Preventing avoidable harm: learning lessons

A significant number of patients will experience some form of healthcare-associated harm during their hospital stay and, in many cases, this harm is caused by unreliable healthcare systems and processes. The Health Foundation is calling for a move away from an approach that largely looks at what can be learned when something goes wrong to one that looks at how it is possible to make sure whole systems go right in the first place, moving attention from measuring errors to designing for safety.

The extent to which healthcare can endanger patient safety is acknowledged worldwide.[1] In the UK, a case note review published in the *British Medical Journal* in 2001 confirmed that 11.7% of admissions in two hospitals led to an adverse event.[2]

A 2010 report from the Health Foundation, *How safe are clinical systems?*, presented findings from research into the reliability of healthcare systems conducted by a team from Imperial College and Warwick Medical School. It focused on five key systems and processes – availability of information when making clinical decisions; prescribing; handover; availability of equipment in operating theatres; and the availability of equipment for inserting intravenous lines – in seven NHS organisations. This research found that the reliability of care pathways can vary even within the same organisation, with between 13% and 19% of care processes failing to be completed to the agreed standard every time.[3]

The Health Foundation concluded its 2010 report by saying that it believed it was no longer acceptable to treat the level of variation in reliability it had identified as being acceptable or inevitable. It set about looking for a way forward and subsequently published the report *Using safety cases in industry and healthcare*,[4] which looks at research carried out by a team led by Warwick Medical School into the use of 'safety cases' in safety-critical industries and their potential application in healthcare.

Safety cases were developed by the oil, nuclear and rail industries in response to high-profile accidents and other drivers such as the privatisation of the UK railways. They are built around an explicit agreement of the level of safety that is deemed acceptable. Staff collect evidence from a range of different sources to build a sound argument that systems are safe and risks are controlled and monitored. These arguments and their supporting evidence

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are called safety cases.

Once risks have been identified, modifications can be put in place to ensure that those risks are reduced or eliminated and the system reliably delivers the expected levels of safety. Safety cases could provide a structured tool for showing that the local risks to clinical systems have been both identified and addressed.

Providing evidence

In safety-critical industries, manufacturers and operators of systems have to provide evidence of adequate safety performance of their systems to the respective regulatory authorities. The way this is done has changed over the past 20 years, predominantly in response to major accidents and changes to the economic environment. In the past, in these industries, safety would be claimed through satisfaction of specific standards and technical requirements specified by the regulator. However, this resulted in the practice of 'tick-box' safety management, which put a focus on compliance with standards and regulations rather than on an understanding of risks. It also hindered technological progress.

The use of safety cases is now an accepted best-practice in UK safety-critical industries and has been widely adopted by companies as a means of providing rigour and structure to their safety management systems.

The Health Foundation has been researching whether a similar approach could work in healthcare through its improvement programme *Safer Clinical Systems*.[5] Dr Elaine Maxwell, assistant director of Patient Safety at the Health Foundation, said: "The UK is a leader in terms of technical expertise and practical experience in the use of safety cases in other industries. Applying this approach in healthcare is really interesting. It would allow us to bring together information about a number of different harms to get an overall picture of safety within a clinical system."

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The recently published *Using safety cases in industry and healthcare*, report entailed an in depth review element to provide evidence, as well as a development element to work up practical examples. Experts conducted short reviews of literature and current safety case practices in six safety-critical industries to describe the use of safety cases in each industry and to identify any lessons that could be relevant to the adoption of the safety case concept in healthcare.

The six industries reviewed included commercial aviation, automotive, defence, nuclear, petrochemical and railways. A common trend across these industries is that manufacturers and operators of systems need to demonstrate the absence of unreasonable risks.

In the safety-critical industries reviewed for this project, the development and maintenance of safety cases are regulatory requirements and accepted best practice. Currently, no such explicit regulatory requirement exists in healthcare. A review of recent developments in the use of safety cases (also referred to as assurance cases) for medical devices was conducted, as well as a systematic review of the published literature for evidence of the purposeful application of the safety case concept within healthcare.

