**New Challenges for Patient Safety** 

The developments described in the previous chapters are required because our present vision of safety is not adequate for the challenges we face. Our arguments for these developments rest on analyses of the nature of safety in healthcare as it is delivered today. However, as is well known, healthcare is changing rapidly and there are many new opportunities, pressures and challenges. We believe that these coming changes will have further implications for how safety is understood and practiced which will increase the urgency and importance of the transition to a broader vision.

In this chapter we briefly summarise some of the recent and forthcoming developments in healthcare. These have been widely discussed and we are only concerned to summarise some key points. The primary purpose of the chapter is to consider the implications for patient safety and for the strategies and practices we set out in the remainder of the book.

# The Changing Nature of Healthcare

The problems faced by healthcare, and many of the challenges for patient safety, arise in part from the very success of modern medicine in combating disease. Because of improvements in diet, nutrition, medicine and environment many people are living longer but also living with one or more chronic conditions such as diabetes, cardiovascular disease and cancer. Diseases which were once fatal are now becoming chronic conditions.

The survival rate for cancers, infections and AIDS, strokes, cardiovascular disease and many other previously fatal diseases have improved significantly even in the last decade. For instance a recent French study of 427,000 new adult cancer cases diagnosed between 1989 and 2004, showed significant improvements in 5 year survival for most cancers, especially prostate cancer (Grosclaude et al. 2013). In the French population of 65 million people over 320,000 new cancers are diagnosed every year; of these 150,000 are designated as 'cured' within the same

year and a further 150,000 can expect to survive at least 5 years. Similar improvements in survival and quality of life in AIDS patients have been seen in developed countries with the introduction of HAART therapies (Highly Active Antiretroviral Therapy) (Borrell et al. 2006). Most people treated for chronic conditions are going back to work, family and home, with the personal ambition of leading as healthy life as possible. These developments present huge challenges for healthcare systems in providing care and yet remaining affordable.

The traditional hospital cannot remain the main provider of care and core of the medical system simply because it would be unaffordable. Hospitals are still of course essential in any future vision of healthcare but will increasingly focus on investigations and procedures that require a very high level of expertise and sophisticated technology. The proportion of beds devoted to high dependency and intensive care will increase while the overall number of beds will reduce (Ackroyd-Stolarz et al. 2011).

Medical innovations have lead progressively to shorter hospital stays. Earlier diagnosis and less invasive treatments, such as laparoscopic surgery, mean that treatment can be instituted earlier and with less disruption to a person's life. Genomics and preventive medicine will potentially allow even earlier diagnosis and preventative treatment. Increasingly care will need to move outside the hospital which will require a very different vision of primary care. Hospitals specialists will move outside the hospital taking their expertise to homes and to other facilities (Jackson et al. 2013). Because of the growth of point of care testing and the refinement of many treatments, it will be possible to provide a considerable amount of care in community settings. Surgery, radiotherapy, chemotherapy and haemodialysis can all potentially be provided in out-patient settings or smaller community centres.

From		То
One size fits all	Approach	Personalized medicine
Fragmented, One-way	Communication	Integrated, two ways
Provider centred	Focus	Patient centred
Centralized-Hospital	Location	Shift to community
Invasive	Treatment	Less invasive, image-based
Procedure-based	Reimbursement	Episode-based, Outcome-Based
Treating sickness	Objective	Preventing sickness- "Wellness"

Box 10.1. A Summary	of the Healthcare Paradigm Shift Needed for the Future

Adapted from (http://www.gilcommunity.com/)

The changes outlined above have profound implications for all health professionals (Box 10.1). Over the last 50 years hospital based medical specialties have been dominant in terms of status, reward and expertise. Specialisation has brought the greatest rewards although this has led to a loss of generalist skills and the ability to deal with the complex co-morbidities of care of older patients (Wachter and Goldman 2002). The need for traditional surgery is declining because of the availability of less invasive interventions carried out by radiologists, gastroenterologists and cardiologists. The role of the doctor is also changing rapidly as more care can be given by nurses and other professionals leaving the doctor in a more supervisory capacity and as the arbiter of complex decisions.

### Improved Safety in Some Contexts

While we cannot know exactly what new risks will arise we can at least anticipate some of the areas in which safety may either be enhanced or threatened; some classic hazards will probably decline while others will increase or change in nature. We are mainly concerned with outlining potential new risks but it is important to balance this with an illustration of how innovations and changing patterns of care can bring dramatic improvements in safety.

