The Essentials of Patient Safety

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Preface

Patient safety is the foundation of good patient care. When a member of your family goes into hospital or receives other healthcare then above all you want them to be safe. There is something horrifying about being harmed, or indeed causing harm, in an environment of care and trust. I believe that safety is a touchstone and guide to the care that is given to patients. The clinician or the organisation that keeps safety to the fore in the midst of many other often competing priorities achieves something remarkable and provides the care that we would all want to receive.

As you will see however there is compelling evidence that, while healthcare brings enormous benefits to us all, errors are common and patients are frequently harmed. The nature and scale of this harm is hard to comprehend. It is made up, world wide, of hundreds of thousands of individual tragedies every year in which patients are traumatised, suffer unnecessary pain, are left disabled or die. Many more people have their care interrupted or delayed by minor errors and problems; these incidents are not as serious for patients but are a massive and relentless drain on scarce healthcare resources.

Understanding how to make healthcare safer is hard and actually making care safer is harder still. Healthcare is the largest industry in the world and extraordinarily diverse in terms of the activities involved and the manner of its delivery. We are faced with hugely intractable, multifaceted problems which are deeply embedded within our healthcare systems. Understanding and creating safety is a challenge equal to understanding the biological systems that medicine seeks to influence.

This short introduction is taken from my book *Patient Safety* (2nd edition, 2010). My aim has been to make the essentials of patient safety available to everyone. The topics addressed include the evolution of patient safety; the research that underpins the area, understanding how things go wrong, and the practical action needed to reduce error and harm and, when harm does occur, to help those involved. The main book covers these topics in more depth and a number of additional topics such as measurement, safety culture, design, safety campaigns and safe organisations.

If this introduction succeeds in its aims I hope you will be convinced that patient safety is critically important for both patients and healthcare staff in every setting throughout the world. Hopefully you will be inspired to immerse yourself more deeply in the subject and join the many other people working for safer healthcare. Treating patients one at a time brings obvious and immediate benefits but working to improve the safety of healthcare as a whole may ultimately benefit many more.

Charles Vincent
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CHAPTER 1
The Evolution of Patient Safety

Medical error and patient harm have been described and studied for well over a century. However, apart from a few isolated pioneers, the medical and nursing professions did not appear to recognise the extent and seriousness of the problem or, if they did, were not prepared to acknowledge it. The great majority of clinical staff have always been safety conscious in their personal practice. Patient safety however is a broader endeavour that requires thinking beyond the individual patient to consider the characteristics of the whole system of healthcare

One of the great achievements of the last ten years is that medical error and patient harm are now acknowledged and discussed publicly by healthcare professionals, politicians, and the general public. Before this medical error was seldom acknowledged to patients, almost never mentioned in medical journals and not even considered by governments. The fact that thousands, probably millions, of people were being harmed unnecessarily and vast amounts of money being wasted seemed to have escaped everyone's attention. From our current understanding this seems a curious state of affairs. It is as if an epidemic were raging across a country without anybody noticing or troubling to investigate.

How then did patient safety evolve and emerge to assume its present importance? This first chapter outlines some of the main influences and drivers of patient safety to show how it has become one of the defining features of practice and policy.

Defining patient safety

Achieving safe care is part of the broader quest to achieve high quality care on a number of dimensions. The Institute of Medicine (1) sets out six dimensions (Box 1.1), with safety leading the way as the dimension that is perhaps most critical to patients and families. Patient safety can, at its simplest, be defined as:

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

The definition also refers to the amelioration of adverse outcomes or injuries, which broadens the definition beyond traditional safety concerns towards an area that would, in many industries, be called disaster management. In healthcare amelioration 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 to support the staff involved.

Box 1.1 The dimensions of quality

Safe – avoiding injuries to patients from the care that is intended to help them

Effective – providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse)

Patient-centred – providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions

Timely – reducing waits and sometimes harmful delays for both those receive and those who give care

Efficient – avoiding waste, in particular waste of equipment, supplies, ideas, energy

Equitable – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location and socioeconomic status

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Patient safety – reducing harm or reducing error?

Patient safety is sometimes equated with preventing error (3). This seems innocent enough, but 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 (4). 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.

- 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.

- Not all harm is due to error. Consider all the myriad forms of harm that can come from healthcare: complications of surgery, infection from unsafe injections, infection from overcrowded hospitals, adverse drug reactions, overdoses from badly designed infusion pumps and so on. If we equate patient safety with error reduction we run the risk of not addressing any form of harm which is either not due to error, or only partly due to error.

- Many errors do not lead to harm and, indeed, may be necessary to the learning and maintenance of safety. Surgeons for instance, may make quite a number of minor errors during a procedure none of which really compromise the safety of the patient or the final outcome of the operation (5).

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Tragedy and opportunities for change

> *'The knowledgeable health reporter for the Boston Globe, Betsy Lehman, died from a drug overdose during chemotherapy. Willie King had the wrong leg amputated. Ben Kolb was eight years old when he died during 'minor' surgery during a drug mix up. These horrific cases that make of the headlines are just the tip of the iceberg'.*
> (Opening paragraph of the Institute of Medicine report, To err is human (1))

Certain 'celebrated' cases attain particular prominence and evoke complicated reactions. The public account of these stories is usually a gross over simplification of what actually occurred and, as we shall see later, the causes of such events are often complex. Such disastrous cases however come to symbolise fear of a more widespread failure of the healthcare system, provoking more general concerns about medical error (6). Perhaps it isn't just a question of finding a good, reliable doctor. Perhaps the system is unsafe? Such concerns are magnified a hundred fold when there is hard evidence of longstanding problems in a service and a series of tragic losses. This is well illustrated by the events that led to the UK Inquiry into infant cardiac surgery at the Bristol Royal Infirmary (Box 1.2) which is still vividly remembered in Britain (7). Many other countries have experienced similar high profile tragedies.

Box 1.2 Events leading up to the Bristol Inquiry

In the late 1980s some clinical staff at the Bristol Royal Infirmary began to raise concerns about the quality of paediatrics cardiac surgery by two surgeons suggesting that mortality was substantially higher than in comparable units. Between 1989 and 1994 there was a continuing conflict at the hospital about the issue between surgeons, anaesthetists, cardiologists and managers. Agreement was eventually reached that a specialist paediatric cardiac surgeon should be appointed and in the meantime that a moratorium on certain procedures should be observed. In January 1995, before the surgeon was appointed, a young child was scheduled for surgery against the advice of anaesthetists, some surgeons and the Department of Health. He died and this led to further surgery being halted, an external inquiry being commissioned and to extensive local and national media attention.

Parents of some of the children complained to the General Medical Council which, in 1997 examined the cases of 53 children, 29 of whom had died and four of whom suffered severe brain damage. Three doctors were found guilty of serious professional misconduct and two were struck off the medical register.

The Secretary of State for Health immediately established an Inquiry, costing £14 million, chaired by Professor Ian Kennedy. The Inquiry began in October 1998 and the report published in July 2001 made almost 200 recommendations.

(Adapted from Walshe and Offen 2001)

Error in medicine

Twenty years ago medical error was hardly mentioned in the medical literature let alone discussed publicly. In 1994 Lucian Leape, a surgeon from Harvard, published a prescient and seminal paper (8) which addressed the question of error in medicine

head on and brought some entirely new perspectives to bear. Leape began by noting that a number of studies suggested that error rates in medicine were particularly high, that error was an emotionally fraught subject and that medicine had yet to seriously address error in the way that other safety critical industries had. He went on to argue that error prevention in medicine had characteristically followed what he called the 'perfectibility model'. If physicians and nurses were motivated and well trained then they should not make mistakes. If they did make mistakes then punishment in the form of disapproval or discipline was the most effect remedy and counter to future mistakes. Leape summarised his argument by saying:

> *'The professional cultures of medicine and nursing typically use blame to encourage proper performance. Errors are caused by a lack of sufficient attention or, worse, lack of caring enough to make sure you are correct'* (Leape 1994 p1852).

Leape, drawing on the psychology of error and human performance, rejected this formulation on several counts.

- Many errors are often beyond the individual's conscious control; they are precipitated by a wide range of factors, which are often also beyond the individual's control

- Systems that rely on error-free performance are doomed to failure

- Error prevention that relies exclusively on discipline and training is also doomed to failure

Leape went on to argue that if physicians, nurses, pharmacists and administrators were to succeed in reducing errors in hospital care, they would need to fundamentally change the way they think about errors(8). He explicitly stated that the solutions to the problem of medical error did not primarily lie within medicine, but in the disciplines of psychology and human factors, and set out proposals for error reduction that acknowledged human limitations and fallibility and relied more on changing the conditions of work than on training.

Professional and government reports: patient safety hits the headlines

In 1999 the US Institute of Medicine published a report called 'To err is human' (1), which bluntly set out the harm cause by healthcare in the United States and called for action on patient safety at all levels of the health care system. Without doubt the publication of this report was the single most important spur to the development of patient safety, catapulting it into public and political awareness and galvanising political and professional will at the highest levels in the United States.

President Clinton ordered a government wide study of the feasibility of implementing the report's recommendations. However as Lucian Leape recalls one particular statistic provided a focus and impetus for change:

> *'However, while the objective of the report, and the thrust of its recommendations, was to stimulate a national effort to improve patient safety, what initially grabbed public attention was the declaration that between 44,000 and 98,000 people die in US hospitals annually as a result of medical errors'.* (9)

'To err is human', the first of a series of reports on safety and quality from the Institute, was far more wide ranging than the headline figures suggest. A large number of studies of error and harm were reviewed including the causes of harm, the nature of safe and unsafe systems and the role of leadership and regulation. The principal aim of the report was to establish patient safety as a major requirement and activity of modern healthcare, by establishing national centres and programmes, expanding and improving reporting systems and driving safety in clinical practice through the involvement of clinicians, purchasers of healthcare, regulatory agencies and the public.

An organisation with a memory: learning from adverse events in the NHS

Since the publication of the Institute of Medicine report many governments and professional organisations have released reports and official statements on patient safety. The British equivalent of the Institute of Medicine report was prepared by a group led by Professor Liam Donaldson, the UK's Chief Medical Officer (10). Unlike the Institute of Medicine report, it emanated from government and was bravely authorised for release by the then Secretary of State for Health Alan Milburn.

The report's primary emphasis was, as the title suggests, on learning. Reviewing the systems of learning from errors in the NHS, the report identified numerous weaknesses with the processes and contrasted this unfavourably with other high-risk industries. Great stress was also laid on understanding the underlying causes of adverse events and on the potential parallels between healthcare and other high risk industries. The report argued that all human beings who work in complex systems are prone to similar errors and subject to similar pressures. The themes and progress on culture, teamwork, reporting, systems thinking highlighted in these reports will all be examined in later chapters. But first we need to examine the studies of the nature and scale of harm. Can it really be true that healthcare kills tens of thousands of people each year in the United States and, by implication, perhaps hundreds of thousands across the world?

KEY POINTS

Patient safety is the avoidance, prevention and amelioration of harm from healthcare

Tragedies and high profile cases have raised public awareness of patient safety

Some errors cause harm but many do not

Blame and discipline are an ineffective response to most safety problems

Government and professional reports brought patient safety into the mainstream

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CHAPTER 2
The Nature and Scale of Harm to Patients

How safe is healthcare? How often do errors occur? Are the high profile cases rare isolated accidents in an otherwise safe systems or are they, in the time honoured phrase, just the tip of the iceberg? Defining and measuring error and harm is not as simple as it might seem. We can however gain an understanding of the overall scale of the problem and the challenges we face. As we shall see, while rates of error and harm vary in different settings, there is now substantial evidence of very high rates of error in many contexts and considerable evidence of harm to patients.

