

Exploring the potential use of safety cases in health care

Report of the Health Foundation's Safety Cases Working Group

Executive summary

The Safety Case Working Group was convened by the Health Foundation between October 2013 and January 2014 to crystallise our understanding of safety cases – both in terms of how they are applied in other industries and how they might be applied in health care – and to make some recommendations for how the Health Foundation and the wider system could take this work forward. This report summarises the working group's conclusions, explores possible applications of safety cases in health care, and provides recommendations for further work.

Conclusions

The working group agreed that the key elements of a safety case are:

- a structured high-level argument...
- with evidence to support the argument...
- which makes the case for the safety of a service (as far as that is possible)...
- which is part of a proactive process that involves identifying risks and controls.

While the concept of a safety case cannot be directly imported into health care from other industries, it was agreed that the three potential applications for safety cases in health care are:

- to **approve** the safe introduction of new products, processes or infrastructure
- to **improve** the safety of health care services
- to **assure** the safety of health care services.

Using safety cases for **product approval** was the original application of safety cases in other industries, and there may be potential for using safety cases to build on existing processes for the approval of drugs and medicines in the UK.

The Health Foundation's Safer Clinical Systems programme¹ has demonstrated the benefits of safety cases in promoting a safety culture that includes proactive thinking about safety as part of a suite of diagnostic tests and interventions for **service improvement**.

Using safety cases as part of an **assurance process** – both internal and external – offers perhaps the greatest potential benefit, but requires boards, regulators, professionals and the public to actively welcome the identification of risks.

The working group identified a number of potential benefits to developing safety cases in health care. Key benefits include the following:

- They bring together and synthesise a range of information and evidence relating to a particular service.
- They can have a positive impact on capability and safety culture.
- They provide a structure for proactively assessing future risk.

¹ www.health.org.uk/areas-of-work/programmes/safer-clinical-systems

Safety cases also provide a unique opportunity to have more open discussions about risk in health care and what we mean by acceptable levels of safety. Having these informed conversations will be a greater challenge for those providers who have yet to reach the necessary level of maturity.

The benefits of using safety cases will only be achieved if they are introduced as part of a wider effort to be more candid about the risks associated with health care, and with the development of the necessary human factors skills to undertake the analysis required to inform them.

Recommendations for further work

It was agreed that, once the evaluation of Safer Clinical Systems phase 2 was published,² the work on safety cases would be fully appraised. Consideration will then be given to the recommendations for further work outlined below:

- To establish a persuasive evidence base for the potential benefits of safety cases for safety culture and patient outcomes, so that the case can be made to boards, regulators, frontline professionals and the public. This could be achieved through case studies, pilots, further research or evaluation or other materials.

- To consider the level of training, support and guidance that NHS staff would need to support a safety case approach, and building capability among clinical, risk and governance professionals to improve how risk is diagnosed and assessed.
- To develop NHS-specific tools, with training and support, that could be used to support safety cases as a service improvement approach.
- To describe in more detail the different ways safety cases could be used, and how the definition and component elements would vary accordingly.
- To better understand the conditions that create the most fertile ground for improvement using safety cases, and to identify factors that ensure safety cases can be targeted on those areas of greatest need.
- To develop a short, accessible definition of the safety case approach that better illustrates it as an activity or approach, rather than an end product; and to investigate further what we really mean by a ‘safety claim’ in health care.
- To integrate the safety case approach with the framework for measuring and monitoring safety developed by Charles Vincent, Susan Burnett and Jane Carthey.³

² The report *Safer Clinical Systems: evaluation findings* was published in December 2014. See www.health.org.uk/scsevaluation

³ Vincent C, Burnett S, Carthey J. *The measurement and monitoring of safety*. London: The Health Foundation, 2013. www.health.org.uk/measuresafety

Exploring the potential use of safety cases in health care

1. Introduction

Improving the safety of people using health care services has been a priority for the Health Foundation over the past decade. Our Safer Patients Initiative, which ran from 2004 to 2008, was the first major improvement programme to begin to address the issue of patient safety in the UK.⁴ We continue to inspire improvements in patient safety through our wide-ranging programme, research and policy-influencing activities.

