Safer Clinical Systems

A new, proactive approach to building safe healthcare systems

A reference guide for clinicians and managers

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It’s time to do something different in patient safety

In healthcare, our approach to patient safety is almost entirely reactive. In other words, the first thing that has to happen to trigger the system is that we harm a patient. This retrospective ‘find and fix’ approach is an admission that we are not safe – it is a search for a breakdown in safety, not an assurance of safety. The time between harms may be long, but we do not know whether the next harm will happen tomorrow or next month – in other words, we do not know whether we are ‘safe’ today by luck or by design. Reporting and learning when things have gone wrong is important, but it is not enough.

The one key thing that other safety-critical industries do that healthcare does not is that they search proactively to identify hazards and assess their risk. As a result, they pre-emptively control or manage the risk in order to obtain safe outcomes. The Safer Clinical Systems approach embodies this philosophy. There are some crucial lessons here that can inform the paradigm shift needed for the NHS to become proactive in building safe systems for our patients.

In the Introduction to Part 1 of this guide we set out the conceptual basis of our approach, and explain why we challenge the current reactive approach so robustly. We then offer a structured step-by-step method of creating safer systems for our patients, outlining the purpose of each step, what you might expect to gain from each of them, and identifying the tools and techniques you could use to support each step.

In Part 2 we provide a more detailed account of these particular tools and techniques.

Part 3 gives a more detailed discussion of the conceptual underpinning to the Safer Clinical Systems approach.
Part 1: The Safer Clinical Systems approach

Introduction

We are still harming too many patients

Patients are harmed every day in our healthcare systems. Wrong medicines are given to patients, the right medicine is given in the wrong dose, treatments are omitted or delayed, patients in hospital beds develop pressure ulcers or fall and break their femurs, otherwise diligent and capable clinicians unaccountably leave objects inside patients after operations. Some patients die in the care of doctors and nurses.

How many patients are harmed or die? Estimates vary, but it is generally agreed that about 10% of hospital admissions result in an ‘adverse event’ where a patient is harmed.1 About half of these incidents are thought to be avoidable. In community settings, we often do not really know how often patients are harmed, we would suggest that patient safety is at least as big a problem there as it is in acute settings.

The inquiry into Mid Staffordshire NHS FT and subsequent investigations into several other hospitals and trusts resulted in lengthy and costly interventions. These inquiries were in part triggered by a higher than expected level of patient mortality. Research published in 2015 indicated that as many as 3.6% of hospital deaths are avoidable.2 In February 2015, the Secretary of State for health referred to the level of avoidable deaths – suggested to be about 1,000 per month in the UK – as a ‘scandal’. Harm persists.

We’ve known about this issue for at least fifteen years

We have known that medical care is problematic for a decade and a half. Since the publication of key documents in the United States in 1999 and the United Kingdom in 2000, we have known that we could and must do better.3 In response, the NHS set up the National Patient Safety Agency (NPSA) in the UK in 2001 to make patients safer. Though it was not referred to formally as a safety management system, the work of the NPSA amounted to an introduction of formal safety management in the NHS. This system was based upon reporting and learning; its underlying mechanism was known as the National Reporting and Learning System.4 It was therefore fundamentally a reactive system.

But the aspiration for safety has not been achieved. There was an expectation that in a culture that eschewed individual blame and accepted that, by and large, clinicians intended to do their best for patients, errors and adverse events should be reported. After reporting through local risk management systems, harmful events as well as ‘near-misses’ (which might indicate future risks) were to be investigated thoroughly. In response to this investigation, we would change the way we worked and become safer.

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4 This work was transferred to the NHS Commissioning Board – NHS England – in June 2012.
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Has this been effective? In some ways, certainly. There is little doubt that a great deal of knowledge has been gained over the years about what happens to patients, where it happens and who was responsible, and we know that we have a duty to investigate when things go wrong. Nevertheless, harm persists. Why?

The quality of our learning systems is poor

The safety management system that we have adopted falls down in many respects. In the first place, it is widely recognised that we still do not have a culture that understands human behaviour and very often seeks to identify and blame individuals who, while trying to do their best in difficult and complex systems, make understandable errors. Of course, this blame culture, as it has come to be known, tends to suppress the reporting of adverse events or mistakes and reduces our ability to learn how to change. The reporting systems themselves are usually quite cumbersome and time-consuming for busy clinicians. Commissioners and regulators require serious incidents such as pressure ulcers or harmful falls to be reported. Near-misses, which should open a window onto future risks to patients, are reported less often and are rarely analysed in depth. Finally, the quality of the investigations carried out in response to patient harms can be very variable. There is an accepted protocol to carry out investigations into adverse events, but it is rarely applied thoroughly. Incident investigations themselves have become largely administrative rather than learning processes and they very rarely address those future risks revealed by near-misses that might allow us to prevent future harm. Overall, the maturity level of healthcare systems in managing safety is usually assessed as ‘bureaucratic’. There is little focus on learning from situations where the system works and no harm occurs or where an intervention prevents harm. The NHS needs to improve its ability to be a learning organisation. Don Berwick emphasised this in his 2013 report, saying ‘the most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end.’

We need a new approach

While healthcare continues to harm patients, other industries have become safer and safer. The aviation, process and power generation industries continue to have safety problems, but fewer than in the past. Some industries have been called ‘high reliability organisations’ (HROs) because of their excellent record in quality and safety despite the pressures under which they operate: these include both commercial and military enterprises. The literature abounds with descriptions and commentary on how this high reliability has occurred and what might be learned from HROs. But we have not become reliable in healthcare. Even when we know exactly what to do for a patient, we often don’t do it consistently and reliably every time; simple daily processes like accurate prescription of medicines, availability of equipment or completion of safety checks are known to fail at worrying levels.

How have other industries become safer while healthcare continues to harm the very people it cares for? No one can pretend to know the complete answer. Most recently, there have been calls to learn from other industries by establishing an independent investigation organisation, as did the aviation industry. The Healthcare Safety Investigation Branch now operates under the auspices of the new

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3. MaPSaF [http://www.nhs.nhs.uk/resources/?entryid45=59796] evaluation carried out on SCS programme
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body, NHS Improvement. Will that help us to learn from harmful events? Perhaps – if it is organised appropriately and managed in a blame-free manner and if it considers all factors including attitudes, behaviours and culture as well as structure process and outcome. But is that the best thing we can learn from other safety-critical industries?

We must identify risk proactively

To reiterate what we stated at the outset: other industries are proactive in the management of risk and safety, but in healthcare, our approach to patient safety is essentially reactive. In building patient safety, the first thing that has to happen to trigger the system is that we harm a patient. Our approach is to search for a breakdown in safety rather than to ensure safety at the outset. We do not know whether we are ‘safe’ today by luck or by design.

It was this knowledge that initiated the Safer Clinical Systems approach. In Safer Clinical Systems, we have tried to develop a new, proactive approach to patient safety. This is not to say that reporting and learning when things have gone wrong is not important, but it is to say that this is not enough. We have tried to base the development of safer clinical systems on learning about safety from other industries – industries which have often included an appreciation of the realities of human behaviour and human error, and which, overall, are proactive.

In the UK, before a chemical plant is opened or a new aircraft brought into service, it must be demonstrated to the appropriate authorities that it will be safe (within certain appropriate limits). The risks are expected to be known in advance, as well as their consequences: how often will this piece of equipment fail to perform? How likely is operator error to create risks? What has been done to eliminate, reduce or mitigate risks? Can the risk and likely safety of the enterprise be quantified? Has the way people behave – the ‘human factors’ – been taken into account? What is the acceptable level of risk?

Healthcare is far more complex than other industries. It is a sociotechnical system – a system that uses technology, but where technology is only a part of a complex system operated by human beings on human beings. Can the proactive approaches from other industries ever be applied in healthcare? We believe that they can and they must. It is perplexing that many clinicians and managers cannot look at the journey of a patient through our healthcare systems and say with any confidence where the patient will be most at risk and what has been done to eliminate, reduce or mitigate that risk.

Our current approach has signally failed to create safety. We need to be proactive. We need to be aware of how humans create and manage risk in complex systems. We need to understand human error and how to avoid it. We need to develop Safer Clinical Systems for our patients.

The safety case

Throughout the Safer Clinical Systems programme, we have used a tool adapted from other safety-critical industries to bring together our knowledge of safety in the areas in which we have worked. This tool is known as a safety case. As used in this context, a safety case is a document that provides a shared understanding of where risks exist, what control measures are in place and what uncontrolled risks to safety remain. It serves to highlight areas that need to be worked on and it can provide assurance to stakeholders. (‘Assurance’ is a term used in governance to describe knowledge or avoidance of doubt). Page 57 describes how you might construct a safety case and how you can use it.

A realistic assessment of safety would, of course, have to include risk assessment as well as an honest view of human error and human failure. Before going further, therefore, we must highlight two key areas where an early understanding will help in developing safe clinical systems: human factors and risk.
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The importance of human factors

Human factors is a hybrid discipline encompassing elements of psychology, social psychology, risk and ergonomics. This discipline has been central in building safety in other safety-critical industries and deserves some early attention in this document, since many of the techniques and tools we use in Safer Clinical Systems have their origin here.

Though human factors is often understood as the set of non-technical skills that underpin safe human performance – such as communication, situational awareness, decision-making and leadership – there is another aspect of human factors that focuses on the identification of risk within a system and the development of interventions and strategies to eliminate, reduce or mitigate risk. These two aspects of human factors are sometimes referred to as ‘person-based human factors’ and ‘system-based human factors’. These two approaches find common ground in the importance that they assign to human behaviour and how it is influenced by context. They are usually called ‘performance influencing factors’ and include distractions, communication factors, information provision and support for key tasks. Both elements of human factors have been important in developing Safer Clinical Systems and are part of the guidance that we provide in this document.

The importance of human factors is difficult to overstate. When incidents and adverse events are analysed in detail, it is often found that harmful events are influenced mostly by human factors such as those mentioned above, as well as by the design of the system and its capacity for human error. Work at one of the trusts taking part in the Safer Clinical Systems programme aggregated the outputs of incident analysis to identify which factors were predominant in a large number of critical failures in patient care. The two top categories of what were called ‘contextual risk factors’ or ‘performance influencing factors’ were communication and prior knowledge of where patients would be at risk. These categories reflect precisely the two approaches to human factors, underlining the importance of both non-technical skills and a systematic understanding of pathway risk.

Part 2 of this document provides further guidance and discussion on the techniques and possibilities of human factors.

Risk in clinical systems

Throughout this guide, we use the term ‘risk’. Formally, we define risk as: the combination (usually multiplicative) of the likelihood of occurrence of a hazard and the severity of the consequences of a hazard (frequency x severity). In practice, this really means the chance of something going wrong for patients. In many industries, the estimation of risk may be precise and quantitative – how likely is this valve to fail or this pilot to press the wrong button? – but in healthcare, our estimated risk is usually derived through a highly subjective process using crude metrics such as ‘highly likely’ or ‘moderate’. Despite this, we believe that these methods and estimates have real value. This is especially true when the knowledge and estimation of risk are carried out by teams of involved professionals through consensus.

A chief characteristic of the Safer Clinical Systems approach is a focus on managing clinical risk. This is achieved through a proactive focus on risk and its identification in a patient pathway, in contrast to the traditional focus on counting things that have already gone wrong for patients. This is because, as in other safety-critical industries, there is a recognition that safety depends upon the management of risk.

11 Health and Safety Executive http://www.hse.gov.uk/humanfactors/topics/pifs.pdf
The focus on patient outcomes that runs through healthcare systems is not necessarily a reflection of good safety management practice, but of the need of managers, and, indeed, political systems, to identify and highlight simple, easily understandable measures. It is a great deal easier to talk about numbers of patient deaths or numbers of pressure ulcers than about the factors that influence them – factors relating to risk, or culture or care process reliability. Numbers of patient deaths, for instance, easily identified through comparing mortality ratios from hospital to hospital, are not a reflection of quality of care or patient safety within the hospitals for a number of well-known reasons.13

At the heart of Safer Clinical Systems is a new approach to safety in the healthcare sector – an approach based on learning from excellence in other industries and also on the special needs of healthcare. We believe that the approach, the tools and techniques, the emphasis on culture and context and the prominence of human factors in this work constitutes a new paradigm for patient safety.

Who should use Safer Clinical Systems?
Safer Clinical Systems has been developed with teams and is used by them. It is a truism to say that no one person knows the whole story, but nowhere is this more true than in healthcare, where different professions or location based teams have widely differing roles and can frequently find it hard to break out of their own ‘silo’.

To use Safer Clinical Systems effectively, you will need a cross-disciplinary group including as many professions as possible. There will usually be doctors, nurses, AHPs where appropriate, governance and quality professionals where you have them and patients. As you carry out some of the techniques we describe here, you will find that all voices count and that if your team listens as well as speaks, a new consensus of understanding will be built. You will see risk and safety from different perspectives and, because of the focus on patient pathways, you will see how all professions influence the patient experience.

How to use this guide
In the next section, we present an overview of the Safer Clinical Systems five-step methodology. This helicopter view outlines the key steps and should help you to see how you might apply it to your own patient pathway or discipline.

Each of the steps is then described in more detail so that you can see which tools and techniques you might use and what benefit carrying out these processes might have for you. Details of the tools, with worked examples where possible, are presented in Part 2 of the reference guide.

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How to build Safer Clinical Systems

Safer Clinical Systems: methodology in a nutshell
Safer Clinical Systems is a way to reduce risk and harm to patients, improve reliability and develop a better safety culture. It has five key steps, which we describe below. It uses tools and techniques developed from the Safer Clinical Systems programme or modified for healthcare from other safety-critical industries.

The essence of Safer Clinical Systems is to approach safety proactively, but there are also emphases on creating a culture of safety, on using human factors properly and on assessing and assuring safety to internal teams and stakeholders.

Safer Clinical Systems calls for a new paradigm in understanding, designing and managing our healthcare systems to work for patient safety. To get started, Figure 1 provides a graphical representation of the five steps used to create Safer Clinical Systems.
Part 1 – The Safer Clinical Systems approach

**Step 1: Pathway definition and context** – scope the pathway to be developed and be clear about its boundaries. Use qualitative and quantitative assessment of organisational and safety culture.

**Step 2: System diagnosis** – high-level mapping of the pathway and its linkages to wider systems. Identification of hazards; detailed human factors analysis of critical steps, risk factors and performance influencing factors; setting reliability measures and targets for outcomes and key care processes.

**Step 3: Option appraisal** – develop a shared understanding of the risks to patients in the pathway based on the outputs of Step 2. Consider options to reduce risk and build safety and test these options against outcome and practicality.

