Safety and Ethics in Healthcare:
A Guide to Getting it Right

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SAFETY AND ETHICS IN HEALTHCARE

to those who suffer needlessly

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Foreword

It has become customary to link the start of our present widespread concern with patient safety to the Institute of Medicine's influential report, *To Err is Human*: *Building a Safer Health System*. And, indeed, the 1999-2000 period was a watershed for the patient safety movement. The year 2000 saw the beginning of a flurry of high-level statements from government agencies in various countries that broadcast the extent of the harm caused by medical errors and systemic deficiencies. But the operative word here is 'broadcast'. These high-impact publications did not so much break new ground as bring to prominence research evidence and epidemiological findings that had been in the public domain for well over a decade.

One of the many reasons why this book is so very significant is that its clinician-authors, Professor Bill Runciman and Professor Alan Merry, have been carrying out innovative studies in anaesthetic safety (*inter alia*) over the past 20 years or so. They are among the true pioneers of the patient safety movement and this long exposure to the conceptual and methodological problems besetting this field makes itself apparent in this book. Few authors could write with such knowledge and authority as that displayed here.

Some years ago, I heard a newly appointed director of safety announce that safety management was not rocket science. And he was absolutely right. Rocket science is trivial compared to the complexities and difficulties that confront those charged with assuring that their operational risks are *kept as low as reasonably practicable* (the ALARP principle) while *still staying in business* (the ASSIB principle). ALARP without ASSIB would be relatively easy; it is trying to achieve both of these things at the same time that is so hard.

Even in highly standardized and largely automated domains such as commercial aviation and nuclear power generation, managing safety is a difficult and constant challenge. But healthcare has very few of these mitigating features. Its activities and equipment are highly diverse, its products are delivered in a close and personal fashion and their recipients are vulnerable and needy people (see Chapter 5).

If safety management anywhere is intrinsically complex, ensuring patient safety is especially so, not least because the necessity of managing it is not always apparent. If your core business is to heal the sick and repair the injured, then it is not unreasonable to assume that patient safety is simply a naturally emergent property of these therapeutic processes. But it is not. It is something that needs to be trained for and managed, just like any other medical activity. Recognizing this and acknowledging that healthcare professionals are fallible and will commit harmful errors are the first steps along this path.

Making an error, even one with damaging consequences, rarely equates to incompetence – it simply confirms the maker's humanity. The capacity to go wrong is an inerasable part of being human: we cannot change the human condition, but we can change the conditions under which human beings work. This is the first rule of error management, a process that lies at the heart of effective safety management.

Prerequisites for engaging in any demanding activity, but especially the struggle for improved patient safety, are conceptual frameworks – 'road maps' that set out, clearly and simply, the 'geography' of the task. And herein lies one of the considerable merits of this book. Chapter 1 presents a comprehensive and comprehensible representation of the major dimensions of quality in healthcare in which the major goals – acceptability, effectiveness, efficiency, safety, timeliness, and the like – are mapped on to the various layers of the health system: the patient, the clinician, the team, the organization, and so on. A second model provides a framework for classifying patient safety information – and it is here that the extensive experience of the authors makes its mark. Together, these two schemes integrate and make sense of the enormous volume of material that could otherwise be overwhelming. They define the 'woods' that would be so easy to lose sight of when confronted with so many diverse 'trees'.

Adverse events in any complex hazardous enterprise are rarely the result of single causes, either human or technical. They mostly arise from the (often diabolical) conjunction of many contributing factors originating at different levels of the system. Analyses that assign these contributions to separate categories (i.e., human error, workplace deficiencies, organizational conditions, and the like) produce numbers that, while convenient to manipulate, distort the very essence of event aetiology, namely the complexly interactive nature of their causation. These properties are best caught by stories and case studies. Narratives rather than numbers are the primary data of the safety sciences. Don't get me wrong – numbers have their place, but not when they add up to little more than vacuous clerking.

