

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

Bill Runciman, Alan Merry
and
Merrilyn Walton

SAFETY AND ETHICS IN HEALTHCARE

to those who suffer needlessly

Safety and Ethics in Healthcare

A Guide to Getting it Right

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ASHGATE

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Published by	
Ashgate Publishing Limited	Ashgate Publishing Company
Gower House	Suite 420
Croft Road	101 Cherry Street
Aldershot	Burlington, VT 05401-4405
Hampshire GU11 3HR	USA
England	

Ashgate website: <http://www.ashgate.com>

British Library Cataloguing in Publication Data

Runciman, Bill

Safety and ethics in healthcare : a guide to getting it right

1. Medical errors - Prevention 2. Medical ethics 3. Medical policy 4. Health facilities - Safety measures 5. Medical care - Quality control

I. Title II. Merry, Alan III. Walton, Merrilyn
362.l'068

Library of Congress Cataloging-in-Publication Data

Runciman, Bill.

Safety and ethics in healthcare : a guide to getting it right / by Bill Runciman, Alan Merry, and Merrilyn Walton.
p. cm.

Includes index.

ISBN: 978-0-7546-4435-4 (hardback)

ISBN: 978-0-7546-4437-8 (pbk.) 1. Medical ethics. 2. Clinical medicine--Decision making. 3. Medical errors. 4. Health services accessibility. I. Merry, Alan. II. Walton, Merrilyn. III. Title.

[DNLM: 1. Medical Errors. 2. Quality of Health Care--ethics. 3. Safety Management--ethics. WB 100 R939s 2007]

R725.S244 2007

174.2--dc22

2006031461

ISBN: 978-0-7546-4435-4 (HBK)

ISBN: 978-0-7546-4437-8 (PBK)

Printed and bound in Great Britain by TJ International Ltd, Padstow, Cornwall.

Contents

<i>List of Boxes</i>	<i>vii</i>
<i>List of Tables</i>	<i>ix</i>
<i>List of Figures</i>	<i>xi</i>
<i>Foreword</i>	<i>xiii</i>
<i>Preface</i>	<i>xvii</i>
<i>List of Abbreviations</i>	<i>xxi</i>
<i>Acknowledgements</i>	<i>xxiii</i>
<i>About the Authors</i>	<i>xxv</i>

PART 1: WHAT IS WRONG WITH HEALTHCARE

1	Setting the Stage: An Overview of Healthcare	1
2	Risk and the Harm Caused by Healthcare	29
3	Healthcare: A Dysfunctional System	59
4	Naming, Blaming and Shaming	83

PART 2: UNDERSTANDING THE BASICS

5	Human Error and Complex Systems	109
6	Knowing What to Do	135
7	Ethics, Professional Behaviour and Regulation	157

PART 3: WHAT TO DO WHEN THINGS GO WRONG

8	When Things Go Wrong: Looking After the People Involved	179
9	When Things Go Wrong: Preventing a Recurrence	197

PART 4: PREVENTING THINGS FROM GOING WRONG

10	Getting the Best Out of People	221
11	Getting the Best Out of the System	247
12	Where to Now?	279

APPENDICES

<i>Appendix I:</i>	<i>Preferred Terms and Definitions for Key Safety and Quality Concepts</i>	295
<i>Appendix II:</i>	<i>Public Expenditure on Healthcare in Selected Countries</i>	299
<i>Appendix III:</i>	<i>Risk Matrix</i>	301
<i>Appendix IV:</i>	<i>Evidence-Based Medicine: Sources of Information</i>	303
<i>Appendix V:</i>	<i>International Code of Medical Ethics</i>	305
<i>Appendix VI:</i>	<i>Jonsen's Ethics Framework</i>	307
<i>Appendix VII:</i>	<i>Severity Assessment Code (SAC)</i>	309
<i>Appendix VIII:</i>	<i>The Advanced Incident Management System (AIMS)</i>	311
<i>Appendix IX:</i>	<i>Soft Systems Methodology (SSM)</i>	313
<i>Appendix X:</i>	<i>Sources of Information for Patients</i>	317

INDEX		319
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List of Boxes

1.1	A death at Duke	4
1.2	An extreme example of irrational health policy	14
1.3	An example of a perverse incentive	17
1.4	A tragic outcome from an unnecessary procedure	19
2.1	An avoidable near death experience	33
2.2	The Bristol Enquiry	37
2.3	Examples of medical record review adverse event classification	40
2.4	Examples of preventable adverse events after discharge from hospital	42
2.5	Hypoxic brain damage under anaesthesia in retreat	47
3.1	Life in the chasm	60
3.2	Factors which may adversely affect the design and function of the healthcare system	65
3.3	Rest in peace: death by oversight	68
3.4	Factors which may adversely affect the performance and behaviour of healthcare professionals	71
3.5	Fatigue can kill	73
3.6	Tests (and a patient) repeatedly falling into cracks in the system	74
3.7	Teaching hospitals or learning hospitals?	75
3.8	An outlying patient	78
4.1	When things go wrong	83
4.2	<i>Kite vs Malycha</i>	85
4.3	Two cases of manslaughter	90
4.4	Harold Shipman – the audit and the inquiry	90
4.5	A tragic case, resulting in a charge and acquittal from manslaughter	92
4.6	The wrong drug – a smoking gun	103
5.1	Information available to the health professional	113
5.2	An exercise to demonstrate the gap between information in the world and information in the mind	113
5.3	Rescue from a fatal overdose	117
5.4	Saved by a double error	120
5.5	A dangerous optimizing violation – a case of hit and run	123
5.6	Minor errors leading to a major outcome	127
5.7	A (preventable) massive stroke after a minor procedure	129
6.1	Delays in recognizing evidence	136
6.2	Sources of information related to medical decision making	137
6.3	Dying for (yet more) evidence	138
6.4	Some repeatedly identified deficiencies in clinical trials	139