**Step 4: Planning** - define patient safety improvement objectives in risk reduction and reliability improvement; design interventions to be enacted through redesigning ‘hard’ systems (the things we do to care for patients) and ‘soft’ systems (the way we interact with patients and each other, and the way we use the hard systems).

**Step 5: System improvement** - carry out and evaluate system improvement cycles; work with teams to carry out initial system redesign followed by continuous improvement cycles; reassess hazards and risk using the same techniques employed in the diagnostic (Step 2). Use human factors interventions to support change.
Part 1 – The Safer Clinical Systems approach

Safer Clinical Systems – the five steps

Here we outline each step in more detail and what you might expect to gain from each of them, and provide a general guide to the tools and techniques you might apply. The five steps are set out sequentially, but you should expect there to be a degree of iteration between the steps as learning accumulates.

Getting started: governance

A robust programme structure can provide a useful backdrop to undertaking this work. A multidisciplinary team can provide vital support as ‘critical friends’ and develop a measurement plan to identify improvements in safety. An Executive Lead for the programme is essential to provide access to the Board, partly to ensure awareness, but most importantly to facilitate the extension and sustainability of the methodology.

Step 1 – Your pathway and its context

*Why this is important*

The purpose of this preparatory step is to allow your team to become established, to begin to define the pathway, to build relationships with the staff working in the pathway and – most importantly – to develop a deep understanding of your culture and context.

Because patient care takes place within the organisational culture and context and is influenced by them, we begin with an organisational assessment. You will need to develop an understanding of both the trust and of the culture within the pathway itself. To do this we recommend you use two key diagnostic tools: the *Manchester Patient Safety Framework* (MaPSaF) and the *Safety Culture Index* (SCI).

*What do we mean by ‘a pathway’?*

The *pathway* is defined by a patient journey, not by organisational structures. As Safer Clinical Systems is based on taking a systems approach, it is necessary for the pathway being studied to extend outside any single ‘microsystem’ to take account of what happens before and after that might impact on patient safety. This should enable you to ‘zoom out’ to look at wider organisational and contextual issues that affect what happens in the microsystem rather than just looking within, to the limited subculture in a single department or team. The belief is that this will then lead to changes in those influencing factors that may inhibit change or may help sustainability of a specific change and enable the learning to spread more widely in the whole system.

*Tools & techniques you can use*

*Existing evidence of safety*

- Gather data from the Incident Reporting and Analysis systems where it is available.
- Refer to other sources such as safety and quality Dashboards.
- Highlight past harms and some of the factors that have been associated with them.
Part 1 – The Safer Clinical Systems approach

Manchester Patient Safety Framework (MaPSaF)

Use the MaPSaF tool to:
- Facilitate reflection on patient safety culture.
- Stimulate discussion about the strengths and weaknesses of the patient safety culture.
- Reveal any differences in perception between staff groups and between staff and patient/carer.
- Help understand how a more mature safety culture might look.
- Help evaluate any specific interventions needed to change the patient safety culture.

The Safety Culture Index (SCI)

Use the Safety Culture Index to:
- Provide a quantitative assessment of key components of organisational culture using UK-based norms from other health organisations.
- Evaluate twelve key dimensions of safety.
- Determine differences between professional groups in their understanding of the patient safety culture they experience.
- Signpost cultural interventions.

Your outputs from Step 1

At the end of your Step 1, you should have a collective agreement about the pathway, the culture (especially the safety culture) within the organisation and the pathway team itself (that is, the staff responsible for delivering patient care on this patient journey), and detailed knowledge of past harms that have occurred.

If you have used MaPSaF, you will have started a shared discussion about safety and your organisation’s level of maturity, and you will know something about the areas you want to change – perhaps in your use of incident reporting, perhaps in the depth of your root cause analyses (RCAs). Finally, if you have used SCI, you will know how you compare with others across key dimensions of safety and where your improvements should be sought.

It is not essential to use both of these tools, but at least one – probably SCI – should be part of this first step. It is possible to use MaPSaF after the SCI to explore some of the areas of concern that are revealed.
Step 2 – System diagnosis

Why this is important

The purpose of this next step is for the team to undertake a detailed diagnostic assessment of the pathway you have chosen and to understand in real depth the factors affecting the current safety status, both positive and negative. Out of this step will come the identification of hazards, risk, reliability and harm in each pathway, as well as specific process and contextual measures. In short, you will know where in the pathway your patients are at risk of harm, and you will begin to see why, and what can be done to prevent it.

Tools & techniques you can use

Process mapping

Use process mapping to:
- Create a high-level description of the stages and key elements in your patient pathway
- Develop a collective understanding of the pathway and the people, departments and processes involved
- Provide a basis for detailed hazard and risk assessment to improve safety.

Failure mode and effect analysis (FMEA)

Use FMEA to:
- Assess the things that can go wrong for patients at each stage of the process map
- Identify the most significant risks in the pathway – risk ranking
- Build a collective understanding of the high-level risk profile in the pathway.

Human factors analysis

Use the human factors analysis to:
- Unpack high-risk elements of the process map to understand the details of patient care in the pathway
- Create a Hierarchical Task Analysis (HTA) of key tasks influencing safety
- Zoom in to understand the way things go wrong
- Identify and share the human factors that introduce risk (including ‘performance influencing factors’)
- Understand how human error in the pathway influences risk.

Your outputs from Step 2

Step 2 provides the foundation for improvement. Without a full system diagnosis, clinicians and managers will not be aware of the ranking of risks and therefore where their action should best be targeted. In addition, experience of using this methodology has shown that in most cases (1) team members acquire a much better understanding and appreciation of the role of others and (2) risks are revealed during this step that were not previously recognised. Many of these newly recognised risks are significant in patient care.

At the end of this step you will have a detailed understanding of the processes and tasks taking place in your system or patient pathway. You will know something of the reliability of
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key elements and you will know where failures are likely and where patients are at risk. You will also know something of how humans affect the safety of the system, both positively and negatively.

Taken together with the outputs of Step 1, in which you will have assessed the context and the culture of your patient pathway, you should now be ready to look at options for change and to recognise which ones will make the greatest difference to the safety of patients.

**Step 3 – Option appraisal**

**Why this is important**

By now you will understand the context and culture, know where your patients are at risk of harm, which risks are most problematic, how humans contribute to risk and safety and what influences their performance – and you will be ready to effect change.

The purpose of this stage is to assess options for change, select preferred options and develop the action plan (Step 4) that will be implemented in system improvement cycles (Step 5). During Step 5, your changes will be tested and evaluated and may result in a revisiting of alternative options.

**Tools & techniques you can use**

There are many tools available for option appraisal. To be successful, option appraisal must make sure that all risks are clearly identified and ranked, without exception. This is because, in practice, there can be a natural tendency to exclude from consideration options that seem too difficult to enact due to budget, human resource or culture. If key options are ruled out, then the team has a responsibility to use the organisation’s governance processes to record and escalate the uncontrolled risks.

This means that option appraisal should use a two-stage process. Stage one is to rank the risks; stage two to address the feasibility, costs and return on investment. Without stage one, the truly difficult issues will not be addressed or escalated.

Use option appraisal to:

- Identify possible interventions on the basis of the risks identified in Steps 1 and 2.
- Address the risks in the pathway by rank
- Address context as well as the tasks or processes themselves
- Appraise feasibility and practicality.

We emphasise the importance of using a robust ranking of risk in carrying out option appraisal. This is important because it helps to ensure that, at the very least, the seemingly difficult problems – those that might go beyond the responsibility of the improvement team to matters of organisational culture and resource, economics or even political context – are recorded.

**Your outputs from Step 3**

Options for change have to be developed by consensus. There are no foolproof methods for doing this, but the involvement of all professions and stakeholders is critical. It is quite possible that the options you develop and appraise may sometimes be ruled out by the resource limitations in your organisation, or by other practical considerations; you may have
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to carry out an iterative process in deciding what is practical. Your key output will include:

1. A clear description of each option – what it is, how it was derived and assumed impact/outcome
2. A statement of the criteria to be used in assessing one against another, for example
   - Degree of risk reduction expected
   - Ease of implementation, i.e. technically simple
   - Time required to implement, i.e. quick operational changes within pathway versus longer term strategic changes in the wider system
   - Fit with trust strategy, vision, values
   - Acceptability to other stakeholders
   - Measurable impact on reducing risk
   - Measurable impact on improving reliability
   - Cost
3. Weighting each option against the criteria

Note: ‘option appraisal’ implies that all options are recognised and that there is an understanding of what interventions may be used to address risk. For that reason, there is considerable overlap between option appraisal and intervention planning. These two sections should be read together so that the techniques in Step 4 can inform the options in Step 3. In addition, Step 5, System Improvement, may also draw on the techniques in the next section, as even more knowledge is built around the pathway and its risks.

Step 4 – Planning

Why this is important

Detailed planning is important for any improvement work. Having identified your key risks to manage and your options for change, you should be ready to plan your Safer Clinical Systems programme. For this, you will need to understand some of the interventions you could make.

Tools & techniques you can use

Task analysis
Revisit your outputs from Step 2.

   Use your detailed process map or task analysis (HTA) to:
   - Identify where tasks need support or redesign for safety
   - Challenge the process design – do you need additional safety steps? Can you remove any?
   - Identify and manage tasks where human performance is a safety issue.

Designing for safety
Use the tools in designing for safety to:
   - Identify the most powerful way to manage a risk (the hierarchy of control)
   - Prevent mistakes (managing human error)
   - Use checklists correctly (checklists)
Part 1 – The Safer Clinical Systems approach

- Design change through consensus (participatory design)
- Improve staff involvement (engaging conversations)
- Identify drivers and resistors to change (force field analysis).

Your outputs from Step 4

This step and the previous one will have been your opportunities to reflect on the findings of the system diagnosis phase and identify practical improvements. In healthcare, the urgency of the need to build safety often leads to rapid responses. This is understandable and sometimes we may have little choice. But the tallest buildings have the deepest foundations; good planning, based on detailed knowledge, will do a better job!

Step 4 will have provided you with a plan to improve patient safety in your pathway based on the proactive identification of risk. You will have pinpointed the problem areas and developed plans to eliminate, contain or minimise risks of harming patients – and you will have involved others in the process.

Step 5 – System improvement

Why this is important

At this point, you will have identified and listed all the hazards in your pathway and their relative risk, identified all current mechanisms for risk control and highlighted possible interventions you may need to make by considering the nature of the underlying causes of risks. During Steps 3 and 4, you will have systematically evaluated potential interventions and have developed a planned series of interventions that you are now going to carry out. The purpose of Step 5 is to carry these out and continuously evaluate your system improvement cycles.

The key element in system improvement is measurement: you must be able to demonstrate progress to maintain the support and commitment of staff at all levels.

Tools & techniques you can use

Measurement plan

Use a measurement plan to:
- Set clear, quantifiable goals for safety improvements
- Ensure that your plan addresses patient outcomes as well as reliability of essential care processes
- Ensure that you have considered possible negative effects of your work
- Share information and build co-operation.

The safety case

Use a safety case to:
- Bring together all elements of your work: culture, diagnostics, risks and risk control measures, key improvement actions
Part 1 – The Safer Clinical Systems approach

- Serve as a basis for continual improvement in safety by including your measurement plan
- Provide assurance to internal and external stakeholders.

**Your outputs from Step 5**

Your key outputs from Step 5 will be the changes you bring to the risk and safety of your pathway. Your impact on patient safety (through both outcomes and care process reliability) should be demonstrable and shared as widely as possible.

Further measures of culture (through the Safety Culture Index, for example) may also demonstrate changes in the attitudes, beliefs and behaviour of staff. In the next section, we outline some of the changes in these areas we have identified through Safer Clinical Systems.
Part 1 – The Safer Clinical Systems approach

Safer Clinical Systems – what you can expect to gain

Risk reduction
Using a Safer Clinical Systems approach provides teams with a proactive assessment of the risks embedded in the pathway and their ranking. The team’s work is therefore explicitly targeted at eliminating, minimising or mitigating risk.

In our Safer Clinical Systems work across eight NHS trusts with a wide range of pathways and patient groups, pathway risks were addressed using the methodology in this guide. At the beginning of the programme, each site conducted an analysis of hazards, risks and existing risk control measures as part of the diagnostic phase. Sites were asked to summarise and categorise as high, medium or low the chief risks identified during the diagnostic exercise. We also asked the sites to re-evaluate these risks in the same way after introducing their interventions during the course of the Safer Clinical Systems programme. These assessments and reassessments were carried out by those most closely associated with the programme: clinicians directly involved in the pathway, supported by project managers. Despite the subjective nature of assessing risk, the judgment of key staff is a valuable indicator of initial and current system risk, and indeed may be the only one possible in a complex socio-technical system.

Overall, the eight sites that took part in this exercise reported a total of 80 systematically identified risks where existing control measures were weak or absent and where interventions were designed and introduced to reduce risks to patients. Of those 80, the sites reported that 50 had been reduced (Table 1 and Figure 2).

Table 1 Numbers of risks reported and those with risk reduction

<table>
<thead>
<tr>
<th>Site</th>
<th>No of risks reported</th>
<th>Number with reported reduction</th>
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<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
<td>12</td>
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<tr>
<td>3</td>
<td>3</td>
<td>2</td>
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<tr>
<td>4</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>16</td>
<td>7</td>
</tr>
<tr>
<td>6</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>7</td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>8</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>50</td>
</tr>
</tbody>
</table>

Looking only at risks categorised as ‘high’ during the diagnostic phase, and excluding any ambiguous current risk evaluations (where a risk was categorised as high/medium, for example), the sites identified a total of 57 risks where control measures were inadequate. Of these, sites reported a reduction to either ‘low’ or ‘medium’ in 40 cases (Table 2 and Figure 2). Of these, 12 key risks were currently evaluated as ‘low’.

Table 2 Numbers of ‘high’ risks reported and number

<table>
<thead>
<tr>
<th>No of ‘high’ risks reported</th>
<th>Number with reported reduction</th>
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</thead>
</table>
Part 1 – The Safer Clinical Systems approach

<p>| | | |</p>
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<td>2</td>
<td>10</td>
<td>10</td>
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<td>3</td>
<td>2</td>
<td>2</td>
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<tr>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>9</td>
<td>6</td>
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<tr>
<td>6</td>
<td>9</td>
<td>8</td>
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<tr>
<td>7</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>57</td>
<td>40</td>
</tr>
</tbody>
</table>

The risks described by sites as having been reduced were identified during the diagnostic phase of the programme, and included incorrect prescriptions for acute medicines, accuracy of information provided for critical handovers and key patient evaluations prior to surgery.