The risk associated with a particular event is commonly defined as the product of its likelihood and severity. But, as Carl Macrae[1] argued very recently, such an assessment gives little or no indication of the true nature of the threat posed by this or similar events. What is important is not the actual outcome of any one event, but what the consequences could have been had it combined with other factors – each possibly inconsequential by itself – to breach the organizational defences and barriers. Event narratives play a vital referential role in assessing the organizational risks of these 'could-have-beens'. A crucial stock-in-trade for those making these judgements is a head full of varied case studies. Ideally, these stories should also include serious organizational accidents in healthcare institutions. For the moment, however, these accounts are relatively few and far between, though such reports are gradually finding their way into the public domain – see the seminal analysis of a vincristine tragedy by Toft.[2]

One of the many strengths of this book is that it is richly studded with case studies drawn from a wide variety of activities and specialties. These along with the integrating frameworks, the penetrating analyses of the present healthcare

system, the extensive coverage of research and the in-depth consideration of the ethical issues make up what must be the most comprehensive toolkit currently available. In short, the book has – in Ron Westrum's[3] elegant phrase – *requisite imagination*. It will, I am sure, be a landmark publication.

James Reason

Notes

1. Macrae, C.J. (2006), 'Assessing Organizational Risk Resilience: Assessing, Managing and Learning from Flight Safety Incident Reports', University of East Anglia, School of Environmental Sciences: PhD Thesis.
2. Toft, B. (2001), 'External Enquiry into the Adverse Incident that Occurred at Queen's Medical Centre, Nottingham, 4th January 2001', London: Department of Health.
3. Westrum, R. (1991), *Technologies and Society: The Shaping of People and Things*, Belmont CA: Wadsworth Publishing Company.

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Preface

The vast majority of humans have a spontaneous urge to help their fellow beings when they are in trouble. Attempts to alleviate pain, sickness and suffering are evident from the beginnings of recorded history. A considerable number of people systematically set out to help their fellow humans by training for roles in healthcare. Our overwhelming experience has been that almost all of these people, all over the world, are highly motivated to help those afflicted by disease and injury.

Healthcare has become progressively more refined over the centuries and now constitutes a vast health 'industry'. There have been huge advances over the last 150–200 years with the development of safe, effective anaesthesia and pain relief, asepsis and modern surgery, antibiotics, immunization, new drugs and diagnostic techniques, and a far better understanding of the scientific basis of medicine, culminating in advances such as organ transplantation, molecular engineering and nanotechnology.

However, increasingly, this road is not an easy one to travel for those delivering the care. As more and more people survive into old age, the burden of caring for them becomes greater and greater. Although it is now possible to alleviate many of the afflictions that beset mankind, no society can afford to pay for all the healthcare that is now available or technically possible. People working in healthcare increasingly have to do more with less. Rationing takes many forms, mostly covert, and the less privileged in most societies end up struggling to get their proper share of the available healthcare dollar. All too often, those in the front-line have to deal with the consequences of this 'rationing by default'.

All involved in healthcare want to be able to do the right thing at the right time, in the right way, for the right people – those who will most benefit from the available resources. All too often, though, people who train in healthcare in order to devote themselves to providing care and comfort for their fellow human beings find themselves rushed off their feet simply doing the basic tasks and completing all the paperwork. Healthcare professionals find themselves placing frail, sick people in ever lengthening queues, sometimes asking them to wait for hours in the middle of the night under uncomfortable and even unsafe conditions. Worst of all, people find themselves working under conditions they would rather avoid in which the safety margin for those they are caring for has been greatly diminished. We are all aware that under these conditions the chance of making a mistake which can seriously harm or even lead to the death of a patient is greatly increased. What can we do about this? How can one be sure that one is doing the right thing when faced with having to practice an uncertain science on vulnerable patients in a complex system under ever-changing conditions? When does one cross the invisible line from reasonable to irresponsible or unethical behaviour by tolerating conditions or

tacitly accepting practices which may be regarded as unacceptable, even though one may have little immediate control over them?

