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PATIENT SAFETY

A case study in reducing risk

As the final report from the Francis inquiry nears, new research explores the potential benefits of using the 'safety case' approach in healthcare. By Elaine Maxwell and Angela Marciano

How do we know when healthcare is safe? To date, the way we have been addressing that question worldwide is largely by measuring harm – recording data on pressure ulcers, falls, venous thromboembolisms, serious adverse events, never events and so on.

Making predictions about the future safety of an organisation based on measurement of harm alone is not without difficulties. Healthcare is a process, with a number of inter-related interventions leading to a particular outcome.

For example, for a patient to receive the correct medication there is a process in which a drug is first prescribed, then dispensed and then administered. In order for safe treatment to occur, each of these steps must be completed correctly. Reliance on outcome measures without a deeper understanding of how these are brought about – by design or by luck – may lead to a false sense of safety.

One possible solution may be found by looking beyond healthcare to sectors that at first appear radically different, but face equal challenges to safety.

New approach

"Safety cases" were developed by the oil, nuclear and rail industries in response to their own high-profile inquiries into safety failures, which demonstrated that reliance on outcome measures and compliance with prescriptive regulatory standards alone was not enough.

The new research, *Using Safety Cases in Industry and Healthcare*, draws parallels between the healthcare sector now and safety-critical industries such as the aviation, petrochemical and nuclear industry 15-30 years ago. Safety management was patchy and poorly standardised, and relied on a prescriptive approach to safety regulation in which the regulator set out a large number of specific safety interventions that had to be implemented.

This approach did not prevent major accidents. The explosion and fires on the Piper Alpha oil platform in the North Sea in 1988, as a result of which 167 people lost their lives, ruthlessly exposed the shortcomings of predominantly reactive and prescriptive approaches to safety management and safety regulation.

The learning acquired over decades across diverse safety-critical industries – including fragmented mixed economies such as the UK's railways – ultimately led to a new approach to safety management and regulatory oversight.

Proactive techniques

Now accepted best practice, indeed mandatory for most UK safety-critical industries, the safety case is a risk-based argument with supporting evidence to demonstrate that services are operating at an agreed level of safety.

A distinguishing feature of all the industries reviewed in the report is the implementation of highly structured approaches to safety management to ensure



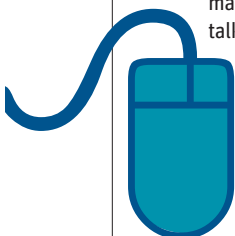
'Safety cases have the potential to radically change how we assess if an organisation is safe'

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The healthcare sector can learn how to reduce risks to patients from other safety-critical industries

on safety from a range of sources, including risk assessments, incident reporting, human factors analysis and operational experience. Local intelligence is essential as it enables healthcare teams to focus on targeted interventions that take local circumstances into account.

The safety case approach is also likely to be attractive to healthcare professionals. By asking them to look at hypothetical scenarios, safety cases can avoid the potential for blame that can occur when discussing actual incidences of patient harm.

“Safety cases have the potential to radically change how we assess whether an organisation is safe. It is possible that they will allow us to move from compliance-based assessments to one where organisations are assessed on their ability to proactively manage risks and prevent incidents occurring in the future,” says Dr Mark-Alexander Sujan from Warwick Medical School, who led the research.

The Health Foundation is already testing how this approach could work in healthcare through its Safer Clinical Systems programme.

Eight healthcare organisations are preparing their own safety cases addressing different clinical processes. For example, a team from Royal United Hospital Bath Trust is aiming to improve the reliability and safety of medication for people with Parkinson’s disease admitted to hospital – recognising that timely medication is critical for these patients and delays can contribute to falls, dehydration and other harm.

The safety case approach allowed the team to structure their safety management activities and to identify the

types of evidence they would need to construct a credible argument that their process is adequately safe.

To understand how harm could occur from incorrect, missed or delayed drug doses, they undertook a process diagnostic from home to admission and back home using structured tools, including failure modes, effects analysis and hierarchical task analysis, to identify hazards in the systems that put safe medication at risk.

The team has agreed control measures for the hazards contributing to the highest risks and is implementing them. Data is being collected to examine how successful the measures are at increasing the reliability of the process. Results will be available at the end of the year.

Next steps

In the coming weeks, the publication of the Francis report into failures of Mid Staffordshire Foundation Trust will trigger a discussion about how we can be sure that care is actually safe. For a comprehensive and convincing answer we need structured and transparent systems for patient safety management. Adopting safety cases can support organisations to understand whole systems and to focus on the highest risks in their locality.

As in other safety-critical industries, safety cases may also be used by regulators to assess the presence, rather than absence, of safety.

The UK is a leader in terms of technical expertise and practical experience in the use of safety cases in other industries. We should seize this opportunity to learn from others about how to get the big picture on safety within a clinical system before a failure occurs. ●

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that organisations are proactively identifying, assessing, mitigating and monitoring risk. The safety case regime is a means of establishing a formal structure for carrying out and documenting these activities.

Safety cases are built around an explicit articulation of the level of safety that is acceptable. The system is then investigated for hazards and their risks to safety. Interventions are designed and implemented to reduce risk to ensure that the required level of safety is met.

Content of a safety case

A safety case consists of three key elements: claims, arguments and evidence. In general it should clearly describe the following elements:

- The safety objectives that are to be achieved.

- Hazards that have been identified and how the risk they pose has been assessed.

- Risk control measures that have been put in place.

- Evidence that the risk control measures are successfully reducing the risk when they are put into practice.

What does this mean in practice? Many healthcare professionals will already be familiar with at least some of these elements, and will have experience of applying these in some form to the improvement of high-risk activities such as use of medical devices. The safety case provides a framework for extending the rigour to all clinical processes.

Unlike performance management dashboards, which aggregate and summarise data, safety cases increase the depth of scrutiny by gathering evidence