# The measurement and monitoring of safety

Drawing together academic evidence and practical experience
to produce a framework for safety measurement and monitoring

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# Health Foundation commentary

The publication of the report *An organisation with a memory*[*] in 2000 focused attention on measuring harms to patients and learning from errors. It led to the establishment of the National Patient Safety Agency in 2001 and the National Reporting and Learning System in 2003. This was a landmark step for England and Wales, moving to a healthcare system that began to acknowledge and measure harm caused as a consequence of poorly managed or delivered healthcare at a national level.

At around the same time, a number of national initiatives were developed to reduce harm – most notably those to reduce harms such as MRSA bacteraemia (Saving Lives 2005) and deaths from Clostridium difficile (Commission for Healthcare Audit and Inspection 2006). Despite this, more than 10 years later, it is difficult to know whether patients are any safer in the NHS than they were.[†]

Why is this? There are a range of factors: as our recent report, *Lining Up: How is harm measured?*,[‡] and the current debate on hospital mortality rates show, measuring avoidable harm is not as straightforward as it might sound. While diagnosing death is unambiguous, adjusting for risk in order to compare organisations is heavily contested territory. And measuring less clear cut harms such as infections is potentially more complicated as the process is dependent on social factors in the practice setting as well as technical ones.

What we currently measure is not how safe healthcare systems are now but how harmful they have been in the past. The Health Foundation believes that we cannot improve patient safety until we have a clear understanding of how to know if care is safe in the first place.

High risk industries are characterised by the shift they have made from measuring and responding to specific incidents of harm to assessing the presence of conditions that create safety. Such industries actively manage the environment to both manage the hazards that give rise to risk and also to create resilience in the face of unanticipated risks.

To move healthcare to this next generation approach we need to know what methods, tools and indicators are being used, and should be used, to measure patient safety. We commissioned Professor Charles Vincent and his colleagues from Imperial College London to bring together evidence from a range of sources (published research, public data, case studies and interviews), both from within healthcare settings and from other safety critical industries. The authors have synthesised this evidence and have proposed a single framework that brings together a number of conceptual and technical facets of safety. This framework provides a starting point for discussions about what 'safety' means and how it can be actively managed.

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[*] *An organisation with a memory*: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. 13 June 2000

[†] Vincent C, Aylin P, Franklin BD, Holmes A, Iskander S, Jacklin A, Moorthy K. Is health care getting safer? *BMJ* 2008;337:nov13_1;a2426.

[‡] www.health.org.uk/publications/lining-up-how-is-harm-measured

As the report demonstrates, the definition of safety is becoming more sophisticated in other industries and in some areas of healthcare. The focus is moving from counting harms after the event towards looking at hazards that might give rise to error, or safety failure before harm has occurred. This approach has its own challenges as even the definition of error can be ambiguous and has been interpreted by some as deviation from a standard process or rule. But we know from other industries, and from our own programmes, that some variations are intentional responses to local context and may, in fact, increase safety.

I know this from my own experience in relation to the venous thrombo embolism (VTE) guidance. When my mother was at the end stage of lung cancer she was coughing up large volumes of blood. One day she called the GP service because of a swelling on her leg and the GP initiated the VTE guidance. My mother was admitted to hospital to have a scan and potentially start on anticoagulants. Fortunately we were able to discuss the implications of this with the medical staff and agree that, in her case, the risk of increasing the bleeding from her lungs meant that deviating from the national guidance would be safer than adhering to them.

The lesson from my mother's experience is that the central goal of safety is to avoid potential harm rather than compliance with systems and processes.

The authors note that the range of models and approaches to measuring patient safety used by most people in healthcare is relatively narrow compared with other high risk industries. We don't believe it is possible to foresee every possible risk, but an organisation that has gone through the process of demonstrating that hazards have been identified, controlled and monitored will be more resilient in the face of unexpected events. Such an active approach requires a shift in mindset about the ways in which safety is monitored and measured.

While there are lessons to be learned from other industries, many of their systems are predicated on a state of stable operations and an existing track record on safety. Translating these approaches into the NHS, with the complexity of healthcare and unpredictable demand, means that demonstrating active safety management is more challenging than for many other industries. In this environment, safety needs to be considered on a number of levels. This report helps us by describing a framework of what should be measured and monitored; we now have to test and develop how it could be implemented in practice.

Intuitively, the framework seems to encompass the key components of a safety system. However, the authors recognise that some of the constructs will need a great deal of consideration before they can be made into practical tools to be used locally. They also suggest that their recommendations will need to be adapted and customised for different audiences and settings. Additionally, this report focuses on process, and the relationship between this and structural determinants of safety, such as staffing, needs to be elaborated.

The Health Foundation will be exploring how to develop and adapt the framework, involving a range of stakeholders including those working in frontline healthcare practice, patients and carers – people whose insight is critical to adapting the framework and whose support is vital if we are to see any real positive change to patient care.

This publication marks a stepwise change in thinking about how to know that care is safe: we hope it will trigger debate and discussion that will help shape safety improvement work to make healthcare safer for patients in the future.

**Dr Elaine Maxwell**
**Assistant Director**
**The Health Foundation**

# Acknowledgements

# Preface

The measurement and monitoring of safety in healthcare poses a number of difficult problems. For instance, in healthcare we have struggled to understand whether we should focus on error, harm, reliability or other indices. We have also struggled to provide a convincing account of the positive face of safety which encompasses both the achievement of keeping individual patients safe in a hazardous environment and the constant monitoring, reflection and action needed to keep an organisation running safely. The measurement of safety is also critical to many current and future Health Foundation programmes, and to the production of evidence for the impact of improvement projects.

In our first discussions with the Health Foundation we began by setting out three major challenges. The first was to address the many technical and conceptual issues inherent in any attempt to measure safety. There are a number of different perspectives, a diverse empirical literature and a need for a clear overview of the core issues. The second was to understand how safety measures can be effectively used in practice by clinical teams, boards and commissioners to monitor and improve safety. The third was to clearly communicate the findings to a number of different audiences. We believed this would require diverse outputs in different formats underpinned by a single common framework.

Readers of early drafts of this report often commented that they had not previously appreciated all the different facets. There are so many diverse perspectives, so many conceptual confusions and no clear framework for organising either our thinking or our measurement strategy. In our interviews and studies of healthcare organisations we found that safety is a very confusing topic for many people and that the measurement and monitoring of safety was often rather narrowly focused.

Increasingly therefore, we focused on finding a framework that embraces the diverse perspectives, makes intuitive sense and which will provide a template for individuals and organisations to measure and monitor safety. The early signs from our case studies suggest that this approach has been useful but we fully realise that the real test will come later with the dissemination of the report and the refinement of the framework in practice.

The present report provides a basis for the Health Foundation's wider work on the measurement and monitoring of safety in healthcare. It is not intended to address the wider issues of measuring other aspects of quality, such as equity and access. Nor have we attempted to cover risk assessment and the communication of risk in the management of particular diseases or treatment of individual patients. These are all important topics but each would require a report in its own right.

We appreciate that few people will read the report in its entirety but it is not intended as the only, or even principal, output. Our aim has been to produce a clear framework with widespread applicability, however we believe that this will only gain acceptance if those concerned with safety can be reassured that it is underpinned by a rigorous review of the relevant literature and survey of current practice. We can make a helpful distinction here between the 'technical' and 'adaptive' phases of such work. This is the technical phase. Once this report has been appraised, then the findings can be adapted and customised for different audiences and settings.

The aim of this report is to provide a framework and approach to measuring and monitoring safety in all relevant dimensions and facets. The report is based on review of safety literature, enquiries into safety practice in other industries, case studies of organisations, and discussions and interviews with a wide variety of people. We begin in Section I by considering the background research and wider context of safety measurement, both in healthcare and in other industries. We use this material to set out a simple, but hopefully comprehensive, framework of the different dimensions of safety measurement and monitoring that must be addressed. In Section II we consider each of these dimensions in turn, setting out relevant concepts and studies and showing how each dimension can be addressed in practice. A short final section, Section III, provides an overview of the core issues and suggests some future directions for both research and practice.

**Charles Vincent**
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**London, April 2013**

# Methods

This report draws together information from academic sources and practical everyday experience.

We began by conducting four scoping reviews covering the research literature and reports from important organisations. These reviews covered:

– safety measurement in a range of safety relevant industries (Jane Carthey);

– conceptual approaches and models of systems safety (Jonathan Benn);

– the measurement of safety in healthcare (Anna Pinto);

– the role of patients and families in monitoring safety (Rachel Davies).

These reviews used author and keyword searches using PubMed and internet search engines together with a review of bibliographic lists to identify relevant publications. They also used the research team's knowledge and experience to identify significant authors and papers, including previous systematic reviews. The websites of key organisations were included where appropriate, enabling us to access technical reports and guidance documents, for example those issued by national and state regulators of different industries. Each scoping review provided a report, with those for safety relevant industries and safety systems also synthesising the findings and drawing out the main practical implications for measurement and monitoring in healthcare. We examined the literature in a number of other areas as we proceeded with the report, for example on the contribution of staff to safety monitoring and on specific topics such as reliability and resilience, drawing on the authors' expertise from their previous research. A technical report on safety metrics (Alex Almoudaris) provided an overview of the technical and other properties of a range of safety measures including dashboards.

While the scoping reviews were underway we conducted interviews with a range of senior staff in national organisations in the UK. The interviewees were: Dr Matthew Fogarty, Patient Safety Lead, Department of Health; Dr Mark Davies, Medical Director, the NHS Information Centre; Robin Burgess, CEO, the Healthcare Quality Improvement Partnership (HQIP); Jan Davies, Welsh Assembly Government; and Dr Alan Willson, Director, NHS Wales 1000 Lives Plus. The help and advice from the Health Foundation and the project's advisory board members was invaluable and supplemented our interviews.

For our case studies in healthcare organisations we developed a template to describe the information we required. We approached organisations the research team knew to be interested in measuring safety. These covered acute, community, mental health and primary care services and specific services, such as obstetrics and anaesthetics, where measurement of safety is well-developed (see list below). The case studies were conducted by interviews and visits to the organisations or via email where visits were impractical, as in the case of Intermountain Healthcare in Salt Lake City, UT, USA. To supplement the case studies, we reviewed websites and board papers relating to patient safety from a range of other NHS trusts in England.

The report draws from each aspect of this work: the scoping reviews, interviews, case studies, and reviews of websites and board papers. We have considered all the information and have tried to interpret and present it in a way that is both readable and thought provoking.

# Case study organisations

| Organisation | Description of services provided | Lead/Coordinator |
|---|---|---|
| 1. Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH), London | An international centre of excellence in child healthcare with 50 different clinical specialties and over 200,000 patient visits to the hospital each year. Provides tertiary and quarternary care to children from the UK and other countries. | Peter Lachman, Deputy Medical Director; Jez Phillips, Assistant Head of Quality, Safety and Transformation – Information Management; Katharine Goldthorpe, Head of Safety and Transformation |
| 2. University College London Hospitals NHS Foundation Trust (UCLH) | UCLH is one of the largest NHS trusts in the UK with eight hospitals providing academically-led acute and specialist services to people from the local area, the UK and internationally. The trust sees over 700,000 patients in clinics and admits over 120,000 patients each year. | Sandra Hallett, Director of Quality and Safety |
| 3. Intermountain Healthcare, Salt Lake City, USA | Intermountain Healthcare (IH) is a nonprofit integrated health delivery system based in Salt Lake City, with over 33,000 employees. Serving the healthcare needs of Utah and Idaho, IH has a system of 23 hospitals with over 150 clinics, hospices, homecare services and an affiliated medical group and health plan. | Pascal Briot, Consultant Analyst; Marlyn Conti, Patient Safety Coordinator; Robin Betts, Quality & Patient Safety Assistant Vice President |
| 4. Aneurin Bevan Health Board (ABHB), Wales | ABHB is a combined acute, community, mental health and primary care organisation serving an estimated population of over 639,000, approximately 21% of the total population of Wales. | Kate Hooton, Assistant Director of Quality and Patient Safety; Dr Grant Robinson, Medical Director |
| 5. Obstetric Services: North Bristol NHS Foundation Trust | NBFT provides a full range of maternity services to women in north Bristol and South Gloucestershire both in hospital and in the community. Annually there are over 6,300 births. | Dr Tim Draycott, Consultant Obstetrician |

| | Organisation | Description of services provided | Lead/Coordinator |
|---|---|---|---|
| 6. | Anaesthetic Services, Imperial College Healthcare NHS Trust, London (ICHT) | ICHT is an academic health science centre providing services to the population of west London, the UK and internationally. The trust has five hospitals. Anaesthesia is provided to around 18,000 patients each year. | Dr Glenn Arnold, Consultant Anaesthetist |
| 7. | Geriatric Services, The Hillingdon Hospitals NHS Foundation Trust, London | The trust employs over 2,500 staff delivering acute care to the residents of the London Borough of Hillingdon, with a catchment population of over 350,000 people. | Dr Julie Vowles, Consultant Geriatrician |
| 8. | Central and North West London NHS Foundation Trust (CNWL) | CNWL is a large and diverse organisation, caring for people with a wide range of physical and mental health needs. The 5,500 staff make up more than 300 different teams, caring for around a third of London's population. | Claire Murdoch, CEO; Ela Pathak-Sen, Associate Director of Quality and Service Improvement; Kingston Kamba, Clinical Safety Manager |
| 9. | Avon and Wiltshire Mental Health Partnership NHS Trust (AWP) | AWP is a mental health trust providing a full range of mental health services across Wiltshire, Bath and North East Somerset, Swindon, South Gloucestershire, Bristol and North Somerset. | Dr Julie Hankin, Clinical Director (Service Improvement) |
| 10. | One Medicare | One Medicare is a primary care service provider that is patient and GP focused. It delivers high quality care along with a wide variety of services tailored to patient needs at seven surgeries located in the north of England. | Dr Richard Jenkins, Medical Director |
| 11. | NHS Wandsworth (now NHS South West London) | NHS Wandsworth is a primary care organisation serving the population of the Borough in south west London including clinical commissioning. | Sandra Iskander, Head of Performance and Patient and Public Involvement (PPI) |

# Section I: Concepts and context

# *Chapter 1:*
# Concepts and challenges

## 1.1   Introduction

Over the last 10 years there has been a deluge of statistics on medical error and harm to patients, a series of truly tragic cases of healthcare failure and a growing number of major government and professional reports on the need to make healthcare safer. There is now widespread acceptance and awareness of the problem of medical harm and, in the last decade, considerable efforts have been made to improve the safety of healthcare. We might reasonably ask if patients are any safer than they were 10 years ago. The answer to this simple question is curiously elusive. The main reason is that until relatively recently, for all the energy and activity, measurement and evaluation have not been high on the agenda.[1] In the last five years many organisations, at least in the British National Health Service (NHS), have gathered large amounts of safety information. Most, however, could not confidently assess whether their patients were more or less safe than in the past.

Measuring safety is, however, not solely about measuring harm. Assessing safety by what has happened in the past, although informative, does not by itself tell you how dangerous it is now or will be in the future. Safety is concerned with the myriad ways in which a system can fail to function, which are necessarily vastly more numerous than the acceptable modes of functioning. Some of these failures may be familiar, even predictable, but the system may also malfunction in unpredictable ways. Safety is partly achieved by being alert to these perturbations, responding rapidly to keep things on track. Doctors, nurses and managers do this all the time in healthcare, probably to a greater extent than any other industry. But when they succeed, or the system compensates in other ways, these actions are in a sense invisible. Safety is, as is often said, a 'dynamic non-event'. How can one measure something so intangible?

First we must consider some of the core concepts and challenges to measuring and monitoring safety, including how to define safety and whether we should focus on harm, error or the broader context of reliability and quality.

## 1.2   Defining safety

At its simplest, patient safety can be defined as:

> *'The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare.'* [2]

Healthcare is, in many cases at least, inherently hazardous and the definition implicitly acknowledges this. Amelioration of harm in healthcare firstly refers to the need for rapid medical intervention to deal with the immediate crisis, but also to the need to care for injured patients and support the staff involved. We should, however, treat this simple definition as only a starting point for a deeper inquiry. Safety does not just mean avoiding serious injury. Simply trying to avoid damage is not enough; rather we must reduce errors of all kinds and pursue high reliability as an essential component of high quality care. We will see that some theorists, and indeed many practical safety managers, adopt a view where safety is seen more as the ability to anticipate and effectively respond to hazards and difficulties. Successful units and organisations, and individual clinicians, are resilient in the sense that they deal effectively with the constantly changing, but always hazardous, terrain of healthcare.

## 1.3 Safety in the context of quality

Safety cannot be seen in isolation from broader concerns about cost and quality. Of necessity, safety is always only one consideration in a broader endeavour, whether in healthcare or in any other field. As an oil executive expressed it: 'Safety is not our top priority. Getting oil out of the ground is our priority. However, when safety and productivity conflict, then safety takes precedence'.[2] Similarly, in healthcare, the main objective is providing healthcare to large numbers of people at a reasonable cost, but this needs to be done safely.

The relationship between safety and quality of care has been expressed in different ways. Safety is perhaps best seen as one aspect of the broader concern with quality of care, which encompasses efficiency, effectiveness, timeliness and patient experience.[3] Broadly speaking, quality addresses the intended results of the healthcare system. Safety, on the other hand, is concerned with the many ways in which a system can fail to function, which are necessarily vastly more numerous than the acceptable modes of functioning. Some have suggested that there is no important distinction between safety and quality in healthcare. Certainly some indicators, particularly process measures, can equally well be viewed as measures of either quality or safety. However, this does not mean that we should simply view the concept of safety as unnecessary.

What then leads to an issue being badged as a safety issue rather than a quality issue? The most dramatic examples tend to be of rare incidents, such as the death following an injection of vincristine discussed in chapter 6. On an individual level, these are some of the most tragic failures one could imagine. However, at a population level, the harm from, for example, failure to give thrombolytics or to carry out routine investigations may be much greater. Consider this summary of a study of 9,356 patients with suspected angina pectoris:

*'The authors determined the appropriateness of angiography in 9,356 patients with suspected angina pectoris … and measured outcomes at three years. More than half of the patients who had appropriate indications for angiography did not have the procedure. Not undergoing coronary angiography when indicated was associated with a 2.5-fold worse composite outcome (cardiac death, myocardial infarction and acute coronary syndrome).'* [4]

Quality of care was poor for many of these patients; care was not timely or appropriate. Furthermore, poor quality care was associated with harm, not in the sense that it directly caused harm but in the sense that some patients came to harm because of deficiencies in their care. The more general point is that poor quality care and unsafe care are, in this instance at least, one and the same thing.

Brown, Hofer, Johal and colleagues[5] have argued that failures of different kinds will be viewed differently as safety issues or more general quality issues according to the strength of causation and the immediacy of harm. Essentially events that cause definite harm and are clearly related to specific lapses or problems in the process of care are more likely to be described as safety issues. So the injection of a dangerous intravenous drug into the spine is a dramatic and tragic safety issue. Failure to vaccinate is a safety issue if the patient concerned goes on to contract the disease that the vaccination was supposed to prevent. Failure to provide beta blockers after discharge from hospital following a heart attack, however, is less likely to be perceived as a safety issue even if the patient then suffers another heart attack; the reason is not that the failure in care was not important but that the link with the subsequent heart attack is less clear-cut.

In many of these examples there is an underlying failure in the delivery of care that may or may not be linked to harm and, correspondingly, may or may not be viewed as a safety issue. However, when measuring and monitoring safety we cannot and should not attempt to assess whether each instance of poor reliability leads to harm. Care that is not reliably delivered does not always lead to harm; however a prerequisite of a safe system is surely that basic processes are very reliable. It is therefore critical to assess the reliability of care delivery and the systems that support clinicians if we are to assure ourselves that an organisation is safe.

## 1.4 The expanding perimeter of safety: defining what is unacceptable

In the 1950s many complications of healthcare were recognised, at least by some, but they were largely viewed as the inevitable consequences of medical intervention.[6,7] Gradually, certain types of incidents and harm have come to seem both unacceptable and potentially preventable. The clearest example in recent times is healthcare-associated infection, which is no longer viewed as an unfortunate side effect of healthcare. With increased understanding of underlying processes, mechanisms of transmission and methods of prevention, coupled with major public and regulatory pressure, such infections are becoming unacceptable

to both patients and professionals. The list of 'never events' put forward in various countries, such as wrong site surgery or suicide of a patient while in hospital, is similarly a willingness to say that certain types of failure cannot be tolerated.

In the last 10 years, as more types of harm have come to be regarded as preventable, the perimeter of patient safety has expanded. A larger number of harmful events are now regarded as 'unacceptable' and so become issues of safety rather than quality. In addition to infections and 'never events' we could now include, in the English NHS, pressure ulcers, falls, venous thromboembolism and catheters with associated urinary tract infections. The Francis Report into Mid Staffordshire Hospitals NHS Trust again highlighted the areas of malnutrition and dehydration, both major risks to patients and surely now falling into the 'safety' arena rather than the quality one. We should also consider adverse drug reactions in the community that cause admission to hospital, polypharmacy and general harm from over-treatment. All these, in the past, might have been regretted but may now receive greater attention by being viewed under the safety umbrella.

We are also seeing increasing concern with the performance of individual healthcare practitioners. Analyses of safety incidents have, of course, often shown that the cause of such incidents lies more in the wider system than with the unfortunate member of staff most closely associated with the incident. However, some safety problems are due to reckless sub-standard performance, whether wilful or due to sickness or incapacity. Regulation of both organisations and individuals is steadily tightening and all professional organisations are clear that every healthcare professional has a duty to draw attention to a colleague's poor performance. Revalidation of doctors, with an appraisal every five years, is finally being introduced in the English NHS. Blowing the whistle on safety issues is actively encouraged at the highest levels, although many whistle-blowers are still shabbily treated and persecuted for their efforts. All of these developments represent an increasing concern with safety and determination to improve basic standards.

The perimeter of safety is therefore expanding but we should not necessarily regard this as a retrograde step. A long-standing concern with safety in such specialties as anaesthesia and obstetrics is actually a marker of the high standards that these specialties have achieved. Safety here is an aspiration to better care and labelling an issue as a 'safety issue' is a strongly motivational, perhaps emotional, plea that such outcomes cannot and should not be tolerated.

## 1.5 Safety, harm and error

Patient safety is sometimes equated with preventing error. This seems innocent enough, but it is a potentially limiting assumption. There is no question that an understanding of error is fundamental to patient safety; however, there are differences of view as to whether the focus of patient safety research and practice should be on error or on harm. Formulating an objective of a specific programme purely in terms of error reduction makes sense when, for instance, the aim is simply to reduce failures in a clinical process in the reasonable belief that this will increase overall reliability, efficiency and safety. However, when we consider the overall aim of patient safety there are a number of reasons for keeping harm in the forefront of our minds.

The first is very simple. Harm is what patients care most about. We will all put up with errors in our care, to some extent at least, as long as we do not come to harm. Second, consider all the myriad forms of harm that can come from healthcare: complications of surgery, infection from unsafe injections or overcrowded hospitals, adverse drug reactions, overdoses from badly designed infusion pumps and so on. Should we assume that all these are necessarily due to error? If we equate patient safety with error reduction we run the risk of not addressing any form of harm that is either not due to error, or only partly due to error. Third, many errors do not lead to harm and may even be necessary to the learning and maintenance of safety. Surgeons, for example, may make several minor errors during a procedure, none of which really compromise the patient's safety or the final outcome of the operation.[8] Hofer, Kerr and Hayward have pointed out that some errors may be entirely unrelated to harm. They imagine a hypothetical study which reveals errors in the care process in 60% of patients who have a reaction to blood transfusion. This finding should certainly alert us to the possibility that errors are causing harm. However they go on to argue:

*'Now, suppose that in transfusions in which no reaction occurred there was also an error rate of 60%. Can we argue that the errors caused the adverse event? Can we infer that by engineering out the errors, transfusion reactions would be eliminated? It is clear we cannot.'* [9]

This difficulty of linking errors to harm is an example of the more general problem of linking process measures to outcome[10] and is not particular to patient safety. The broader message is that while monitoring error is surely an important facet of safety, we should not assume that errors always lead to harm. We should also remember that the relationship between errors and any harm that does occur may be complex.

## 1.6    Influences on safety

Multiple factors potentially affect the safety and quality of care delivered to patients. Structural factors, in Donabedian's terminology, represent both physical structures (buildings and equipment) but also basic institutional characteristics such as the number and qualifications of staff.[11] These characteristics can be changed, but generally only slowly, and the link between these factors and patient outcomes is not yet well understood. Some structural factors, such as staffing levels and the organisation of intensive care, have been linked to the safety of care.[12–14] Human resource practices, which influence staff morale and working environment, have also been shown to relate to patient outcomes, even including hospital death rates.[15]

These fundamental characteristics of a hospital or other healthcare organisation are mediated by a number of more transient factors, such as morale, motivation and safety culture, which affect staff attitudes and behaviour, which in turn affect the clinical work carried out.[10] Teamwork, individual performance, use of technology, working conditions, and organisational ethos and culture may all be relevant. These are the 'mediating variables' in measurement terms, more easily described as 'influences' or 'contributory factors'. They may only affect care indirectly, but are also potential reflections of the safety of an organisation and its potential to improve care in the future. Looking further ahead at the possibility of deriving measures that are more reflective of the likelihood of harm, we might wish to assess hazard levels, the ability of systems to recover when errors occur and other indices that might reflect overall systems safety.

## 1.7    Safety culture

Safety culture has assumed a considerable importance in patient safety. A good safety culture is certainly an important foundation of a safe organisation, but it can be difficult to say exactly what a safe culture is and still more difficult to measure it effectively or assess its influence. Safety culture is a very broad and somewhat diffuse concept, as this definition, originally cited in a UK Health and Safety Commission report,[16] shows:

*'The safety culture of an organisation is the product of the individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety programmes. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures.'* [2]

A safety culture is therefore founded on the individual attitudes and values of everyone in the organisation. A strong organisational and management commitment is also implied; safety needs to be taken seriously at every level of the organisation. The chief executive needs to provide clear and committed leadership, communicated throughout the organisation, that gives the safety of patients and staff a priority. Cleaners on the wards must be conscious of infection risks, nurses alert for potential equipment problems and drug hazards and managers monitor incident reports.

Safety culture is discussed further in chapters 3 and 9. For now we must note that safety culture has seldom been used as a routine assessment in healthcare and has been mainly used as a research instrument. In healthcare, only a very few studies have shown a link between safety culture and other indices of reliability, safety behaviour or harm. Safety culture is undoubtedly a potentially important index and even predictor of safety performance, but it is far from being the infallible marker of safety that some might claim.

## 1.8    The social context of measurement

Measurement in clinical practice tends to be accepted uncritically as a true reflection of the phenomenon of interest. Blood tests, vital signs and pathology results are all trusted indices, even though their interpretation and meaning for an individual patient may be extremely difficult. However, the definition of the measures is clear and the method of measurement unambiguous. In contrast, measures of safety are, as we have discussed, difficult to define with precision. In addition, even when the measure is apparently reasonably clear-cut, there are multiple influences at work within the process of measurement and collection of data. This is true for many measurement systems, but is well illustrated in a recent study of a major safety intervention.

The reduction of central line infections in the state of Michigan is a landmark study in patient safety.[17] Matching Michigan was a subsequent intervention in the English NHS aiming to replicate the achievements in the USA, although, as it turned out, some British units already had very low infection rates. Mary Dixon-Woods and colleagues studied the data collection process that underpinned the British intervention and evaluation. They found considerable variability in many aspects of the measurement process.

*'Variability was evident within and between ICUs in how they applied inclusion and exclusion criteria for the program, the data collection systems they established, practices in sending blood samples for analysis, microbiological support and laboratory techniques, and procedures for collecting and compiling data on possible infections. Those making decisions about what to report were not making decisions about the same things, nor were they making decisions in the same way. Rather than providing objective and clear criteria, the definitions for classifying infections used were seen as subjective, messy, and admitting the possibility of unfairness. Reported infection rates reflected localized interpretations rather than a standardized dataset across all ICUs.'* [18]

Much of the literature on performance measures suggests that people may wilfully adjust definitions and others aspects in order to produce a better evaluation. In this study, however, it was clear that variability arose not because people were concealing, obscuring or deceiving but because counting was as much a social practice as a technical practice.[18] In some instances units actually adjusted their definitions to show higher rates of infection because they judged the large numbers of low-risk patients they treated to be distorting the true rate of infection.