These data were indicative of a substantial perceived reduction in system risks. For all diagnosed risks, participants reported a reduction in 62% of cases; for risks diagnosed as ‘high’, participants reported a reduction in 70% of cases. Risks previously identified as ‘high’ and then judged as ‘low’ were reported in 21% of cases.

![Changes in risk profiles of Safer Clinical Systems pathways](image)

*Figure 2 Changes in numbers of risks identified at the start and conclusion of programme*
Safety Culture Index

The Safety Culture Index (SCI) is a culture assessment tool based upon a psychometrically rigorous framework. It is a comprehensive survey tool derived from a number of research studies. The first version of the measure was described by Spurgeon and Barwell (1996) and was further developed by Spurgeon et al (1999). The SCI scales have been shown to be reliable and to have content- and criterion-related validity across a variety of healthcare contexts.

The scale assesses norms in 12 key attributes of organisational culture. The tool was used across eight NHS trusts on two occasions – during Step 1, defining the pathway and assessing the organisational context, and again after progressing the Safer Clinical Systems programme.

The tool allows measurement at individual, team and organisational levels and also represents the four generic components of culture to be found in the literature – Task, People, Control and Change. These components, alongside the levels, form an SCI profile matrix that can be assessed and monitored as a key measure of healthy safety culture.

Using the SCI following the implementation of the Safer Clinical Systems programme, significant improvements in safety culture were identified in six out of the eight participating trusts. The following are examples of the positive changes and levels achieved:

<table>
<thead>
<tr>
<th>SCI scales</th>
<th>Percentage improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation in decisions</td>
<td>21%</td>
</tr>
<tr>
<td>Sharing information</td>
<td>20%</td>
</tr>
<tr>
<td>Vision and mission</td>
<td>20%</td>
</tr>
<tr>
<td>Blame-free climate</td>
<td>18%</td>
</tr>
<tr>
<td>Working in collaboration</td>
<td>17%</td>
</tr>
<tr>
<td>Checking and accountability</td>
<td>16%</td>
</tr>
<tr>
<td>Coping with work demands</td>
<td>11%</td>
</tr>
</tbody>
</table>

In the context of the Francis Report and its exhortations to the NHS to change its safety culture, this is a critical outcome.

Assurance – the safety case

Using a safety case as a system to profile risk and drive risk reduction – a central theme in Safer Clinical Systems – has a clear utility in improvement work. Improvement activities in complex organisations need to be set in a framework of a pathway and its embedded risks to our patients. A safety case provides that framework and sets out measures and interventions needed to achieve the goals in proactive risk reduction.

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A safety case also provides assurance. Both internal stakeholders (such as the board of the organisation) and external stakeholders (such as the regulators of a public organisation) have a legitimate interest in the level of risks to patients. In general, this is derived from outcome measures such as levels of patient mortality and adverse events, and also from the incident reporting that should take place in a safe organisation.

All these measures are set firmly in a reactive approach to risk – they are gathered after a patient has been harmed and often cast insufficient light on future risks.

A safety case, however, is a structured assessment of where risks exist to patients and the degree to which they are controlled – this is a level of assurance not usually available in healthcare settings, though it is common in other safety-critical industries. In practice, this type of assurance does not also provide reassurance in that risks are exposed and disclosed. However, responsible safety behaviour requires boards and other stakeholders to become ‘problem-seekers’ rather than ‘comfort-seekers’. For both managers and regulators, the safety case has clear potential to support a mature, managed and proactive approach to safety.

New perspectives on safety
In developing a deep understanding of patient safety and risk, teams carrying out the Safer Clinical Systems programme used several sources of information and a number of techniques. Using a series of semi-structured interviews and group discussion, we evaluated the changes in belief, attitudes and confidence in understanding patient safety, and also sought responses in answer to the question ‘What approaches to proactive safety were most useful?’.

Overall, the depth of knowledge and the confidence in the teams had improved – but of particular interest was the value placed on the techniques and sources used to inform safety knowledge. The usual sources used in evaluating safety included incident reports, serious incident analyses and regulators’ reports. In practice, none of these was judged as being as useful for informing a proactive approach to safety as the novel techniques provided on the programme. Process mapping, task analysis, failure mode and effect analysis provided the most information to guide improvement.

The use of systematic tools has been common practice in other industries and is beginning to gain ground in healthcare. The new perspective is the move from a reactive to a proactive safety management system.

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17 Dixon-Woods, M. Measuring what matters: how can we know we are delivering prudent healthcare? Presentation to 1000 Lives Campaign, 2014
In summary: A radical change to a new, proactive approach is essential

Harm persists, and we believe that despite all the progress that has been made in the technology of medicine over the past 20 years, a new approach is needed to build patient safety. It is certainly true that the science of medicine will continue to develop interventions that are life-saving and that will improve the quality and extent of people’s lives. That is not the issue: the issue is that these technologies are delivered within a complex system and that the system too often fails its patients.

We do have a safety management system: it began in 2000 with the report *An Organisation with a Memory*. Since then we have had the establishment of the National Reporting and Learning System, the many reports into safety and quality following the events at Mid Staffordshire, numerous reports and reviews of hospital safety, the inspiring *A Commitment to Learn, a Promise to Act* produced by Professor Don Berwick for the UK government, countless calls for openness, transparency and whistleblowing, and the creation of an external investigating body for when things go wrong for patients.

What do all of these things have in common? The answer is simple: they are reactive. They only swing into action after a patient has already been harmed. The result is that interventions are specific to the clinical microsystem in which the error occurred. They tend to ignore human factors and give no assurance that the underlying causes of harm and error (which will often transcend the microsystem) are being addressed. Risk management is too often a bureaucratic process designed more to assure the regulator than to manage either patient risk or enterprise risk and, as such, rarely contributes to system-wide improvements in safety.

There is a clear need for a proactive approach to patient safety. This may not be easy; unlike engineers who build a new power station or launch a new model of aircraft, clinicians and managers are operating in a living, breathing system where patients cannot simply be placed on hold while we transform our processes. This doesn’t make things easy, but nor does it make things impossible: we have shown how system risk can be reduced and patient safety culture materially changed by the interventions of Safer Clinical Systems. And change must come because of the complex and tightly-coupled nature of the healthcare system. Such systems are known to fail, regardless of the good intentions of the people who work within them. 18

Our existing safety management system, built on reaction to past harm, is not good enough. The bolting on of emergency planning mechanisms is necessary but insufficient. Patient pathways and high-risk areas wherever they exist must be proactively assessed for risk, and this assessment must be systematic, evidence-based, free from blame and cognisant of the organisational context. That is what Safer Clinical Systems is all about.

It is time to learn how to be safe before a patient is harmed. It is time to build Safer Clinical Systems.

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18 This is known as the normal theory of accidents; ref Perrow. C.( 1999) Normal Accidents: Living with High Risk Technologies; Princeton Press
Part 2: Tools and techniques

Introduction

We now provide a guide to the tools you will need to build safety in your pathway or clinical area. We have provided worked examples where possible to guide the process. Some of these tools will be unfamiliar to clinicians and healthcare managers in exactly the same way that incident reporting and analysis was unfamiliar a decade ago. Safety and quality have their own technical domains and they are different from the technologies of nursing and medicine; they must be learned and applied, as they have been elsewhere. Aviation did not become safe by simply training good pilots – it became safe by applying safety science and human factors to complement skill in flying.

Overview

Step 1 Your pathway and its context (page 25)
- Manchester Patient Safety Index (MaPSaF)
- Safety Culture Index (SCI)

Step 2 System diagnosis (page 26)
- Process mapping
- Failure mode and effect analysis (FMEA)
- Human factors analysis (including task analysis and PIF analysis)

Step 3 Option appraisal (page 40)
- Option appraisal

Step 4 Planning (page 41)
- A basic model of change
- Hierarchy of control
- Managing human error
- Using checklists
- Engaging conversations
- Force field analysis

Step 5 System improvement (page 55)
- Measurement plan
- Safety case

Step 1 – your pathway and its context

MaPSaF (Manchester Patient Safety Framework)
- A way to get the team thinking about safety, safety culture and behaviour
  http://www.nrsl.npsa.nhs.uk/resources/?entryid45=59796

Safety Culture Index
- Delivers quantitative measures of 12 key dimensions of safety culture
Contact research@perform.gotadsl.co.uk for details of this tool
Step 2 – system diagnosis

Process mapping

Purpose
Process mapping is a powerful tool to help understand a patient pathway or the process of care. It’s a graphical tool – it produces a visual representation as an aid to understanding, sharing information and formulating ideas for change.

It provides:
• A visual, concrete description of the pathway
• Focus on the patient and the patient voice
• Goal clarification for the pathway
• Clarification of complex processes
• Understanding of the links with other systems and processes
• Knowledge of key steps and which steps add value to the pathway
• Shared understanding amongst the team
• Opportunity to involve and engage staff
• A launch point for identifying hazards and risks

Task by task outline
1. Walk the process
2. Get the right people in the room
3. Set out the ground rules, objectives and ethos
4. Construct a high-level process map of 6-12 steps
5. Work together to construct a detailed process map
6. Verify accuracy with other stakeholders and update accordingly.

Task 1 – Walk the process
• In constructing a process map, it will help if the improvement team or project team has some initial understanding of the pathway.
• Gather some initial data to orient the sessions by observing the pathway – walking the process.
• Put yourself in the shoes of the patient and follow the pathway.
• Remember that you won’t be able to observe everything.
• When you bring the multidisciplinary team together, you should not try to impose your own understanding on the group.

Task 2 – Get the right people in the room
A key benefit of process mapping is to unlock the tacit knowledge of people involved. No one person understands all aspects of a system, no one person can see the full effects of changes or identify hazards and risks to patients.

A process mapping session should therefore be a multidisciplinary, consensus-based process.
• Assemble participants from all key groups – this will probably include medical staff, nurses, managers and possibly AHPs or administrative staff.
Part 2 – Tools and techniques

Step 1 – your pathway and its context

- A process mapping session should include 5-8 people plus a facilitator – they should ideally be drawn from both senior and junior staff.
- If your pathway crosses organisational boundaries, be sure you have participants from each area.
- You will all need to set aside up to half a day.
- You’ll need a decent-sized wall, a roll of several metres of plain paper, plenty of coloured pens, post-its and paper for taking notes. A white board will be useful as well.

Task 3 – Set out the ground rules, objectives and ethos
- Process mapping is about understanding and representing a process through consensus. Your team should understand that this is a part of a process aimed at helping patients through reducing risk and harm, and is a collective endeavour.
- Keep in mind that this is only a starting point: the team is not there to solve all the problems in this one session.
- In Safer Clinical Systems, we emphasise the need to carry out a full review before we start trying to solve the problems.
- You may need to remind the team of this. Let’s be sure we have a full diagnosis before we write the prescription!
- Your objectives will be to map the pathway from beginning to end.
- The rules are that everyone has a part to play, everyone should be listened to and that no one person should dominate the discussion

Task 4 – Construct a high-level map

Agree the start and finish points of the pathway
- To begin mapping, you need to set your start and finish points – the first and last steps in the process. This is important, because it defines the scope of the session and the end-product – the physical process map.

Document the main steps in sequential order
- Add the main activities in the order in which they occur. Remember that you are describing the process as it is done in practice – not as you think it should be done. Using post-it notes here is helpful so that you can rearrange them if you need to. Some processes will take place in parallel, so you need to bear that in mind.

Reflect and review
- Aim to build a high-level process map of between 6 and 12 steps. Pause at this point to let the group reflect on the diagram.
- Question and challenge: have we got the right steps, in the right sequence? Have we missed any? Does it reflect reality? Can we use this to get to the next level of detail?

Task 5 – Construct a detailed process map
- The high-level process map is your starting point to gather more detailed information about the pathway. For each of the activities or decision points in the high-level map, you will now go on in exactly the same way to map the process details as steps – activities, decisions, documentation, information storage and retrieval – within each.
Part 2 – Tools and techniques
Step 2 – system diagnosis

• This is where the map will get complex so be sure to record the details and keep a log of issues as they emerge. You will identify problems, waste in the system, error traps and so on. Keep a record of these so that they will inform the FMEA sessions and any process redesign that might take place later.

• You should end with a description of the process that the group agrees is representative of what really happens for the patient. Where you are not sure as a group what happens in an activity, accept that. You can go back and ask others, or set up a further session, or carry out observations to fill in the details later.

Figure 3 shows a very simple illustration of how a finished chart may appear. This is a high-level process map for the trauma pathway in an Accident and Emergency department. It was constructed to provide an understanding of the handover process in the department.
Part 2 – Tools and techniques

Step 1 – your pathway and its context

![High-level process map for a trauma pathway](image)

Figure 3 High-level process map for a trauma pathway
Complete handovers of responsibility can therefore be added as in Figure 4. The first handover here, from paramedic to trauma team, can then be mapped in more detail. Part of this is shown below as two parallel processes, together with the information transferred at that point.

![Process Map](image)

**Figure 4** A more detailed process map of part of the handover pathway

This example of a process map shows a consensus description as an aid to the team in understanding, in this case, handovers. Its purpose is to serve as a starting point in developing safe, reliable systems. You can see that since there are parallel processes here, we can display the map as ‘swim-lanes’ of paramedic team and trauma team. In a more detailed analysis, these swim-lanes themselves could be decomposed into team leader, trauma nurse and so on if we needed to know more about staff’s specific roles. We can also add some detail of the information flow to the map, as shown in the pink box (Figure 4).

As you build detailed maps, the process steps can be assessed for hazards (what can go wrong) and risks; see the reference guide to FMEA for more details on the next steps.

**Task 6 – Verify the process map**

- After the session or sessions, you will need to verify the map with a range of stakeholders. Choose people who have an interest in the area either because they work directly in the pathway or because they have a responsibility for what happens there.
- You will need to establish a common view that this is correct before you can go on to identify hazards, risks and options for change. This is where an orderly description of the pathway or the process becomes most important.
- If you haven’t yet done this, you will need to produce a formal map to discuss with stakeholders.
**Failure mode and effect analysis (FMEA)**

**Purpose**
In this part of Step 2 of system diagnosis – FMEA – you will go on to identify systematically how things go wrong.

FMEA is a systematic analysis of a process to identify the possible ways it might fail. You can use FMEA to examine the effects or results of failures and the possible causes. FMEA originated in high-risk industries and has been employed in sectors such as automotive, aviation and railways for many years.

More recently it has been adopted in healthcare and is now promoted by patient safety bodies such as the NPSA and the US Department of Veterans Affairs (VA).