Defining harm in healthcare

Safety in other domains is assessed by the incidence of accidents and injuries; aviation accidents, road accidents, lost time injuries at work and other types of mishap are counted and tabulated by various means. In healthcare we would ideally, we would 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. Defining harm however is a particularly difficult issue in healthcare for a number of reasons:

- In other arenas establishing cause and effect between accident and injury is reasonably straightforward. In contrast, patients are generally, though not always, sick and separating the harm due to healthcare from that due to illness is often difficult.

- Some treatments given in healthcare are necessarily 'harmful' to the patient; radiotherapy and chemotherapy are two obvious examples.

- Harm from healthcare may not immediately be detected or may only gradually become apparent. In fact, a cause celebre of medical error - the chemotherapy overdose of Boston Globe reporter Betsy Lehman - was only discovered on a routine review of research data(1).

- Even if a patient is harmed this does not necessarily point to any deficiencies in care. One patient may get pneumonia because of a major lapse in basic care; another may receive exemplary care but still succumb to pneumonia.

Once harm has been defined then once has to find ways of measuring it which can be tricky, particularly if the events are rare or if the patient's exposure to hazards is hard to assess. The principal have been 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'* (2).

The concept of an adverse event

The most commonly used definition of harm in patient safety is the 'adverse event'. This concept has originally described by the authors of the Harvard Medical Practice Study, described below, which set out to assess harm from healthcare in New York State in the mid 1980s. They defined an adverse event as:

> *'An unintended injury caused by medical management rather than by the disease process and which is sufficiently serious to lead to prolongation of hospitalisation or to temporary or permanent impairment or disability to the patient at time of discharge or both'* (3).

Medical management includes acts of omission (for instance a failure to diagnose or treat) and commission (giving an incorrect treatment). Injury therefore on this definition may result either from harmful treatment or from failing to provide proper care. The injury has to be unintended, since injury can occur deliberately and with good reason, such as a necessary amputation. Note especially that adverse events may or may not be judged as being preventable. For instance a complication in surgery that was judged to be almost inevitable because of the patient's condition would be considered as an adverse event, but an unpreventable one.

Studying adverse events using case record review

Retrospective reviews of medical records aim to assess the nature, incidence and economic impact of adverse events and to provide some information on their causes. The classic, pioneering study in this area is the Harvard Medical Practice Study, still hugely influential. The Harvard group developed the original process of review of medical records to detect adverse events. The basic process is as follows. In phase I nurses or experienced record clerks are trained to identify case records that satisfy one or more of 18 well-defined screening criteria – such as death, transfer to a special care unit or re-admission to hospital within 12 months(4). These have been shown to be associated with an increased likelihood of an adverse event(5). In phase II trained doctors analyse positively screened records in detail to determine whether or not they contain evidence of an adverse event using a standard set of questions.

Studies in many countries have followed this basic method and have come to broadly similar conclusions (Table 2.1). Rates of adverse events in most recent studies lie between 8% and 12%, a range now accepted as being typical of advanced healthcare systems(6). Note however that only about half the adverse events detected are thought to be preventable with current standards of care, though we might aim to eliminate many more as healthcare evolves. These findings suggest that healthcare can actually be considered a public health risk:

'Of the top 20 risk factors that account for nearly three quarters of all deaths annually, adverse in-hospital events come in at number 11 above air pollution, alcohol and drugs, violence and road traffic injury' (7)

Table 2.1 Adverse events in acute hospitals in ten countries

Study	Authors	Date of admissions	Number of hospital admissions	Adverse event rate (% admissions)
Harvard Medical Practice Study	Brennan et al, 1991; Leape et al, 1991	1984	30195	3.7
Utah-Colorado Study	Thomas et al, 2000	1992	14052	2.9
Quality in Australian Health Care Study	Wilson et al, 1995	1992	14179	16.6
United Kingdom	Vincent et al, 2001	1999	1014	10.8
Denmark	Schioler et al, 2001	1998	1097	9.0
New Zealand	Davis et al, 2002	1998	6579	11.2
Canada	Baker et al, 2004	2002	3745	7.5
France	Michel et al, 2007	2004	8754	6.6% per 1000 days admission
United Kingdom	Sari et al, 2007	2004	1006	8.7
Spain	Aranaz-Andre et al, 2008	2005	5624	8.4
The Netherlands	Zegers et al, 2009	2006	7926	5.7
Sweden	Soop et al, 2009	2006	1967	12.3

Types of adverse event

The most frequent adverse events in most studies are surgical complications, healthcare acquired infections and adverse drug events. In the UK complication rates for some of the major operations are 20-25% with an acceptable mortality of 5-10% (8). However at least 30-50% of major complications occurring in patients undergoing general surgical procedures are thought to be avoidable. Nosocomial infection, or healthcare associated infection (HCAI), is the commonest complication affecting hospitalised patients. Approximately 5-10% of patients admitted to hospital in Britain and the United States acquire one of more infections; millions of people each year are affected (9).

Many adverse drug events occur outside hospital, often then leading to hospital admission. For instance, in Boston Tejal Gandhi and colleagues reviewed 661 out patients on a variety of drug regimens (10). Incredibly, almost a quarter of these people were assessed as suffering adverse drug reactions and about 6% of the patients were suffering serious reactions. Serious adverse drug reactions included bradycardia, hypotension and gastrointestinal bleeding, many of which were clearly preventable. Other consequences were less serious, in that they did not present immediate threats to life, but were certainly serious for the patient. For instance, one patient suffered prolonged sexual dysfunction after his doctor failed to stop a selective serotonin uptake inhibitor; another had continued sleep disturbance due to taking an anti-depressant that his doctor was not aware of. Such reactions represent prolonged, avoidable suffering over many months, to say nothing of the waste of time and resources.

The impact and cost of adverse events

The majority of adverse events, about 70% in most studies, do not have serious consequences for the patient; the effects of minor events may be more economic, in the sense of wasted time and resources, than clinical (6). Some, such as the reaction to anaesthetic, are not serious for the patient but are classed as an adverse event because there was an increased stay in hospital of one day; it was probably not preventable in that it would have been hard to predict such an idiosyncratic reaction. Others however, as the remaining examples show, cause considerable unnecessary suffering and extended time in hospital.

In Britain the cost of preventable adverse events is £1 billion per annum in lost bed days alone as, on average, an adverse event leads to an extra week in hospital (11). The Institute of Medicine report (1999) was able to estimate that in the United States the total national costs associated with adverse events and preventable adverse events represent approximately 4% and 2% respectively of national health expenditure (12). Costs of direct hospital care, essentially additional time in hospital, have recently been estimated from the Dutch adverse events study finding that about 3% of all bed days and 1% of the total health budget could be attributed to preventable adverse events (13). The real overall costs are probably a good deal higher, as these estimates do not include additional treatments and investigations or any of the associated societal costs discussed above. Remember also that these estimates are confined to the hospital sector; we have no idea of the additional costs of adverse events in primary care or mental health.

The human cost of adverse events is the greatest of all. Many patients suffer increased pain and disability from serious adverse events. They often also suffer psychological trauma and may experience failures in their treatment as a terrible betrayal of trust. Staff may experience shame, guilt and depression after making a mistake with litigation and complaints imposing an additional burden (14). These profoundly important aspects of patient safety, generally given far too little attention, are considered later.

Vulnerability to harm: the old and the frail

Curiously, relatively little attention has been paid to patient safety in older people although they are particularly vulnerable to healthcare error and harm, as are the very young (15). Most people in hospital are old. In Britain for instance patients over 65, mostly with multiple long term conditions, account for about 60% of admissions and

70% of bed days; many of these people are also physically frail and may have some degree of cognitive impairment (16). Dramatic, usually sudden deaths of younger people, attract more attention than the slow decline of an elderly person from dehydration, drug errors and neglect.

Although attitudes, culture and delivery of healthcare all influence the quality of care provided, older people are also vulnerable to harm for solid physiological reasons. They are more likely to suffer from multiple conditions, receive multiple treatments and to stay longer in hospital. A longer stay increases the risk of all the complications of hospitalisation. In addition, the frailty of older people means that they have a reduced physiological reserve and are more strongly affected by, say, an adverse drug event than their younger counterparts and take much longer to recover.

Once weakened they become vulnerable to a downward spiral in which for example a fall weakens them, an infection sets in, followed by delirium which makes feeding difficult, in turn leading to malnutrition and increasing frailty; such a scenario once entrenched is very hard to reverse (17). All too often, once the older patient has recovered sufficiently to leave hospital, the combined effect of these geriatric syndromes will have lead to (often irreversible) functional decline, loss of independence and possibly institutionalisation. Conversely, active and effective management of these conditions at an early stage can produce rapid improvement on several fronts.

Detecting adverse events: reporting and learning systems

Systematic records reviews provide the most comprehensive assessment of the scale of harm but they can be quite resource intensive. Many healthcare systems have relied extensively on voluntary reporting of adverse events and related incidents as a means of monitoring safety. Such safety reporting systems have drawn their inspiration from similar systems in other industries, particularly aviation and the nuclear industry. Most industrial reporting systems have a broad remit in that reporting of near misses, general safety issues and anything that worries the pilots or operators is encouraged (18). All the reporting systems give feedback in the form of regular reports on recent incidents and, crucially, actions taken to enhance safety; they may also give feedback to individuals who make reports.

Reporting systems operate at different levels within the healthcare system. Some operate primarily at local level others at regional or national level. Typically there is a standard incident form, asking for basic clinical details and a brief narrative describing the incident. Staff are asked to report any incident which concerns them or might endanger a patient; in practice serious incidents are followed by an urgent telephone call to the risk manager. In more sophisticated systems where staff within a unit may routinely monitor a designated list of incidents, although staff are free to report other issues that do not fall into these categories.

Information from local reporting systems may be collated and analysed in much larger state wide or national systems. National and other large scale systems are expensive to run and have the disadvantage of being primarily reliant on the written 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 incident only appearing at national level(19). For instance the United Kingdom Reporting and Learning System (RLS) collects incident data from the British National Health Service in England and Wales. Incidents collected in local risk management systems are forwarded to the NRLS and

analyses of different types of incidents undertaken, alongside a variety of other national initiatives. The technical and analytic challenges of such a system are considerable, as it deals with simply staggering numbers of incidents; by early 2009 the database contained over 3 million incidents in total most of which, of necessity, have not been subject to any formal analysis.

Reporting systems were established in response to the scale of harm revealed by case record review studies. The studies had shown the underlying problem; reporting systems were meant to provide information about adverse events on an ongoing basis. However incident reporting systems are actually very poor at detecting adverse events (20). For example Sari and colleagues (21) carried out a classical case record review of 1000 records and compared the findings with locally reported incidents. The reporting system detected only 5% of adverse events discovered by reviewing records. This means that voluntary reporting systems are pretty useless as a means of measuring harm. However, as we will see, they can be valuable as a means of surfacing safety issues in order to learn about the vulnerabilities of the system.

Analysis, feedback and action from reporting systems

The real meaning and importance of incidents is apparent only in the narrative. To make real sense of an incident you must have the story and, furthermore, the story must be interpreted by someone who knows the work and knows the context. The implication of this is that if healthcare incident reports are to be of real value they need to be reviewed by clinicians and, ideally, also by people who can tease out the human factors and organisational issues. One of the main problems that healthcare faces is that the number of reported incidents is so vast in mature systems that only a minority of incidents can be reviewed by those with relevant expertise (20).