This study shows very clearly that even when there is an apparent clear event to monitor and measure there will always be local interpretation and adaptation, and that these adaptations are often for very good reason. Some patients with possible central line infections did not appear in the figures because they were rapidly and effectively treated before the precise source of the infection could be identified. Units developed a number of different methods of data collection, each with associated advantages and disadvantages. The differences do not matter a great deal if a consistent approach is adopted over time and each of the units are mainly concerned with monitoring their own performance. These findings should, however, make us cautious about comparisons between units or organisations unless we are very sure that like is being compared with like.

## 1.9   Summary

In this chapter, we have set out some of the conceptual background and sketched some of the challenges we face in attempting to monitor safety in healthcare. In the next chapter we examine the evolution of safety measurement and monitoring in one exemplar health system, the English NHS. We then consider what we can learn from looking at how safety measurement and monitoring has evolved in other safety relevant industries. Next we broaden our understanding further by examining the theoretical background and the implications for measurement of the various models of system safety. We then use these ideas to provide the foundations for a model of safety measurement and monitoring which is developed in Section II.

# *Chapter 2:*
# The development of patient safety and its measurement in the NHS

## 2.1  Introduction

The dangers of healthcare have been long understood. Systematic data collection of the hazards of healthcare can be traced back at least to the time of Florence Nightingale's publications in the 1860s.[2] In this chapter, we outline the evolution of patient safety and trace the development of safety measurement and monitoring, looking at recent experience and current challenges. We use the NHS in England as an example to illustrate the influences and activities at national policy level and hospital or local level. We hope that this report will be useful for healthcare professionals and organisations in many countries. However, our examples and case studies are mainly derived from the English NHS so they form the focus of this chapter, with some reference to other countries and systems as appropriate to the context.

The chapter draws on the knowledge of the research team and from the interviews with key people in a range of national organisations such as the NHS Information Centre and the Department of Health. It also draws on information from our case study hospitals in England and a review of the websites and board papers of a selection of NHS trusts.

## 2.2  Safety in the NHS: 1900–99

The UK saw some remarkable safety initiatives in the last century; the key developments are set out in Table 2.1. Throughout this period there were service failures and investigations, highlighted in the table, followed by new initiatives to prevent similar failures in future. For example, seven public inquiries into service failures in hospitals caring for elderly patients were summarised in a report presented to parliament in 1968. This led to the establishment of the Hospital Advisory Service (HAS) in 1970, the precursor of the current inspection and regulation arrangements and the Care Quality Commission (CQC).[19]

Patient safety in the UK really emerged as a high profile issue in the late 1990s from a wide set of influences. These included: the growth of audit and other quality activities in the 1970s and 1980s; the realisation that clinical problems underlie much litigation; the example of other industries that have focused on safety; psychological research on human error;[20] and the major adverse events review studies in the USA and Australia.[21,22] A series of high profile events also contributed to the heightened importance of patient safety, including the Bristol paediatric cardiac surgery inquiry.[23]

## 2.3  Safety in the NHS 2000–08

In 2000, Chief Medical Officer Sir Liam Donaldson published a highly influential report, *An organisation with a memory (OWAM)*,[24] that paved the way for a national programme of action. The report set out for the first time the annual figures for known reported harm: 400 people known to have died or been seriously injured from events involving medical devices; nearly 10,000 people known to have experienced adverse reactions to drugs; and hospital-acquired infections (HAIs) costing the NHS nearly £1bn per annum. It described the NHS as having an old-fashioned approach to learning lessons when things go wrong and set out a way forward designed to enable the NHS to successfully 'modernise its approach to learning from failure'. Four key areas were identified as 'must do's' to improve patient safety.

–  Unified mechanisms for reporting and analysis when things go wrong.

–  A more open culture in which errors or service failures can be reported and discussed.

–  Mechanisms for ensuring that where lessons are identified the necessary changes are put into practice.

–  A much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.

The publication of OWAM led to the establishment of the National Patient Safety Agency (NPSA) and the national reporting and learning system for patient safety incidents (NRLS). The work to set up and run the NRLS led to each trust developing its incident reporting processes and working to increase incident reporting from staff, especially when the reporting rates by trust were made publicly available. At this stage the measurement and monitoring of patient safety in most NHS organisations focused on incident reporting.[1] Other key events of this period are set out in Table 2.2, again highlighting the service failures that continued to put pressure on the government for further action.

Patient safety featured as the first domain in the national standards for the NHS issued by the government in July 2004, which formed the basis for the inspection and regulation of all healthcare organisations. This helped to bring patient safety onto the agenda of the chairs and chief executives of all healthcare organisations. Looking at trust board papers from 2005/6 the main focus of reporting was on access targets with figures for methicillin-resistant staphylococcus aureus (MRSA) presented to show progress against the national target to reduce rates by a half. A spur to action at board level came from two further hospital 'scandals' involving patient deaths from HAIs, one at Stoke Mandeville Hospital in 2005 and another at Maidstone and Tunbridge Wells in 2007. In both investigations following the outbreaks, hospital managers were severely criticised, particularly for not being aware of the scale of the outbreaks. This led others to realise the importance of infection control data being presented to the boards.

**Table 2.1: Chronology of events related to patient safety in England in the 20th century**

| Year | Development/Event |
| --- | --- |
| 1900 | Concern over high infant mortality, high maternal mortality and a falling birth rate brings maternal and child health into the political arena leading to the 1902 Midwives Act |
| 1928 | Committee established to investigate and report on maternal deaths |
| 1952 | Confidential Enquiry into Maternal Deaths established, later followed by inquiries into peri-operative deaths and into suicides/homicides under mental health services |
| 1963 | Safety in Drugs Committee set up following serious birth defects caused by the drug thalidomide – developed into the current Medicines and Healthcare products Regulatory Authority (MHRA) |
| 1960s –80s | Public inquiries into hospital failures: Ely Hospital; South Ockenden; Farleigh; Napsbury; and Normansfield |
| 1970 | Following the above enquiries the Hospital Advisory Service was set up – now the Care Quality Commission (CQC) |
| 1970s | Growing litigation – clinical risk management develops in hospitals. Office of the Health Service Ombudsman established to learn from complaints |
| 1990s | Inquiries into failures: Alder Hey Hospital; Ashworth Secure Hospital; with new enquiries into doctors – Rodney Ledward and Harold Shipman |
| 1990s | Risk management and incident reporting established in hospitals Litigation increase leads to NHS Litigation Authority and standards for risk management being introduced (Clinical Negligence Scheme for Trusts) Clinical governance introduced as statutory duty for NHS chief executives |
| 1999 | Bristol paediatric cardiac deaths and public inquiry |

**Table 2.2: Chronology of events related to patient safety in England 2000–07**

| Year | Development/Event |
| --- | --- |
| 2000 | Chief Medical Officer Sir Liam Donaldson published *An organisation with a memory* (OWAM).[24] This report set out proposals for improving patient safety in the NHS |
| 2001 | Death of Wayne Jowett from a medication error – high profile investigation and police prosecution |
| 2001 | National Patient Safety Agency (NPSA) set up and the National Reporting and Learning System (NRLS) developed to capture all adverse events reported in the NHS in England and Wales |
| 2001 | Dr Foster Good Hospital Guide published in national newspaper |
| 2001 | Mandatory reporting by hospitals of MRSA; 2009 public access to full data |
| 2002 | National patient and staff surveys start – with questions about patient safety |
| 2004 | Safer Patients Initiative starts in four, then 24, acute hospitals across the UK, working with experts from the Institute for Healthcare Improvement (IHI) in the USA. Aimed at driving system-wide changes to improve patient safety |
| 2004 | Safety is first priority in government national standards for NHS – the basis for inspections by the Healthcare Commission |
| 2004–07 | Healthcare Commission conducts 14 investigations into hospital failures including Northwick Park and Cornwall Partnership Trust |
| 2005 | Stoke Mandeville Hospital failure investigated |
| 2006 | Chief Medical Officer says 'The pace of change is too slow' |
| 2007 | Maidstone and Tunbridge Wells Hospital failure investigated |

## 2.4   Developments since 2008

The next developments in measuring and monitoring patient safety in England came in Lord Darzi's review, *High quality care for all*, issued in June 2008[25] and setting out the government's plans for NHS reform with a focus on driving up standards of quality and safety. Table 2.3 sets out the main developments during this period. This review led to the introduction of a range of indicators measuring mortality, complications and survival rates, and patient perceptions of care to enable clinicians to benchmark and improve their performance. The introduction of a list of reportable 'never events' was also important in signalling that trusts must implement national guidance on how to prevent them, for example site marking and the World Health Organization (WHO) safe surgical checklist to prevent wrong site surgery. Financial incentives were introduced, with a small proportion of trusts' income being conditional on their performance against quality indicators – now called Commissioning for Quality and Innovation (CQUIN). This was in addition to the financial incentives already in place for trusts to reduce their clinical negligence risk.

In 2010 the coalition government issued *Liberating the NHS*,[26] setting out plans to devolve more freedoms to improve services to trusts whilst holding them accountable through the NHS Commissioning Board (NHS CB) for delivering improved outcomes in safety, quality and clinical effectiveness. The NHS CB, supported by the National Institute for Health and Clinical Excellence (NICE) and working with professional and patient groups, is developing a Commissioning Outcomes Framework (COF) that measures the health outcomes and quality of care (including patient-reported outcome measures and patient experience) achieved by clinical commissioning groups. The COF will support the NHS CB to identify the contribution of clinical commissioning groups to achieving the priorities for health improvement in the NHS Outcomes Framework. It will also enable the commissioning groups to benchmark their performance and identify priorities for improvement.

**Table 2.3: Chronology of events related to patient safety in England 2008–12**

| Year | Development/Event |
|------|-------------------|
| 2008 | Health Minister Lord Darzi's review: *High quality care for all.* This led to the introduction of local quality indicators measuring mortality, complications and survival rates as well as patient perceptions to enable clinicians to benchmark and improve their performance. Financial incentives were introduced (CQUIN) and trusts were required to produce annual quality accounts alongside their financial accounts |
| 2009 | National 'Patient Safety First' campaign launched which drew on the learning from the Safer Patients Initiative |
| 2009 | Department of Health issues first list of 'never events' including wrong site surgery – events that must be investigated and reported to external authorities |
| 2010 | The coalition government white paper, *Liberating the NHS*, leads to the development of the NHS Outcomes Framework and a range of work streams nationally on quality, innovation, prevention and productivity (QUIPP) |
| 2010 | NHS Outcomes Framework published with two of the five domains central to patient safety |
| 2010 | Summary hospital mortality indicator developed to measure deaths following admission to hospital including those within 30 days of discharge |
| 2010 | NHS Safety Thermometer set up to provide standard methods of measuring indicators in the Outcomes Framework such as falls with harm, pressure ulcers, venous thromboembolism risk assessment |
| 2011 | Specific Hospital Mortality Indicator developed and published by hospitals |
| 2012 | Public inquiry into deaths in Mid Staffordshire NHS Foundation Trust |

Later in 2010, the NHS Outcomes Framework was published,[27] setting out the areas where the government required improvement over the next five years. The Framework now forms the basis of the quality criteria set by commissioners and paid for under the CQUIN arrangements (see above). It has five domains, two of which are most relevant to patient safety measurement and monitoring. These are domains 1: Preventing people from dying prematurely, and 5: Treating and caring for people in a safe environment and protecting them from avoidable harm. Each domain has an overarching set of indicators to measure progress, with areas for improvement where indicators or measures are being developed. The government's aim is for the NHS to prove that outcomes in the safety domain are improving, which is, to say the least, a considerable challenge.

The NHS 'Safety Thermometer' has been developed to help to measure 'harm-free care' and is seen as the starting point for the development of a more sophisticated system of measurement. The NHS Safety Thermometer measures the proportion of patients who experienced four types of harm, using both prevalence and incidence measures and comparing this to the proportion of patients who received harm-free care over time. The four types of harm measured are pressure ulcers (grades 2, 3 and 4), falls with harm, urinary tract infection in patients with a catheter, and new venous thromboembolism. Organisations can add to the Safety Thermometer dashboard to tailor it to include measures relevant to the local clinical context.

## Quality accounts

Since 2010 each trust has been required to produce quality accounts alongside its financial accounts. These provide an annual review of safety and quality in the trust, covering key national targets and those set by the trust board and through local commissioning. They also include information about the trust's participation in national clinical audits. Trusts have a wide range of information available to them about patient safety (Table 2.4), some of which will be included as public information in the quality accounts.

**Table 2.4: Sources of safety information available locally**

| Internal to the trust | – Dashboards<br>– Risk management papers<br>– Adverse event reports<br>– Complaints<br>– Clinical audits<br>– Cancer peer review reports |
|---|---|
| Publicly available | – Care Quality Commission<br>– Dr Foster Intelligence<br>– NHS Choices<br>– Public websites<br>– Coroners' reports |
| Stakeholders requiring or with information | – Clinical commissioning groups<br>– Primary care<br>– Health overview and scrutiny<br>– Patient groups |

Clinical audit has grown in scope over the last 20 years and there are now an estimated 80–100 national clinical audits taking place, with 35 being mandated for trusts to participate in. Trusts must report their participation and relevant information from the audits in their quality accounts. Data are available publicly about the performance of trusts in a number of these clinical audit reports, for example the national hip fracture database report.[28] Here, a trust can compare its clinical performance with that of other trusts for a range of process and outcome measures.

## 2.5   Information available to the public about safety in hospitals

Safety in many high risk industries is marked by strong external regulation and a considerable amount of publicly available safety information. Healthcare used to be comparatively secretive but this attitude, in England at least, is changing rapidly.

Over the last 10 years, and in particular since the Bristol paediatric cardiac surgery inquiry,[23] there has been an increase in the information made available to the public about the quality of hospital care. Some of this has been driven by the medical profession, notably the paediatric cardiac surgeons. However, other drivers have included politicians, the public (for example through campaigns to reduce infections in hospitals) and also organisations such as Dr Foster Intelligence. While 10 years ago it was unusual for trust boards to have information about the number of pressure ulcers or infections in their hospitals, let alone put it in the public domain, this is now commonplace, with information readily available on trust websites and in board papers.

## Care Quality Commission

The CQC website provides information about trusts' performance against the national standards and against targeted service reviews such as for dignity and nutrition or children's services. These reports contain a wealth of information relating to safety culture, for example the care and welfare of people who use services, meeting patients' nutritional needs, and supporting staff through training and development.

## Patient and staff surveys

Data are available online from the national surveys of staff and patients. These include inpatients, outpatients, maternity services and the staff survey. Each of these contains information about the safety of services. The staff survey contains questions relating to patient safety and from the results over time it is possible to assess views on workload pressures, job-related training opportunities, violence and harassment, and the percentage of staff witnessing potentially harmful errors or near misses.

## Dr Foster Hospital Guide

In 2001 Dr Foster Intelligence published the first Hospital Guide, benchmarking the performance of every hospital trust in England and placing information about mortality rates and other indicators of healthcare quality in the public domain (see later chapters). While there was criticism about the way the data was analysed there was also support for its the publication. For example, *the Guardian* argued that 'the tables demand accountability from consultants; by showing how the surgical death rate in different units differs from the national average, they force hospitals to examine the way they deliver care'.[29]

Since then the Dr Foster Hospital Guide has been published annually with new indicators included each year and with increasing interest from the press and from hospital trusts about what it will say about their hospitals and their doctors. The increase in the public availability of information about the quality and safety of care has undoubtedly led hospital trusts to analyse and question their own data. A wide range of information is now available online about each trust. A typical set of information is available here: www.drfosterhealth.co.uk/hospital-guide/hospital/nhs/Musgrove-Park-Hospital-243.aspx

## Public and patient feedback – websites

There are now a number of websites where patients and families can give feedback about the care they receive in hospital. The NHS Choices website gives an overall rating for the hospital in key areas such as cleanliness, being involved in treatment decisions and being treated with dignity and respect. It also provides a rating as to whether patients would recommend this hospital to a friend. While it may be only be a small minority of patients who use this website to report their views, it does nevertheless provide hospitals with a source of information about local opinion to set alongside other internally generated information. The introduction of the 'friends and family test' by the Department of Health in 2013 aims to increase the response rate to the 'willingness to recommend' question by making it mandatory in acute and maternity care from April 2013, with plans for the rest of the NHS to follow. There are also a number of websites for expectant mothers, mumsnet.com for example. These sites provide a platform for people to express their views on their care and many trusts see this as a source of information about their services, often responding to the comments and asking people to get in touch directly to hear their views.

## Healthcare-acquired infections

In 2001 it became mandatory for trusts to report all cases of MRSA bacteraemia to the Health Protection Agency (HPA). This allowed the incidence of MRSA per 1,000 bed days to be calculated for each organisation. As the NHS learned how to measure and monitor MRSA and C. difficile, and how to reduce their incidence, confidence grew in the information available and in 2009/10 this began to be presented to the public in official statistics by trust.

## Other sources of information available publicly

There are many other sources of information available to trusts and to the public about safety in hospitals. These are often specific to a professional group or to a disease or condition and need to be considered in the light of other available information. For example, the General Medical Council (GMC) conducts an annual survey of doctors in training. Questions cover safety at work and safety culture, for example about the intensity of workload and amount of sleep, and the quality of handovers.

## 2.6  Summary

In this chapter we have described the history and development of patient safety and its measurement and monitoring in the NHS. As can be seen, there has been increasing government focus on measuring and monitoring patient safety over the past 10 years, as respective governments responded to the latest crisis and sought to assure themselves and the public that healthcare is becoming safer. Recent developments are more promising, in being both more systematic and more proactive, with new safety responsibilities set out for NHS organisations in the Outcomes Framework and the Safety Thermometer and with a range of financial incentives to demonstrate improved safety.

A very large number of quality outcomes have been specified but the approach to safety has been much narrower, leaving many areas of safety unexplored. The measurement of harm, so important in the evolution of patient safety, has been almost completely neglected. The assessment of reliability, of both processes and behaviour, which has been so critical in other industries, has also received little attention. The use of softer intelligence for monitoring and anticipation of problems, while much used in day-to-day practice, receives little mention in official policy beyond a general endorsement of the importance of human factors. There is clearly more work to be done before we can begin to answer the question: is healthcare becoming safer?

# *Chapter 3:*
# Learning from safety relevant industries

## 3.1 Introduction

Aviation and other safety relevant industries have been frequently held up as examples for healthcare to emulate because of their ability to achieve safety in the face of high risk and potentially catastrophic loss of life. The parallels between healthcare and other industries can be overstated. However, the measurement and monitoring of safety in both high risk (construction, oil, nuclear and aviation) and industrial (food, manufacturing) settings is potentially extremely informative, both in terms of the measures used and the regulatory context in which they operate.

In this chapter we synthesise and report the findings from a scoping review of the research literature and reports from a range of safety relevant industries. These industries include nuclear power, oil, chemical, aviation, mining, food, manufacturing and transportation. Because the potential scope of the review was extensive, we focused on identifying references and sources that would specifically help healthcare organisations learn from the way other industries measure safety. The review used keyword searches with over 14 terms for 'safety measurement'. The websites of key organisations were included (for example, the UK Health and Safety Executive), enabling us to access technical reports and guidance documents issued by national and state regulators of the various industries.

## 3.2 The evolution of safety measurement in other industries

Safety measurement and monitoring has evolved considerably in safety relevant industries in response to a deepening understanding of the nature of safety and increasing regulatory, public and government pressure. In the 1970s and 1980s these industries realised that measures of injury and incidents needed to be complemented by indices that reflected a more proactive approach to safety. 'Lagging indicators' is the term used in industrial settings to define measures that are made after an incident or event has occurred and which assess different types of outcome. These are the reactive measures of an organisation's or system's safety performance. Examples of lagging indicators include lost time injury rates, incident reporting and incident investigation.

In contrast, leading indicators broadly focus on identifying precursors, conditions, events or measures before an incident or event has occurred and which purportedly predict whether an event will occur.[30] Leading indicators involve forms of active monitoring of key control systems[31] or 'activity' indicators that show if the organisation is taking actions believed to lower risk.[32] The essence of leading indicators is that they are proactive and measure variables that are believed to be indicators or precursors of safety performance so that safety is achieved and maintained.[33,34] Examples of leading indicators are safety management system audits, safety cases, safety culture surveys and safety walk-rounds.

A combination of factors has prompted the evolution from a solely reactive measurement approach to the recognition that safety needs to be managed and measured through the use of a balanced set of reactive and proactive safety measures.[31,35] In other industries, the following factors have influenced the evolution of approaches to measuring safety.

– Reports on major disasters that emphasised the failings of management to protect the health and safety of their workers.[36] For example, the Chernobyl disaster report identified that workers did not comply with the correct procedure in doing their job.[37]

– Increased awareness that lost time injury and accident rates do not predict major disasters.[38,39] Low lost time injury rates may lead to management complacency about safety.[40]

– Loss of public confidence in the safety of an industry. For example, the Three Mile Island disaster led to no loss of life but impacted on public confidence to such an extent that it was the catalyst for improved safety legislation in the US nuclear industry.

– Maturity in understanding that safety measurement should be assessed against design expectations rather than simply satisfying the requirements of the regulator.[41]

The UK Health and Safety Executive (HSE) advocates that organisations should use a toolbox of safety measures combining lagging and leading indicators, giving 'a balanced scorecard approach'.[40] Lagging indicators certainly provide useful high level information but they should not be used as targets against which a manager's performance is assessed.[42] Proactive measures (leading indicators) are more relevant and effective performance indicators as they foster an active engagement in safety which is not entirely dependent on recent past performance.[42] We will now review some of the major indices in use in industrial settings.

## 3.3    Injury and accidents

The most basic, but essential, form of safety measurement is reliably monitoring injury and death. In transport three main statistics are used:

– deaths per billion passenger journeys

– deaths per billion passenger hours

– deaths per billion passenger kilometres.

Such data are used to compare and demonstrate the safety of particular forms of travel. For example, following commercial aircraft disasters, commentators often try to restore public confidence by commenting that 'aviation is the safest form of transport'. However, while this statement has some truth for a particular kind of assessment, it disguises important differences between the different measures.

These indices have to be used with care. Simply comparing different forms of transport according to deaths per billion passenger journeys, for instance, can produce a misleading assessment of risk. A typical flight from Los Angeles to New York will carry a bigger risk factor than a typical car journey from home to office. But a car journey from Los Angeles to New York would not be typical and therefore the associated risk is

greater. It is also important to consider that aeroplanes, buses and trains will carry far more passengers than, for example, a car or bicycle.

Each statistic needs to be used in a proper context and the limitations of making cross-industry comparisons need to be understood. For the example of the risks associated with long-range travel from one city to another, the most suitable statistic is the third one – deaths per billion passenger kilometres. This statistic is therefore often quoted in the context that air travel is the safest form of long-range transportation.

## 3.4    Lost-time injuries

In the 1970s and early 1980s, occupational health and safety (OHS) performance measurement was primarily focused on the negative outcomes of workplace incidents and illness. The most common way to identify these failures was the assessment of 'lost-time injury frequency rates' which measure the number of working hours or days lost through workplace injury and work-related illness.

Lost-time injury (LTI) frequency rates are still used in nuclear, chemical, aviation, rail manufacturing and food industries. Several types of injury statistics have become standard across these industries and required by health and safety legislation. The most common measure, injury frequency rate, is equal to the number of injuries per unit of exposure. There are many different categories of injuries where rates can be calculated: for example, lost-time or disabling injuries, recordable injuries (those required by law to be recorded), medical treatment injuries, and first aid only injuries. Different units of exposure are used as the denominator in calculations of frequency rates. These include worker-hour units of exposure – typically 100,000 worker-hours or 1m worker-hours – and the number of workers exposed or affected.

While monitoring injuries is obviously a necessary component of any serious safety management system there are several reasons for not relying too heavily on measures of injury to reflect the overall safety of a system. The following are some of the more important.

– Under-reporting. An emphasis on injury and ill-health rates as a measure, particularly when related to reward systems, can lead to such events not being reported so as to 'maintain' performance.

– Whether a particular event results in an injury is often a matter of chance, so it will not necessarily reflect whether or not a hazard is under control.

– An organisation can have a low injury rate because of luck or fewer people exposed, rather than because it manages health and safety effectively.

– A low injury rate can lead to complacency.

– LTIs can be used simply as a judgement of safety performance, rather than to understand the contributory factors and root causes behind the injury rate.

– There is not necessarily any relationship between 'occupational' injury statistics (such as slips, trip and falls) and control of major accident hazards (such as loss of containment of flammable or toxic material).

The literature provides examples of companies that have been lulled into a false sense of security about the safety of their operations because of an over-reliance on low lost-time injury (LTI) rate data. For example, British Petroleum's senior management was criticised for placing too much emphasis on its low LTI rate in the report into the Texas City refinery disaster (see Box 3.1).[43] Lack of management understanding that LTI data do not provide an accurate measure of performance of the process has been cited as contributing to this incident.[44,45]

## Time between incident measures

Another widely used safety measure in other industries is graphical representations or signs displaying to the workforce and general public the number of consecutive days since the last incident occurred. Different types of incidents can be represented, for example, time since the last LTI-related incident, slip, fall or maintenance-related incident. This safety metric is commonly used on construction sites and in manufacturing plants, but has also been adapted and used in railway, aviation, oil and gas, and nuclear power industries. On construction sites and in factories, signs can often be seen stating 'it has been X days since the last lost time injury accident'. This provides a visual reminder to the workforce of specific types of incident and how successful the organisation has been in preventing them.

## 3.5 Incident reporting data

Incident reporting is another lagging indicator widely used in other industries to monitor safety performance. However, it is critical to realise that incident reporting in industries of all kinds is used to supplement and complement other more systematic measures of safety.

The literature on incident reporting is extensive and includes information on the benefits of reporting,[46–49] how to design incident reporting systems to maximise the safety lessons learnt,[47–49] the importance of feedback to the reporter,[50,51] and the importance of developing a strong incident reporting culture.[52]

Over the years the aviation, mining, nuclear power, oil and gas production, and rail industries have refined the analysis of incident reporting and investigation data. Typically, incident reporting measures matured from an early focus on presenting high level analyses of the number of incidents reported, type, severity and location, to developing more sophisticated process metrics which aim to assess the quality of the reporting and learning process. For example, in commercial aviation the metrics assessed are:

– percentage of incidents where system causes are identified

– percentage of follow-up actions and learning shared

– percentage of incidents investigated to root causes

– average time from incident to investigation completed

– average time from incident investigation completion to correction

– percentage of investigations that show planning failure

– percentage of accident reviews with leadership participation

– percentage where causes of human error are identified

– percentage of incident reports that are shared with other units.

Measurement of safety in other industries has also evolved to include an assessment of the cost of incidents (Figure 3.1). For example, the UK HSE uses a range of cost-related safety measures to demonstrate to managers that a proactive approach to managing health and safety makes good business sense. Common measures include calculating the costs incurred by a business when an incident occurs that is not covered by liability, third party or buildings insurance. Insurance policies only cover a small proportion of the costs of accidents. Costs not covered by insurance can include sick pay; damage or loss of product and raw materials; repairs to plant and equipment; overtime and temporary labour; production delays; investigation time; fines and potential loss of business reputation and future contracts.

