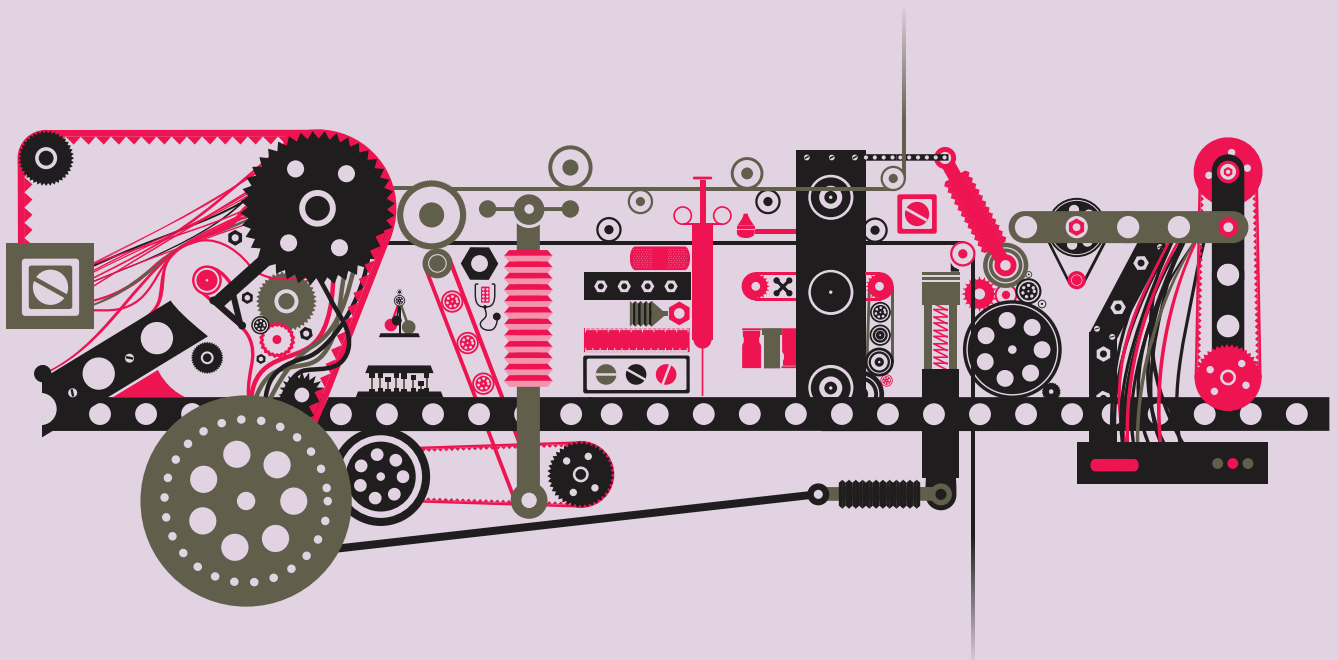


Safer Clinical Systems: evaluation findings

Learning from the independent evaluation of the second
phase of the Safer Clinical Systems programme

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Executive summary

High-risk industries – such as aviation, oil and gas, and mining – are distinguished by their use of proactive methods for detecting hazards and managing risks. Many have achieved exemplary safety performance. In contrast, health care has continued to have a high level of harm events. Hence Safer Clinical Systems – a determined effort to improve the functioning of clinical systems through a hybrid of tools, techniques and principles adapted from those used by hazardous industries and quality improvement, and customised for health care. The Safer Clinical Systems approach aims to improve patient safety not by imposing pre-defined solutions on organisations, but by developing their own capacity to detect and assess system-level weaknesses ('hazards' and the associated risks) and introduce interventions to address them ('risk controls'). It is distinguished by its proactive character, in contrast to approaches that rely mainly on analysis of incidents that have already occurred. Its development was led by a support team at the University of Warwick.

The approach was tested and developed over two phases of a Health Foundation programme. Safer Clinical Systems phase 2, which ran from 2011 to 2014, used learning from a first phase of the programme. This second phase sought to test a prototype of the approach – not one that was fully or finally specified at the outset. The programme involved eight highly motivated teams from hospital sites in the NHS, recruited partly on the basis of previous experience of improvement work. The site project teams typically comprised a clinical lead and a project manager as well as individuals with a clinical or managerial background.

The programme was evaluated independently by a team from the University of Leicester, University of Birmingham, Imperial College and Johns Hopkins University using qualitative methods (interviews and observations) and quantitative methods. Each site was treated as a case study, and cross-case comparison was undertaken.

Safer Clinical Systems phase 2 was structured around four sequential steps through which the support team guided site teams. The first two steps – pathway definition and context, and system diagnosis – formed the diagnostic phase, where sites sought to define their patient pathways and make visible any weaknesses or flaws. The next two steps – options appraisal and planning interventions, and system improvement cycles – comprised the improvement phase. At various points during the programme, sites were asked to produce a safety case for their pathway. A safety case involves a structured, evidence-based argument showing the extent to which hazards have been detected and the associated risks controlled. It is a well-established technique for regulating hazardous industries outside of health care.

The diagnostic phase was highly valued by programme participants for its ability to identify weaknesses that had not been previously recognised or understood. Diagnostic work undertaken by the sites identified a large number of hazards and risks along patient pathways. These included: poor reliability of systems; poorly designed or poorly articulated systems; inadequate communication and coordination; staff shortages; deficits in competence, skills and confidence; and organisational cultures oriented towards blame and that did not prioritise learning.

Designing and implementing interventions to address these problems proved very challenging. Teams struggled to choose the right interventions – and right number of interventions – and many of the hazards and risks were too 'big and hairy' to be tractable to quality improvement methods based on plan-do-study-act (PDSA) cycles. Many of the problems were beyond the scope of control of small project teams. There were around 100 interventions across the sites, from the (apparently) simple to the extremely ambitious. Examples included introducing new meetings or ward rounds, standardising patient information or practices and procedures, instigating new forms/checklists, creating designated spaces, and initiating IT solutions.

Sites were asked to focus on a small number of measures (usually around five), called the 'safety set', which were intended to assess how far reliability of processes was improving over time. These were measures selected (and sometimes developed) by the sites themselves, not imposed externally. But developing the measures and setting up data collection systems proved technically daunting for most site teams.

The evaluation team conducted independent analysis of data collected from four sites, which between them had collected data on 19 measures. By the end of the programme, four of the 19 measures showed some evidence of improvement, four showed evidence of possible improvement (more data needed), ten showed no change, and one showed evidence of possible deterioration. The other four sites, which were not independently evaluated, selected 18 measures between them. Of these, four measures demonstrated no change, three had no data available, two could not be interpreted due to poor-quality presentation, and nine were inconclusive. A bigger and better picture of progress can be gained by adding qualitative research findings (from ethnographic observations and interviews) to the quantitative measures; these tell a more positive story of how participating in the programme and applying its principles and techniques helped the teams to strengthen organisational cultures related to patient safety, to become more resilient, and to build capacity for improvement.

The safety case technique was a centrepiece and an innovation of the Safer Clinical Systems approach. The specifics of guidance on the design and content of the safety cases evolved over the course of the programme, and it took a number of iterations to find a suitable format. The final safety cases prepared by the sites were variable. Some were very candid about the persistence of hazards and poor reliability along the defined pathways. Others were perhaps over-optimistic about the extent to which risk in the system had reduced.

The evaluation concludes that much of the Safer Clinical Systems approach is ingenious, and well-grounded in established practices from hazardous industries. It proved difficult to demonstrate substantial progress on reliability measures at the sites over the course of the programme, but other data suggested improvements relating to culture and capacity for problem-solving. The diagnostics were one of the programme's main strengths, but they revealed many system defects that were not tractable to improvement using quality improvement methods based on PDSA cycles led by small clinical teams. This was because the problems identified were 'big and hairy' in character, reflecting deep structural,

organisational and institutional challenges. They therefore required radical redesign and high-level authority and resources. The Safer Clinical Systems approach remains highly promising, but in need of further refinement and testing.

The evaluation team make a number of recommendations. They suggest:

- further theoretical development of the Safer Clinical Systems approach that is attentive to the many critiques of risk-management techniques in other industries
- further refinement and development of the specific package of methods, including strengthening the selection, development and specification of interventions
- increased recognition of the kinds of hazards and risks that can be resolved by small clinical project teams and those that need to be 'owned' by senior management.

Further analysis is also needed to assess whether the approach is better or more cost-effective than other approaches to improving safety, to clarify the role of patient and public involvement, to determine how best the skills and competences required to use the approach can be mustered, and to assess how to align the approach with the regulatory, organisational and financial structures and norms of the wider environment.

Other recommendations go beyond the Safer Clinical Systems approach itself. The evaluation has demonstrated:

- the need to improve skills and processes relating to measurement of quality and safety in the NHS
- the need for improvement interventions to be selected or developed in ways that are attentive to the evidence base and are well fitted to the problems they are trying to solve
- the need for clarity about when improvement approaches based on PDSA cycles are appropriate and when they are not
- the need for tight and logical coupling between hazards, interventions and measures.

Boards of NHS organisations may require considerable support to embrace new ways of thinking more proactively about detecting and managing risk. Though the safety case technique is promising, it needs much further development and evaluation and is likely to yield benefit only if the wider environment – including the behaviour of those responsible for the strategic oversight, direction and regulation of the health care system – is favourable.

The findings of the evaluation

Introduction

High-risk industries – such as aviation, oil and gas, and mining – are distinguished by their use of proactive methods for detecting hazards and managing risks. Many have achieved exemplary safety performance. In contrast, health care continues to have a high level of harm events. Hence Safer Clinical Systems – a determined effort to improve the functioning of clinical systems through a hybrid of tools, techniques and principles adapted from those used by hazardous industries and quality improvement, and customised for health care.

The Safer Clinical Systems approach is notable for the following features.

- It is explicitly grounded in established practices from hazardous industries, customised for health care. Shifting from the currently dominant preoccupation with incidents that have already happened, it seeks to enable organisations to make improvements by giving them a structured methodology with which to proactively identify hazards and control risks. In this way, it seeks to avert incidents before they can occur.
- It recognises the importance of developing expertise and confidence within local teams, and seeks to provide teams with tools for self-learning so that they can become self-sufficient and have a broad understanding of how to devise solutions and optimise change.
- Through its emphasis on understanding clinical pathways and on systems diagnosis, it seeks to promote deep understanding of local context at the level of the zoom-in (the clinical microsystem) and the zoom-out (the wider contexts).
- It seeks to draw attention to systems factors such as task design, physical environments, communication and team structure, and their role in patient safety.

- It seeks to allow teams to develop local solutions (or select or adapt existing solutions) that are bespoke to their own contexts rather than providing ‘off-the-shelf’ interventions, and similarly to select or develop and apply their own measures.
- Adapting a regulatory technique widely used in other hazardous industries, it seeks to use the safety case approach as a novel way of evidencing the hazards, risks and risk mitigation along clinical pathways, and of communicating the degree to which risk is controlled.

Following on from phase 1, the second phase of the Health Foundation’s Safer Clinical Systems programme involved eight highly motivated teams, with a track record in improvement work, based in acute hospitals from across the NHS. This report presents the findings of an independent evaluation of the approach, as applied in Safer Clinical Systems phase 2.

1. Background

Safer Clinical Systems is an approach for improving safe and reliable health care based on learning from a range of high-risk sectors such as aviation, oil and gas, and mining. It was developed by a team at the University of Warwick led by Professor Matthew Cooke, and based on principles adapted from high-reliability organisations, established risk management techniques from hazardous industries, and quality improvement methods.

The approach aims to improve patient safety not by imposing pre-defined solutions on organisations, but by developing their capacity to detect and assess weaknesses ('hazards' and the associated risks) in their systems and to introduce interventions to address them ('risk controls'). The approach offers a package of tools and techniques (see box 2 on page 9) that are mostly imported from other environments, but which have been adapted, customised and repackaged specifically for health care.

Applying this approach is intended to enable organisations to create sustainable and flexible systems that deliver high-quality care to the patient, are demonstrably free from unacceptable levels of risk, and have the resilience to withstand normal and unexpected variations and fluctuations. Central to the approach is the building of safety cases (see section 7), which are widely used in hazardous industries. Safety cases are intended for site teams to show that they have detected hazards and risks in their systems, described the risk controls in place, made an assessment of the current level of safety, and can communicate this in the form of a structured, evidenced argument to senior leaders (board and executive level) within their organisations.

The Safer Clinical Systems approach has been developed, tested and refined over two sequential programmes (phases 1 and 2) sponsored by the Health Foundation and delivered by a technical 'support

team' comprising the developers of the approach from Warwick University and the Health Foundation. The phase 2 programme sought to pilot a version of the Safer Clinical Systems approach that had been updated in the light of learning from phase 1. In order to maximise learning, the aim was to test out and further develop a prototype of the approach – not one that was fully or finally specified at the outset. Eight NHS sites, all acute hospitals in England or Scotland, took part in this second phase, which is the subject of this report.

Box 1: The approach vs the programme

It is useful to distinguish the Safer Clinical Systems *approach* from the *programme* used to deliver it. The *approach* designed by the support team comprises the tools, techniques and processes that the site teams used to make their systems safer.

The *programme* (across two phases) had two purposes: first, to provide opportunities to develop and trial the approach in real time with motivated NHS teams; second, to provide infrastructure for the organisation, delivery and support of the approach for participating sites. The programme thus included training events, collaboration between teams and technical support, among other things.

In this evaluation report, the focus is mainly on the approach rather than the programme.

The eight participating teams were selected through a competitive process from a large number of applicants to the Health Foundation. They were required to demonstrate some track record in improvement work, since training in improvement methodology was not included in the programme. The teams typically comprised a clinical lead and project manager as well as individuals from a clinical or (less frequently)

managerial background. Each site team had an executive sponsor from within their own organisation. The settings in which they were working were highly diverse, ranging from large urban children's hospitals to small rural hospitals mostly caring for older people. The projects they undertook were also different. Four sites sought to improve their handover processes; the other four sought to improve processes relating to prescribing of medication.