It is impossible to analyse all reports in detail and for common incidents largely pointless; better to analyse a small number of reports in depth than carry out a cursory analysis of a large number which often produces little more than a few bar charts. Once analysis has been carried out though, there are various ways in which action can be taken. Some issues are only of concern in a particular unit, faulty equipment for instance or a system of handover within that unit. Others 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.

Reporting will always be important, but has been overemphasised as a means of enhancing safety. The fact that only a small proportion of incidents are reported is not, in my view, critically important. As long as the system receives sufficient reports to identify the main safety issues the absolute number of reports is not critical. Reporting systems serve an important function in raising awareness and generating a culture of safety as well as providing data. However the results of reporting are often misunderstood in that they are mistakenly held to be a true reflection of the underlying rate of errors and adverse events. Incident reporting is crucial, but is only one component of the whole safety process. Incident reports in themselves are primarily flags and warnings of a problem area. Once collected however they must be analysed and understood which is the subject of the next chapter.

KEY POINTS

Adverse events are injuries that are due to healthcare management rather than to the underlying disease

Adverse events may or may not be preventable

Studies of medical records in many countries suggest that 8-12% of hospitalised patients suffer one or more adverse events

Older people are particularly vulnerable to harm from healthcare

Voluntary reporting systems are poor at measuring adverse events but useful for learning about the vulnerabilities of healthcare systems

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CHAPTER 3
Understanding How Things Go Wrong

Human error is routinely blamed for accidents in the air, on the railways, in complex surgery and in healthcare generally. Immediately after an incident people make quick judgements and, all too often, blame the person most obviously associated with the disaster. The pilot of the plane, the doctor who gives the injection or the train driver who passes a red light are quickly singled out. However these quick judgements and routine assignment of blame prevent us uncovering the second story (1). This is the story in its full richness and complexity, which only emerges after thoughtful and careful inquiry. While a particular action or omission may be the immediate cause of an incident, closer analysis usually reveals a series of events and departures from safe practice, each influenced by the working environment and the wider organisational context (2).

What is error?

In everyday life recognising error seems quite straightforward, though admitting it may be harder. My own daily life is accompanied by a plethora of slips, lapses of memory and other 'senior moments', in the charming American phrase, that are often the subject of critical comment from those around me. (How can you have forgotten already?). Other errors may only be recognised long after they occur. You may only realise you took a wrong turning some time later when it becomes clear that you are irretrievably lost. Some errors, such as marrying the wrong person, may only become apparent years later. An important common theme running through all these examples is that an action is only recognised as an error after the event. Human error is a judgement made in hindsight (3). There is no special class of things we do or don't do that we can designate as errors; it is just that some of the things we do turn out to have undesirable or unwanted consequences. This does not mean that we cannot study error or examine how our otherwise efficient brains lead us astray in some circumstances, but it does suggest that there will not be specific cognitive mechanisms to explain error that are different from those that explain other human thinking and behaviour.

The most precise definition of error, and most in accord with everyday usage, is one that ties it to observable behaviours and actions. As a working definition, John Senders and Neville Moray (4) proposed that an error means that something has been done which:

- Was not desired by a set of rules or an external observer
- Led the task or system outside acceptable limits
- Was not intended by the actor

This definition of error, and other similar ones (5) imply a set of criteria for defining an error. First, there must be a set of rules or standards, either explicitly defined or at

least implied and accepted in that environment; second, there must be some kind of failure or 'performance shortfall'; third, the person involved did not intend this and must, at least potentially, have been able to act in a different way. All three of these criteria can be challenged, or at least prove difficult to pin down in practice. Much clinical medicine for instance is inherently uncertain and there are frequently no guidelines or protocols to guide treatment. In addition the failure is not necessarily easy to identify; it is certainly not always clear, at least at the time, when a diagnosis is wrong or when at what point blood levels of a drug become dangerously high. Finally, the notion of intention, and in theory at least being able to act differently, is challenged by the fact that people's behaviour is often influenced by factors, such as fatigue or peer pressure, which they may not be aware of and have little control over. So, while the working definition is reasonable, we should be aware of its limitations and the difficulties of applying it in practice.

Types of error

In his analysis of different types of error James Reason (6)divides them into two broad types: slips and lapses, which are errors of action, and mistakes which are, broadly speaking, errors of knowledge or planning.

Slips and lapses

Slips and lapses occur when a person knows what they want to do, but the action does not turn out as they intended. Slips relate to observable actions and are associated with attentional failures (such as picking up the wrong syringe), whereas lapses are internal events and associated with failures of memory (such as forgetting to give the drug altogether).

Mistakes

Slips and lapses are errors of action; you intend to do something, but it does not go according to plan. With mistakes, the actions may go entirely as planned but the plan itself deviates from some adequate path towards its intended goal. Here the failure lies at a higher level: with the mental processes involved in planning, formulating intentions, judging, and problem solving(6). If a doctor treats someone with chest pain as if they have a myocardial infarction, when in fact they do not, then this is a mistake. The intention is clear, the action corresponds with the intention, but the plan was wrong.

In daily life errors are frequently attributed to stupidity, carelessness, forgetfulness, recklessness and other personal defects. The implication is that the person who makes an error has certain characteristics which produce the error and, furthermore, that these characteristics are under their control and they are therefore to blame for the errors they make. This is error seen from the individual perspective; when applied to understanding accidents Reason refers to this as the 'person model'(7). Efforts to reduce error are, from this perspective, targeted at individuals and involve exhortations to 'do better', retraining, or adding new rules and procedures. For errors with more serious consequences, more severe sanctions come into play such as naming and shaming, disciplinary action, suspension, media condemnation and so on. However, while reckless behaviour may well deserve blame and sanction, we need to approach error rather more thoughtfully.

Error in context: the person and the system

James Reason and others have argued that that errors cannot be understood in isolation, but only in relation to the context in which people are working. In considering how people contribute to accidents therefore we have to distinguish between 'active failures' and 'latent conditions' (8).The active failures are errors and other types of unsafe act. These are committed by people at the 'sharp end' of the system who are actually operating it or working with a patient. The active failures are wrongly opening the bow door of a ferry, shutting down the wrong engine on an airliner, or misreading the anaesthetic monitor. These unsafe acts can, and often do, have immediate consequences.

However, other factors further back in the causal chain can also play a part in the genesis of an accident. These 'latent conditions' as they are often termed lay the foundations for accidents in the sense that they create the conditions in which errors and failures can occur. This places the operators at the sharp end in an invidious position as James Reason eloquently explains:

> *Rather than being the instigators of an accident, operators tend to be the inheritors of system defects …their part is usually that of adding the final garnish to a lethal brew whose ingredients have already been long in the cooking (6)*

Considering the wider influences of the healthcare systems does not mean simply blaming everything on 'the system'. Rather one needs to preserve individual accountability but understand the interplay between the person, the technology and the organisation. A strong sense of personal responsibility is fundamental to being a good clinician. People who deliberately behave recklessly and without regard to their patients' welfare deserve to be blamed, whether or not they make errors. However sometimes good people can, for complicated reasons, make simple mistakes with very serious outcomes. Let us look at an example.

Understanding how things go wrong

> *'Mr David James…was prepared for an intrathecal (spinal) administration of chemotherapy as part of his medical maintenance programme following successful treatment of leukaemia. After carrying out a lumbar puncture and administering the correct cytotoxic therapy (Cytosine) under the supervision of the Specialist Registrar Dr Mitchell, Dr North, a Senior House Officer, was passed a second drug by Dr Mitchell to administer to Mr James, which he subsequently did. However, the second drug, Vincristine, should never be administered by the intrathecal route because it is almost always fatal. Unfortunately, whilst emergency treatment was provided very quickly in an effort to rectify the error, Mr James died some days later'* (9)

Professor Brian Toft was commissioned by the Chief Medical Officer of England to conduct an inquiry into this death and to advise on the areas of vulnerability in the process of intrathecal injection of these drugs and ways in which fail-safes might be built in (9). The orientation of the inquiry was therefore, from the outset, one of learning and change. We will use this sad story, and Brian Toft's thoughtful report, to introduce the subject of analysing cases. Although the names of those involved were made public I have changed them in the narrative as identifying the people again at this distance serves no useful purpose. This case acts as an excellent, though tragic, illustration of models of organisational accidents and systems thinking.

Box 3.1 The death of David James

Mr James arrived on the ward at about 4.00pm; he was late for his chemotherapy, but staff tried to accommodate him. The pharmacist for the ward had made an earlier request that the cytosine should be sent up and that the Vincristine should be 'sent separately' the following day. The pharmacy made up the drugs correctly and they were put on separate shelves in the pharmacy refrigerator. During the afternoon the ward day case coordinator went to the pharmacy and was given a clear bag containing two smaller bags each containing a syringe – one vincristine and one Cytosine. She did not know they should not be in the same bag.

Dr Mitchell was informed and approached by Dr North to supervise the procedure, as demanded by the protocol. The staff nurse went to the ward refrigerator and removed the transparent plastic bag containing two separate transparent packets each one containing a syringe. She noted that the name 'David James' was printed on each of the syringe labels, delivered it and went to carry on her work.

Dr Mitchell looked at the prescription chart noting that the patient's name, drugs and dosages corresponded with the information on the labels attached to the syringes. He did not, however, notice that the administration of Vincristine was planned for the following day or that its route of administration was intravenous. Dr Mitchell, anticipating a cytotoxic drugs system similar to the one at his previous place of work had presumed that, as both drugs had come up to the ward together, both were planned for intrathecal use. He had previously administered two types of chemotherapy intrathecally and it did not therefore seem unusual.

A lumbar puncture was carried out successfully and samples of cerebro-spinal fluid taken for analysis. Dr Mitchell then read out aloud the name of the patient, the drug and the dose from the label on the first syringe and then handed it to Dr North. Dr Mitchell did not, however, read out the route of administration. Dr North, having received the syringe, now asked if the drug was 'Cytosine' which Dr Mitchell confirmed. Dr North then removed the cap at the bottom of the syringe and screwed it onto the spinal needle after which he injected the contents of the syringe.

Having put down the first syringe, Dr Mitchell handed the second syringe containing Vincristine to Dr North, again reading out aloud the name of the patient, the drug and dosage. Once again, he did not read out the route of administration. Dr North was surprised when he was passed a second syringe, because on the only other occasion that he had performed a supervised intrathecal injection only one syringe had been used. However, he assumed that that '...the patient was either at a different stage in his treatment or was on a different treatment regime than the other patient.'

Dr North, with the second syringe in his hand, said to Dr Mitchell 'Vincristine?' Dr Mitchell replied in the affirmative. Dr North then said 'intrathecal Vincristine?' Dr Mitchell again replied in the affirmative. After which Dr North removed the cap at the bottom of the syringe and screwed it onto the spinal needle. He then administered the contents of the syringe to Mr James with ultimately fatal results.

Adapted from Toft 2001

Background to the incident

Provided Vincristine is administered intravenously (IV), it is a powerful and useful drug in the fight against leukaemia. The dangers of inadvertent intrathecal administration of Vincristine are well known: there are product warnings to that effect, a literature that stresses the dangers and well publicized previous cases. In this hospital there was a standard written protocol which, at the request of hospital staff, had been changed so that Cytosine and Vincristine would be administered on different days to avoid any potentially fatal confusion. Drugs for intravenous and for intrathecal use were also supplied separately to the wards, again to reduce the chances of mixing up the different types of drug.

