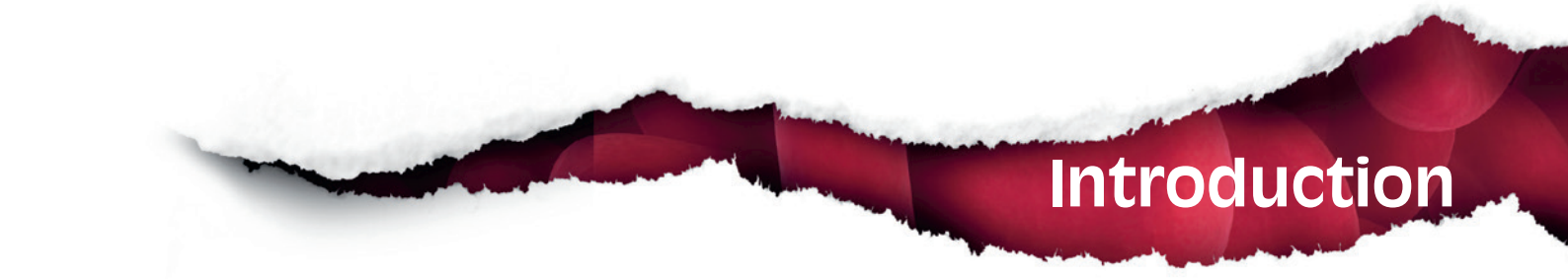
Chapter 1

EXPECTING THE WORST



Introduction

In the short time since the first edition of this book was published in 2003, the world has experienced a number of dramatic, sometimes terrifying crises: the Asian tsunami; hurricane Katrina; the earthquakes in Kashmir, Haiti and Chile; deadly tyhoons in the Philippines; flooding in Bihar; drought and firestorms in Greece and Australia; the global financial meltdown; the BP Deepwater Horizon oil-rig disaster, and many more in every aspect of human affairs.

And there have been medicinal crises aplenty: the Pan Pharmaceuticals recall of 1500 products in Australia; the withdrawal of Vioxx and Bextra; the MMR controversy and vaccination crisis; Adderall XR; Ritalin; Exanta; the TGN1412 incident; H5N1 (avian flu); H1N1 (swine flu), Tamiflu (supply and possible side effects in children); SARS; contaminated products (e.g. contact lens solution in the US, injectibles in China); E. coli outbreak and vaccine supply crisis in the US; recall of Perrigo acetominophen; troubles with Ketek, Rosigitazone and Black Cohosh; the early end of Pfizer's development of torcetrabip.

If the title of this book seems to encourage a pessimistic view of human affairs, it is not intended to do so. Expecting and planning for the worst that can happen is what all intelligent organisations do. Once they have done that, they can concentrate on the business of achieving the best for themselves and their stakeholders, knowing that they are, at least, prepared. Expecting and planning for the worst is part of the mind-set of organisational confidence, maturity and optimism – and survival.

'Emergency exits are being pointed out to you now'

Shortly after we get on an airplane, anywhere in the world, we go through a familiar ritual. The flight attendants demonstrate basic emergency routines and identify the emergency exits. We do not expect that we will need to carry out these actions, and are probably aware that air transport is a very safe mode of travel. The builders of the airplane, the operating company and the flight crew are not planning to create a situation in which emergency procedures will be required. But we would be very worried if such life-saving procedures were not planned, practised and communicated.

Although the probability of an emergency is low, we want to know that risks have been assessed and that the appropriate measures are in place and can be implemented. We see evidence of such planning everywhere; lifebelts on ferries, fire extinguishers and emergency stairs in buildings, emergency telephones on motorways, lifeguards on beaches, airbags and seat-belts in cars, and so on.

Do you... **Expect the worst**

Do you and your family have an emergency evacuation plan if there's a fire in your home or the hotel you're staying in? Does everyone know exactly where to go and what to do?

There were around 50,000 domestic fires in the UK in 2008, in which nearly 300 people died. (www.communities.gov.uk)

2007 figures for the US are 414,000 fires and 2,895 deaths. (Quoted by US Fire Administration, http://www.usfa.dhs.gov/citizens/all_citizens/home_fire_prev/sprinklers/)

Who survives emergencies and crises?

Your chances of surviving a crisis as an individual or an organisation are enormously increased if you are prepared.

Among many other things, this means:

- Vividly imagining the event actually happening
- Planning the best escape or damage-limitation behaviour
- Ensuring practical resources, escape routes, communications are available and accessible
- Involving and briefing everyone at risk
- Repeatedly practising emergency routines, evacuations, communications
- Frequently reviewing and revising the plan

Those who listen to flight safety briefings and read the safety information for the specific aircraft they are in are more likely to get out safely in an emergency.

The same principles apply to organisational crisis of all kinds, whether or not there is any consequential physical danger – death of key personnel, data loss, fraud, product failure, and so on.