The literature review identified that research on, and application of, safety cases in the healthcare environment is scarce, with the majority of papers identified describing different aspects relating to safety assurance of medical devices.

There were, however, some examples where the safety case concept had been applied to the wider health informatics field. Connecting for Health had led in this domain. Unfortunately, despite encouraging findings, there appears to be little awareness of these developments within the wider health informatics or patient safety community at present.

The reviews carried out as part of the Health Foundation's work programme suggest that the main drivers for development currently are the standardisation efforts of organisations such as the FDA. The literature reviews further suggest that healthcare organisations need to take greater responsibility for actively compiling evidence that the complex systems they

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operate to provide patient care are, in fact, safe. However, this will only be possible when adequate resources and training opportunities are provided to these organisations to enable them to build up the required capability.

Application scenario

As part of the project, a workshop was held with stakeholders from the healthcare community to discuss opportunities and challenges for the adoption of safety cases.

An appropriate application scenario for the study was considered to be that of the process of patient infusion – administration of IV fluids – using infusion devices in a hospital department.

The clinical safety case in this scenario, for example, would need to support the claim that 'patient infusion in department X of hospital Y is acceptably safe'. This scenario was chosen because it concerns a safety-critical activity; involves one or more programmable devices and their operators; and has a reasonable level of complexity.

Before moving on to the safety argument and the evidence, the scope of the clinical safety case needs to be defined. It is, therefore, necessary to identify and record the definition of 'acceptably safe' and the scope of the clinical safety case. Figure 1 illustrates the top-level claim and the main argument that the report authors envisage would support it.

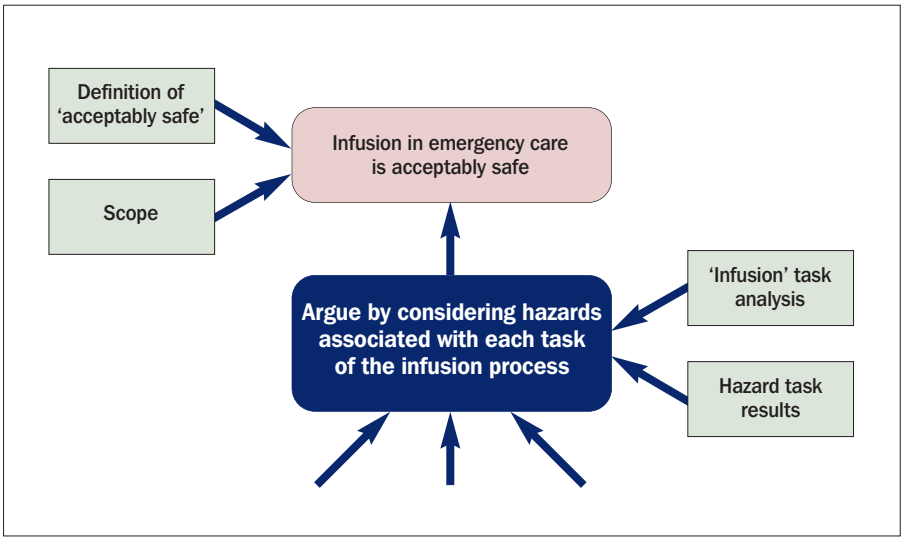

Figure 1: Proposed clinical safety case top-level claim.

One way to support the claim is to break down the sub-tasks that make up the activity and argue their safety individually. This would require an 'infusion' task analysis to be undertaken, including a description of manual and mental activities, task and element durations, task frequency, task allocation, task complexity, environmental conditions, necessary clothing and equipment, and any other unique factors involved in or required for one or more people to perform a given task. A multidisciplinary hazard and operability study (HAZOP) would also be needed.

It would also be important to identify dependency on other departments. Patient diagnosis, and probably drug prescription, are outside the scope of the activity of infusion but are still critical inputs. The

clinical safety case would need to identify and record these inputs.

The report recommends the following steps to develop this proposed clinical safety case.