Defences, discussed further below, are the means by which systems ensure safety. Sometimes the term is used to encompass almost any safety measure, but it more usually refers to particular administrative, physical or other barriers that protect or warn against deviations from normal practice. Administering Cytosine and Vincristine on separate days, for instance, is clearly intended to be a defence against incorrect administration. The separation of the two drugs in pharmacy and the separate delivery to the ward are other examples of defences against error. Having two doctors present checking labels and doses is another check, another barrier against potential disaster. Sometimes however, as in this case, a series of defences and barriers are all by breached at once. This is brilliantly captured in James Reason's Swiss Cheese (7) metaphor of the trajectory of an accident which gives us the sense of hazard being ever present and occasionally breaking through when all the holes in the Swiss Cheese line up.
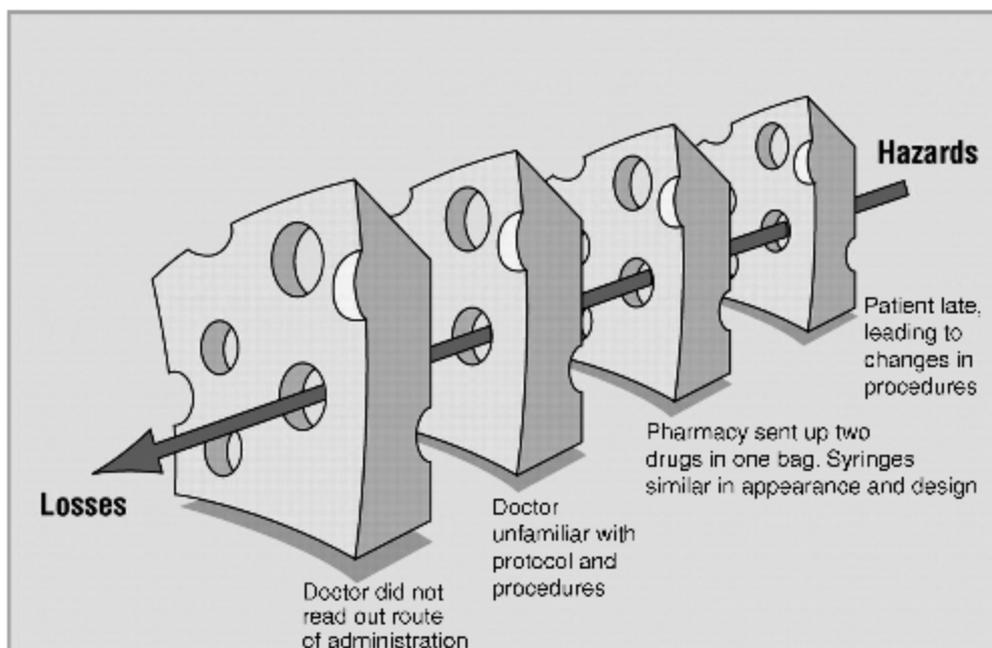

Figure 3.1 Swiss Cheese: vulnerabilities in the system (after Reason, 1997).

Death from spinal injection: a window on the system

From the chronology one can see the classic 'chain of events' leading toward the tragedy. Dr Mitchell was quite new to the ward, unfamiliar with the chemotherapy regime and did not know the patient. The pharmacy somehow, although separating the

two drugs, placed them in a single bag. Although the doctors involved can be held responsible for their specific actions and omissions, one can also see that circumstances conspired against them. However, the case also illustrates some much more general themes, issues that pervade healthcare and indeed other organisations, and which are right now as you read this putting patients at risk. We will consider three recurring safety issues.

Assumption that the system was reliable

The unit where David James died had used these drugs for many years without a major incident. After an event of this kind, and a subsequent analysis, we can see that the systems, while reasonably robust, nevertheless had many vulnerabilities. Huge reliance was placed on custom and practice and on people simply knowing what they were doing. With experienced staff who know the unit's procedures, this works reasonably well, but when new staff join a unit without clear induction and training the system inevitably becomes unsafe. In fact, the unit where David James died seems to have been a well run unit, where professionals respected each other's work and things went well on a day to day basis. Paradoxically, safety creates its own dangers in that an uneventful routine lulls one into a false sense of security. The safer one becomes the more necessary it is to remind oneself that the environment is inherently unsafe. This is what James Reason means when he says that the price of safety is chronic unease (10).

The influence of hierarchy on communication

When asked why he did not challenge Dr Mitchell, Dr North said:

> *'First of all, I was not in a position to challenge on the basis of my limited experience of this type of treatment. Second, I was an SHO (junior doctor) and did what I was told to do by the Registrar. He was supervising me and I assumed he had the knowledge to know what was being done. Dr Mitchell was employed as a registrar … in a centre for excellence and I did not intend to challenge him'. (9)*

Dr North was in a very difficult position. He assumed Dr Mitchell, as a registrar, knew what he was doing and reasonably points out that he himself had limited experience of the treatment. However he did know that Vincristine should not be given intrathecally, but he failed to speak up and challenge a senior colleague. Criticism might be made here of both Dr North, for not having the courage to request further checks, and of the Dr Mitchell for not taking the junior doctor's query more seriously and at least halting the procedure while checks were made.

Physical appearance of syringes containing cytotoxic drugs

Syringes containing Vincristine were labelled 'for intravenous injection' and syringes containing Cytosine 'for intrathecal use'. You might think this is fairly clear cut, but on a busy ward with numerous injections being given every day, the design and packaging of drugs is an important determinant of the likelihood of error. In the final few minutes leading up to the fatal injection, the doctors involved were not helped by the similarity in appearance and packaging of the drugs. First, the labels were similar and, while the bold type of the drug and dose stood out there were no other strong visual cues to draw a reader's eye to the significance of the route of administration.

Second, the syringes used to administer the two drugs were of similar size; the size of the syringe did not give any clues as to the route of administration to be used. Third, both drugs were clear liquids administered in similar volumes; neither colour nor volume gave any indication of the proper route of administration. Finally, the most dangerous physical aspect of all, in Toft's opinion, is 'that a syringe containing Vincristine can also be connected to the spinal needle that delivers intrathecal drugs to patients. Clearly, once such a connection has been made the patient's life is in danger as there are no other safeguards in place to prevent the Vincristine from being administered' (9).

Syringes of drugs for intrathecal use could have their own specific, unique fitting, colour and design and thankfully, years later, these are now being developed. While this might not eliminate the possibility of injecting the correct drug, it does add a powerful check to wrong administration. In the same way, fatalities in anaesthesia that resulted from switching oxygen and nitrous oxide supplies were eliminated by the simple expedient of making it impossible to connect the nitrous oxide line to the oxygen input. In daily life there are thousands of such checks and guides to behaviour. When you fill your car with unleaded petrol you use a small nozzle; larger nozzles for leaded or diesel will simply not fit into the filling pipe. It is shameful that these design modifications have still not been implemented ten years after this tragic death.

Seven levels of safety: 'organisational' accidents

Many of the accidents in both healthcare and other industries need to be viewed from this broad systems perspective if they are to be fully understood. The actions and failures of individual people usually play a central role, but their thinking and behaviour is strongly influenced and constrained by their immediate working environment and by wider organisational processes. The organisational accident model (8) describes the immediate errors and problems and the background latent conditions.
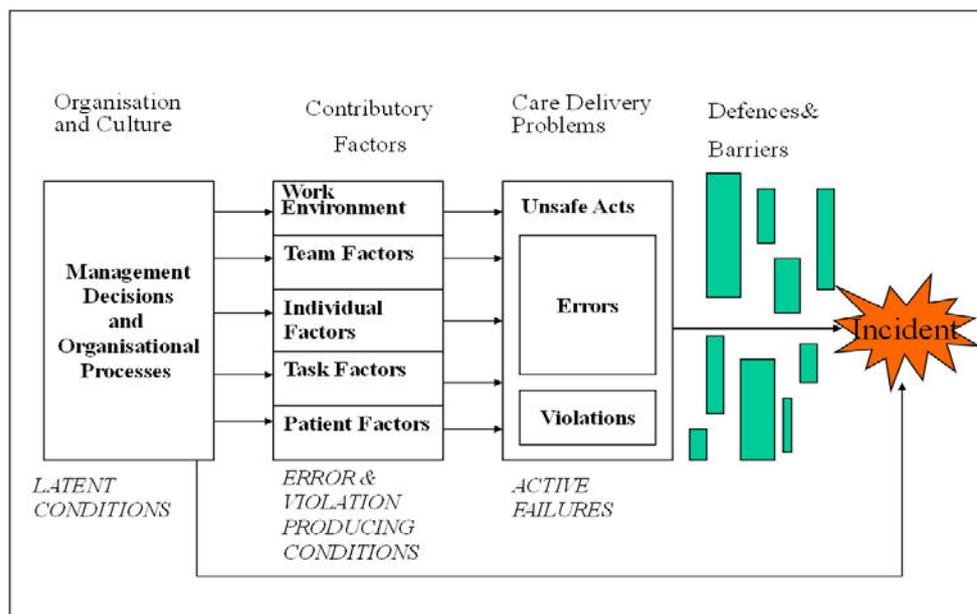

Fig 3.2 Organisational accident model (Adapted from Reason, 1997)

We have extended Reason's model and adapted it for use in a healthcare setting, classifying the error producing conditions and organisational factors in a single broad framework of factors affecting clinical practice (2). The 'seven levels of safety' framework describes the contributory factors and influences on safety under seven broad headings:

- *Patient factors*. The patient's condition has the most direct influence on practice and outcome. Other factors such as personality, language and psychological problems may also be important as they can influence communication with staff.

- *Task factors*. The design of the task, the availability and utility of protocols and test results may influence the care process and affect the quality of care.

- *Individual factors*. Individual staff factors include the knowledge, skills and experience of each member of staff, which will obviously affect their clinical practice.

- *Team factors*. Each staff member is part of a team within the inpatient or community unit. The way an individual practises, and their impact on the patient, is influenced by other members of the team and the way they communicate and support each other.

- *Working conditions*. These include the physical environment, availability of equipment and supplies and the light, heat, interruptions and distractions that staff endure.

- *Organisational factors*. The team is influenced in turn by management actions and by decisions made at a higher level in the organisation. These include policies for the use of locum or agency staff, continuing education, training and supervision and the availability of equipment and supplies.

- *Institutional context*. The organisation itself is affected by the institutional context, including financial constraints, external regulatory bodies and the broader economic and political climate.

The investigation and analysis of clinical incidents

Reason's model and the framework described above provide the foundations of the 'London protocol' a systematic method of analysing clinical incidents, one of a number developed in healthcare (www.cpssq.org). The incident acts as a 'window' on the healthcare system revealing both strengths and vulnerabilities of the system(11). The London protocol aims to guide reflection on incidents in order to reveal these weaknesses.

During an investigation information is gleaned from a variety of sources. Case records, statements and any other relevant documentation are reviewed. Structured interviews with key members of staff are then undertaken to establish the chronology of events, the main care delivery problems and their respective contributory factors, as perceived by each member of staff. The key questions are 'What happened? (the outcome and chronology); How did it happen? (the care delivery problems) and Why

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did it happen? (the contributory factors). The investigator needs to differentiate between those contributory factors that are only relevant on that particular occasion and those which are longstanding or permanent features of the unit. For instance there may be a failure of communication between two midwives which might be an isolated occurrence or might reflect a more general pattern of poor communication on the unit. Ideally the patient, or a member of their family, should also be interviewed though as yet this does not often happen.

From accident analysis to system design

We are now at a transitional point in the book between the understanding and analysis of incidents and the coming chapters which discuss methods of prevention and quality improvement. The seven levels framework has outlined the patient, task and technology, staff, team, working environment, organisational and institutional environmental factors that are revealed in analyses of incidents. These same factors also point to the means of intervention and different levels on which safety and quality must be addressed, which we will illustrate in the next two chapters.

