Changing the patient safety mindset: can safety cases help?

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SAFETY CASES IN INDUSTRY
In the UK and several other countries, including Norway, Australia and New Zealand, operators of safety-critical systems, such as nuclear power plants, public transportation systems and defence equipment, must develop a safety case to demonstrate that their systems are acceptably safe to operate. In these countries, the development, review and maintenance of safety cases are regulatory requirements. In the UK, this regulatory practice extends as of October 2023 to high-rise residential buildings following the Grenfell Tower fire in 2017, during which 72 people died.

So, why are these countries promoting the safety case approach across their safety-critical industries? The most tangible reason is the shift from a prescriptive regulatory regime towards a goal-based approach. In this approach, regulators establish overall safety goals, offering developers and system operators flexibility to determine the most suitable methods for ensuring compliance. A safety argument is then used to justify how the evidence generated from these methods satisfies the established goals. Goal-based regulation is thought to be better suited to environments with technological innovation, which often outpaces prescriptive standards. However, there are, arguably, less obvious but even more important reasons for pursuing the safety case approach. Rather than thinking of safety cases only as written documents, or safety case reports, safety cases should be considered as a structured approach for thinking about safety. The mindset underpinning safety cases encourages proactive, and continual, engagement with safety drawing on a broad and diverse set of data sources, it promotes transparency and critical reflection about a system’s or organisation’s risk position, and it enables dialogue and discussion, that is, serves as a communication tool. Where safety cases are applied without the accompanying shift in mindset, they can degenerate into a bureaucratic and paper-based exercise without delivering safety benefit, as was identified in the loss of a Royal Air Force Nimrod aircraft in 2006.

SAFETY CASES TO IMPROVE PATIENT SAFETY
In the NHS in England, manufacturers of health information technology have been required to submit clinical safety cases since 2013. However, this is a domain with a narrow technological focus and limited organisational support. Safety cases for wider health services (rather than just the technology) have been advocated to the best of our knowledge for the first time by one of us in a publication in 2006. Building on this conceptual work, the safety case concept was introduced into the Safer Clinical Systems (SCS) programme, funded by The Health Foundation, starting in 2008.

Other than our pre-existing research interest, why did we think safety cases would be a valuable addition to SCS and patient safety practice? To appreciate the reasoning, it is worth reflecting on the state of patient safety research and practice back in 2008 and to contextualise the predominant mindset. Much effort was dedicated to the implementation of incident reporting systems and counting (rather than learning from) the number of incidents and adverse events. Quality improvement (QI) principles focusing on reducing waste and increasing reliability were highly influential. In contrast, SCS was set up specifically as a systems-based programme. The safety case approach was intended to be a vehicle to support organisations in shifting their mindset towards embracing such thinking in a structured and systematic way.
To change the existing reactive and QI focused mindset, we needed to strike a delicate balance. On the one hand, we needed to be prescriptive in terms of how to use the safety case approach and provide sufficient scaffolding for organisations unfamiliar with this way of thinking. On the other hand, we recognised that a workable version of safety cases as a way of thinking about patient safety had to be co-created with healthcare organisations, as industrial practice could not simply be transferred across. SCS provided an opportunity for experimentation, the end result of which formed the basis for the NHS England National Patient Safety Syllabus. This first national syllabus for patient safety is in itself a continuation and reflection of the changing patient safety mindset.

**LESSONS FROM THE INDEPENDENT EVALUATION**

The independent evaluation of SCS undertaken by Liberati and colleagues and reported in this journal is noteworthy for several reasons. First, the funding body (The Health Foundation) is to be acknowledged in their insight that such independent evaluation of complex systems-based programmes is a necessity to develop the rigorous evidence base required to identify what kinds of practices can improve patient safety and under what conditions. This is reflected in the fact that the independent evaluation received funding on the same scale as the SCS programme itself. Second, the independent evaluation was based on a robust framework suitable for the analysis and evaluation of such a complex socio-technical systems change programme. The evaluation of the safety case approach as part of SCS was based on 850 hours of observation, 143 interviews as well as inspection of the safety case reports produced by the participating organisations. Based on this rich data, the evaluation team was able to identify important contextual factors enabling or inhibiting the successful adoption of the safety case approach in healthcare.