Healthcare acquired infections have been one of the greatest challenges of recent years and, in some countries, one of the most visible successes in enhancing safety. For instance, surgical site infections are among the most common healthcare associated infections, accounting up to 31 % of healthcare-associated infections in hospitalized patients. However the incidence of clinical significant surgical site infections (CS-SSIs) following low-to moderate-risk ambulatory surgery in low risk patients is declining rapidly through a combination of shorter length of stay and new operative techniques and technologies (Owens et al. 2014). With 80 % of surgery becoming day surgery, nosocomial infection could even become a minor safety issue rather than one that dominates the safety agenda as it has in recent years. This is a radical example of the power of innovation, both in new technologies and organisation of care, in tackling problems that resisted the efforts of even sustained classic quality and safety improvement efforts at the frontline.

Infection and anti-microbial resistance is of course a massive and continuing challenge and remains a major threat to the health of the population, particularly older people with a number of co-morbidities (Yoshikawa 2002; Davies and Davies 2010). We are simply arguing that innovations in surgical care and changing patterns of delivery may well result in a decline in certain types of healthcare acquired infections and therefore a changing pattern of risk.

# New Challenges for Patient Safety

Evolution in healthcare, or indeed in any industry, inevitably bring new risks as well as benefits. Some risks arise directly from new technologies and from new forms of organisation. Other risks come, as we have argued, from the very increase in standards that innovation brings as clinical teams and organisations struggle to adapt to the new expectations. For instance, patients are being discharged earlier from hospital after surgery. This is clearly beneficial but, concomitantly, brings new risks. Errors in post-operative care and errors in non-operative management already cause more frequent adverse events than errors in surgical technique (Anderson et al. 2013; Symons et al. 2013). These trends will probably continue and even accelerate.

### Increasing Complexity

Evidence based guidelines (mostly developed for people with single diseases) are inappropriate for those people with multiple conditions, resulting in potential overtreatment and over-complex regimes of assessment and surveillance. Problems of harm due to over-treatment and from polypharmacy are likely to increase, exacerbated by the lack of oversight of individual patients in community settings. Clinical judgment becomes more important, not less, as evidence based guidelines become less applicable because of the increasing complexity of patients' illnesses. There is an increased need to listen and determine patients' priorities at the same time as new forms of organisation potentially make this more difficult.

# The Challenges and Risks of Care Coordination

The coordination of the care of individual patients, at least those who are more seriously ill, is currently managed through a loose network of hospital doctors, general practitioners and nurses with precise arrangements varying across countries. Care will need to be coordinated and managed much more actively when more is delivered in the community. This will require different models of oversight and a very different organisation of care.

The provision of care to populations of people demands an integration of hospital care, primary care and home care in organisational structures which are already emerging in various forms in England (Dalton 2014). In the United Kingdom general practitioners will struggle to coordinate the increasingly complex care provided. It will be necessary to coordinate high technology resources and services in community clinics to fully supervise patients' health trajectories. Expanded teams and community based care will mean that non-physician providers take on larger responsibilities for patient care.

Patients' pathways are becoming more complex every day. A patient with a chronic condition often has a succession of carers, each for a short period of time, and with a dedicated role. Outside the hospital, and sometimes inside, there may be no overall coordination of care, except through the efforts of the patient and family themselves. Errors resulting from poor coordination between carers and patients are already common (Masotti et al. 2009) and could well increase dramatically. Information technology, team interventions and patient focused solutions can all play a part in the resolution of this issue but the challenge is immense and the solutions difficult to implement.

### The Benefits and Risks of Screening

Evidence is mounting that ever earlier detection and ever wider definition of disease is having some adverse consequences for healthy people. Diagnostic scanning of the abdomen, pelvis, chest, head, and neck can reveal "incidental findings" in up to 40 % of individuals being tested for other reasons (Orme et al. 2010). Most of these "incidentalomas" are benign. A very small number of people will benefit from early detection of an incidental malignant tumour, but many others will suffer the anxiety and adverse effects of further investigation and treatment of an "abnormality" that would never have harmed them (Moynihan et al. 2012).