KEY POINTS

An error is something realised only after the event

Slips and lapses are errors of action and memory

Mistakes are errors of knowledge and planning

Errors can only be properly understood in context

Patient, task, individual, team, environment, organisational and institutional context factors may all influence incidents and accidents

Incidents may act as a 'window' on the healthcare system

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CHAPTER 4
Improving healthcare processes and systems

Guy Cohen was Director of Quality, Safety and Reliability at NASA until the mid-1990s. Don Berwick, then working on improving the quality of health care in the Harvard Community system, had asked how to improve healthcare faster and more effectively; in their first five hour meeting Cohen had barely started telling him what he had learned about quality and safety. Berwick recalls the response to his initial question:

> *'"How do you get good enough to go to the moon"? Guy Cohen had no one-liners to offer me. He didn't say "report cards" or "market forces" or "incentive pay" or even "accountability". In fact, as I recall, not one of those words came up in the time we spent together. His view of human nature, organisations, systems, and change would not permit one-line answers'* (1)

In healthcare, we are coming to understand how difficult the safety problem is, in cultural, technical, clinical, and psychological terms, not to mention its massive scale and heterogeneity. We have seen, in the analysis of individual incidents, just how many factors can contribute to the occurrence of an error or bad outcome and there are correspondingly many possible solutions. We could try to improve the efficiency and reliability of processes. We could rely on teamwork and leadership. Or we could turn to automation and technology. There are multiple possibilities and lines of attack. We can however distinguish two broad approaches to improving patient safety. These two visions of safety are seldom explicitly articulated, but are ever present themes in debates and discussions about patient safety.

Two visions of safety

One broad approach is to simplify, standardise and improve basic processes and reduce reliance on people by automating or at least offering as much support as possible in those tasks for which people are necessary. Ideally, the human contribution to the process of care is reduced to a minimum as in industrial production or commercial aviation. Such approaches are rooted in a basic industrial model, in which the solutions to errors and defects rest in an increasing standardisation usually coupled with a reliance on technology. Careful design of the basic processes of care and appropriate use of technology overcomes human fallibility, vulnerability to fatigue and environmental influences. Examples of safety measures within this broad framework would include: simplification and standardisation of clinical processes, more fundamental re-design of equipment and processes, computerised medication systems, electronic medical records and memory and decision support, whether computerised or in the form of protocols, guidelines, checklists and aides memoires.

The second, contrasting approach, which I have called `people create safety' argues for an alternative to the rigid, proceduralised, technocratic driven view of safety that more truly reflects the realities of clinical work (2). Proponents of this view are rightly extremely impressed by how often outcomes are good in the face of extreme complexity, conflicting demands, hazards and uncertainty. Making healthcare safer depends, on this view, not on minimising the human contribution but on understanding how people, look ahead, overcome hazards and, in effect, create safety. These approaches are discussed in the following chapter.

Quality improvement

Manufacturing industries have made huge gains in safety, efficiency and cost-effectiveness by close attention to the design, maintenance and performance of the processes used in factories. Rather than inspect products afterwards to identify defects, those concerned with quality control and management sought to build quality in to the process (3). The report on the British NHS by Lord Darzi similarly puts quality at the heart of the NHS does and makes it clear that everyone should play their part in promoting and driving higher quality care for patients (4). In healthcare this has become as aspiration but not yet a reality.

Doctors, nurses and others often find it hard to understand that approaches developed in manufacturing can have any relevance to healthcare. We deal with patients as individuals, how can we learn anything from companies that make cars? In fact of course cars and computers can now be completely customised and matched to individual needs and preferences. Healthcare is also full of processes, of varying degrees of complexity, which are very akin to manufacturing processes: pharmacy, ordering test results, the blood service and so on. The methods of quality management are well described in many books (3, 5). Quality methods are sometimes presented simply as a set of tools and techniques, but properly conceived the various systems aim at substantial and enduring organisational change based on principles and values that each organisation must define for itself.

Simplifying and standardising the processes of healthcare

Compared with manufacturing industry healthcare has little standardisation, comparatively little monitoring of processes and outcome, and few safeguards against error and other quality problems (6). Most healthcare processes were not designed, but just evolved and adapted to circumstances. Many healthcare processes are long, complicated and unreliable. The process of prescribing, ordering and giving drugs is a good example of complexity and lack of standardisation. David Bates gives an example of the problems that he observed in his own hospital before a sustained attack on medication error and adverse drug reactions:

> *'Take for example the allergy detection process used in our hospital several years ago, which was similar to that used in most hospitals at the time. Physicians, medical students and nurses all asked patients what their allergies were. This information was recorded at several sites in the medical record, though there was no one central location. The information was also required to be written at the top of every order sheet, although in practice this was rarely done. The pharmacy recorded the information in its computerised database, but it found out about allergies only if the information was entered into the orders, and often it was not. Checking by physicians, pharmacy and*

nursing staff was all manual. This information was not retained between the inpatient and outpatient settings, or from admission to admission. Not surprisingly, about one in three orders for drugs to which a patient had a known allergy slipped through' (7).

The system Bates describes has now been replaced by one in which all allergies are noted in one place in the information system, drugs are mapped to "drug families" (for example penicillin) so that they can be checked more easily, information is retained over time and checking for allergies is routinely performed by computers, rather than tired and fallible human beings. Many healthcare systems however have not benefited from such an overhaul. Ordering and reading of X-rays, communication of risk information about suicidal or homicidal patients, informing patients and their family doctors about abnormal test results, booking patients in for emergency operations, effective discharge planning; all these and many more are vital for safe healthcare, yet day to day experience tells patients and staff that they are far from error free.

Reducing medication error

Designing and building simpler, standardised processes which rely less on human vigilance is therefore a powerful way of making at least some parts of healthcare much safer, as well as cheaper and more efficient. The Institute for Healthcare Improvement (www.ihi.org) has pioneered quality improvement in healthcare drawing together ideas and practical experience from healthcare and many other sources. We will use their approach to reducing medication error as an overall framework to illustrate the potential of process improvement, addressing the particular role of technology in a later section.

There are three basic elements to improving the safety of a medication process:

- Design the system to prevent errors occurring in the first place
- Design the system to make errors more visible when they do occur
- Design the system to limit the effects of errors so that they do not lead to harm

Preventing errors is, broadly speaking, achieved by reducing the complexity of information that healthcare staff need, reducing the opportunity for mixing up different medications and trying to limit errors that occur because staff are trying to do too many things at once. Errors can be made more visible by using a variety of additional checks, both by people (staff and patients) and by computers. For instance, having a pharmacist reviewing orders before dispensing, asking staff to repeat back verbal orders and careful use of laboratory monitoring systems are all means of detecting errors that may have occurred. Even with all these checks and system improvements errors will sometimes occur, if only because of the enormous numbers of drugs given. The final protection is to always be ready to mitigate the effects of any error, to assume in fact that errors will occur and to prepare for it. Anticipating error is a sign of a safe, rather than unsafe system. In this case keeping antidotes for high-risk drugs on hand at the point of administration is a key defence against harm to patients. These then are the general principles derived in years of experimentation, evaluation and practical application with many organisations. Let us see how this works in practice.

Table 4.1 Principles for reducing medication error

Reducing errors due to information complexity	Limit hospital formularies to essential drugs and doses
	Pharmacists on ward rounds to monitor and advise
	Briefing at handover and shift change on circumstances that increase risk of error, such as an unfamiliar disease, new staff or unusual drug regimens
	Provide an information system that allows access to patient information for all staff and allows electronic prescribing
Reducing errors due to complex or dangerous medication	Remove high risk medications, such as concentrated electrolyte solutions, from patient care areas
	Label high risk drugs clearly to indicate their danger
	Remove or clearly differentiate look alike or sound alike drugs
Reducing errors due to multiple competing tasks	Wherever possible reallocate tasks such as calculating, drawing up and mixing doses to pharmacy or the manufacturer
	Establish standard drug administration times and avoid interruptions at those times
	Assign one person to necessary double checks who does not have other duties at that time; use double checks sparingly and make them properly independent
	Standardise equipment and supplies, such as intravenous pumps, across all units
	Involve patients in active checks such as identifying themselves, checking drugs and allergies

Adapted from Berwick 1998

Reducing medication errors and adverse drug events

St Joseph Medical Centre is a 165 bed hospital in the heart of Illinois, providing a variety of services including open heart surgery and trauma care. The hospital has established a number of safety projects backed by a strong commitment to cultural change and backing from senior executives (8).

In June 2001 a survey of records suggested an ADE (adverse drug event) rate of 5.8 per 1000. Flowcharting of the medication process showed that it was complicated and labour intensive. Multiple members of staff were involved from the

time the order was written to the point where the patient received the medication. Common sources of errors included unavailable patient information, unavailable drug information, miscommunication of medication orders, problems with labelling or packaging, drug standardisation, storage, stocking and process flaws. By May 2003 ADEs were running at 0.50 per 1000, a tenfold reduction, and the process of medication delivery had been hugely simplified and standardised. How was this achieved?

Box 4.1 Reducing medication errors in St Joseph Medical Centre

- Added an adverse drug event hotline leading to a 10-fold increase in reporting of adverse drug events and medication errors

- Monthly reporting of medication data to hospital quality council

- Developed pre-printed heparin orders

- Developed a single form that could be used for reconciliation of medications at both admission and discharge

- Separated sound-alike and look-alike medications in the pharmacy and on the nursing units

- Implemented daily rounds by a clinical pharmacist who compares medication orders to lab values

- Standardised intravenous drip concentrations

- Decreased the amount of stock medications kept on patient care units

- Eliminated the use of high-risk abbreviations

- Changed process for non-standard doses so that all are prepared and packaged in pharmacy

- Standardised epidural pumps and use yellow coloured tubing with these pumps

From Haig et al 2004

Standardisation of processes was a major feature of this programme with particular attention paid to high-risk medications. For instance all adult intravenous medications were standardised and a single, weight based, Heparin Nomogram was developed and used throughout the hospital. A particularly popular intervention was increasing the availability of pharmacists on nursing units to review and enter medication orders. This gave the pharmacist the opportunity to identify potential dosage errors and

drug interactions and saved nurse time. Finally, the patients themselves were engaged in the process. Each patient admitted to the hospital is now given a Medication Safety Brochure that provides advice for them and a form on which to list their current medication. Patients are also actively encouraged to check with staff if they have been given unfamiliar medication and a 'medicines reconciliation' process ensured that patients leaving hospital returned to the medication appropriate to their life at home. Technological innovations, in the form of automated medication dispensing machines, formed the next phase of the drive to further reduce errors.

Using information technology to reduce medication error

Information technology can reduce error in a number of different ways: improving communication, making knowledge more readily accessible, prompting for key pieces of information (such as the dose of a drug), assisting with calculations, monitoring and checking in real time, and providing decision support(6). Many medication errors occur because clinicians do not have the necessary information about either the patient of the drug or because test results are not available. Hand written prescriptions, transcribing errors and calculation mistakes are also major problems. Several medication technology systems have been developed to address these and other problems operating at various stages of the medication and delivery process. They show great promise but, as David Bates warns, are not a panacea:

> *'Information technologies …. may make some things better and others worse; the net effect is not entirely predictable, and it is vital to study the impact of these technologies. They have their greatest impact in organizing and making available information, in identifying links between pieces of information, and in doing boring repetitive tasks, including checks for problems. The best medication processes will thus not replace people but will harness the strengths of information technology and allow people to do the things best done by people, such as making complex decisions and communicating with each other'* (7).

