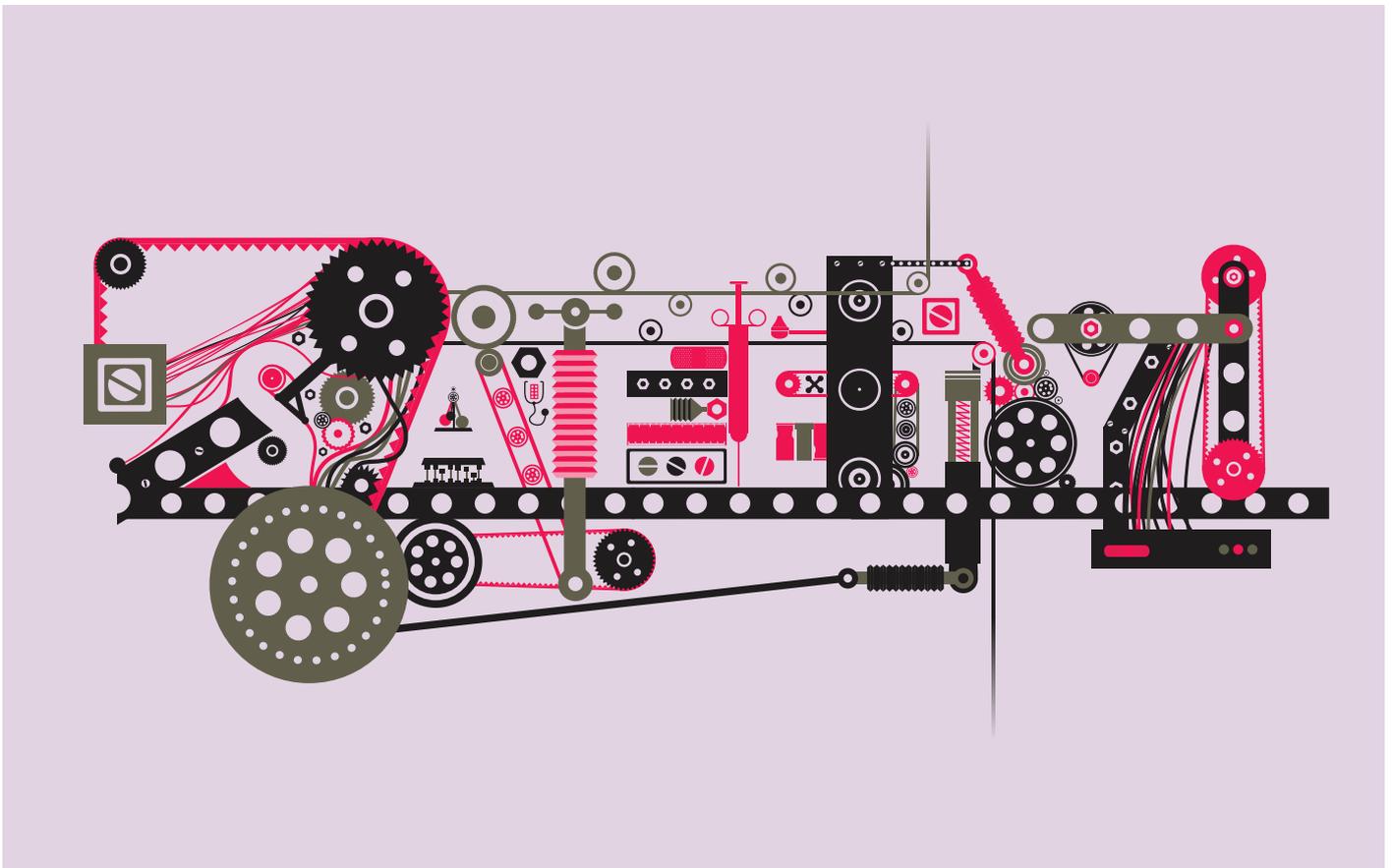


In brief

Safer Clinical Systems: evaluation findings

Health Foundation summary and analysis

January 2015



For more information and to download or order the full report, please visit:

www.health.org.uk/scsevaluation

Getting safer all the time: how the NHS can learn from other high-risk industries