We believe that the time is now right to lead a step change in how we think about patient safety. An approach that seeks to identify and manage risks **before** they lead to harm holds the greatest potential benefit for patients and the public, health care professionals and resources. We have funded research and improvement programmes to explore how this change might be achieved. The use of safety cases is one such approach that the Health Foundation is particularly interested in.

Safety cases... are a proactive technique for illuminating the important, but often invisible, risks in clinical systems, increasing the reliability of the system and so reducing adverse events.⁵

In December 2012, we published *Using safety cases in industry and healthcare*.⁶ The research reviewed how safety cases are being used in six safety-critical industries as well as their emerging use in health care. The authors concluded that 'safety cases have the potential to support health care organisations in the implementation of structured and transparent systems for patient safety management'.

We have also run the Safer Clinical Systems improvement programme, the second phase of which took place between 2011 and 2014. Focusing on improving systems in the areas of clinical handovers and prescribing, eight teams developed safety cases and used a number of tools and approaches to identify hazards and demonstrate how the risks are being managed.

Based on this ongoing work, and the potential for safety cases to offer a more proactive approach to improving safety in health care, the Health Foundation convened a working group in October 2013 'to come to a view about how safety cases, or the principles of the safety case approach, can be applied in health care in order to drive improvements in patient safety in the NHS'. Specifically, the group sought to:

- set out a clear definition (including essential elements) of a safety case, making it accessible and understandable to a range of audiences (including the public, frontline health professionals and boards)

⁴ For information about the programme, see: www.health.org.uk/areas-of-work/programmes/safer-patients-initiative/

⁵ Sujan MA, et al. *Using safety cases in industry and healthcare*. London: The Health Foundation, 2012. www.health.org.uk/safetycasesreport

⁶ Sujan MA, et al. *Using safety cases in industry and healthcare*. London: The Health Foundation, 2012. www.health.org.uk/safetycasesreport

- come to a common understanding of how safety cases have been applied in industry and health care, where they have been effective and why, and identify any gaps in our current understanding
- come to an initial view about which elements of a safety case approach are the most attractive to the group, with consideration given to resource requirement, necessary supporting evidence and patient involvement.

We brought together a broad range of individuals from health care policy, practice and regulation, together with academics with expertise in safety cases as well as those involved in developing safety cases as part of the Safer Clinical Systems programme (see appendix for the working group's full membership). The group was chaired by Hugh McCaughey, Chief Executive of South Eastern Health and Social Care Trust, and met four times between October 2013 and January 2014.

2. Areas of likely application for safety cases

In section 3 of this report, we summarise the key topics of interest that the working group tackled in its discussions. This preceded the more detailed discussion in our final meeting of how safety cases could be applied in health care. The working group agreed that there are three potential applications for safety cases in this context, which are listed below along with a summary of the discussion.

The potential applications are:

- to **approve** the safe introduction of new products, processes or infrastructure
- to **improve** the safety of health care services
- to **assure** the safety of health care services.

Using safety cases to gain **approval** for the safe introduction of something new – be it a nuclear plant or an infusion pump – is considered to be the original application of a safety case. For instance, the US Food and Drug Administration approval process introduced the requirements on medical device manufacturers to provide a 'safety assurance case' (or safety case) as part of the approvals

process for infusion pumps.⁷ Safety cases are also widely used in the nuclear and defence industries internationally.

We also learned that safety cases are currently being used in the NHS. Suppliers of health IT solutions to the NHS have to produce a safety case to demonstrate that a full risk and hazard assessment process was followed. So far, the Health and Social Care Information Centre has trained 2,000 NHS clinicians to be able to review and sign off a safety case.⁸

So in what circumstances could a safety case approach be used to aid the safe introduction of a new process, system or device? Some real-life examples explored by the working group included the following.

- Where a medical product is introduced to the NHS. For instance, we saw from the Poly Implant Protheses (PIP) breast implant scandal that the use of unauthorised silicone filler meant these implants had twice the rupture rate of other implants.
- Where an IT solution is introduced to the NHS. For instance, the failed introduction of the Medical Training Application Service (MTAS) for allocating junior doctor training posts left many junior doctors without placements.
- Where a new process is being considered to improve the quality, safety or efficiency of a service. For instance, it was suggested that the introduction of a standardised method for administering drugs on ward rounds would benefit from a safety case approach.