The system that has probably had the largest impact on medication error is computerized physician order entry (CPOE), in which medication orders are written online. This improves orders in several ways. First, they are structured, so they must include a drug, dose and frequency; the computer, unlike a person, can refuse to accept any order without this information. They are always legible, and the clinician making the order can always be identified if there is a need to check back. Finally, all orders can be routinely and automatically checked for allergies, drug interactions, excessively high or low doses and whether the dosage is appropriate for the patient's liver and kidney function. Clinical staff may fear that these advantages may be offset by the time lost in typing rather than writing orders, but in practice there is minimal difference (9).

Bates and his colleagues (10) showed that the introduction of a computerised order entry system resulted in a 55% reduction in medication errors. This system provided clinicians with information about drugs, including appropriate constraints on choices (dose, route, frequency) and assistance with calculations and monitoring. With the addition of higher levels of decision support, in the form of more comprehensive checking for allergies and drug interactions, there was an 83% reduction in error. Other studies have shown improvement of prescribing of

anticoagulants, heparin and anti-infective agents and reductions in inappropriate doses and frequency of drugs given to patients with renal insufficiency (11).

Evidence of the value of CPOE continues to accumulate. However, many of the systems however remain 'home-grown' systems, and have only considered small numbers of patients in specific settings. Much more research is needed to compare different applications, identify key components, examine factors relating to acceptance and uptake and anticipate and monitor the problems that such systems may induce. Looking further ahead it is possible to envisage the use of many other technologies in the process of medication delivery. Most of these are in the early stages of development, are relatively untested and sometimes delayed by external constraints. Bar coding for instance, widely used in supermarkets, could be enormously useful but cannot be implemented until drug manufacturers have agreed common standards. Considerable advances have been made however in the reliability and efficiency of blood sampling and blood transfusion.

KEY POINTS

Standardising and simplifying clinical processes is a powerful way of increasing reliability

Reducing reliance on human beings with decision support and technology increases reliability in standardised systems

Even in good systems people need to anticipate hazards and create safety moment to moment

Medication errors can be reduced by preventing error, by making errors more visible and by planned limitation of harm from remaining errors

Computerised prescribing reduces medication error but is not a panacea

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CHAPTER 5
People create safety

Clinical staff in addition to simply doing their jobs well, actively create safety as they work. At the coal face, minute by minute, safety may either be eroded by errors and casual deviations from procedure or conversely created by skilful, safety conscious professionals. People partly create safety by being conscientious, disciplined and following rules. However the treatment of complex, fluctuating conditions also requires thinking ahead and being prepared to adjust treatment as the patient's condition changes.

When thinking about safety however we are also calling on a broader vision in which the clinician is anticipating not only the disease, but the functioning of the organisation in which they work, assessing the hazards emanating from both. Safety, from this broader perspective, requires anticipation, awareness of hazards, preparedness, resilience and flexibility, the qualities that those studying high reliability organisations have sought to capture and articulate. Patients too have to anticipate the course of their disease, the gaps in the healthcare system and they and their families play a critical role in ensuring their safety. In this chapter we consider the skills needed by patients, by staff and by clinical teams as they jointly monitor and create safe healthcare.

Box 5.1 Being and feeling unsafe in hospital

Above all we needed safety; and yet Ann was unsafe. ….The errors were not rare; they were the norm. During one admission, the neurologist told us in the morning, "By no means should you be getting anticholinergic agents", and a medication with profoundly anticholinergic side effects was given that afternoon. The attending neurologist in another admission told us by phone that a crucial and potentially toxic drug should be started immediately. He said "Time is of the essence". That was on Thursday morning at 10.00am. The first dose was given 60 hours later. Nothing I could do, nothing I did, nothing I could think of made any difference. It nearly drove me mad. Colace was discontinued by a physician's order on Day 1 and was nonetheless brought by the nurse every single evening throughout a 14 day admission….. I tell you from my personal observation: No day passed – not one – without a medication error. Most weren't serious, but they scared us.

Adapted from Berwick 2003

Patient involvement in patient safety

Patients and their families have a critical, privileged perspective on many aspects of healthcare. The patient may not, of course, understand the technical and clinical issues at stake, but they do observe and experience the kindnesses, the small humiliations, the inconsistencies in care, the errors and sometimes the disasters. In the case of people with chronic illnesses they become experts not only on their own disease but on the frailties, limitations and unintentional cruelties of their healthcare system. The trouble is when we are patients, while we have great insight into the frailties of the healthcare system, we find it astonishingly difficult to make our voice heard, particularly where errors and safety are concerned.

Even an experienced senior doctor can find it hard to make their voice heard when dealing with hospital staff caring for themselves or their family. Don Berwick, currently head of Medicare in the United States, has movingly described his experiences of being with his wife Ann during her treatment for a serious autoimmune condition (1). In his account Don stresses the good will, kindness, generosity and commitment of the healthcare staff but, even after two decades of grappling with the quality and safety of healthcare, he was appalled at the operation of the healthcare systems.

Patients, whether they have a clinical background or not, can provide important safety information. Saul Weingart and his colleagues at Dana Farber Cancer Institute in Boston (2, 3) interviewed 229 patients in hospital, who were both willing and able to participate, asking them three general questions:

- Do you believe that there were any problems with your care during this hospitalisation?
- Do you believe that you were hurt or stayed in the hospital longer than necessary because of problems with your care?
- Do you believe that anyone made a mistake that affected your care during this hospitalisation?

From these simple five minute interviews patients identified a host of process failures such as problems with diagnosis, medication, procedures, clinical services (such as radiology, phlebotomy and laboratory) and service quality. In a second study the team found that patients reported many serious untoward events that were not found in the medical record; however record review also revealed incidents and adverse events that were not reported in patient interviews. Both record review and patient reports are necessary to obtain a reasonably complete picture of the harm from healthcare.

Patients' willingness to engage in safety practices

Patients are usually thought of as the passive victims of errors and safety failures, but there is considerable scope for them to play an active part in ensuring their care is effective, appropriate and safe. Instead of treating patients as passive recipients of medical care, it is much more appropriate to view them as partners or co-producers with an active role (4). The degree to which patients can be involved will vary considerably depending on the nature and complexity of the treatment and the degree of technical knowledge required to understand the treatment process. Most importantly it will depend on the extent to which each person feels willing and able to

play a more active role and whether they are encouraged in this by those who are caring for them (5).

To encourage patients to take a more active stance some organisations have produced leaflets setting out what patients can do to make their own care safer. The United States Joint Commission on Accreditation of Healthcare Organisations for instance has campaigned for patient to 'speak up' to prevent errors in their care (www.jcaho.org). Encouraging patients to ask questions about their medication to make sure they understand, not to take medication unless they are clear about its purpose and to be responsible for their own contribution to their treatment seem reasonable and useful precautions. Much more difficult is the suggestion that patients might actively challenge a health professional. Patients are meant to observe whether their identify band has been checked, tell the staff if they think they might be being confused with another patient and remind nurses and doctors to wash their hands. Although well intentioned this is a considerable extension of the patient's role and, arguably, an abdication of responsibility on the part of healthcare staff.

A small number of studies have assessed patients' willingness to speak up and otherwise check on hospital procedures. Most people are prepared to ask about the reason for a procedure, but many fewer would consider refusing care, such as a radiograph or the taking of blood that they had not been told about. Fewer still say they would be willing to remind doctors or nurses to wash their hands and only about 5% actually did so when the opportunity presented (5, 6). However some small studies have shown patients are much more willing to remind staff to wash their hands when staff and patients are equally involved, in hand hygiene initiatives. Such programmes need to be backed by an educational campaign, prompting aids and a specific request to routinely remind all staff and visitors about hand washing (7).

Establishing a proper and fruitful role for patients to play in patient safety is not straightforward and there are many issues to be resolved. There are however already some impressive examples of patients being actively involved in the management of a hospital, entirely changing the nature and tone of the usual patient clinician relationships. For example by involving patients the Dana Farber Cancer Centre in Boston learnt that patients with neutropenia (a reduction in white blood cells occurring in many diseases) often experienced long, wearying waits in emergency departments, seriously delaying the start of treatment. Telephone screening and direct admission to appropriate wards transformed this process and reduced the risk of infections and other complications. Patients are member of several important hospital committees and regarded as an essential voice in the redesign or improvement of services.

Safety skills

Expert clinicians, indeed experts in many fields, learn to work confidently yet safely, by anticipating and negotiating the hazards of their work. Junior staff learn these skills by trial and error or, if they are lucky, by observing experts recover from dangerous situations. In healthcare, unlike many other high risk industries, these skills are seldom explicitly identified or formally trained.

To identify the key skills and attributes of the safe, but effective, clinicians Sonal Arora and Susy Long (8) interviewed clinical staff who identified dozens of relevant characteristics. These were then grouped into several broad categories of safety skills (Table 5.1). Reviewing the preliminary list shows that clinical staff

Table 5.1 Some critical safety skills

Category	Individual skills	Illustrative quotes
Anticipation and preparedness	• Anticipation of organisational problems • Being able to anticipate the deteriorating patient • Contingency planning with clearly defined levels of care	"One thing that I do on a daily basis, and I would like my juniors to do as well, is to think, what could go wrong today? And I try to cover for that..."
Awareness of oneself	• Not letting your emotions interfere with patient care • Learning from previous mistakes • Recognising one's own limitations • Know who, when and how to call for help appropriately	"Be aware of your own abilities – when events will affect your judgements and working ability."
Conscientiousness	• Being thorough /paying attention to detail • Checking and re checking • Going out of your way to help	"If there is an unexplained clinical problem – keep thinking (and hunting)."
Humility	• Taking criticism constructively • Willingness to listen/take advice • Allowing others to take over	"Doesn't have a chip on his/ her shoulder about taking advise from nurses and juniors"
Vigilance	• Alertness/ being 'on the ball' • Pattern recognition and vigilance for deviation from patterns • Regularly re-reviewing the situation	"Through knowledge and experience comes vigilance for any deviation from an expected course of events."

are very conscious of the importance of these attitudes, behaviours and skills. Note especially that people identified a large number of character traits such as humility, honesty and conscientiousness; we perhaps cannot train these attributes, but we can certainly foster them in the wider culture and ethos of the organisation. Some of the skills however are more tangible and we will briefly highlight two key attributes: anticipation and vigilance.

Anticipation and vigilance

Anticipation is a key component of expertise in many areas. Essentially it involves thinking ahead and envisioning possible problems and hazards. If you drive a car in heavy rain you need to constantly think about what might happen. Suppose the types don't grip? Suppose the car in front brakes suddenly? Thinking in this way is explicitly taught in advanced driving courses as a necessary foundation for safe yet confident driving.

Experts are constantly thinking ahead and looking to the future. For instance, Cynthia Dominguez showed surgeons a video of an operation involving an 80 year old woman with an infected gallbladder that needed to be removed. She 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. She found that experienced surgeons made more predictions about likely problems than their junior colleagues. In particular they predicted that they would have difficulty in dissecting and identifying the surrounding structures, because the gallbladder and surrounding areas would be swollen and inflamed (9). With these predictions in mind they were therefore mentally prepared for the hazards that lay ahead.

Anaesthesia is ideally a routine procedure but a life threatening emergency can occur at any time; anaesthetists are trained in numerous emergency routines and in maintaining a constant awareness of what might happen. Experienced anaesthetists ensure that they have a supply of equipment for emergencies and drugs that will, for instance, will correct a rapidly falling heart rate. This kind of preparation sounds obvious and, in a sense it is, but it is difficult to constantly maintain this kind of `emergency awareness' day after day especially if few emergencies actually occur. Paradoxically, the safer a unit is the harder it is to believe that disaster may strike at any time.

