

The foundational ideas which have informed our thinking are essentially quite simple but hard won in the sense that they are not for the most part embedded in current thinking. We have argued that we need to view safety through the patient's eyes and that safety needs to be approached very differently in the varying settings along the patient journey. This implies in turn that we need to think more explicitly about what kind of safety strategies are most useful in different contexts. We can now draw these themes together and consider the new directions that emerge.

In this chapter we first review the ideas and arguments of the book and summarise the transitions in patient safety that we believe are needed (Box 11.1). We then set out a compendium of safety and risk management strategies which can be selected, combined and customised to any healthcare setting.

### **Box 11.1. Five Transitions for Patient Safety**

- Understanding risk and harm through the patient's eyes
- Assessing both benefit and harm across episodes of care
- Patient safety as the management of risk over time
- Varying safety models dependent on context
- Using a wider range of safety strategies and interventions

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## **Seeing Safety Through the Patient's Eyes**

Our current approach to patient safety, seen from the perspective of healthcare professionals, assumes generally high quality healthcare punctuated by safety incidents and adverse events. This is a sincere vision in that professionals naturally assume that for the most part they are giving good care though they know that there are occasional lapses. In contrast we have endeavoured to see safety through the patient's eyes. A patient may receive wonderful care during one hospital admission,

followed by decline due to inadequate monitoring in the community which is later corrected and their health restored; our five levels of care are a formalisation of these varying standards of care that are experienced along the patient journey. This is a vision of safety from the perspective of the patient, carer and family which is the reality we need to capture (Box 11.2).

**Box 11.2. Seeing Safety Through the Patient's Eyes**

- Isolated errors and incidents are generally less important than the overall coordination of care and the avoidance of major lapses.
- Coordination of care acquires a much greater importance as a safety issue.
- Patients with multiple problems face major challenges in coordinating their own care which can be a considerable burden and source of anxiety.
- Safety interventions to support patients at home will need to focus on organisational interventions such as rapid response to crises and coordination between agencies.
- The healthcare system needs to give more attention to the perspective of patients and families in monitoring and maintaining safety.

Most people understand that all healthcare involves a degree of risk. The level of risk that is accepted must be outweighed by the expected benefits and should be openly expressed. Failures in the healthcare system will always occur to some degree but their consequences can be limited by honesty, transparency, early response and mitigation. We believe, though this could be formally researched, that this is the pragmatic view that most people take of their healthcare. Medicine reduces suffering and improves our lives in many ways but is necessarily limited in what it can achieve. What counts for us as patients is whether healthcare improves our lives overall and whether it lives up to our expectations both technically and in the manner in which the care is provided. The engagement and relationship with clinical staff is important in itself but also affects the overall assessment of whether the care has been beneficial or harmful.

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**Considering Benefit and Harm Along the Patient Journey**

Seeing safety through the patient's eyes has the immediate consequence that we need to view safety along the patient journey. This means that we need to examine episodes of care and consider both risk and harm within an extended timescale. We can still of course examine specific incidents occurring at particular times and this remains a useful exercise. However such an approach will not identify all safety issues and it is not well adapted to either understanding or improving safety in community settings. This longer term approach has consequences for the measurement of harm, for methods of analysis and of course for safety interventions.

The measurement of harm has previously focused on examining the incidence of specific adverse events. There is nothing wrong with such an approach; it provides important baseline information in particular settings which can be used to monitor certain types of harm. However these approaches will need to be extended to assess the balance of benefit and harm over time for any one patient and eventually for populations of patients. Indicators of the reliability and overall quality of care across different healthcare settings might include reduction of repeated hospitalisation, time to response to problem, or the wider impact on work and family (Mountford and Davie 2010). Ideally we need information systems that can track patients over time and provide links between different healthcare settings and forms of treatment. In the longer term we need to develop metrics which can assess the holistic contribution of healthcare to a person's life, in which overall benefits and harm can be assessed and combined. This would truly be a patient centred vision in which the totality of healthcare was assessed not simply the disease specific outcomes. This is not going to be at all easy but is, we believe, the direction that we need to take.

Most of our methods of incident analysis have been restricted to relatively short time periods within a single hospital admission, although the basic concepts have proved robust in other settings such as primary care and mental health. We will have to expand these approaches to examine periods of care rather than a specific incident and its antecedents. We do not yet have fully developed methods to conduct safety analyses over long time periods and so new approaches will need to be developed. Initial analyses have shown that very different considerations emerge such as the critical role of the timing of decisions and actions in the clinical process (Amalberti and Brami 2012). These new forms of analysis will need to encompass a timeframe sufficient to embrace initial assessment, provision of treatment, monitoring the result, and responding to complications while continuing to deliver care. These analyses are likely to place a much greater emphasis on the detection and recovery from problems in the delivery of care.