This book is a guide to getting it right for healthcare professionals. It is about:

- doing the right thing – appropriate and based on best evidence, but acceptable to the recipient;
- in the right way – in a way that is safe, effective and efficient;
- at the right time – when it is needed or most effective; and
- for the right people – those who will benefit most from the proper use of the available resources (which implies equitable access to care).

These are the dimensions of quality in healthcare, and although some are in conflict (equitable access and efficiency, for example), adherence to ethical practice and professional behaviour will help guide healthcare practitioners through the minefield of often conflicting priorities.

The World Health Organization has defined health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'. We must try to ensure that appropriate efforts are directed towards preventing illness and injury as well as providing care when people have been hurt or have become unwell. We must also try to ensure that a powerful few do not selectively consume limited healthcare resources at the expense of the vulnerable and disenfranchised.

The Layout of the Book

This book has four parts. The first is about healthcare today, the things that are wrong with it, and how some of these have come to be. In Chapter 1, the dimensions of quality in healthcare are considered together with a consideration of different approaches to funding for the various layers of healthcare. How resources are distributed, and how they might be, both within and between nations, is touched upon, together with the uncertainty about what may be considered the best healthcare and the variations in care that result. In Chapter 2 we outline the risks associated with healthcare and the nature of iatrogenic harm, referring in some detail to the large studies which have documented this to be a public health problem on a scale that rivals the road toll. In Chapter 3 we consider factors which contribute to making the system dysfunctional – its haphazard evolution, its hierarchies, its competing agendas, and its poor organization. In Chapter 4 we discuss the unfortunate human propensity for naming, blaming and shaming when things go wrong, and how the tort system has contributed to the blame cycle, while failing to adequately compensate those harmed or prevent the same problems from happening again.

The second part of this book is about the basic principles which need to be understood if the safety and quality of healthcare is to be improved. Chapter 5 is about getting an understanding of the nature of human error and how errors differ from violations, about complex systems, and about the factors that predispose to

error and influence outcomes within complex systems. This is fundamental to any attempt to reduce iatrogenic harm or to make the regulation of healthcare more effective. In Chapter 6 we discuss the concept of evidence-based medicine, and the interpretation of the results of medical research. To do this requires a consideration of the problems of fraud in research and of misleading marketing. Chapter 7 is about ethics, professional behaviour and regulation.

The third part of this book is about what to do when things go wrong and how to respond when a patient has been harmed. In Chapter 8 we identify the victims of iatrogenic harm: the patient, primarily, but also the healthcare worker involved in causing that harm. Each needs to be cared for. Open disclosure is essential – getting the facts into the open so that people know what has happened and so that action can be taken to prevent the recurrence of a similar problem. In Chapter 9 we consider methods for preventing similar problems from recurring, preferably *before* a major disaster occurs. Incident reporting is dealt with together with root cause analysis. Having identified a problem, something needs to be done about it. The first step of this is to understand what really went wrong, and this requires looking beyond the 'smoking gun' and identifying the systemic factors which predisposed to an accident in the first place.

The fourth part of this book is about preventing iatrogenic harm and improving quality of practice. In Chapter 10 we focus on how to get the best out of the people involved in healthcare, including the patient. The challenge is to exploit to the maximum what people are good at, and make the best of the valuable resource that they represent. In Chapter 11, we consider the system and how to improve it. This involves gathering information, assembling evidence, identifying risks and problems, making the right decisions and then preventing things from going wrong when carrying them out. This requires optimizing the design of equipment and processes, and enhancing the early detection of and response to problems when they do occur. Finally, in Chapter 12, we consider where we should be going next, and what the attributes of an ideal system might be.

Terminology

It will be evident from the title of this book and the language used so far that we have chosen to use 'generic' terms for those involved in healthcare. We have chosen to talk about patients rather than clients or consumers, although we recognize that a healthy pregnant woman, a child undergoing immunization or an adolescent seeking counselling may not be regarded as patients. The term healthcare professionals embraces doctors (physicians), nurses and practitioners of para-medical disciplines (pharmacists, physiotherapists, occupational therapists, biomedical engineers, and others). We use the term clinician to refer to those involved directly with the interactions between patients and the healthcare system.