The use of safety cases as a **service improvement** tool was illustrated by one of the Safer Clinical Systems sites, but this approach is largely untested in other industries. At that site, the team sought to improve the handover of care between medical and surgical teams for people with established renal failure (ERF), after issues with communication had been found to be affecting the quality of care.

⁷ US Food and Drug Administration. *Guidance for Industry and FDA Staff – Total Product Life Cycle: Infusion Pump – Premarket Notification*. www.fda.gov/medicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm206153.htm#6

⁸ Health and Social Care Information Centre. *What is the role of Clinical Safety?* <http://systems.hscic.gov.uk/clinsafety/intro>

The safety ‘claim’ made by the team was:

Shared care arrangements between renal medicine teams and surgical teams for patients with ERF are safer than currently – ie, the risk associated with the pathway is reduced.

This was more of a goal, and less specific than the claim made in other industries that ‘the service is acceptably safe’.

The team identified a number of hazards in the pathway using a range of information sources and risk assessment activities. The activities helped to instil a proactive safety mindset and provide a structure for safety management activities, but the residual risks in the pathway ‘remained high’. It was suggested that one reason for this may have been due to applying the safety case approach to improve a ‘complex legacy system’.

At the same time, if safety cases are used to improve a service in a continuous way, then the approach to safety matures – it is resource intensive to begin with but then it generates momentum. So if one benefit of safety cases is seen as being ‘a vehicle for changing people’s view of safety’, or of improving safety culture through a journey of realisation, then it is worth considering having claims that are less specific. **The working group recommends that further work should identify the benefits of safety cases on safety culture.**

The group commented that getting NHS boards to understand some of the issues associated with safety can be difficult, and a safety case in its current format may not help to achieve this. This problem may not be helped by the current lack of evidence to demonstrate that safety cases can make health care safer, although the lack of progress in making further improvements in safety suggests that a new approach is necessary.

Safety cases have ‘face validity’ in other industries, and are accepted as best practice. It was agreed that for safety cases to work in service improvement in health care, there would need to be some service-specific tools, with support and training available to all levels of staff, with end products digestible to boards and wider audiences. **This was a recommendation for further work.**

When considering the use of safety cases in health care for **assurance** purposes, then we must bear in mind that the regulatory landscape for the NHS in England is changing. The Care Quality Commission (CQC) has toughened its inspection regime and put in place enhanced arrangements for the ‘intelligent surveillance’ of trust performance.⁹ Monitor is now the economic sector regulator for health care, and has notably increased the number of interventions since the Francis Inquiry.¹⁰ The NHS Litigation Authority is changing how it rewards/incentivises organisations that have fewer, less costly claims and is introducing a new Safety and Learning Service to help support its members.¹¹ There is also now a Trust Development Authority responsible for developing non-foundation trusts.¹²

The working group had representation from each of these national bodies, and there was a general agreement that for safety cases to be used effectively as an assurance tool, there needs to be a constructive approach to them from the regulators. Learning from other industries also suggests that regulators themselves require education and training with the approach, and that the industry in turn requires guidance from the regulator. In aviation, EUROCONTROL has issued a safety case development manual to support organisations. In the automotive industry, efforts are being made to develop templates that organisations can use.

Safety cases encourage transparency about risks, but organisations need to feel that they will not be penalised by regulators for surfacing these risks. We are seeing signs of a new approach from regulators – for instance, in the way that the CQC is asking organisations to demonstrate how they are meeting particular standards, rather than prescribing how they meet the standard.

Safety cases adopt a similar approach, and the regulators believed that an approach which proactively identifies and controls risks would be welcomed. Regulators could ask how safety cases

⁹ Care Quality Commission. *Consultation on changes to the way we inspect, regulate and monitor care services* www.cqc.org.uk/content/consultation-changes-way-we-inspect-regulate-and-monitor-care-services

¹⁰ Hazell W. Exclusive: *Monitor interventions double in response to Francis*. HSJ January 30 2014. www.hsj.co.uk/news/exclusive-monitor-interventions-double-in-response-to-francis/5067481.article

¹¹ NHS Litigation Authority. *Improving patient and staff safety*. www.nhsla.com/Safety/Pages/Home.aspx

¹² NHS Trust Development Authority. www.ntda.nhs.uk

are being used, give credit to those done effectively and identify those done less so, but it would not be appropriate to **require** them from trusts in case it becomes a ‘tick-box exercise’. Crucially, it was felt to be counterproductive to immediately sanction an organisation for the risks identified in its safety case, without giving the board the opportunity to address the risks first. The CQC has already indicated that it would be receptive to a provider that was willing to disclose its problems to the regulator as a sign of an open and transparent culture.