The appendix to this report contains a more detailed account of how two of the sites (one focused on handover and one on medication safety) implemented the approach, and the interventions and outcomes that resulted.

The programme was structured around four sequential steps:

1. Pathway definition and context
2. System diagnosis
3. Option planning and appraisal
4. System improvement cycles

The support team guided site teams through each step, with structured reviews at the end of each one. (See below for more details.)

In each step, the teams were required to complete and submit monthly reports to the support team using an A3 technique – a project management tool derived from Lean (Toyota) improvement methods. A3s present a series of charts and plans, laid out on a single piece of A3 paper, that can allow participants to track the project over time, measure their actual progress against their original objectives, and facilitate communication outside the project team.

The sites were asked to produce several versions of their safety case, with the first one due at the end of step 2 and the last one on completion of step 4, to allow an assessment of the degree to which safety was improving over time.

Safer Clinical Systems: The four steps

Diagnostic phase

Together, step 1 and step 2 can be regarded as the *diagnostic* phase of the project at each site. It involved teams in close-up analysis (zooming-in) and helicopter views (zooming-out) to enable understanding of issues specific to their clinical microsystems and the whole system in which each microsystem was embedded.

Teams were trained to use a variety of methods adapted from high-risk industries (see box 2) in conducting this work.

Step 1: Pathway definition and context (three months). This step had three objectives: to bring together the Safer Clinical Systems team on each site to develop its way of working, conduct a training needs analysis, and clarify time commitments; to clearly define the clinical pathway (from the perspective of a patient journey rather than organisational structures) so that key staff and stakeholders could be identified and involved; and to review the context within which the pathway existed.

Step 2: System diagnosis (five months). This step took place between January and May 2012 and had five objectives: to carry out high-level mapping of the pathway and how it linked and engaged with wider systems; to identify and rank risks and hazards; to understand 'error modes' – where failures happen and how they can be detected; to conduct human factors analysis of critical steps; and to characterise risk performance and performance-influencing factors (see box 2).

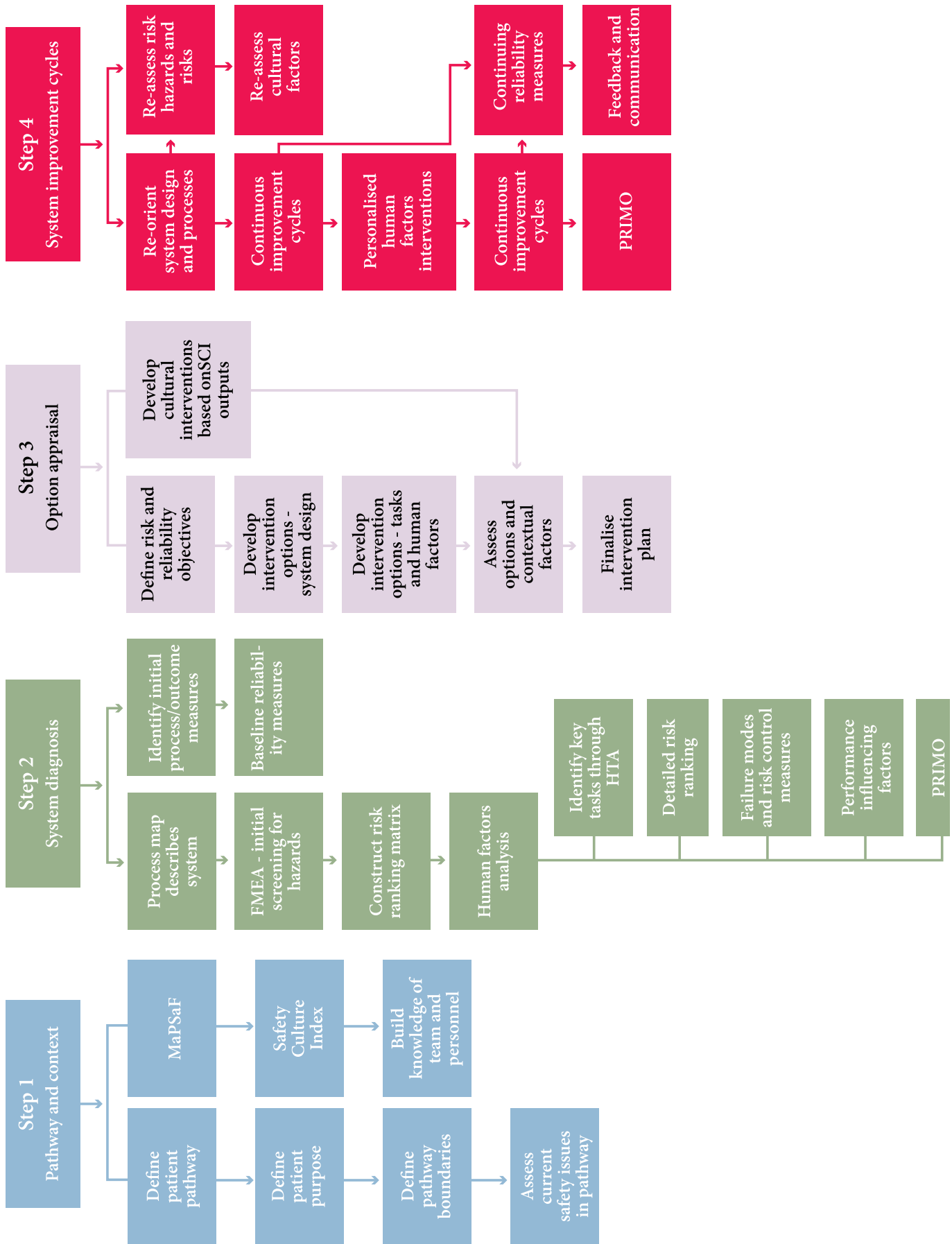
Improvement phase

Steps 3 and 4 were oriented towards improving reliability and resilience. These steps included options appraisal of interventions for improvement, system improvement cycles, and data collection to assess change in reliability over time.

Step 3: Option planning and appraisal (two months). Sites were asked to assess options for change, select preferred options, and develop an action plan. Teams were encouraged to focus on addressing problems in hard systems (those with a concrete reality such as equipment) and soft systems (such as staff culture), and were asked to provide a clear description of each option as well as the criteria to be used in selection (for example, ease of implementation, cost, time to implement, fit with trust strategy, acceptability to other stakeholders, measurable impact on reducing risk, and measurable impact on improving reliability).

Step 4: System improvement cycles (15 months). In this step, the teams aimed to implement and evaluate system improvement cycles and to measure progress.

Figure 1: Overview of the Safer Clinical Systems methodology, as described by the support team



Box 2: The tools and techniques used in each step

Step 1 used two tools to ‘zoom-in’ to define the care pathway of interest, and to ‘zoom-out’ to explore the organisational culture and approach to safety at each site:

- Manchester Patient Safety Framework (MaPSaF) to help health care teams assess their progress in developing a safety culture
- Safety Culture Index (SCI), a validated questionnaire survey given to a sample of staff concerned with assessing the shared attitudes, values and beliefs that support safe working practices.

Step 2 followed a structured diagnostic approach to identify the hazards and assess the risks of the existing pathway. The tools included:

- process mapping to produce a logical step-by-step representation of business activities showing key inputs/ outputs; these were used to visually represent the current process or pathway and the improved pathway
- Failure Mode and Effects Analysis (FMEA) to systematically and proactively identify major vulnerabilities within a system and provide a quantitative risk evaluation to prioritise threats
- Create and Detect maps to track the points in a system where root cause failures happen and where they can be detected
- identification of performance-influencing factors (PIF) and other techniques associated with human factors approaches to think about the interactions between people, the work environment and organisational systems
- Hierarchical Task Analysis (HTA), a goal-driven method for documenting a process by breaking complex sequences down into discrete tasks and subtasks; this was used to draw special attention to the task details – the things that people actually do
- Proactive Risk Monitoring Tool for Organisational Learning (PRIMO) to improve organisational learning based on feedback from staff elicited at regular intervals about basic risk factors. The aim was to repeat PRIMO throughout steps 3 and 4, although this did not happen due to time constraints.

The teams were also encouraged to obtain baseline reliability measures. They were given initial guidance on assessment, measurement, and data collection and analysis methods.

At the end of this step, teams created the first version of their safety cases, intended to offer an initial assessment of hazards and risks in their clinical pathways and the risk controls in place at the outset.

Step 3 involved options appraisal to develop options for change that would target the hazards revealed by the diagnostics.

Step 4 involved system improvement cycles. Iterative plan-do-study-act (PDSA) loops were intended to be the primary method for achieving effective and sustainable improvement. During this step, it was intended that the tools and techniques used earlier would be re-deployed to examine changes over time and build the final safety case.

2. The evaluation

The evaluation team sought to identify the theory (concepts, rationale and assumptions) behind the Safer Clinical Systems approach, to determine how far the approach helped the sites to make their systems more reliable, and to explain *how* the approach might work (the mechanisms of change), while also considering contextual factors.

The evaluators, led by Professor Mary Dixon-Woods and a team at the University of Leicester, with collaborators from the University of Birmingham, Imperial College and Johns Hopkins University, used a mixed-method (qualitative and quantitative) longitudinal study design. They conducted 94 interviews with the project teams, the support team, the Health Foundation and other stakeholders, and 668 hours of ethnographic observations involving non-participant observation of activities in clinical and non-clinical areas, as well as informal discussions.

The evaluation team also independently analysed quantitative data on measures of reliability (the safety set) from four of the eight sites (see box 3). Statistical Process Control (SPC) charts, which report data over time, were used to elicit evidence of changes that might be attributable to project team interventions. The data reported by the other four sites were reviewed but were not analysed independently.

The design of the programme, including the principle embedded in the approach – which was that sites should choose their own measures following completion of the diagnostics phase and after selection of interventions – meant it was not possible to compare the same measures across sites. The amount of baseline data available from the sites was variable, and in some cases measurement began only after interventions had been implemented.

Box 3: Detailed case studies

The evaluators conducted a detailed study of each site to deepen overall understanding of the features of the Safer Clinical Systems approach as a way of enhancing patient safety, and then compared across cases. The case studies were assigned codenames and are not identified by their real names.

Using observations, interviews and analysis of documents, the case studies aimed to:

- find out what it is like to ‘do’ Safer Clinical Systems
- explore how the phased approach worked in practice and each site’s experience of using it
- identify what helped and what hindered feasibility and implementation
- look for unintended consequences
- enable testing and refinement of the programme theory.

Each site was treated as an example of Safer Clinical Systems implementation, but also as contextually unique. This allowed in-depth study of particular features of design and implementation of the Safer Clinical Systems approach by using different sites as exemplars.

The appendix to this report contains two summary case studies (one from a prescribing site and one from a handover site). These sites have been given the fictional names Ashtree and Hollyberry.

3. Theory behind the Safer Clinical Systems approach

The programme designers (the Warwick support team and the Health Foundation) articulated a theory of change for the programme informed by contributions from a number of different fields from health care and beyond. These included human factors, high reliability organisations, resilience engineering, systems thinking, risk management, continuous quality improvement, and organisational development.

A prominent feature of the approach was its goal of changing the way organisations handle safety, from the prevailing reactive and incident-based approach to a more proactive and risk-based one. It sought to move organisations on from looking back at errors and incidents to looking forward and focusing on risk, and to draw attention to systems factors such as task design, physical environments, communication and team structure, and their role in patient safety. The approach also intended to open up lines of communication between clinical teams and senior management teams, so that there was stronger shared purpose and commitment to solving problems.

Members of the support team emphasised that the choice of tools and techniques, and the structure of the programme, had been designed with the NHS and health care in mind. The Safer Clinical Systems approach was not simply a direct import and repackaging of existing interventions.

In interviews, the programme designers often stressed the need to approach safety in a highly structured, technical way, though they held somewhat different views about how flexibly the tools should be used; some worried that the approach risked becoming too rigid and prescriptive, others that the approach would be rendered ineffective by inconsistent application of the methods. The literature on risk management had clearly informed the approach's emphasis on identifying

hazards and scoring risk in terms of probability and impact in order to determine priorities for action.

As such:

- hazards were seen as conditions, events or circumstances that could lead to or contribute to harm
- the programme designers defined risk as the probability of harm, whereas reliability was defined as the probability that a system works according to its specification for a given amount of time.

In seeking to reduce risk and improve reliability, the relationship between specific clinical microsystems that may exist along a clinical pathway (eg, wards, pharmacy services) and the wider organisation was seen to be important to the proper application of a proactive approach. Such an approach works by identifying the hazards and associated risks in systems, and installing risk controls **before an incident happens**.

4. The diagnostics: defining the pathway and systems diagnosis (steps 1 and 2)

For me... the diagnostic was quite an important component. It took a long time to achieve the diagnostic but actually it was a very important learning for the organisation, I think, in that you do have to do this detailed diagnostic in order to be able to really understand what you need to fix. (Executive sponsor, handover site)

The teams started with the diagnostic phase, including the pathway definition. This was seen as a distinctive strength of the programme by the participating site teams. With a few exceptions they valued it highly, and showed evidence of thinking consistent with the programme theory of change. Site teams especially valued the use of specific, dedicated tools and techniques and the emphasis on detecting hazards in existing systems. The diagnostic phase was praised by participants for its ability to make visible aspects of systems that had previously been obscure, to identify weaknesses that had not been previously recognised or understood, and to challenge pre-existing assumptions. Using the programme's tools enabled participants to assess and analyse issues in detail and offered the possibility of critically rethinking a problem. Without the framework provided by the tools and techniques, several sites suggested that they would have been just 'fumbling in the dark,' as one participant put it.