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## **Patient Safety as the Management of Risk Over Time**

We have now arrived at a rather different view of patient safety which includes, but does not conflict with, definitions focused on the reduction of error and harm. The revised aim of patient safety is to maximise the overall balance of benefit and harm to the patient, rather than specifically to reduce errors and incidents. Patient safety becomes the management of risk over time as the patient and family move through the healthcare system. The benefit may be expressed as recovery whenever possible, reduction of suffering or extended survival. This is of course the aim of clinicians everywhere when treating individual patients but we are concerned with how this might be achieved across a system.

The reduction of harm remains important, as does the reduction in errors and incidents, but it is not the dominant perspective. Incidents associated with care will always occur during episodes of care since no human activity can be error free, especially across a system with open access 24 h a day and 7 days a week. Harm

may occur because of single safety incidents but more commonly from an accumulation of poor care that impedes recovery, worsens the prognosis or prolongs disability unnecessarily. Patient safety is both the art of minimizing these incidents and managing risk over longer time periods which will require additional skills and methods. We accept in this vision that errors will inevitably occur but that, in a safe system, very few will have any consequences for the patient. This is in essence a clinical vision but at the level of the system as well as the individual patient. Note that this view gives considerable emphasis to the achievements of patients, families and staff in monitoring, negotiating, adapting and recovering from the inevitable hazards and failures along the patient journey.

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## Adopting a Range of Safety Models

Safety needs to be approached very differently in different environments. We have initially distinguished three classes of safety models that fit different field demands: the adaptive model embracing risks, the high reliability model managing risks, and the ultra-safe model in which risk is controlled or avoided wherever possible. These different responses to risk give rise to different models of safety, each with their own advantages and limitations. The differences between these models lie in the trade-off between the benefits of adaptability and the benefits of standardisation and control.

Healthcare has many different types of activity and clinical settings and so we cannot use one primary model (Box 11.3). We can see parallels and applications of the three models relatively easily in the hospital environment. Radiotherapy, blood products, imaging systems and the management of drugs in pharmacy are all highly regulated, very reliable and operate to industrial standards of precision. Many of these systems rely on a high degree of automation and decision support and the professionals working in these areas are accustomed to working in a highly ordered manner. In other settings, such as obstetrics and elective surgery, risk has to be accepted and managed with coordinated teamwork. High risk surgery, trauma medicine and the treatment of rare and dangerous infections require a more adaptive approach though all benefit from a foundation of standard procedures. We should also bear in mind that much adaptation and resilience in healthcare is unnecessary in that it is employed not from clinical necessity but to compensate for wider system deficiencies (Wears and Vincent 2013).

### Box 11.3. Safety Models for Healthcare

- There is no one universal model of safety in healthcare that can apply across every setting. Each model has its own advantages, limitations and challenges for improvement.
- The choice of a safety model will derive from professional consensus, from real world experience, an understanding of safety and judgements as to what is politically feasible in the context in question.

- Imposition of a given safety model that is inappropriate to the context in question may not be effective and may sometimes even degrade safety.
- Each model has similar potential to improve safety in healthcare by a factor of 10, although the maximum attainable safety figures are context dependent and can vary considerably from one model to another.

In healthcare we may find we need a wider array of models than the three we have outlined. It would be a mistake to assume that these three broad approaches are all we need; they are a helpful simplification of a more complex problem. For instance care in the community is unusual in being highly distributed amongst different people and organisations and also only partially reliant on strict standards. Many industries would manage a very distributed system by careful standardisation of core procedures but this may not be possible when, for instance, managing the care of people with severe mental health problems in the community. We are also aware that the industries we have chosen to illustrate the differing approaches to safety are high hazard, high technology and, while those who work in them support each other, they are not simultaneously concerned with delivering compassionate care to vulnerable people. We will probably need a more thoughtful approach to the systemic management of risk in the care of people with learning disabilities for instance, which will retain the broader strategic understanding but achieve the objective of managing risk through personal relationships as much as through formal strategy.

We will also need to consider how we can move between models. When, for instance, does a previously adaptive approach become sufficiently embedded and understood to begin the transition to a high reliability approach? In part this comes about from innovation, familiarisation and the building of expertise within a community. Innovative surgery for instance always begins in a context of risk and challenge. As experience grows in, for instance the management of aortic aneurysm, the surgery still carries risks but these are known, understood and managed rather than endured.

