Progress and Challenges for Patient Safety

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Twenty-five years ago the field of patient safety, apart from a number of early pioneers, did not exist and the lack of research and attention to medical accidents could reasonably be described as negligent (Vincent 1989). There is now widespread acceptance and awareness of the problem of medical harm and, in the last decade, considerable efforts have been made to improve the safety of healthcare. Progress has however been slower than originally anticipated and the earlier optimism has been replaced by a more realistic longer-term perspective. There has undoubtedly been substantial progress but we believe that future progress, particularly in the wider healthcare system, will require a broader vision of patient safety. In this chapter we briefly review progress on patient safety and consider the principal future challenges as we see them.

Progress on Patient Safety

With the massive attention now given to patient safety it is easy to forget how difficult it was in earlier years to even find clear accounts of patient harm, never mind describe and analyse them. Medico-legal files, oriented to blame and compensation rather than safety, were the principal source of information (Lee and Domino 2002). In contrast narrative case histories and accompanying analyses and commentary are now widely available. Analyses of incidents are now routinely performed, albeit often in a framework of accountability rather than in the spirit of reflection and learning.

Major progress has been made in assessing the nature and scale of harm in many countries. The findings of the major record review studies are widely accepted (de Vries et al. 2008) and numerous other studies have catalogued the nature and extent of surgical adverse events, infection, adverse drug events and other safety issues. The measurement and monitoring of safety continues to be a challenge but progress has been made in developing reliable indicators of safety status (Vincent et al. 2013, 2014).

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Analyses of safety incidents have revealed a wide range of contributory factors and that individual staff are often the inheritors of wider system problems (Reason 1997). However, some safety problems can be linked to the sub-standard performance of individuals, whether wilful or due to sickness or incapacity (Francis 2012). Regulation of both organisations and individuals is increasing and every healthcare professional now has a clear duty to report consistent poor performance from a colleague. Drawing attention to safety issues is actively encouraged at the highest levels, although many whistle-blowers are still shabbily treated and persecuted for their efforts. All of these developments represent an increasing concern with safety and determination to improve basic standards.

Substantial progress has also been made in mapping and understanding safety issues. Surgery, for instance, was long ago identified as the source of a high proportion of preventable adverse events. A decade ago most of these would have been considered unavoidable or ascribed, generally incorrectly, as due to poor individual practice (Calland et al. 2002; Vincent et al. 2004). Studies of process failures, communication, teamwork, interruptions and distractions have now identified multiple vulnerabilities in surgical care. Given the inherent unreliability of the system it now seems remarkable that there are so few adverse events, which is probably testament to the resilience and powers of recovery of clinical staff (Wears et al. 2015). Many surgical units are now moving beyond the undoubted gains of checklists to consider the wider surgical system and the need for a more sophisticated understanding of surgical teamwork in both the operating theatre and the wider healthcare system (de Vries et al. 2010).

A considerable number of interventions of different kinds have shown that errors can be reduced and processes made more reliable. Interventions such as computer order entry, standardisation and simplification of processes and systematic handover have all been shown to improve reliability, and in some cases reduce harm, in specific contexts. We have however relatively few examples of large scale interventions which have made a demonstrable impact on patient safety, the two most notable exceptions being the reduction of central line infections in Michigan and the introduction of the WHO surgical safety checklist (Pronovost et al. 2006; Haynes et al. 2009) (Table 1.1).

While specific interventions have been shown to be effective it has proved much more difficult to improve safety across organisations. The United Kingdom Safer Patients Initiative, which engaged some of the acknowledged leaders in the field, was one of the largest and most carefully studied intervention programmes. The programme was successful in many respects, in that it engaged and energised staff and produced pockets of sustained improvement. However it failed to demonstrate large scale change on a variety of measures of culture, process and outcomes (Benning et al. 2011). Similarly, where studies have attempted to assess safety across a whole healthcare system, the findings have generally been disappointing. Longitudinal record review studies in the United States, France have shown no improvement in patient safety although there have recently been encouraging results from Netherlands (Landrigan et al. 2010; Michel et al. 2011; Baines et al. 2015)