## 3.6 Behavioural based observations and behavioural markers

Many industries use direct observation of performance to proactively monitor safety. In its simplest form the behavioural measurement of safety involves observers using a checklist of task elements (Box 3.2). Targeted behaviours are identified from incident investigation reports, as well as from the opinions of supervisors and workers. The checklist is used by an observer (trained supervisor, evaluator or worker) who visits the work area at a randomly selected time of day and makes observations for approximately half an hour. For each behavioural item on the list, the observer marks 'performed safely', 'performed unsafely' or 'not observed'. This enables a measure to be derived that uses the ratio of the number of items performed safely over the number of items observed.[54,55]

Behavioural observation has several advantages. First, observations can be made frequently (for example, several times a week), which provide data that can be analysed for time trends. Second, there is some evidence that observed behaviour serves as a valid proxy for injuries as a final outcome measure. Evaluations of behavioural interventions have demonstrated that an improvement in behaviours is correlated with a decrease in injury rate. Validation of work-site checklists using injury rates as a criterion has also been achieved.[56,57]

Figure 3.1: Assessing the cost of incidents[53]

Measurement of safety in other industries also includes the evaluation of interventions that aim to improve safety behaviour. Such interventions are called 'behavioural based safety programmes'. Typically, behavioural-based safety interventions involve identifying unsafe versus safe behaviours, setting goals and giving feedback on safety performance which aims to change workers' behaviour.[59]

Behavioural-based safety interventions have been widely used in other industries including manufacturing,[60,61] construction,[59,62] food production,[63] paper mills,[64] shipyard building,[65] sugar cane machinery production and offshore diving.[66]

Measurement of the effectiveness of behavioural-based safety interventions has shown correlations with injury rates, improvements in safety climate and in the use of personal protective equipment.[60] Management commitment is a significant determinant of the outcome of behavioural-based safety interventions.[59,64,67]

## 3.7 Safety culture and safety climate measures

Since 1999 the UK industrial safety regulator, the HSE, has recommended that organisations operating in high risk industries should regularly assess their safety culture.[68] A survey, whether by questionnaire or interview, can only provide an assessment of safety culture at a particular time. For this reason the term 'safety climate' is often used to refer to the findings of assessments of safety culture, the argument being that safety climate is the surface manifestation of safety culture. Safety climate is therefore a snapshot of the state of safety providing an indicator of the underlying safety culture of a work group, plant or organisation.[69]

Safety climate surveys are well embedded as measures of safety culture in industry and have also been translated and applied in healthcare.[70–77] Surveys typically assess workforce perceptions of procedures and behaviours in their work environment that indicate the priority given to safety relative to other organisational goals.[74,78–81] The resulting data offer managers an additional perspective on the state of their safety management systems and can also be used for benchmarking purposes and for analysing trends.

Numerous studies have shown that safety climate survey results are associated with safety-related outcomes such as accidents and injuries,[82] safety performance[83,84] and workers' safety behaviour.[85,86] Safety climate or culture has been associated with employees' safety-related behaviour in industries such as manufacturing,[85,87] shipping,[88] chemical processing[89] and building maintenance.[90] Weigmann and colleagues[91] have found evidence from several studies that safety culture also appears to predict on-the-job injury and accident rates in manufacturing firms,[92,93] offshore oil and gas companies,[73] and also in broad cross-organisational studies of workers in general.[82,94]

Studies of the relationship between positive safety climate and lower accident rates demonstrate that individual employees with a 'positive safety attitude' were less likely to be involved in accidents.[89,94,95] However, to date, few studies have gone beyond correlational evidence to show that safety culture predicts future injury rates or that improving safety culture results in a reduction in injuries.[96]

## 3.8 Safety management systems

High risk and other industries have realised that information about safety is of little use on its own, even when accompanied by analysis and feedback. An organisation-wide approach to safety is required which is usually referred to as a 'safety management system' (SMS) (Box 3.3). This has been defined as 'an organised approach to managing safety, including the necessary organisational structures, accountabilities, policies and procedures'.[41] An SMS combines data from lagging and leading indicators to measure, monitor and manage safety performance on an ongoing basis.[97]

High risk industry regulators and advisory bodies issue industry-specific guidance on how to develop and implement safety management systems. The guidance describes the types of safety indicators that should be measured. For example, in aviation the International Civil Aviation Organisation's *Safety management manual*[41] describes the theoretical background to safety management and how to implement an SMS in a commercial aviation organisation. It includes both reactive measures (safety reviews, audits, incident reporting and investigation) and proactive measures such as prospective risk assessment.

The Railways and Other Guided Transport Systems (Safety) Regulations 2006 (ROGS) came into force in 2006. ROGS provide the regulatory regime for rail safety, including mainline railways, metros and tramways. It is a formal requirement of ROGS that all operators maintain an SMS and hold a safety certificate or authorisation indicating that the SMS has been accepted by the Office of Rail Regulation.[98]

SMS guidance reflects the recognition that without a useful set of metrics, senior managers, supervisors and operators will not be able to identify and measure safety improvements.[99] Furthermore, it is widely understood in other industries (more so than in healthcare) that safety measurement should be targeted at measuring against system design expectations, and that this will lead to more refined safety indicators than measures developed to satisfy the requirements of the regulator.[41]

## 3.9 Safety cases

In some industries, particularly those where there is a possibility of catastrophic outcome, organisations are required to provide evidence of safety before undertaking any hazardous operation. We are now, as most readers will realise, considering a topic barely even discussed in healthcare, where casual innovation and adaptation are the norm, although safety regulations in settings such as radiotherapy or clinical trials are very strict. Risk assessment is also integral to new hospital design, although primarily because of regulation in the construction industry.

A safety case is a 'documented body of evidence that provides a convincing and valid argument that a system is adequately safe for a given application in a given environment'.[100] Safety cases comprise a set of arguments and evidence (both qualitative and quantitative) which substantiate the level of confidence in the safety of a plant or site. Safety cases ideally use prospective and probabilistic risk assessment methods to anticipate 'what could go wrong' with a particular system and to provide evidence that major risks have been identified and suitable control measures put in place.[101]

Safety cases are used by the nuclear, military, rail transport, oil and gas production, and chemical industries to provide the evidence base which demonstrates that a system is designed safely.[100,101] Regulators in these industries require safety cases to be developed prior to new plants being commissioned or going into operation. They are, however, a relatively new concept in other industries. For example, until quite recently safety cases were not formally mandated in aviation. Eurocontrol has now produced a manual to support safety case development in air traffic control[102] and the Civil Aviation Authority has also recently issued guidance on safety case development.[103] Similarly, in the maritime industry safety cases are a relatively new concept and are called 'formal safety assessments'.[104]

Demonstrating the effectiveness of safety cases is difficult because their purpose is to prevent low frequency, high consequence incidents. There is little scientific evidence to support their increasing use, although the key lessons learned from safety cases have been described. The HSE has also experienced a number of difficulties in applying safety cases because the size and complexity of some cases makes it difficult for the regulator to evaluate them.[105]

In healthcare, the potential role of safety cases has been considered in the context of medical device safety. In 2010, the US Food and Drug Administration Agency issued draft guidance on the development of 'assurance cases' for infusion pumps.[106] In the UK regulatory context, both manufacturers of medical devices and

healthcare service providers are regulated and are required to provide some kind of evidence that their products and services are acceptably safe. However, in most cases there is no requirement for a formal safety case for medical devices. The regulatory culture for medical devices in the UK is not one where presenting a reflective argument to demonstrate safety is embedded. The Health Foundation's Safer Clinical Systems programme is currently assessing the potential for wider use of safety cases in healthcare.

## 3.10  Summary

In this chapter we have seen that the measurement and monitoring of safety in other industries has evolved considerably over time to encompass both lagging and leading indicators, to examine several different facets of safety and to use a variety of different methods of assessment and measurement. The specific tools, techniques and methods of other industries may not always transfer easily to healthcare. However, in this chapter we have sought to understand the thinking and principles behind safety measurement in other industries and to use that to inform its evolution in healthcare.

A particularly important reflection from this chapter concerns the approach that other industries have taken to the analysis of incident reporting data, which is considerably more evolved than in healthcare. Other industries have long since realised that incident reporting is complementary to formal measurement and only one part of a much wider enterprise of safety measurement and monitoring.

# *Chapter 4:*
# Approaches to systems safety

## 4.1  Introduction

The wider safety literature offers a number of theories of safety, each with a slightly different focus. In this chapter we review and summarise the various, often rather abstract, models and then consider what this might mean in practice for safety measurement and monitoring in healthcare. While such conceptual models might hold little attraction for many working in healthcare, they are, nevertheless, important sources of new ideas and conceptions of safety that could radically affect the approach taken in practice.

We undertook a review to examine the following questions.

– What is the overall focus and purpose of each conceptual model and how does it account for safety at the system level?

– What are the key concepts or safety-shaping factors identified by each model?

– What are the conceptual implications of the model as an explanation of safety? For example, is the approach proactive/reactive; is safety seen as a process or a state?

– What are the practical implications of the model for measurement and monitoring of system safety? What metrics are suggested; are they leading or lagging indicators; are they tangible and objectively observable?

Here we report the findings from the structured scoping review which synthesised the research and theory relevant to systems safety. Author and keyword searches were performed, along with a review of bibliographic lists to identify relevant publications. The review scoped and summarised the dominant conceptual approaches and models developed to account for safety in complex systems, and drew out the main practical implications for measurement and monitoring of systems safety in healthcare.

## 4.2  The systems approach to safety

The term 'system' is used in many different ways. In this report we use the relatively straightforward sense of 'system safety' used in healthcare, without reference to the wider discipline of systems thinking that permeates systems biology and other disciplines.[107]

To view safety as systemic is simply to acknowledge that it is the result of multiple factors and some process of interaction between those factors. Even without a formal systems model, we can trace the origin of failures or instances of resilience to specific contributory factors. However, with a deeper understanding of systems we can also see that the observed system behaviour can be an aggregation of functioning at lower levels of the system and may also be influenced or constrained by the wider environment. Healthcare organisations are complex systems in both these senses: care is delivered by trained professionals working with medical technologies in complex, multidisciplinary care pathways and in an organisational environment characterised by local operational governance and external regulatory forces.

Many of the models have their origins in systems that are already very safe, which has a marked effect on the concepts used and the factors that are prioritised. Generally, a state of stable operations is envisaged and being safe is simply remaining in this happy state of continuous, trouble-free operation. This does not imply that continuous smooth operation is simple; in practice it will require constant monitoring, adaptation and adjustment.[108] Safety is characterised by nothing untoward happening; it is a 'dynamic non-event'[52] and in a certain sense invisible.

The combination of safety being in a sense invisible and the concurrent need to measure system safety presents profound problems. While major failures and injuries are obvious, system safety is invisible to operators and regulators on a routine, day-to-day basis because

continuous error-free outcomes are the expected norm. It is therefore far from clear how to monitor safety when the system appears to be running smoothly.

However, without accurate, valid and reliable data on the state of safety inherent within a system, we cannot identify vulnerabilities and priorities against which to take corrective action. Furthermore, without a historic record of incidents and their causes, we cannot learn easily from past failures. The challenge of monitoring and regulating system safety is to find a way of quantifying an inherently dynamic property of an organisational system.

## 4.3   Six conceptual approaches

The original theories and frameworks upon which the concepts discussed in this review are based have been described in detail in the original literature. In this chapter we provide an overview of the key features of each concept or theory. The principal original literature sources and relevant empirical literature for each model or approach are cited within the text, together with various articles describing subsequent reviews and developments of each theory. The six approaches, and the names of people who are particularly identified with them, are:

1. Safety as defences in depth (James Reason)

2. Systems safety in healthcare (James Reason and Charles Vincent)

3. High reliability theory and safety (the Berkeley group)

4. Safety as collective mindfulness (Karl Weick and Kathleen Sutcliffe)

5. System dynamics and safety (Rene Amalberti)

6. Safety as resilience (Erik Hollnagel, David Woods and others)

## Safety as defences in depth

James Reason's 'organisational accidents' model is one of the most influential and frequently cited models of systems failure in the modern safety sciences.[20] It has found a receptive audience within healthcare because it seeks to move the analysis of failure away from the accountable (and punishable) individual towards a more systemic understanding of the organisational conditions that provoke human error.[52,109–111]

According to Reason's approach, accidents are caused both by 'active' and 'latent' conditions. Active failures are errors, mistakes and violations committed by human operators at the sharp end of operations, close to the event itself. They are often the triggering event for an incident, but are often themselves the consequences of prior conditions more deeply embedded in the system. These latent conditions (originally referred to as latent failures) result from the decisions of system designers, procedure developers and managerial control over time. These preconditions contribute to systems failure in two ways, as illustrated in Figure 4.1. First, latent organisational and workplace conditions can provoke active errors and violations, for example through understaffing, unworkable procedures or inadequate

**Figure 4.1: Organisational accident model[52]**
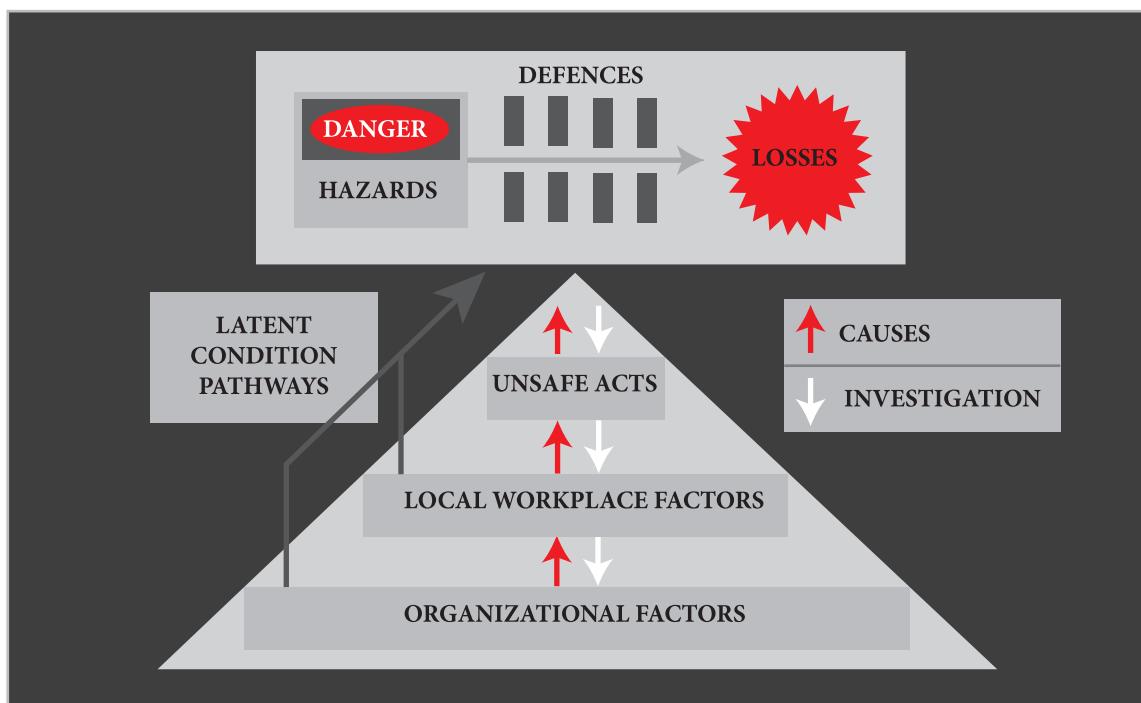
training. Second, they may produce more immediate problems, such as missing equipment, inadequate safety measures, broken alarms and so on.[109] To an extent, latent conditions are always present within a system but may only be revealed once an incident has occurred.

We cannot, in advance of the event, hope to anticipate all the ways in which a condition will combine with others in an accident trajectory. We can speculate and model potential causal trajectories and interactions and even attempt to quantify the likelihood of potential failure from an analysis of past events and incidents. However, we cannot predict with perfect certainty the exact role of specific latent conditions in determining the future safety of the system. Clearly, this makes specification of a set of criteria for proactive monitoring difficult, given that we will never have the resources to assess all possible latent conditions.

Reason and others have taken this general approach from the domain of accident analysis towards the monitoring of system safety. The argument is essentially that, while we cannot specify the precise relationships between latent conditions and likelihood of accidents, we can improve overall safety by monitoring latent conditions and taking action to correct obvious deficiencies and vulnerabilities in the system. Work has been undertaken, for example, to specify safety management systems in the offshore oil exploration and production domain, based on the principles in Reason's framework. The resulting 'Tripod Delta' system was developed in partnership with Shell Oil specifically to focus on measurement and monitoring of what are termed 'general failure types' (GFT), representing latent factors within the system as opposed to incident statistics that represent outcomes.[112] In the Shell Tripod Delta system, 11 GFTs were identified as common to a broad range of operations.[52] These include both technical issues, such as the design of equipment, and wider organisational issues such as the management of maintenance, the proper use of procedures, communication, and incompatible goals, such as conflicts between safety and productivity.

By periodically sampling all GFT items, the system generates a failure state profile indicating the GFTs that are of most cause for concern at any measurement time-point (usually quarterly). Managerial action then involves review of the failure state profiles and proactive actions to improve the worst GFTs, which should improve the general safety health of the organisation over time.

## Systems safety in healthcare

Vincent's framework for the analysis of clinical incidents, commonly known as the London Protocol, builds on Reason's organisational accidents model to provide tangible examples of the various failure types relevant to a healthcare context, drawing on the analysis of specific incidents and the wider healthcare literature (see Figures 4.2 and 4.3).[113,114]

The specific purpose of the London Protocol is to ensure a comprehensive, reflective investigation process for clinical incidents that goes beyond superficial faults or blame to uncover deeper-rooted contributory factors.[115] The London Protocol draws on Reason's organisational accidents model in that it seeks to account for processes that underlie active failures and to explore conditions within the system that may have contributed to the failure. The protocol provides a framework to reflect on an incident in order to identify underlying gaps or inadequacies in the healthcare system. Although applied to a single event, the aim is to identify parameters that are relevant to patient safety across instances and which might therefore pose a risk to future safety. In this sense the protocol is both proactive in its purpose and potentially identifies parameters and metrics for monitoring system safety. The London Protocol acknowledges that holding individuals accountable may sometimes be appropriate, but it additionally fosters a balanced analysis of the whole system in an attempt to support a more open and fair culture within healthcare.[114]

According to the framework of factors influencing clinical practice in healthcare (Figure 4.3), a range of broad classes of environmental, contextual organisational factors and task and team factors may be implicated in a single incident or series. These include factors such as individuals' knowledge and skills; task design; the adequacy of protocols; team communication; organisational culture; administrative and managerial support; specific patient factors concerning the complexity and seriousness of the patient's condition; and the broader regulatory environment in which healthcare organisations operate. The factor types represent the broad spectrum of contributory factors within Reason's model, from active failures close to the event at the sharp end of care to more upstream latent preconditions.

**Figure 4.2: Stages in the development of an organisational accident[52] and an adapted model from Vincent *et al*[114] supporting the London Protocol**
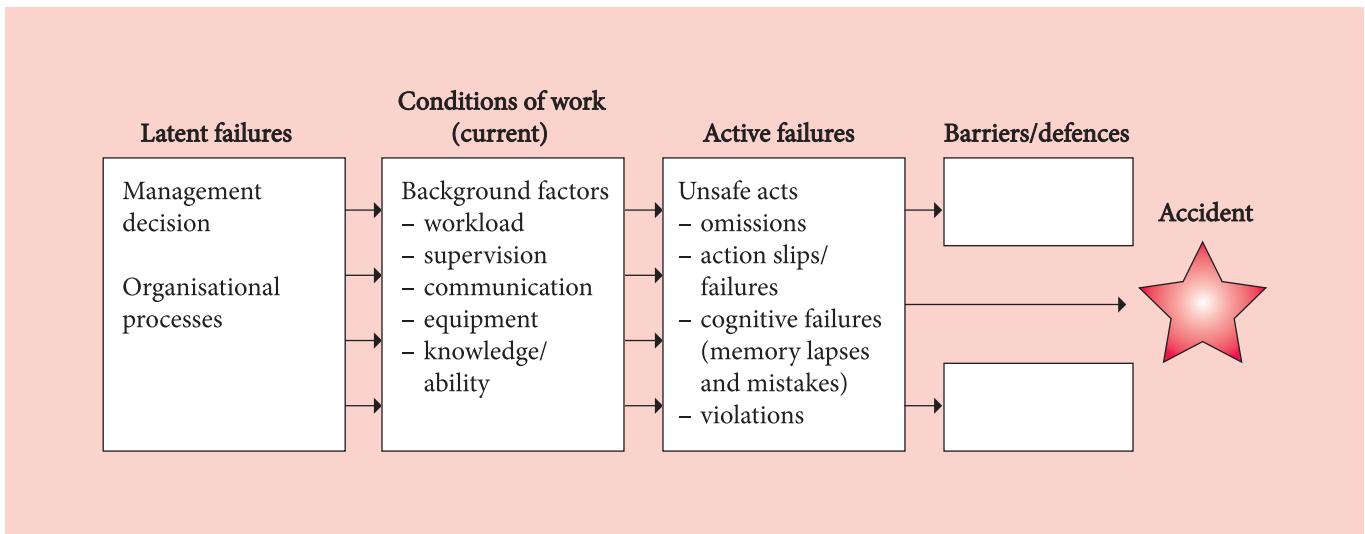


**Figure 4.3: Framework of factors influencing clinical practice[113,114]**

| Factor types | Influencing contributory factors | Examples |
|---|---|---|
| Institutional context | Economic and regulatory context; national health service executive; clinical negligence scheme for trusts | Inconsistent policies, funding problems |
| Organisational and management factors | Financial resources and constraints; organisational structure; policy standards and goals; safety culture and priorities | Lacking senior management procedure for risk reduction |
| Work environment factors | Staffing levels and skills mix; workload and shift patterns; design, availability, and maintenance of equipment; administrative and managerial support | High workload, inadequate staffing or limited access to essential equipment |
| Team factors | Verbal communication; written communication; supervision and seeking help; team structure (consistency, leadership, etc) | Poor communication between staff |
| Individual (staff) factors | Knowledge and skills; competence; physical and mental health | Lack of knowledge or experience of specific staff |
| Task factors | Task design and clarity of structure; availability and use of protocols; availability and accuracy of test results | Non-availability of test results or protocols |
| Patient factors | Condition (complexity and seriousness); language and communication; personality and social factors | Distressed patient or language problem |

# High reliability theory and safety

The study of 'high reliability organisations' (HROs) has its origins in organisational sociology. The theory was developed at the University of California Berkeley in the 1980s by a group of researchers studying safety in high hazard domains.[116] They focused on three HROs in particular: US naval aircraft carrier operations, air traffic control and nuclear power. These systems were chosen because of their comparatively excellent safety record and low failure rate. The work aimed to investigate how organisations could achieve consistent, failure-free performance over prolonged periods of time in the face of variable and demanding conditions.[117] Meeting such challenges requires high levels of accountability, strong basic procedures, multiple redundant checks, rapid feedback for control decisions and high levels of communication between the operators (Box 4.1).

System redundancy is strongly emphasised as a means of safe operation in hazardous environments.[120] During critical operations, for example, multiple checks and observations by different individuals ensure that dangerous conditions are detected rapidly. HROs also engage in varied training and simulation activities for a broad range of operational scenarios in order to prepare for crises. Despite a strong emphasis on protocol and procedure, when dangerous conditions are observed personnel of all levels of seniority have the authority to immediately influence the course of operations without seeking authorisation. During routine operations, HROs tend to have strong hierarchies and make extensive use of standard procedures. However, at times of threat or higher-tempo performance hierarchical and centralised authority may be devolved to experienced front-line operators.[117] Reliability is achieved not by standardisation per se, but by the organisation successfully adapting to the challenge it is facing. The ability to recognise the situational demands and promptly switch control modes is the key safety-delivering factor.

Given the promise of high reliability theory for continuous, failure-free healthcare provision, it is no surprise that the healthcare industry and patient safety community have embraced its main tenets as a framework for safety development. Several authors have addressed the topic of high reliability in healthcare delivery teams,

of one type or another, as the basic functional unit within the healthcare system and as the healthcare equivalent of the high reliability organisation.[121–124]

The literature on HROs, subsequent to the original empirical investigations of the Berkeley group, is almost entirely conceptual with very few formal studies or testing of the original ideas and observations. The potential safety or reliability-shaping factors that have been proposed, such as those associated with organisational culture and collective knowledge, are often quite abstract. These tenets of HRO theory tend to lack the low-level, concrete/tangible specification that would facilitate empirical observation and measurement. The field has remained largely descriptive with few subsequent attempts to measure the characteristics of HROs or relate them to safety outcomes.[125]

## Safety as collective mindfulness

One of the most influential reformulations of the high reliability literature is that of Karl Weick and Kathleen Sutcliffe, who recast the original findings within a single broad framework of 'collective mindfulness'.[126,127] According to Weick and Sutcliffe's definition, mindfulness is:

*'… the combination of ongoing scrutiny of existing expectations, continuous refinement and differentiation of expectations based on newer experience, willingness and capability to invent new expectations that make sense of unprecedented events, a more nuanced appreciation of context and ways to deal with it, and identification of new dimensions of context that improve foresight and current functioning.'* [126]

Mindfulness is characterised by a continuous effort to update routines, procedures, perceptions, expectations and actions based on experience and foresight. Five key processes produce mindfulness in HROs.

1. Preoccupation with failure.

2. Reluctance to simplify interpretations.

3. Sensitivity to operations.

4. Commitment to resilience.

5. Deference to expertise.

The first three processes allow organisations to anticipate and become aware of the unexpected, while the final two provide the means for containing the unexpected.

| | |
|---|---|
| **Box 4.2: Processes of collective mindfulness in organisations**[126] | |

Weick and Sutcliffe's five processes of collective mindfulness in organisations: illustrations of behavioural definitions of each process.

| | |
|---|---|
| 1) Preoccupation with failure | • Reviews of events happen frequently and quickly following their occurrence.<br><br>• Near misses and small anomalies are investigated and elaborated on to promote learning.<br><br>• Reporting is encouraged through a culture that rewards those that report and reflect on errors and mistakes.<br><br>• An open team-working climate exists in which individuals can actively monitor and question others' actions and interpretations. |
| 2) Reluctance to simplify interpretations | • Avoidance of simplified interpretations of the current situation that may ignore data concerning accumulating anomalies.<br><br>• HROs make few assumptions regarding the current state of the system and encourage people to actively seek clarification.<br><br>• Diverse perspectives are brought together through multidisciplinary collaboration and team working.<br><br>• A culture in which mutual respect and trust are maintained in order to ensure that interactions and collaborations are successful. |
| 3) Sensitivity to operations | • Maintaining an understanding of the system's current overall situation, operational status and projected future status.<br><br>• Operators actively seek out information regarding the state of the system through integration and extrapolation of information.<br><br>• Real-time, up-to-date information is made available on how critical actions are progressing and their consequences.<br><br>• Frequent operations meetings; widely disseminated up-to-the minute information that permits early identification of problems. |
| 4) Commitment to resilience | • Detection and containment of errors at early stages through anticipation but intelligent monitoring, improvisation and recovery.<br><br>• Responding to unexpected disturbances to gain rapid real-time learning and feedback on the effectiveness of their responses.<br><br>• Rapid and accurate communication processes along with experience in varied operational scenarios.<br><br>• Training through simulated scenarios that allow people to practice recovery, improvisation and response to variation. |
| 5) Deference to expertise | • In high-demand situations, operational autonomy and decision authority can be delegated to front-line experts.<br><br>• Front-line operators are capable of assuming a high degree of responsibility for operational control at specific times.<br><br>• Supervisory oversight allows delegation of responsibility but also the assumption of control by successively higher levels should the situation deteriorate.<br><br>• Operators are willing to enlist help when they reach the limits of their knowledge but also to interrupt operations if they determine a safety risk. |

## Systems dynamics and safety

In the next two sections we review two approaches that embrace a more dynamic systems view of safety and reliability. Both see reliability as a process of compensation and response to dynamic variation, rather than a simple state or set of properties. An influential model within the safety sciences domain is proposed by Rene Amalberti and depicts the dynamic pressures that cause a system to migrate towards the boundaries of safe operations over time (Figure 4.4).[128,129]

The model suggests that many accidents are caused more by violations of rules and standards rather than unintended errors. Violations are described as deliberate deviations from standard instructions. Levels of non-compliance tend to vary according to the type of instruction, the nature of the work, and the social and organisational context, being influenced by both individual motivation and wider social and organisational processes. Violations may not be deliberate in the sense of being planned and intended but the individuals concerned will be generally aware that they are cutting corners and not conscientiously following safety rules.