Providing health care is often complex and high risk. There are many ways in which it can go wrong, with latent hazards that may ultimately emerge as harm to patients. Health care providers seek to control risks by having incident reporting systems and risk registers to try to keep track of all the safety challenges that staff document. While often generating huge amounts of data, these methods yield an incomplete picture of the extent to which systems are safe. Analysis tends to be based on reports of what has gone wrong in the past. This has an important part to play in monitoring and measuring safety but may not be a good indicator of the next problem to arise or the underlying causes of harm.

What are 'hazards' and 'risks'?

Hazards are conditions or events that can lead to or contribute to harm.

Risks involve an assessment of the likelihood of a hazard occurring and the severity of the consequences.

Other hazardous industries such as aviation, mining and nuclear power have managed to reduce risks to the public and to staff, and pay constant attention to further improvements in safety. They do this through systematically understanding their work processes and the risks associated with them, and then redesigning the processes with safety objectives in mind. In many of these industries, companies are required to provide regulators with a safety case – a structured assessment of all the processes that contribute to a particular activity or installation, which allows a reasoned claim to be made about how safe it is. These industries do not achieve results on safety by chance; it has taken sustained resources and focus at all levels over many years.

In health care, despite the progress made in recent years, the approach to safety and process improvement is less mature. Significant resources are invested in tracking and responding to past harm to patients and many impressive projects have been undertaken on specific safety issues, both nationally and locally. However, there has so far been only limited mainstream investment in ensuring that the processes that underpin the delivery of health care are designed in a way that will enhance safety.

The health system works through a complex mesh of clinical, information and support processes that all need to be co-ordinated for each of the millions of patients who use the NHS in different ways each year. Our analysis reveals that all too often, the processes that patients and staff have to rely on are poorly defined and unreliable. To protect patients in this environment requires constant effort and double checking by the people providing health care. This comes at a cost in terms of stress and efficiency and (as the high rate of harm in health care testifies) is a far from fool-proof strategy for ensuring safety.

Redesigning processes so that the problems are addressed at source is the right approach, but our analysis shows progress on this front is constrained by operational deficits, as well as estates, staffing and organisational culture problems and deep-rooted IT issues.

This combination of unreliable processes and pervasive constraints represents the operational reality for many working in health care. In this context, setting ambitious goals for patient safety without investing in developing systems that are capable of reliably delivering care is like extolling drivers to drive vehicles more safely without investing in traffic lights, road signs or well-designed road layouts.

From 2008 to 2014, the Health Foundation worked with a team at the University of Warwick on two phases of an improvement programme to develop, test and refine Safer Clinical Systems – an approach for improving safe and reliable health care. The approach sought to adapt tools for systems analysis and the safety case technique from other industries and apply them to front-line clinical care. The results offer insights and challenges for leaders, locally and nationally, which cannot be ignored if the health care system is to make progress in making care safer for patients.

This *In brief* identifies lessons from the independent evaluation of the programme – published in the report *Safer Clinical Systems: evaluation findings** – and makes recommendations for those leading improvement in safety.

* Available at www.health.org.uk/scsevaluation

About Safer Clinical Systems

As described in more detail in *Safer Clinical Systems: evaluation findings*, the Safer Clinical Systems approach was developed and refined over two sequential phases of the Safer Clinical Systems programme. Phase 1 ran from 2008 to 2011, and worked with four sites. Eight teams from acute trusts across England and Scotland were selected to take part in phase 2, which ran from 2011 to 2014. Four teams focused on prescribing and four on handover, all in different service settings. The programme was designed and supported by a team of technical experts from the Health Foundation and Warwick University.

The clinical teams were working on pathways of care across the hospital, across primary and secondary care, or within hospital units. Their aim was to improve the prescribing or handover systems along the patient pathway to the level where they would be demonstrably free from unacceptable levels of risk, and had the resilience to withstand known and unexpected variations and challenges.