FMEA relies on input from all people involved in the care process. As with process mapping, it can contribute to the development of a shared vision and a culture of safety.

**Task 1 – Get the right people in the room**
- As with the process mapping sessions, one of the key benefits here is to unlock the tacit knowledge of people involved.
- No one person understands all aspects of a system, no one person can see the full effects of changes or identify hazards and risks to patients.
- Continuing from process mapping to FMEA should be a **multidisciplinary, consensus-based** process, almost certainly with many of the same team members as you had before.
- You will need to assemble participants from all key groups: this will probably include medical staff, nurses, managers and possibly AHPs or administrative staff.
- Once again, if your pathway crosses organisational boundaries, be sure you have participants from each area.

**Task 2 – Set out the ground rules, objectives and ethos**
- An FMEA session should be made up of a consensus group, where each person contributes positively as part of a process aimed at helping our patients. It will not provide all the answers in one session.
- You will probably need to go from FMEA to a more detailed examination of how human factors influence performance, and identify failures in the key steps from that perspective in order to fully understand your pathway.
- This is part of the Safer Clinical Systems diagnostic phase. Solutions will be suggested, and recorded for later work, but our key objective here is to understand as fully as possible the **hazards** (what can go wrong) and the **risks** (the potential for harm).
- Your **objectives** will be to take each step in the process map you have already built, and assess the inherent hazards and the risks. The **rules** are that everyone has a part to play, everyone should be listened to and that no one person should dominate the discussion.
Task 3 – Review the process map

- Your consensus process map should be on display. It might help to display both the initial high-level process map and the more detailed one and seek initial views from the team as to which high-level steps are the most hazardous to patients.
- Your knowledge of existing data from risk management (from incident reports, incident investigations and audit data) will aid discussion at this point.
- Before you proceed, the group needs to feel confident that the process map is an accurate representation of what actually takes place in this pathway and is therefore worth assessing.

Task 4 – Carry out a sequential analysis of hazards, risks and causes

- This task is the heart of FMEA. For each of the steps in the pathway described in your process map, you will identify what can go wrong, how it could affect the patient, what causes are implicated and what current risk control measures are in place.
- At the end of this process, you will be able to highlight the most critical risks. You will have conducted a relative risk analysis through a consensus process. The data from this session will inform your subsequent judgment of where a more detailed human factors-based analysis will be needed and will also feed into options appraisal, Step 3 of the Safer Clinical Systems programme, in which you will be designing and evaluating options for change.
- The diagram in Figure 5 outlines the process. We have also provided templates for each step – one for the basic FMEA (Figure 6) and a second for detailed risk ranking (Figure 7).
**Human factors analysis**

**Purpose**
The systems-based human factors analysis described here is based upon understanding the goals of the system, the tasks and subtasks needed to accomplish them, the possible failures and risks involved and the factors that cause them.

The starting point of the analysis is a **Hierarchical Task Analysis** (HTA). HTA is a goal-driven method for documenting a process by breaking complex sequences into discrete tasks and subtasks. As with process mapping and FMEA, these tasks can then be analysed individually for failure modes and risk. An HTA has some additional advantages, however. HTA allows you to develop the activity up to the level of detail required, with special attention to specific task details: the things that people actually do. This forms the basis of an analysis of the factors that affect the tasks – the ‘performance influencing factors’ (PIFs). By examining this in detail, we can begin to identify and manage human error. These data will all feed into Steps 3 and 4 (option appraisal and planning) and will help to develop ways to improve safety and reliability of the pathway.

**Task-by-task outline**
- Get the right people in the room
- Agree the goal of the step you are analysing and the boundaries of the analysis
- Build a hierarchical task analysis (HTA) by identifying subtasks necessary to achieve the goal
- Carry out risk ranking of each task and subtask to identify where things go wrong
- Identify failure modes of how things go wrong
- Analyse contextual and task factors that influence why things go wrong
- Record your findings

**Task 1 – Get the right people in the room**
- As in Step 2, system diagnosis, human factors analysis should be conducted as a **multidisciplinary, consensus-based** process. The selection of the team involved, however, will be more specific: you will need to include only those staff involved in the particular goal and subtask set you are analysing.
- The emphasis here is on task experts – the staff with the most practical and relevant knowledge and experience. For example, if you were analysing the risks of a handover in the Hospital at Night pathway, you would certainly need to include nurse practitioners, junior doctors and specialist registrar, but not necessarily general management or administrative staff (Figure 8).
Part 2 – Tools and techniques

Step 2 – system diagnosis

Figure 8 Selection of the right people to act as task experts

Task 2 – Agree the scope of the analysis and the key goal

From the process or activity map and the FMEA carried out earlier, you will have identified key areas of risk where a more detailed analysis is needed. The first step is therefore to identify the scope of the analysis as the activity to analyse further, and the overarching goal of that activity. In a handover situation, a process map may include activities as shown in Figure 9.

![Figure 9 Relevant activities from the process map](image)

You may choose the high-risk element shown to examine in more detail (Figure 10).

![Figure 10 Identification of high-risk elements of the process map](image)

You will then decide on the chief goal of this activity, perhaps as ‘care for patients at night’, and agree the pre-conditions or the situation that defines the scope of the analysis, for example, ‘Adult inpatient wards participating in HaN at site x’.

Task 3 – Build a hierarchical task analysis (HTA)

HTAs can be built using a software support tool or by using paper and post-it notes. There are some advantages to using a software tool, but if you do, you must ensure that you also have a projector so that you can share the developing analysis with the full team.

Key principles in HTA

- Agree the purpose of the HTA. HTAs are versatile and can be used for analysing human performance and behaviour or for checking that the system design accounts for all necessary activities in a safe manner.
- Agree the boundaries of the analysis.
- Use multiple information sources – the right people.
- Describe the overall goal and then the sub-goals or sub-tasks needed to accomplish it.
- Specify a plan that describes the triggers for, or sequence of, the subtasks (e.g. ‘Do in sequence’ or ‘Do 3 if EWS is greater than 4’).
- Describe tasks as action statements (e.g. ‘Check patient ID on wristband’).
- Stop breaking down the tasks when you judge the risks to be acceptable – in other words, where a task is believed to be high-risk, try and break it down into more detail.

Start the process by placing the overall goal and the preconditions for the analysis at the top of the chart. Then go on to decide by consensus the subtasks needed (Figure 11). Staying with our example of handover to Hospital at Night, we might see the subtasks as:

- Convene HaN Team
- Set up information systems
Part 2 – Tools and techniques

Step 1 – your pathway and its context

- Ensure all relevant wards participate in handover
- Receive care requests from each ward
- Prioritise tasks
- Allocate tasks
- Respond to care requests
- Record interventions
- Manage real-time events

Task 4 – Evaluate task risks

Each task in the HTA is automatically assigned a number by software tools. Tasks can then be assessed for risk using the same methodology adopted for FMEA (Table 3).

Task risks should be assessed after completing each level of the hierarchy so that you know which tasks need further decomposition. The general rule is that where risk is low, you can stop further breakdowns of tasks. What constitutes an acceptable risk, however, depends on your judgment rather than on any numerical value of relative risk.
Each of these main tasks can then be further broken down into those subtasks necessary to achieve the goals. (To help with this, software packages are available).
### Part 2 – Tools and techniques

**Step 1 – your pathway and its context**

Table 3 Example of table generated for assessment of risks for each task

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
<th>Severity of Consequences</th>
<th>Likelihood of Error</th>
<th>Likelihood of Recovery</th>
<th>Rank Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Convene H@N team</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
<td>12</td>
</tr>
<tr>
<td>1.1</td>
<td>Do in sequence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Ensure full team is present</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
<td>12</td>
</tr>
<tr>
<td>1.3</td>
<td>Ensure team includes senior doctor and experienced NPs</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
<td>12</td>
</tr>
<tr>
<td>1.4</td>
<td>Ensure team has adequate experience</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>Prepare H@N hub</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>Set up information systems</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>Plan 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1</td>
<td>Do in any order</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>Prepare whiteboard</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3</td>
<td>Prepare Excel spreadsheet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Plan 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1</td>
<td>Ensure all participating wards are included in H@N team</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>4.2</td>
<td>Record information provided by reporting doctors</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>4.3</td>
<td>Questions from multidisciplinary team</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>4.4</td>
<td>Make handwritten notes on each case</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
<td>12</td>
</tr>
<tr>
<td>4.5</td>
<td>Enter tasks on whiteboard/Excel sheet</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>Plan 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1</td>
<td>Do in sequence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2</td>
<td>Prioritise tasks from handover</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>5.3</td>
<td>Allocate tasks</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>Plan 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.1</td>
<td>Respond to care requests</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>6.2</td>
<td>Record visit/intervention in patient records</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>6.3</td>
<td>Record intervention at H@N hub</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>1</td>
</tr>
<tr>
<td>6.4</td>
<td>Update whiteboard</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.5</td>
<td>Update Excel sheet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Plan 9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.1</td>
<td>Do in sequence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.2</td>
<td>Treat as appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.3</td>
<td>Record visit/intervention in patient records</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>Plan 10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.1</td>
<td>Do in sequence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.2</td>
<td>Update Excel sheet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Plan 10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.1</td>
<td>Manage real-time events</td>
<td>High</td>
<td>High</td>
<td>Medium</td>
<td>19</td>
</tr>
<tr>
<td>10</td>
<td>Plan 10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.1</td>
<td>Receive request from ward staff</td>
<td>High</td>
<td>Low</td>
<td>Medium</td>
<td>6</td>
</tr>
<tr>
<td>10.2</td>
<td>Decide if request can be addressed</td>
<td>High</td>
<td>Low</td>
<td>Medium</td>
<td>6</td>
</tr>
<tr>
<td>10.3</td>
<td>Plan 10.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.3.1</td>
<td>Ask SDWS score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.3.2</td>
<td>If above 4, visit ward within 20m</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.4</td>
<td>Allocate task</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>9</td>
</tr>
</tbody>
</table>

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Task 5 – Identify failure modes
Having built an HTA to the level of granularity required and evaluated risk, we can carry on with a formal scoping of failure modes. This can be carried out in the same way as it was for FMEA, or by prompting the group to consider known failure mechanisms.

These errors are best based upon the judgment of the team. In order to provide prompts for the team, each task step is classified into one of the following types:

• Action
• Information retrieval
• Checking
• Communication
• Selection.

These general types were developed in the context of safety-critical industries and may need to be extended for healthcare. The inclusion of general prompts relating to key non-technical skills such as leadership and decision-making might be useful depending on the situation and the nature of the task.

Task 6 – Evaluate performance-influencing factors
Performance-influencing factors (PIFs) are also identified through facilitated discussion. A critical feature of the Safer Clinical Systems approach is the requirement to zoom out from the microsystem into the wider system context, e.g. directorate/ trust/ secondary care/ primary care interface. This needs to be done as a conscious and deliberate activity in order to understand influencing factors in the wider context.

Factors known to be implicated in clinical risk are shown in Table 4.
Table 4 Factors known to be implicated in clinical risk

<table>
<thead>
<tr>
<th>Factor Types</th>
<th>Contributory Influencing Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Factors</td>
<td>• Condition (complexity &amp; seriousness)</td>
</tr>
<tr>
<td></td>
<td>• Language and communication</td>
</tr>
<tr>
<td></td>
<td>• Personality and social factors</td>
</tr>
<tr>
<td>Task and Technology Factors</td>
<td>• Task design and clarity of structure</td>
</tr>
<tr>
<td></td>
<td>• Availability and use of protocols</td>
</tr>
<tr>
<td></td>
<td>• Availability and accuracy of test results</td>
</tr>
<tr>
<td></td>
<td>• Decision-making aids</td>
</tr>
<tr>
<td>Individual (staff) Factors</td>
<td>• Knowledge and skills</td>
</tr>
<tr>
<td></td>
<td>• Competence</td>
</tr>
<tr>
<td></td>
<td>• Physical and mental health</td>
</tr>
<tr>
<td>Team Factors</td>
<td>• Verbal communication</td>
</tr>
<tr>
<td></td>
<td>• Written communication</td>
</tr>
<tr>
<td></td>
<td>• Supervision and seeking help</td>
</tr>
<tr>
<td></td>
<td>• Team structure (congruence, consistency, leadership, etc.)</td>
</tr>
<tr>
<td>Work Environmental Factors</td>
<td>• Staffing levels and skills mix</td>
</tr>
<tr>
<td></td>
<td>• Workload and shift patterns</td>
</tr>
<tr>
<td></td>
<td>• Design, availability and maintenance of equipment</td>
</tr>
<tr>
<td></td>
<td>• Administrative and managerial support</td>
</tr>
<tr>
<td></td>
<td>• Environment</td>
</tr>
<tr>
<td></td>
<td>• Physical</td>
</tr>
<tr>
<td>Organizational &amp; Management Factors</td>
<td>• Financial resources &amp; constraints</td>
</tr>
<tr>
<td></td>
<td>• Organizational structure</td>
</tr>
<tr>
<td></td>
<td>• Policy, standards and goals</td>
</tr>
<tr>
<td></td>
<td>• Safety culture and priorities</td>
</tr>
<tr>
<td>Institutional Context Factors</td>
<td>• Economic and regulatory context</td>
</tr>
<tr>
<td></td>
<td>• National health service executive</td>
</tr>
<tr>
<td></td>
<td>• Links with external organisations</td>
</tr>
</tbody>
</table>

Task 7 – Record your findings

Keep a detailed record of these analyses. You will need them to prioritise your options and interventions during Step 3 and Step 4 of the programme.

Where we understand how the design of a system or the influence of contextual factors enables errors or failings in reliability, we will need to account for this in both options appraisal and the development of the safety case.
Part 2 – tools and techniques

Step 3 – option appraisal

Purpose
The diagnostic work will have been undertaken in Systems diagnosis, Step 2. At this stage, teams will need to consider what interventions are emerging from these findings, as these will potentially be the ones undertaken in System improvement cycles, Step 5.

It is important to remember that Safer Clinical Systems involves looking at the whole pathway, not just a single microsystem, and understanding the management of contextual risk as well as processes in a pathway. Interventions may therefore be process- or context-related, and may occur at various levels within the pathway and within the organisation.

The interventions will certainly include some whole-system actions that influence many or all points along the study pathway and potentially will influence other clinically unrelated pathways. Hence, one contextual intervention may eliminate several risks along a pathway or in other areas of the organisation.