While there was general agreement that the undertaking and continued update of a safety case demonstrates the maturity of an organisation – that it is ‘problem facing’ and willing to engage with the risks of its processes – it may not demonstrate that the organisation is achieving better outcomes for patients.

Another Safer Clinical Systems site was helpful in describing how safety cases could be used as an assurance tool. The team sought to assure the safety of its own clinical handover of patients between medical services and the hospital at night service. They made an ‘assurance statement’ of the safety of the handover, based on an identification of hazards, an assessment of their likelihood and severity, a description of how well the risks are currently controlled, what residual risks remain, and what is being done/should be done to manage these risks.

The group discussed whether safety cases would be appropriate for public consumption, which has not been the case in other industries. It was agreed they would need to be adapted if they were going to be useful for patients and the public. More generally, there would be multiple stakeholders with an interest in safety cases, but a single presentation would not be suitable for all audiences. Another problem raised was that the demand for transparency could have the unintended consequence of making people want to hide their flaws for fear of repercussions. The least desirable outcome would be having some kind of ‘safety theatre’, where safety cases are produced to make it appear that an organisation has engaged with safety rather than genuinely doing so.

The working group recommends that pilots, case studies and other materials should be developed to help build the evidence base for safety cases and introduce the concept to different stakeholders in a more accessible way.

3. Areas of discussion and consensus statements

There were a number of themes that either arose in discussion more than once, or were identified by the group as important to address in order to take forward work on safety cases in health care. These discussions are summarised below, with a consensus statement on each issue, whether or not a firm conclusion could be drawn.

3.1 How can we define and describe a safety case?

The working group was tasked with setting out ‘a clear definition (including essential elements) of a safety case, making it accessible and understandable to a range of audiences (including the public, frontline health professionals and boards)’. It was felt that although technically correct and a helpful starting point, the definitions of safety cases as taken from their application in other industries would only go so far to help to achieve this goal. Some of the more accessible definitions include:

*... a risk-based argument and corresponding evidence 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 ongoing basis.*¹³

*... to provide 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.*¹⁴

While these definitions are helpful, the working group felt that they remained ‘jargony’ and would compound the problem of the concept not being accessible to the health care sector. One way to tackle this would be to describe the different ways

¹³ Sujan MA, et al. *Using safety cases in industry and healthcare*. London: The Health Foundation, 2012. www.health.org.uk/safetycasesreport

¹⁴ Kelly T. *Arguing safety – a systematic approach to managing safety cases*. York: University of York, 1998.

in which safety cases can be used (for example, at the service or organisational level) and how the definition and different elements would vary accordingly. **This was a recommendation for further work.**

It was suggested that there is a need to be explicit about what distinguishes a safety case from, for example, a good risk assessment. This could be done by being explicit about a safety case requiring two critical elements: high-level argument and supporting evidence.

Consensus statement

A safety case is typically made up of the following elements:

- a structured, high-level argument...
- with evidence to support the argument...
- which makes the case for the safety of a service (as far as that is possible)...
- which is produced as part of a proactive process that involves identifying risks and controls.

Further work is required to develop a short, accessible definition of a safety case for the NHS.

3.2 Importing the safety case model from other industries

In *Using safety cases in industry and healthcare*, Sujan *et al* describe the evolution that has taken place over the past 20 years in industries such as oil, nuclear and rail to demonstrate how safe their systems are.¹⁵ Previously, manufacturers and operators had to meet specific standards from regulators, but this approach was proven to be ineffective. It was replaced by a requirement that manufacturers and operators demonstrate that they have a systematic approach to identifying and controlling risks. This is often achieved through a safety case.