The independent evaluation found that participants felt that safety cases offered the opportunity to rethink patient safety and that the safety case reports could support communication about risk and patient safety with senior executives. However, the evaluation also evidenced that participants felt that this way of thinking required education and support and that the benefits were not necessarily immediately obvious to everyone. In addition, some participants suggested that in following this way of thinking about patient safety, they identified systems-based risks, which they felt unable to influence. Lastly, the evaluation raises the issue that the concept of what constitutes an acceptable level of risk is not easily operationalised in healthcare.

**CHANGING THE MINDSET**

There has been extensive debate about whether practices from safety-critical industries can be applied to improve patient safety. While such deliberations remain important, it is crucial to consider the cultural context and the patient safety mindset in healthcare because this influences significantly whether and how successfully safety practices are adopted. Arguably, over the past 25 years there has been substantial change—or progress—in how we research, discuss and improve patient safety, even if this might not be borne out in measures of patient safety based on established methods. However, there has been much interest in systems thinking, human factors and ergonomics and resilience engineering (Resilient Health Care and Safety-II) in patient safety. In the NHS, these concepts are driving fundamental change to responding to patient safety incidents with the new Patient Safety Incident Response Framework (PSIRF), which casts aside established approaches such as root cause analysis as outdated and, largely, unhelpful and replaces these with systems-based learning response approaches underpinned by compassionate engagement with those affected.

With this changing patient safety landscape, it is very timely to revisit the concept of safety cases. Some of the findings of the independent evaluation could potentially be reframed to understand the safety case approach as a tool to help influence the patient safety mindset and drive the change. The key issue is that we use safety cases as a way of thinking critically and differently about safety. We can regard safety cases as the structured instrument that helps us consider what gives us confidence that our patients and staff are safe both in terms of our current and future risk position and in terms of our ability to deliver safe care under changing conditions, ie, from a Safety-II perspective. Safety cases emphasise the need for a diversity of data sources and measures of patient safety. They can integrate qualitative as well as quantitative evidence. But they challenge us to argue a case, that is, to reason about how the data supports claims, to remain curious and to critically reflect on where the gaps in the evidence and the arguments might be and, by extension, to identify priorities for improvement.

The participants in SCS at the time did not benefit from the recent expansion of patient safety education available to both patient safety specialists and the wider healthcare workforce. Examples from the NHS in England include the National Patient Safety Syllabus, the PSIRF and associated training as well as education in the professionalisation of healthcare investigations based on systems thinking and human factors/ergonomics offered by the Health Services Safety Investigations Body. These programmes promote systems thinking and provide fertile ground for the adoption of safety cases, which, in turn, can function as an overarching framework and communication tool for patient safety, for example, by identifying local patient safety priorities and documenting and monitoring how suggested interventions will improve these.
The independent evaluation highlighted that the safety case approach supported participants in systems thinking and in identifying organisational and systems factors contributing to patient safety risks. While such contributing factors, such as national shortages of skilled healthcare workers, might be beyond the control of individuals and organisations, it is important that these issues are captured and documented. In this way, systemic factors can be reviewed at the regional and national level, for example, through thematic reviews and national learning reports. Safety cases provide an approach that both supports identification of systemic factors and provides the necessary transparency to enable learning at the wider system level, even if in the short-term local stakeholders might not be able to mitigate the risk associated with systemic factors.

When used as a regulatory instrument, a safety case usually demonstrates that relevant risks have been reduced as low as reasonably practicable. However, in healthcare no such notion exists, and it is debatable how and to what extent consensus could be reached considering the dynamic and often personal nature of the evidence recorded in the safety case report but arising from the assurance activities that produce this evidence and from the critical review and supportive oversight enabled by it. In this sense, the safety case is a socio-technical process, not simply a risk-based technical document.

As with any approach, there is the risk that safety cases are used in a bureaucratic way without contributing to changing the mindset. In this way, safety cases might degenerate into reports, which do not provide additional value and simply contribute to safety clutter.

CONCLUSION
Safety cases reflect a systems-based approach that supports transparent reasoning and learning about safety at both the local and the wider health system level. We need to embrace the mindset that the safety case approach is not simply a report nor a safety management tool—it is an approach to support safe clinical work.

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