Beyond the primary function of enabling a deeper and more informed understanding of clinical pathways and their potential for harm, the diagnostic phase served two other functions. First, it enabled a process of building relationships and opening up lines of communication with staff in clinical and managerial positions, who did not always have the opportunity to know each other or understand tasks and roles. Second, using formal risk appraisal tools gave much-needed legitimacy and credibility to the analysis that the teams conducted. In contrast, informal analyses or hypotheses

about the problems were seen as much less credible and much less likely to be persuasive. At executive level, the diagnostic phase was seen as offering insights that more rushed or less systematic approaches lacked.

Site teams described the benefits of using the diagnostic tools in combination ('It's hard to know how you would use one without the other'). But there was little consensus on how the various diagnostic tools fitted together or what the optimal combination might be. Some participants reported adhering fairly rigidly to the methodology ('We just do what we are told'). Others made local adaptations for pragmatic reasons (eg, time pressures, meeting schedules).

One area where several teams departed from the approach prescribed by the support team was in fixing some problems as soon as they found them, rather than waiting to carry out steps 3 and 4. If problems identified during the course of the diagnostics were alarming in their capacity to cause patient harm, some teams felt it would be immoral and wrong to delay fixing them (especially if the solution was very straightforward). Teams also sometimes wanted to generate some 'quick wins' and demonstrate to colleagues that the project team was capable of practical action.

Findings of the diagnostics

Site teams found that characterising their patient pathway led to an understanding of the nature of the hazards and risks along these pathways and the reasons for them. The diagnostics showed that many clinical systems were highly unreliable and laden with potential to harm patients.

Clinical staff at the sites were typically under severe production pressures with very high workload and multiple competing priorities. Staff shortages often meant that it was not possible to ensure that systems functioned

as they were supposed to. One site, for example, found that the number of GP referrals to the emergency department (ED) frequently exceeded the capacity of the medical on-take doctors to clerk-in within the four-hour target. As a result, patients might be transferred to a ward before their medicine chart was written and they might then have a further delay before medicines were documented, prescribed and administered.

The diagnostics showed that organisational and professional cultures were not always fully aligned with the goal of achieving patient safety. At some sites, for example, staff perceived that there was a blaming culture, that junior doctors felt alienated and lacking in support, that roles were poorly defined, that staff tended to be highly task-focused because of the pressure of workload, and that multi-disciplinary working was weak.

Reliable functioning of many clinical microsystems was also challenged because it depended on staff in training (junior doctors), non-permanent staff (locum nurses, doctors and other staff) and others whose competence, skills and confidence were highly variable. Most prescribing was done by junior doctors, yet they tended to make a lot of errors. Systems for feeding back errors detected by pharmacists were often non-existent or did not work well, so there were few opportunities for doctors to learn from their mistakes.

The diagnostics further identified that some issues relevant to patient safety were not given sufficient priority; delayed or omitted doses were often not recognised as a patient safety problem, and handovers were not always given the priority they needed. Multiple examples of issues being seen as ‘someone else’s problem’ were identified, and were often understandable given the high levels of demand on staff.

Much of the variability and associated unreliability arose because of the absence of clearly agreed standards. Consultants did not always provide the necessary leadership in taking charge of these problems, and did not effectively standardise their practices – meaning that junior staff and nurses had to spend effort learning and anticipating what each one would expect. On one site, for example, individual consultants’ requirements for how long a patient should be kept nil by mouth (NBM) before a surgical procedure varied between four and 10 hours.

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 or

formulated as a way of achieving a defined goal for the patient. Roles and responsibilities for achieving particular tasks or goals were often not clearly defined, and there was ambiguity about whose job it was to do certain tasks. 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. For instance, one site found that the process for ensuring that temporary suspensions of medication were reviewed was ineffectual, which meant that medications that should have been administered to patients might not be given.

The zooming-in feature of the diagnostics enabled the sites to identify single components of systems that were prone to malfunctioning. Often these were mundane, but symptomatic of long-standing lack of investment (for example, in IT systems) and had implications for patient safety. The physical design and layout of hospital facilities – including unsuitable rooms that were too small, inconveniently located, or poorly laid out – contributed to hazards in some sites. Other mundane problems related to coordination and action on key tests and items of information.

Communication and coordination were among the most important sources of hazards in the eight sites. Again, poorly functioning IT systems were heavily implicated in some of the problems: under-investment led to delays in implementation; sometimes the hardware was outdated or inappropriate; often the software was incompatible with other systems or was ill-suited to the job at hand, or was difficult, slow and tedious to use.

All sites also experienced challenges in coordinating different professional groups to meet in one place at the same time. The reasons for this often lay in long-standing working practices, shift patterns, job specifications and roles of different professional groups. On one site, trying to get the surgical team and the medical/nursing team together to agree on a care plan and share information was dubbed ‘never the twain shall meet’. Even when professionals did meet, exchange of information did not always take place smoothly or effectively.

Some sites experienced challenges in ensuring that patients were assessed as the assessment teams were peripatetic to the main ward where the patients were located. On one site, a major problem in coordinating care for patients undergoing specific types of surgery was that relevant information that should have been available on admission was often scattered throughout the notes rather than being systematically collated and easily accessible. This meant that patients' procedures might end up being cancelled on the day, wasting resources and exposing patients to risk of harm.

In a number of sites, hazards that surfaced in the clinical pathway under study had their origins in the multiple microsystems along the pathway and in wider organisational contexts. For example, one acute medical unit (AMU) was located in an organisation that was seeking foundation trust status and was focused on meeting the emergency access four-hour waiting-time target. A large proportion of admissions to the AMU came from the emergency department (ED). But because ED doctors saw their role as providing emergency treatment and referring the patient on to appropriate services, the quality of medications history, prescribing, and documentation of medicines administration was often poor. This caused multiple problems for the AMU.

Staff across the sites often depended on patients themselves as a source of information, but patients arriving in hospital without the information needed to ensure their safety was a problem across all sites. In one handover site, older people who might be distressed and suffering from dementia were often admitted to the emergency department from residential care homes without anyone accompanying them and with little information given about the reasons for their attendance.

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.

Some sites realised that they did not have complete insight into processes, systems and hazards along their pathway when they came to implement their interventions, and thus suggested a need to revisit and re-apply the diagnostics as projects progressed.

It's not a linear process and you do go back trying to understand another bit of the process that you thought you understood, but actually didn't as well as you had hoped. (Interview, prescribing site)

Many sites (though not all) reported that they had been surprised by the findings of the diagnostics, which brought home the often complex and unhelpful situations in which staff were working. Pre-existing assumptions were challenged; particular issues that had been assumed to be problematic were sometimes found not to be, and vice versa. At one site, for example, the team were able to identify that many emergency readmissions were, in fact, from care homes rather than from patients who were living on their own, as had initially been assumed.

5. Interventions and system improvement cycles (steps 3 and 4)

When the diagnostics had been completed, site teams moved on to designing and implementing interventions to address the hazards and risks they had identified during the diagnostics phase. They were encouraged to use the classic Institute for Healthcare Improvement (IHI) Model for Improvement approach (see box 4).

The site teams used a variety of techniques to appraise the options for their interventions, though they were not always clearly documented and it was a step that many sites struggled with. In most cases, the options appraisal involved eliciting ideas from stakeholders (for example, junior doctors, nurses, pharmacists and others), and then ranking them.

Consulting and engaging with colleagues when planning interventions gave voice to staff who might otherwise feel excluded or alienated from these processes. Though capturing local expertise was fundamental to designing realistic, workable interventions, several participants noted that securing regular access was difficult, especially with key groups. It proved especially difficult to engage patients: sites were unclear about how to manage the involvement of patients optimally or did not have positive experiences of doing so (box 5).

Box 4: What is the Model for Improvement?

The Model for Improvement is a quality improvement approach strongly associated with the Institute for Healthcare Improvement (IHI) in Boston, USA. Informed by the work of W Edwards Deming, it involves ‘rapid cycle’ improvement in which a hypothesised solution is offered and then tested on a small scale before any changes are made to the whole system. The cycle involves a sequence of steps known as PDSA (Plan-Do-Study-Act) with the aim of making exponential improvements by planning a change, trying it out, observing the results and acting on what is learned.

In the ‘plan’ phase, ideas for improvement are detailed, tasks assigned, and expectations confirmed with the testing team. Measures of improvement are selected. In the ‘do’ phase, the plan is implemented, and any deviation from the plan is documented. In the ‘study’ phase, the results from the test cycle are studied, and questions are asked regarding what went right, what went wrong, and what will be changed in the next test cycle. In the ‘act’ phase, lessons learned from the study phase are incorporated into the test of change, and a decision is made about continuation of the test cycles. For the next cycle, these steps are repeated.

After testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles, the team may implement the change on a broader scale — for example, for a pilot population or an entire unit. The team can spread the changes to other parts of the organisation or to other organisations. For further details, see www.ihl.org/resources

Box 5: Patient and public involvement: an aspiration for Safer Clinical Systems

The nature and extent of patient and public involvement in quality improvement work varied from project to project, and it was seen as having a number of distinct functions across the different sites:

1. *Securing staff and executive engagement through patient stories.* Patient stories were seen as powerful tools for securing local support for the Safer Clinical Systems work. One site contacted the local branch of a patient support society, and involved an 'expert patient' at the stakeholder event and throughout the project to emphasise to the trust board the importance of timely and accurate medicines.
2. *Understanding patient priorities and experiences through 'expert' patients or representatives.* One site that cared for children ran a workshop with the Young Persons' Advisory Group to explain the pathway and to obtain their views on the type of information that should be handed over to the night team. This allowed the team to identify that handover should include more of the child's personal history and any 'intuitive' concerns that the nursing staff or their parents might have.
3. *Enabling patients to contribute to improvement work.* This took the form of commentary or endorsement of proposed interventions.

At the beginning [patient and public involvement is] important, really important because their views are paramount and actually when we did the options appraisals it was good too because we could say, right, "This is what we're going to do, what do you think?" And just to have their endorsement was useful. (Interview, prescribing site)

4. *A means of generating outcome measures (eg, patient satisfaction).*

And then on a weekly basis we do a questionnaire to any patients with [Parkinson's] that are in the hospital just to see how confident they are that their medicines are being managed well and whether they're being given on time, and do the nurses know about the condition, and that kind of thing. (Interview, prescribing site)

Challenges and barriers

Some issues could be seen as generic to any effort to involve patients and the public in health care: the ethical and practical considerations of involving vulnerable patients (the frail elderly, the very young); difficulties in securing patient engagement; and lack of expertise on the part of project teams in how to engage patients and the public.

Two other challenges emerged that were more specific to the nature of Safer Clinical Systems. First, staff recognised that involving patients and the public in a project that highlighted risks in care had the potential to cause alarm and distress to patients; they felt that educating patients to the level of understanding that would be required for them to meaningfully engage with the work and to avoid raising concerns could be prohibitive to broader engagement efforts. Second, participants were not always clear about how and when to involve patients in system improvement cycles, particularly when problems and interventions were to do with processes that would not be obvious to the patient and where the patient would not be expected to hold a view.

Consulting with staff was associated with a number of advantages, particularly in securing ownership from those engaged in the consultation and eliciting ideas from the sharp end of care. However, it was not free of problems. It seemed likely to favour 'bright ideas' that might seem attractive in principle but be hard to operationalise; it seemed to encourage an emphasis on acceptability of interventions rather than effectiveness; and it was hard to eliminate ideas, as it might involve rejecting proposals from staff. Further challenges arose because the options presented for discussion and scoring were not all interventions; some were better characterised as broad and/or aspirational objectives (for example, effective communication on the ward round) rather than specific interventions.

The challenges of options appraisal meant that not all of the interventions were well-suited to, targeted on, or fully aligned with the problems that were identified during the diagnostic stage. Site teams were not always able to fully articulate the theory of change behind some of their interventions – that is, the mechanisms through which an intervention might be expected to work or why it might result in the outcomes sought. They sometimes struggled to articulate the link between their interventions and the specific failure modes or other hazards they had identified.

Some sites chose many different interventions, sometimes with several dozen in one site. This approach had the benefit of tackling the hazards from multiple vantage points. But it also risked a series of uncoordinated efforts, where too much was going on, energy was dissipated, and focus was lost. Other sites selected a small number of interventions (three, for example) which had the advantage of enabling focus and more sustained energy. But if one or more failed, there was not a lot to fall back on.

The 100 or so interventions chosen by the teams across the sites were of different types. Some appeared superficially mundane (eg, introduction of a new form); others involved more fundamental service configuration. Some were extremely ambitious in scope; others were narrower and focused on single system components.

Some interventions did not really target risk and reliability, instead focusing on aspects of patient experience. More broadly, some hazards and risks that had been identified during the diagnostics phase were not the focus of any interventions. In some cases, this was because teams sought to conserve their energy and

focus by not trying to tackle everything at once, or to avoid duplication and overlap with other activities in their organisations.

Some interventions, such as improving multidisciplinary meetings and ward rounds, were well designed and consistent with the available evidence. Interventions tended to work better when they helped make people's jobs easier and quicker, made people feel included, facilitated learning, and were aligned with the various pressures, norms and incentives in the system. For example, teams that managed to get interdisciplinary ward rounds or huddles going found that, especially over time, positive effects could be detected in terms of organisational culture, clarity about tasks, and trapping errors.

In many cases, the options appraisal process did not (due to lack of time or skills) appear to give sufficient attention to the evidence base in the published literature. Thus, there was a tendency to select interventions – posters and information interventions aimed at patients – that have limited efficacy or need to be set up in specific ways to achieve the desired effects. Sometimes teams selected interventions that were known to work, but they did not also deploy the specific supporting infrastructure that was required to enable them to be effective, or they selected interventions with poor evidence of efficacy or that depended on particular implementation strategies. For instance, a system for improving handover introduced in one of the sites had been adapted from one published in the literature, but without much of the supportive infrastructure in place, including specific teamwork training and integration with the IT system.