Increased screening also brings more direct hazards. There is evidence from epidemiological studies that the organ doses corresponding to a common CT study (two or three scans, resulting in a dose in the range of 30-90 mSv) result in an increased risk of cancer. The evidence is reasonably convincing for adults and very convincing for children. However 75 % of physicians significantly underestimate the radiation dose from a CT scan, and 53 % of radiologists and 91 % of emergency-room physicians do not believe that CT scans increased the lifetime risk of cancer. It has been estimated that about 0.4 % of all cancers in the United States may be attributable to the radiation from past CT scans. Given the rapid increase in CT scans this estimate might in future be in the range of 1.5-2.0 % (Brenner and Hall 2007).

#### The Benefits and Risks of Information Technology

The revolution in information technology is having a massive impact on healthcare but also bringing new risks (Wachter 2015). Information technology can reduce risks to patients by providing effective and timely clinical decision support (Jones et al. 2014), improving coordination and communication, and may become a major driver of clinical performance and quality (Weiner et al. 2012; Classen et al. 2011). Various forms of tele-health facilitate and support people in their own homes (Baker et al. 2011; Anker et al. 2011). The massive introduction of IT in healthcare will probably be associated with a reduction of errors due to poor checking, poor readability, and poor traceability (Wachter 2015).

Information technologies are also making decades of stored data usable, searchable, and actionable by the healthcare sector as a whole. This information is in the form of 'big data', so called not only for its sheer volume, but for its complexity, diversity and timeliness. Analysis of big data can help clinicians and organizations deliver higher-quality, more cost-effective care. Big data can potentially lead to the development of an anticipatory health care system, where providers can create personalized evidence-based medicine, tailored to patients' personal preferences for how (Groves et al. 2013).

However such dramatic changes could have negative consequences for both the quality and safety of care if not properly organized, taught to professionals and patients, and accompanied by careful implementation and testing. New risks generated by these technologies are ethics (confidentiality), increased inequalities between regions and social categories, and paradoxically a reduction of direct contact between patients and professionals (Taylor et al. 2014).

Public information on safety will be increasingly available. Public reporting of safety and quality standards is expected to provide accountability and transparency thereby enhancing trust between patients, regulators, payers, and providers (Werner and Asch 2005). Alongside these benefits of public reporting, however, there are potential risks which include a potential loss of trust either in particular institutions or in healthcare more generally. Developing optimal data collection instruments and assuring adequate quality from participating centres are significant challenges (Resnic and Welt 2009). Although considerable efforts are being made to assess safety in a scientific way that allows comparison between hospitals and other facilities, the views expressed on social media could be a much more important determinant of a hospital's reputation.

#### The Burden of Healthcare: Impact on Patients and Carers

Finally, there is a substantial risk, as care moves into the community, that more demands will be placed on patients and their carers. These demands are potentially quite diffuse and wide ranging as new technologies emerge which are suitable for use in the home. Patients will increasingly have to work collaboratively with hospital and other staff to manage and coordinate their care.

While personal responsibility for care is very important for people who are in reasonable health (Roland and Paddison 2013) it becomes increasingly unrealistic as a person becomes frail and suffering from multiple problems. The burden of organisation of care is greater for patients who are elderly, less well educated, or from less affluent communities or who also have mental health problems. New technology will not solve problems associated with health literacy, which is not likely to improve greatly in the near future. If people are going to be cared for in their homes, both patients and carers will need much more comprehensive support and instructions in the nature of the disease, the treatments they give themselves and most importantly in the detection and response to deterioration.

The phrase 'burden of treatment' refers to the considerable demands that healthcare systems place on patients and carers (Mair and May 2014). For instance patients or their caregivers often have to monitor and manage their symptoms at home, which can include collecting and inputting clinical data. Adhering to complex treatment regimens and coordinating multiple drugs can also contribute to the burden of treatment. Coping with uncoordinated health and social care systems can further add to an ever growing list of management responsibilities and tasks facing patients and their caregivers. This is real work and can be overwhelming—it is time consuming and calls for high levels of numeracy, literacy, and, sometimes, technical knowledge. People who are socially isolated, poorly educated, have low health literacy, are cognitively impaired, do not speak the local language, or who have sensory or physical challenges will simply find this impossible. Mair and May (2014) propose that a key future quality metric will be the extent to which care disrupts people's lives and that a key question for doctors to ask their patients is 'Can you really do what I am asking you to do?'.