The model is particularly important for healthcare because rules tend to be less binding and less explicit than in other high hazard industries. Despite the fact that many guidelines and policies exist, these are often viewed as recommendations rather than strictly enforced rules. For example, the busy healthcare professional may not follow procedures in a strict and logical manner but instead may choose the pathway that appears to be most useful and productive at the time. If this approach does not result in censure or other untoward consequences then the individual may continue to deviate from the original procedure in pursuit of increased performance and productivity. This kind of movement can result in a gradual shift to the boundary of safety until a negative outcome occurs and forces a return to a stricter adherence to the rules and standards.

Amalberti's model was developed through experience of research and development in safety management across a number of high risk domains. A major strength is that it combines a dynamic systems view of safety and risk with a psychological appreciation of the behavioural drivers underlying violations.[129] At the social level, deviations may become normalised and from then

**Figure 4.4: Amalberti's model of system migration and transgressions in practice[128,129]**
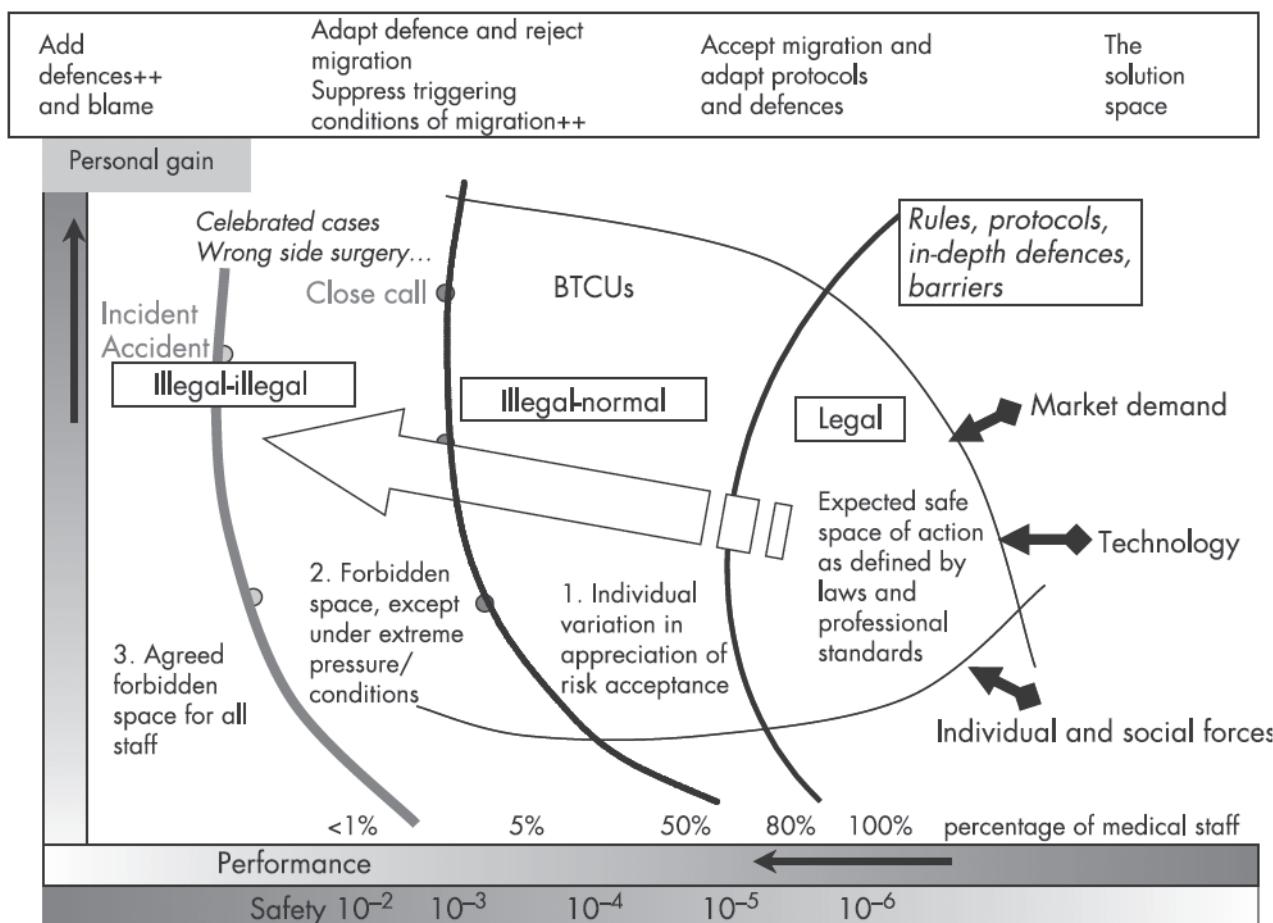
on accepted as routine, if provoked by consistent and persistent conditions over time. A limited number of empirical studies[130] have examined these ideas but assessment of the validity of the model in formal studies presents considerable challenges.

## Safety as resilience

A similar philosophy to that underpinning the study of HROs underlies the development of 'resilience' and 'resilience engineering'.[131] Resilience refers to the ability of individuals, teams and organisations to continually recognise, adapt to and absorb variations, disturbances, disruptions and surprises in order to maintain safe functioning.[131] Resilience engineering has been described as focusing on proactive resilient strategies, as opposed to reactive defences and barriers, and therefore supposedly not reliant upon hindsight and analysis of past failures. Resilience is therefore a dynamic property of a sociotechnical system and explanations of resilience in organisational systems have been sought using system dynamics models.[132,133]

Hollnagel employs the concepts of 'safety 1' and 'safety 2' in order to distinguish the resilience engineering approach from existing approaches in healthcare and other industries.[134] Safety 1 focuses firmly upon what can go wrong and how to prevent it from going wrong. It involves investigation and management to reduce incidents and harmful outcomes and is essentially retrospectively focused. Reducing harmful outcomes is also the aim of safety 2, but the focus of safety 2 is on 'what goes right' and specifically the ability of the system to correct for expected and unexpected variations – that is, to display resilience.

Resilience is perhaps most clearly shown at the team level in healthcare, echoing the critical role of teamwork in maintaining safety described in chapter 1. Collaborative cross-checking, for instance, may be an indicator of resilience as it represents a team's ability to detect and mitigate errors before harmful consequences occur.[135] There have also been proposals to measure 'institutional resilience' using checklists of behavioural indicators and traits. Carthey *et al* drew upon Reason's[52] concepts of commitment, competence and cognisance to define a checklist of factors representing facets of institutional resilience within healthcare. Regardless of how resilience is conceptualised, a strong requirement is placed on the adequacy of monitoring and information feedback systems in healthcare organisations if the system is to detect and anticipate potentially harmful variations in time to take mitigating action.[136]

Resilient safety management depends on the ability of managers and operators to detect and anticipate dynamic vulnerabilities within the system and develop strategies for meeting these challenges.[131] Effective information systems for monitoring and analysing variations are therefore an integral component in the development of resilient systems. The resilience approach is contrasted with an approach that relies on counting errors and intervening to try to reduce error rates. In contrast, resilience shows itself by the absence of errors and an organisation's investment in continuous anticipation of the dynamic potential for failure. The capability of an organisation to generate this foresight and act before failure or harm occurs may thus be one measure of resilience.

The concept of 'resilience' shares many aims with that of 'high reliability' theory and we may perhaps be forgiven for asking, 'what's new?'. The contribution of resilience theory is, at the very least, to galvanise the evolution of safety science after the systems movement into a cohesive approach and agenda, using a rich and plausible narrative that integrates a broad range of systems dynamics theory and accident causation models. The promise of this approach is that the developers of future safety management systems may build on current safety 1 capabilities by drawing on safety 2 principles. It remains to be seen to what extent these theoretical developments might be validated in empirical studies and to what extent they will prove useful in practice.

## 4.4    Synthesis of conceptual contributions to monitoring systems safety

The principal features of the various models and their implications for safety measurement and monitoring are summarised in Table 4.1. Each model is assessed according to its potential for guiding measurement and monitoring in healthcare.

The column headings are:

- **Conceptual approach** – the overall conceptual approach

- **Parent theory** – the specific theory (one of the six described above) – description and indicators

- **Safety shaping factors** – these are the particular factors that the theory in question holds to be particularly important in maintaining safety

- **Type of indicators implied and proximity to safety event** – this column indicates whether the safety factors are leading or lagging indicators of safety and how closely they are linked to routine operations and safety events

- **Level of analysis** – at what level of the organisation does this factor have its effects? The implication is that this is the appropriate level of the system at which to define specific metrics for monitoring

- **Tangibility** – how abstract or generic a concept is and how easily specifiable in objectively observable terms. This criterion is a somewhat subjective judgement but gives an indication of how difficult the measure might be to operationalise and use in practice.

**Table 4.1: Safety shaping factors**

| Conceptual approach | Parent theory | Safety shaping factor (or class of factors) | Type of indicators implied and proximity to safety event | Level of analysis | Tangibility |
|---|---|---|---|---|---|
| Systems approach to safety | Safety as defences in depth against organisational accidents | Redundancy and adequacy of defences in depth[52] | Lead indicators; adequacy of safeguards | Multiple but tends towards sharp-end | Moderate/high |
| | | General failure types[52] | Latent, upstream, leading indicators | Reported at organisational level | High (domain specific) |
| | | Organisational factors[52] | Focus on latent factors upstream of active failures | Organisational level reporting system | Moderate (socio-technical system) |
| | Safety as systemic in healthcare | Safety culture (multiple authors) | A lead indicator presumed to influence operational behaviour | Organisational or sub-unit level | Moderate/low |
| | | Factors influencing clinical practice | Includes both latent and active failure types. Lead indicators. | All levels | High (domain specific) |
| High reliability theory and safety | Safety as 'high reliability' | Characteristics of high reliability organisations[116] | Lead indicators presumed to deliver reliability | System level (organisation) | Moderate/low |
| | | Normal accidents[137] | High level, upstream factors | System level | Low/intangible |
| | | Characteristics of high reliability teams[123] | Lead indicators; team behaviour | Team level | Moderate |
| | | High reliability team working practices[138] | Lead indicators; team climate | Team level | Moderate/low |
| | Safety as collective mindfulness | Collective mindfulness[126] | Lead indicators | Organisational | Low |

| Conceptual approach | Parent theory | Safety shaping factor (or class of factors) | Type of indicators implied and proximity to safety event | Level of analysis | Tangibility |
|---|---|---|---|---|---|
| Systems dynamics and safety | Safety as resilience | Factors contributing to system resilience[131,134] | Highly proactive; lead indicators | Multiple levels of the system; orientation towards strategic safety management | Low; focus is on systems dynamics |
| | Safety as resistance to system migration | Factors influencing operator violations and system migration[129] | Mainly lead indicators (system migration is an outcome) | Multiple levels from individual psychology to organisational behaviour | Moderate/low; focus on behaviour and systems dynamics |

## 4.5 The implications for monitoring system safety in healthcare

The range of models and approaches currently considered by most people working in healthcare is quite narrow, certainly compared with those working in the safety sciences or in safety management in other industries. These various conceptual approaches provide a rich foundation for development of better safety monitoring systems in healthcare and elsewhere. While the models do provide a general indication of the approach that should be taken (for instance a strong focus on leading indicators) the majority are not underpinned by specific empirical studies and do not have very clear implications for measurement. These developments in safety science theory may therefore represent an advance in our understanding of systems failure from a theoretical stance, but not necessarily in terms of our ability to derive tangible criteria for metrics.

Conceptual approaches may suggest criteria that are not immediately or obviously objectively measurable. Many of the problems associated with conceptual models of safety, reliability and resilience concern underlying or latent properties that are less familiar in medicine but widely encountered in the social sciences. Developments in psychometrics can still guide our investigation of the reliability and validity of such concepts. Multivariate techniques from the social sciences, such as factor analysis, allow empirical investigation of underlying concepts. Similarly, statistical techniques to examine the multilevel structure of nested systems have long been used in educational research in the form of multilevel or hierarchical linear modelling.

The appropriate set of indicators will vary depending on dynamic local conditions and contextual threats. Effective monitoring of system safety is delivered through engineering an information system that recognises the dynamic nature of system safety and that resilience emerges through a delicate balance between multiple factors at any single point in time. Understandably, this poses a huge challenge for the development of safety management systems to support optimal control in the interests of maintaining this hard-won resilience.

## 4.6 Summary

Recent thinking in the safety sciences towards a theory of resilience affords us the possibility of understanding how healthcare organisations continuously adapt, in the face of dynamic risks to patient safety, to maintain failure-free performance the majority of the time. The lessons of dynamic systems theory suggest that we cannot necessarily prescriptively define the safety shaping factors that will be relevant in the future. We may, however, be able to step back a level and monitor the system's capacity to identify and resolve risk. This approach might involve monitoring process metrics such as: data input to the safety monitoring system, rate of safety issue detection, frequency of completed remedial actions, cycle time for safety issue case closure, rated effectiveness of safety issue actions.

For many practical (and other) reasons, counting and analysing accidents and failures is both compelling and necessary. However, much of healthcare is not in the happy position of experiencing near fault-free operations and it is arguable that it would therefore be premature to import models of safety derived from industries that are already very safe. Clearly, though, the focus of safety management is moving to complement this reactive perspective with a more proactive one. The richness of conceptual approaches to the problem, summarised in this report, must therefore serve as a challenge to the established and dominant reliance on incident reporting and root cause analysis, as it exists within healthcare.

# Chapter 5:
# A framework for safety measurement and monitoring

## 5.1 Approaches to patient safety

The first section of the report has provided us with essential background to safety measurement and monitoring. We now pose a fundamental question. What exactly do we want to know when we ask whether a healthcare organisation is safe? The organisation in question might be a general practice, a ward or department, an entire hospital or health system. Anyone who has ever listened to a board, a clinical meeting or a group of any kind discuss this question will know that many different views will be advanced and defended with passion, if not always with clarity. One reason these discussions are so difficult is that the underlying question has a number of different facets, which are not always clearly distinguished. Let us try to disentangle the various perspectives. We can distinguish a number of different questions.

## Has patient care been safe in the past?

We might look back to past records of infection rates, surgical complications, evidence of delayed or missed diagnosis, examining trends over months or years. If these rates are stable or on a downward trend, we might infer that this is a safe organisation. However, our information may not be complete. For example, we might not know if care is equally safe in all wards and departments or if the measures available adequately reflect care across the organisation. In addition, past performance is not a guarantee of future safety.

We also need to consider the safety of staff as well as patients. Staff too face biological, chemical and radiological hazards as well as the risk of certain kinds of physical injury that we may also wish to monitor. There are also some risks to their psychological wellbeing, particularly if they work for an organisation with little concern for its staff.

## Are our clinical systems and processes reliable?

We have described how poor reliability can create the conditions for unsafe care. Across an organisation, reliable delivery of care to agreed standards is a fundamental requirement for safety. This reliability certainly extends to basic clinical processes such as hand hygiene, the timely administration of antibiotics before operations, the timely ordering of diagnostic tests and many other fundamental processes. It also applies to the clinical systems supporting the delivery of care, such as ensuring clinicians have all the information they need about a patient in order to make a decision about care or that they have the correct medical equipment available and functioning correctly.

## Is care safe today?

This is a very different kind of question. We might have been safe in the past but safety can erode very easily. What kind of information would tell us whether we are safe now? We certainly need to examine relatively stable features of the organisation, such as its staffing, standards and guidelines. However, we might also want to examine more transient features, such as staff attitudes and behaviour, which can change, for better or worse, relatively rapidly. In addition to this, as every clinician and manager knows, problems and crises that potentially threaten safety occur on a daily or even hourly basis, such as a sudden influx of very sick patients, staff sickness or equipment breakdowns. Here the question is not so much what is in place, but what capacity the organisation has to respond.

We might also want to ask whether patients and families believe the organisation to be safe. When patients ask 'Am I safe?' they draw to some extent on their knowledge of the organisation and available public information. However, ultimately they may consider a rather more pointed question: 'Do I feel safe?'

The experience of safety probably depends very much on their moment-to-moment experience of care. Safety may be conveyed more by the manner of the staff, the care they take, their concern for checking details, and their empathy and compassion.

## Will care be safe in the future?

This question cannot of course be answered with certainty. Nevertheless it is important to ask the question because it draws our attention to other facets of safety that are relevant to both the present and the future. There are ways of considering and assessing future risk and of making an organisation more resilient. We might want to look ahead to identify threats to safety, which may come from any quarter, and consider the organisation's capacity to respond to longer-term threats and problems. How resilient is the organisation and how able is it to learn, adapt and respond to the inevitable challenges?

## Are we responding and improving?

An organisation may be well aware that some patients are harmed and that reliability is not all it should be. However, for patients, the response to that knowledge is all-important, both for the patient who may have been harmed and subsequent patients who may or may not suffer similar injuries. A safe organisation is surely one that, while acknowledging problems, is responsive to them and learns from them so that other patients may be safe in the future. Integrating safety information from across the organisation and having a means of reflecting and learning is absolutely critical. This would include effectively learning from past incidents that identified vulnerabilities in the system and then taking action to correct those problems, knowing that these actions have indeed improved safety and have not introduced new risks.

## 5.2    Five dimensions of safety measurement and monitoring

Asking whether an organisation is safe leads us to a number of questions that address these different facets of safety. These in turn have led us to reflect on what kind of information we would ideally need to give us a comprehensive and rounded picture of the organisation's safety. We can group these into five broad classes.

1. **Past harm**: this encompasses both psychological and physical measures
2. **Reliability**: this encompasses measures of behaviour and systems
3. **Sensitivity to operations**: the information and capacity to monitor safety on an hourly or daily basis
4. **Anticipation and preparedness**: the ability to anticipate, and be prepared for, problems
5. **Integration and learning**: the ability to respond to, and improve from, safety information

We believe that this framework encompasses the principal facets of safety revealed in the preceding chapters but also provides a simplicity and clarity with which to guide and inform safety measurement and monitoring. The next five chapters develop these themes further and provide practical examples of safety measurement and monitoring in practice.

# Section II: Dimensions of safety measurement and monitoring

## Chapter 6:

# Has patient care been safe in the past? The measurement of harm

## 6.1    Introduction

Patient safety initially focused on rarer, often tragic, events. However, as safety was more systematically studied it became clear that the frequency of error and harm were much greater than previously realised and that the safety of all patients needed to be addressed. Patient safety now involved much more than the prevention of such tragic but rare events. We needed to address healthcare-acquired infection (HAI), adverse drug events, complications and harm from falls and pressure ulcers, together with a host of other rare and less predictable incidents. If we want to assess harm from healthcare then we have to consider all these kinds of events.

Drawing on the extensive knowledge and experience of the authors, in this section we consider a typology of harm, looking at the different ways that harm can be defined. We then move on to look at the different ways harm can be measured and monitored, providing examples from our case studies of how this is being put into practice.

## 6.2    What do we mean by harm?

Patients receive treatment for their injuries or diseases with a view to recovering and receiving certain benefits. When we assess the quality of care we are attempting to specify how far these benefits have been obtained. We are also concerned with understanding the gap between the care that should have been provided and the care that was actually provided. Making such assessments poses a number of technical and logistical challenges. However, we are at least dealing with a reasonably narrow set of intended outcomes. Treatments are aimed at a particular disease and the desired outcomes in terms of recovery of function, quality of life and normalisation of biological parameters can be specified.

The assessment of safety, however, presents a massive additional challenge. Clinical quality outcomes can be specified but it is not possible to specify safety outcomes in the same way. The reason is simple. There are relatively few ways in which things can go right but innumerable ways in which things can go wrong and, by the same token, many different ways in which patients can be harmed. We are therefore attempting to measure a universe of possibilities that can only be partly specified in advance. This is difficult.

## 6.3    A typology of patient harm

If we want to measure incidents, errors or harm we need to first classify the kinds of harm we are concerned with and then provide definitions of specific harms. We propose the following broad system of classification of types of harm to individual patients from healthcare.

### Treatment-specific harm

By this we refer to harm that may result from specific treatments or the management of a particular disease. This would include adverse drug reactions, surgical complications, wrong site surgery and the adverse effects of chemotherapy, with varying causes and degrees of preventability in any specific case. Within these we can distinguish known complications of treatment, such as a post-operative stroke after an episode of hypertension during surgery, and events such as death from a spinal injection of vincristine which, while treatment-specific, is clearly not an inherent risk of the treatment.

### Harm due to over-treatment

Patients may also be harmed from being given too much treatment, either through error (for instance a drug overdose) or from well intended but excessive intervention. For example, the overuse of antibiotics

may lead to C. difficile infection; excessive use of sedatives increases the risk of falls; dying patients both young and old may receive treatments that are painful and of no benefit to them. Those most vulnerable to this type of harm tend to be older people with multiple conditions being treated simultaneously. Polypharmacy and the consequent drug interactions are a major hazard, in that the benefits received from multiple treatments can be outweighed by the risks and adverse consequences.

## General harm from healthcare

While some types of harm result from treatments given for specific diseases, others reflect more general risks. Hospital-acquired infections, falls, delirium and dehydration are examples of problems that can affect any patient with a serious illness. We should recognise of course that some patients, such as older patients or those in intensive care, are more likely to sustain these harms than others and that certain diseases render patients more liable to fall, sustain infections and so on.

Some of these events are relatively rare and hard to detect in measurement systems. Harm from wrong identification, allergic reaction, reactions to transfusions or from equipment malfunction is sufficiently common to be known but too infrequent to monitor routinely. We are only able to assess these less frequent forms of harm indirectly through patient reports, complaints, or reporting systems, particularly specialised reporting systems such as that for blood transfusion reactions.[139]

## Harm due to failure to provide appropriate treatment

We know that many patients, perhaps the majority, fail to receive standard evidence-based care and that for some this means their disease progresses more rapidly than it might. Examples include failure to provide rapid thrombolytic treatment for stroke, failure to provide rapid and effective treatment for myocardial infarction, and failure to give prophylactic antibiotics before surgery. These problems can of course be seen as poor quality care, rather than as a safety issue, but the outcome for the patient at least may well represent avoidable harm.

## Harm resulting from delayed or inadequate diagnosis

Some harm results because the patient's illness is either not recognised or is diagnosed incorrectly. For example, a patient may delay contacting their doctor for months after noticing rectal bleeding, delaying a cancer diagnosis. Alternatively, they may be misdiagnosed by their primary care physician, who fails to refer them.

In either case the cancer advances and the outcome is probably poorer. This type of harm has not necessarily been traditionally considered within the realm of patient safety, unless in the context of a glaring diagnostic error, but to the patient it is clearly a form of harm.

## Psychological harm and feeling unsafe

Adverse outcomes in healthcare commonly have a psychological impact as well as a physical one and both patients and staff may be affected. More serious events may induce a range of psychological consequences. For example, recent work on shared decision making has highlighted the psychological effects on women who developed clinical depression following a mastectomy for breast cancer. Establishing patient values and preferences before procedures are carried out is critical to later adjustment.[140] Awareness of unsafe care may have consequences for the wider population if it leads to a loss of trust. For instance, people may be unwilling to have vaccinations, give blood, donate organs or receive transfusions.

## 6.4    Defining measures of harm

The measurement of harmful events in other industries was discussed in chapter 3. In healthcare we would ideally like to have a general index of safety, rather like rates of road or rail accidents, so that we could track progress over time and ask more sophisticated questions about the safety of different parts of the system and the factors that increased or degraded safety. We can see, however, that in healthcare the situation is rather more complicated as we are dealing with many different types of harm. We are very unlikely to find a single measure, or even a small number of measures, that provides an accurate reflection of the overall level of harm. Studies that assess 'adverse events' certainly provide us with a general indication of the scale of the problem but we will probably need to specify the types of harm more precisely to achieve accurate measurement.

Measures of all kinds need to be both valid and reliable. The technical issues of validity and reliability are complex, subject to considerable debate and a full exposition is well beyond the scope of this report. The concepts are nevertheless important in guiding us to questions we should ask when confronted by any measure.

Validity refers to the extent to which a concept or measurement is well founded and corresponds accurately to the real world. We might, for instance, ask whether 'adverse event' is a meaningful measure of overall harm. When we consider formal tests, such as measures of safety culture, we would ask whether the measure actually assesses what it is intended to measure.

Do the items on the scale reflect our understanding of safety culture? Do the findings from studies of safety culture support the idea that this is a useful measure?

Reliability is a rather different concept. Reliability is a reflection of how well a measure provides consistent results in different circumstances. A particularly important issue in the assessment of adverse events is whether two different reviewers of a set of case notes would come to the same conclusion about the presence or absence of an adverse event.

In addition to the technical requirements of measures of any kind, the measurement of safety in healthcare presents a number of additional problems which are well summarised by Peter Pronovost and colleagues:

*'A prime challenge in measuring safety is clarifying indicators that can be validly measured as rates. Most safety parameters are difficult or impossible to capture in the form of valid rates for several reasons: (1) events are uncommon (serious medication errors) or rare (wrong-site surgical procedure); (2) few have standardized definitions; (3) surveillance systems generally rely on self-reporting; (4) denominators (the populations at risk) are largely unknown; and (5) the time period for exposure (patient day or device day) is unspecified. All of these may introduce bias. Creating measurement systems that are relatively free of such bias would be costly and complex.'* [141]

The choice of denominator has a huge influence on our assessment of how safe or how dangerous a process appears to be. This warrants further commentary and several authors, including Pronovost *et al*, have discussed the issue:

*'Deciding on the best denominator is an added dilemma in the error rate equation. In general, the denominator should quantify exposure to risk for the outcome of interest. For example, when a patient who is hospitalized experiences a narcotic overdose, is the appropriate denominator the patient or patient day, the prescribed*

*or dispensed doses, all administered medication doses, or all administered narcotic doses?'* [141]

We can see that the choice of denominator makes an enormous difference to the error rate and to the interpretation of the standard of care. Supposing a patient is given 10 different drug doses per day, stays in hospital for 10 days and sustains one adverse drug event from an overdose. This could be seen as an adverse drug event of 1%, being one event in 100 doses – certainly serious but perhaps not too alarming. However, calculate by the day and the rate is 10%, and by the admission the rate is 100%. Suddenly what looks like a technical issue for statisticians takes on new life.

The guiding principle of this short section is that we should never take any measure at face value. We must always interrogate it to consider its meaning and what it truly reflects about the safety of care. We must pay particular attention to the reliability of the data source and the denominators. This does not guarantee that the measure will be valid and useful but it will reduce the chance of misinterpretation.

## 6.5    Approaches to the measurement of harm

Healthcare organisations and researchers have taken a number of different approaches to measuring harm, using different methods and exploiting different data sources. Some, such as mortality, focus on a very specific issue. Others, such as record review, attempt to cover a very broad range of possible types of harm. None of the measures available can claim to reflect all the kinds of harm discussed above and it is important to realise that they focus on different issues. An organisation may have low levels of mortality but a high rate of adverse events overall, or vice versa. The utility of each measure, and indeed their validity, is still being explored.

We have grouped the available measures in four broad types: mortality statistics, methods that rely on record review, methods that rely on staff reporting, and the use of routine databases. We will review these in turn, considering their main strengths and limitations and providing examples of their application.

## 6.6    Mortality statistics

Since 2001 hospital standardised mortality rates (HSMR) in England have been made public in the Dr Foster Hospital Guide (see chapter 2). Trusts now have available a range of mortality statistics, including a one-year and three-year figure and for specific conditions such as fractured neck of femur and abdominal aortic

aneurisms, all available for comparison with peer hospitals. These figures are all risk-adjusted for age, the underlying seriousness of the patient's disease(s), the social and economic context, and other factors known to affect the likelihood of death.

More recently a new indicator has been developed – the summary hospital mortality indicator (SHMI). This combines data from the Office for National Statistics (ONS) death registrations linked to Hospital Episode Statistics data in order to capture deaths that occur outside hospitals within 30 days of discharge. Funnel plots are produced to summarise the findings (see Figure 6.1) that indicate which hospitals can be considered as outliers, having either unusually high or unusually low mortality.