Several sites developed good interventions such as checklists or standardised forms, but they did not always develop implementation strategies that were grounded in evidence about how to make such interventions work. For instance, a checklist that would summarise each patient's clinical information to facilitate a smooth handover was eventually abandoned because it proved impossible to implement. A handover toolkit that was distributed to clinical staff in the participating specialty led to some puzzlement over what doctors should do with it. A sticky form to be completed by the lead team following the patient's admission and attached to the front of the medical notes proved very difficult to implement, as staff were not always sure whose responsibility it was to fill it in. Physical solutions to some hazards – such as designating areas as 'quiet' or 'protected' for the completion of prescribing and handover tasks – were also eroded by problems of implementation.

Across the sites, there were issues relating to accurate and consistent documentation and specification of interventions. Some things that appeared to be interventions were not identified as interventions by site teams (they might, for example, be described as ‘quick wins’ instead), and some things mutated over time, gradually becoming re-designated as interventions. In one site, for example, an innovative measurement tactic involving a ‘dabber audit’ – where medication charts were dabbed with an ink stamper to indicate whether they were correct or needed further action – came to be regarded as a powerful motivator of behaviour and an educational tool. Virtually all sites reported that they needed to keep interventions under continual review. However, the extent to which sites conducted authentic PDSA cycles varied between the teams; in some cases, interventions seemed to be tested (and abandoned) using more intuitive methods.

There was not necessarily any equivalence between the apparent ‘size’ of an intervention and its potential for disruption, nor the effort required to implement it. Sometimes, apparently small or straightforward interventions turned out to be very difficult to implement because they disrupted established routines and understandings of professional role. In one site, a move to same-day surgery and away from admitting patients the day before their operation took many months and huge effort to bring about, despite a sound underlying rationale. Some seemingly big interventions went more smoothly, because they enjoyed priority alignment and receptive environments. One site had considerable success in ensuring that patients admitted to the AMU were clerked within four hours because this was a goal across the wider organisation. Similarly, the ability of another site to organise and finance a community-based team to support older people in care homes was very much helped by a commitment from the trust and clinical commissioning group to reduce readmissions.

Local contexts were important in influencing the appetite and capacity of staff for becoming involved in the interventions. The projects were running in an outer context of large-scale reorganisation and high levels of demand, and teams were often stretched to the limit. Colleagues outside the project team usually had little time or capacity to engage in the change efforts. Trying to get staff along pathways to engage with interventions was often very difficult when they had to cope with so many competing demands.

More broadly, organisations varied in how well they were set up for doing improvement work. Sites with a culture of continuous quality improvement, where staff were encouraged to innovate and make changes to improve patient safety and increase efficiency, were distinctive for their willingness to recognise that something was not right and to commit to fixing it. However, there was also a tendency to prefer – or defer to – established Model for Improvement-style methods rather than trying new approaches to improvement. In addition, overlaps with other improvement initiatives sometimes led to duplication, confusion, and distraction for staff.

A major limitation for project site teams was that many hazards were simply outside the scope of their control. Often, this was when the problem to be tackled was ‘big and hairy’ in character, involving deep structural issues – such as IT systems or workforce design – that were unlikely to be capable of resolution by the team. Instead, such problems needed responsibility to be taken elsewhere – either by the organisation or the broader health economy.

Many of the problems identified by the diagnostics were simply not tractable to the quality improvement efforts of a small project team, no matter how hard they tried, how enthusiastic they were, or how persuasive they sought to be. The project teams did not have the authority, the positional power, the financial clout, the ability to provide incentives and sanctions, or the ability to control processes and systems that were needed to tackle the problems revealed in the diagnostics phase. Participants emphasised the constraints imposed by the wider institutional and national context, and their limited influence on stakeholders external to their own organisations.

Thus, despite careful diagnostics undertaken by the project teams, the Safer Clinical Systems interventions escaped few of the problems of implementation known to plague quality improvement efforts.¹ The hazards identified during the diagnostics phase were often grounded in complex, deep-seated and long-standing problems. Even when they had the appearance of being simple problems that would be relatively easy to fix, they were not susceptible to any straightforward remedy.

¹ See, for example, the 2012 report, *Overcoming challenges to improving quality*, which identifies 10 key challenges that consistently emerged from a study of 14 different improvement programme evaluations. www.health.org.uk/overcoming-challenges

6. Measurement

Since improving reliability was a key goal of the Safer Clinical Systems approach, measurement was key to monitoring progress. Over the course of the programme, the idea emerged of focusing and prioritising the measures to be used in the form of a ‘safety set’. This was defined as:

... a small number of measures of reliability that are used to assess whether the risks in the clinical pathway are reducing or being eliminated.

Each site selected the measures they would use for their safety set, and any further measures they also wished to monitor. The teams invested a great deal of effort and energy in developing measurement plans for their safety set and in their attempts to ensure transparency. However, it was evident that measurement was a struggle. Site teams had varying levels of ability for managing the demanding tasks associated with selecting and defining measures, establishing reliable data collection systems, and interpreting and reporting data in appropriate ways. Teams needed to have the technical skills to choose measures, facilitate realistic and accurate data collection, and analyse the data; but their knowledge of measurement, biases and data quality control was often relatively modest.

The effort required to collect data – whether relying on routine data or generating new data – was often underestimated. As is normal, routinely collected data (for example, from hospital administrative systems) turned out not to be as clean or well set-up as had been anticipated. Data collection systems were not always run exactly as designed. In one site, a special form that was supposed to be used for data collection was not always used, with data instead being collected in notebooks or on pieces of paper. In another site, it proved hard to get reliable data collection at weekends. Attempts to collect

data from junior doctors at the end of night shifts met with difficulty, as doctors were tired and wanted to finish their clinical tasks before going off duty.

The challenges involved in producing high-quality measurement plans were so pervasive across the sites that they point to a systemic problem. Measurement is a highly technical task requiring a degree of expertise and experience that is rare in the NHS. The teams did have some training and support, but it is unlikely that this was a sufficient ‘dose’ to develop the competencies required or to overcome the challenges associated with setting up and running robust data collection systems.

Some improvement in performance could be detected on some of the reliability measures used by the site teams. More generally, however, much of the data reported by the teams showed no change or the data were difficult to interpret. In some cases, the absence of detectable change can be attributed to very late introduction of some interventions associated with the challenges of implementation, and some change might occur in the future.

The evaluation team undertook independent analysis of the data from four sites (two handover and two prescribing), examining their safety set measurement plan and subjecting the raw data submitted by the site teams to Statistical Process Control (SPC) analysis. For purposes of the evaluation, the quantitative outcomes considered were each team’s safety set; supplementary or additional data not in the safety set were not considered.

The sites varied in how many safety set measures they reported: of the four intensive case studies, two sites each reported on four measures, one reported on five, and one reported on six. Of these 19 measures:

- ten demonstrated no change
- four showed evidence of improvement

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- four showed evidence of possible improvement or recovery of a deteriorating process (more data would be needed to confirm)
 - one showed evidence of possible deterioration.

For the four sites where the evaluation team did not undertake independent analysis, the data as reported by the sites on their safety set measures was used. Only one of these sites appeared to have undertaken appropriate SPC analysis. The four sites varied in how many measures they reported: one reported on two measures, one on three, one on six, and one on seven. Of the 18 measures reported:

- two could not be interpreted due to quality of presentation in the safety case
- three had no data available
- four demonstrated no change
- nine were inconclusive in the absence of SPC analysis, and caution is needed in interpreting any of these measures as evidence of improvement without further analysis.

It remains unclear whether using local measurement in the way it was deployed in the programme is realistic or sustainable, though the principle should not be abandoned until there has been further exploration of ways to support it. It is, however, important to emphasise that the sites' efforts to develop measures and gain knowledge of the reliability of their systems is a significant achievement that distinguishes these sites from most others in the NHS and beyond.

Further, it is important to stress that the quantitative measures of change on the reliability measures in the safety sets do not tell the whole story of progress in the Safer Clinical Systems sites. Ethnographic observations and interviews, plus the supplementary data collected by the sites, offered a more positive picture, showing how participating in the programme and applying its principles and techniques had helped to strengthen aspects of culture related to patient safety, while also building capacity and resilience.

Many of the project team members – including nurses, doctors and pharmacists, and other professional and managerial staff – reported that they had learned a lot from using the various diagnostic tools and techniques. The knowledge and skills gained were considered valuable for instigating, measuring and implementing new projects in different parts of the organisation, or for use with others outside their organisations, leading towards opportunities for future sustainability.

Further evidence of positive effects included evidence of breaking down barriers and fostering good relationships between different staff groups who had previously had little to do with each other, despite caring for the same patients. In one site, for example, observations showed that a ward huddle had been established to encourage an open environment in which the junior clinical staff felt confident to ask questions. One of the strengths of the huddle, which grew in importance over time, was its 'everyday' nature. Observations of the huddle suggested that it was successful in catching errors before they reached the patient, and that it performed an important role in promoting a ward culture where junior staff felt they could speak up.

7. Safety cases: a technique for communicating current hazards and risk controls

So it [the safety case] actually tracks the logic, actually describes the problem, describes how a team identify that it's a problem, what the evidence is that they've collected about risk or reliability or harm or whatever [together with] evidence of improvement. And then almost pulling that together to say, therefore, "This is the case that we're making to give you assurance, Mr board member or chair or public – that actually we've made the system safer. And we've managed all the risks to a tolerable level." So it's pulling together the argument and evidence. (Interview, programme designer)

Used to regulate hazardous industries (box 6), safety cases have been little used in health care to date. One of the innovations of the Safer Clinical Systems approach was the development of the safety case technique as a way of showing that a structured assessment of hazards and risks had been undertaken and of describing the risk controls that were in place. The intention of the programme was that safety cases would be developed iteratively by each site over time, providing a means both of tracking progress (for example, in strengthening of risk controls) and of communicating between the clinical teams and the board.

Box 6: Safety cases in a wider context

Safety cases are sometimes dated back to the Windscale nuclear accident in 1957 and the Flixborough Chemical Plant in 1974, but the term appears to have become formally used following Lord Cullen's 1990 report into the 1988 Piper Alpha explosion on an oil rig in the North Sea. The Offshore Installations (Safety Case) Regulations 1992 and 2005 laid down a licensing regime based on safety cases, requiring those operating offshore facilities to prepare a safety case, submit it to the Health and Safety Executive, and demonstrate that the major hazards have been identified and the risks reduced to a level that is 'as low as reasonably practicable' (the so-called ALARP principle).

The safety case model is now widely used in regulating a range of hazardous industries in Europe and Australia. The general idea behind a safety case regime is that operators are required to make a well-structured case to the regulator, which must (among other things) demonstrate that a thorough assessment of hazards has been undertaken and how their internally generated risk management plan will reduce risk to an acceptable level. The regulator can then accept or reject the case, and grant or withhold approval of the risk management plan. If accepted, all the detail in the case is enforceable, in that organisations must comply with their own specifications and will be held to this by regulators. Demonstrations of adequate risk management practices as specified in safety cases are now used as the basis for regulation of worker and public safety in aviation, nuclear power, the chemical industry, and railways.

For more information, see *Using safety cases in industry and healthcare*. www.health.org.uk/safetycasesreport

Despite their ubiquity, in practice it has remained difficult to prove the benefits of safety case regimes in hazardous industries. Producing evidence of more general change in safety over time is not straightforward. It can be very difficult to determine precisely the level of evidence needed to show that a system is safe, and the relationship between reliability of specific components and safety remains elusive. Further, industries where the safety case approach has been applied are typically subject to rapid technological evolution, so it is hard to determine the extent to which any improvements are attributable to environmental or secular change rather than the introduction of licensing based on safety cases.

Thus, there was no straightforward framework available to the evaluation team in terms of examining the submitted safety cases. It was difficult to do further investigation into issues such as enforcement given that it was not part of the brief of the programme, and given that enforcement in a health care context would work quite differently from settings where the safety case is part of the regulatory apparatus, with legal underpinning. The main focus of the evaluation was therefore to offer comments in the spirit of critique and to identify good practice that might be used to inform further development.

Part of the work of the programme was to develop a way of producing safety cases in health care, and accordingly the approach evolved over the course of the programme. In the early stages, the sites needed considerable guidance to write safety cases, as they involved a very different way of writing and thinking to the usual reports in health care. Over time, sites gradually became much clearer about the purpose of the document as thinking evolved about how they could best be structured. Each site submitted the final version of their safety case in January 2014. These were based on guidance provided by the support team, who explained in the programme handbook that:

A safety case is built from the argument and evidence supporting the claimed (current) level of the safety of a system in a defined operational context... As both argument and evidence are "context sensitive", our safety case must clearly define the context. For the purposes of this safety case, an argument is defined as "a connected series of propositions put forward in order to establish a conclusion".

In Safer Clinical Systems, a safety case is a mature evaluation of the hazards and associated risks in a defined pathway, together with an assessment of current risk control measures – and therefore of "residual risk" – the level of uncontrolled risk currently present in the pathway. This evaluation then creates the safety claim – a statement of how safe the system is at present. Clearly, the uncontrolled risks become the target of improvement interventions.

Sites were also advised that the final safety case could also act as the final report for the projects.

The guidance given to the teams explained that for each hazard, the sites should present the arguments to support the claimed level of risk (the 'safety claim') – for example, by describing the effectiveness of existing risk controls. The evidence to support these arguments should be referenced, with the argument structure explaining the purpose of each piece of evidence. Sites were required to state their level of confidence in the argument and evidence, acknowledging that the logic of the arguments is not infallible and neither is the evidence.