The first step for each team was to develop an in-depth understanding of the patient pathway they were working in. The programme supported teams to undertake a level of process analysis akin to what is seen in other high-risk industries but rare in health care. It involved applying detailed diagnostic techniques to map individual tasks and subtasks within critical processes, and analysing the hazards associated with each step. The teams then ‘zoomed out’ to understand the wider systems within which the processes in question were embedded.

Following the diagnostic phase, the teams were encouraged to conduct a detailed options appraisal to select appropriate interventions in the form of ‘risk controls’ that would improve reliability. The teams also selected or developed measures to assess progress. Next, they undertook system improvement cycles to implement the interventions.

The teams used the data they collected, along with observations made during the diagnostic phase, to develop a safety case. This assessed the current level of safety of the pathway in question and what more would be required to control risks effectively.

In parallel to the Safer Clinical Systems programme, the Health Foundation convened a working group, which brought together safety case experts from academia and other industries with NHS leaders to understand how the safety case technique could be applied in health care. The findings of this group are summarised in the box on page 7.

Findings of the evaluation

Poor process design and multiple hazards

The evaluation team[†] paint a rich and sobering picture of clinical systems that were often ‘highly unreliable and laden with potential for harm to the patient’. For example, one team mapped 99 hazards along the shared care pathway for renal patients having a surgical intervention. The lack of medical review by senior doctors and the lack of a surgical plan for each patient were identified as two of the highest risks; other risks included failing to meet the requirements for a safe discharge and the failure of surgeons to provide ongoing review of the patient’s care.

Though the challenges to safety identified by the eight project teams were often significant, the systems they chose to analyse were not necessarily areas that would show up as problems through current metrics. Nor is there any reason to think that what was revealed by the diagnostics was unusual or specific to the sites. What was exposed through the analysis was an endemic lack of process clarity and reliability, which is likely to be repeated (to a greater or lesser extent) in every organisation across the NHS and beyond. It points to pervasive risks to patients that are ‘below the radar’ of current incident reporting and risk management systems.

The evaluation of the Safer Clinical Systems programme suggests that the NHS needs to make a fundamental shift to give greater attention to process design. As the evaluators put it:

In many cases, systems for achieving particular tasks or functions had never been purposefully designed or made explicit; instead their practice had become accepted through repeated use. As a result, many microsystems were not properly documented... and... there was ambiguity about whose job it was to do what. Newcomers to the clinical areas in several sites learned about the systems by observing others and being told what to do as they did it, and such systems were highly vulnerable to degradation. Where systems had been purposefully designed, it was not necessarily with safety as the core design principle. Many systems, by default rather than design, prioritised efficiency and task completion over safety, and processes for ensuring that tasks were actioned were weak.

[†] The evaluation team involved researchers from the University of Leicester and University of Birmingham in the UK, and Johns Hopkins University in the USA.

Wider management issues restricting progress

The efforts made by the eight teams to improve their pathways revealed many wider system issues that were implicated in the hazards they identified at the point of care. The evaluators used the term ‘big and hairy problems’ to describe these long-standing contextual factors. Typically, these problems were ‘symptoms of deep organisational pathologies with long histories and complex dynamics’ – problems so entrenched that they had often come to be accepted as inevitable.

The evaluators highlight five management issues that act as barriers to progress in improving patient safety:

- **Inconsistent staffing**, which created a challenging environment for the reliability of care – for example, having to rely on training grade and locum staff, who had variable skills and confidence. It could often prove challenging to get staff together in one place, let alone introduce changes to how things were done, due to long-standing work practices, shift patterns and job specifications.
- **Problems with support systems and structures**, which often contributed to poor communication and coordination and made it difficult to introduce change. This included, for example, long-standing issues around IT, the layout and design of facilities and equipment, and the coordination of key tests and pieces of information. These were often symptomatic of a lack of investment.
- **High workload pressures and multiple competing priorities**, with staff shortages often meaning that it was not possible to ensure that systems functioned as they were supposed to.
- **Organisational and professional cultures** that were not always fully aligned with the goal of achieving patient safety. Some issues relevant to patient safety were not given sufficient priority or were seen as ‘someone else’s problem’, in part because staff were already stretched to the limit (and beyond) with their day-to-day work.
- **A widespread lack of process design and standardisation**, exacerbated by a lack of capacity or resources for system design within organisations, and by consultants and other senior staff who did not always provide the necessary leadership in taking charge of problems or standardising their practices.