A patient's journey crosses many medical settings and services, in different contexts, and therefore is necessarily exposed to the whole range of safety models. Controlling risk not only requires managing each setting and the transitions between settings, but also being alert to the fact that safety interventions that are effective in one setting may adversely affect safety in other contexts. For instance a cautious and restrictive control of laboratory services aimed at reducing error that is effective in raising standards locally, might adversely affect safety more widely through the reduction in the availability of timely laboratory results.

The external environment is also a critical determinant of which approach to safety can be adopted. An ultra-safe system relies not only on internal procedures, standardisation and automation but also on being able to control the external environment and working conditions. This is achieved by limiting exposure to risk, as when an airline grounds flights in bad weather, and also by controlling working conditions

so that there are, for example, strict controls on how many hours civil aviation pilots can fly and how long they must rest before flying again. With enough resource this would be achievable in some areas of healthcare, and indeed some areas are already very safe. However if we cannot control the demand and working conditions, we necessarily have to rely on more adaptive approaches to safety; a different model may be intrinsically safer but simply not feasible in a particular context. While civil aviation is indeed a source of inspiration and learning such a model is only currently applicable in a relatively limited set of circumstances in healthcare. The approach taken to safety in any healthcare setting may ultimately depend in part on what is politically feasible which will vary by discipline, organization and jurisdiction.

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## Developing a Wider Range of Safety Strategies

The dominant vision of safety improvement is to increase the reliability of basic procedures. These might be the standard procedures in operating theatres, the prevention of venous thromboembolism or procedures to minimise central line or other infections. A number of major interventions have shown that with sufficient will, a sophisticated approach to implementation and the necessary resources, reliability can be markedly improved in a least a set of core processes.

We still have very limited safety strategies for dealing with the day to day realities of healthcare. The dangers to patients when staff are working in difficult conditions are sometimes discussed though generally in terms of the need for more staff which may, of course, be a reasonable request; if more staff were available, or their time was better used, then it might be possible to meet core standards. However in healthcare we will never be able to meet basic standards all the time and in all contexts. We need therefore to relinquish the hope that we will ever be able to do this in all circumstances and pose a different question. How can we ensure that care is safe, even if not ideal, when working conditions are difficult? How, for instance, should one manage an emergency department at times of very high workload or during major emergencies when the care of some less seriously ill patients is inevitably delayed or compromised. What strategies are available to a young nurse or doctor faced with an absurd workload, multiple competing demands and many sick patients? People do adapt and cope of course, but on an individual basis rather than with a considered team based strategy. Developing considered approaches to the management of risk in such situations is a priority for the next phase of patient safety (Box 11.4).

### Box 11.4. Developing a Wider Range of Safety Strategies

- We should extend our safety strategies to include risk control, monitoring and adaptation, and mitigation
- We must not be ashamed to propose strategies that aim to manage risk rather than optimise care as long as the final result is beneficial to the patient and robust to context.

- Developing and implementing considered team based responses to difficult working conditions will be safer than relying on ad hoc improvisation
- Healthcare uses a very limited set of safety interventions. The limited progress in patient safety is partly due to the underuse of the available strategies and interventions. It is like driving a car and only using first gear.

We also need to consider how best to customise specific safety interventions. For example reviews of studies of interventions to reduce falls have provided conflicting evidence of effectiveness – some studies showed strong effects, others none. Frances Healey and colleagues argued that the conflict is only apparent and due to the fact that two very different kinds of interventions have been tested; some trials adopted a one size-fits-all implementation of a set bundle of procedures while others, in contrast, developed an individualized approach to each patient with responsive care planning and post-fall review. The standard intervention has been shown in large randomized controlled trials to have little effect; the more personalized approach, which stresses an adaptive response to risk, is proving very much more effective. Healey comments that this ‘makes complete sense in the context of falls risk being a complex combination of intrinsic and extrinsic factors and personal attitudes to risk, in an acute environment where physical condition and therefore falls risk factors are rapidly changing’ (Healey et al. 2014 and personal communication 2015).

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## A Compendium of Safety Strategies

We have proposed five broad safety strategies each associated with a family of interventions. We have provided illustrations of how each strategy might be applied in hospital, home and primary care. The reality is no doubt considerably more complicated and needs to be further explored. But even now, with incomplete understanding, we can set out a suite of potential interventions to improve safety and manage risk.