Outcomes are determined by a combination of the patient's underlying condition and the care they actually receive. Any kind of outcome indicator is only a very indirect reflection of the safety and quality of care provided. A death in hospital can simply mean the arrival of a terminally ill person who died shortly after admission. Even when terminally ill patients are excluded and risk adjustments carried out, comparisons of institutions on such indicators can be problematic. Differences may still reflect differences in patient populations as well as other factors such as data quality and random variation.[142]

Some authors have been particularly critical of the use of mortality statistics as an indicator of hospital performance. For example, Lilford *et al* have commented that we must be cautious about using mortality data for performance management purposes:

'*… measurement of outcomes for research purposes is useful to help organisations detect trends and to spot extreme outliers but league tables of outcomes are not a valid instrument for day-to-day performance management by external agencies. That is to say, sanction and reward should not be applied to the 'worst' 5% of providers on outcome, because these will not be the 5% with the worst quality.*'[10]

Most commentators, however, would acknowledge that unexpected rise in mortality might indicate underlying clinical problems and should be investigated; this is the most appropriate use of this kind of data. In mental health, one of the important indicators is that of suicides and unexpected deaths of people who have recently been in contact with mental health services.

**Figure 6.1: Examples of funnel plots used to summarise SHMI data, with control limits**
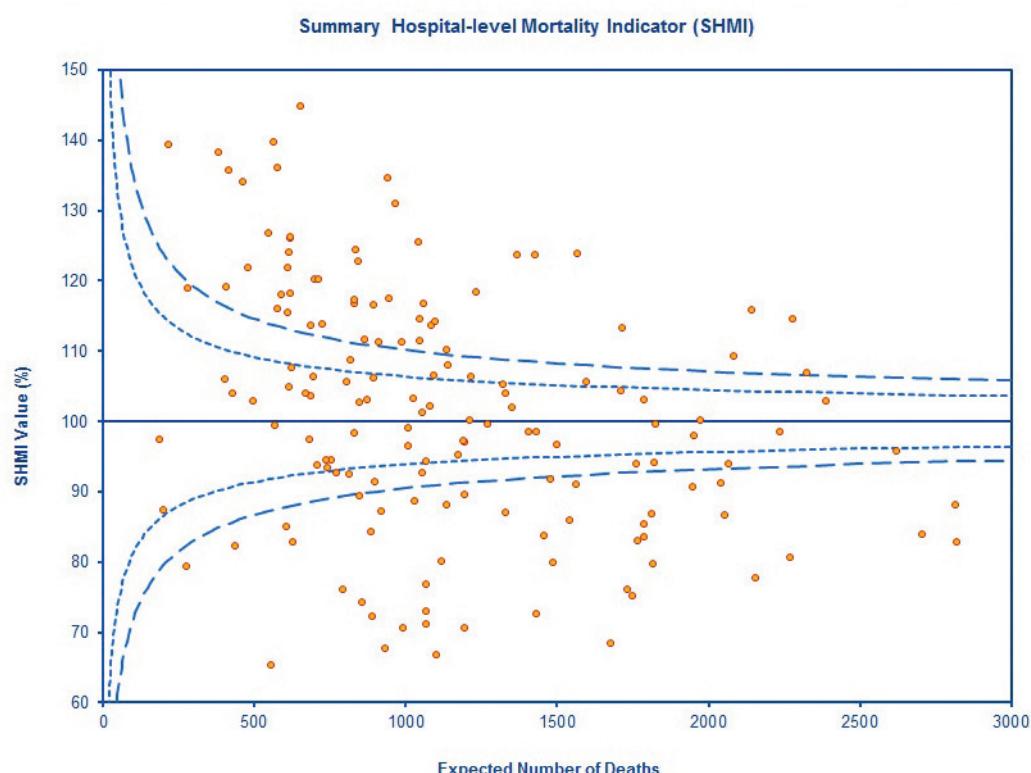
In our case study site in Avon and Wiltshire this figure is reviewed regularly and lessons are learnt from coroners' reports and other case reviews. The monitoring and reflection on mortality statistics is of considerable importance. The important point to bear in mind is that an increase in mortality on its own does not necessarily imply declining clinical standards. It is a warning and a sign that further investigation is needed.

Issues of case mix adjustment matter much less if a unit or institution simply wishes to track its own progress over time and use the mortality or morbidity data as a stimulus and measure of improvement. If one makes the reasonable assumption that the patient population is relatively stable over time, then an organisation can certainly use mortality or morbidity data as an indicator.[142] Any change does reflect, albeit imperfectly, an improvement or deterioration in safety and quality, although it may be difficult to link specific changes in clinical practice with changes in mortality.

## 6.7    Systematic record review

Patient safety is underpinned by large-scale studies of adverse events that have all used case record review as the methodology for detecting adverse events. This is a two-stage process in which notes are first scanned, usually by nurses, for a list of indicators that might suggest adverse events. Notes with indicators, such as readmission to intensive care, are then forwarded for specialist review to assess the presence or absence of an adverse event. Case note review is sometimes viewed as time consuming and comparatively expensive. Nevertheless, with experience and refinement, and the development of training packages,[143] it can be carried out relatively inexpensively and produce systematic, detailed analyses. Some organisations carry out formal, annual case note reviews and use these as the basis of their quality assurance and improvement systems. Record reviews could be repeated over time, and trends studied, particularly as it would then be possible to define and monitor specific types of adverse events rather than just assess the overall rates. Reliability and validity of judgement of adverse events is not as good as we would wish and could certainly be improved if specific definitions of particular classes of adverse events were developed.

### Selective case note review

Many trusts now review the notes of all patients who have died while in their care. This may be for all deaths or for a subset, such as excluding patients who were receiving palliative care. For example, in one of our case study sites, Aneurin Bevan Health Board (ABHB), case note review is used systematically to review all deaths. This is conducted by senior doctors with themes drawn out and presented at organisational level. The Health Board has a 'learning committee' that reviews all the lessons from the review of deaths, the 'global trigger tool' (see below) reviews and from other sources to plan improvements.

With the publication of the Specific Hospital Mortality Indicator (SHMI) showing deaths within 30 days of discharge from hospital there is further work to be done to develop methods for case note review involving both hospital and primary care.

### The 'global trigger tool'

Another class of instrument is sometimes put forward as a measure of safety, namely 'trigger tools'. Essentially, medical records are screened, by a clinician or sometimes electronically, for certain triggers which might indicate that an adverse event has occurred. These might include a return to the operating theatre, a death in hospital or more specifically a low platelet count or the need for renal replacement therapy. Trigger tools can certainly be useful in providing a 'panoramic view of safety'[141] to flag up worrying trends and areas.

It is not currently clear whether the trigger tool can be used as a measure of adverse events or whether it reveals the same adverse events as the original case record review. Some recent studies have certainly used the method in determining adverse events, though they have been clear about going beyond triggers to a full determination of the occurrence of an adverse event.[144] The trigger tool, like any other method, can be misused. Some of our case study sites commented on the tendency for case note reviewers to confuse triggers with adverse events or for trusts to carry out analyses of triggers and present these in annual quality accounts. So where hospitals claim, 'we achieved a 50% reduction in adverse events', in some cases they mean that there were 50% fewer triggers, which is not quite the same thing. Triggers are clues that an adverse event may or may not have occurred, not adverse events themselves. They are certainly useful as a screen, but the subtle shift towards using triggers as measures is a little disquieting.

Our case study sites have implemented the global trigger tool (GTT) and made a proper distinction between triggers and adverse events. The ABHB uses the GTT, selecting and assessing a random sample of 20 notes per month in each of its two large acute hospitals. The notes are assessed by a regular team of trained auditors who are senior nurses and pharmacists. A doctor reviews those notes where harm is identified. The aim of this work is 'to establish the GTT as a measure of patient harm and reduce adverse events per 1,000 patient days to 10 by June 2013'.

Great Ormond Street Hospital (GOSH) uses the 'paediatric trigger tool' (PTT) to review the medical records of a sample of 20 patients each month to identify any events that resulted in harm or had the potential to cause harm. After analysing the PTT data, the trust realised that the tool most frequently identifies 'minor harm'. Trends from the PTT reviews are triangulated alongside other sources of data; this has led to increased attention being paid to reducing healthcare-associated pressure ulcers, which emerged as a recurrent theme in the trigger tool reviews.

## 6.8 Reporting systems

Reporting systems in healthcare were originally intended to provide a means of both measuring and learning from adverse events and other safety issues. We discuss the potential for learning from these systems in chapters 2, 3 and 10. Our focus in this chapter is on a narrower question: 'Can we use reporting systems to produce a reliable measure of adverse events?'

A number of studies have now compared the findings from reporting systems with assessments of harm to patients using systematic case record review.[145–147] As an example, we will consider the study by Sari *et al*, who carried out a classic case record review and compared the findings with locally reported incidents. Results showed that the routine reporting system implemented in this large hospital missed most patient safety incidents that were identified by case note review and detected only 5% of those incidents that resulted in patient harm.[146] From this and other studies we know that incident reporting systems are very poor at detecting adverse events.[148] Other studies have reported slightly better findings, but most studies have found that reporting systems only detect 7–15% of adverse events.[147]

### Targeted incident reporting

Several organisations use prospective or targeted incident reporting, often for a defined period, to address a known safety issue. For example, in some primary care practices there are set weeks when every adverse event is recorded. From this, staff may be asked to report specific issues such as missing test results on a targeted basis for the following month. In one hospital when incidents appear ad hoc but staff report otherwise then targeted reporting is used. For example, when a number of incidents were reported relating to sterile trays in theatres, for a set period staff were asked to report every incident where there were problems with these trays.

### Mandatory reporting of 'never events'

Some safety events are rare but have tragic consequences, for example, deaths from injecting intravenous drugs into the spinal cord. These are the most prominent, most disturbing safety events that correspond most closely to the 'accidents' of other domains. These events are captured in the list of 28 'never events' drawn up by the National Quality Forum in 2004 and since adopted by many organisations as a safety target (see Box 6.1). We will never be able to systematically measure never events and hopefully will not need to. Identification of these rare but terrible events will always have to rely on reporting, at least until reliable ways of searching electronic medical records emerge.

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**Box 6.1: Examples of NHS never events list 2012/13**

Surgical

- Wrong site or wrong implant surgery
- Retained foreign object post operation

Medication events

- Wrongly prepared high-risk injectable medication
- Maladministration of potassium-containing solutions
- Wrong route administration of chemotherapy
- Intravenous administration of epidural medication
- Inappropriate administration of daily oral methotrexate

Mental health

- Suicide using non-collapsible rails
- Escape of a transferred prisoner

General healthcare

- Falls from unrestricted windows
- Transfusion of ABO-incompatible blood components
- Misplaced naso- or oro-gastric tubes
- Misidentification of patients

Maternity

- Maternal death due to post-partum haemorrhage after elective Caesarean section

Full definitions of never events can be found at: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132352.pdf

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The impact of defining some kinds of serious incident as never events is currently not clear, but certainly represents a shift from a learning perspective to one of governance and accountability. This has the undoubted benefit of giving safety a very high priority within organisations, but may also have the unintended effect of restricting the focus to a narrow range of safety issues. Never events also mark a new and rather stronger statement of minimum safety standards in healthcare that may, in the long run, prove the more important development.

## 6.9    Safety indicators from existing data sources

The requirements in the NHS to monitor and report on a wide variety of different indicators can be time consuming. Staff can be burdened with excessive form filling and multiple submissions of the same data to different outside organisations. One potential solution is to make more effective use of the huge and comprehensive administrative databases that healthcare systems have to monitor basic activity, financial and clinical information. In the past, British clinicians have tended to distrust this information, claiming that the coding is carried out by people who, though trained, do not have the clinical understanding to always code correctly. Recent comparisons between clinical and administrative databases, such as the UK Health Episode Statistics, have suggested that the routine databases may be more comprehensive.[149] Here we look at the ways that more routine data can be used to derive indicators of safety.

### Using routine data

A number of important quality indicator programmes have been established around the world, with hospitals signing up on a voluntary basis to share information, benchmark their performance against their peers and learn from each other. In the USA, the Agency for Healthcare Research and Quality (AHRQ) has led the way in establishing core sets of indicators, backed by substantial research programmes, that can be used nationwide. There are three sets of indicators: prevention quality indicators, inpatient hospital indicators and, most recently (released in 2004), patient safety indicators.

The patient safety indicators were developed with exemplary thoroughness and due attention to a number of key issues affecting their validity and usefulness. It is critical to appreciate that the indicators do not necessarily indicate unsafe care and still less specific errors; the clinician panels rated only severe transfusion reaction and retained foreign body as very likely to be due to error. While this is important for individual cases, it is less critical when aggregating data over time. Any organisation would like to reduce these events and once they are monitored programmes can be put in place to reduce them and the programmes themselves can be evaluated.

Groups around the world have adapted the AHRQ patient safety indicators for use in their own systems. Raleigh and colleagues have recently reported that in both the USA and Britain indicators are associated with an increased length of stay. For example, post-operative infections have been found to lead to an average additional 10 days in hospital, painful for the patient and expensive for the organisation.[150] Paul Aylin and colleagues have translated the indicators for use with English administrative data and tracked the indicators over time for the NHS.[1]

In the obstetrics unit in North Bristol NHS Foundation Trust the clinicians have developed a dashboard of indicators of the quality and safety of care delivered to women and babies. When considering what indicators were most important they conducted a review of the literature and available guidance, finding over 300 indicators in use with 39 different definitions for one indicator. The unit's team has reduced the list to 12 core indicators.

In the UK, another of our case study sites, GOSH, is taking an innovative approach to using safety indicators by developing composite measures of harm. The need to be able to interpret and monitor different sources of information on the same topic, such as infections, has led GOSH to create composite indicators such as for serious patient harm and for infection rates over time. The combined infection safety index comprises a composite rate of a number of HAIs which are adjusted for patient activity levels.

## 6.10 Reflections on the measurement of harm

We began by considering the diversity of the harm that can befall patients within the healthcare system. Most patients are vulnerable to some degree to infections, adverse drug events, falls, and the complications of surgery and other treatments. Patients who are older, frailer or have several conditions may experience the adverse effects of over-treatment, polypharmacy and other problems such as delirium, dehydration or malnutrition. In addition, patients may also suffer harm from rare and perhaps unforeseeable events, stemming from new treatments, new equipment or rare combinations of problems that could not easily have been foreseen. Above all, it is clear that none of the measures we have discussed are able to encompass all possible sources of harm and all should be regarded as useful, but partial, assessments of the underlying broad issue of harm.

We also know, from the discussions in earlier chapters, that the measurement of harm does not equate to the measurement of safety. Some have even sought to play down the assessment of harm as a distraction from the proactive effort to define and build safer systems. We believe, in contrast, that the measurement of harm remains a critical foundation of safety and that we need to devise more specific and more nuanced measures of harm that can be tracked over time and clearly demonstrate that healthcare is becoming safer. We do, however, need to look beyond the measurement of harm if we are to provide a more rounded approach to safety measurement and monitoring: indeed, this is the subject of the next four chapters.

# Chapter 7:

# Are our clinical systems and processes reliable? Reliability of clinical systems, processes and behaviour

## 7.1 Introduction

Reliability has been a focus of safety conscious industries such as aviation and nuclear power for many years with impressive results. Although not sufficient to ensure safety, reliability is an essential foundation. Reliability contributes to safety, but is concerned only with the probability of occurrence of a failure, not with the severity or otherwise of its consequences.

Reliability has improved in many industries to the extent that we now assume our microwave oven and mobile phone will work every time we use them, that our car will always start and the brakes will always work. The area in which airlines may not be seen as reliable is in handling our luggage; here the worst performer in a recent online report was said to have lost 28 items for every 1,000 passengers; reliability was seen as poor at 97.2%. In healthcare the situation is very different and it is well established that many systems have poor reliability. Some studies have found reliability as low as 50% in delivering recommended evidenced-based care for clinical conditions. Different patient characteristics may explain some variation but it might reasonably be expected that the routine processes that support clinical care, such as ensuring relevant information is available to doctors in clinics, will have high reliability.

We should note here that we are not concerned in this chapter with the characteristics of so called 'high reliability organisations' discussed in chapter 4 but rather with how to measure and monitor basic reliability in healthcare. The terminology of HROs is unfortunately very confusing. These 'high reliability' characteristics are actually mostly concerned with adaptability and flexible response to hazards. In fact these organisations are also reliable in the simple sense of having many standardised processes which function in a fault-free manner.[125]

In this chapter we draw on the authors' previous research and the findings from the scoping reviews reported earlier, together with our case studies, to consider the reliability of clinical systems, processes and behaviours in healthcare.

## 7.2 Reliability and migration to the boundaries of safety

In any systems there are pressures for greater productivity, less use of resources and occasions where missing or broken equipment forces adaptations and short cuts; add to this that we are all, occasionally or frequently, in a rush to get home, get on to the next case, tired or stressed and apt to stray over the edge. These occasional lapses can become more tolerated over time and systems can move, in Rene Amalberti's wonderful phrase, to the 'illegal normal' phase of operations (see chapter 4). This exactly captures the day-to-day running of many systems where, as we have seen, deviations from procedure are widespread but give rise to no particular alarm. The concept of routine violations is not part of the thinking of managers and regulators; in truth it is a very uncomfortable realisation that much of the time systems, whether healthcare, transport or industry, operate in an 'illegal normal' zone. The system continues in this state because the violations have considerable benefits, both for the individuals concerned and for managers who may tolerate or even encourage them, in the drive to meet productivity standards.

Over time these violations can become more frequent and more severe so that the whole system 'migrates' to the boundaries of safety. The same violations may be committed as in the second phase, but these are now routine and so common as to be almost invisible to both workers and managers. The organisation has now become accustomed to operating at the margins of safety. At this stage, any further deviance may easily result in patient harm, and is generally counted as negligent or reckless conduct.

## 7.3 Defining reliability in healthcare

In disciplines such as engineering or software design, reliability is commonly defined as: 'the probability of a component, or system, functioning correctly over a given period of time under a given set of operating conditions'.[151]

In this context, 'functioning correctly' refers to functioning according to a given specification. Reliability is usually expressed in terms of failure rate per hour for systems operating in continuous mode, or probability of failure on demand for demand-based systems. In a healthcare context, the US Institute for Healthcare Improvement (IHI) similarly defines reliability as 'failure-free operation over time'.[152] Electronic and software systems possess a clear specification and their reliability is assessed against this specification in terms of defined inputs and outputs.

In healthcare systems, or indeed in other complex systems, it can be more complicated to define with precision what 'functioning correctly' means. The most important reason for this is that the reliability can only be strictly assessed against a precisely defined, and thus standardised, process. This in turn relates to the process under consideration and the degree to which it can be component processes that are relatively standardised and clearly defined.

Protocols and guidelines for clinical care come in various forms but all are, to some degree, an attempt to specify and standardise treatment for a particular condition, such as the management of acute asthma in emergency departments or the management of diabetes in primary care.[153] Previously derided by some as 'cookbook medicine' they are increasingly both accepted and embedded in formal decision support systems, care pathways and in national frameworks and targets. In these situations the protocol provides guidance, but there is an expectation that the standard procedures may always be modified according to the clinician's judgement and the patient's preferences. There will always be occasions when guidelines cannot or should not be followed; for example, patients with multiple conditions and problems cannot easily be treated according to strict guidelines, or the patient themself may simply decide against a particular course of action.

So reliability is not an appropriate concept to apply to the entirety of a patient's treatment. Some variation is to be expected and indeed embraced if it enhances the outcome or is preferred by the patient. Additionally, some variation, for instance in the manner in which patients are identified, may be adapted to personal style and circumstances without compromising the basic identification process. However, much flexibility in healthcare stems not from necessary adaptation but from unnecessary, casual and inappropriate departure from good clinical practice. Basic clinical processes that underpin reliable care may be simply inefficient and thus unreliable. In addition staff may simply not follow essential basic procedures that can and should be performed in a standardised manner. Monitoring of vital signs, hand washing, risk assessment for thromboembolism and certain aspects of handover would all fall into this category. For these specific processes, assessing reliability is entirely appropriate and necessary.

In summary, the concept of reliability can be applied most meaningfully to those aspects of healthcare systems that are characterised by a higher degree of agreement and standardisation. Here we consider two broad areas:

– reliability of clinical systems

– reliability of human behaviour.

## 7.4 Reliability of clinical systems in the NHS

Given the complexity of healthcare it is difficult to assess the size and pervasiveness of the problem of low reliability and its impact on clinical systems. Some processes, such as the administration of radiotherapy, operate to industrial standards and very high levels of reliability. Other processes, however, are haphazard to say the least. Burnett and colleagues[154] studied four clinical systems in the NHS: clinical information in surgical outpatient clinics, prescribing for hospital inpatients, equipment in theatres, and insertion of peripheral intravenous lines. They examined the reliability of these systems and explored the systems factors involved where failures occurred. Seven UK hospital organisations were involved in the research with each system studied in three of these. Reliability was defined as 100% fault-free operation if, for example, all patients had the required information available at the time of their appointment.

Reliability was found to be between 81% and 87% for the systems studied, with significant variation between organisations for some systems (see Figure 7.1). Put another way, the clinical systems therefore failed on 13-19% of occasions. In each case where measured, about 20% of reliability failures were associated with a potential risk of harm. These levels of reliability strongly suggest not just inefficient systems but systems where the underlying processes are inadequately specified and where roles and responsibilities of clinical staff are ambiguous and ill defined.

**Figure 7.1: Comparisons of reliability across topics and organisations**
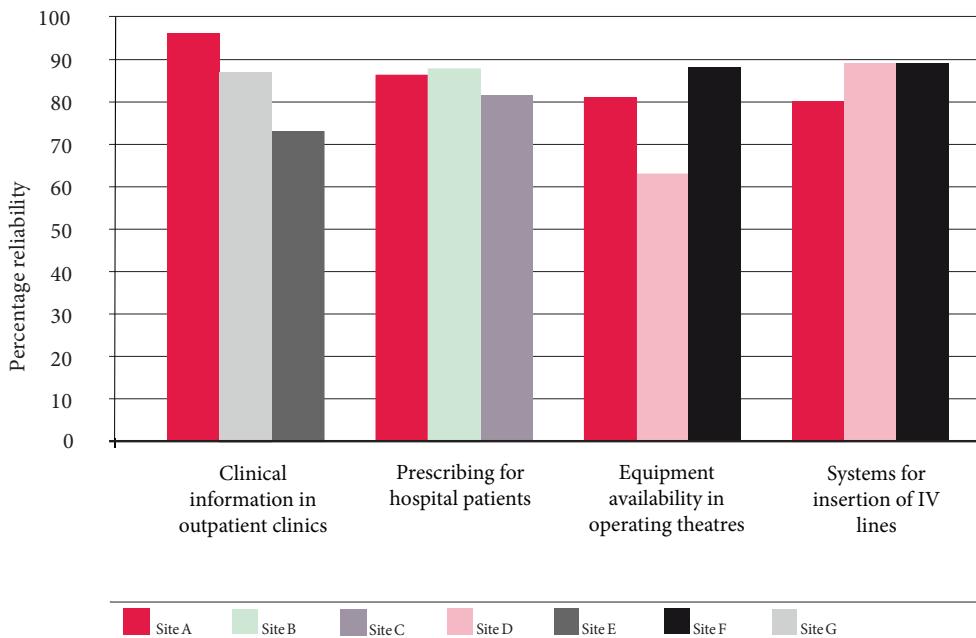


Assuming such levels of reliability are typical in a UK hospital means:

– doctors dealing with missing clinical information for three in every 20 outpatients seen

– missing or faulty equipment in one of seven operations performed

– time wasted by nurses and pharmacists correcting problems and searching for records or equipment for four or five patients every day on a typical 30-bedded ward.

On this basis it is hardly surprising that patient safety is routinely compromised in NHS hospitals and that clinical staff come to accept poor reliability as part of everyday life.

When asked to record how cases of poor reliability were dealt with, in some cases staff described the workarounds they had developed, for example obtaining information from patients rather than their health records or using disposable gloves as tourniquets, for which the risks could not directly be assessed. In some cases, risks were taken such as making clinical decisions without information and transferring used sharps to sharps bins in remote locations. These workarounds are an example of 'first order problem solving', which is essentially adapting one's work to cope with the basic inefficiencies of the system.[155] Clinical staff are extremely adept at this but it can inhibit more fundamental organisational change. This is covered in more detail in a later section in this chapter.

Common factors causing poor reliability were found across systems (see Box 7.1 below). Other factors were common to more than one system including stock

control, handwriting and the management of 'outlier' patients on remote wards. This would suggest that improving common system factors in organisations could have a bigger impact on patient safety than current approaches focusing on individual areas of risk. More important perhaps is the need to develop a culture of challenge so that poor reliability and the associated potential for patient harm are no longer accepted by staff as part of normal everyday work.

**Box 7.1: Factors contributing to poor reliability[154]**

- Staff accept poor reliability as normal, thus not reporting or challenging problems

- Lack of feedback mechanisms to individuals (eg to doctors regarding prescribing errors)

- Lack of feedback within systems (eg stock control for cannulation equipment)

- Lack of standardisation, for example in how certain drugs are prescribed, how doctors' handovers are conducted, and how equipment is stored in theatres

- Poor communication, both written (eg poor documentation of medication changes in patients' health records) and verbal (eg handovers interrupted)

- Lack of ownership of reliability problems, for example blaming others for operating tray content

## 7.5 Following the rules: reliability of human behaviour

Delivering safe, high quality care is an interplay between disciplined, regulated behaviour and necessary adaptation and flexibility (considered in chapter 8). Rules and procedures are never a complete solution to safety and sometimes it is necessary to depart from standard procedures in the pursuit of safety. However, for essential standardised procedures, safety is maintained by the conscientious, disciplined following of rules.

Protocols for routine tasks are standardised and specified precisely because variation is thought to be, at the very least, unnecessary and, on occasion, positively dangerous. Protocols of this kind are equivalent to the safety rules of other industries: defined ways of behaving intended to either improve safety or achieve a required level of safety.[156] Examples in healthcare include checking equipment, hand washing, not prescribing dangerous drugs when unauthorised, following the procedures when giving intravenous drugs and routinely checking the identity of a patient. Such standard routines and procedures are the bedrock of a safe organisation, but there is ample evidence that such rules are routinely flouted in healthcare.

– Hand washing. Studies have found that average levels of compliance, before major campaigns were instituted, have varied from 16–81%;[157] compliance is probably higher in environments such as the operating theatre where the routine of getting scrubbed is solidly embedded. The causes of infection are undoubtedly complex, however contamination through hand contact is a major source and hand hygiene a major weapon in the fight against infection.[158] In spite of this it has proved extraordinarily difficult to persuade healthcare workers to wash their hands.

– Medication errors. Studies over the last 10 years have found that errors in medication administration occur in approximately 3–8% of non-intravenous drug administrations.[159]

– Intravenous drug administration, requiring some technical skill and the use of equipment, offers additional hazards and possibilities for error over oral medication. Katja Taxis and Nick Barber[160] observed 430 intravenous drug doses and found that almost half involved an error, either in the preparation of the drug or its administration. Typical errors were preparing the wrong dose or selecting the wrong solvent. The more complex the procedure, the more chance there was of an error occurring – a theme we will return to in later chapters.

## 7.6 Monitoring the reliability of clinical processes and systems

Assessments of reliability in the UK NHS are typically described as audits. The meaning of the term audit has evolved over the years. Initially it was used to describe a basic assessment of some aspect of clinical practice, later widening to be focused on assessment against standards and guidelines and sometimes including some aspects of quality improvement. A UK hospital or other organisation will now typically have a rolling programme of clinical audits, some locally determined and some in response to national imperatives. These are reported to their relevant clinical and management groups and summarised in the organisation's quality accounts.

The case study sites interviewed as part of our research provided numerous examples of measures of reliability of care processes. These measures were wide ranging. Some are externally mandated by regulators and others have been developed by healthcare organisations themselves to monitor their process reliability.

Examples of externally developed process reliability measures include:

– percentage of all inpatient admissions screened for MRSA

– percentage compliance with all elements of the pressure ulcer care bundle

– case note tracking and accurate record keeping according to standards set by the NHS Litigation Authority

– percentage of inpatient risk assessments completed and linked to care plan

– percentage of community risk assessments completed and linked to care plan.