6.5	The difference between association and causation	143
6.6	Ways of expressing risk	147
6.7	Angioplasty and cardiac surgery	152
7.1	The ethical framework of Kerridge, Lowe and McPhee	162
7.2	Respecting a patient's beliefs	163
7.3	Fulfilling a patient's wishes	164
7.4	The principles developed by the Tavistock Group	165
7.5	Extraordinary measures?	168
7.6	A natural death	170
7.7	The end of the line	172
7.8	The Bundaberg Hospital scandal	173
7.9	Perceived problems with self-regulation	174
8.1	The immediate response	180
8.2	A checklist for planning meetings for handling bad news	183
8.3	An airway disaster	185
8.4	Following up – people and issues	190
8.5	A torrential, fatal bleed	191
8.6	A creative response to a catastrophe	192
9.1	Awake paralysis – again and again and again	198
9.2	Basic information	201
9.3	Examples of people who may be sent a copy of the notification after a severity assessment code (SAC) has been allocated to an incident	202
10.1	Presenting a recently admitted patient at the evening handover round	222
10.2	The patient as a force for safety	223
10.3	Ten tips for patients for safer healthcare	224
10.4	Credentiailling	228
10.5	A failed admission	230
10.6	Ten tips for clinicians for safer care	231
10.7	Typical tasks and portfolios in a clinical department	235
10.8	Typical MET call-out criteria	238
11.1	Catastrophic failures – again and again and again	247
11.2	A continent of ignorance in a sea of information	252
11.3	Safety practices with very strong or strong evidence of efficacy	254
11.4	Preventing brain damage and death from hypoxia during anaesthesia – defence in depth	258
11.5	A potentially fatal dose error	261
11.6	Going solid	262
11.7	The WHO resolution on patient safety: four action areas	270
11.8	The World Alliance for Patient Safety Initiatives	271
11.9	An example of quadruple-loop learning: oximetry and capnography in anaesthesia	272
12.1	The fallacy of the business case – an example	284

List of Tables

1.1	A selection of important causes of death world-wide	1
1.2	Utilities calculated by the ‘time trade-off’ technique	12
1.3	The cost of healthcare interventions by QALY	13
2.1	Death rates by exposure to various activities	31
2.2	Overall death rates from various activities	32
2.3	The Goldman cardiac risk index	34
2.4	Laparoscopic cholecystectomy – risks of recognized complications	36
2.5	Sources of information about things that go wrong in healthcare	39
2.6	Adverse event rates from medical record reviews	41
2.7	Main types of adverse event identified by medical record review	43
2.8	Types of incident identified by incident monitoring	46
2.9	Sentinel events on the ‘official’ lists	49
4.1	Medical insurance premiums in Australia from 1960 to 2000	87
4.2	Why patients complain – results of a review of 290 complaints	93
5.1	A classification of error	115
6.1	Check list for evaluating the quality of a clinical trial	141
6.2	Hierarchical categories of evidence defined by Eccles et al.	145
7.1	Some of the potentially conflicting considerations commonly encountered by clinicians making ethical decisions	159
9.1	Examples of actions which might be recommended after an RCA	214
10.1	The seven learning areas and 22 topics of the patient safety education framework	242
11.1	The layout of this chapter	248
12.1	Prerequisites or determinants for health as defined by the Jakarta Declaration	287

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List of Figures

1.1	The dimensions of quality and organizational layers of healthcare	5
1.2	Adherence to quality indicators, according to condition	8
1.3	Per capita health expenditure in relation to gross domestic product (GDP) in selected countries; \$ in purchasing power parities	10
1.4	The relationship between QALYS purchased and expenditure	13
1.5	An integrated framework for safety, quality and risk management in healthcare	22
1.6	A generic reference model for deconstructing individual incidents	24
2.1	A framework for risk management	30
2.2	Adverse events, ranked by percentages of 2,300 events from a medical record study, compared with percentages of 346 medico-legal files at a tertiary referral hospital	48
4.1	Dealing with accidental harm in healthcare: The elements of an appropriate response and some mechanisms by which these are usually achieved	98
5.1	Schematic representation of the types of error that can be made in making and carrying out a plan	114
5.2	'Swiss Cheese' diagram: the latent and <i>active</i> errors which caused the events in Boxes 5.6 and 5.7	130
5.3	Foresight versus hindsight	131
6.1	Example of a Forest plot	148
7.1	The 'regulatory pyramid'	175
9.1	A flow diagram of actions that may be taken after an incident	203
9.2	The event flow chart	210
9.3	Excerpt from Figure 9.2 with the addition of a clearly articulated contributory factor to the flow diagram	212
9.4	Cause and effect diagram	213
10.1	Regulation, from the 'soft' to the 'hard' end of the spectrum	226
10.2	A structured grid for the learning objectives for four levels of healthcare workers	240
11.1	The Red Bead Game	249
11.2	The PDCA cycle and ramp representing a process for progressive improvements of quality in organizations	259
11.3	The attributes of an individual clinician and of an organization, each depicted as three sides of a safety triangle	273

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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 ineradicable 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 Macrae¹ 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's³ 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.