Important points
• The options should emerge from the work of Steps 1 and 2.
• Options should address risk as a first consideration.
• Options will include contextual change as well as process change.
• Appraisal should consider impact (on pathway and more widely) and feasibility.
• When considering options, remember that the results of the Safety Culture Index (SCI) should work with other information to help you to understand the context in which you are introducing change and guide you to possible interventions. The aim should be to create a context that supports safer practices, not simply an improvement in the SCI indices.

Part one: Choice of intervention shortlist
• This is a narrative of the rationale for the shortlist of proposed interventions, including how sustainability has been taken into account.
• It will explain how the diagnostic work undertaken in Steps 1 and 2 has led to this intervention and how it is believed the intervention will take the organisation nearer to its desired future state in a sustainable manner.

Part two: Evidence to support decision-making
For each intervention, create a narrative of the pros and cons of undertaking it. Consider factors including:
• Potential impact
  o on pathway
  o on whole system
• Feasibility
• Ease of implementation
• Financial consequences
• Fit with organisational objectives and priorities
• Chance of sustaining change
**Part 2 – Tools and techniques**

**Step 4 – Planning**

**A basic model of change**

**Purpose**
A basic model of change is based on three questions:

- Where are we now?
- Where do we want to be?
- How are we going to get there?

In Safer Clinical Systems we would add a fourth question: how will we maximise the chances of sustaining the change?

**Task 1 - Where are we now?**
What is the current situation or status quo? To get acceptance that we need to change, we have to demonstrate that the status quo is no longer a feasible option. This has to be shared and developed with those that will be affected by any change. In Safer Clinical Systems, Steps 1 and 2 are designed to do this through the range of tools and techniques used and the way they are used to involve people in the pathway. Within these steps we will have had to adopt a range of influencing strategies, first to get people’s attention and then to persuade them that things need to change, that they can be changed to reduce risk to patients and that it is worthwhile doing this. If key individuals or groups are not fully engaged, it will be important to engage them as soon as possible. This will also take us on to consider the next question...

**Task 2 – Where do we want to be?**
Before we can begin to formulate a plan for change, we need to have some shared clarity about where we want to take things, where we want to be and by when. How will risk be managed and mitigated in the future? What is acceptable risk in this pathway? Therefore, what do we want to be different, what should we stop doing and what should we start doing?

Answers to these questions will begin to emerge from the work done in Steps 1 and 2, which identify risk and whether it is managed or controlled, bearing in mind the critical caveat of Safer Clinical Systems that we do not assume or jump to conclusions about solutions.

These interventions are likely to be aimed at different aspects of the pathway, and, in aggregate, will take us to where we want to be. As we answer this question, we then start to consider the next one...

**Task 3 - How are we going to get there?**
Step 4 is about developing a plan of action(s) to take us toward the different sort of pathway system, and is likely to have a range of hard and soft system interventions to take us there. ‘Hard’ systems are the things we do to care for patients, which are manifest, existential, and ‘soft’ systems are the way we interact with patients and each other and the way we understand and use the hard systems. We will probably need to operate on two levels in parallel, i.e. the overall pathway, the ‘zoom-out’, and the specific interventions aimed at particular parts of the pathway, the zoom-in. Each of these interventions is likely to generate its own set of actions, some of which may overlap, and some that will be discrete. All will be undertaken within the overall pathway context.

**Task 4 - How are we going to maximise the chances of sustaining the change?**
During Step 4 we will want to continuously review the criteria that we know help to maximise the chances of our changes being sustained beyond the active intervention phase. Two well-known
‘tools’ which help to explore the psychological and cultural dynamics involved in the system are the change equation and force field analysis.

**The change equation**

Resistance is a natural, universal, inevitable human response to a change that someone else thinks is a good idea, and resisting change or improvement does not make someone bad or narrow-minded. We’ve all done it and our response will be one of three things: fight, flight or freeze.

The change equation is a useful tool in recognising and understanding the change from another person’s point of view before attempting to find a way to overcome any resistance. It works best with specific individuals, not a homogenous group such as ‘doctors’ or ‘the board’. Focus on a key member of the group.

**Dissatisfaction + Vision + Capacity + First steps > Resistance**

- Dissatisfaction – with the present situation
- Vision – an understanding of what the change would look like
- Capacity – sufficient resources to make the change happen
- First steps – an appreciation of how the change is to be implemented
- Resistance – the psychological and/or resource cost to the individual or group, of making the change.

If any of the first four elements are zero there will be insufficient impetus to overcome any resistance to change. The biggest problem may be the assumptions (untested) we make about what people know or understand.

To apply the change equation to a particular person(s) who is resisting the change or not becoming involved in the first place:

**Dissatisfaction – ask the questions**

- How satisfied is the person with the current state of things?
- Is any dissatisfaction shared with their colleagues?
- How is the dissatisfaction understood and experienced?

**Vision – ask the questions**

- Do they understand what is being proposed/described – is there a clear statement?
- What does this person want for their patients, themselves and their colleagues?
- What are their values and beliefs, goals and desires?
- What could the new system look like?

**Capacity – ask the questions**

- What resources are needed to achieve the change (including energy and capability)?
- How can resources be generated or shared?
- Has this person shown in the past that they are willing to try out new ideas (innovator or early adopter)?
- Is there anyone this person respects who has made the change who could help them/influence them?
First steps – ask the questions

- What first steps might people undertake that everyone agrees would be moving in the right direction?
- Do they know what these are (they may be willing but not able because they do not know)?

By working with these factors, people will be pulled towards a change. This is usually better than pushing people into it. People must reach a point where they realise that the costs and risks of the status quo outweigh those of the change.

**Force field analysis**

**Purpose**

Force field analysis (FFA) is a diagnostic technique for looking at the variables involved in determining whether change will take place in an organisation – for analysing who and what increase the likelihood of change, and who and what resists it.

Once change priorities have been agreed, a force field analysis can be used to identify actions that would enhance their successful implementation.

Force field analysis suggests strategies for reducing the effect of forces which can prevent change occurring. It is based on the concept of ‘forces’, specifically the perceptions of those in an organisation about particular factors and their influence on change.

Force field analysis has been used during system diagnosis, Step 2, and can be applied both at the level of the pathway and at the level of the individual intervention, to help identify, share and understand the forces driving and resisting the change(s) you want to make. There will be overlap and interaction between soft and hard system factors in how they impact the willingness and ability of people to make and sustain the changes needed to reduce risk and improve safety. The change equation is a way of further breaking down and understanding the resisting forces, i.e. why are particular individuals resistant to the proposed changes or to becoming involved or engaged with the process of improving safety? It helps to see the proposed changes from their perspective.

**Basics**

- Driving forces – those factors affecting a situation that initiate and maintain change and push it in a particular direction.
- Resisting forces – those factors restraining or reducing the driving forces.

Reducing resisting forces is preferable because it allows movement towards the desired state without increasing tension. Group norms are an important force in resisting and shaping organisational change. Change involves shifts in organisational situations and processes – in ways of doing things – whereas transition is the psychological reorientation people have to experience when a significant change takes place. Change (an event) may be viewed, intellectually, as gain, but the associated transition (a process) is often experienced as loss. It is that which people fight, not necessarily the change itself. The use of appropriate change tools helps to identify and develop strategies for managing the transition and are needed to underpin sustained behavioural change.

**Benefits of FFA:**

- Requires those involved to define the change required – where are we now and where do we want to be – in order to develop a consensus.
- Encourages a wider perspective on factors in macro- as well as micro-context.
Part 2 – Tools and techniques

Step 4 – planning

- Draws out and tests assumptions about the change.
- Enables a consensus to be developed among stakeholders about how to tackle a desired change.
- Turns assumptions and beliefs about a situation into defined ‘forces’ – factors to be tackled.
- Helps to develop a shared strategy for action.

Task by task outline

- Get the right people in the room
- Agree ground rules
- Define the nature of the change required
- Identify the forces driving the change from the current state to the desired
- Identify the forces resisting the change
- Sort out the forces to differentiate them, for example
  - Determine the relative magnitude of these forces
  - Identify polarising forces where a change in one may influence a change in the other
  - Sort positive and negative forces in terms of their relative importance
- Develop an action plan to minimise the impact of resisting forces and to strengthen or release the driving forces

Task 1 – Get the right people in the room

- As with the application of other tools and techniques, one of the key benefits here is to unlock the tacit knowledge of people involved. No one person understands all aspects of a system, no one person can see the full effects of changes.
- Using force field analysis should therefore be a multidisciplinary, consensus-based process, almost certainly with many of the same team members as you had before. You will need to assemble participants from all key groups – this will probably include medical staff, nurses, managers and possibly AHPs or administrative staff. Once again, if your pathway crosses organisational boundaries, be sure you have participants from each area.

Task 2 – Set out the ground rules, objectives and ethos

- This should be a consensus group session, where each person contributes positively as part of a process aimed at helping our patients. Not all may fully agree, but all should have the opportunity to contribute and to question so that all can agree, to some extent, with the conclusions and actions. You will not have all the answers in one session – you will probably need to go from a whole pathway-based force field analysis to specific intervention-based FFAs to understand all the potential forces driving or inhibiting the desired change.
- Remember that this is part of the work to develop and apply interventions to change the way things are done in order to improve safety. There will be some degree of testing and shaping interventions in this process.
- The rules are that everyone has a part to play, everyone should be listened to and that no one person should dominate the discussion.

Task 3 – Define the nature of the change required

- Define the nature of the change required, the desired state – what you want to move to. This assumes that you are clear about where you are now – where you want to move from.
Part 2 – Tools and techniques

Step 4 – Planning

What is not acceptable in the current situation: what do you want to stop happening or to start, what do you want to do differently or better?

• In defining the change you want to move to, it may be helpful to put yourself in the mindset of the future situation when you have achieved your change and describe the situation as you now see it, e.g. you are a year or two in the future, and the system, or a specific part of it, now looks like this.

Task 4 – Identify the forces driving the change from the current state to the desired state

What do you think is driving toward the required change? What are the factors affecting a situation which initiate and maintain change and push it in a particular direction? You can consider these under possible headings such as people, financial, technical, local.

• Information about harm, risks, complaints, etc.
• Patient views and feedback
• Views and opinions of those working in the pathway
• Views and opinions of those outside the pathway
• Technology and equipment used within the system
• Trust-wide support/attitudes
• External organisations
• Skills and training

NB – it is helpful to do both task 4 and task 5 on a flip-chart so that all can see it. It is also helpful to adopt a brainstorming approach on the first pass, i.e. capture the forces and then go back and sort them in task 6 (see below).

Task 5 – Identify the forces resisting the change

In a similar way, identify those forces resisting the change that you want to make: people, technical etc. These are the factors impeding the driving forces, those which restrain or reduce them. A state of equilibrium is reached when the driving forces and restraining forces cancel each other out. Increasing driving forces results in an increase in the restraining forces. The equilibrium is maintained, but under increased tension.

When attempting to bring about change it is better to decrease the resisting forces because it allows movement towards the desired change without increasing tension.

Task 6 – Sort out the forces to differentiate between them

In order to be able to develop an action plan you need to have some sense of which forces are most important or how they affect the change you want to make:

• Determine the relative magnitude of these forces
• Identify polarising forces where a change in one may influence a change in the other
• Sort positive and negative forces in terms of their relative importance – ability to affect more than one opposite force, size of the projected impact, ease of implementation, likely time to realise effect, etc.

Driving forces may not always be positive and resisting forces not always negative, so you need to listen carefully to what people involved in the change are saying when identifying forces. How do they perceive the forces?
Task 7 - Develop an action plan to minimise the impact of resisting forces and to strengthen or release the driving forces

Your action plan should concentrate on reducing resisting forces on the basis that removing or reducing them will allow the driving forces to work naturally. As was said above, a state of equilibrium (inertia) is reached when the driving forces and restraining forces cancel each other out. Increasing driving forces usually results in a corresponding increase in the restraining forces, thus maintaining the equilibrium but under increased tension.

When attempting to bring about change, it is better to decrease the resisting forces because it allows movement towards the desired change without increasing tension and can minimise the effort required. First, prioritise the key forces resisting change and focus on how they might be reduced. Often, it ultimately comes down to specific people or groups of people who are resistant to the change because they do not accept or believe the data, they do not know how to use equipment or technology, their group norms (behaviour, world view, beliefs) are not focused on safety, they are overloaded, etc. Focus your planning on minimising these key forces first.

The hierarchy of control

To help identify the best way to control a risk, you can consider a ‘hierarchy of control measures’ commonly used in other industries and which has relevance to many healthcare settings. The general principle is to adopt solutions from the top of the hierarchy before considering those lower down.

It is possible to construct many hierarchies and the literature contains several alternatives that are of use in differing situations. We believe the model shown in Figure 12 is helpful. (All hierarchies begin with ‘elimination’, as eliminating the risk altogether is preferable to risk reduction.)

![Figure 12 The hierarchy of risk control](image)

The hierarchy of control provides a framework to inform what interventions can be made for best effect.

- **Eliminate** risks – substitute hazardous equipment and/or processes with ones that are inherently safer.
- **Contain** risks – design equipment and processes to protect users from the hazards.
- **Minimise** risks – institute suitable systems of working.
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There are a number of examples of this approach. Following are two examples from healthcare:

**Example 1:** Paracetamol is often drawn up in a syringe when given to babies to allow accurate dosing. This is an easy way of introducing it into the mouth, but there have been occasions of it being drawn up in a syringe, then given intravenously.

Options:
- Eliminate the hazard: use a different, safer drug or preparation, e.g. the oral solution is cloudy but not a preparation that can be given orally or intravenously.
- Contain the risks: ensure that preparations of oral paracetamol cannot be drawn up in a syringe for intravenous use (by introducing purple syringes with different outlet size (Figure 13); oral preparation bottle has stopper that only fits purple syringe).
- Minimise risks: adopt working practices that take into account reliable checking procedures, training and supervision.

![Figure 13 Options for risk control](image)

**Example 2:** This relates to amphotericin, an antifungal drug. Recent reported mistakes were partly related to fact there are two different preparations with different doses. There have been incidents where the dose of one preparation was used for the other preparation, with fatal outcomes.

Options:
- Eliminate the hazard: only one preparation of amphotericin available. As mentioned, this is usually judged the highest level of safety intervention.
- Contain the risks: drug only available in specialist areas where regularly used, consultant-only prescription.
- Minimise risks: adopt working practices that take into account reliable checking procedures, training and supervision, including mandatory pharmacist checking, better bottle labelling, improved checking procedures with reductions of interruptions identified from the diagnostic phase to ensure the associated risks do not reach your system at all, or finding other ways to prevent the risk from occurring.