– Examples of process reliability measures set by organisations themselves include:

– percentage of patients with two complete sets of vital signs in a 24-hour period

– percentage of patients who have their allergy status clearly documented

– percentage compliance with completing blood traceability slips

– percentage of patients who were consented by a consultant surgeon (in trusts where delegated consent is not permitted in their consent policy and procedure)

– percentage of patients with an accurately completed falls risk assessment within 24 hours of admission.

An example of a trust monitoring compliance with prescribing guidelines is given in Figure 7.2. This is part of North Bristol NHS Trust's regular quality report to the trust board.

**Figure 7.2: Monitoring compliance with prescribing guidelines**

**Preventing deterioration oxygen correctly prescribed (source clinical audit)**
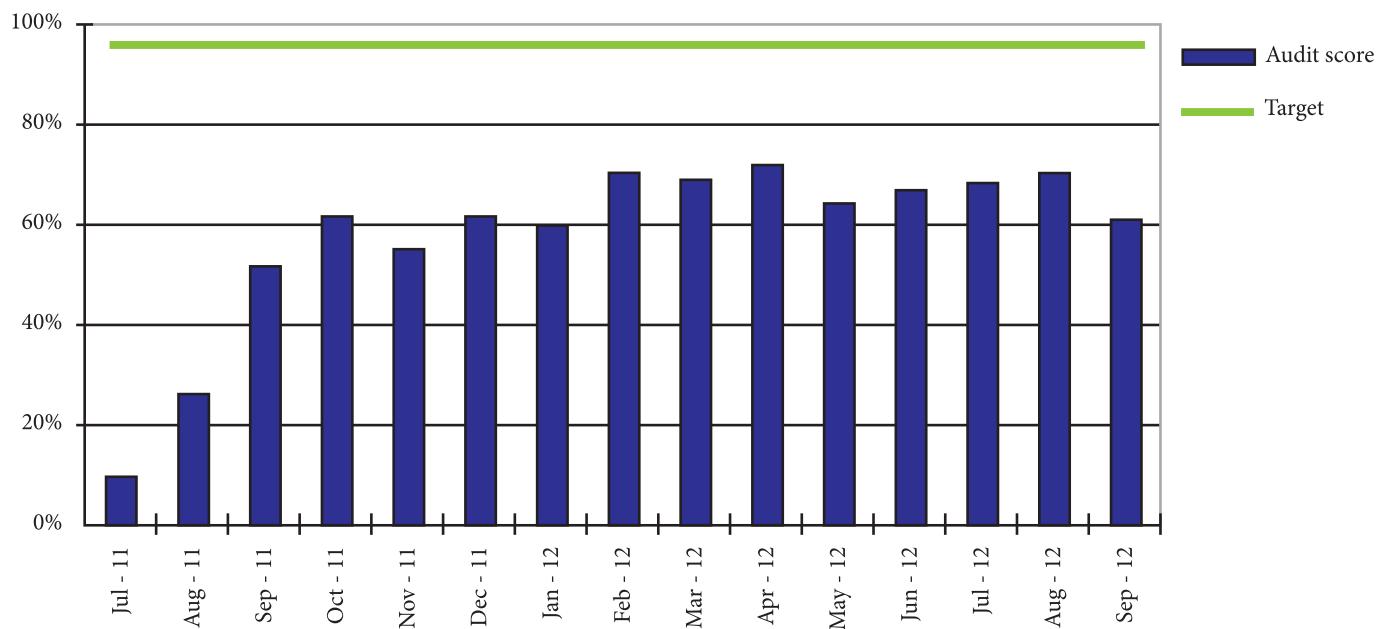


Through observation in wards and departments, organisations now routinely collect data on compliance with hand hygiene. In Scotland the compliance across all healthcare organisations is reported to the Scottish Government Health and Social Care Directorates (SGHSCD). It forms part of the zero-tolerance approach to non-compliance with hand hygiene launched by the Cabinet Secretary for Health and Wellbeing in 2009.[161]

## Aiming higher: 100% reliability of care delivery

Clinical audits are potentially valuable measures of reliability but tend to be focused on specific points of the care process. Some organisations are moving beyond this to a more holistic view and aiming for 100% reliability across an entire clinical system.

National programmes, like the 'productive' series,[162] have raised awareness of how to improve reliability in care processes. The productive ward, operating theatre and outpatients programmes are based on six sigma principles and provide tools which aim to improve the reliability of clinical processes in wards, theatres, community hospitals and GP practices. The programme focuses on reducing waste and variation, standardising and measuring processes, and outcomes associated with the team's aims for the programme, such as reducing handover times.

Many of these programmes make use of 'care bundles', in which related care processes, previously performed separately, are 'bundled' to make sure that they are given together and to reduce the chance of important aspects of care being missed. Perhaps the best known assessment of reliability of delivery of agreed standards of clinical care is from Peter Pronovost's work in Michigan where a group of intensive care units worked together to deliver 100% reliability in a set of evidence-based interventions to reduce the incidence of catheter-related bloodstream infections (see chapter 1).[17] The principle of care bundles has been applied in the UK in the Safer Patients Initiative (SPI) where hospitals measured the reliability of a number of care processes and worked to improve to 100%.[163] These included, for example, reducing ventilator-associated pneumonia, reducing catheter-related infections, and early detection of the deteriorating patient.

The Welsh Critical Care Improvement Programme report sets out the methods adopted across Wales to implement care bundles in critical care with the associated measurement tools, reporting measures for every unit in Wales. See: www.wales.nhs.uk/sitesplus/documents/829/NLIAH%20WCCIP%20Report.pdf

## 7.7 Real compliance and apparent compliance with clinical processes

We should note that audit results should not always be taken at face value and, in some circumstances, can provide false reassurance. For example, healthcare organisations in the UK typically measure compliance with the WHO Surgical Safety Checklist by carrying out monthly or quarterly audits of completion of the checklist. This forms part of the clinical audit programme. Percentage levels of compliance with each section of the checklist are calculated and reported on scorecards or dashboards (that is, percentage level of completion of the sign in, time out and sign out sections of the checklist). So, for example, a hospital's monthly audit data may show 95% compliance with the 'sign in' process, 98% compliance with the 'time out' process and 80% compliance with the 'sign out' process. Taken at face value, the audit data are interpreted as indicating an issue with levels of compliance for the 'sign out' and attention focuses on targeting improvements in that area. However, we need to consider what such audits are actually measuring.

The checklist compliance audits are actually measuring the extent to which staff tick that they have read out the various statements on the WHO Surgical Safety Checklist. These data are then aggregated and inferences made about reliability and levels of compliance with using the checklist. There is nothing inherently wrong in this, but the information is limited unless backed up by periodic observation of checklist use in practice. By only measuring the completion rate for which statements on the checklist are ticked and the 'signing off that sections of the checklist have been completed', we may inadvertently be creating a perverse incentive. Over time, operating theatre teams learn that they can demonstrate high reliability by simply ticking the checklist boxes and statements. The potential safety improvements from the checklist are therefore lost because the measurement and monitoring we have developed shapes behaviour in unforeseen and unsafe ways.

## 7.8 Reflections on the reliability of clinical systems

Organisations carry out a wide variety of assessments of reliability of processes, of staff compliance with procedures and of the maintenance and use of equipment. In most cases these are not seen as contributing to an assessment of the overall reliability of a system. There are a number of reasons for this. First, staff are simply not used to thinking in terms of standardisation and reliability of processes that, for example, would come naturally to engineers. Second, many of these assessments are made in response to external demands from different organisations and therefore tend to be viewed in isolation. Third, with some exceptions, there is seldom any attempt to make an initial assessment of what processes in a clinical unit or organisation are essential to safety or to set targets for reliability.

The next step for many organisations is to specify all processes that are expected to be reliable across the whole system and the levels of reliability expected. This seemingly simple step would be a massive transformation in healthcare and represent a move from gradual improvement towards an engineering perspective in which systems are designed to operate to certain specifications under a range of conditions. Monitoring reliability across a system would be a major challenge, though all processes could be assessed periodically, but this is undoubtedly the direction of travel if healthcare is to achieve true reliability.

# *Chapter 8:*
# Is care safe today? Sensitivity to operations

## 8.1    Introduction

If we want to be safe when we drive a car, operate machinery or walk across a city we have to continuously monitor our own actions, attend to the environment and adapt and respond as necessary to changing circumstances and hazards. Those working in risky environments, whether in a cockpit, an operating theatre or a primary care clinic, also have to maintain this alertness and safety awareness.

> *'At the coal face, minute by minute, safety may either be eroded by the actions and omissions of individuals or, conversely created by skilful, safety conscious professionals.'* [2]

We can expand this vision to consider the safe running of an organisation. Certainly one must monitor harm and consider the reliability of systems over time, but safety also requires monitoring on a day-to-day basis. Clinicians monitor their patients, watching for subtle signs of deterioration or improvement, but also have to monitor their teams for signs of discord, fatigue or lapses in standards. Managers have to be alert to the impact of staff shortages, equipment breakdowns, sudden increases in patient flow and a host of other potential problems. It is difficult to encapsulate all this activity under one term. However, the phrase 'sensitivity to operations' comes close. In this phrase 'operations' means all the workings of an organisation, not surgical operations or procedures. It is used in the accounts of high reliability organisations to describe the acute awareness people working in these organisations have of the workings of the organisation and their sensitivity to subtle changes and disturbances (see chapters 3 and 4). Sensitivity to operations is akin to the heightened awareness of an experienced paediatrician at the bedside of a very sick child, only applied to a whole organisation.

Drawing on the findings from the scoping reviews reported earlier together with our case studies, here we consider how healthcare organisations can answer the question, 'Is care safe today?'

## 8.2    Defining sensitivity to operations

Sensitivity to operations is a term used by high reliability theorists and later chosen as one of the core dimensions of 'collective mindfulness'.[164] In healthcare, sensitivity to operations encompasses more than checks of patient identity, vital signs and medications. It includes awareness by staff, supervisors and management of broader issues that can affect patient care, ranging from how long a person has been on duty and the availability of needed supplies to potential distractions and wider organisational issues and threats to patient safety.

A safe organisation relies on individuals continuously interacting as they develop, refine and update a shared understanding of the situation they face. Describing the attributes of safe organisations, Schulman[165] commented on the importance of cultivating and rewarding sensitivity and attentiveness, and emphasised the importance of watching for unusual or puzzling events that are outside the usual run of operational performance.

Sensitivity to operations permits early identification of problems so that actions can be taken before they threaten patient safety. Organisations and teams that exhibit sensitivity to operations deploy resources and have measurement systems in place that enable people to see what is happening and understand its significance and potential impact. Such organisations place a strong emphasis on 'usable intelligence', meaning that information must be communicated in a format that is comprehensible and prompts immediate action.

Collective mindfulness is a vital part of mental health service delivery. Here staff risk assess situations on an ongoing basis, for example when visiting a patient at home or considering whether to discharge a patient who may be at risk. In one of our case study sites, Avon and Wiltshire Mental Health Partnership NHS Trust, staff receive regular training and communication about the risks to assess and the vigilance needed to keep patients safe. An example from a recent newsletter about reducing suicides in the community is provided in Box 8.1 below.

### Box 8.1: Excerpt from Avon and Wiltshire Mental Health Partnership NHS Trust newsletter

**Be alert to changing risk**
Risk, by its very nature, is a dynamic concept, and the level and degree of risk demonstrated by one individual can vary from moment to moment. When planning and implementing risk management interventions, take account of the factors, circumstances or situations that can cause the person's risk profile to fluctuate.

**Be alert to risk at times of service transition**
When service users are required to deal with and respond to transitions, then the level of risk can increase. Such transitions may include handovers of care from one team or service to another or discharge from a part of the service.

**Take seriously previous attempts using high lethality methods**
People who have previously acted on suicidal thoughts using violent methods are most likely to be at increased risk.

**Look at all risk indicators – not just stated intent**
Consider ALL risk factors when planning risk management interventions; treat with caution statements from a service user that they have no plans to kill themselves.

**Access as much of the record as possible**
Key assessment and risk management information may be contained in previous health and social care records (including those records held by other care providers, such as GPs). Make all reasonable attempts to obtain this information as a way of informing assessment and care planning processes.

**Engagement, Engagement, Engagement!**
Effective collaborative engagement with the service user is the best way to reduce suicide risk. Situations where relationships between the service user and the service are strained increase risk markedly.

In clinical teams, closed loop communication and other forms of information exchange are a particularly important means of promoting the shared situational awareness that underlies sensitivity to operations. Closed loop communication consists of a team's ability to exchange clear concise information, to acknowledge receipt of that information, and to confirm its correct understanding.[124] Effective communication promotes shared situation awareness of the bigger picture among team members, allowing them to choose the appropriate treatment or intervention based on an understanding of a given patient's status at a given point in time. For example, the safety of the transfer of a post-operative patient from the operating theatre to the intensive care unit (ICU) is dependent on effective handover between the operating theatre team and the ICU team. If peri-operative complications specific to a particular patient are not communicated and confirmed as being understood, the ICU team will not have the same shared situational awareness and understanding of the 'bigger picture' as the operating theatre team.

## 8.3 Mechanisms that support sensitivity to operations in healthcare

Sensitivity to operations relies on individuals and teams maintaining awareness and being constantly alert for problems. However, it can be encouraged and enabled by a variety of formal and informal mechanisms. Some of the formal mechanisms used by healthcare organisations to develop sensitivity to operations are externally mandated, whereas others have been implemented after lessons were learnt from organisations noted for their best practice in patient safety or following participation in national campaigns. Examples of externally mandated measures are whistleblowing policies and procedures; learning from complaints and informal concerns to Patient Advice and Liaison Services (PALS) teams; patient and staff surveys; and for foundation trusts, having a governing body comprising patients and the public from the community the organisation serves. In this section we outline a number of mechanisms, identified in our case studies, that promote sensitivity to operations.

### Safety walk-rounds

Safety walk-rounds enable operational staff to discuss safety issues with senior managers directly. The benefits of safety walk-rounds are well described in the industrial safety research literature.[166–168] Known by the terms 'managing by walking around' or 'managing by wandering around' in industry, walk-rounds essentially provide an important source of 'real-world safety intelligence' and increase open communication

between senior managers and the workforce. As a safety performance measure, safety walk-rounds are used as a visible indicator of senior management commitment to safety that has been identified in many studies as a key element of a good safety culture.[93,169]

Safety walk-rounds have been implemented in many NHS organisations following the National Patient Safety First Campaign in 2009.[170] The organisations we interviewed all use executive patient safety walk-rounds to learn about patient safety in wards, teams and departments. Differences between organisations were identified in terms of the approach and structure of executive walk-rounds. One organisation uses a standard approach in which an executive walk-round happens every Tuesday morning. In contrast, another organisation wanted to ensure that walk-rounds were not seen as 'royal visits', and used unscheduled 'out-of-hours' visits by executive directors who 'walk the floor' seeking information from patients and staff as part of its walk-round programme. In our case study site in Avon and Wiltshire the mental health trust has implemented a programme of 'patient safety visits'. In advance of a scheduled visit, executive directors are supplied with a portfolio of information on incidents, complaints, PALS queries and so on for the clinical area. They then visit this area to meet with staff, service users and carers to discuss patient safety issues, accompanied by a member of the nursing directorate. The visit is then documented in a report which records any actions to be followed up.

Safety walk-rounds have been adapted and implemented successfully in healthcare organisations.[122] They can have a positive impact on safety culture when implemented as part of broader safety improvement programmes.[122] However, their purpose needs to be clearly understood and they need to be introduced and embedded in the wider organisational structures. Simply carrying out the required number of walk-rounds each month (a target in some safety campaigns) may reduce a potentially subtle form of gaining safety information to a box ticking exercise. Staff quickly realise that visits of this kind are worthless. In one hospital these visits were described by the nursing staff as 'seagull management': the leaders would arrive, make a lot of noise, create a stir, fly off and leave staff to pick up the mess!

It is also critical to understand that walk-rounds are not simply informal chats between senior healthcare managers and frontline healthcare staff.[122] Rather the intelligence they provide needs to be integrated into the formal quality and safety structures of an organisation (see Box 8.2).

*' … many organizations mistakenly think the key component is leadership walking around, and that a Walk Round is an informal conversation between leadership and providers. In fact, the real power is that these conversations elicit useful information within a formal structure. The information is documented and analysed, combined with relevant information from root cause analyses and other reporting systems, and regularly discussed in meetings involving the Clinical chairs, chiefs, and senior leaders. These leaders of the organization accept and have clear responsibility for actions to resolve identified problems. Learning from these issues and the actions to be taken then becomes part of the operations-committee agenda.'* [122]

## Using designated patient safety officers

Patient safety officers (PSOs) are medical consultants who are given a specific role to actively seek out, identify and resolve patient safety issues in their clinical units, serving as a source of usable safety intelligence about frontline safety operations. The PSO role was adapted in Great Ormond Street Hospital from good practice at Johns Hopkins Hospital in Michigan and Cincinnati Childrens Hospital Medical Centre, USA with one PSO in each clinical unit, all of who are consultants. The Deputy Medical Director for Patient Safety has a monthly meeting with each PSO that focuses on what intelligence about safety has been gathered from the clinical unit in the past month and whether safety concerns have been raised about a given unit. This facilitates the quick escalation and resolution of patient safety threats. Note that PSOs are consultants: the approach is a useful way to engage senior doctors in patient safety. It also ensures that PSOs have seniority and authority within their department.

At Great Ormond Street Hospital NHS Foundation Trust, the Executive Patient Safety Walk-round Programme has made over 150 visits to wards and other clinical areas of the hospital over the past three years. It is solely concerned with giving staff, patients and families the opportunity to identify safety issues with the aim of resolving them. Parents are often, but not invariably, involved in executive walk-rounds.

Issues identified on walk-rounds are categorised as low, medium and high priority, with low and medium issues handled at unit level. All the issues identified are entered into a database that is updated weekly. The database enables detailed searches to be made, by issue, ward, unit and priority. Following this an action report is generated that is sent to the ward, Executive Patient Safety Walk-round team, general manager and unit chair. Three high priority actions are allocated to a named Executive Patient Safety Walk-round team member to follow up and resolve within one month.

The trust audits its performance of resolving issues identified in walk-rounds. Information on the trust's website presents data from one audit which demonstrates that the clear-up rate of high priority issues is improving: in 2011, 50% were resolved and 26% were partly resolved. Those that remained unresolved were generally about physical space and long-term issues like staffing levels that simply cannot be dealt with within the desired timeframe.

Thematic analysis of issues identified on executive walk-rounds is also carried out. The most frequently identified issues are environmental problems relating to the physical space and design of the hospital, which accounted for just over 25% of all issues. Equipment was second (23%) and processes third (almost 20%).

Each clinical unit includes the key themes identified in walk-rounds in their monthly 'zero harm' report to the board. This ensures that safety intelligence from the walk-rounds is considered alongside information from other sources including serious incidents, red-rated complaints and the risk register.

## Operational meetings, handovers and ward rounds

Operational meetings, handovers, ward rounds and meetings with patients and carers are all sources of intelligence that support sensitivity to operations. They provide a forum for cascading patient safety information across teams. For example, ad hoc operational meetings held by senior managers to unblock beds and improve the flow of patients through a hospital identify safety issues relating to infection outbreaks, outliers, and thwart the potential for unsafe discharge of patients. Handovers and ward rounds create shared team situational awareness of the management plan for a particular patient or service user.

One of our case study sites, Central and North West London Mental Health Trust, described how wards hold weekly meetings with service users and carers, giving them the opportunity to raise patient safety issues and discuss these openly with ward staff. The trust reports that these meetings elicit information about service users' and carers' concerns, thus providing a useful source of safety information that may not have been identified from formal sources. The involvement of carers often reveals new information that signals deterioration in a service user's mental wellbeing and alerts the mental health team to potential issues. In another case study site, a care of the elderly ward had introduced fortnightly 'tea with matron' sessions. These were introduced when ward sisters recognised the need to discuss potential post-discharge safety issues like medication compliance with a patient's carers in an informal setting.

## Briefings and debriefings

Briefings and debriefings are used by ward staff, operating theatre teams and healthcare managers. For example, briefings carried out by operating theatre teams provide an opportunity to identify and resolve equipment, staffing or theatre list order issues before a case starts. Debriefings at the end of the theatre list support reflective learning on what went well and what could be done better tomorrow. Increasingly, briefings and debriefings are being introduced in other healthcare domains including the pioneering work at North East SHA to introduce briefings to staff working in safeguarding adults and mental health teams, as part of the organisation's human factors training programme.

## Day-to-day conversations

Day-to-day conversations between healthcare teams and healthcare managers also support sensitivity to operations. Senior healthcare managers whose roles are to implement organisation-wide strategies to improve patient safety recognised the importance of proactively seeking out safety information in everyday conversations with frontline healthcare teams, patients and carers and triangulating that information alongside other safety measurement data. For example, informal conversations are used to identify attitudes and behaviours that alert senior managers to poor team safety culture. This information is then mentally compared and contrasted to patient safety information from other sources, like incident reporting and audit data, to form an impression, and leads to recognition of the need to intervene:

*'Quite often intuitive information synthesises with information from formal and informal sources. Whilst independently, the information is disparate and vague … when you put it together, you start to see a picture emerging which indicates that something is not right.'*
Director of Quality and Safety

Within healthcare teams, day-to-day conversations elicit information that fosters shared team situational awareness. Examples include one-to-one nursing care in an intensive care unit or continuous observation of a high risk mental health patient or collaborative cross-checking[135] in teams, where team members continuously check and intervene to prevent incidents.

A range of informal approaches are used to identify patient safety risks through conversations with healthcare staff. Examples from our case studies included informal coffee mornings with ward nurses led by a chief nurse and chairperson and actively seeking out information in conversations with frontline staff.

*'I seek out the junior doctors and use them as informal advisers to identify patient safety issues on wards.'*
Associate Medical Director of Patient Safety

Conversations with staff may also reveal more subtle signs of potential safety problems, betraying attitudes that suggest an acceptance of unreliability and harm to patients and a potentially more endemic poor culture.

A mental healthcare professional's response following an inpatient suicide is: *'well the patient had a mental illness and was determined to take his own life – what is the point of carrying out an investigation?'*

In an acute hospital, an ICU consultant or nurse expresses the attitude: *'pressure ulcers are inevitable in ICU patients because it is difficult to turn them'.*

In a maternity unit: *'We are dealing with a complex case mix of women who are giving birth … post-partum haemorrhages are an inevitable complication of labour.'*

## Using patient interviews to identify threats to safety

Patient interviews and service user meetings also facilitate sensitivity to operations. This is particularly important in mental health services where service users participate in the executive walk-rounds described above. In another example, the quality improvement team at UCLH routinely uses patient interviews in its quality improvement work to obtain information on patient safety risks. The approach to interviewing is to let the patient 'tell the story of their inpatient stay' and then reflect back to them the key safety and quality of care issues that have been raised (to confirm that the information has been interpreted correctly). Semi-structured interview methods are less effective because the person leading the patient interview interrupts the flow of the conversation, making the interaction awkward and disrupting the patient telling their story.

Patient interviews were recently used at UCLH as part of an improvement project to reduce readmissions among urology surgery patients. Several patient safety issues were identified in these interviews, including:

– the difficulties experienced by patients who have had complex urology surgery accessing expert urology help once discharged from hospital

– concerns regarding information that is given to patients and their carers prior to, or at the point of, discharge. For example, being discharged without being provided with information on how to manage any symptoms

– assumptions being made by ward staff that patients understand the information given to them.

Interview information was triangulated with other sources of data from incident reports, complaints, readmission data, case note review and interviews with a community care provider.

## 8.4 Timeliness of response and feedback

Timely action and intervention to thwart potential safety risks is the other key component of sensitivity to operations. Real time information from safety measurement performance systems supports sensitivity to operations by improving the timeliness with which healthcare teams receive safety intelligence. For example, a clinical director receives weekly hand hygiene data that indicate a decrease in compliance with hand washing on a ward. In practice, different timescales are appropriate to different contexts. Sometimes, in clinical settings, safety needs to be monitored on a minute-by-minute basis. Managers typically may have to resolve the bulk of minor problems either on a daily basis or within a week or so. Below we give an example of an anaesthetic feedback system that provides both real time monitoring of specific patients and monthly feedback to anaesthetists.

### Routine monitoring in anaesthesia

Anaesthesia is now a very safe specialty and serious adverse outcomes are rare. However, safety can be compromised by both deliberate deviations from best practice for a given situation or inadvertent, unplanned, uncontrolled variations in care that may or may not be detected or recovered prior to harm occurring. For example, failed intubation in the ready room leading to a 'can't intubate, can't ventilate' scenario with harmful consequences for the patient. More subtle deviations can also increase risk for the patient. For instance, failure to ensure adequate peri-operative patient temperature management can increase infection risk, which itself can lead to adverse surgical outcomes for the patient. Superficially minor variations in routine anaesthetic care processes may have harmful consequences. In fact, given the relative safety of modern anaesthetics, anaesthetic practices and equipment, minor routine deviations may collectively account for more avoidable patient harm than major events, yet it is very difficult to monitor and visualise this routine variation.

The anaesthetics department at St Mary's Hospital, Paddington, provides anaesthetic services for a broad range of surgery types, both emergency and elective (Boxes 8.3 and 8.4). A new initiative goes beyond the usual retrospective collection of audit and outcome data to continuously monitor quality and safety of anaesthetic care using measures collected in the post-anaesthetic care unit (PACU). Prior to the initiative, anaesthetists did not receive routine feedback on quality of care delivered to all surgical patients and had to follow up on a case-by-case basis with visits to PACU.

Anaesthetists can now review the safety and quality of care on a month-by-month basis, analyse trends over time using process control principles, and compare personal performance with that of peers.

The initiative embodies 'sensitivity to operations' in that every patient is monitored for a range of anaesthetic-relevant post-operative outcomes and that the work of the anaesthetics department is monitored continuously with rapid feedback. Data is presented and analysed using process control principles capable of detecting significant/abnormal variation quickly. If a process begins to run out of control or generate abnormal results that represented a risk to patients, the system would detect, flag and distribute this information to facilitate rapid, effective action.

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**Box 8.3: Continuous quality and safety monitoring in anaesthesia**

Data are collected from every patient at the bedside in the post-anaesthetic recovery unit (PACU) by trained nurses.

- Indicators collected include: patient temperature on arrival in recovery; patient reported pain; post-operative nausea and vomiting (PONV); quality of recovery scale score; time to transfer patients to surgical wards.

- Information is presented in simple graphical and comparative formats including flagging of important anomalies for further investigation.

- The high frequency of the monitoring and feedback means that recipients become familiar with the reports and use of the data becomes routine.

- The initiative is clinician-led, confidential and specific to the practice of anaesthetists. It is therefore credible and trusted by the recipients.

- Individual anaesthetists receive personalised monthly reports that contain cross-sectional and longitudinal (run chart) presentations of their personal caseload with benchmarks with peers and departmental averages.

- The anaesthetics department receives statistical summaries that are presented at periodic audit meetings.