Table 1.1 Progress in patient safety over two decades

	Where we were (1995)	Where we are now (2015)
Foundations	Incident reporting, continuous improvement and development of best practice	Largely unchanged. More translation and use of industrial approaches to safety, increased attention to incident analysis, learning and feedback
Definition	Harm defined from a professional standpoint, rooted in a medico-legal and insurance perspective. Narrow vision of causality, direct association between technical care and harm	Patient safety still linked to a medico-legal perspective. Broader understanding of human error and organisational influences
Perimeter of inclusion	Dominant technical vision of care, improved clinical protocols as main priority for improving safety	Recognition of the importance of human factors and human sciences. Organisational factors and safety culture are additional priorities for safety
Measurement	Counting incidents and adverse events	Largely unchanged

Compared to a decade ago, we now have a good understanding of the phenomenology of error and harm, a considerable amount of epidemiological data, some understanding of the causes of harm, demonstrations of the efficacy of certain interventions and the effectiveness of a few. We do not have clear evidence of wide sustained change or widespread improvements in the safety of healthcare systems. All in all, progress looks reasonable if not spectacular. Given the level of resources allocated to safety, still tiny in comparison with biomedicine, progress looks reasonably good.

We believe that the concept of patient safety we are working with is too narrow and that future progress, particularly outside hospitals, will require a broader vision. In the remainder of this chapter we set out some challenges and confusions that we regard as particularly critical. These provide both the motivation for our work together and also an introduction to our approach.

Harm Has Been Defined Too Narrowly

We agree with those who seek to provide a more positive vision of safety (Hollnagel 2014). The punitive approach sometimes taken by governments, regulators and the media is, for the most part, deeply unfair and damaging. Healthcare while enormously beneficial is, like many other important industries, also inherently hazardous. Treating patients safely as well as effectively should be regarded as an achievement and celebrated.

We make no apologies however for continuing to focus on harm as the touchstone for patient safety and the motivation for our work. We will put up with errors and problems in our care, to some extent at least, as long as we do not come to harm

and the overall benefits clearly outweigh any problems we may encounter. Many errors do not lead to harm and may even be necessary to the learning and maintenance of safety. Surgeons, for example, may make several minor errors during a procedure, none of which really compromise the patient's safety or the final outcome of the operation.

Patient safety, particularly the large scale studies of adverse events, has its origins in a medico-legal concept of harm. We have, for the most part, now separated the concept of harm from that of negligence which is an important achievement, though we still tend to think of safety as being the absence of specific harmful or potential harmful events (Runciman et al. 2009). Harm can also result from loss of opportunity due to a combination of poor care and poor coordination whether inside the hospital, at the transition with primary care, or over a long period of time in the community. Evidence is growing that many patients suffer harm, in the sense that their disease progresses untreated, through diagnostic error and delay (Graber 2013; Singh et al. 2014). In some contexts, this would simply be seen as poor quality care falling below the accepted standard. But for the patient a serious failure can lead to untreated or unrecognised disease and, from their perspective, to harm.

Box 1.1 Safety Words and Concepts

The term 'medical error' has been used in a variety of ways, often as shorthand for a poor outcome. We use the term error is in its everyday sense as a retrospective judgement that an action or omission by a person did not achieve the intended outcome. We use the term reliability when considering processes and systems rather than the actions of people.

The aims of the patient safety movement can be stated in a number of different ways:

- To reduce harm to patients, both physical and psychological
- To eliminate preventable harm
- To reduce medical error
- To improve reliability
- To achieve a safe system

All these are reasonable objectives but they are subtly different. We suggest that the central aim must be to prevent or at least reduce harm to patients, while acknowledging that the concept of harm is difficult to define and other objectives are also valid. As the book develops we will suggest that the most productive way to approach patient safety is to view it as the management of risk over time in order to maximise benefit and minimise harm to patients in the healthcare system.

We believe that the current focus on specific incidents and events is too narrow and that we need to think about harm much more broadly and within the overall context of the benefits of treatment. As the book evolves, we endeavour to develop a different vision which is more rooted in the experience of patients. As patients, the critical question for us is to weigh up the potential benefits against the potential harms which may, or may not, be preventable. While we certainly want to avoid harmful incidents, we are ultimately concerned with the longer term balance of benefit and harm that accrues over months or years or even over a lifetime.