The final safety cases produced took a number of different forms and ranged in length and in the number of appendices they included. The safety case is a technical document, but it is also an instrument for communicating with the board, and therefore needs to be accessible and clearly presented. Some safety cases were exemplary in terms of clarity. Others were harder to follow, perhaps lacking an accessible summary, or not written very clearly (for example, using excessive bullet points or telegraphic-style language) or were too technical, or not clearly organised. Some required a high level of background knowledge of the Safer Clinical Systems approach in order to interpret the safety case. It seemed easiest to grasp the central message when the safety claim and confidence argument were presented early in the document. Some did well in explaining the detail of particular microsystems, but more generally, it might be very hard for people unfamiliar with a system to understand what was going wrong, and why, unless they themselves had been involved in the diagnostics. Stories from patients or staff to illustrate the impact of some of the systems defects and hazards might have been very helpful.

The sites had been advised to use five headings: pathway described, hazards identified, risks understood, confidence argument (ie, the extent to which teams were confident in the argument and evidence) and conclusions, as well as providing an explanation of context and pathway to introduce their safety case. In the event, sites produced very different documents, organised in quite different ways. There was considerable variability in what was reported in the main document and what was attached as appendices. In future, it may be useful to trial various templates more systematically.

A review of the final safety cases submitted by the teams found the following:

- **Explanations of context/pathway described:** Clear explanations of context and pathway were provided in most cases. Diagrams or other visual representations were very helpful in explaining the pathways for patients, but were not provided in all cases.
- **Hazards identified:** Some hazards were clearly described in vivid and explicit language, leaving little doubt as to the nature of the problem. Others were less easy to grasp, particularly for those without a clinical background or unfamiliar with the approach. Clarity might be improved by including a full table of hazards as an appendix or supporting document, and putting a short summary table in the main text.
- **Risks understood:** The accounts of risks understood were variable. Often, the hazards identified and the risks understood were described together in the form of tables. The risk controls described were sometimes interventions. More clarity may be needed in the concepts underlying risk controls. Some sites described the residual uncontrolled risk in their pathways well; others made no mention of it.
- **Confidence argument:** The confidence arguments varied in their clarity, and there was some evidence of confusion about the nature of a confidence argument at some sites. The claim about safety was sometimes presented very clearly and explicitly, and sometimes less directly, taking the form of reports of project activities. It thus did not answer the question about the robustness of the case so much as it answered the question, ‘What did we do?’. This may have occurred because sites were using the safety cases for the dual purpose of a final report, so it was difficult to be clear about the current safety or reliability of the system.
- **Conclusions:** Sites were asked to state how safe the pathway is now, to identify the most significant risks and which of them are not adequately controlled, to specify which interventions are required and how success in reducing risk could be demonstrated, and to link the interventions to the measurement plan. Sites varied in how they used this section. In several instances it was very brief and did not contain all of the information requested.

It was not always straightforward to match up the data presented in the safety cases with the measurement plans that had been submitted for the safety sets. Sometimes definitions or labelling had changed substantially. Some measures in the measurement plans did not appear in the corresponding safety case. Some data charts were presented with exemplary clarity and were clearly annotated to show baselines and introduction of interventions, with upper and lower control limits clearly visible. Other charts were poorly labelled or almost impossible to read due to small font size. Many charts purporting to show progress over time were not presented as proper SPC charts, or via any other valid statistical approach, and in some instances the evaluation team were concerned that the sites had inferred improvement without adequate justification.

Interventions were not always described with sufficient clarity or precision; often, just brief telegraphic titles were given. Safety cases were often poor at documenting when the interventions were implemented and what their fate had been when implemented.

Some safety cases were very candid about the persistence of hazards and poor reliability along the pathways. At one site, the safety case notes that the diagnostics had found 99 ways in which the pathway could fail, reported that the level of reliability in the microsystem remained lower than acceptable, and emphasised that radical redesign was needed. Another site concluded that while risk management in relation to medicines was largely acceptable within hours, it was unacceptable out of hours.

In some instances, there was evidence of over-optimism about the extent to which risk in the system had really reduced, and perhaps over-confidence about safety. This was particularly the case where data were interpreted as showing improvement without correct SPC analysis being reported, and where there was a mismatch between what was in the safety case and some of the data collected through ethnographic observations.

One problem in terms of frankness is that the final safety cases were, in some senses, the final reports for the sites participating in the programme. They were keen to document progress and to justify the investment they had made in their interventions. While this is understandable, it might not always have given completely authentic insights into the hazards involved and how far risks have been mitigated. Testing of safety cases in 'real-life' situations will help in assessing the extent to which this is likely to be a persistent issue with this approach. It will also be important to clarify the specific skills involved and who should undertake the preparation of safety cases (for example, whether individuals in organisations should be trained up or whether external technical experts should work with organisations to produce the safety case).

A further challenge concerns how to ensure that boards understand and respond appropriately to safety cases. Participants hoped that safety cases – by making visible, articulating and defining an issue thoroughly and showing where any gaps in controlling risk lay – would help secure senior management attention and make problems harder for trusts to ignore.

In the absence of a regulatory mandate, however, the safety case did not form part of an enforceable agreement in trusts, which meant that their role was ambiguous and very different from their standard use in hazardous industries. Lack of clarity about safety cases at executive level in the participating sites may have inadvertently reinforced the perception that the project team (rather than the organisation as a whole) was responsible for safety and making changes to support safety. Boards may require some education and support to get to grips with the underlying principles and terminology, and in determining how to approach safety cases in constructive ways.

Between October 2013 and January 2014, the Health Foundation convened a working group to bring together perspectives on the current use of safety cases, and their potential for application in health care. The group included representatives from health care policy, practice and regulation, and academics with expertise in safety cases, as well as those involved in the Safer Clinical Systems programme. This group agreed that safety cases had some potential in principle to deliver a number of possible benefits: to bring together and synthesise the range of information and evidence relating to a particular service; to deliver a positive impact on capability and safety culture; and to provide a structure for assessing future risk proactively. It agreed that the safety case model could not be directly

imported from other industries, but there were three possible applications in health care: to approve the safe introduction of new products, processes or infrastructure; to improve the safety of health care services; and to assure the safety of health care services. The latter offered perhaps the greatest potential benefit, but would require a willingness on the part of all stakeholders (boards, regulators, professionals and the public) to commit to the ethos behind the approach. A careful and phased approach to the use of safety cases, with evaluation alongside, is likely to yield most benefit.

For more information on the findings of the Safety Cases Working Group, see the supplement to this report, available from www.health.org.uk/scsevaluation

8. The site teams' experiences

Box 7: What project teams features were important for implementing the Safer Clinical Systems approach?

1. **The right people with the right expertise.** Many participants linked the composition and working of their site team to their ability to meet the many challenges of the programme. Team members needed diverse skills in order to perform different roles and draw together to work towards an overall project goal; these included knowledge of specialist clinical areas (eg, a pharmacist) and project management and networking skills, as well as being able to see the 'bigger picture'. It was deemed essential to have a clinical lead with protected time and a dedicated and highly skilled project manager with some experience of working in the NHS, who was responsible for overseeing the phases of the project, submitting data and reports to the Health Foundation, and generally keeping the project on track.
2. **Stability of team membership over time.** This was important to avert problems of loss of continuity and to maintain networks of contacts. Individuals were added to and left teams over the course of the programme, but substitutions were not always like-for-like.
3. **High level of organisation and expertise.** The key challenge identified almost universally by site teams was time. Many participants spoke about the difficulty of getting people in the same room; running the project and servicing the accountability requirements was very demanding and required a high level of organisation and expertise. Interviews at some sites emphasised the consequent need to minimise the bureaucratic burden associated with the project.
4. **Clear demarcation of roles and responsibilities.** Roles had not always been as clearly specified as they might have been. For the future, the definition of roles and functions may need to be firmer; for instance, it is now clear that a data analyst is an important member of the team, as is someone with a strong background in the design and development of interventions. Such people can be found in some, but not all, NHS organisations.
5. **Personal qualities such as enthusiasm, motivation and perseverance.** Good interpersonal skills as well as dedication, commitment and optimism were repeatedly mentioned as essential characteristics, and enlisting people with strong, likeable personalities in the site team was seen as necessary to keep projects going despite setbacks and difficulties. One team met regularly outside working hours, including socially, in order to thrash out various issues that they had not had time to resolve during normal working hours.
6. **Quality of leadership.** Leadership was required to build consensus and coalition around shared goals for improvement, particularly where long-standing conflicts and tensions are evident. Project teams drew both on senior-level support within their organisations and on 'distributed leadership', where leaders throughout the organisational hierarchy have influence. Having to report progress to executive structures within their own organisations helped to keep teams on track, and managerial support was also important in securing the involvement and endorsement of those with the power to get things done. The clinical lead needed to have an appropriate sphere of influence and negotiating skills to ensure that these colleagues were willing to make extra effort to help the project to succeed.

As shown in box 7, a number of project team features emerged as important to the implementation of the Safer Clinical Systems approach. The large volume of work associated with the projects and learning the techniques – together with volatility in team membership – meant that it was not easy to ensure that all team members were fully competent across the curriculum, including in skills necessary to undertake measurement, data collection and data analysis required for their projects. There was evidence that site team members sometimes struggled with underlying concepts such as the distinction between the terms ‘hazard’ and ‘risk’, which were often used interchangeably and incorrectly.

Participants emphasised the importance of training and support to implement the Safer Clinical Systems approach, which was highly technical and required significant effort to master; they felt that trying to follow the approach by learning it from a manual alone, without a support team, would probably end in failure.

Several sites would have found a more cyclical, recursive approach more helpful – one that would have enabled them to return to a problem and repeat the diagnostics (or elements of them) as new issues appeared.

High levels of turbulence (internal and external to the teams) affected continuity and the stability of learning over time. The NHS was going through reorganisation, and many sites struggled to maintain continuity in their teams. The ‘project-saturated NHS’ was not seen as well aligned to initiatives that required extra time to understand and fix things, and some site teams had to deal with competing organisational priorities or even competing improvement programmes or approaches. Boards could be impatient with the apparently slow progress of the Safer Clinical Systems projects. When projects demonstrated alignment with organisational priorities, some teams were better able to secure support from more senior clinical staff or from members of the executive team.

9: Conclusions and recommendations

Much of the Safer Clinical Systems approach is ingenious, and firmly grounded in established practices from hazardous industries. The pathway definition and diagnostics stages and safety case technique were the stronger elements of the approach, while the options appraisal, intervention development and implementation aspects need significant redesign if they are to be used in health care. The programme has also suggested potential value in the principle of using a safety case approach to evidencing the hazards, risks and risk mitigation along clinical pathways, and of communicating the degree to which risk is controlled, though considerable further work will be needed to mature and evaluate the technique. The successful use in health care of the Safer Clinical Systems approach in general, and the safety case technique in particular, is likely to require a favourable outer environment, where the system stewards (regulators, commissioners and so on) recognise the value of a proactive approach to hazard detection and avoid simplistic blaming behaviours.

The participating teams are to be congratulated on the huge efforts, enthusiasm and commitment they invested in the programme. As a result, they achieved ‘eye-opening’ revelations into their clinical pathways and were able to identify multiple fallibilities that could result in harm to patients. Many of these vulnerabilities arose because clinical microsystems had never been purposefully designed, but were instead improvisatory in character and prone to degradation; or because they were not designed with safety as the organising principle; or because systems did not operate with the degree of reliability needed to assure safety. These are very important insights for improvement in the NHS.

Some hazards and risks identified by the diagnostics could be resolved by standard quality improvement methods such as PDSA cycles run by small project teams. But, critically, many of the ‘big and hairy’

problems revealed by the diagnostics were symptoms of deep-rooted organisational pathologies with long histories and complex dynamics, and they required a different approach – such as radical systems redesign, improved staffing, or new IT infrastructure. A focus on the problem-solving capacity of health care organisations is needed to optimise the Safer Clinical Systems approach. This means that organisations will need to recognise the different kinds of problems that contribute to hazards and risks, and fit the methods they use to address them to the characteristics of each problem – rather than assuming that all problems are tractable to the same methods.

Overall, as an example of a proactive, problem-sensing approach to diagnosing and treating defects in systems likely to create the conditions for harm, the Safer Clinical Systems approach should be regarded as very promising. Many of its principles are sound; some of its features can be updated in light of learning from this programme. The approach would benefit from further use-in-practice and evaluation. The evaluation team recommends the following to move the work forward.

1. More detailed and explicit specification of the theoretical foundations of the Safer Clinical Systems approach would be helpful, particularly in helping to mature the science of patient safety. It will be important to acknowledge and explicitly account for some of the critiques of the approaches and theories that underlie Safer Clinical Systems – including, for example, the tendency of risk management systems to degrade into ‘paper safety’.
2. Further refinement and development of the specific package of methods is needed, in particular to ensure that methods of diagnosis are well matched to the problems they seek to assess. A cyclical rather than a linear approach is likely to be most useful.