- Surgical wards receive monthly reports on ward transfer delays including comparisons with other wards.
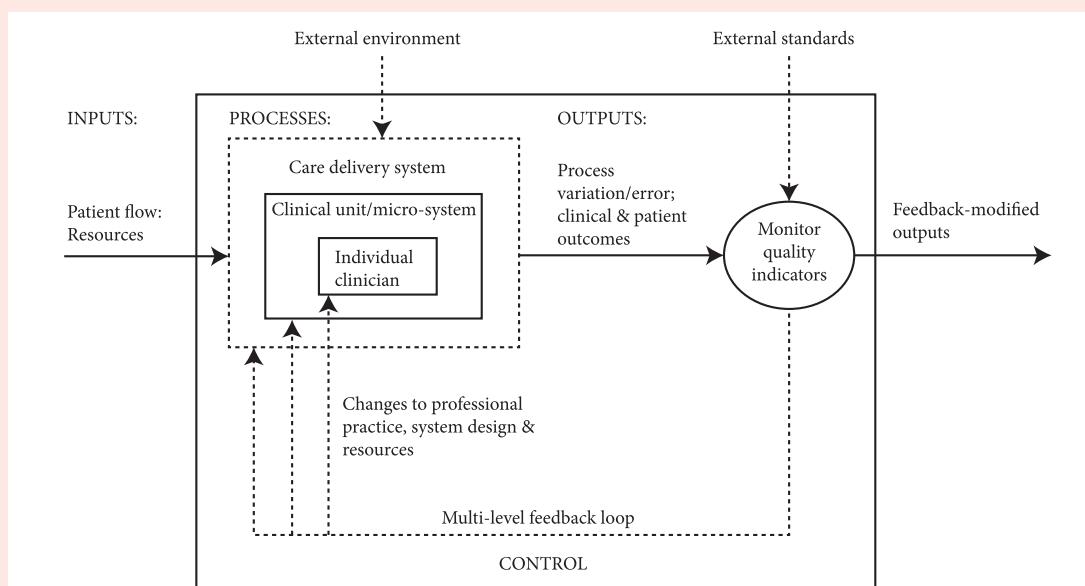
## 8.5 Reflections on sensitivity to operations

The healthcare organisations interviewed have different approaches to monitoring safety on a day-to-day basis and some are clearly more evolved than others. This may be because some organisations have a greater appreciation of the importance of this kind of information. However, it may also be that some approaches work more effectively in one organisation than in another – indicating that the 'fit' between the methods used to achieve sensitivity to operations and the organisation is important. For example, weekly meetings with service users provide a forum for safety issues to be discussed in a mental health setting. However, the short length of stay of most acute inpatients makes this approach less feasible.

The case study evidence we have gathered shows that healthcare organisations use a variety of formal and informal approaches to draw out safety information that enables them to understand how frontline healthcare services are delivered. Timely action and intervention to thwart potential safety risks is the other key component of sensitivity to operations but this was harder to determine. Some examples of emerging good practice were identified in the case studies. For example, weekly safety meetings have recently been set up in one hospital where the aim is to triangulate key sources of information and implement actions to resolve emerging patient safety issues. This mechanism has been implemented to improve the response time.

It also demonstrates recognition that waiting to respond to a problem until the monthly patient safety committee meets results in delays and potentially increases the risk that a patient will be harmed.

One of the key lessons for healthcare organisations is how to ensure that once usable safety intelligence is gathered, it is acted on in a timely way. This component of sensitivity to operations does not fit well in an NHS culture where 'management by committee' dominates. By their very nature, monthly or even quarterly committee meetings have the potential to slow down response times because safety information may not be acted on until action is sanctioned by the responsible committee. We may therefore need to rethink some of the structures and processes that we accept as the architecture of a safe organisation to enable healthcare organisations to act on information more quickly.

# *Chapter 9:*
# Will care be safe in the future? Anticipation and preparedness

## 9.1    Introduction

Anticipation is a key component of expertise in many areas and a critical element of safety. Essentially it involves thinking ahead and envisioning possible problems and hazards, enabling those involved to make plans and be prepared. If you are planning a car journey you need to think about what might happen. You may check the oil and water levels and the tyre pressure to prevent a breakdown. In planning the route you may look at the traffic information for accident black spots, road works and likely traffic jams. You may also look at the weather forecast to avoid snow and ice. Here the driver is using a range of available information from different sources to review possible scenarios, make plans and be prepared. Ambulance services often use historic data of accidents by location and time of day to deploy vehicles to areas of highest risk in anticipation, enabling them to respond as quickly as possible.

In clinical work the treatment of complex, fluctuating conditions also requires thinking ahead and being prepared to adjust treatment as the patient's condition changes: the ability to anticipate and respond is an essential part of delivering safe clinical care. However, when considering the safety of an organisation we are calling on a broader vision where clinicians and managers are using information to anticipate the safe functioning of the organisation in which they work, assessing the hazards and taking action to reduce the risks over time. Safety, from this broader perspective, requires anticipation, preparedness and the ability to intervene to reduce risks at the ward, department or systems level.

We would suggest that, for the most part, there is no special type of information that is or is not suitable for reflecting on future hazards and potential problems. Rather it is a question of encouraging questioning, even in conditions of current success and stability, and

creating opportunities for individuals and teams to spend time envisioning scenarios. A review of trends in harm to patients, in reliability of procedures or reflections on the current culture of the organisation could all provoke questions about how resilient the organisation might be in more hostile circumstances in the future.

Drawing on evidence from our reviews of the literature and from our case studies we begin this chapter with a reminder that anticipation and preparedness are critical to effective clinical practice and that these qualities are well developed, if not specifically taught, in many expert frontline staff. Anticipation and preparedness at an organisational level is less developed although there are some important recent developments in the use of formal techniques and innovative uses of data.

## 9.2    Anticipation and preparedness in clinical practice

Experts are constantly thinking ahead and looking to the future. In a study of the control of fighter aircraft Amalberti and Deblon[172] found that in pre-mission planning, which often took longer than the mission itself, pilots spent a great deal of time analysing each part of the route for possible threats, whether from hostile aircraft, personal factors, weather or technical breakdown. During the flight itself pilots devoted over 90% of the time when they were free to think and to anticipate; typically they developed a 'tree' of events that might occur which became more or less salient over the course of the flight.

Cynthia Dominguez and colleagues showed surgeons a video of an operation involving an 80-year-old woman with an infected gallbladder that needed to be removed. They used the video as a prompt to ask the surgeons how they prepared for such an operation and what they

would be thinking at each stage. Experienced surgeons made more predictions about likely problems than their junior colleagues. In particular they predicted, and were therefore prepared for, difficulty in dissecting and identifying the surrounding structures because the gallbladder and surrounding areas would be swollen and inflamed. With these predictions in mind they were therefore mentally prepared for the hazards that lay ahead; like the fighter pilots, they mentally mapped the route and anticipated likely hazards along the way.[173]

A key component of both pilots' and surgeons' expertise lies in predicting and avoiding dangerous situations. Expertise is not so much an ability to improvise and escape danger but having prepared strategies to deal with problems. Expert clinicians do not rely on their brilliance at escaping from dangerous situations but on trying to avoid them in the first place and having solid routines to fall back on when a crisis does emerge (Box 9.1).

### Box 9.1: Anticipation and preparedness in surgery

*'You need to have a strategy ready when there is bleeding: cold, automatic responses to a hazardous situation ingrained in your mind so that it can be done without stress and strain. What to do if the groin starts to bleed is one of the worst situations. When teaching I give them a list of things they're going to do. I get them to repeat it to me over and over again so that when it does happen to them, and it will eventually, they don't need to think, they just go into autopilot.*

*The first thing is to put a pack in which stops the bleeding. The second thing is to ask for some extra help; you need another person to use the sucker, because often you're on your own with the theatre sister. Third, you need to tell the anaesthetist you've got some bleeding. You then need to elevate the foot of the bed which lessens the amount of bleeding and to extend the wound without moving the pack. Once you've got it controlled you can get everything else you need sorted out'.* [2]

Anticipation and preparedness is also integral to the safe management of mental health service users. Preventing incidents of violence and aggression towards other service users and staff involves community and acute mental health teams being vigilant, anticipating the factors known to contribute to incidents of violence and aggression, and identifying early warning signs. Contributory factors include a history of past violence, substance misuse, heat, noise and overcrowding. Early warning signs of physical aggression are body language

and verbally abusive behaviour. Risk assessment is an integral part of the care planning process in mental health settings and the use of individual risk assessments for service users supports staff to predict future deteriorations in mental health and to communicate this information across the multidisciplinary team involved in a patient's care.

Teams may also anticipate error and, more importantly, use specific strategies to anticipate and forestall potential problems (see for example, the discussion of organisational resilience in chapter 4). Teams, when working well, have the possibility of being safer than any one individual because a team can create additional defences against error by monitoring, double-checking and backing each other up: when one is struggling, another assists; when one makes an error, another picks it up. Several authors have described how healthcare teams in emergency departments[174,175] and operating theatres[176] anticipate and thwart potential safety events. This can extend to more formal collaborative cross-checking, where one person, role, group or unit provides feedback about the viability or possible gaps in another's plans, decisions, or activities. An organisation can monitor the effectiveness of cross-checks to detect erroneous plans.[135]

We can also find the skills of anticipation in unexpected quarters. For example, the WHO Surgical Safety Checklist is usually thought of as a means of improving reliability of essential surgical processes such as giving antibiotics in a timely fashion. Although the checklist contains a list of items that must be conscientiously checked, it also prompts the surgical team to anticipate and prepare for potential problems (Box 9.2). The checklist forces a brief period of reflection (the 'time out') in which the theatre team works through a series of questions aimed at highlighting potential problems.

### Box 9.2: Anticipated critical events in the Surgical Safety Checklist

To the surgeon:

- What are the critical or non-routine tasks?
- How long will the case take?
- What is the anticipated blood loss?

To the anaesthetist:

- Are there any patient-specific concerns?

To the nursing team:

- Has sterility been confirmed?
- Are there any equipment issues or concerns?

## 9.3 Predicting risk in healthcare organisations

Empirical studies show that people are generally very poor at forecasting trends or the prediction of events.[177] There is, nevertheless, value in attempting to anticipate wider organisational problems in that this exercise will increase the likelihood of identifying future problems even if it is not possible to predict with any certainty how they might manifest.

Healthcare organisations frequently review the lessons learnt from serious incidents in other organisations and review their own practice to try to ascertain, 'Could this happen here?' Incident analysis is being used here, very properly, as a means of anticipating future problems. For example, a case of wrong site surgery in one organisation led another organisation to instigate a wide-ranging review to assess whether they could ever operate on the eye of a person who was already blind in the other eye. They concluded that their present arrangements were inadequate and made radical changes to their procedures. Similarly, community pharmacies have systems in place to share learning from serious incidents across branches. This enables staff not directly involved in the incident to reflect on their own systems and anticipate whether what went wrong elsewhere could happen in their own pharmacy. In one community pharmacy chain, lessons learnt from incidents that occurred when pharmacists were distracted by customers and staff while carrying out the final dispensing check led to the adoption of a 'red mat' which the pharmacist stood on during the final checking stage. The red mat signified to other team members that a safety critical task was being carried out and aimed to reduce distractions and interruptions.

Ideally, however, we would like to go beyond reflection on incidents to systematically assess factors that might function as early warnings of more serious problems, identifying safety problems before harm occurs. We begin with a discussion on the use of risk registers in the English NHS, which provide an ongoing record of potential safety issues. We then turn to the use of more formal predictive techniques of human reliability analysis and safety cases. An ideal indicator would tell us when and to what degree the system is becoming unsafe. We currently do not have the necessary understanding to confidently assess when a system is unsafe, although there is no shortage of candidate measures. As examples, we consider the use of safety culture and staff indicators as potential predictors of safety problems.

## 9.4 Risk registers

In the English NHS divisional, departmental and trust risk registers are commonly used across healthcare settings and are mandated by external regulators like the NHS Litigation Authority. Typically, a quarterly risk capture process is carried out, led by the trust's risk manager (or equivalent). Divisions and departments are asked to update their local risk registers, grading all identified risks using a standard risk matrix. Risks are collated and those with the highest risk scores are included in the trust risk register and/or (depending on the seriousness of the risk) the Board Assurance Framework (BAF). Senior managers seek assurance that action plans are in place to mitigate the risks identified and that these are delivered to deadline.

Some of our case study sites have mature risk register and assurance framework processes in place that capture a wide range of risks from both clinical and corporate departments. For example, at UCLH the workforce, facilities, information technology and research departments are all required, alongside clinical divisions, to submit a quarterly risk register return. This ensures that risks pertaining to IT system design and implementation, medical device maintenance and availability, professional registration checks and research governance are identified and analysed alongside clinical risks.

However, the extent to which risk registers can be used as a source of information to anticipate whether care will be safe in the future is open to question. There are a number of challenges here. First, the quarterly timeframe for the risk capture process inhibits the extent to which the information is timely. Second, many of the risks that populate the register are identified retrospectively as lessons learnt from incidents, complaints and external regulatory audits. As discussed in the preceding section, prospective risk assessment methods like human reliability analysis (HRA – see below) are not yet fully embedded in the NHS. This has a knock-on effect for risk register processes where only a minority of risks identified will have been identified prospectively. Third, in some trusts staff attitudes towards the risk register mean it is seen as a 'tick box' exercise whose purpose is to satisfy external regulatory requirements, rather than used as a living document that navigates healthcare teams through potentially unsafe situations.

## 9.5    Human reliability analysis

Human reliability analysis (HRA) methods take a process of care and systematically examine it to identify and anticipate possible failure points. As discussed in Section I of the report, in other industries (like the nuclear and off-shore oil and gas industries), HRA is an integral part of developing 'safety cases' that provide evidence to external regulators that the potential failure scenarios in a design have been identified and reduced to an acceptable level.

Techniques which claim to assess reliability of systems in advance of their operations have been particularly closely associated with the development of the nuclear industry. In order to gain public acceptance and an operating licence, designers and builders of nuclear power plants have to demonstrate in advance that the designs and proposed methods of operation are safe. This requires a minutely detailed specification of the actual processes, a quantitative assessment of the likelihood of different kinds of failure and an assessment of the combined effects of all possible kinds of error and failure to give an overall assessment of safety.

Other industries use a plethora of qualitative and quantitative human reliability analysis tools to proactively identify and mitigate safety risks before they lead to harm.[178,179] These include industry specific methods like the human error analysis and reduction technique (HEART)[180] and technique for human error rate prediction (THERP),[181] controller action reliability assessment (CARA) for air traffic management[182] and tools designed for use across different industries, for example, the systematic human error reduction and prediction approach (SHERPA).[183,184]

### FMEA and HRA methods in healthcare

Some of the simpler methods have been adapted and applied widely in healthcare, most notably failure modes and effects analysis (FMEA). FMEA has been used in a myriad of healthcare settings including chemotherapy drug administration,[185] intravenous drug administration,[186,187] intravenous SMART pump implementation,[188] dialysis units,[189] and handovers.[190]

Evidence from our case study sites showed that FMEA has not been widely used and integrated into the design of new clinical services (Box 9.3). Rather it is used on a project-specific basis. For example, FMEA was used to identify risks associated with an interventional radiology service and to identify potential failure modes along the anticoagulant patient pathway. One of the challenges for healthcare organisations is the absence of in-house expertise. Taking HRA tools off the shelf and applying them without an expert facilitator is challenging.

HRA methods are being developed and used in the Safer Clinical Systems (SCS) programme run by the Health Foundation and Warwick Medical School. One example from the SCS programme is the development of a prototype system for identifying and monitoring those organisational processes that give rise to latent conditions that can contribute to failures in a dispensary environment at Hereford Hospitals (known as PRIMO). The proactive risk-monitoring system is used to identify empirically a preliminary set of 'basic problem factors'

through qualitative analysis of narratives submitted by pharmacy staff about problems they encountered during their daily work. These factors are monitored and rated based on staff perceptions elicited through a questionnaire. As such, PRIMO promotes anticipation of what could go wrong and supports the development of a proactive safety culture.[191]

The work of the SCS programme is essential to ensure more widespread use of HRA methods in the design of healthcare systems. HRA methods provide a structured way for factors such as workload, patient familiarity, communication across interfaces, and levels of decision-making expertise to be anticipated in the system design phase. Unless and until such methods become embedded in service design, healthcare organisations will lack the tools needed to anticipate patient safety issues in the design stage, leaving them overly reliant on heroic interventions by healthcare teams to prevent incidents.

## 9.6    Safety cases

Safety cases (discussed in chapter 3) are used by the nuclear, military, rail transport, oil and gas production, and chemical process industries to demonstrate the evidence base which shows that a system is designed safely.[101] In healthcare, the potential role of safety cases has been primarily discussed in the context of medical device safety.[106,192] Beyond the pioneering work of the Health Foundation's SCS programme where safety case development is being piloted, we did not identify any examples of healthcare organisations which had developed a safety case to inform them whether care will be safe in the future.

In 2010, the US Food and Drug Administration Agency issued draft guidance on the development of 'assurance cases' for infusion pumps.[106] This applies the concept of safety cases used in industry. In the UK regulatory context, both manufacturers of medical devices and healthcare service providers are regulated and are required to provide some kind of evidence that their devices and the services they provide are acceptably safe. However, the regulatory context for medical devices in the UK focuses on certification and audit, rather than 'goal-setting' and devolution of control to manufacturers to put forward an argument and evidence to support device safety. Sujan et al[193] have argued that this leads to assumptions and dependencies that may not be documented properly and unintended consequences of changes may go unnoticed. There is also no formal assessment of issues such as confidence in the evidence or the assembly of diverse evidence to mitigate possible uncertainty. In short, the regulatory culture for medical devices in the UK is not one where presenting a reflective argument to demonstrate safety is embedded.

## 9.7    Safety culture

Safety culture (see chapter 3) has been shown to be associated with accident rates and a variety of other indices of safety, but relatively few studies have attempted to actually forecast future accidents from current measures of culture. Safety climate in nursing staff has been strongly associated with both patient outcomes (urinary tract infections and medication errors) and injuries to staff (back and needle stick injuries).[194] A positive safety climate was associated with a reduction in all these indices, except needle stick injuries. Singer et al[195] showed that hospitals with higher scores on safety climate were less likely to have patient safety indicator events: the effect was small but, in a sample of over 18,000, strongly significant. The relationship was mostly accounted for by a reduction in pressure sores and ulcers, perhaps the most visible and most susceptible to the attitudes and practices of individual staff.

Safety culture surveys can also be used rather differently as a foundation for a safety programme. For instance, Peter Pronovost and colleagues at Johns Hopkins used short surveys of safety culture and strategies for leadership as a baseline for their attempts to improve patient safety.[196] Senior managers perceived safety to be better developed than members of the patient safety committee, and frontline staff perceived that their immediate supervisors were more concerned with safety than were senior managers. These surveys highlighted that senior leaders needed to become more visible to frontline staff in their efforts to improve safety and that there was a need for strategic planning and a much more proactive approach to safety.

More recently, de Wet et al[197] carried out a safety culture survey of 49 GP practices in the west of Scotland that showed significant differences in safety climate perceptions at the practice team level. Perceptions of safety climate were influenced by respondents' years of experience, whether they were community or practice based, their professional roles and practices' training status. Practice managers and GPs perceived the safety climate more positively than other respondents.

Safety climate has also been assessed using safety culture maturity matrixes.[198–202] Safety culture maturity matrices display a set of key indicators on the y axis and an evolutionary measure of cultural maturity on the x axis. Originally developed as part of the 'Hearts and Minds' project for Shell plc, one such matrix, the Manchester Patient Safety Framework (MaPSaF), was adapted for use in primary care settings and has since been developed into versions for mental health, acute and ambulance trusts and community pharmacy.[198]

The MaPSaF uses critical dimensions of patient safety and for each of these describes five levels of increasingly mature organisational safety culture. The dimensions relate to areas where attitudes, values and behaviours about patient safety are likely to be reflected in the organisation's working practices, for example, how patient safety incidents are investigated, staff education, and training in risk management (see Table 9.1). The levels of maturity, based on a model originally put forward by Westrum[203] and modified by Parker and Hudson,[204] show the journey from a pathological, reactive, bureaucratic, and proactive to generative organisational typology.

### Table 9.1: MaPSaF risk dimensions

1. Commitment to overall continuous improvement
2. Priority given to safety
3. System errors and individual responsibility
4. Recording incidents and best practice
5. Evaluating incidents and best practice
6. Learning and effecting change
7. Communication about safety issues
8. Personnel management and safety issues
9. Staff training and education
10. Team working

Information is gathered by setting up a series of focus groups where healthcare staff assess the maturity of their local team and organisation. MaPSaF is a flexible tool that can be used to encourage healthcare teams to reflect on their safety culture, identify strengths and weaknesses and reveal differences in perception between staff groups. By enabling self-reflection on the current safety climate, it supports organisations to anticipate and plan how to evolve their cultural maturity (see Box 9.4 for an example).

### Box 9.4: Using MaPSaF to assess hospital safety culture

An acute NHS foundation trust set up 10 focus groups with a cross-section of its staff. The organisation wanted to take a baseline measure of its safety culture. Focus groups were facilitated by an external facilitator. The focus groups comprised pharmacists, doctors (including consultants, registrars and senior house officers), nurses of all grades, radiographers, nursing assistants and ward clerks.

Using MaPSaF, the following key weaknesses in the organisation's safety culture were identified.

- Lack of feedback from the incident reporting system prevents organisation-wide learning.
- An excessive number of policies and procedures and too little emphasis on reviewing whether people are following policies and procedures.
- Lessons learnt from clinical audit were not fed back to frontline healthcare teams.
- There was a poor risk assessment culture. Risk assessments were viewed by staff as a 'tick box' exercise.
- Disconnects in terms of how well safety solutions are disseminated across the entire organisation.
- Recommendations from incident investigations were often not implemented. There was poor cross-departmental learning and sharing of generic lessons from incident investigations.
- The trust's culture was one of meeting the requirements of external regulators. Staff felt that the trust was '… *very good at passing externally set safety tests but lacked a coherent strategic approach to improving patient safety because of the focus on satisfying the requirements of external regulators.*'
- Senior managers had a top down approach to patient safety and did not engage staff in the development of safety solutions.

'*All staff would say patient safety is a priority, but they do not always behave in ways that puts patient safety at the centre of clinical care.*' Infection Control Nurse

'*Within the department there is a mixture of blame and support when an incident occurs. Some line managers practise what they preach and are supportive of staff involved in incidents whereas others are not.*' Radiographer

## 9.8 Staff indicators of safety

A range of indicators relating to staff are available in organisations that can potentially be used to anticipate whether care will be safe in the future. Examples of just some of the types of staff-related safety indicators typically reported on trust scorecards or dashboards include: sickness absence rates; number of staff who have completed mandatory training on medication safety, blood transfusion, safeguarding adults and children and so on; frequency of sharps injuries per month. Healthcare organisations also anticipate whether they will be able to provide safe care in the future by carrying out regular patient acuity to skill mix reviews on wards. The results of these reviews are used to prioritise recruitment of particular staff groups. Box 9.5 provides an example from a Head of Nursing at a London trust about how they monitor safe staffing levels on wards.

## 9.9 Reflections on anticipation and preparedness

In this chapter we have looked at the topic of anticipation and preparedness in organisations. We have emphasised how the anticipation of hazards and problems is a critical aspect of clinical expertise. However, at an organisational level this capacity is comparatively little developed in healthcare. Our findings from the case study sites and from the literature highlight this as an area where the NHS is currently weak. It is clear that the different dimension of safety and the associated analysis for anticipation needs to be further explored in both research and practice.

There is a plethora of safety-related information in trusts but the extent to which it is systematically used to anticipate whether care will be safe in the future varies across healthcare organisations and between care settings. Furthermore, some useful methods like HRA and safety cases are not widely known about or used in service design. This is perhaps the next challenge for us to really begin to improve patient safety.

### Box 9.5: Example of anticipating whether staffing levels are safe

**Monitoring staff indicators of safety and anticipating potential safety risks – sourced from St George's Healthcare Trust**

'There are no nationally agreed levels of optimum staffing, because differences in case mix, ward size and ward layout affect the level of staff required. Requirements also vary on a day-to-day basis. When there are high vacancies in an area there are nevertheless implications for patient safety.

To address this issue, St George's Hospital developed a safe staffing policy. The aim of this policy is to act as a guide for managers and staff to ensure safe staffing levels are defined for each inpatient area. Areas define their staffing as either green (staffing as expected) amber (staff missing but patient acuity is manageable) or red (staff missing or insufficient numbers to cope with patient needs). The policy then outlines the procedure to be followed; taking a staged approach to escalation procedures should staffing levels cause concern.

For example, the trust monitors nurse-to-patient ratios and safe staffing levels daily. Safe staffing levels are assured using a number of approaches. In addition to daily monitoring of safe staffing levels, the trust uses electronic rostering, the Safer Nursing Care Tool (from the NHS Institute of Innovations and Improvement) and professional judgement to assure itself that staffing levels are safe.

When clinical areas report unsafe staffing they also report the actions that have been taken to resolve the problem. This provides an opportunity for senior managers to check that the actions taken will lead to quick resolution or whether there is a need for further escalation.

Monitoring safe staffing levels on a daily basis enables the trust to respond to emerging threats to patient safety.'

## *Chapter 10:*

# Are we responding and improving? Integration and learning

## 10.1  Introduction

All healthcare organisations will, if they look, discover numerous incidents and deviations from best practice. Safe organisations actively seek out such incidents and respond by attempting to learn from them and to feed such learning back to influence their future functioning. Healthcare organisations collect and use safety information in clinical teams; in wards and departments; in divisions and directorates; and at the executive and board level. They also place information in the public domain for patients and the public to view and make assessments. Feedback might be aimed at an individual member of staff, at a team or at changing the structure or organisation of an entire clinical department.

With the wide variety of safety-related data available it is often hard to know how to integrate the diverse sources and types of information or what weight to give to different types of information. Deciding on the appropriate action to take on safety information is also a considerable challenge. Should one respond rapidly to single incidents or develop a more thematic understanding of vulnerabilities within a longer-term strategy? At one end of the scale, learning and acting on immediate safety concerns may take place within minutes. In contrast, an annual review of trends in harm to patients or reviews of process and system reliability is probably the only way to address substantive issues with a longer implementation time.

In this chapter we address some critical questions relating to measuring and monitoring patient safety.

–  How do we integrate the wealth of patient safety information collected by healthcare organisations and analyse it in a meaningful way?

–  How can that information then be used to support organisational learning and implement sustainable improvements?

From our case studies we provide examples of how organisations are integrating safety information, how they are learning from it and how they feedback and respond to it. Such information may, of course, also provide a foundation and direction for longer-term programmes of improvement, but describing such programmes is beyond the scope of this report.

## 10.2  The challenge of integrating diverse sources of safety information

One of the challenges facing risk management or patient safety departments is how best to integrate the multiple sources of data that potentially shed light on safety issues. Hogan and colleagues examined six different sources of data routinely collected in a hospital and also reviewed a sample of 220 case records, finding 40 (18.8%) adverse events.[205] Extrapolating over a year, case record review of all admissions would have yielded about 8,700 incidents, of which 4,900 would have been adverse events. During the same period there were:

–  484 incidents reported

–  462 incidents detected from administrative data

–  221 complaints

–  176 health and safety incidents

–  21 inquests

–  10 claims.

Systematic record review revealed many more incidents and adverse events than any other source, as in previous studies.[146] Most importantly, there was very little overlap between these different data sources; the great majority of incidents only emerged from one source.

This study shows the scale of the challenge facing healthcare organisations wishing to develop a sustainable strategy for learning from, and responding

to, safety issues. All these data sources are important but there is almost no overlap between them. In addition to these sources we might also consider clinical audits of various kinds, analyses of routine data, observations of behaviour and, in the short term at least, informal conversations with patients, families and staff across the organisation. Healthcare organisations need to find ways of integrating and weighting these various sources of data if risks and hazards are to be effectively prioritised.[143]

## 10.3 The integration of safety information

The integration and discussion of safety information must be carried out at different levels of the organisation. Some issues are primarily relevant to a particular ward or department and should be resolved at that level, only escalating when they prove intractable. Boards need more generic information that has been previously analysed to reflect higher level trends and patterns. In this section we give examples of units and organisations that have successfully integrated different kinds of safety information to provide a picture of past and current safety and, in most cases, a means of discussing future risk. None of these case studies should be taken as definitive: all the organisations would describe themselves as in the process of developing their systems.

### Integration at clinical unit level

Great Ormond Street Hospital NHS Trust has made a significant investment in a team of data analysis experts who have developed an automated information management system. The system enables the trust to integrate information from different sources in monthly 'zero harm' reports produced for each clinical unit. A typical monthly zero harm report includes:

– number of days since the last serious incident (SI) in that unit, together with some narrative about the type of SI, lessons learnt and recommendations

– central venous line, MRSA and methicillin-sensitive staphylococcus aureus (MSSA) infection rates

– hand hygiene compliance rate

– WHO Surgical Safety Checklist compliance rate per clinical unit

– common themes identified in executive walk-rounds

– medication errors

– top three risks from the clinical unit's risk register.