Safety Is a Moving Target

Safety is, in a number of respects, a constantly moving target. As standards improve and concern for safety grows within a system, a larger number of events will come to be considered as safety issues. In a very real sense innovation and improving standards create new forms of harm in that there are new ways the healthcare system can fail patients.

In the 1950s many complications of healthcare were recognised, at least by some, but largely viewed as the inevitable consequences of medical intervention (Sharpe and Faden 1998). Gradually, certain types of incidents have come to seem both unacceptable and potentially preventable. The clearest example in recent times is healthcare-associated infection, which is no longer viewed as an unfortunate side effect of healthcare. With increased understanding of underlying processes, mechanisms of transmission and methods of prevention, coupled with major public and regulatory pressure, such infections are becoming unacceptable to both patients and professionals (Vincent and Amalberti 2015).

In the last 10 years, as more types of harm have come to be regarded as preventable, the perimeter of patient safety has expanded. A larger number of harmful events are now regarded as ‘unacceptable’. In addition to infections we could now include, in the British NHS, pressure ulcers, falls, venous thromboembolism and catheter associated urinary tract infections. In the United Kingdom the Francis Report into Mid Staffordshire Hospitals NHS Trust highlighted additional risks to patients, such as malnutrition, dehydration and delirium all of which are now being viewed as safety issues. We should also consider adverse drug reactions in the community that cause admission to hospital, polypharmacy and general harm from overtreatment. All these, in the past, might have been regretted but are now receiving greater attention through being viewed under the safety umbrella.

The perimeter of safety is therefore expanding but this does not mean that healthcare is becoming less safe. A long-standing concern with safety in such specialties as anaesthesia and obstetrics is actually a marker of the high standards these specialties have achieved. Safety is an aspiration to better care and labelling an issue as a safety issue is a strongly motivational, sometimes emotional, plea that such outcomes cannot and should not be tolerated (Vincent and Amalberti 2015).

Only Part of the Healthcare System Has Been Addressed

Patient safety has evolved and developed in the context of hospital care. The understanding we have of the epidemiology of error and harm, the causes and contributory factors and the potential solutions are almost entirely hospital based. The concepts which guided the study of safety in hospitals remain relevant in primary and community care but new taxonomies and new approaches may be required in these more distributed forms of healthcare delivery (Brami and Amalberti 2010; Amalberti and Brami 2012).

Care provided in a person's home is an important context for healthcare delivery but patient safety in the home has not been addressed in a systematic manner. The home environment may pose substantial risks to patients, greater in some cases than in the hospital environment. Safety in the context of a patient's home care is likely to require different concepts, approaches and solutions to those developed in the hospital setting. This is because of the different environment, roles, responsibilities, standards, supervision and regulatory context in home care. Critical differences are that patients and carers are autonomous and are increasingly taking on professional roles; they rather than the professional become the potential source of medical error. Additionally, stressful and potentially hazardous conditions, such as poor lighting, mean that socio-economic conditions take on a much greater importance.

In both primary care and care at home the risks to patients are rather different from those in hospital, being much more concerned with omissions of care, failure to monitor over long time periods and lack of access to care. These areas have not traditionally fallen within the area of patient safety but are undoubtedly sources of potential harm to patients. The concept of the patient safety incident, and even of adverse events, breaks down in these settings or is at least stretched to its limit. Suppose, to take just one example, a patient is hospitalised after taking an incorrect dose of warfarin for 4 months. The admission to hospital could be viewed as an incident or a preventable adverse event. This description however hardly does justice to 4 months of increasing debility and ill health culminating in a hospital admission. In reality, the admission to hospital is the beginning of the recovery process and a sign that the healthcare system is at last meeting the needs of this patient. The episode needs to be seen not as an isolated incident but as an evolving and prolonged failure in the care provided to this person.

We Are Approaching Safety in the Same Way in All Settings

'But we are not like aviation' someone will inevitably say in any discussion of the value of learning from commercial aviation and comparing approaches to safety in different sectors. Well no, healthcare is not like aviation in any simple sense. But some aspects of healthcare are comparable to some aspects of aviation. An surgical operation does not have a great deal in common with a commercial flight but the pre-flight checking process is comparable to the pre-operation checking process and so learning how aviation manages those checks is instructive.