Maintaining such safety awareness means anticipating the disease but also the vagaries of the organisation and the possibility that others may not check as assiduously as you would wish. My colleague Ros Jacklin expresses this clearly in an example that spans all the stages of situation awareness:

> *'I feel that one of the keys to being a safe practitioner comes down to vigilance - looking for problems before they happen, when they still are in the brewing stage. For instance, if you are on call, find out who has been operated on that day, and have a brief look at them before you go to bed, whether or not anyone specifically asks you to. If the patient looks dry, you might check that there's nothing to suggest bleeding, and increase their fluids a little overnight. Otherwise, no one notices that they are dry until their urine output has dropped. If that were to happen, you can probably easily rectify the patient's fluid status with IV fluids at this stage, but if for any reason there is a delay, the patient may find themselves in established renal failure' (Jacklin personal communication).*

Teams create safety

Healthcare is delivered by teams of people rather than by individuals. Even when a patient has a particular relationship with their family doctor, surgeon or nurse, that person is supported by a network of people who are essential for the delivery of safe, effective care. Teams, like individuals, may erode or create safety. A team that is working poorly multiplies the possibility of error. Conversely teams, when working well, have the possibility of being safer than any one individual. 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.

If you work in a team, as we almost all do, you may not think much about how it functions and what factors make a team work well. Some days, everything just seems to go smoothly and it's a joy to work with your colleagues. On another day the team is fragmented, every communication seems to be misunderstood, the work takes twice as long as usual and you go home stressed and exhausted. It's easy to blame others for being difficult or obstructive, which people sometimes are. However, in healthcare, if we look a little deeper we see that there is a fundamental underlying problem; teams are not designed, teamwork processes are not specified and the whole system relies on goodwill and the native resilience and adaptability of healthcare staff.

Team interventions: briefing, checklisting and daily goals

Watching teams and teamwork quickly reveals that a group of well intentioned individuals does not make a team and further, that teamwork has to be planned and organised. In some studies of urology and general surgery up to a third of standard team tasks of standard communication and the checking of equipment were not completed (10, 11). Improving team training is one possible response to such problems. However there are other, simpler, approaches which turn out to have quite profound effects.

Clarity and communication: the adoption of daily goals

Recall the case of David James who died from a spinal injection of vincristine. One of the features of this case was that almost everyone involved made assumptions about the knowledge and abilities of those around them. We assume, by default, that other people have the same understanding of a situation as we do and, even worse, that we have correctly communicated our intentions and wishes. Many instructions for patient care are given rapidly, in a hurry, often in a kind of clinical shorthand and with many assumptions about the kind of basic care that will be provided. In a fixed team that works together day in and day out, this generally works pretty well. However few teams, especially ward teams, are like that; it's a shifting population of people on a variety of shift patterns, supported to varying degrees by temporary staff.

Peter Pronovost (12) posed two simple but critical questions to intensive care doctors and nurses after the daily rounds: (1) How well do you understand the goals of care for this patient today? And (2) How well do you understand what work needs to be accomplished to get this patient to the next level of care? These questions seem unnecessary, almost insulting. These people are caring for very sick patients; surely they know what they are meant to be doing? A formal survey revealed however that only 10% of nurses and doctors surveyed understood the goals of care for specific patients.

Following some interviews and exploration the team introduced a daily goals sheet that asked staff to state the tasks to be completed, care plan and communication with patients and families. The daily goals sheet first forces explicit objectives to be stipulated for each patient, which can be reviewed and monitored. Second, it ensures that everyone works from the same set of assumptions and to the same plan.

Box 5.2 Daily goals in intensive care

Room No		Date	
	Initial as goals are reviewed		
	07.00 – 15.00	15.00-23.00	23.00- 07.00
What needs to be done for the patient to be discharged from the ICU?			
What is the patient's greatest safety risk? How can we reduce that risk?			
Pain management/sedation			
Cardiac volume status			
Pulmonary/ventilator (PP, elevate HOB)			
Mobilisation			
ID, cultures, drug levels			
GI/Nutrition			
Medication changes (can any be discontinued?)			
Tests/procedures			
Review scheduled labs; morning labs & CXR			
Consultations			
Communication with primary service			
Family communication			
Can catheters/tubes be removed?			
Is this patient receiving DVT/PUD prophylaxis			
Mgt. management; PP, plateau pressure; HOB, head of bed; ID, infectious disease; GI, gastrointestinal; labs, laboratory tests; CXR, chest radiograph; DVT, deep vein thrombosis; PUD, peptic ulcer disease			

The impact of this simple intervention was remarkable. Within eight weeks the proportion of nurses and doctors who clearly understood the daily goals for the patient increased from 10% to 95%. Staff found the short term goals sheet to be a simple tool for setting priorities and guiding the daily work of the team. Nurses now felt that they were an active part of the team working in partnership with physicians. Remarkably, following the introduction of the daily goals sheet, length of stay reduced from 2.2 days to 1.1 days allowing an additional 670 patients each year to receive intensive care, though the authors are cautious about attributing this change solely to the goals sheet.

Briefing and checklisting in surgery

A number of studies have now been carried out which demonstrate the value of checklisting and briefing which, although sometimes described separately, in practice usually occur together. The most influential study of surgical checklists has undoubtedly been that led by Atul Gawande as part of the World Health Organisation (WHO) World Alliance for Patient Safety 'Safe Surgery Saves Lives' campaign (13).

The WHO surgical safety checklist ensures that the entire operating theatre team understands the patient, the surgical procedure the equipment needed and that evidence based interventions such as antibiotic prophylaxis or deep vein thrombosis prophylaxis are reliably given. The 19 item checklist is completed in three stages— before induction of anaesthesia (sign in), just before skin incision (time out), and before the patient leaves the operating theatre (sign out). Items on the checklist must be verbally confirmed with the patient and other team members (14). The WHO Safe Surgery Saves Lives Study Group introduced the checklist in eight countries worldwide studying 3733 patients before and 3955 patients after the implementation of the checklist. After implementation, deaths were reduced from 1.5% to 0.8% and in-hospital complications by from 11% to 7.0%. In some sites the checklist prompted the introduction of techniques that are now standard in developed countries; for instance use of a pulse oximeter rose from 60% to over 90% in one study site over the course of the study.

Briefings and checklists are however not a panacea. According to how they are used, can be either a positive or negative influence on team performance. A surgeon, for instance, can ostensibly take part in the briefing but express their superiority and detachment by not really listening and carrying out other tasks at the same time. A checklist can be read out by a nurse in a clipped and dismissive way which closes down all possibility of discussion within the team.

These two interventions are important examples of how teamwork and patient care can be improved with relatively simple measures, though persuading clinicians to use them and actually implement them may of course be monumentally difficult. Daily goals, pre-operative and post-operative checklists seem mundane, and this partly accounts for clinicians' resistance to their use. However, a checklist is not a piece of paper or even a list; it is a team intervention which, used well, can affect the wider team functioning, the relationships across professions and hierarchies and even the values and safety culture of the team.

These interventions just touch on some aspects of teamwork and it is important not to think that safety just means using more checklists. The real impact of these approaches is to bring a shared understanding, to specify team leadership in particular situations, to anticipate problems. These wider endeavours require a more sophisticated understanding of teamwork than we have at the moment and need to be fostered in new types of training involving groups of healthcare professionals in novel simulations and other environments.

Surgical Safety Checklist

World Health Organization | **Patient Safety**
A World Alliance for Safer Health Care

Before induction of anaesthesia → **Before skin incision** → **Before patient leaves operating room**

(with at least nurse and anaesthetist) (with nurse, anaesthetist and surgeon) (with nurse, anaesthetist and surgeon)

Before induction of anaesthesia	Before skin incision	Before patient leaves operating room
Has the patient confirmed his/her identity, site, procedure, and consent? ☐ Yes	☐ **Confirm all team members have introduced themselves by name and role.** ☐ **Confirm the patient's name, procedure, and where the incision will be made.**	**Nurse Verbally Confirms:** ☐ The name of the procedure ☐ Completion of instrument, sponge and needle counts ☐ Specimen labelling (read specimen labels aloud, including patient name) ☐ Whether there are any equipment problems to be addressed
Is the site marked? ☐ Yes ☐ Not applicable	**Has antibiotic prophylaxis been given within the last 60 minutes?** ☐ Yes ☐ Not applicable	**To Surgeon, Anaesthetist and Nurse:** ☐ What are the key concerns for recovery and management of this patient?
Is the anaesthesia machine and medication check complete? ☐ Yes	**Anticipated Critical Events** **To Surgeon:** ☐ What are the critical or non-routine steps? ☐ How long will the case take? ☐ What is the anticipated blood loss?	
Is the pulse oximeter on the patient and functioning? ☐ Yes	**To Anaesthetist:** ☐ Are there any patient-specific concerns?	
Does the patient have a: **Known allergy?** ☐ No ☐ Yes	**To Nursing Team:** ☐ Has sterility (including indicator results) been confirmed? ☐ Are there equipment issues or any concerns?	
Difficult airway or aspiration risk? ☐ No ☐ Yes, and equipment/assistance available	**Is essential imaging displayed?** ☐ Yes ☐ Not applicable	
Risk of >500ml blood loss (7ml/kg in children)? ☐ No ☐ Yes, and two IVs/central access and fluids planned		

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.   Revised 1 / 2009   © WHO, 2009

Figure 5.1 Surgical Safety Checklist (from WHO, 2009) Reproduced with permission by WHO, World Health Organization 2009, WHO Surgical Safety Checklist.

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CHAPTER 6
The Aftermath

Many patients experience errors during their treatment, whether they realise it or not, and some are harmed by healthcare. The harm may be minor, involving only inconvenience or discomfort, but can involve serious disability or death. Almost all bad outcomes will have some psychological consequences for both patients and staff, ranging from minor worry and distress through to depression and even despair. The experiences of these people tend not to be fully appreciated, and yet understanding the impact of such injuries is a prerequisite of providing useful and effective help.

Injury from medical treatment is different from other injuries

Patients and relatives may suffer in two distinct ways from a medical induced injury. First from the injury itself and secondly from the way the incident is handled afterwards. Many people harmed by their treatment suffer further trauma through the incident being insensitively and incompetently handled. Conversely when staff come forward, acknowledge the damage, and take positive action the support offered can ameliorate the impact both in the short and long term. Injured patients need an explanation, an apology, to know that changes have been made to prevent future incidents, and often also need practical and financial help (1). The problems arise when ordinary impulses to help are blunted by anxiety, shame or just not knowing what to say.

The emotional impact is particularly complex because a medical injury differs from most other accidents in some important respects. First, patients have been harmed, unintentionally, by people in whom they placed considerable trust, and so their reaction may be especially powerful and hard to cope with. Imagine the complex of emotions you might experience if you were accidentally injured by a member of your own family. Secondly they are often cared for by the same professions, and perhaps the same people, as those involved in the original injury. As they may have been very frightened by what has happened to them, and have a range of conflicting feelings about those involved. This too can be very difficult, even when staff are sympathetic and supportive.

The full impact of some incidents only becomes apparent in the longer term. A perforated bowel, for example, may require a series of further operations and time in hospital. As with all injuries the effects and associated problems can multiply over time, especially if recovery is only partial. Chronic pain for instance will affect a person's mood, ability to care for their children ability to work, their family and social relationships and their sexual relationship.

As relationships deteriorate, the person may become more isolated, less engaged and consequently more prone to depression; this in turn makes work, family life and child care more difficult (2). The whole scenario may be compounded by the financial problems induced by not being able to work, and the anxiety about the future that this causes. Most of this is unseen by the healthcare organisation which caused the injury in the first place (3).