3. It will be important to assess whether some kinds of diagnostic tools and techniques are better suited to some kinds of pathways and some kinds of problems than others. Options include: a full menu of tools and techniques, explaining the purpose and strengths and weaknesses of each, and encouraging teams to select a package best suited to their particular contexts; and identifying a minimum set that all teams should use, and providing options of extra tools to fulfil specific goals. The question of how often the diagnostics should be run in full, and the extent to which this might depend on features of clinical pathways and safety problems, should be addressed.
4. While it is clear that a significant amount of time needs to be spent on diagnostics, the time required is likely to vary across different organisations, pathways and clinical areas, and it needs to be customised. Some pre-assessment to determine the appropriate length of time for the diagnostics would probably be helpful. Nurturing straightforward solutions and early wins during the diagnostics might be encouraged, provided that a way can be found to define the characteristics of interventions that are suitable for this kind of immediate treatment.
5. A formal comparison of the yield from the Safer Clinical Systems approach and other ways of doing diagnostics would be of value, and should include an analysis of costs as well as an assessment of the findings of the process and of the credibility afforded to the findings by different stakeholders.
6. The options appraisal and intervention development phases need to facilitate strong intervention design and high-quality implementation strategies. Collating and sharing the evidence base for improvement interventions is likely to be important in supporting intelligent intervention design.
7. Responsibility for responding to the findings of the diagnostics (that is, the responsibility for supporting the improvement to happen) should lie with senior management, not with small clinical teams. Senior management should identify the level at which changes need to be made and who should make them, with what resource and authority. This will mean strengthening the problem-solving capacity of health care organisations from the top to the bottom.
8. For future iterations of the approach, it would be useful to give explicit consideration to the possible roles for patient and public involvement – together some guidance about when and how to do it.
9. Explicit consideration should also be given to task and role specificity in using the approach. Teams might usefully include a technical expert in safety tools, an expert in measurement and data analysis, and several with clinical expertise, for example.
10. It is unlikely that the approach can be learned from a manual; the skills are likely to require specific training based on a well-specified curriculum.
11. Future applications of Safer Clinical Systems should aim to show that the interventions or risk controls arising from its processes are not only directed at making care safer, but at improving task performance in ways that will impact on other objectives.
12. The Safer Clinical Systems approach is likely to benefit from analysis demonstrating whether it works better than other approaches, whether it is a cost-effective use of resources, and how the costs of not deploying it can be estimated.
13. Increasing the compatibility of Safer Clinical Systems with the norms, values, and needs of institutions, organisations and professions is likely to be a key objective. This is likely to mean seeking to address challenges and opportunities relating to the role of professional autonomy and scientific evidence in health care organisations, as well as addressing the overwhelming need for NHS organisations to demonstrate accountability in very particular ways to commissioners, regulators and others.
14. For the future, improvement efforts should draw on some established techniques for prioritising interventions – for example, by asking:
 - Will this intervention address major risks?
 - What is the probability that we can implement this intervention?
 - What is the probability that it will be effective here?
15. Where appropriate, senior management may encourage the use of the Model for Improvement (see box 4) for solving particular problems, but should not default to this approach for all problems. Whatever approach is used, the teams implementing it need the right expertise.

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16. The challenges of measuring quality and safety in health care need to be more forcefully tackled. Important hypotheses to be explored include whether the problems of measurement for safety in health care could be mitigated by:
- more extensive training of specific team members
 - attaching an external consultant to the team with the right expertise
 - improving skills in measurement through high-quality open-access courses.
17. Work needs to be done to optimise the format and structure of safety cases for health care, and in particular to ensure that they are a suitable instrument for communicating with board members. Evaluation of their cost-effectiveness may also be required. How boards would prioritise (when resources are limited) between different safety cases, and between safety cases and business cases for investment, needs to be evaluated.
18. Executive and board members of NHS organisations are likely to need educating in how to understand and respond to safety cases. The extent to which boards are prepared to invest in safety cases (and the diagnostic work required to prepare them) in the absence of a regulatory mandate should be assessed.
19. If safety cases are to be developed and evaluated further as a technique, it may be necessary to reach agreement with the relevant regulators and other bodies that organisations using them will be protected from regulatory action based on the intelligence they contain. Care needs to be taken to avert some of the known problems both with this technique and with risk management methods more generally, including their use in a mechanistic, ritualised or tokenistic manner. The system stewards need to understand their responsibilities in this regard to avoid creating an unfavourable environment for proactive risk detection and management approaches.
20. Improvement work needs to find a better fit between the findings of diagnostics and the nature of the organisational response, and by clearly locating the responsibility and imperative to act with senior management. The role of clinical teams in making improvements will continue to be important, but should be clearly and explicitly linked to assessments of the solvability of problems. There needs to be tight and logical coupling between hazards, interventions and measures, which is reviewed and revised over time.

Appendix: Summary case studies

1: Ashtree

Ashtree’s Safer Clinical Systems project aimed to improve the safety and quality of shared care of renal patients having a surgical intervention (elective or emergency) by improving handover processes. The project focused on patients undergoing kidney transplant, live kidney donation or other procedure, and it sought to ensure that staff had all the relevant information they needed about each patient undergoing the intervention.

The clinical pathway

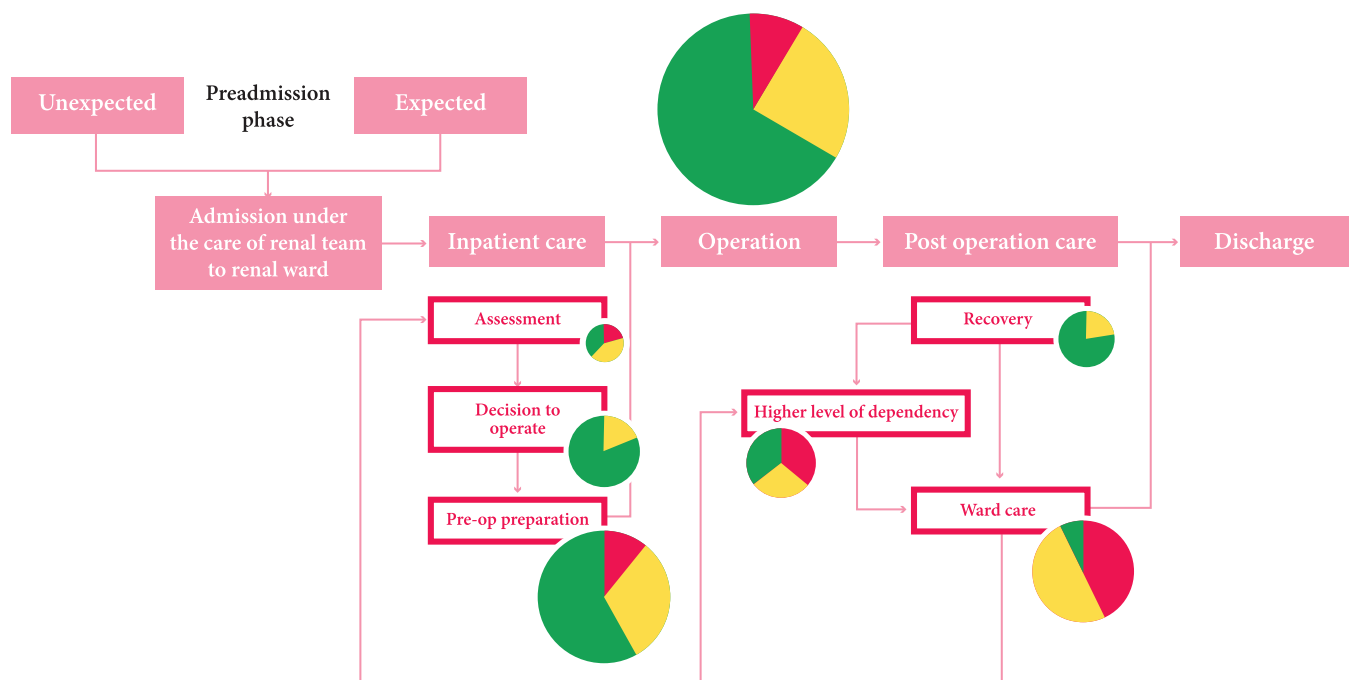
The Ashtree team’s work to define the clinical pathway showed that patients who were planned for surgery were admitted and clerked into one of two wards by the on-call renal team the day before their operation. If deemed fit, they were prepared for theatre, underwent their operation, were returned either to high dependency care or to one of the two main renal wards to recover, and then discharged.

If a patient was either deemed unfit for surgery or key information (including test/investigation results) was not yet available, the operation would be cancelled or rescheduled. Managing the pathway required considerable coordination between the renal and surgical teams.

The diagnostic phase

The Ashtree project team used a combination of tools, including Failure Mode and Effects Analysis (FMEA) and Hierarchical Task Analysis (HTA), to identify the main hazards and risks along the pathway, from pre-operation assessment through to discharge (figure A1). They found there were 99 ways in which the pathway could fail, but subsequently narrowed these down to the highest-risk tasks and hazards. Lack of medical review by senior doctors and lack of a surgical plan for each patient were classified as two of the highest risks.

Figure A1: High-level task map using FMEA to show where the highest number of failures occur (size of diagram) and the highest risks are present (red=high risk, yellow=medium risk, green=low risk)



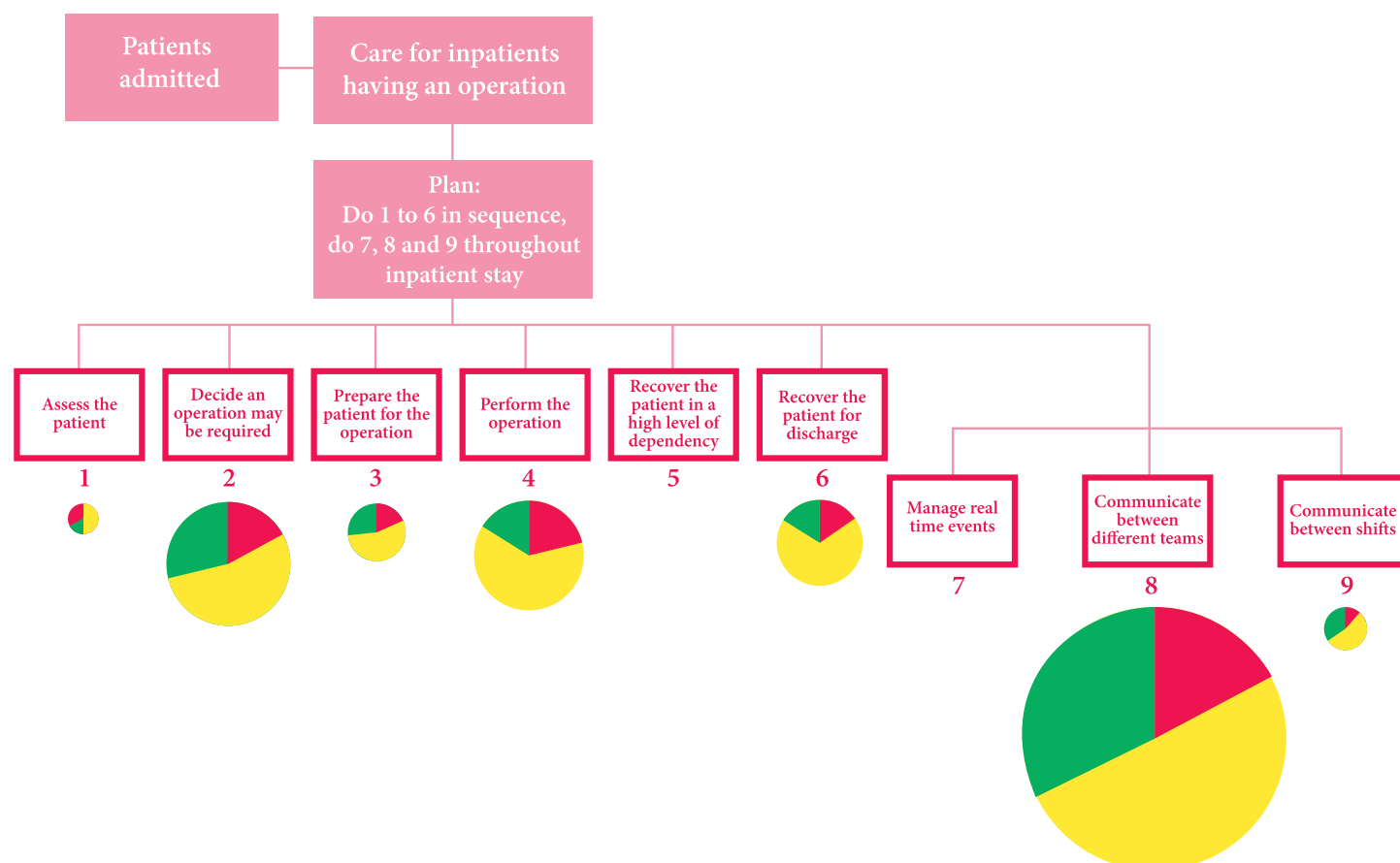
Along with other sites involved in the Safer Clinical Systems programme, Ashtree found that poor communication – in this case between renal and surgical teams – was a significant problem (see figure A2), contributing to a high operation cancellation rate (12%). Cancellations and delays were associated with many unwanted consequences, but an immediate and visible source of harm was that patients could spend long periods nil by mouth (NBM) before they went into theatre or without having an operation at all, which affected their wellbeing and experience of care.

The hazards that were uncovered arose from the way care was organised at this hospital for this patient group and from established organisational cultures and patterns of working. Patients on the renal unit were often well known to the renal clinical teams. The renal teams sometimes regarded other specialties as not fully cooperating or integrating their practices with them – for example, ‘borrowing’ paperwork and not putting it back correctly after use. Surgeons operating on renal patients were generally regarded by renal staff as involved in patient care in a peripatetic or episodic way: they performed operations, but were perceived as paying mostly fleeting visits – often giving insufficient priority to recording information about the patient’s surgical care.

Information relevant to surgery was not systematically collated or easily accessible, and patients’ medical records were often insufficient as a guide. The work ethic of individual on-call junior doctors – an important control measure in determining whether, and how thoroughly, admissions were reviewed – was regarded as a relatively precarious defence against harm. The transition points of handing over of information – namely, when patients went to theatre, and recording the correct information on the IT system once the patient was in theatre – were highly vulnerable to failures that could result in harm.

As discussed in section 4, there was a high level of variation between surgeons at the hospital in terms of how long they wanted patients to be kept NBM before surgery, and nurses also varied in how they interpreted and implemented surgeons’ preferences. There were also problems with recording aspects of surgery during and after operations. Only in 55% of cases was all the relevant information recorded on the trust’s IT system, causing problems in terms of managing patients post-operatively and in preparing discharges.

Figure A2: High-level task map using HTA to show where the highest number of tasks (size of diagram) and the highest-risk tasks occur (red=high risk, yellow=medium risk, green=low risk)



In selecting interventions, the project team decided to target the following six high-risk tasks that needed to be done reliably in order to improve safety (reliability measures in parentheses):

1. Medical assessment by a more senior team doctor at the patient assessment step (% of patients undergoing a senior medical review).
2. A surgical management plan at the decision-to-operate stage (% of patients with a documented pre-operative plan by a surgeon).
3. Organise haemodialysis session when preparing the patient for operation (% of haemodialysis patients for whom surgery is delayed).
4. Complete and make available documents on IT system at the operation stage (% of patients going to theatre with key points of IT peri-operative care plan filled in).
5. Meet the requirements for safe discharge when preparing the patient for operation (% of patients readmitted within 30 days of surgery).
6. Communicate between different teams in an ongoing care review (% of patients with a documented post-operative surgical review on day 1).