The objection to the simple comparison is important. Safety in healthcare does need to be approached differently from safety in commercial aviation. The wholesale transfer of aviation approaches to healthcare at the very least requires considerable adaptation; crew resource management acted as an inspiration to surgical and anaesthetics teams but surgical team training has now developed its own style and history (Gaba 2000; Sevdalis et al. 2009). We now need to go further and consider a still more important issue which is that safety may need to be approached differently in different areas of healthcare. Specialty specific approaches (Croskerry et al. 2009) are emerging but models, methods and interventions do not often distinguish between settings.

Healthcare is a particularly complex environment. We might say that healthcare is 20 different industries under one banner. Consider the hospital environment with multiple types of work, many different professions and varying working conditions across clinical environments. There are areas of highly standardized care such as pharmacy, radiotherapy, nuclear medicine and much of the process of blood transfusion. All of these are highly standardized and rely heavily on automation and information technology. They are islands of reliability within the much more chaotic wider hospital environment. On the ward standards and protocols provide important controls on hazards (such as infection from poor hand hygiene) but day-to-day conditions demand constant adaptation and flexibility. Other sections of the hospital, such as the emergency department, continually have to deal with unpredictable patients flow and workloads; their activity needs considerable hour-by-hour adaptation because of the huge variety of patients, the complexity of their conditions and the vulnerabilities of the healthcare system.

The risks and the nature of the work vary across all these settings. In spite of this we are essentially using the same concepts, the same analytic toolbox and the same suite of interventions in all settings. Many of these approaches can be customised and adapted to different settings. However we will argue later in the book that risk needs to be managed in very different ways in different environments and that the approach of, for instance, commercial aviation is very different from that of professionals working in more fluid risky environments such as fire-fighters. In healthcare we may have to adapt our approach to safety according to the nature of the work, the working conditions and use a variety of underlying models of safety.

Our Model of Intervention Is Limited

The most dramatic safety improvements so far demonstrated have been those with a strong focus on a core clinical issue and a relatively narrow timescale. These interventions, such as the surgical safety checklist and the control of central line infections, are of course far from simple in the sense that they have only succeeded because of a sophisticated approach to clinical engagement and implementation. More general system improvements may extend to an entire patient pathway. For instance the introduction of the SURPASS system using checklists and other improvements to communication along the entire surgical pathway and showed a

reduction in surgery complications (de Vries et al. 2010). Bar coding and other systems have massively enhanced the reliability of blood transfusion systems, incrementally improving each step of the pathway (Murphy et al. 2013).

We should however be wary of modelling all future safety interventions on our most visible successes. At the moment the primary focus is on developing interventions to address specific harms or to improve reliability at specific points in a care process. This, entirely reasonable, approach is evolving to include the reliability of entire care pathways or areas of care (such as an out-patient clinic). We will argue however that, in addition to increasing reliability, we also need to develop proactive strategies to manage risk on an ongoing basis, particularly in less controlled environments. There is also a class of strategies and interventions, particularly those that focus on detecting and responding to deviations, that are particularly critical for preventing harm to patients. These approaches do not feature as strongly in the classical quality and safety armament.

We also need to recognise that safety, for any person or organisation, is always only one of a number of objectives. For instance, many sports involve an element of risk and potential harm. When we become patients we necessarily accept the risks of healthcare in pursuit of other benefits. Similarly a healthcare organisation can never treat safety as the sole objective, even if they say safety is their 'top priority'. Of necessity, safety is always only one consideration in a broader endeavour, whether in healthcare or in any other field. As an oil executive expressed it: 'Safety is not our top priority. Getting oil out of the ground is our priority. However, when safety and productivity conflict, then safety takes precedence' (Vincent 2010). Similarly, in healthcare, the main objective is providing healthcare to large numbers of people at a reasonable cost, but this needs to be done as safely as possible.

Healthcare Is Changing

We have argued that, for a variety of reasons, we need to expand our view of patient safety. This argument has been made from our understanding of current healthcare systems. However we also believe that the rapid evolution of healthcare, combined with increasing financial pressures, brings an additional urgency to the quest for a new vision.