The evaluators sum up the accumulated impact of this in words that will resonate with many health care staff in front-line organisations:

The consequence of these multiple defects was that staff were often hassled and distracted by the ‘small stuff’ – components of systems that did not work properly, and took large amounts of time to repair or rescue – and found it hard to keep the bigger picture in mind. Systems were therefore often stressful to use, created distractions or interruptions, and wasted resources and time. This level of unreliability was likely to contribute to problems in assuring safety.

Finding time to identify problems and design effective interventions

The teams that participated in the Safer Clinical Systems programme received substantial training and were expected (and supported) to conduct a detailed system diagnosis and options appraisal before starting to introduce changes. Their diagnosis often led to a realisation that what they initially thought was the problem (or the cause of the problem) was, in fact, not the most important issue to address. This enabled them to target the organisation’s time and resources more effectively. For example, by analysing the care pathway for older people, one team realised that readmissions were mostly associated with residents of care homes rather than people living independently, as they had initially assumed. This led them to focus their efforts on improving coordination and communication with care homes. Another organisation looking at handover processes had assumed that the problems lay in the handover meeting, but the analysis identified that attention should instead be focused on the preparation work required to support these meetings.

While it would appear self-evident that a proper diagnosis is necessary to ensure that time and resources are being used effectively, it is telling that the rigour of analysis carried out as part of the Safer Clinical Systems programme felt very countercultural. Many staff struggled to find the time to prioritise mapping the processes of care and associated risks. With the intense operational pressures on the NHS, there is a risk that organisations will continue to rush to take action assuming they know the solution, rather than take the time needed to really understand the problems they are seeking to address.

When it came to designing solutions to the problems that had been identified during the diagnostic phase, teams often prioritised getting on quickly with what could be done. Partly because of the design of the programme – which could be refined in the future – they spent relatively little time working out what the

appropriate type of solution would be, based on the diagnosis; how their proposed solution would actually make a difference; undertaking the detailed design work necessary; or researching whether what they were planning had been tested elsewhere.

There was a considerable skills gap in some aspects of system analysis, measurement design, data collection and interpretation – even for these teams, who were selected to participate in the programme on the basis of a good track record of improvement work.

Improvement in safety culture

While the programme evaluation pays testament to the eight project teams' commitment and ingenuity, for all the reasons highlighted here most of the teams fell short of achieving their specific goals within the timescales of the programme.

However, almost all the participating sites saw a significant improvement in safety culture, as measured through a validated tool, over the lifetime of the programme. While 'bottom-up' process analysis and improvement is often very challenging and can be frustrating, involving staff in this work helped them objectively identify problems and think about how to address them. It was helpful to do this in a way that was not overshadowed by a reactive focus on individual incidents and the blame that can accompany them.

Reflections

The insights gained through the Safer Clinical Systems programme diagnostic work help us understand that risk in systems is inherently complex and broad, with many interconnected issues. For example, while including pharmacists in ward rounds may be a very effective way of improving medication safety, it requires addressing issues of prioritisation, work practices, professional relationships, education and training, and many others.

The evaluation suggests that many safety challenges – including those associated with everyday processes such as handover and prescribing – require radical redesign of cross-cutting IT, staffing or other systems that cannot be reasonably delegated to front-line project teams. No small clinical team can, for example, unilaterally require that a professional group such as pharmacists start work an hour earlier in order to join ward rounds. Realising the potential of ideas and insights generated by front-line teams will often require substantial time and support from operational managers skilled in process diagnosis and design as well as the wider skills needed to achieve complex change.