The options appraisal phase

The project team set up a multidisciplinary implementation group including transplant coordinators, nurses, theatre staff, porters, radiologists, surgeons and nephrologists. In a mixture of informal and formal meetings, they undertook a formal options appraisal process, using intervention-brainstorming sessions to identify methods to control risk. The team ranked over 60 proposed interventions based on scores for cost, risk reduction, acceptability and sustainability.

The time-consuming intervention selection process was performed over three five-hour sessions, yet the project team still felt that options appraisal was not afforded sufficient time.

The interventions ('risk controls') and outcomes

A shared board round

This intervention was intended to improve coordination between the renal and surgical teams, addressing the absence of a handover mechanism before and after surgery. Patients due to have surgery were identified by a

pink magnet on a whiteboard in the renal unit, and their notes were marked with a pink sticker. Discussions were led twice a week by an operations manager/transplant coordinator.

The reliability measures for this intervention were: the percentage of patients with a documented pre-operative plan by a surgeon; the percentage of patients readmitted within 30 days of surgery; and the percentage of patients with a documented post-operative surgical review on day 1.

The goal was that 95% of board rounds be attended by at least one consultant surgeon and 80% by a representative from the surgical teams (ie, at least a surgical registrar was present). The project team perceived that this intervention saved time and effort, and enabled effective sharing of information, fostered new relationships, encouraged better teamwork and improved patient safety.

At the time the board round was introduced, the surgical team was short-staffed and thus some were reluctant to be involved. Initial requests for junior surgical representatives to attend daily were largely unsuccessful. Changes to working practices were written into two consultants' job plans in the hope that it would encourage other colleagues to volunteer.

Adaptations to admissions proformas

During the diagnostics phase it was found that admissions proformas (elective and emergency) were generally completed the day before surgery (or sometimes on the day), and they did not make clear that a senior medical review and surgical plan were required. An amended proforma, introduced around June 2013, included two sections to be completed by a senior doctor (a senior medical review) and a surgeon (a surgical management plan) respectively. This was intended to provide an opportunity for surgeons to record the date and time of the procedure, whether (and for how long) their patient should be NBM, and identify any pre-operative issues that needed to be addressed.

The goal was that for patients admitted for surgery or those who had surgery within 72 hours of admission, 95% of proformas would have the senior review section completed (for elective patients, either by nephrology or anaesthetist; emergency by nephrology only) and 95% of elective proformas would have a surgical plan completed.

The proformas developed by the project team were not formally evaluated by the evaluation team, but a number of defects in their design were apparent, including a confusing layout, lack of a professional appearance, unclear instructions for completion, and potential for duplication of information.

Pre-operative assessment in clinic

During the diagnostics it had been found that all elective patients were admitted and assessed on the day before surgery by the surgical on-call team who visited the renal unit. The intervention comprised moving the pre-operative assessment into an outpatients clinic, with a date for the assessment arranged in advance of the scheduled date for surgery. An experienced nurse would complete an extensive pre-operative admissions form and a consultant anaesthetist would conduct an expert senior medical review. Patients could be admitted on the morning of surgery, and have dialysis in their normal unit at their normal time rather than endure the disruption of coming into the hospital where they were going to have surgery. The need to change to the new system was given added urgency because the new hospital, due to open in 2014, would have a reduced number of beds, and it would probably not be possible to continue with the practice of admitting patients the day before.

The reliability measures for this intervention were: the percentage of patients undergoing a senior medical review; the percentage of haemodialysis patients for whom surgery is delayed; and the percentage of patients readmitted within 30 days of surgery.

Despite the appeal of this intervention, the clinics had only just begun functioning at the end of May 2013 due to the need to secure the right staff and the right space for them and the amount of time and effort involved in this. Once established, the clinic was open one afternoon a week alongside three other clinics held in the unit's own outpatients department. In June 2013, four renal patients who needed to have a surgical procedure under general anaesthetic were being seen every week.

Challenges in optimising the clinics included a lack of qualified nurses, the length of the pre-operative forms, and the length and complexity of patients' medical histories. Despite these, the project team were confident that the clinics would save some patients the ordeal of having their surgery cancelled on the day. Several staff suggested that this had already happened, though it was more difficult to evidence quantitatively.

Ticket for intervention/‘My operation’

The ticket for intervention (later relabelled ‘My operation’) was a patient-held tailored A5 information booklet about timing of surgery (and other interventions) and what to expect in the post-operative period. It provided space to record information about the patient's milestones for recovery and safe discharge. The reliability measure for the intervention was the percentage of patients undergoing surgery with a completed ticket for intervention, evidenced by a copy taken and filed in the patient's notes.

Development was not straightforward. It proved difficult to get feedback from surgical colleagues, provoking concern that they would not want to use it. The intervention was eventually introduced around the same time as the pre-operative clinics, in late June 2013. The team reported that around half of the surgeons used the document, meaning clinical staff did not feel they could rely on it as it was not always completed.

Peri-operative care plan theatre education

Completion of documents relevant to surgery on the trust's IT system was poor, resulting in inaccurate data, loss of revenue, frustration, delay and organisational conflicts. The project team had planned to work with the trust to help redesign the way the data are collected using the software system. However, the plan had to be abandoned due to uncertainty about the renewal of the IT contract and the need to focus on the new hospital project. The redesign of the IT system was replaced with theatre education, involving training on key aspects of data that need to be recorded for safe theatre care. This was to be delivered in small group sessions and PDSA work, spreading from one theatre to the other three.

The reliability measure for this intervention was the percentage of staff from main theatre who attended theatre training sessions.

Again, delivery of the intervention ran into challenges. The clinical lead, who was due to deliver it, was struggling for time to do so. The redesign of the IT system was completed in April 2014 and rolled out in May 2014.

Conclusion

To conclude, the safety claim made on the basis of Ashtree's safety case was that the care pathway in question is safe. However, the level of reliability of key tasks (hazards) in the system – particularly around shared care and communication – remains lower than acceptable.

Ashtree's experiences of applying the Safer Clinical Systems approach

The Ashtree team was a high-functioning, cohesive team that was very well led and managed, and was judged to demonstrate a high degree of fidelity to the Safer Clinical Systems approach. The team participated enthusiastically in learning sessions, followed the principles and procedures of the approach carefully, and showed considerable determination to master the various techniques and apply them conscientiously. They might be regarded as a model team in terms of their internal relationships, personal qualities, competence, and willingness and ability to engage faithfully with the approach.

The project team felt that they had been successful in securing engagement of their clinical colleagues despite the setbacks and delays, and that they were making inroads into improving the safety and experiences of their patients.

Ashtree's completion of the pathway definition and diagnostics phases was exemplary. The team reached a clear and deep understanding of the high-risk steps and hazards faced and yielded insights that would probably have been unavailable by other means. The project team would have benefited from more time and greater support in the selection and development of interventions – many of which were difficult to introduce or achieve reliably – and from a more comprehensive and detailed strategy for achieving the adaptive work of implementation.

The context was challenging. An impending merger of two acute hospitals in the city into one new hospital meant that staff on the renal unit had to reapply for their own positions as a consequence of the reduction in the number of wards. This contributed to feelings of uncertainty and demoralisation and may have affected their engagement with the project and what it was trying to achieve. Other organisational changes were occurring, including applying for foundation trust status and changes in leadership at chief executive level.

Given the challenges involved in implementing the interventions identified qualitatively, it might be expected that relatively little impact would be evident in the quantitative analysis. Nonetheless, some evidence of improvement was found in the percentage of patients with a documented pre-operative plan and in the percentage of renal patients going to theatre with key points of the peri-operative care plan filled in. There is a slight indication of a reduction in 30-day readmission rates, however this should be interpreted with caution until further data become available. The other three measures did not improve over the project timescale, but neither did they deteriorate.

2: Hollyberry

The Safer Clinical Systems project at Hollyberry aimed to reduce medications prescription errors, establish measures of safe prescribing, and increase the safety of the prescribing pathway, for all patients admitted from either primary care or the emergency department (ED) to the acute medical unit (AMU). The project also hoped to embed a continuous improvement culture on the ward and disseminate learning more widely.

The patient pathway

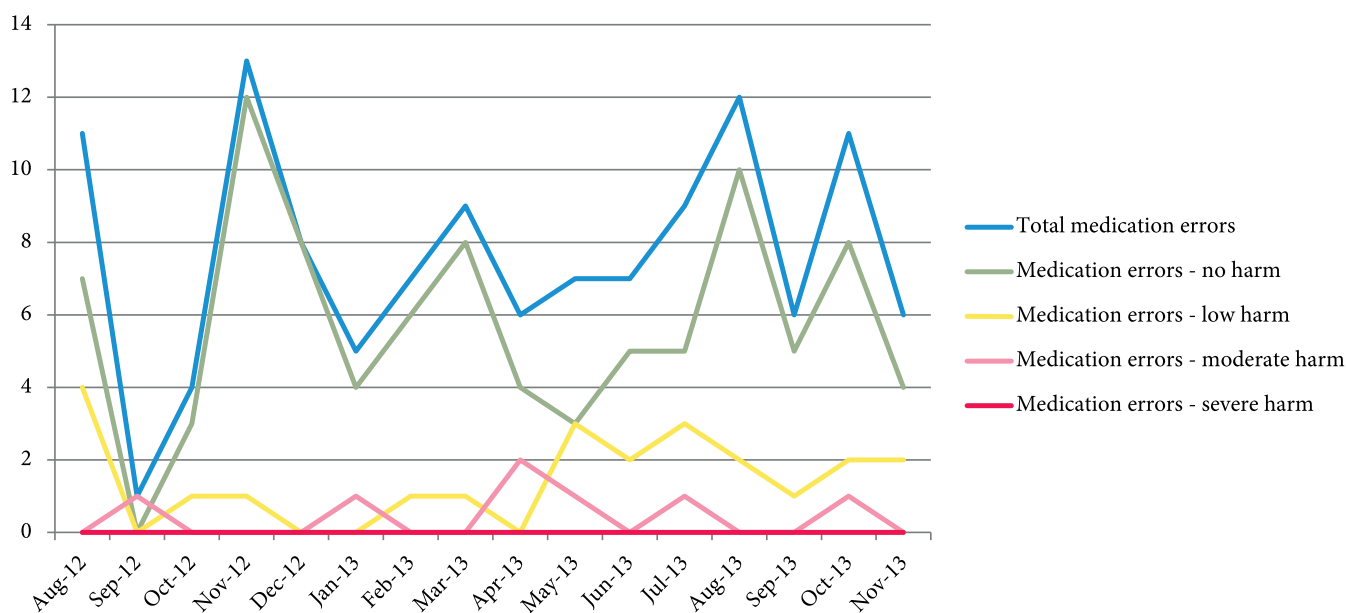
The project team at Hollyberry defined the pathway as the patient's journey through the AMU from admission to transfer, either to another ward or home. The Hollyberry AMU operated as a short-stay ward accommodating a diverse group of 1,800 patients per month, admitted via primary care or the ED before they were discharged or relocated to an appropriate specialist

ward after an average of 16 hours. The AMU had more than 40 beds in total; part of the ward formed the assessment and ambulatory unit (AAU), where patients were managed rapidly in order to avoid assigning them to a hospital bed if they did not require inpatient treatment.

The diagnostic phase

Reflecting the experience of other project teams involved in the programme, the team at Hollyberry felt that the diagnostic phase helped them not only to confirm some suspected hazards but also to reveal hazards that had not previously been identified. A large number of hazards centred on medicines reconciliation, clerking-in of patients, and quality of prescribing. The team collected a large amount of data on each (for example, see figures A3, supplied by the Hollyberry team).

Figure A3: Medication incidents reported on the ward, by severity



Medicines reconciliation was found to be a problem in both the ED and AMU. Doctors in the ED saw their role as providing emergency treatment and referring the patient on to appropriate services, so they typically did not take a full medicines history or prescribe on an inpatient medicines chart. Only one in three patients admitted to the AMU from the ED had an inpatient drugs chart on arrival, which may or may not have been complete. In the AMU, clinicians did not know what medication the patient was taking on a regular basis, or what medications patients had already been prescribed during their time in the hospital.

Delays in staff clerking patients into the ward meant that the length of time patients spent without a medications chart could be prolonged (up to 4 hours 50 minutes at the weekend), and during this time nursing staff were unable to administer medications, including pain relief and time-critical medications.