**Containing** the risks might centre on physical layout, equipment ergonomics or workflow.

In practice, you might find that many familiar interventions for safe design fall into the ‘**minimise**’ category. These would include:
- Checklists
- Briefing/debriefing
- Non-technical skills training
Managing human error

In clinical practice, adverse events can originate in many ways. Human failures are often at the heart of adverse events. To help in developing interventions and building safety into your system, you will need to understand some of the mechanisms of human error. This is our starting point.

Human error as a consequence of the way we work

Human agents in healthcare can create safety through their resilience and flexibility in the face of complex situations, but they can also degrade safety through error. The term ‘human error’ is often used to explain mistakes made by clinicians. This can be appealing, but is unhelpful in addressing adverse events.

Human error, properly understood, is not a cause but a result. For example, a clinician makes a selection error by picking up an incorrect drug to administer to a patient. Human error, yes, but a closer examination may reveal that the error was enabled by, for example, poor labeling of the medication; poor lighting in the ward; similarity in names of medications; interruptions by colleagues during a drug round; fatigue caused by low levels of resource on a long shift. To prevent human error, therefore, we need to recognise that it is a starting point for understanding, not an explanation.

When human failings are found to be a factor in safety, you will need to base your interventions on how human error can be prevented. Merely suggesting that staff should be more vigilant or work harder will not reduce errors. The following guidance is intended to help you to understand how errors occur, what the different types of errors are, and to suggest approaches to preventing error. A key principle throughout, which should apply to your recommendations, is to make it easy to do the right thing.

Human performance and conscious attention

Human performance will vary depending on the task we are carrying out. Some tasks will be based on learned skills and require little conscious attention (driving a car on a familiar route, for example, or riding a bike) while others will require more conscious attention (reaching a difficult diagnosis).

A widely recognised framework for understanding this is called the Skill, rule and knowledge (SRK) framework (Figure 14). This describes how:

- Skills-based behaviour is often carried out automatically, using little conscious attention, and is essentially based on sensory-motor co-ordination. Errors here are called slips or lapses.
- Rule-based behaviour uses a higher level of conscious attention and is planned, following a general pattern of ‘if X, then Y’. Errors here are called rule-based mistakes.
- Knowledge-based behaviour uses even more conscious attention and is concerned with understanding events and problems at a fundamental level. Errors here are called knowledge-based mistakes.


**Error management**

Though the above may seem theoretical, understanding these modes will help you to manage human error in a clinical context. For example, skill-based tasks are usually triggered by simple **signals**, such as a mark on a patient’s body to indicate the site of surgery; rule-based tasks are managed through choices – they are **signposted** by *aides memoire*, job cards and task support generally. Knowledge-based tasks depend on **symbols** – fundamental factors which are manipulated to solve problems, such as arriving at diagnoses or treatment plans through judging results and symptoms. Where an error may occur, if you identify the type of behaviour taking place, you should be able to come to a view as to what type of intervention might be required to build safer systems and practices.

Consider whether a rule-based task needs further support through a job aid or checklist, for example, or whether cognitive tasks need further training or team support.

**Violations**

Where a policy or a procedure exists but has not been followed by the conscious choice of a member of staff, a rather different error mode exists which is not a slip or a mistake. This is termed a violation.

Violations are common and are not necessarily bad. It is natural for people to find the most efficient way to work; this may lead them, for example, to find better methods than those outlined in policy; these are termed routine violations.

On the other hand, some violations are made for other reasons and can markedly degrade safety. Where a safety rule exists (an example may be the use of the WHO checklist for surgical safety) and is not followed, to the detriment of patient safety, this would be termed a reckless violation.

In unusual circumstances, a clinician may take a conscious decision to break the rules for what might be a sound clinical reason – to use sub-optimal equipment in an emergency, for example. This would be termed an exceptional violation.

Where staff deviate from established procedures, you must try to establish why, if you are to design-in safety:

- Was the procedure recognised, trained-in and supported? In other words, was it live?
- Was the procedure appropriate for the task?
- Was the violation routine, reckless or exceptional?
- Correct understanding of the nature of a violation, when it occurs will help you to develop better safety strategies.

Where violations have occurred, we recommend the use of the Incident Decision Tree to help separate poor practice or conscious violation for reckless reasons from those errors enabled by the way we work.

Using checklists

Checklists can be very powerful tools in the search for safe practice. Unfortunately, they come in all shapes and sizes and serve several purposes, so great care must be taken in their design.

Many ‘checklists’ would better be described as data sheets or aides memoire. These notes apply to the formal, deliberate and orderly process that takes place either immediately before or immediately after a safety-critical activity or when an abnormality or emergency is detected. An early question has to be what is the problem for which this checklist is the solution?

Problem definition matters

If the checklist is simply an aide memoire for an individual who both writes and uses it (shopping list), then detail and structure are not very important. If crossing off or ticking gives the user a warm feeling, go ahead and do it. Items can be added, removed or skipped at will and the cost of failure in safety terms is low. If each item in a checklist is safety-critical, however, then adding, removing or skipping is a different matter entirely. If any item is not safety-critical, its right to be included should be challenged robustly.

Gaining and maintaining compliance

For checklists that are safety- or quality-critical, content is clearly central, but discipline in checklist use must be maintained. Sharing an understanding of checklist formulation, providing education for checklist users and the maintenance of discipline in their use should all be part of checklist production.

Effective use of a checklist is both an intellectual and a behavioural exercise. The checklist is not a substitute for clinical skills and knowledge, but a support to enable their reliable delivery in both routine and challenging circumstances.

Checklist design and use should take into account the conflict for mental resource between demands generated by thinking and demands generated by controlling activity. The preferred solution is to separate thinking and doing, as each compromises the quality of the other.

Safety or process-critical checklists

There are three broad categories of checklist:

- Normal
- Non-normal
- Emergency

The ‘normal’ checklist – typically ‘challenge and response’

- The focus of the checklist is the task and the safe completion of the task rather than building social relationships.
- It is a checklist rather than a ‘to-do’ list.
- Any relevant activity is ordinarily complete (e.g. Think/Do conflict) and the checklist forms a checking function.
- If an item has not been completed, the reading of the checklist stops at that point. It only resumes when the relevant activity has been completed.
- Interrupted checklists are usually restarted from the beginning, or at least the beginning of the relevant section, if there are clear section boundaries.
- Normal activity is stopped during checklist completion.
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- The number of items on the checklist should be minimised so that anxiety about inactivity is minimised.
- The language used should be ‘professional’ – specific and unambiguous – rather than ‘social’, with minimum use of non-specific or irrelevant words.
- Briefings and checklists serve different purposes. Burying one within another will severely compromise the effectiveness of both.
- An unambiguous statement that a checklist is complete allows activity to recommence.

The ‘non-normal’ checklist – usually ‘read and do’
- This type of checklist is a ‘how to’ guide for when things cease to be normal.
- The goal is to restore normality or control the trajectory of the abnormality.
- Its structure is based on the support of memory for ambiguous or infrequently experienced situations.
- Its use shows the recognition of fallibility and is not a sign of weakness or failure.
- The first step is to establish clear and correct identification of the abnormality.
- Since the event is not an emergency, performing the correct activity slowly and deliberately is preferable to an immediate but inappropriate response.
- In healthcare it is probably inappropriate or even impossible to have a checklist for all non-normal situations; however, for those that have a clear potential to get out of hand if not handled with deliberate care, working to a plan thought out away from the field of battle (checklist) is the preferred option.

The ‘emergency’ checklist – initially completed from memory
- The situation is recognised as an emergency.
- There is an immediate need for action.
- The initial stabilising activity is completed from memory according to an appropriate algorithm.
- The number of items in the immediate response is ordinarily restricted to five (maximum seven to conform to the capacity of working memory – typically five unrelated items plus or minus two)
- These initial items are usually shown in a box on the checklist and are generally referred to as ‘the boxed items’.
- Once the situation is stabilised (not necessarily resolved), the ‘boxed’ items are confirmed as completed using the checklist. (Errors increase in stressful situations.)
- Subsequent items in the checklist are designed to set up a sustainably safe condition and are performed as ‘read and do’ as in the abnormal situation.

The WHO Safe Surgery checklist is probably the best-known checklist in healthcare. Its designers identified ten safety-critical items:
1. The team will operate on the correct patient at the correct site.
2. The team will use methods known to prevent harm from anaesthetic administration, while protecting the patient from pain.
3. The team will recognise and effectively prepare for life-threatening loss of airway or respiratory function.
4. The team will recognise and effectively prepare for risk of high blood loss.
5. The team will avoid inducing any allergic or adverse drug reaction known to be a significant risk for the patient.
6. The team will consistently use methods known to minimise risk of surgical site infection.
7. The team will prevent inadvertent retention of instruments or swabs in surgical wounds.
8. The team will secure and accurately identify all surgical specimens.
9. The team will effectively communicate and exchange critical patient information for the safe conduct of the operation.
10. Hospitals and public health systems will establish routine surveillance of surgical capacity, volume, and results.

**Engaging conversations**

*(with thanks to Jeanne Hardacre)*

**Purpose**

Engaging conversations meet one of our basic human needs. We all want to feel valued by others. When we do, we are more willing to give our time and effort to colleagues and to behave in ways which are not solely centred on our own agenda. Engaging conversations are key to tapping into our goodwill and our willingness to work cooperatively.

Getting people involved in your Safer Clinical Systems work is one of the most difficult parts of the programme. Engaging conversations are therefore crucial if your improvements are to have a good chance of lasting. For someone to invest extra time and energy in supporting Safer Clinical Systems, they need to feel that they are being listened to and that their views matter. If you invite someone to be a part of a Safer Clinical Systems discussion, how they feel at the end will be central to whether they decide to commit any more time or effort.

Engaging conversations matter because they deepen colleague relationships and help people to understand each other better. Faced with the need to change practice, people are then much more likely to try something new, together.

*When was the last conversation you had with a colleague which left you feeling positive, appreciated and eager to go that extra mile? And how frequently do those sorts of conversations happen in your day? What turns a standard conversation into an engaging one?*

**Good practice**

The following guidance draws on academic research, a range of literature and many years’ experience observing NHS conversations, some of which engage people and some of which do the opposite, despite the best of intentions.

**The ‘right’ people**

- ‘Getting the right people’ together sounds so obvious. Building a shared understanding will only be possible if participation extends beyond the ‘usual suspects’. But once ‘the right people’ are together, the way conversations are conducted can make or break their chance of engaging anyone. No one person understands ‘the truth’ about how clinical care happens. Each person perceives things in their own way; each perspective has its own validity. The patient’s perspective is often overlooked or under-valued.
- Think as broadly as possible to identify people who might have contrasting or alternative perspectives to offer. This might mean more tricky conversations, but leaving people out
potentially threatens the sustainability of whatever actions are decided. It’s better to know that someone is vehemently opposed to an idea and hear them explain why, than to leave them to be quietly resentful.

- One purpose of an engaging conversation is for participants to develop a shared understanding of something, such as why safety problems occur. Such an understanding is deeper the more perspectives it includes. However, in reality, it’s nearly impossible to imagine getting every perspective that would be valuable, so work with what you can get.
- Some tangible value is usually derived from any engaging conversation, even if it has fewer participants than had been hoped.
- All effective engaging conversations help to build a sense of shared purpose and mutual understanding. These are the building blocks for keeping people engaged.

Getting them together

- Easier said than done! Sometimes you know whose input you want, but, for a range of reasons, they can’t be persuaded to give their time to a meeting. Sometimes it is just not practical to have everyone together at the same time.
- Be flexible. It may be that several 1-1 or small group conversations are the only way. As long as you use the principles of an engaging conversation, they will be of value.
- If you hit a brick wall with staff who just don’t seem interested, you need to make a judgement. It will take time and energy talking to them to understand why they are unwilling or feel unable to get involved. The reasons may seem insurmountable (e.g. lack of time on shift, no support from manager, disillusionment). You must decide how important their engagement is for the long-term sustainability of the work.
- If the work cannot be sustained without the engagement of certain staff, it will be important to address the apparently insurmountable obstacles. Proceeding without the engagement of key people is an option with obvious risks. Keep the long-term sustainability of the work at the centre of your decision-making.

Early contributions

- The tone of a conversation – whether between two people or many – is set within the first minute or two. If during this time, only one person speaks, it sends out a clear message: they are here to do most of the talking; we are here mainly to listen, and perhaps contribute when asked. If your aim is to energise people and get them actively engaged, this is a fatal message to send, even implicitly.
- So give everyone a specific chance to speak within the first five minutes. And repeat this – turn-taking around the room if people seem reluctant – to ensure everyone has chance to say what they think or ask what they need to ask.
- The norm of meetings in organisations is that many people wait for permission to speak. This ‘permission’ may be explicit or implicit. Do not underestimate how much people will keep their thoughts to themselves unless asked. Directly and genuinely asking a person if they have any thoughts they’d like to throw in is an empowering method to use.

Make the rules of engagement explicit

To enable maximum involvement, the following principles are useful:

- **No interrupting.** Being able to contribute knowing you will not be interrupted enables much more free-flowing expression of ideas. If people know they will definitely get a chance to
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speak, they are less likely to interrupt or hog airtime. Ensure you prevent people being interrupted and make this an explicit agreement among participants.

- **Shared airtime.** Balance the promise of uninterrupted speaking time with an explicit agreement about sharing airtime. This helps participants to be judicious in choosing when to contribute, without discouraging them.

- **What you really think.** Often people sit there not saying what they are really thinking. This may be due to politeness, fear or normalised behaviour. As long as this continues, their engagement will be limited. An explicit invitation to express any doubts, worries and frustrations can help avoid these becoming blockages to engaging in the conversation.

- **Feelings are fine.** A team of healthcare staff without feelings would be a scary prospect! Ensure that feelings are given the respect and care they deserve. In issues related to patient safety, there may be feelings of fear or guilt in relation to possible or actual things that go wrong. Stress and physical or mental tiredness are often brought into meetings. Participants need to know that their feelings are part of the conversation. Expect, accept and talk openly about them. The more accepted a person feels, the more they will be able to contribute openly.

**Facilitation**

- Effective facilitation by someone who understands and believes in engagement is very important. A facilitator or chair who feels uncomfortable with the ideas suggested here is not the right person to facilitate an engaging conversation.

- The task is not for the faint-hearted, as the conversation needs to be purposeful and productive in relation to the task while at the same time attending to a range of issues to ensure an effective process.

- Skills and confidence in facilitating in this way are effectively developed in others through co-facilitation and modelling, and are very valuable assets to develop in any team.
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Measurement plan

Getting started

A measure refers to what you would expect to change in response to your intervention, or something you need to assess in order to identify whether your intervention is responsible for any change seen. Examples include rates of prescribing errors, infection rates, mortality, levels of patient satisfaction or number of missing items from handovers.