The working group felt that the safety case model could not be directly imported into health care as it currently stands. There was no clear definition of what constituted acceptably safe care in health,

which meant that making a safety claim would be difficult. It was suggested that it may be better to think of the use and application of safety cases as risk-benefit arguments when considering the introduction of new and difficult procedures, technologies or care pathways, for instance.

Consensus statement

Safety cases, as used in other industries, should not be directly imported into the context of health care. Although the core concept stands, implementation will need to be tailored to the health care context and will then vary according to how it is applied.

3.3 Risks and opportunities of using safety cases

Building on the findings of the Sujan *et al* research report, the group emphasised the power of safety cases to act as a 'communication tool', as well as how they can help organisations identify gaps in their current approach to identifying and managing risks. Further benefits can include integrating evidence from a diverse range of sources, exposing implicit assumptions about safety, creating greater transparency, improving how resources are targeted, and preventing awareness of safety issues 'falling down the cracks'.

The research also warned that safety cases must not become just another 'filed return'; they must be grounded in reality and not become a paper exercise, and they should not be automatically outsourced to external consultants (although there can be benefits to acquiring additional expertise and capacity to support people to develop them). Initial feedback from the Safer Clinical Systems programme suggests that one of the greatest benefits is the impact that undertaking the analysis to develop a safety case can have on improving the safety culture of an organisation. So while it was recognised that external support can be valuable, this should not detract from the value gained by building internal capacity and capability.

¹⁵ Sujan MA, et al. *Using safety cases in industry and healthcare*. London: The Health Foundation, 2012. www.health.org.uk/safetycasesreport

One criticism of the safety case approach – or more specifically of undertaking the activities that informed the safety cases in the Safer Clinical Systems programme – is that it can be very resource intensive. The early experience of the programme suggests the need for external training and support if it is to be applied elsewhere. However, safety cases help to surface issues and therefore the effort involved should be judged against the risks of continuing to deliver services without knowing about or addressing the risks. Similarly, there was an acknowledgement of the steep learning curve involved, but this would eventually require less effort as people became more practised in developing safety cases.

One strength of safety cases is their ability to draw information together (they are also known as ‘synthesis documents’), but they must explain why something is happening, and not just note that it happens. The group agreed that the process of writing a safety case was not divorced from the process of investing time in diagnosing the problem, given that capacity for the latter would be the most significant constraint and yet where the greatest value lay.

Consensus statement

The key **potential** benefits to developing a safety case are that it: brings together and synthesises the range of information and evidence relating to a particular service; can surface previously unidentified issues; can have a positive impact on capability and safety culture; and provides a structure for proactively assessing future risk.

3.4 Targeting the use of safety cases

Some of the early feedback received from the Safer Clinical Systems programme suggests that the process of developing a safety case using the diagnostic tools surfaced a number of process risks, which were not necessarily on the team’s radar beforehand. At the same time, the working group felt that, in principle at least, there was real benefit to establishing a means by which safety cases could be targeted on those areas where the greatest benefit could be had – both in terms of the risk presented by a service, and what we might understand as ‘fertile ground’ for improvement.

It was noted that the amount of work that goes into a safety case is dependent on the amount of diagnostic information already in existence and should be proportionate to the risk presented. But again, it is difficult to determine the level of risk without undertaking some of the activities that form an integral part of a safety case. One of these activities is to establish the ‘fidelity’ of the information sources and evidence to support the claim, and this is critical to being able to target efforts in the right areas.

Consensus statement

In principle, the safety case approach should be applied to those areas of greatest risk to patient safety, and to those circumstances that create the most fertile ground for improvement. But further work is required to understand the most effective ways to do this.

3.5 Capacity and capability

For some organisations, the real challenge in adopting a safety case approach will be having the necessary systems and behaviours to collect and synthesise the data, intelligence and evidence and present this in a coherent safety case document. In this sense, the working group felt it was important to disaggregate the resources required for the production of a safety case and the costs of generating the necessary data to inform it.

As we know from some of our other work,¹⁶ there is a preoccupation with the use of retrospective data, and the NHS tends to be much better at collecting data on harm than on risk. While safety cases offer the opportunity for the NHS to be more proactive in managing safety, the group was also reminded that historical data make a good ‘starting point’ for building the evidence to support a safety claim. Safety cases would provide the opportunity to make better use of data already collected, inspire people to collect more relevant data, and synthesise and share it in a more meaningful way.

