies drivers and developments in the adoption of safety cases. The paper argues that safety cases might best be used in healthcare to provide an exposition of risk rather than as a regulatory tool to demonstrate acceptable levels of safety. Safety cases might support healthcare organisations in establishing proactive safety management practices. However, there has been criticism that safety cases practices have, at times, contributed to poor safety management and standards by prompting a "tick-box" and compliance-driven approach. These criticisms represent challenges for the adoption of safety cases in healthcare, where the level of maturity of safety management systems is arguably still lower than in traditional safety–critical industries. Healthcare stakeholders require access to education and guidance that takes into account the specifics of healthcare as an industry. Further research is required to provide evidence about the effectiveness of safety cases and the costs involved with the approach.

1. Introduction

Patient safety is an area of significant public concern. In the UK, there has been much media coverage of the findings of the Public Inquiry into the failings at Mid Staffordshire NHS Foundation Trust. The report suggests that between 2005 and 2009 as many as 1200 patients died needlessly as a result of inadequate and often appalling standards of care (Francis, 2013). There is evidence from a wide range of countries and health systems that suggests that patients around the world are suffering preventable adverse events (Vincent et al., 2001; Davis et al., 2002; Baker et al., 2004; de Vries et al., 2008; Thomas et al., 2000; Brennan et al., 1991). Adverse events cause unnecessary suffering, and they also have significant financial implications resulting from additional bed days and extended care requirements of patients, as well as from increased insurance and litigation costs (Vincent et al., 2001; Ovretveit, 2009).

Healthcare organisations have been encouraged to consider lessons from safety management in safety–critical industries in order to improve the safety of patients and reduce the number of adverse events (Department of Health, 2000; Kohn et al., 2000). For example, in the English National Health Service (NHS) lessons learned about incident reporting in aviation have contributed to the establishment of a national incident reporting system (National Reporting and Learning System) (Carruthers and Phillip, 2006). There is also an increasing number of documented examples of the application of risk analysis methods such as Failure Mode and Effects Analysis (FMEA), which healthcare organisations are becoming more familiar with (Apkon et al., 2004; Burgmeier, 2002; Steinberger et al., 2009; Sujan and Felici, 2012).

In UK safety–critical industries, manufacturers and operators of safety–critical systems, such as nuclear power plants and

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petrochemical facilities, have to submit a safety case to the respective regulatory authority (Maguire, 2006). In these industries safety cases provide an accepted means for demonstrating and assessing that a disciplined and effective approach to managing risk has been adopted, and that the resulting system can be regarded with confidence as acceptably safe (Bloomfield et al., 2012a). However, there has also been criticism of the safety case approach suggesting that poor safety case practices were a key contributor to accidents by prompting a "tick-box" and overly compliance-driven approach to safety (Haddon-Cave, 2009). Studies also suggest that there was a lack of evidence about their effectiveness as a tool for regulatory oversight (Leveson, 2011; Steinzor, 2011).

In healthcare there has been recent interest in the safety case concept, in particular for medical devices (Sujan et al., 2007) such as infusion pumps (FDA, 2014), and for health information technology (Health and Care Information Centre, 2013a, 2013b; Sujan et al., 2013). However, there is little established evidence about the role of safety cases for improving safety management practices in healthcare more widely (Sujan et al., 2015). There is also relatively little guidance on safety case use that is based on lessons across different industries rather than being very industry-specific. This lack of evidence and guidance is particularly problematic since safety management practices and the regulatory context in healthcare differ significantly from other safety–critical industries. Safety management in healthcare is arguably still largely driven by a reactive mindset and a regulatory approach that relies on routinely collected outcome data (such as mortality rates). There is a threat that within such a culture and environment safety cases might be perceived as another document-producing regulatory tool, or as a replacement to actual proactive thinking about patient safety risks.

Are safety cases a potential threat to mindful safety management or simply a necessary evil, or do safety cases have the potential to make a positive contribution to the development of more systematic and rigorous safety management practices in healthcare under the right circumstances? This paper presents lessons from a study (Bloomfield et al., 2012a) that reviewed the application of safety cases in six safety–critical industries (automotive, civil aviation, defence, nuclear, petrochemical and railways). The paper analyses drivers and developments in the adoption of safety cases across these industries. Based on such a broad, cross-industry review of safety case practices, the paper then examines critically challenges, lessons and prerequisites for the potential widespread and systematic development of safety cases within healthcare.

The paper is structured as follows. Section 2 briefly summarises the conceptual background to safety cases. Section 3 reflects on a review of safety case practices in six different industries, and identifies lessons across these industries for the adoption of safety cases. Section 4 briefly reviews the emerging use of safety cases in healthcare. Section 5 discusses the findings of the cross-industry analysis and identifies opportunities and challenges for the adoption of safety cases in healthcare. Section 6 concludes with the main implications for practice and for research.

2. Safety cases

Many of the current regulatory approaches in the UK require 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 to control these risks appropriately. With these approaches the regulator formulates goals, but the demonstration that the goals have been achieved is left to the manufacturers and operators of systems. This provides them with the flexibility to argue their case taking into account the specific context and any technological advances. In the UK, these duties are often fulfilled through the use of safety cases. This current regulatory approach is the result of a shift from compliance-based to more goal-based regulatory approaches over the past 20 years. Under a predominantly prescriptive regulatory regime, manufacturers and operators claim safety through the satisfaction of specific standards and technical requirements specified by the regulator, rather than by demonstrating that certain higher-level goals have been met. The compliance-based approach has been criticised for prompting bureaucratic practices of safety management, where risks may not be properly understood, and for potentially hindering progress in industries that are driven by technological innovations (Hawkins et al., 2013; Habli and Kelly, 2006; Bishop et al., 2004). The goal-based approach aims to overcome these shortcomings of prescriptive regulatory regimes by providing both more responsibility as well as more flexibility to operators of systems.

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 (UK Ministry of Defence, 2007). A key characteristic of the 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. Safety cases are usually confidential, but there are publicly available safety cases (see for example the Safety Case Repository (Dependability Research Group University of Virginia). The literature also includes descriptions of real safety case developments, as well as suggestions for high-level arguments and argument strategies (for example Barker et al., 1997; Chen et al., 2014; Chinneck et al., 2004; Habli et al., 2010). The use of safety cases is an accepted best practice in UK safety–critical industries, and is adopted by companies as a means of providing rigour and structure to their safety management systems. This is in line with recommendations provided by Lord Cullen in the highly influential Public Inquiry into the Piper Alpha oil platform explosion (The Honourable Lord Cullen, 1990). The report emphasises that meeting regulatory requirements should only be a secondary function of the safety case. The safety case should, first and foremost, provide assurance to the operators of safety–critical systems themselves that they have followed a systematic and thorough approach to ensure that their systems are safe (The Honourable Lord Cullen, 1990).

However, safety cases are not a panacea for successful safety management, and there has been criticism of the approach. It is important to critically review the lessons, criticisms and challenges of safety case practice in order to make suggestions for the meaningful adoption of safety cases in other industries, such as healthcare.

3. Review of safety case practices in six safety–critical industries

3.1. Aims, methodology and limitations

The recent interest in safety cases from industries like healthcare, which have little practical experience with the concept, justifies a longitudinal study into existing "good practices" as well as potential concerns. A review of safety case practices across different industries was undertaken (Bloomfield et al., 2012a, 2012b). The aim of the review was to document the different regulatory contexts, the key developments and drivers, and the types of safety cases and their content for each industry in order to provide an