- **Interviews** – Key staff, such as nurses, physicians, pharmacists, medical device manufacturers and hospital IT administrators, would provide input at different stages of the development.
- **Analysis of documents** – Several types of documents, such as manuals for infusion pumps and other devices, hospital procedures, incident reports (if made available), prescription forms etc, will be consulted. Information systems may be examined, and how they are used in the process of infusion (for example, to identify patient records). This, along with interviews, will assist in understanding and documenting the protocols that are followed to carry out patient infusion.
- **Task analysis** – Task analysis is a user-focused approach to the analysis of activities. Various methods exist – for example, hierarchical task analysis – but they all attempt to break down tasks for further analysis. Task analysis is useful because apart from identifying potential error modes, it also identifies information flows and dependencies on other parts of the hospital. The resulting model will be the basis for the hazard analysis.
- **Hazard and operability study (HAZOP)** – The HAZOP is crucial. HAZOP is one of the most widely applied hazard identification approaches in the safety-critical domains. A multidisciplinary HAZOP team is likely to provide significant insight, in particular from nurses – not only are they the users, but they also possess tacit knowledge about the process and interact with patients, physicians and others in the hospital to carry out this particular activity.
- **Safety argument development in assurance and safety case environment (ASCE)** – ASCE, the Adelard safety case tool, provides a graphical environment for the development of safety cases. The CAE (or GSN) approach in ASCE could be used to develop and report this clinical safety case.

Current safety case use in healthcare

Medical devices
The FDA is recommending the adoption of assurance cases as part of the pre-market notification submission for infusion pumps.

Health informatics
Connecting for Health previously issued guidance on the preparation of a clinical safety case for health informatics products.

Education
Education and training need to be provided to the organisations producing safety cases as well as the bodies reviewing them.

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Recommendations

The report recommends that pilot studies be developed to help demonstrate clinical safety cases in areas of recognised patient safety risk. These pilots should be constructed bottom-up, with the support of clinicians to ensure that they are clinically relevant.

Measures of success, such as enhanced clinical engagement and improved communication, need to be defined, and then investigations undertaken to discover through which mechanisms these are met by participation in the development of clinical safety cases.

Regulatory bodies may wish to investigate in collaboration with relevant stakeholders whether the adoption of clinical safety cases could be a feasible regulatory instrument and whether this approach could contribute to greater transparency in the regulatory process.

It would also be necessary to provide training and education to healthcare organisations in the systematic and proactive approaches to patient safety risk management and the Health Foundation is testing these approaches through its Safer Clinical Systems programme.[5]

Conclusion

The report concludes that safety cases have the potential to support healthcare organisations in the implementation of structured and transparent systems for patient safety management. Similar structured approaches have already proved to be effective tools in safety-critical industries.

Dr Mark-Alexander Sujan, from Warwick Medical School, who led the research, concludes: "Safety cases have the potential to radically change how we assess whether an organisation is safe. It is possible that safety cases 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."

The *Using safety cases in industry and healthcare* report highlighted a number of potential benefits of using safety cases in healthcare, including:

- The promotion of structured thinking about risk among clinicians and fostering multidisciplinary communication about safety.
- Integrating evidence sources.
- Aiding communication among stakeholders.
- Making the implicit explicit.

Risks and challenges identified include safety cases:

- Becoming a paper exercise.
- Being removed from everyday practice.
- Being produced by the wrong people.

References

1 World Health Organization (2009). WHO Patient Safety Research: Better Knowledge for Safer Care. Geneva: World Health Organization.

2 V2. Neale G, Woloshynowych M and Vincent C. 'Adverse events in British Hospitals: preliminary retrospective record review'. *BMJ* 2001; 322 (7299): 517-9.

3 The Health Foundation: *How safe are clinical systems*? (2011). http://www.health.org.uk/publications/evidence-in-brief-how-safe-are-clinical-systems

4 The Health Foundation: *Using safety cases in industry and healthcare*. http://www.health.org.uk/publications/using-safety-cases-in-industry-and-healthcare

5 http://www.health.org.uk/areas-of-work/programmes/safer-clinical-systems Accessed 28 January 2013.

> 'The literature review identified that research on, and application of, safety cases in the healthcare environment is scarce.'