Box 6.1 Perforation of the colon leading to chronic pain and depression

A woman underwent a ventrosuspension – the fixation of a displaced uterus to the abdominal wall. After the operation she awoke with a terrible pain in her lower abdomen which became steadily worse over the next 4 days. She was very frightened and repeatedly told both doctors and nurses but they dismissed it as 'wind'.

On the fifth day the pain reached a crescendo and she felt a 'ripping sensation' inside her abdomen. That evening the wound opened and the contents of her bowel began to seep through the dressings. Even then, no one seemed concerned. Finally, the surgeon realised that the bowel had been perforated and a temporary colostomy was carried out.

The next operation, to reverse the colostomy, was 'another fiasco'. After a few days there was a discharge of faecal matter from the scar, the wound became infected, and the pain was excruciating, especially after eating. She persistently asked if she could be fed with a drip but the nursing staff insisted she should keep eating. For 2 weeks she was 'crying with the pain, really panicking – I just couldn't take it any more'. She was finally transferred to another hospital where she was immediately put on a liquid diet.

A final operation to repair the bowel was successful but left her exhausted and depressed. She only began to recover her strength after a year of convalescence. Three years later she was still constantly tired, irritable, low in spirits and 'I don't enjoy anything anymore'. She no longer welcomes affection or comfort and feels that she is going downhill, becoming more gloomy and preoccupied.

Her scars are still uncomfortable and painful at the time of her periods. Her stomach is 'deformed' and she feels much less confident and attractive as a result. As her depression has deepened, she has become less interested in sex and more self-conscious about the scar. Three years later the trauma of her time in hospital is still very much alive. She still has nightmares about her time in hospital and is unable to talk about it without breaking into tears. She feels very angry and bitter that no one has ever apologised to her or admitted that a mistake has been made.

Adapted from Vincent (2001)

When a patient dies the trauma is obviously more severe still, and may be particularly severe after a potentially avoidable death. Relatives of patients whose death was sudden or unexpected may therefore find the loss particularly difficult to bear. If the loss was avoidable in the sense that poor treatment played a part in the death, their relatives may face an unusually traumatic and prolonged bereavement. They may ruminate endlessly on the death and find it hard to deal with the loss.

What do injured patients need?

Imagine that you or your husband, mother or child has, inexplicably, suffers a medical injury. What would you want? Well, I imagine you would want to know what happened, you would want an apology, you would want to be looked after and, later on, you might want steps to be taken to prevent such things happening again to anyone else. If the injury led to you being off work or unable to care for your children, you would certainly

appreciate some financial support to help you during the recovery period. If the person concerned was not going to recover, then long term support would be needed. In a study of the reasons for litigation my colleagues and I found exactly this. Injured patients wanted:

- An explanation
- An apology
- For action to be taken to prevent similar injuries
- Compensation, in some cases only

Most wanted the clinicians concerned to realise what they were experiencing; feeling ignored or not heard was a particularly painful and intensely frustrating experience which potentially delayed recovery and adjustment (1). As one patient said to me 'If only I had been told honestly I could have faced it so much better'.

Every injured patient has their own particular problems and needs. Some will require a great deal of professional help, while others will prefer to rely on family and friends. Some will primarily require remedial medical treatment, while in others the psychological effects will be to the fore. In the short term, the two most important principles are to believe the patient and to be as honest and open as possible which means that the error or harm must be disclosed to the patient and their family.

Breaking the news about error and harm

The ethics of open disclosure of errors are crystal clear and expressed in a many clinical codes of ethics. Here is an example from the American Medical Association:

> *'Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgement. In these situation the physician is ethically required to inform the patient of the all the facts necessary to ensure understanding of what has occurred'* (AMA 1999 www.ama.org)

When something has gone wrong, healthcare staff should take the initiative to seek out the patient and/or family and face the situation openly and honestly. Most patients, whether or not they have experienced an error, are strongly of the view that they wanted to be told about all harmful errors, and to know what happened, how it happened, how it would be mitigated and what will be done to prevent recurrence (4). Avoiding or delaying such a meeting unnecessarily will only suggest there is something to hide. A senior member of staff needs to give a thorough and clear account of what exactly happened. At the first interview, junior staff involved with the patient may also be present. The patient and their relatives need to have time to reflect on what was said and to be able to return and ask further questions. Remember that people may be numb with shock after an incident and be unable to cope with very much information. Several meetings may be needed over the course of weeks or months. Telling patients or their families about disappointing results and dealing with their reactions is not easy. Nevertheless, if done with care and compassion, such communication maintains trust between the people involved and can greatly help the patient's adjustment to what has happened.

Box 6.2 Communication after an error or adverse outcome

- Give bad news in a private place where the patient and/or family may react and you can respond appropriately.
- Clearly deliver the message. The adverse outcome must be understood. 'I'm sorry to report that the procedure resulted in ….
- Wait silently for a reaction. Give the patient/family time to consider what has happened and formulate their questions.
- Acknowledge and accept the initial reaction. The usual reaction to bad news is a mixture of denial, anger, resignation and shock. Listen.
- Resist the urge to blame or appear to blame other health professionals for the outcome
- Discuss transition support. Tell the patient/family what steps will be taken to provide medical, social, or other forms of support.
- Finish by reassuring them about your continued willingness to answer any questions they might have. Discuss next steps.
- Consider scheduling a follow-up meeting. Some patients will want to talk only after the crisis has subsided
- Afterwards, document a summary of the discussion. Ideally share this with the patient and family

Adapted from Pichert, Hickson, Pinto, Vincent (2011)

In the longer term

When serious harm has been done, acknowledging and discussing the incident is just the first stage. The longer term needs of patients, families and staff need to be considered.

A common theme in interviews with injured patients is that none of the professionals involved in their care appreciated the depth of their distress. I can recall several patients left in severe pain who were deeply depressed and at times suicidal; although great efforts were being made to deal with their physical problems, no one had thought to ask about their mental state. Risk managers, clinicians and others involved with these patients can ask basic questions without fear of 'making things worse'. Some of the most crucial areas of enquiry are feelings of depression, anxiety, anger, humiliation, betrayal and loss of trust - all frequently experienced by injured patients.

Injured patients may receive support, comfort and practical help from many sources. It may come from their spouse, family, friends, colleagues, doctors or community organisations. An especially important source of support will be the doctors, nurses and other health professionals who are involved in their treatment. It is vital that staff continue to provide the same care and do not withdraw from the patient through guilt or embarrassment. Many patients have derived comfort from the empathy and sadness of staff involved in tragic incidents describing, for instance, the warmth and support they found in the staff's own sadness at the event.

Supporting staff after serious incidents

Human beings make frequent errors and misjudgements in every sphere of activity, but some environments are less forgiving of error than others. Errors in academia, law or architecture, for instance, can mostly be remedied with an apology or a cheque. Those in medicine, in the air, or on an oil rig may have severe or even catastrophic consequences. This is not to say that the errors of doctors, nurses or pilots are more reprehensible, only that they bear a greater burden because their errors have greater consequences. Making an error, particularly if a patient is harmed because of it, may therefore have profound consequences for the staff involved, particularly if they are seen, rightly or wrongly, as primarily responsible for the outcome. The typical reaction has been well expressed by Albert Wu in his aptly titled paper 'the second victim'.

> *'Virtually every clinician knows the sickening feeling of making a bad mistake. You feel singled out and exposed - seized by the instinct to see if anyone has noticed. You agonize about what to do, whether to tell anyone, what to say. Later, the event replays itself in your mind. You question your competence but fear being discovered. You know you should confess, but dread the prospect of potential punishment and of the patient's anger'* (5).

Junior doctors single out making mistakes, together with dealing with death and dying, relationships with senior doctors and overwork, as the most stressful events they have to deal with (6). Medical students anticipate the mistakes they will make as doctors even before entering medical school:

> *'I think one of the scariest things about becoming a doctor is realising how much responsibility you have and that human error happens all the time. I thought about it even before I decided that I definitely wanted to go to medical school'* (7).

In a series of in depth interviews with senior doctors Christensen and colleagues (8) discussed a variety of serious mistakes, including four deaths. All the doctors were affected to some degree, but four clinicians described intense agony or anguish as the reality of the mistake had sunk in. The interviews identified a number of general themes: the frequency of mistakes in clinical practice; the infrequency of self-disclosure about mistakes to colleagues, friends and family; and the emotional impact on the physician, such that some mistakes were remembered in great detail even after several years. After the initial shock the clinicians had a variety of reactions that had lasted from several days to several months. Some of the feelings of fear, guilt, anger, embarrassment and humiliation were unresolved at the time of the interview, even a year after the mistake.

Strategies for coping with error, harm and their aftermath

Many of the doctors interviewed in these various studies study had not discussed the mistakes or their emotional impact with colleagues. Shame, fear of humiliation, fear of punishment all acted to deter open discussion and isolate people from their colleagues. Hopefully, as patient safety evolves, healthcare staff will be able to be more open about error and more open about their need for support when errors do occur. While there is little formal guidance, and almost no research on this topic, the following suggestions may be useful.

- *Acknowledge error.* The potential for error in medicine, as in other activities,

needs to be recognized and openly acknowledged. Education about the ubiquity of error, its causes and likely consequences, would promote a more realistic attitude and constructive approach.

- *Openness about error.* Open discussion of error, particularly by respected senior figures, is very powerful because it provides a mandate for such discussions to occur at other times. In effect, the junior nurse or doctor learns that it is acceptable to discuss errors openly because their seniors do it.

- *Open disclosure*. An agreed policy on openness is a critical for staff as for patients. Many staff are still torn between their own desire for a more open stance and the more cautious approach that they perceive to be demanded, rightly or wrongly by managers and colleagues.

- *Training in disclosure*. Training in disclosing and explaining error is critical. Facing a patient harmed by treatment, or their naturally distressed and angry relatives, is a particularly difficult clinical situation for which little guidance or training is available. Both patients and staff will benefit if clinical staff have some training in helping dissatisfied, distressed, or injured patients and their relatives.

- *Formal and informal support*. Understanding and acceptance from colleagues is always important but sometimes people need more than general support and expressions of confidence. The range of potential support extends from a quiet word in a corridor to the offer of extended psychotherapy. Sometimes a private discussion with a colleague or a senior figure will be sufficient; some hospitals employ recently retired senior doctors as mentors.

Few organisations however have put staff support service into practice in an organised and effective way or fully understood the need for such a service. Brigham and Women's Hospital in Boston is an exception, the home of a remarkable experiment in both patient and staff support that has its origins in a near disaster in 1999 in which Linda Kenney, the founder of Medically Induced Trauma Support Services, experienced a grand mal seizure during an operation. Linda Kenney and Frederick van Pelt, the anaesthetist involved, began in parallel to establish support services for patients and a peer support programme for clinical staff. The staff support programme aims to recruit credible, experienced clinical staff with personal understanding of the impact of error who are immediately available to provide confidential reflection and support. In addition to an active commitment to disclosure and apology, Brigham and Women's Hospital has started to develop an Early Support Activation (ESA) with MITSS for patients and families in conjunction with the hospital's departments of social services and patient relations. The long-term strategy is to have a comprehensive emotional support response for patients, families and care providers (9).

KEY POINTS

Injured patients have been harmed by people they trusted so their reactions can be especially intense

Injured patients may suffer a second trauma if the incident is badly handled

Providing an explanation, apology, financial and other support and acting to prevent recurrence are critical to maintaining trust

Making an errors that harms a patient is one of the most stressful experiences in a clinical career

Open disclosure and support are critical for patients, families and staff

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