Outcome measures relate to changes in health status of patients and user experience in patient safety: this includes direct measures of harm. Examples include mortality, harm due to preventable causes and patient experience.

Process measures are quantitative assessments of key steps in the pathway required to ensure the outcomes. This includes reliability of the steps as well as time measures and quantification of components of the pathway. Examples include reliability of completing components of a checklist and percentage of correct prescriptions completed.

Balancing measures are quantitative assessments of any predictable adverse effects of the interventions you have chosen. An example is reduced length of stay balanced by readmission rate.

Proxy measures are indirect measures or signs that approximate to or represent an outcome in the absence of a direct measure or sign. They should only be used when direct measures are not possible and there is either quantitative evidence of a direct correlation or a robust argument linking the proxy to the outcome. They should also be associated with an argument of local applicability. These measures will need to take into account any potential confounders. Examples include length of stay and readmission rates.

Confounders are factors that might independently affect your process or outcome measures. They may include data issues, such as when your proxy outcome is affected by both safety issues and non-safety issues. Examples: the cycle of rotation of junior doctors may affect the number of prescribing errors; reduced readmission may be due to fewer adverse events post-discharge, but could be due to more community admission avoidance; reduced length of stay caused by new technologies rather than decreased adverse events.

Data items are pieces of data you need to collect for your measure. For example, to determine the rate of falls, you would need data to feed the denominator (number of patients) and the numerator (number of falls), and a definition of what counts as a fall.

Table 5 provides an example of a table to help you develop your measurement plan and select your measures.
Check your measurement plan (with thanks to Professor Mary Dixon-Woods)

Use this list to help check your measures collection plan.

- Are the measures cheap enough to be used widely?
- Are the measures sustainable? Can you carry on using them after the project has ended?
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• Are there any specific privacy/ confidentiality/ information governance issues associated with using these measures and ensuring that data can be used in anonymised form?
• Check: could there be unwanted consequences of this measurement strategy?
• What is the potential for gaming (manipulation of data to produce a favourable impression) associated with these measures? How will you guard against this risk?
• In what ways might introducing this measure have unwanted impacts on the behaviour of staff (e.g. by encouraging them to improve on the thing being measured to the neglect of other important things that are not being measured)? How will you guard against these risks?
• Check: can you assure data quality?
• What quality assurance measures will be put in place?
• How will you prepare and check the data before submission?
• What is the likelihood that there could be missing data?
• How can you minimise the risk of missing data?

Are your measures:
• Robust? Are they subject to systematic or random variation?
• Valid? Do they really represent the thing you are trying to measure? Do they reflect safety improvement?
• Sensitive? Will they pick up small changes or just big ones?
• Specific? Are they likely to be affected by things unrelated to the thing you really want to measure?
• How feasible is it for you to collect these data without excessive burdens (on staff time, IT infrastructure, financial costs and so on)?
• Have you chosen a realistic number of measures?
• Do you have the right systems in place and the personnel available to collect data? If so, have these systems been tested?
• Are the measures simple to use, requiring minimal training and unlikely to irritate staff or distract them from their clinical work?
• Do the measures help rather than interfere with workflow? To what extent might there be duplication of existing data collection?

**Safer Clinical Systems Safety Case**

**Purpose**
A safety case is a reporting mechanism currently used in non-healthcare industries. We introduced the use of safety cases in Safer Clinical Systems to the ‘sharp end’ of clinical practice in order to bring all the differing strands of the programme together in one place – the organisational context in which you work, the culture, the hazards and risks in your pathway, how they are currently controlled and where the gaps in control are.

In classical safety engineering, safety is defined as the avoidance of harm (death, injury, reduction in quality of life), which requires that we must first identify the ways in which
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harm may occur. In Safer Clinical Systems we achieve the eventual avoidance of harm by minimising risk as our prime goal (eliminating, containing or minimising). This is why we do hazard identification (Step 2 of Safer Clinical Systems).

The first step in creating the case for the present level of safety is to create an overall safety claim for the pathway. This is a succinct statement of the existing perception of the level of risk and harm in our defined system and the acceptability, or not, of this (e.g. we believe this pathway is safe because ... but recognise the following safety issues....) and then divide this into a series of arguments that state the risk posed by each of the identified system hazards. For each hazard, we then present the arguments that we have to support the claimed level of risk, e.g. describing the effectiveness of existing risk controls. We then state the evidence referenced to support these arguments, where the argument structure explains the purpose of each piece of evidence. Finally, we state the level of confidence we have in our argument and evidence, acknowledging that the ‘logic’ of our arguments isn’t infallible, and that the evidence isn’t infallible.

Introduction
A safety case can serve many purposes. It can be used as a snapshot of safety, showing where you are now. It can be used as a tool in improving safety. It can be shared to build knowledge and consensus about safety. And it can be used, in a short form, as an assurance statement for internal and external stakeholders. There is a level of technical knowledge required in both building and understanding a safety case. We make no apologies for this, for it is surely the responsibility of all people who have operational or executive responsibility for safety and risk to understand the discipline.

Current systems often assess the safety of a system by measuring harm alone. The Safer Clinical Systems approach acknowledges that the absence of all harm is an important goal, but that the reason that harm has not resulted may be due to chance rather than a system that is inherently safe. In other words, risks may still be present in the system, e.g. as latent factors or adverse performance-influencing factors. By reducing the risks in the system, the likelihood of an end result of a variety of harms is decreased.

A safe system is therefore one where risk has been minimised. One of the consequences of this is removal of harm, but also an increased resilience for unexpected hazards. 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. We can take a broad view of our ‘system’ in which the study pathway exists, but that system must be clearly defined (as in Step 1). As both argument and evidence are ‘context sensitive’, our safety case must clearly define the context. For the purposes of this Safer Clinical Systems safety case, an argument is defined as ‘a connected series of propositions put forward in order establish a conclusion’.

Figure 15 shows the components of a safety case and their logical connections. The process begins with a statement of how safe/unsafe the pathway is. Following this are a series of arguments or evidence sets which describe the way Safer Clinical Systems actually works – an evaluation of the hazards and resulting risks in the pathway (from Steps 1 and 2), an estimation of current risk control measures and risks which are not adequately controlled
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(‘residual risks’), also derived from Steps 1 and 2; a description of necessary interventions (which you will have planned and begun to deliver in Steps 3 and 4). The ‘confidence argument’ is simply a reflective description of where the information comes from and the degree of confidence in the data.

![Safety Case Diagram]

**Figure 15** The components of a safety case

**Using a safety case**

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.

Safety cases can be implicit, i.e. the tacit knowledge within the team as to how the pathway is safe, or explicit, i.e. stated in a document. The benefit of making a safety case explicit in a document is that the case can be communicated, discussed and examined for areas of improvement.

A safety case is established as a living document that then evolves over time, for example as the system is defined, evidence is collected, the context changes and improvements are made. We can ask about the safety case at any time: ‘What’s the current safety state?’

The development process encourages discussion and debate and allows the team to recognise where further information is required. It is not designed primarily as a reporting tool, but it can be used to update those external to the work. This might include the trust board, commissioners or regulators.
The guide on how to produce safety cases for Safer Clinical Systems was originally developed by the Warwick Medical School technical support team in association with Dr Tim Kelly at the University of York. Work has also been completed on a review of how safety cases are used in other sectors and the theoretical potential for their use in health. The report highlights a number of potential benefits of using safety cases in healthcare, including:

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

Key points to remember

- The safety claim describes the present state, and will include a logic trail to demonstrate how the reliability of a process contributes the hazards and the harms that may result.
- The argument describes the conditions (resources, structures, plans, policies, culture) in place, the assessment undertaken, the mitigation processes and the rationale that link them to the safety claim above. These arguments are based on risk, not harm alone.
- The evidence is in many forms both qualitative and quantitative. Initially this will have been collected in Steps 1 and 2, but further evidence will emerge through the safety improvement process.
- The level of confidence in that evidence needs to be described with explanation of its limitations, reliability and generalisability.
- The development of safety cases for healthcare services: Practical experiences, opportunities and challenges
Part 3: Systems thinking in healthcare

Introduction
This part of the guide is for those interested in a more detailed discussion of the conceptual underpinning to the Safer Clinical Systems approach. It provides an in-depth and reflective view of systems in healthcare and their implications for safety. This section describes more about the person-centred approach to safety and contrasts it with the system-centred approach to safety, which has characterised other safety-critical industries.

Why focus on systems?
There have been many patient safety initiatives in health systems around the world. These have been motivated by trying to prevent harm and distress (and potential tragedy) to patients and their families. Many have resulted from high-profile tragedies such as those relating to the events at Mid Staffordshire NHS Foundation Trust.

Keeping patients safe is the primary goal of clinicians, and it has largely been clinicians who, with contributions from healthcare managers, have led patient safety programmes and raised the profile of clinical failures. Delivery of safe patient care is the basic business of the healthcare industry, and if this is poor, it demonstrates a fundamental deficiency in the functioning of the organisation. In addition to the costs, both human and financial, organisations risk additional burdens from having to provide remedial care for patients adversely affected, potential re-admission, a longer stay in hospital, etc. They may also suffer from a critical breakdown in reputation and trust. Poor care is inefficient care.

Safer Clinical Systems was a Health Foundation-supported programme intended to develop and test new ways to build patient safety. In this guide, we describe a methodology that brings together approaches to safety from other high-risk industries as well as original work undertaken by the Safer Clinical Support Team and the many NHS trusts that were involved. We summarise many of the different approaches that we took and provide simple practical guides for the approach itself and for the tools we used.

Not surprisingly, we have focused our work on systems and on the culture in which those clinical systems are embedded. This is because we believe that the traditional approach, often exemplified by reporting incidents, trying to learn what went wrong for the patient and attempting to deal piecemeal with improvements is usually ineffective.

At the very heart of the Safer Clinical Systems approach, therefore, is an appreciation of the context and culture in which we work, the knowledge that our systems largely determine our performance and the recognition of how humans work within systems.

Above all, however, this new approach is a system for creating safety proactively, before a patient is harmed.

Safer Clinical Systems
In recent years, there has been an increasing realisation that patient safety is a whole-system issue. The way in which a system operates is a major determinant of the risk in that system – and risk can lead to harm. In the past our focus has been on investigating adverse events and on making
recommendations for change to ensure that mistakes are not repeated. The recommendations usually apply to the very specific circumstances of the individual event — and yet many of the factors contributing to the event are common to other adverse events. It is probably true to say that the common solutions are focused squarely on the individual practitioners associated with the events and any training, supervision or disciplinary needs that can be identified. At an organisational level, recommendations often focus on developing new policies and informing staff of what they should be doing.

Other high-risk industries have taken a different approach. They favour a methodology that proactively searches for risks in the system rather than dwelling on past harm. Here we describe an approach that follows this methodology and that tries to shift the balance far more towards the organisation and the environment and away from the individual. This is not to say that the analysis of past harms in unimportant – far from it; this will remain the duty of clinicians and managers and, carried out correctly, provides an invaluable insight into patient safety.

**Patient safety is a continuing problem**

Despite many initiatives in developing better safety for patients in hospitals, being admitted and treated is still a hazardous process. About 10% of patients receive care that isn’t merely of a poor standard, it is actually harmful (see box below).

<table>
<thead>
<tr>
<th>Incidence of patient harm across a wide range of countries</th>
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<tbody>
<tr>
<td><strong>Systematic Review:</strong> 9.2% [De Vries 2008]²⁹</td>
</tr>
<tr>
<td><strong>Latin America:</strong> 10.5% [Aranaz-Andrés JM, 2011]²⁰</td>
</tr>
<tr>
<td><strong>Canada after discharge:</strong> 23% [Forster 2004]²¹</td>
</tr>
<tr>
<td><strong>New Zealand:</strong> 11.2% [Davis, 2002]²²</td>
</tr>
<tr>
<td><strong>Sweden:</strong> 12.3% [Soop 2009]²³</td>
</tr>
<tr>
<td><strong>England:</strong> 10.8% [Vincent 2001]²⁴</td>
</tr>
</tbody>
</table>

The studies cited in the box above have all taken place since 2001, during a decade that has seen an unprecedented and rising interest in patient safety. Documents highlighting the problem and setting out goals for public healthcare providers were followed by safety and quality initiatives in many countries.²⁵,²⁶ The USA saw the 100,000 lives campaign, managed by the influential Institute for Healthcare Improvement;²⁷ among many high-profile local and national initiatives, the UK saw the foundation of the National Patient Safety Agency and the Safer Patients Initiative, sponsored by the Health Foundation.

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Asking the legitimate question, ‘Has patient safety improved?’ yields some surprisingly ambiguous responses. In some areas – hospital-acquired infections, for example – it does seem as if patients are less at risk from MRSA and *Clostridium difficile* than they were during the 1990s. For most other indicators, though, the picture isn’t clear. Charles Vincent provides a summary of these data and concludes, rather worryingly, that while there is some evidence of falling overall mortality in hospitals, of nine other patient safety indicators, seven showed an increase, indicating falling levels of patient safety.  

Two further studies provide more information. Landrigan and colleagues conducted a retrospective review of a range of safety indicators included in the IHI Global Trigger tool over a five-year period in ten US hospitals. They found little evidence of improvement. There were no significant changes in the level of harm per 1,000 patient days or in the rate of preventable harms to patients. In UK hospitals, a thorough evaluation of the Safer Patients Initiative found that the introduction of the programme was associated with improvement in only a few indicators in specific areas, such as the monitoring of vital signs, but found no evidence of more significant or widespread organisational change.

**Systems thinking**

Systems thinking is a way of understanding how individual elements in a greater whole influence each other. It is a process of understanding the inter-relatedness of system components and seeing all those components as part of a common process with a particular common purpose. In practical terms, it recognises that reacting merely to a specific, often small, part of a problem not only frequently fails to solve the problem but also brings the danger of unintended consequences. Our approach to systems thinking in healthcare is probably best understood as a conceptual framework, a body of knowledge and a toolkit that has been developed to try to make larger patterns clearer and to help researchers and improvement teams to determine how to change them most effectively.

All things exist in systems. In healthcare, individual system components include the patient, the clinicians, the equipment and the environment in which the care takes place. Systems thinking in general is a process of understanding the interrelatedness of the system components as part of a common process with a common purpose. In several public services there has been a growing recognition that improvements in quality and safety need to occur at a so-called ‘systems’ level in order to be widespread and sustainable. In healthcare this requires focusing not only on the clinical care of the patient but also on the many systems that support and enable clinical care.