¹⁶ For details of our work on patient safety, see: www.health.org.uk/areas-of-work/topics/patient-safety/making-care-safer

The potential for a ‘safety case-light’ approach was discussed. In other words, would it be possible to retain the bulk of the benefit of a safety case without taking the same degree of effort and resource that is normally required to produce the evidence to support one? This would make it, superficially at least, more attractive to an already stretched NHS, but at the same time it might raise the risk of safety cases becoming a tick-box exercise. Given that the benefits of a safety case are largely accrued through the diagnostic techniques that accompany it, questions remain about the feasibility of this ‘light’ approach.

It was remarked that, generally speaking, people in the NHS do not receive the necessary support and training in diagnosing and assessing risk, and there is no systematic way of doing this in the NHS. It might also be unreasonable to expect risk managers to undertake a safety case and present the difficult messages it may uncover to the board. Feedback from one of the Safer Clinical System site teams noted that clinical involvement in the production of the safety case had the advantage of bringing a sense of ownership to teams, although clinicians would need to be released from their clinical work to produce them, and people from across the pathway would need to attend key meetings. This is a broader issue that is relevant to most kinds of safety and quality improvement work.

Consensus statement

An integral part of developing a safety case is to collect the right information and evidence to support an organisation’s understanding of risk, with the appropriate resources allocated to it. The prevailing approach to risk management means that NHS staff will require support and training in order to better diagnose and assess risk, and will need protected time to be involved in the production of a safety case.

3.6 Using safety cases to have more open discussions about risk in health care

The safety claim about the level of risk of a particular service, product or process – often articulated, by a service provider to an external body, as a 1 in X chance of failure – is at the heart of

how safety cases have been used in other industries. However, it was felt that it would be ‘prohibitively difficult’ to calculate the risk of failure and the current level of safety in health care, due in part to the many variables that can influence it. The working group also questioned whether the public, regulators, the media and even NHS trust boards were ready to engage in a mature discussion about what level of risk is acceptable, or hear the level of risk that currently exists.

The requirement for NHS trust board meetings to be held in public made this potentially more difficult for some organisations. On the other hand, this is an issue that demands transparency, so that all stakeholders have a better understanding of levels of risk. We have seen recent examples – Kettering General¹⁷ and Colchester Hospital¹⁸ – of how an organisation’s failure to be open about its risks generates an angry reaction from the public.

The question of acceptable levels of risk is not only influenced by who is asking the question, but also by the level of maturity and development that the organisation has reached. For those organisations that do not yet possess the level of maturity to have open conversations about risk, the safety case approach presents particular challenges but also perhaps a unique opportunity for them to begin developing these conversations.

Consensus statement

Safety cases offer a unique opportunity to have more open discussions about risk in health care and what we mean by acceptable levels of risk. This will be a greater challenge for those providers who have yet to reach the necessary level of maturity to have these informed conversations. There also remains a critical role for the regulators, the public, the media, national agencies and government to create an environment in which such open disclosures are viewed positively and actively encouraged.

¹⁷ Devlin L. Kettering Hospital withholds death inquiry findings. BBC News, January 21 2014. www.bbc.co.uk/news/uk-england-northamptonshire-25766360

¹⁸ Meikle J. Colchester hospital faces criminal investigation over waiting list figures. *The Guardian*, November 26 2013. www.theguardian.com/society/2013/nov/26/colchester-general-hospital-criminal-investigation

3.7 Making the case for safety cases

The working group underlined the need ‘to make the case for safety cases’. This was necessary given the strain that the NHS is currently under to meet the dual challenge of meeting the efficiency target set for it and the ever-changing needs of the population it serves. A number of potential benefits were discussed in section 3.3 – including around changes to levels of risk and in the safety culture of an organisation – but there remains a lack of evidence to support the application of safety cases in health care. **The working group recommends that more is done to establish this evidence base.**

There is then the issue of communicating any potential benefits to the intended users of safety cases, which begs the question ‘Who is the audience for a safety case and what is in it for them?’ For instance, boards need to see the value-for-money benefit and potential impact of any new approach. Although potentially insightful for clinicians, there was concern that the approach would not make sense for many frontline professionals. What does the patient do with the information when it is presented to them? And how does this approach affect the relationship between the provider (who is demonstrating their ability to identify and manage risk) and the regulator (who seeks assurance from that)? **The working group recommends that this would need to be translated for people at different levels of the system.**

Consensus statement

Making the case for the use of safety cases by people at all levels of the system (boards, clinicians, the public) would be a critical phase in the promotion of safety cases. Prior to this, more work needs to be done to establish a persuasive evidence base for the use of safety cases.