# A Global Revolution Rather Than a Local Evolution

We can foresee that healthcare systems will change dramatically in the way they are organised and the way care is delivered. We will need different kinds of hospitals with fewer beds, shorter stays, advanced technologies and new competencies. Much more care will be delivered in the home and community, as we cope with extended life expectancy and the rise in chronic conditions.

The consequences for those working in healthcare and the organisation of care are profound. In addition to this people no longer view healthcare as they have in the past and assumptions about what is achievable and what is expected are also changing rapidly. Ageing and well-being are coming to be seen as the right of every citizen with the concomitant expectation of reasonable living conditions, medical support, social rights, pensions, and an ability to maintain a full life in the community. This is an empowering emphasis in most respects but it greatly increases the challenges for healthcare as the demands seem ever growing and sometimes impossible to meet. We are now sometimes seeing a presumption of error and poor care if the outcome does not meet expectations rather than, in the past, an acceptance of the course of the disease with only secondary consideration of the possibility of error.

The patient journey is new for healthcare but already replaced in many people's minds with the concept of a lifetime citizen journey. Medical problems are no longer considered in isolation but in the longer term context of a person's life. Legal aspects of this transformation in mindset are already clearly visible. For instance when a patient is harmed by healthcare and seeks compensations there are legal guidelines for assessing the amount due. This total compensation is assessed on several dimensions which include physical disability, suffering and permanent damage and the impact on personal and professional life, loss of earnings and so on. In France the assessment of compensation used to be restricted, apart from some exceptional cases, to the immediate aftermath of the event with the assumption of recovery in a reasonable time period. However in recent years the legal guidelines on both time period and quality of life have been greatly extended so that compensation can now be made for reduced wellbeing and quality of life in the mid and long term (Béjui-Hugues 2011)

We will also need in the coming decade to rethink and adapt the surveillance of the healthcare system, learn more from the introduction of electronic information for the purpose of surveillance, develop accreditation methods which encompass patient journeys, assess the impact of the movement of professionals and patients across borders, and last but not least, rethink the whole payment scheme of healthcare to reflect the growing collective and interdependent nature of care delivered to patients. The list might seem long but these are not suppositions about the future but present realities. These changes, already well underway have important implications for the management of safety in healthcare. We have already argued that we need an expanded vision of safety along the patient journey and which is adapted to multiple contexts. This is already necessary but will be given greater impetus by the changes summarised above and by the inevitable challenges to safety in periods of transition. We believe that we need to try to anticipate the risks both of the new systems and of the transitional period with its inevitable upheavals. The management of risk, and the wider vision of patient safety, needs to be integrated into the new and evolving systems.

#### **Key Points**

- The population is ageing due to the advances of modern medicine combined with improved diet and environment. Many people are now living with chronic conditions that were once fatal.
- Multiple innovations in technical care, such as minimally invasive surgery, have significantly shortened hospital length of stay
- Improving standards of care, new technology and new organisations can bring huge benefits but also create new risks and place new burdens on both patients and professionals. Those tendencies are expected to continue and accelerate with the new advent of genomics and personalised medicine.
- A new model of healthcare needs to emerge in which there is a transition from carer and hospital centred rationale to a focus on the patient's journey across settings with much care delivered at home and in the community. These changes are already underway and having a considerable impact on hospitals.
- Some hazards, such as nosocomial infections, should reduce. However we should anticipate new risks such as increased problems in the coordination of care, more problems with over treatment and the integration of multiple treatments in patients suffering from a number of diseases.
- Information technology and personalized medicine are often cited as solutions to these new patient safety problems, but will probably need significant adaptation and maturation before delivering all their potential capacities for safety improvement.
- The 'burden of treatment' may become considerable as more care moves to the home and community. A key question for doctors to ask their patients is "Can you really do what I am asking you to do?"
- We have already argued that we need an expanded vision of safety along the patient journey which is adapted to multiple contexts. This is already necessary but will be given greater impetus by the changes summarised above and by the inevitable challenges to safety in periods of transition.
- The changes required have huge implications for the organisation of healthcare and for the work of professionals. Perhaps most importantly for the healthcare system, it is also a profound change of the whole society, and in the expectations of its citizens.

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