The systems approach in healthcare was perhaps most visibly introduced following the inquiry into infant cardiac surgery at the Bristol Royal Infirmary. In this inquiry, though individual errors or lapses in performance were identified, there was an attempt to see them as the product of systems that had failed to work properly. The inquiry adopted an approach that effectively began with an examination of the organisational context and practices before considering the performance of individual events and clinicians.

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Part 3 – Systems thinking in healthcare

Systems thinking in patient safety

When things go wrong for a patient, especially when there seem to be failings in professional competence or vigilance, it can be difficult to think in terms of systems factors. In many industries we have often tended to assign personal blame to those actually in the critical situation – the last person to touch the controls of an aircraft, or in the case of healthcare, perhaps the last person to treat the patient. In the sections below, we explore the key differences between what might be called a person-based approach and a more mature systems-based approach.

The person-based approach

When an accident, adverse event or lapse in quality occurs it is natural to try and trace the cause and ask why and how it happened. In general, this has two aims: to learn where in the process the error occurred, and to judge whether any individuals were responsible and should be blamed. In this context, by far the most common allocation of cause is human error. Implicit in this concept is the assumption that of many causal factors in what is sometimes a long chain of events, the action or inaction of a small number of human beings is of crucial significance.

What often follows in these situations is a focus on punishment or reward, the reduction of the role of humans in systems as far as may be possible, and an increase in ‘command and control’. Blame, which seems to be a natural consequence of the identification of human error, frequently follows.

The systems approach

Healthcare systems are highly complex and can interact in unexpected ways. Our understanding of healthcare systems in recent years has moved from a person-centred approach towards a view that recognises that errors are more often consequences rather than causes. Performance is shaped by local circumstances, by the nature of the task and the tools, equipment and environment in which the activity is carried out. In this model, the human being is only one factor among many and the final outcome is a product of the interaction of many factors.

The systems approach, therefore, views causality in a different way. It demands a more nuanced explanation where the goal is to understand why an event occurs, through building up knowledge of how errors are affected by elements of the system.

The model of organisational accidents

Person-centred views of safety or quality events often reflect the so-called ‘domino theory’, where human error triggers a following error, and then a subsequent error, and so on, until the event occurs: a row of dominoes falling down, fully determined and with an easily identifiable initiating step in the chain.

In place of the domino metaphor, the dominant image in systems thinking in healthcare has become the ‘Swiss cheese’ model, introduced by James Reason to illustrate his ‘model of organisational accidents’. This describes a system as possessing a series of layers of defence that prevent error. In an ideal world none of these defences would be breached; in reality, the defences might resemble slices of Swiss cheese and have many ‘holes’, or routes, through which failures may propagate. When all the holes in the series of slices become aligned, defences in depth have failed and an incident occurs. Part of this model is the distinction between active failures, which may be thought of as unsafe acts committed by people directly in contact with the patient, and latent failures, which

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arise from organisational states resulting ultimately from decisions made by procedure writers, designers, administrators and management.

The Swiss cheese model, which has become widely accepted in healthcare, was developed because the very basic approach of the domino model did not allow the identification of wider systems factors which, when modified or improved, could be expected to allow better performance across the wider organisation.

**Other systems approaches**

The Swiss cheese model, which has been accepted for many years, is usually regarded as a linear model, which assumes that a latent error is a constant condition and therefore accessible to change. It assumes, for example, that if only enough information were available we would be able to predict accurately how all the different factors within the system would interact and be able to manage quality and safety effectively. In practice, however, systems factors vary constantly: the level of resource may be sufficient at times and at other times not, even varying within a day, a shift or an hour. Levels of training may be excellent or up-to-date in one ward and have only begun in another. In addition, factors that may be perfectly safe in isolation may become unsafe in combination with other variables within the system. Adverse events can therefore be seen as the result of a conjunction of a number of different factors: it was a lack of adequate supervision, combined with the violation of procedure, combined with the desire to deliver a care package, combined with the lack of reliable communication and checking that allowed the intrathecal administration of an incorrect drug in the most well-known of medical adverse events, the vincristine incident.

In this way, adverse events can be viewed as emergent, nonlinear and difficult to predict. Why does this matter? Because it represents a move from a deterministic view of organisations to a probabilistic view, and, in practical terms, it raises significant questions from managers with regard to top-down control mechanisms and other traditional methods used in improvement.

Whatever the issues may be around predictability or the management of organisational risk factors, in healthcare the application of the systems approach is sadly lagging behind its recognition. Though systems factors such as training, team management, task design and communication have been clearly implicated in adverse events or poor quality of care, the factors have not yet been subject to systematic measurement or widely applied improvement programmes.

**What are ‘clinical systems’?**

An understanding of a systems approach in healthcare might begin with the report *Crossing the Quality Chasm.* Following a systems approach to safety pursued in other safety-critical industries, this document identified the ‘clinical microsystem’ as the frontline interface between the patient and the immediate healthcare individual or team where care is delivered. The practices within a clinical microsystem determine the quality of the patient experience, but themselves sit within an organisational context. The organisational system in turn resides in a wider political and economic context.
environment. This hierarchy of systems determines through its many interactions how care is provided to the service users.

The links between the organisational system, however, and the clinical microsystem are not well understood. How do organisational systems actually affect clinical care? What are the routes through which this takes place? What factors would need attention and management in order to assure quality and safety? We do not believe that healthcare has arrived at a clear answer to these questions. When talking about systems, for example, NHS staff often think exclusively in terms of policies, procedures or protocols rather than in terms of the factors that make up the context of the event. Retrospective analyses of why things go wrong frequently ask the question ‘Were the appropriate systems in place?’, as if preventing recurring events were a simple matter of identifying failing protocols or policies.

We believe that this is an insufficiently nuanced view of clinical systems. A more comprehensive appraisal should encompass all the variables that make up the workplace and influence performance. These include tangible factors like procedures, equipment, task support, working conditions and resources, but also should include less concrete factors such as team or organisational culture and the explicit or implicit messages communicated throughout the organisation. The most complete approach to understanding these systems factors has been developed by extending Reason’s model of organisational accidents. In classifying conditions that would tend to increase error in clinical practice, or ‘contributory factors’, Charles Vincent’s ‘London Protocol’ for learning from adverse events reflects systemic issues that may well go beyond the local area in which a patient safety incident occurred, and therefore highlight areas for change or improvement.37

The protocol includes a set of contextual or influencing systems factors which an investigator is urged to consider when trying to understand how things went wrong for a patient. This methodology is not intended, we believe, to address all systems factors that influence care delivery, but to direct the investigator to those factors with a known effect at the point of care.38 The factors themselves – such as communication, teamwork and task design – may have their origin in financial policies, information technology or in corporate services more generally, as well as in less tangible factors such as leadership and clinical engagement. Many of these factors are pervasive, in that they extend throughout the organisation, so that identifying them through incident analysis points us to factors that may influence care delivery in many other situations. Identifying these factors and interactions retrospectively, however, does not always lead to systems changes. Interventions following a safety incident are usually local rather than organisational, and findings from many investigations can be difficult to aggregate into meaningful organisational learning.

The underlying approach to safety management in the NHS is essentially reactive. There is an expectation that trusts will generate high levels of incident reporting and incident analyses, which should inform managers regarding systems factors and lead to those systems changes that cross boundaries and have positive effects in many areas at once. This process becomes difficult in practice for a number of reasons, most cogently because of the persistence of a culture of blame throughout the service.39 This has the undoubted effect of depressing reporting levels and therefore suppressing organisational learning.

A systems approach to patient safety

Proactivity

Reactive methods of looking for safety learning or systems change are beset with problems, of which blame culture is perhaps the most common. What is the alternative?

We believe that a systems approach to patient safety must begin by being proactive – that is to say, not waiting until something has already gone wrong for a patient, but taking a prospective approach to managing risk. There are a number of techniques routinely used in other safety-critical industries that support this process: the most common ones used sometimes in healthcare are process mapping and failure mode and effect analysis (FMEA). More detailed approaches used less commonly are task-based analyses such as hierarchical task analysis, management of performance influencing factors and other techniques, many of which have emerged from the hybrid discipline of human factors.

Human factors

This discipline falls into two broad approaches based either on the understanding of the role of the human and his or her tasks in the system (‘system-based human factors’) or on key non-technical skills such as communication and teamwork (‘person-based human factors’). In both approaches, there is a recognition that the role of humans as both a source of error and a source of safety is crucial and must be understood in advance and in the context of a system.

Human error or human factors has been heavily implicated in safety incidents in all industries. Its management can only really be accomplished by building an understanding of the system and the role of human agency proactively, through designing out error traps and waste, supporting error-prone tasks and so on. Human factors accepts that error is inevitable, but also that it can be managed by designing the system to fit with the person rather than the person with the system, making it easy to do the ‘right thing’.

Risk and reliability

A systems approach to safety would seek to apply these proactive approaches more fully and to use them to begin to unpick the relationships between, for example, Microsystems and the larger organisation. In conducting analyses of this nature, there will be a strong focus on identifying and managing risk (the probability of harm) proactively, and on understanding the level of reliability (the probability that a system works according to its specification for a given amount of time) in patient care. Proactive knowledge of risk allows us to review the design of the system; knowledge of the reliability of safety- or quality-critical steps should allow us to design interventions aimed at increasing the reliability of care.

Safety culture

Safety culture is a quality of the wider organisation describing how individuals, teams and systems understand and manage safety. It is based on individual attitudes, beliefs and behaviours. Most workers believe that safety culture has a material effect on human performance and that it is a critical element in the context of practice. A safe clinical system would therefore exist in a cultural environment that supports safety through openness and fairness, and has a shared understanding of such factors as risk, reliability and error.
Understanding the organisational context

Many safety or quality improvement initiatives fail. Imposed ‘solutions’ developed from outside the clinical microsystem often fail to engage clinical staff and lack sustainability as a result. Interventions that look perfectly sensible from the outset can be difficult to implement if the wider organisational context doesn’t support them, or if the prevailing culture is unwilling to embrace the changes.

We believe that understanding the organisational context and factoring this into the design of safety interventions is essential to building sustainable change, and the Safer Clinical Systems approach seeks to address this through starting the programme with a contextual assessment. In part, this involves a familiarisation step to ensure that all staff along the chosen patient pathway understand and support the objectives and approach of the project.

A more formal appreciation of safety culture and organisational attributes as seen from the perspective of those involved in the projects can be built through two additional processes: the Manchester Patient Safety Framework (MaPSaF) and the Safety Culture Index.40 Taken together, these data provide the teams with a triangulated perspective on context. It includes qualitative views of safety and safety management from key personnel and also a quantitative measure of perceptions of effectiveness, contribution, accountability and development – terms that describe major elements of organisational safety culture.

The objective realities that these terms go some way towards measuring are likely to have significant effects on safety interventions, both positive and negative, and need to be understood at each site. Any changes in cultural attributes that result from Safer Clinical Systems may also be detected through these instruments.

Systems changes and human factors in Hospital at Night

A senior clinician working on Safer Clinical Systems Step 1 was responsible for ensuring patient safety in three acute sites. There was considerable organisational resistance to change. Detailed human factors-based task and risk analysis across all sites showed very variable systems, with one site’s practices placing patients at an unacceptable level of risk. The use of a structured, consensus-based systems analysis helped to build support for a radical system redesign at the critical site, building in reliable handovers and redundant checks for at-risk patients.

This redesign was based on eliminating risks identified through human factors analysis, taking into account task design and support, risk analysis and ranking and the effect of performance influencing factors in frontline care. Once a reliable design was established across all three sites, the clinician judged that further interventions were needed, again on a human factors basis, to ensure that the handovers themselves were reliably identifying and managing patients most at risk. This involved training in person-based human factors or ‘non-technical skills’ to help support good leadership, communication and decision-making in the hospital at night teams.

In this case, which was typical of Step 1 work in Safer Clinical Systems, the key elements were a knowledge of systems design and systems risk, the involvement and input from staff at all levels, and the application of human factors knowledge.
Afterword – risk and escalation

Safer Clinical Systems is about introducing a systematic, proactive approach to building patient safety. It is able to reduce the perceived risk in patient pathways, and as a consequence of this, safety culture – both as measured by the Safety Culture Index and as reported by those working in the clinical pathways – changes for the better. We have witnessed confidence and maturity in teams who have used this approach to patient safety.

However, what can frontline staff do when they identify significant residual risks as a result of this work that they feel cannot be changed – the big problems that are just too difficult to address? What if there is no resource to provide extra pharmacists? What if the organisation simply cannot locate and recruit or even afford the nurses needed for the night shifts? What if the senior managers in the organisation seek comfort and do not wish to seek out and confront problems honestly?

This is where a risk-based approach and the processes of escalation in an organisation become absolutely vital. In the UK, the secretary of state for health, with the widespread support of the parties and stakeholders, has emphasised the need for people to speak up freely and without blame or victimisation when things are known to be unsafe for patients. One of the most significant future advantages of Safer Clinical Systems – especially through its use of the safety case – is that it provides a systematic approach to addressing residual risks in the system. Through evidence and argument, safety is brought clearly into focus.

Where risks are identified, the programme focuses on the elimination of risk through system redesign, or containment of risks, or minimising their effects (described as the hierarchy of control). However, some risks cannot be easily addressed from the sharp end alone. So what next?

Here, risk awareness and good governance are essential. Uncontrolled risks have to be managed appropriately. In most cases they will be placed on the risk register of the organisation – sometimes used wisely as a live document and improvement tool, but sometimes a repository of things we can do nothing about but that continue to worry us. We believe that uncontrolled risks to patients should be escalated and reviewed honestly through systematic appraisal of risk, as is conducted in Safer Clinical Systems. In most cases a senior manager (probably an executive board member) must take the responsibility for how to deal with uncontrolled risks to patients. He or she may decide, for example, to simply transfer the risk to another trust and cease to offer the services concerned; they may decide that it is better to try and mitigate the risk through detailed resilience planning and day-to-day monitoring; or the organisation may simply decide to accept the risk. In those cases, the escalation of risk must go beyond the healthcare organisation concerned – to those who commission, regulate or fund.

No one today can seriously doubt that healthcare is increasingly under pressure. The contribution of a systematic proactive approach to risk and safety cannot be overestimated. The thread of risk goes from the sharp end of clinical practice all the way through the organisation and its executives, and on to regulators and commissioners. Building safer clinical systems for patients has to acknowledge this risk, do what can be done through the techniques described in this reference guide and escalate those risks that remain.

Without this risk-based, proactive and systematic approach to safety we will be continuing to react to patient harm – and it will have already taken place.