3.8 Placing safety cases in the context of other developments in patient safety

Alongside the regulatory developments in the English NHS described in section 2, further opportunities should be sought to embed the application of safety cases in the context of developments in Scotland, Wales and Northern Ireland. It was raised that there had been little discussion of the role of commissioners in safety cases, but they should be ‘demanding’ a demonstration that the services they purchase on behalf of their patients are safe. It was subsequently raised that the experience of other industries (automotive, aviation and railways) suggests that safety cases can have a positive role where services are distributed across a number of different organisations and actors, which reflects the way that health care services are configured across the UK.

In 2013, the Health Foundation published the research from Charles Vincent and colleagues on measuring and monitoring safety in health care.¹⁹ The research identified the need for organisations to measure how risks are being anticipated and prepared for, and for information from a broad range of sources and perspectives to be integrated and learned from. The group agreed that the safety case approach could help to address the questions in the framework, and further thought should be given to how the two concepts relate to each other in future work.

¹⁹ Vincent C, Burnett S, Carthey J. *The measurement and monitoring of safety*. London: The Health Foundation, 2013. www.health.org.uk/measuresafety

Appendix: Members of the Safety Cases Working Group

| Name | Organisation |
|--------------------------------|--|
| Hugh McCaughey (Chair) | Chief Executive of the South Eastern Health and Social Care Trust |
| John Illingworth (Secretariat) | Policy Manager, the Health Foundation |
| Dr Maureen Baker | Clinical Director for Patient Safety, Royal College of General Practitioners (RCGP) |
| Professor Nick Barber | Director of Research, the Health Foundation |
| Dr Steve Cross | Quality and Safety Manager, United Lincolnshire Hospitals NHS Trust |
| Dr Vin Diwakar | Medical Director, Birmingham Children's Hospital NHS Foundation Trust |
| Professor Mary Dixon-Woods | Professor of Medical Sociology, Leicester University |
| Professor Katherine Fenton OBE | Chief Nurse, University College London Hospitals NHS Foundation Trust |
| Dr Matthew Fogarty | Head of Patient Safety Policy and Strategy, NHS England |
| David Gurusinghe | Technical Claims Manager, NHS Litigation Authority |
| Dr Rishi Hazarika | Senior Policy Advisor, Monitor |
| Elaine Inglesby-Burke | Director of Nursing and Executive Lead for Nursing, Governance, Quality and Safety, Salford Royal NHS Foundation Trust |
| Professor Tim Kelly | Professor of High Integrity Systems, Department of Computer Science, University of York |
| Alison Lovatt | Clinical Improvement Network Director, Yorkshire and Humber Improvement Academy |
| Dr Melinda Lyons | Senior Consultant , DNV |
| Dr Kathy McClean | Medical Director, NHS Trust Development Authority |
| Dr Carol Peden | Associate Medical Director for Quality Improvement, Royal United Hospital Bath and NHS England (South) |
| Penny Pereira | Assistant Director, the Health Foundation |
| Cate Quinn | Regulatory Policy Manager, Care Quality Commission |
| Dr Brian Robson | Executive Clinical Director, Healthcare Improvement Scotland |
| Professor Peter Spurgeon | Director, Institute of Clinical Leadership, University of Warwick |
| Dr Mark-Alexander Sujjan | Assistant Professor, University of Warwick |
| Dr Simon Watson | Clinical Associate/ Consultant Nephrologist, NHS Lothian |
| Dr Andy Weale | Consultant Vascular & Renal Transplant Surgeon, North Bristol NHS Foundation Trust |
| Dr Janet Williamson | Director of Programmes, NHS Improving Quality |