The report also includes a specific safety measure of the unit's choice. This can be used to highlight a specific safety problem that the unit wants to escalate to senior managers or an example of safety improvements.

Integrating data from many of the different sources of safety intelligence described in previous chapters results in a high level 'big picture' safety summary for each clinical unit.

### Integration and learning at board level

Well-integrated safety information is also essential for boards. At the executive and board level, safety information is summarised into dashboards and reports with indicators often set alongside financial and access targets. Most English hospitals have a committee reporting to the board with the remit for quality and safety and an executive lead, often the medical or nursing director. It is here that the full range of safety information is considered.

The board at Central and North West London Trust (CNWL), which provides community and mental health services over a wide area, commissioned the quality directorate to develop a dashboard of safety and quality information. The indicators on this comprise a) quality priorities for mental health and allied specialties reported in CNWL's quality account, and b) board agreed indicators of quality. The dashboard includes 35 indicators of which 14 concern clinical safety.

Data are collected using a variety of methods including patient survey, clinical audit and via internal database. Indicators are RAG-rated (red, amber, green) and presented separately for each geographical area the trust covers. Action plans are assigned to amber and red indicators and are included on the dashboard. A version is also accessible to the public on the CNWL website. A quarterly summary report is produced that comments particularly on indicators where targets have been missed, indicators that have improved to amber or green, and indicators that have dropped to amber or red. Where appropriate, team and/or patient identifiable information by location is fed back to directorates/service lines so that action can be taken to rectify issues. Board minutes reveal the wide range of safety issues discussed including, in one six-month period, incidents relating to controlled drugs, the serious incident policy, non-compliance with procedures and the potential impact on patient safety, workforce capacity and a CQC report on the use of restraint in the learning disabilities service.

## Integration across a whole system of care

One of our case study sites, Intermountain Healthcare in the USA, has developed an online reports portal for quality and patient safety that incorporates a set of 80 patient safety metrics housed in a dimensional database with web-enabled reporting and statistical process control (SPC) charts on demand. These reports include the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission core measures, Agency for Healthcare Research and Quality (AHRQ), National Quality Forum (NQF) and other key indicators. Intermountain captures patient harm from existing databases; its preferred method is data documented by the care provider as part of the patient care workflow. This approach allows Intermountain to pull data from electronic records, triggers and also manual audits or chart reviews.

Data are presented in process control charts and comparative tables available via the reports portal. Data access security assures confidentiality and use for legitimate business needs. Dashboards have been developed and used for quality and patient safety and clinical programmes based on requirements, goals and objectives. Most recently a patient safety score card (PSSC) was developed that tries to provide a single measurement of patient safety defects. The PSSC uses data from core measures, HAIs, hospital-acquired conditions (HACs), AHRQ patient safety index (PSI) failures, ICD9 complication codes, sentinel, and reportable events.

## Using multiple information systems at a population level

The Acute Trust Quality Dashboard was developed by the East Midlands Quality Observatory, bringing together in one dashboard all the available information relating to safety and quality from a wide variety of data sources across an entire population. The metrics and methodologies were developed through their network and suggested by 'many individuals and organisations'. Indicators have been selected drawing from the five domains of the NHS Outcomes Framework, the 2011/12 NHS Operating Framework and other sources to populate the domains with relevant measures and valid and robust data. A sixth domain has been created for the dashboard – 'Organisational approach to quality' – that contains metrics which look at organisational behaviour. The aim of the dashboard is to stimulate questioning and investigation, share learning and enable service improvement.

This dashboard is intended: 'to show quality of care in a statistically sound but easy to understand way using a set of indicators that encompass a range of

trust services; we want this to be available for free to everyone'. This source and examples of dashboards are available at: www.emqo.eastmidlands.nhs.uk/welcome/quality-indicators/acute-trust-quality-dashboard/

# 10.4  Learning from incident reporting in healthcare

Properly construed, a reporting system should be seen as an 'information, analysis, learning, feedback and action' system. Few healthcare organisations have achieved this on any level, but we can at least begin to envision the kind of data collection, analysis and response that is required. At the moment many healthcare reporting systems expend the majority of their effort on data collection, to the detriment of other aspects.

Safety reporting systems in healthcare have drawn their inspiration from similar systems in other industries, particularly aviation and the nuclear industry. We should note, however, a critical difference between healthcare and most other industries which is that other industries tend to only receive a few hundred reports a year even at a national level. For example, every report to an aviation reporting system can be examined in detail by pilots or other professionals who can, if they wish, contact the person who submitted the report in order to deepen the analysis. In contrast, a single healthcare organisation can receive thousands of reports, severely limiting both the depth of analysis and the possibility of feedback to individuals.

Reporting systems operate at different levels within the healthcare system. Some operate primarily at local level (risk management systems in hospitals), others at regional or national level. Local reporting systems typically provide a standard incident form, now often online, asking for basic clinical details and a brief narrative describing the incident. Sophisticated systems have also been established to investigate and understand a variety of specific issues, such as transfusion problems or safety in intensive care. National and other large-scale systems are expensive to run and have the disadvantage of relying mainly on brief electronic reports, perhaps supplemented by telephone checking. On the positive side their sheer scale gives a wealth of data, and their particular power is in picking up events that may be rare at a local level with patterns of incidents only appearing at national level. In Britain, reporting systems have been the principal means of learning from patient safety incidents. The centrepiece of the National Patient Safety Agency's strategy, and of a number of government reports, was the creation of a National Reporting and Learning System (NRLS) which integrated information from local systems.

The nature and purpose of all of these systems can only be fully understood by appreciating on what level they operate, who the audience is and how feedback and action are managed. In many cases little thought is given to this so that national systems are dealing with issues best addressed locally and vice versa, resulting in huge frustration and duplication of effort. Examples of national systems include the NRLS in England and the Danish Confidential and Non-Punitive Adverse Event Reporting System. At a regional level examples include the Pennsylvania Reporting System (PA-PSRS) in the USA and the Calgary Reporting System in Canada.

## Incident investigation and analysis

Incident analysis, when thoughtfully conducted, has wider purpose than finding out what events led up to the particular incident. Certainly it is necessary to find out what happened and why in order to explain to the patient, their family and others involved. However, if the purpose is to achieve a safer healthcare system, then it is necessary to go further and reflect on what the incident reveals about the gaps and inadequacies in the healthcare system in which it occurred. The incident acts as a 'window' on the system.[206] Incident analysis, properly understood, is not a retrospective search for root causes but an attempt to look to the future. In a sense the particular causes of the incident in question do not matter, as they are now in the past. However, the system weaknesses revealed are still present and could lead to the next incident.[206]

Generally speaking, in all areas of healthcare, only incidents with serious consequences are selected for detailed investigation and analysis (although we recognise that some healthcare organisations recognise the importance of investigating near misses where serious harm was prevented). This is partly due to regulatory demands but may also reflect a narrow view of the purpose of investigation and/or local resource constraints. One might instead select 10 instances of a particular type of problem, with a varying severity of outcome, and examine them for common themes with a view to mounting longer-term improvement programmes.

In many organisations root cause analysis (RCA) investigations are conducted by a trained manager or clinician. In Central and North West London Mental Health Trust over 500 staff have received RCA training and where a two-person team is conducting an investigation, at least one of them must have done RCA training. At UCLH, in-house incident investigation training has been developed by the trust risk manager, human factors specialist and education team. Incident investigators receive regular feedback through peer review of reports.

In industry, incident reporting measures matured from an early focus on presenting high level analyses of the number of incidents reported, type, severity and location of incident to developing more sophisticated process metrics aiming to assess the quality of the reporting and learning process (see chapter 3). Measurement of safety in other industries has also evolved to include in-depth analysis of the cost of incidents. In healthcare some of these indicators are used, such as time from incident to investigation and completion of investigation, however there is potential for other metrics to be developed in healthcare to assess systems-wide responsiveness and learning.

## 10.5  Rate of reporting and performance management: a word of caution

In some countries healthcare organisations face considerable pressure from regulators and government to increase reporting levels. For example, organisational feedback reports provided by the former UK National Patient Safety Agency (NPSA) benchmarked hospital incident reporting rates per 100 admissions against other similar organisations. The NPSA argued that organisations that reported more incidents would have a better and more effective safety culture. The reporting rate indicator established by the NPSA has been incorporated into domain 5 of the NHS Outcomes Framework 2012/13. The Framework describes two overarching indicators for domain 5, 'treating and caring for people in a safe environment and protecting them from avoidable harm', as follows: (i) patient safety incidents reported and (ii) safety incidents involving severe harm or death. For the overarching indicator (i), the technical appendix of the Outcomes Framework describes the 'outcome sought' from this measure as, 'improved readiness of the NHS to report harm and learn from it.' This well-intentioned attempt to improve reporting is unfortunate because the number of incidents reported probably bears little or no relationship to organisational learning from incidents. A narrow focus on reporting will inevitably lead to less resource being invested in the more critical issues of feedback and learning. Local healthcare organisations will strive to perform well on the NHS outcomes indicator and may in some cases focus on improving their reporting rate at the expense of analysis, learning and integration.

Data from some of our case study sites show variation across organisations in terms of their interpretation of the reporting rate indicator. Whereas some organisations interviewed were fixated on driving up reporting rates, others demonstrated a mature understanding of the limitations of the measure.

*'Evidence about the importance of having a good reporting culture from other industries has been translated into a reporting measure which is interpreted as indicative of the safety culture of the organisation. Having an open and just safety culture requires far more than a high reporting rate.'*
Director of Quality and Safety

## 10.6 Feedback and action

Feedback and action, whether from reporting or from integrated information, can happen at multiple levels in an organisation, at different time points and with different purposes.[50] The bounce back and rapid response ensures that staff remain engaged and understand that their reports are being taken seriously. However, once analysis has been carried out there are various ways in which action can be taken. Some issues are only of concern in a particular unit, such as faulty equipment or a handover system within that unit. Other issues need action across an organisation if, for instance, staffing levels are shown to be inadequate. Feedback that is restricted to a local system or specialty is attractive because it can be rapid and because it is being shared within a community of experts who understand the significance of the incident and the lessons it conveys. However, some safety issues, such as the design of equipment or drug packaging, cannot easily be addressed by any single organisation and need action at a regional or national level.

| **Box 10.1: Types of feedback** | | |
|---|---|---|
| **Feedback** | **Type** | **Content and examples** |
| A: Bounce back information | Information to reporter | • Acknowledge report filed (eg automated response) <br> • Debrief reporter (eg telephone debriefing) <br> • Provide advice from safety experts (feedback on issue type) <br> • Outline issue process (and decision to escalate) |
| B: Rapid response actions | Action within local work systems | • Measures taken against immediate threats to safety or serious issues that have been marked for fast-tracking <br> • Temporary fixes/workarounds until in-depth investigation process can complete (withdraw equipment; monitor procedure; alert staff) |
| C: Risk awareness information | Information to all front line personnel | • Safety awareness publications (posted/online bulletins and alerts on specific issues; periodic newsletters with example cases and summary statistics) |
| D: Inform staff of actions taken | Information to reporter and wider reporting community | • Report back to reporter on issue progress and actions resulting from their report <br> • Widely publicise corrective actions taken to resolve safety issue to encourage reporting (eg using visible leadership support) |
| E: Systems improvement actions | Action within local work systems | • Specific actions and implementation plans for permanent improvements to work systems to address contributory factors evident within reported incidents <br> • Changes to tools/equipment/working environment, standard working procedures, training programs, etc <br> • Evaluate/monitor effectiveness of solutions and iterate |

Our case study data have identified many different feedback methods used to disseminate lessons learnt from incidents to healthcare teams. The following examples illustrate various types of local feedback mechanisms in use.

At Great Ormond Street Hospital (GOSH) the cardiothoracic clinical director uses the intranet to give timely, specific feedback to the cardiothoracic unit team. Web links have been developed to illustrate the relationship between safety measurement data and lessons learnt from serious incidents. Lessons from serious incidents are web-linked back to the relevant sections of clinical guidelines on the departmental intranet site. In this way, when a clinical guideline is accessed on the intranet, pop-up boxes appear that remind team members of lessons learnt from past serious incidents relating to specific sections of the guideline. This acts as a feedback loop so the team can see where a deviation from the clinical guideline contributed to the last serious incident. It also makes clear the links between various types of safety measurement data and clinical guidelines.

In a mental health setting, Avon and Wiltshire Partnership Trust has developed a series of safety newsletters to convey key messages from incidents to healthcare teams working in community and acute mental health settings. Each Safety Matters newsletter focuses on a specific theme and describes lessons learnt from incidents involving violence and aggression, medication errors, and suicides and unexpected deaths. Additionally, the trust has developed its own internal safety alert system, known as red top alerts. Red top alerts are issued by the trust following the investigation of serious incidents to enable sharing of lessons learnt across all teams. Assurance that this information has been effectively cascaded is provided by managers who are given a deadline to communicate the key messages and report back that this has been done. Thus the alerts are a mechanism where several types of feedback, shown in Box 10.1, are integrated into one publication (ie raising risk awareness, informing staff of actions taken and improving work systems safety).

## 10.7  Organisational learning and improvement

The challenge at the higher levels of organisations is first to integrate the information, then analyse it in a meaningful manner, draw lessons and, where necessary, initiate improvement programmes. Central and North West London Community Trust has developed a process by which all safety indicators are integrated

and analysed to bring out learning themes for the organisation. From this an annual organisational learning report is produced which goes to the board and to service and clinical directors. This report is not a substitute for other safety measures but rather it combines the learning from them. Themes are generated using a services comparator where information is gathered from all areas covered by the trust. The report enables clinical and service directors to benchmark themselves against other directorates. It also provides an organisation-wide picture on where action is required and the overall learning themes. Safety themes from preceding years are presented such that directorates can track their performance over time. All this information is also looked at quarterly to identify sudden peaks of activity or problem centres. Recommendations are made in the report and corporate governance checks if they have been implemented. Sometimes the themes pulled out will become safety priorities for the trust.

The trust holds an annual board seminar to consider the learning across the strands and themes from all the safety-related information. From this plans for improving patient safety are developed for the year ahead. An example of organisational learning here is in the trust's approach to recruitment. A particularly serious untoward event four years ago highlighted the skills, abilities and attitudes of staff as contributory factors. The response to this single incident might reasonably have been to offer training to the staff involved. However, the incident revealed wider organisational problems that demanded a very different response. This led to a major workforce development plan involving the trust reviewing and revising its approach to recruitment, centralising nurse recruitment and setting the standards very high so only the best would be recruited. The CEO described how in the first round they had 240 applicants of whom they shortlisted 40 nurses for interview, taking them through a process involving assessments (similar to those they would use on the wards). They finally took on just one new member of staff. This sent a clear message about standards of care and as the CEO said, a 'shockwave' throughout the organisation. This rigorous approach has now been in place for several years and has been further refined. The example reveals how reflection on a small number of incidents can lead to an assessment of wider safety issues and also how the monitoring of safety critical indices, like staffing and skills, can form part of an overall safety strategy.

## 10.8 Reflections on integration and learning

This chapter has described how some of the case study sites integrate and learn from various types of safety information. There are differences in the approaches taken by different healthcare organisations. This is understandable, given the diversity of the clinical services provided across different care settings and the different patient populations served. We have also emphasised the importance of feedback, action and improvement as key elements of integration and learning. It is essential that healthcare organisations balance the focus of collecting and integrating safety information with appraising how it is used to deliver meaningful feedback, action and improvement.

# Section III:
# Reflections and implications

# Chapter 11:
# Guiding principles for safety measurement and monitoring

Safety measurement and monitoring is complex and multi-faceted, yet vitally important if safety is to improve. We have considered the challenges, reviewed safety measurement in the NHS, reviewed the approaches of other industries and been informed by a variety of conceptual models and approaches to safety. We learned from other industries that catastrophic errors are not always foreseen or predicted by the safety data that are collected and monitored. We have also studied a number of organisations and gained much from the advice and knowledge of many healthcare researchers and practitioners. We have found a bewildering array of concepts, metrics, approaches and debates about how safety is best measured and monitored. We have, nevertheless, also found that many healthcare organisations have made substantial progress in safety measurement and monitoring.

Asking whether an organisation is safe leads us to a number of questions that address these different facets of safety. We tried to find, in this diversity, a simple yet valid framework to structure our own thinking. This in turn led us to reflect on what kind of information we would ideally need to give us a comprehensive and rounded picture of an organisation's safety. We have suggested that there are five fundamental classes of safety information reflecting different dimensions of safety:

– measures of harm, both psychological and physical

– measures of reliability, which encompass behaviour, processes and systems

– the information and capacity to monitor safety on an hourly or daily basis

– the ability to anticipate problems and be prepared

– integration of and learning from safety information.

We think that this framework not only encompasses the principal facets of safety revealed in the preceding chapters but also provides simplicity and clarity with which to guide and inform safety measurement and monitoring. We can see, however, that much remains to be done to translate the findings of this report for different contexts and different audiences. We hope that wherever people work in healthcare, the material assembled in this report and the approach taken will provide ideas, inspiration and practical suggestions to enhance safety measurement and monitoring in any organisation.

We initially thought that it might be possible to sketch out the main directions for safety measurement in different healthcare contexts. However, we soon discovered that this would require another report of about the same length. In any case, we believe that this would be done better in collaboration with people from the relevant settings. Instead we have set out some guiding principles for safety measurement and monitoring that we think are relevant in all contexts. These principles are not set in stone, but rather suggested directions of travel derived from our synthesis of the experiences of many people and organisations and the wider safety literature.

# Ten guiding principles for safety measurement and monitoring

## 1. A single measure of safety is a fantasy

The search for simple metrics has at times led to claims that it is possible to use a specific measure, such as standardised mortality, as a generic indicator of safety performance. A hospital advertises its enviably low mortality rate in the front entrance and uses this information to claim that it is one of the safest organisations in the country. Can we trust this claim? Can any single measure give us the assurance that a healthcare organisation is safe? Boards and others responsible for safety sometimes search for the elusive single measure of safety that will enable them to sleep well because the single universal safety metric is within bounds. We believe that this is a fantasy – an understandable one but a fantasy nevertheless. In most organisations there are just too many different activities, too many different dimensions of safety and too many factors that influence safety. We certainly think that a great deal can be done to assure safety, but not that this can be encapsulated in a single measure. Worse, such a reductionist approach to measuring safety may have the consequence of making healthcare organisations less safe through providing false reassurance and complacency in the face of continuing hazards.

## 2. Safety monitoring is critical and does not receive sufficient recognition

Healthcare organisations use a variety of formal and informal approaches to elicit safety information that enables them to understand how frontline healthcare services are delivered. Timely action and intervention to thwart potential safety risks is the other key component of sensitivity to operations, which does not always fit well with rigid structures and management by committee. External regulators place considerable emphasis on monitoring harm and incidents, but the critical role of an organisation's approach to monitoring safety does not always receive sufficient attention. Time to walk, talk and watch is critical to monitoring and maintaining safety. However, this cannot be done if staff are burdened with administrative tasks and not empowered with the freedom and authority to monitor and intervene when necessary.

Patients, carers and others play a particularly critical role in this regard both in monitoring their own safety and that of the wider safety of the healthcare system. Just like healthcare teams, patients and carers create safety by intervening and thwarting potential safety issues. For instance, someone caring for a person with a serious mental health problem has to maintain constant vigilance about the potential for harm. By learning from past events, by listening and perceiving, and by foreseeing future areas of risk, carers operationalise these dimensions of safety. They are an essential but all too often underused defence in preventing patient harm.

It is also becoming increasingly apparent that patients and families provide some of the best and most pertinent warnings of deteriorating and dangerous organisations. While regulators struggle with intermittent visits and a lack of timely data, patients have immediate experience of poor or dangerous care. Generally speaking, healthcare has not captured the patient and carer role in safety and translated it into meaningful patient- and carer-centred safety metrics. Future work is needed in this area to ensure that what we are measuring is relevant to the people we serve.

## 3. Anticipation and proactive approaches to safety

Evidence from other industries has shown that safety measurement evolves over time and that there have been important differences between industries in the pace and path that this evolution has taken. Common to all industries is the recognition of the need to move away from an over-reliance on lagging indicators to a mixed model that combines both lagging and leading indicators. But where is healthcare in this evolutionary process? The case study evidence indicates that while healthcare organisations do not rely solely on reactive measures of safety further development of leading indicators in healthcare is needed. One of the notable findings from our case studies was that those organisations interviewed provided many fewer examples of 'anticipation and preparedness' metrics than metrics in the other four classes of safety information in our conceptual framework.

## 4. Integration and learning: invest in technology and expertise in data analysis

Safety information is fragmented both within NHS organisations and across the wider system. At a local level many organisations have an array of safety relevant information that consists both of formal intelligence and local intelligence from informal conversations and observation. Integrating this information at an appropriate level and in a usable and comprehensible format is probably the greatest challenge.

Some of the healthcare organisations we interviewed had a much more evolved approach to safety measurement than others. Those with integrated data management capacity were able to collate safety information from many different sources in a timely way. Boards in these organisations recognised that

investment in data analysts and information technology was essential in order to help clinicians collect and use information in a meaningful way. Such organisations had moved away from roles such as 'clinical audit facilitator' or 'unit risk manager' and introduced new roles for people with skills and expertise in the collection and use of safety and quality information within divisions and directorates. Investment in data analyst teams and automated data capture has enabled some organisations to collect and present safety data in formats that are accessible to clinicians, managers, executive and non-executive directors alike.

## 5. Mapping safety measurement and monitoring across the organisation

Safety measurement and monitoring has a number of dimensions and must, to some extent, be customised to local settings and circumstances. The assessment of other dimensions of quality, in particular clinical outcomes, necessarily varies between contexts: surgical outcomes are assessed in a different way from those in maternity or mental health. The same is also true for safety, even though in practice organisations tend to rely solely on generic safety indices such as incident reporting. In fact, in each clinical context we should be considering what kinds of harm are prevalent; what features of care must be reliable; and how we monitor, anticipate and integrate safety information. As we have seen, harm can take various forms and all different categories of harm must be considered. Assessing the reliability of key processes, behaviours and systems by sampling at defined intervals is also fundamental. All this information needs to be integrated at the different levels of the organisation and also set alongside wider quality and financial metrics. In this report, we have focused almost entirely on safety as this is the area in which there is most confusion. However, safety cannot be assessed in isolation and must always be considered alongside the wider objectives and metrics of the organisation.

## 6. A blend of externally required metrics and local development

We have learned that safety measurement, and particularly safety monitoring, must be customised to local settings and local circumstances. This is not to advocate a free-for-all of locally derived metrics: there are many indices that can and should be agreed nationally or even internationally. But day-to-day monitoring, anticipation and preparedness are necessarily local activities, whether at ward or board level.

Although our case study sites showed uniformity in terms of some of the external safety metrics they applied, there were also important variations across sites. Going forward it is important to remember that some types of metrics will be more or less appropriate to a given healthcare organisation, depending on the type of care setting and each organisation's culture and infrastructure. While recognising that some types of measures need to be standardised, we also need to balance the pursuit of standardisation of safety metrics with a recognition that there is not a 'one size fits all solution' where safety measurement and monitoring is concerned. The importance of this issue was raised by the paediatric and mental health case study sites which commented that one of their biggest challenges is inheriting safety measures originally designed in an acute setting that do not marry with their specific patient population.

## 7. Clarity of purpose is needed when developing safety measures

Healthcare can learn from other industries' experiences in being clear on the design, purpose and target audience for safety measures. Quality and safety dashboards often contain a myriad of red, amber and green metrics that are reviewed as one agenda item in a three-hour board meeting. Healthcare regulators, national agencies and commissioners of services need to consider the criteria for safety measures and be clear on the purpose of each measure. Specifically we need to ask the following questions.

– Who is each safety measure being developed for?

– How and in what context will the safety measure be used?

– Is it measuring what it claims to measure?

– Can this metric be used to reliably detect or demonstrate deterioration or improvement?

– What untoward consequences will this metric have?

When safety measures are developed, healthcare regulators, national agencies and commissioners of services need to beware of perverse incentives leading to gaming and excessively complex or burdensome data collection. They also need to ensure that safety measures are tested in practice prior to implementation. An approach that looks promising to a regulator or a government department may in practice have a variety of unforeseen and unwanted consequences.

## 8. Empowering and devolving responsibility for the development and monitoring of safety metrics is essential

Other industries have recognised the need to empower managers, supervisors and operational staff to develop safety metrics suitable for their specific operations. In future healthcare regulators, national agencies and commissioners of services need to be flexible and allow clinical units to develop bespoke measures relevant to their clinical context. Similarly, healthcare managers need to have a flexible approach when developing safety measures. Enabling clinical units to adapt measures so that they are relevant to their specific clinical context is vital to avoid clinicians becoming disenfranchised.

The nuclear industry has a goal-setting approach that devolves responsibility to demonstrate safety to industry companies. The current approach of some healthcare regulators is highly prescriptive, rather than goal setting. We need to move towards a goal-setting approach in which regulators and managers set goals and standards that require organisations to demonstrate that their care is safe but allow some flexibility in how this is achieved. Organisations need to be able to answer the question: 'is healthcare getting safer across your organisation and what measures do you have to show this?'

## 9. Collaboration between regulators and the regulated is critical

In healthcare, one potential risk to the evolution of safety measurement is fragmentation of key safety information across multiple national and local stakeholders. The NHS has a number of regulators (unlike the aviation and nuclear industries where there is a single regulator) and numerous other government stakeholders who are custodians of safety information.

The net effect of this fragmentation is that producing single source safety measurement reports that triangulate data from many safety metrics (like those cited for the oil and gas and mining industries) relies on the collaboration of a broad range of stakeholders. Furthermore, even if this collaboration were achieved, differences between local NHS organisations (for example, in the grading of harm on incident reports) would make meaningful benchmarking across organisations difficult. We also believe that the multiplicity of regulators in the NHS and the fragmented approach to regulation is potentially a threat to safety. Huge resources are consumed in meeting external demands to the detriment of the critical activities of monitoring, anticipation and, above all, improvement. Worse, equating safety with satisfying the regulators provides false reassurance and allows organisations to miss glaring safety issues simply because they fall outside the regulatory framework.

## 10. Beware of perverse incentives

Some types of measurement introduce perverse incentives that can lead to 'ticking the box' or behaviour that circumvents the original purpose of the safety measure. That is to say, certain safety measures create behavioural side effects where managers and operators demonstrate that they can meet a target, but they do so in a way that undermines the intended purpose of the measure. Where financial penalties are imposed if a healthcare organisation exceeds a threshold on a given safety indicator, this may promote under-reporting by clinical teams. In obstetrics, some health authorities have imposed a threshold target for perineal tears. If the target is exceeded, financial penalties are imposed. This type of performance management approach promotes under-reporting or encourages clinicians and hospital managers to focus on reducing one type of harm, as opposed to implementing a more holistic approach to measure, monitor and implement interventions for all potential types of harm.

## Final reflections

We have found that our framework and the classifications of the various metrics and approaches have helped us to clarify the issues and find a way forward. We believe that the five dimensions are relevant in all areas of healthcare and that any unit, department or organisation can use the dimensions and the related questions to structure its own approach to safety measurement and monitoring.

We have admired the huge efforts that some healthcare organisations invest in measuring and monitoring patient safety. We recognise that the cost of safety measurement and monitoring will need to be fully assessed as measurement systems evolve. We also note how, in many organisations, there has been considerable evolution and there is evidence of greater maturity in approaches to safety measurement if one compares where we are now to where we were when the landmark report *An organisation with a memory* was published. However, further cultural shifts in the approach to safety measurement among healthcare regulators, managers and clinical teams are needed to refine the current approaches.

We can now see the way forward and the broad outlines of an effective approach to safety measurement and monitoring. We hope that this report and the many approaches described will provide both inspiration and practical guidance for all those faced with the challenge of keeping patients safe in the hazardous environment of healthcare.

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We are here to inspire and create the space for people to make lasting improvements to health services.

We conduct research and evaluation, put ideas into practice through a range of improvement programmes, support and develop leaders and share evidence to drive wider change.