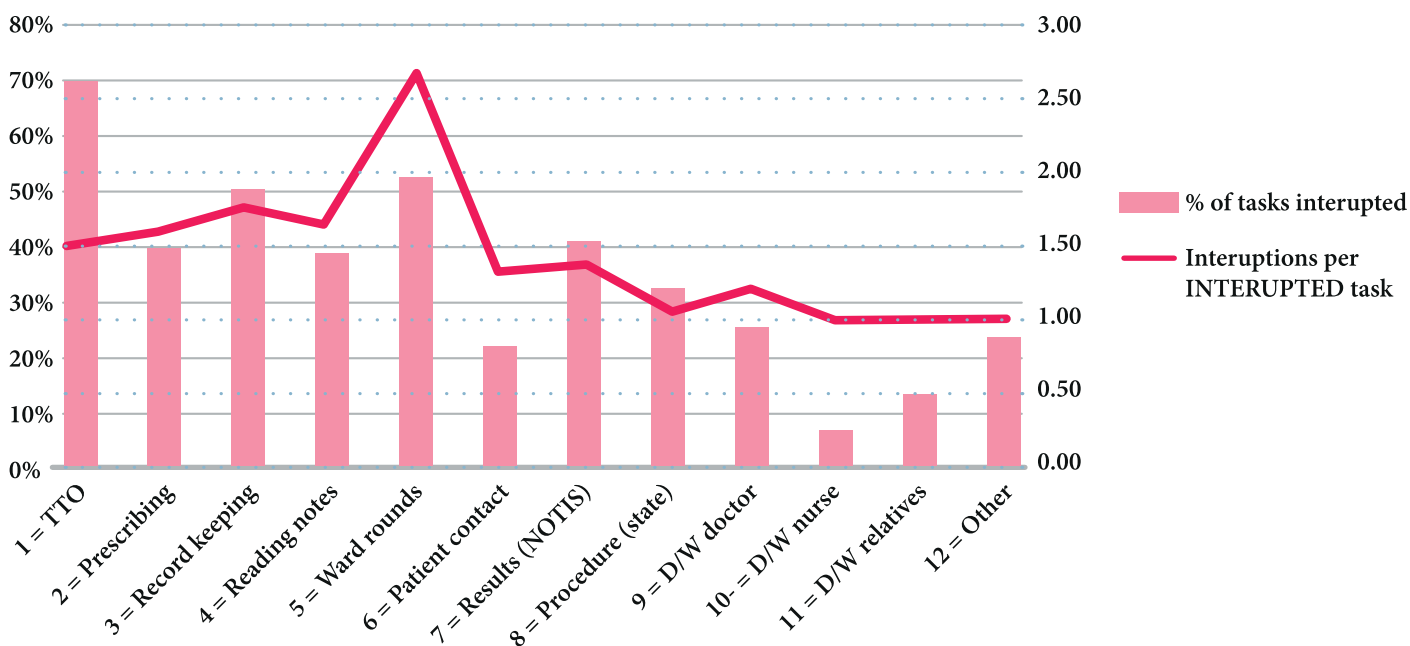
Prescribing errors were linked not only to the problems of incomplete and missing drugs charts and failures in medicines reconciliation, but also to interruptions and distractions during clerking and prescribing (see figure A4, supplied by the Hollyberry team). Errors included incorrect dosage, incorrect medications, lack of awareness about allergies, and unintentional interactions between medications. Online prescribing support was found to be poor: intranet access to the online British National Formulary (BNF) and trust guidelines was complicated, so doctors did not use it to check medicines regularly.

The Safety Culture Index and other tools used in the diagnostic phase (see box 2) revealed that those responsible for most of the prescribing – junior doctors – felt unsupported and lost. The ward round was supposed to be as a form of ‘safety net’ during which prescribing errors could be picked up and corrected, but at the start of the project junior doctors often lacked confidence in raising issues in this forum.

The availability of pharmacy staff was also identified as a hazard, with only a small amount of cover available out of hours on evenings and weekends. During office hours, the pharmacy staff near the AMU had to prioritise checking ‘to take out’ (TTO) medications, so that patients could be discharged from the hospital. But TTOs often took longer than they should, because earlier failures to conduct medicines reconciliation meant that mistakes had to be corrected. Out of hours, the on-call pharmacist (who was not based on the ward) had to prioritise completing TTOs for the whole hospital, meaning that often no one was available to check medicines charts on the ward.

Out of hours and at weekends, many AMU staff were locum doctors. Audits estimated that 70% of locums had never worked on the AMU before, and they sometimes struggled with access to systems and ended up logging in using other people’s passwords (a known safety hazard).

Figure A4: Interrupted tasks and interruptions per interrupted task



The project team further identified a high turnover of nurses (8%) on the AMU as a potential hazard. Having an established and long-term nursing team was thought to be important to stability and support, especially for junior doctors and locum doctors.

The project team identified five high-risk areas where practice was not considered safe and where they felt improvements could be made. As time went by, the team chose to focus on general areas (those noted in parentheses) rather than specific tasks, as these tasks contained several interconnected elements:

1. Interruptions were common during clerking or prescribing (better clerking of patients).
2. Junior doctors' perceptions of ward rounds and the pressure to multi-task as risky (improve incoming information).
3. Online prescribing support and trust guidelines that were not considered intuitive (reduce delays and improve standards of prescribing).
4. Poor knowledge of prescribing and a poor culture around medicines safety (increase clinical pharmacist cover).
5. Locum doctors unfamiliar with ward practice created additional risks, particularly out of hours, because prescribing support was poor (change safety culture/ engagement).

The reliability measures agreed by the team for their safety set were:

1. Percentage of patients admitted to the AMU ward who are clerked within four hours of admission.
2. Proportion of patients with a drug chart at the nurses' drug round on the ward.
3. Proportion of patients with a complete and satisfactory drug chart on the ward.
4. Percentage of patients for whom the pharmacist has completed a medicines reconciliation check on the ward.

The options appraisal process

The project team (a clinical lead, project pharmacist and project manager) designed and implemented various interventions intended to make the process of medicines management easier, safer and clearer for all staff involved and to reduce risk of harm for patients.

However, the tight deadline for the options appraisal was problematic in deciding which interventions to take forward.

In common with other project teams involved in the programme, the Hollyberry team found that some issues identified in the diagnostic phase – in this case, the high number of locum doctors and high turnover of nursing staff – were outside the project's scope of control. The Hollyberry team put a case to the hospital's patient safety improvement group to reduce the number of 'first-time' locums, and agreed to keep a watching brief on this.

The project team realised that it was not just a question of having more pharmacists around to correct errors made by the medical staff; they wanted to change the organisational culture around medications safety, raising its profile and reducing errors rather than just correcting them.

Some efforts by the project team to make improvements were not formally identified as interventions. For example, the IT team was asked to provide a direct link to the BNF and trust guidelines on the intranet homepage to address the IT problems uncovered by the diagnostics. This was identified more widely within the hospital, and initiated as a trust-wide initiative. No measurement of its use was collected, so its impact is unknown.

The interventions and outcomes

Hollyberry was an example of a site that used many small interventions, which were often tested and adapted over time. They included the following.

Posters for patients

The project team produced a poster, displayed on the ward, which asked patients to bring their medication with them when they came to hospital. The spread of its use across the hospital and other trust sites was considered an indicator of its success. A second poster, to be displayed in GP surgeries and pharmacies, was also being designed. The poster was considered part of the wider maturation of the safety culture, prioritising accurate prescribing for both staff and patients. However, any change in the number of patients bringing in their medications was not recorded as part of the safety set.

Green bags for medicines brought into hospital

A system of 'green bags' was reinvigorated to encourage patients to bring their medications and to have a recognised system for storing them safely while they were in the hospital. This involved liaising with the ambulance service, ward staff and ED staff. In practice, use of the green bags was highly variable.

Changes to the clerking process

The project team identified that delays in clerking and lack of clarity about what stage patients were at in the clerking process meant delays in getting correct medications to patients. They introduced a 'traffic light' assessment document showing where the patient was in the clerking process. They also took steps to ensure that patients were clerked-in on the morning ward round, rather than after it. The time taken to clerk-in a patient was being measured on the ward and was adopted into the safety set. The team contributed to a business case for additional pharmacy staff to reduce risks associated with busy times.

A clerking proforma was introduced by the AMU to help make sure that the correct information about new patients' medicines was gathered. This drew attention to specific issues – for example, whether patients had time-critical medications for conditions such as Parkinson's or epilepsy. Again, use of the form was variable in practice. Other changes to the clerking process included sticking small prompt cards on the computers on wheels to help with the coding of bed data, but these cards were sometimes removed and replaced with others by staff from other departments.

Pharmacy diary

A black A4 diary, placed in a see-through holder at the door to the pharmacy/office, aimed to improve communication between the ward staff and ward pharmacist. Ward staff used it to record any urgent medication requests or queries, which were prioritised by the pharmacists. The diary was well used by ward staff and pharmacy staff, who used it to prioritise their workload.

Increased pharmacy input

The project team encouraged the pharmacists to write a business/ workforce case to increase pharmacy cover on the wards to 12 hours per day, 7 days a week. They made changes to the bed management system to enable the pharmacists to see which patients had not had medicines reconciliation on admission, but this was not

widely used in practice. Late in the project, the business case was approved and pharmacy is due to be increased, and integrated into the multidisciplinary team.

Observations suggested that pharmacists on the ward did not all seem particularly engaged with the Safer Clinical Systems project; possibly this was because the hazards identified in the clinical pathway did not directly relate to the pharmacists and they did not feel they saw a reduction in errors by doctors.

Ward huddles

The ward huddle was a short multidisciplinary meeting focused on safety, conducted before the ward round at 09.00. The huddle was timed so that consultants, junior doctors, senior nursing staff and a pharmacist could be included. Although this superficially appears to be a small success, it should not be underestimated. It represents a major shift in working patterns and contributed to an improvement in the profile of patient safety. Its 'everyday' nature meant the junior staff felt more confident to ask questions and the huddle grew in importance as the project progressed.

The project manager encouraged clinical staff to read and engage with the day's safety message written on a laminated card, aiming to integrate the learning more effectively in ward culture. The success of the huddle was mixed, often dependent on whether the consultant leading it was enthusiastic or not. Yet this intervention helped the ward to start to make a shift from a process-driven outlook with a focus on speed, to a quality-driven outlook with a focus on safety. Overall, ethnographic observations suggested much-improved awareness and openness to patient safety issues, and a willingness to discuss in the huddles.

Inductions

The project team planned to get involved in the induction process, first for the out-of-hours locum consultants, and second as part of a multidisciplinary induction for the junior doctors to help orientate them on the ward. The first proved difficult for the site team to influence. The second slowly fizzled out because of lack of engagement and the wider workload of the project manager. Instead, the project manager began to work with a document created by a consultant, which was a long and detailed introduction to the AMU. This was a 'work in progress' by the end of the project, with the document being abbreviated to highlight important information.

Hassle boxes and engagement with safety messages

Having used hassle boxes to assess staff concerns about medications, the team maintained these boxes as a means of feedback and as an intervention to ensure that staff remained engaged and felt that they were being listened to. This intervention was not measured within the safety set, but can be considered an example of an attempt to mature the safety culture and maintain an awareness of the importance of the project's focus. The team identified a number of opportunities like NHS Change Day to engage staff, discuss safety, and promote their messages and the project.

The dabber audit

Initially designed as a method of data collection, this intervention involved using ink stampers ('bingo dabbers') in different colours to assess the presence and accuracy of information on medications charts. The project team had thought carefully about making the data collection process simple. The aim was to ensure that the data collection process for all measures placed a low burden on staff.

Capacity issues meant that both nurses and doctors sometimes ended up filling in the audit retrospectively from notes, decreasing the relevance and accuracy of the data. Also, the nurses were not consistently engaged with this data collection and use, and they did not feel they could access relevant feedback.

Throughout the project, the Safer Clinical Systems team questioned whether the dabber audit could be classed as an intervention, as the process of data collection started to change practice and behaviour. Again, it seems to have been important in raising the profile of patient safety.

Conclusion

To conclude, Hollyberry's safety claim made on the basis of their safety case was that medication management at transfer of care is hazardous. Staffing levels, effective team functioning, and systems and processes to mitigate hazards were found to vary. While risk management was largely acceptable within hours, it remained problematic and unacceptable out of hours.

Hollyberry's experiences of applying the Safer Clinical Systems approach

The project team, whose members appeared to work closely together, was composed of strong and dedicated individuals who inspired involvement, but who purposefully began to move away from a reliance on individuals towards embedding the project within the ward. The support team described this as a 'whole systems approach'.

The visibility of the project was considered a unique strength. The team's integration into the physical space of the AMU helped to integrate the project as a whole: the project manager's office was on the same corridor as that of the clinical lead, and was in close proximity to the ward. Staff were reminded of the project at all times and were encouraged to 'pop in' to the project office and report errors and raise concerns with the project team.

Staffing on the AMU did improve over the course of the project, but it is difficult to attribute the improvements solely to the project. Doubling the number of regular consultants reduced the number of 'first-time' locums and helped to ensure continuity of staff and care routines. Steps were taken to support nurses and doctors in working together when the former were newly qualified.

The project team felt that engagement with medical staff on the ward had been quite good, and doctors and nurses both contributed to the initial analytical work, although the team struggled to keep nurses engaged due to a shortage of staff and high turnover. The team felt that more time working with the nurses to help them understand the impact of medicines safety on their role might have increased their engagement with the project.

Other stakeholders, such as the ED and primary care, were not involved in the hazard-definition process but were invited to attend. The team took steps to secure senior management engagement at a strategic level, though it is not clear if this filtered down to frontline staff. It was not possible to secure commitment to the project outside the ward.

At the start of the project, related pressures on the ED caused problems for the AMU. The trust as a whole was seeking foundation status, and needed to improve patient flow and meet waiting-time targets, placing operational pressures on the AMU. Patient safety and medicines reconciliation were not always seen as organisational priorities.

The team collected a large amount of data, including medication errors resulting in harm, medication errors per 1,000 bed days, and time since moderate or severe harm. Other data collected included the percentage of doctors based or previously based on the ward, taken from rota data; and time to clerking, collected automatically via the admissions system. Measures of patient experience were collected on a questionnaire that was administered by senior school students, and the team were proud of how well this worked.

Overall, the safety set shows either improvement or at least no deterioration in every measure. Meaningful improvements were made in timely clerking-in of patients on the AMU, during regular hours, out of hours and at the weekends. Further work is needed to achieve improvements in drug chart use, with the data collected for the study proving a vital resource in this pursuit. Further analysis is required to understand potential improvements made in medicines reconciliation.

Finally, it is difficult to measure a return on investment in a project as diverse as medicines management with multiple different interventions. The project team felt it was hard to demonstrate the impact of improvements to medications safety in real terms. Many of the project impacts were more evident through qualitative rather than quantitative measures – for example, reflected in changes in the kinds of conversations staff were having about patient safety, and improved awareness and sensitivity to medications safety.

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