Supporting staff at the front line to understand and improve the processes of care they typically know best is a critical ingredient of sustainable improvement. Such work addresses the issues that **can be** resolved at the front line and unearths problems that need to be understood and addressed elsewhere in the organisation. The learning from Safer Clinical Systems is that the NHS needs to expand the skills and time provided to do this beyond front-line project teams to operational managers, so that there is also sufficient embedded capacity to continually improve both clinical care and support systems.

Ensuring that managers and clinicians have the skills and time needed to design safer systems and processes requires investment that may seem hard to justify given current financial constraints and the squeeze on management capacity. However, given that poor process design and reliability are likely to be the root cause of poor efficiency as well as poor quality and unsafe care, it seems unlikely that the NHS will be able to reliably deliver the outcomes required unless it does make such investments. With the major financial and operational pressures confronting NHS services, this is precisely the time to get serious about ensuring NHS organisations have the system design capability they need to ensure that core processes deliver safe and efficient care.

Practical recommendations for those leading improvement in safety

Front-line teams involved in improvement

- Consider how to build the skills to make sure that you really understand your systems and the hazards involved in the service you are providing.
- Choose and design improvement interventions carefully. Research whether the intervention has worked elsewhere, and identify exactly what is needed to support it – for example, training, particular features of context, and so on. You should also recognise that even seemingly simple changes can take a long time to implement, though this should not deter staff working on things that will really address the root cause of problems.
- Engage senior leaders in the work. Make sure that senior leaders understand the analysis and the role they will need to play in helping to address wider system issues.

Senior leaders in provider organisations

- Know the limits of what current data sets reveal about risk in the system. Don't expect that any summary dashboard or risk log can capture all the issues that need consideration. Invest in giving front-line staff and operational management the space and skills to understand the systems they are likely to know best. Recognise that you may need to develop new skills to help you understand and act on the results of diagnostic work undertaken by those doing improvement work in your organisation.
- Do not expect that small-scale improvement projects alone will enable the organisation to meet its safety goals. You also need to address underlying system challenges, such as problems associated with estates, IT, staffing and culture.
- Support people leading improvement to undertake detailed diagnosis before they develop tactics to improve care. Ask them how proposed interventions will reduce risks, and help them find learning from similar interventions elsewhere. Try to have a balance of quick wins and more substantial system redesign, recognising that the latter will take time and persistence to deliver.

Commissioners, regulators, policy makers and politicians

- Recognise that process management and reliability in health care are behind many other industries. The scale of the challenge (and therefore opportunity for higher quality and efficiency) requires long-term mainstream investment and attention rather than expecting sufficient progress to be made through individual short-term initiatives alone. Greater expertise in understanding and improving systems, as well as skills in measurement, needs to be available to front-line teams – ideally as a core part of what can be expected of operational managers.
- Acknowledge that risk and reliability are significant and complex challenges for health care. Providers should be supported to develop and share their insights into the nature of the hazards and risks in their systems, rather than assuming that it is possible to set sufficient meaningful performance metrics externally.
- Encourage a mature understanding of the nature of risk and harm among the public, through consistent messages and action from politicians, regulators and other agencies.
- Support the critical role of local diagnosis, goal-setting, system development and integration at individual provider level, recognising that this will require

stable leadership. External regulation should be developed that is flexible enough to enable providers to demonstrate how they are addressing the specific issues in their context rather than solely how they meet externally set requirements.

- Develop better approaches to identifying and addressing industry-wide problems (such as staffing rules, financial incentives, procurement and cross-organisation information and IT infrastructure) and recognise that progress on these fronts is likely to be critical if ambitious safety goals are to be met at individual provider level.
- Build stronger mechanisms to ensure that learning about both the successes and failures of improvement work flows across the system, so that providers are easily able to know what others have done. Providers should invest time and resources in learning from others – and it should be made easy for them to do so.

What will the Health Foundation be doing next?