Table 11.1 brings together many of the strategies and interventions described in previous chapters and offers some comments on their applicability, current use and challenges for implementation. The strategies and interventions can operate at different levels and have divided these into frontline, organisation and system levels. This is not a complete account by any means as, for one thing, we have not included patients and families as users of these approaches. However it makes the general point that some interventions are more useful on the frontline while others are more useful at system level. Care bundles for instance are a frontline team intervention, although managers and regulators may encourage and even mandate their use. Risk control approaches can be used within a clinical team in deciding not to start an operation unless all the equipment is available. However, most risk control interventions, such as restricting demand or controlling working conditions, will be at organisation or system level and require considerable authority to implement. To be effective of course they also need the backing of frontline staff.

**Table 11.1** A compendium of safety strategies and interventions

**A Compendium of Safety Strategies and Interventions**

**An incomplete taxonomy**

Strategy	Interventions	Level of Implementation		Degree of use	Challenges
		Frontline	Organisation System		
Safety as best practice: aspire to standards	Focal safety programme to reduce specific harms	✓		Used ++	Allocate more time to implementation
	Improve reliability of targeted processes	✓		Underused +	Reduce disparity within settings
	Improve continuous professional education to adopt best practices	✓	✓	Used +	Limited time allocated to education and training
	Develop more sophisticated guidelines for complex patients		✓	Underused	Personalised medicine in progress
Improvement of systems and processes	Staff training, assessment and feedback	✓	✓	Used +	Excessive use of temporary staff
	Standardisation and simplification of key processes	✓	✓	Underused ++	Increasing volume of policies and wasteful processes
	IT to support decision making	✓	✓	Used +	Usability and integration into workflow remain problematic
	Automation of processes	✓	✓	Underused +	Reluctance to adopt
	Improved equipment design	✓	✓	Used +	Manufacturers not sufficiently engaged in safety
	Formalising team roles and responsibilities	✓	✓	Used	Models available but seldom implemented
	Standardisation and enhancement of handover	✓	✓	Used	Models available but seldom implemented
	Improve working conditions : light, noise, physical environment	✓	✓	Used +	Ample margin for progress
	Reduce interruptions and distractions	✓	✓	Underused ++	Not considered as a problem
	Improve organisation and level of staffing		✓	Underused +	Economic constraints and fixed professional roles
Creation of new roles and posts to improve coordination		✓	Underused +	Economic constraints and fixed professional roles	

Optimisation strategies



Risk management strategies									
Risk control	Withdraw services	✓	✓	Underused ++	Political constraints and potential adverse social impact				
	Reduce demand	✓	✓	Underused ++	Political constraints and potential adverse social impact				
	Place restrictions on services	✓	✓	Underused ++	Political constraints and potential adverse social impact				
	Place restrictions on individuals	✓	✓	Underused ++	Response often too late and too punitive				
	Place restrictions on conditions of operation	✓	✓	Underused +	Does not conform to healthcare culture				
Monitoring, adaptation and response	Prioritisation of care either temporarily or permanently	✓	✓	Underused ++	Politically difficult at local level				
	Improve safety culture	✓	✓	Underused +	Often advised but seldom effectively implemented				
	Improve detection of deterioration	✓	✓	Underused +	In progress with increasing attention to failure to rescue				
	Develop emergency response systems	✓	✓	Used +	Many examples but could be more widely employed				
	Develop team cross checking and monitoring	✓	✓	Used +	Models available and huge potential for increased use				
	Briefings and anticipation of hazards	✓	✓	Used +	Models available and huge potential for increased use				
	Improve organisational response to pressures and threats to safety	✓	✓	Underused +	Needs exploration, study and development				
	Negotiate response to regulatory demands	✓	✓	Underused	Adversarial relationship between providers and regulators				
Mitigation	Policy of explanation, apology and support for injured patients	✓	✓	Used +	Policies exist but practice lags behind				
	Rapid response to physical harm	✓	✓	Used +	Rapid response in hospital but may be slower in community				
	Psychological support for patients and families	✓	✓	Underused +	Policies exist but practice lags behind				
	Peer to peer support programmes for staff	✓	✓	Underused ++	Models exist but few examples of effective implementation				
	Formal support and mentoring for staff	✓	✓	Underused ++	Models exist but few examples of effective implementation				
	Insurance of staff and organisation against claims	✓	✓	Used ++	Widely used but not linked effectively to safety initiatives				
	Proactive response to complaints and claims	✓	✓	Underused ++	Models exist but few examples of effective implementation				
	Proactive response to media	✓	✓	Underused	Some examples of good practice but frequently difficult				
	Open dialogue with regulators	✓	✓	Underused ++	Huge scope for improved and more productive relationships				

We realise that these proposals are just a starting point in that considerable work is needed to map and articulate the full range of strategies and interventions that are currently in use and which might be adopted. This has been done for ‘best practice’ approaches, and to some extent for interventions to improve the system. But we need a much fuller description of all types of strategy and intervention if we are to develop a truly comprehensive approach to safety.