Outcomes of care have improved rapidly all over the world. People now survive illnesses, such as myocardial infarction and stroke, which were once fatal. As the effectiveness of healthcare improves, increasing numbers of patients are ageing with their illness under control. Current projections suggest that by 2030 as many as 25 % of the population in many countries may surviving into their 90s. In many cases an illness which was once fatal has become a chronic condition with all the related implications for the individual, society and the healthcare system. The treatment of chronic conditions (such as diabetes, respiratory diseases, depression, cardiac and renal disease) is now the major priority. The phenomenal increase in

diabetes alone (although not driven by ageing per se) threatens to destabilise healthcare systems and the general increase in multiple comorbidities and more complex health problems places huge stress on healthcare systems. The question of what 'best practice' actually is for any individual patient is itself becoming a very difficult issue.

The impact on global cost of healthcare is considerable, with average costs increasing by 1 % of national gross domestic product (GDP) between 2000 and 2013 (World Bank). By 2030 there may be 30 % more patients with chronic conditions which might require a further increase in funding of between 2 and 4 % of GDP, depending on the approach taken by the country in question. There is a major risk that by 2030, institutional care for the aged will be unaffordable and that, in the absence of alternatives, there will be a crisis of quality in care for the aged. While alternative systems are evolving there could be if anything an increased risk of failures and harm to patients.

The need for healthcare to evolve and adapt is to a very large extent the consequence of the successes of modern medicine. The focus of care needs to move rapidly from high quality care in hospitals to a focus on the entire patient journey over years or even over a lifetime. These changes are long overdue but becoming increasingly urgent. The shift to the management of care over long time periods and many settings has a number of consequences with implications for safety. Patients stay in hospital less time, live at home for years with their disease, with a consequent transfer of responsibility from hospitals to primary care. This requires effective coordination across all health care organisations, in particular at the transition points, in order to mitigate risk and enable positive outcomes. Reducing complexity is crucial.

Finally, patients are more knowledgeable and informed than previously. They are increasingly aware of their rights to information and access. The public expects a system that meets their needs in a holistic and integrated way, with a seamless system of effective communication between transition points. Last but not least there is an increasing emphasis on the prevention of disease and the maintenance of health. This turns the concept of the patient journey into the concept of the citizen or person journey.

The combination of austerity, rising healthcare costs, rising standards and increased demand will place huge pressures on healthcare systems which will increase the likelihood of serious breakdowns in care. At the same time innovations in the delivery of care in the home and community, while providing new benefits, will also create new forms of risk. Our current models of safety are not well adapted to this new landscape.

In this chapter we identified a number of challenges for patient safety. In the next three chapters we begin to consider how these challenges are to be met and establish the foundations for the more practical and strategic chapters that follow later in the book. First however we build the foundations beginning with the simple idea that care given to patients is of varying standard and, equally important, that the care given to any one patient varies considerably along their journey.

Key Points

- Major progress has been made in assessing the nature and scale of harm to patients in many countries
- A considerable number of interventions of different kinds have shown that errors can be reduced and processes made more reliable.
- The most safety improvements so far demonstrated have been those with a strong focus on a core clinical issue and a relatively narrow timescale. It has proved very much more difficult to improve safety across whole organisations
- Improving safety at a population level has been even more challenging and findings have generally been disappointing.
- Safety is, in a number of respects, a constantly moving target. The perimeter has expanded over time as new forms of harm have been identified as safety issues.
- Patient safety has evolved and developed in the context of hospital care. The concepts which guided the study of safety in hospitals remain relevant in primary and community care but new approaches to safety will be required in these more distributed forms of healthcare delivery
- The successes of healthcare and improved living conditions mean that people live longer with chronic conditions which were once fatal. This has led to considerable transfer of responsibility from hospitals to home and primary care. Safety models, safety methods, and interventions strategies must change accordingly.
- The combination of austerity, rising healthcare costs, rising standards and increased demand will place huge pressures on healthcare systems which will increase the likelihood of serious breakdowns in care. Innovations in the delivery of care in the home and community, while providing new benefits, will also create new forms of risk. Our current models of safety are not well adapted to this new landscape.

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