The Health Foundation is currently supporting a subset of the organisations that participated in the Safer Clinical Systems programme to apply what they learned to new service areas. We will continue to evaluate the work and share learning and resources as they emerge.

During 2015, we will consider the design of a third phase of the Safer Clinical Systems programme, building on what has been learned from the work to date.

One of the early conclusions from the Safer Clinical Systems work was that there would need to be better ways of understanding safety, given that approaches to measuring safety in the NHS have traditionally focused on harm rather than understanding risk or wider system issues. This insight led to the commissioning of research into measuring and monitoring safety, published in 2013.[‡] The Health Foundation is now leading a programme to test and apply in practice the measuring and monitoring framework that emerged from this research.

The Foundation will continue to engage in the debate on how the NHS needs to evolve at all levels in order to meet the broader challenges raised by the Safer Clinical Systems programme. We will be working to ensure that insights from the front line of health care delivery play a key role in informing health care policy.

To keep up to date with our work on patient safety, visit www.health.org.uk/areas-of-work/topics/patient-safety

[‡] Vincent C, Carthey J, Burnett S. *The measurement and monitoring of safety*. The Health Foundation, 2013.

Using safety cases in health care

The safety case is a technique that is widely used in other high-risk industries. Service providers develop a structured assessment of hazards and risks in a specific system and describe the risk controls in place so that a reasoned claim can be made about how safe the system is.

The Health Foundation has led the way in seeking to understand how the concept of safety cases could be applied to health care. Building on research published in our 2012 report *Using safety cases in industry and healthcare* (www.health.org.uk/safetycasesreport), and to complement the emerging findings from the Safer Clinical Systems programme, we convened a working group to explore how this work could be taken forward. The group met four times between October 2013 and January 2014. Its members comprised representatives from health care policy, practice and regulation, academics with expertise in safety cases, and those involved in the Safer Clinical Systems programme.

The group agreed that, when coupled with the diagnostic tests and interventions piloted in the programme, safety cases had the potential to deliver a number of benefits, principally:

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

The use of safety cases was felt to be appealing because it places the onus on the provider, rather than an external body, to make the case for how safe its services are. This ought to then be a continuous process, made relevant to the local context and kept up to date in light of new information that emerges about hazards and risks.

The working group identified some lessons for those wishing to apply safety cases in their own context, avoiding the real risk that this kind of intervention could become an overly bureaucratic exercise in ‘paper safety’.

There was agreement that while the safety case model could not be directly imported from other industries, it has three potential applications in health care:

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

The latter would require a willingness from all stakeholders (boards, regulators, professionals and the public) to proactively root out, and welcome, the risks identified in health care services. It would require a maturity of approach that is not currently widespread, particularly in terms of avoiding blame and censure of those teams and organisations that do identify hazards in their systems. This issue of transparency was a recurring theme for the group. It was agreed that 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 if there is a commitment to build the system analysis skills needed to develop and interpret safety cases.

The group concluded that more work would need to be done to understand exactly how and where the safety case model could be most usefully applied in health care, and the necessary conditions that would ensure it made a positive overall impact. The Health Foundation is supporting these efforts by funding a small number of organisations to further test the application of safety cases.

The final report of the Safety Cases Working Group has been published as a supplement to *Safer Clinical Systems phase 2: evaluation findings*. It is available to download from www.health.org.uk/scsevaluation

The Health Foundation is an independent charity working to improve the quality of health care in the UK.

We are here to support people working in health care practice and policy to make lasting improvements to health services.

We carry out research and in-depth policy analysis, run improvement programmes to put ideas into practice in the NHS, support and develop leaders and share evidence to encourage wider change.

We want the UK to have a health care system of the highest possible quality – safe, effective, person-centred, timely, efficient and equitable.

The Health Foundation

90 Long Acre
London WC2E 9RA

T 020 7257 8000
E info@health.org.uk

Registered charity number: 286967
Registered company number: 1714937

For more information, visit: www.health.org.uk

Follow us on Twitter: www.twitter.com/HealthFdn

Sign up for our email newsletter:
www.health.org.uk/enewsletter