We can point to similar developments in other fields which may serve as a model for how this might be done. There is, for instance, enormous interest in influencing the behaviour of people in a variety of ways; these include diet, smoking, exercise, road safety, the payment of taxes and a host of other policy objectives. There are numerous psychological and social theories which purport to explain changes in human behaviour through a variety of mechanisms each with implications for intervention. In weight loss for instance one might seek to enhance self-esteem as a means of increasing adherence to a diet or place more emphasis on extrinsic motivations such as offering financial incentives (Box 11.5). Susan Michie and colleagues have developed the Behaviour Change Wheel (BCW), a synthesis of 19 frameworks of behaviour change found in the research literature (Michie et al. 2013). The BCW has at its core a model of behaviour known as COM-B standing for capability, opportunity, motivation and behaviour. The BCW identifies different intervention options that can be applied to changing each of the components and policies that can be adopted to deliver those intervention options.

#### **Box 11.5. Contrasting Approaches to Changing Risky Behaviour**

Suppose one wished to reduce the propensity of young drivers to engage in risky driving practices such as driving too fast. One would canvass all the options including improving their ‘capability’ to read the road and adjust their driving to the conditions, restricting their ‘opportunity’ to drive recklessly by means of speed limiters or speed humps, and establishing whether a promising approach would be to try to change their ‘motivation’ to drive safely through mass media campaigns or legislation and enforcement. Any or all of these may have some effect. The Behaviour Change Wheel provides a systematic way of determining which options are most likely to achieve the change required.

Adapted from Michie et al. (2014)

Changing behaviour is of course one way of managing risk, particularly in respect of adherence to safety critical procedures. However, in this context, we are drawing a broader parallel with the strategic approach to classifying, interpreting and designing interventions. Michie and colleagues point, as we do, to the plethora of potential interventions, to the fact that most interventions are used singly or in limited combinations. Their approach has been to draw out the distinguishing features of each approach, to classify and integrate in a broad conceptual framework of behaviour change interventions.

Our ‘incomplete taxonomy’ is a first step towards a similar initiative in the systemic management of risk in healthcare and potentially in other settings. We now need to map the landscape, assess the distinctive assumptions and approach of each strategy and intervention and begin to consider how to customise and combine the interventions to the challenges facing us. At the moment, in most cases, we are only using a fraction of the potential interventions open to us. Drawing on the full range and intervening at all levels of the system would give us much more leverage and power in confronting the challenges of keeping healthcare safe in a time of austerity and rising demand.

### Key Points

- There are five major transitions between the current vision of patient safety and the broader one we need for the future.
- Our current approach to patient safety assumes generally high quality healthcare punctuated by occasional safety incidents and adverse events; this as a vision of safety from the perspective of healthcare professionals. We need to also understand risk and harm through the patient’s eyes
- Viewing safety through the patient’s eyes has the immediate consequence that we need to view safety in the context of the patient journey. This means that we need to examine episodes of care and consider both benefit and harm within an extended timescale.
- Patient safety is the art of minimizing incidents but also managing risk over longer time periods which will require additional skills and methods. We accept in this vision that errors will inevitably occur but that, in a safe system, very few will have any consequences for the patient.
- Safety needs to be approached very differently in different environments. Healthcare has many different types of activity and clinical settings and so we cannot use one primary model.
- We need to develop a wider range of safety strategies and interventions. We should extend our safety strategies to include risk control, monitoring and adaptation, and mitigation
- We have very limited safety strategies for dealing with the day to day realities of healthcare. People adapt and cope, but on an individual basis rather than with a considered team based strategy. Developing considered approaches to the management of risk in such situations is a priority for the next phase of patient safety.
- A compendium of safety strategies and interventions is already available. The slow progress in patient safety is in part due to the fact that we are not using the full range of interventions available. It is like driving a car using only first gear.
- Considerable work is needed to map and articulate the full range of strategies and interventions that are currently in use and which might be adopted.

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