Many organisations have no crisis management plan and so reduce their chances of successfully dealing with the unwelcome and the unexpected – Toyota and BP representing the most spectacular failures of crisis-preparedness in recent times. Will you be ready when a drug is suddenly alleged to be killing patients? When your hospital's surgery-survival rates are questioned? When you are accused of unethical practices? When you failed to pick up early signals of a major problem?

When you travel together you sometimes die together **Consider the worst**

Polish President Lech Kaczynski, his wife and entourage of nearly a hundred people died simultaneously in the Smolensk air crash of 10 April 2010. Senior advisers, military chiefs, ministers, MPs, academics and the head of the Polish national bank were amongst the many dead. An unimaginable tragedy for Poland and its people.

Any country, government, organisation, company, group or family risks losing whole categories or generations of people if they take collective risks – like flying together. The risk may be low, but it is not zero.

There was a comparable disaster on a smaller scale in 1994 in the UK. The headline read:

Security chiefs killed in air crash: 29 lost as helicopter 'explodes' off Scotland – Most of high command in war against terrorism said to have been on board*

*Story by: Ian Mackinnon, Chris Blackhurst, David McKittrick and Christopher Bellamy, The Independent, Friday, 3 June 1994

http://www.independent.co.uk/news/security-chiefs-killed-in-air-crash-29-lost-as-helicopter-explodes-off-scotland--most-of-high-command-in-war-against-terrorism-said-to-have-been-on-board-1420006.html

Where are the emergency exits?

If we look at healthcare, what evidence would we find that there were well-prepared plans for emergencies in patient and drug safety? In response to a sudden and possibly catastrophic loss of public confidence in a drug product, would we switch effortlessly into pre-planned and rehearsed procedures like the crew of the airplane? Or might we find ourselves disoriented, panicking and having to start from scratch?

It's evident from the many scares and crises around the world, some with deeply damaging results for the reputation and effectiveness of regulation, medicine and pharmaceuticals, that there is still a long way to go.

The principles of crisis management apply in general to all organisations of any kind or size, but the particular threats and solutions vary from sector to sector. In patient safety we face issues of great seriousness, with the potential for widespread damage and outrage.

The answers are here

This manual addresses the need amongst all professionals concerned with patient safety to understand the issues involved in crisis management, to adopt best practice and to produce robust plans, which as far as possible prevent crises, or effectively manage those that do occur.

The diversity of cultures and local conditions prevent the production of a comprehensive document which could be immediately applicable in all possible situations. The idea here is to present a core of material which provides a foundation to support any country or organisation in setting up or reviewing effective crisis management regimes.

The content of this book is organised as follows:

- A brief summary of planning processes for those who want a quick overview ('If you read nothing else, read this!')(Chapter 2)
- A review of the theory of crisis management for those who wish to have a deeper understanding of the subject (Chapters 3 and 4)
- A detailed analysis of the planning process with practical proposals for all aspects of crisis management, with a new chapter on the contemporary preoccupation with vaccines and crises in that field, and an account of the typical first day of a drug safety crisis (Chapters 5–8)
- Case studies, a model crisis management plan, checklists, guidance notes and extensive references to printed and electronic sources (Appendixes and throughout the book)

By adapting this material to local circumstances, readers will be able to produce comprehensive and robust strategies capable of managing any incident.

The manual is designed to be used primarily as an aid to planning or reviewing crisis management procedures. It can also be used, *in extremis*, as an emergency brief where such forward planning has not taken place, or the plans or personnel responsible for them are not available.

Each chapter begins with at statement of its objectives and a summary of its content.

Have a safe holiday!

When you are next staying in a hotel by yourself or with your family, check where the fire equipment and the emergency exits are; check that the emergency exits can be opened and walk the emergency stairs or route until you are out of the building. Make sure your children know exactly what to do in an emergency, maybe in the dark.

When you are next sitting in your office, imagine that the next phone call you receive informs you of patient injuries or deaths from a medicine or facility for which you are responsible. Are you prepared?

Are your crisis management plan and the crisis team ready and waiting for instant implementation and action?

A note on the use of the term risk in this book:

For most readers of this publication the concept of risk will be inextricably associated with the drug safety concepts of benefit, harm and effectiveness. In this material, the word almost always has its more general meaning of the probability of any event with negative consequences. Similarly, risk assessment in the discussion of crisis management refers to the review of all risks of whatever kind, which may, of course, include the risks associated with medicinal products, but is by no means confined to them.

Protecting Research Subjects **The Crisis at Johns Hopkins**

ELLEN Roche, a 24-year-old technician at the Johns Hopkins Asthma and Allergy Center and a healthy volunteer in a study of asthma funded by the National Institutes of Health, died on June 2, 2001. Prompted by Roche's death, the Federal Office for Human Research Protections reviewed the system at the Johns Hopkins Medical Institutions for protecting research subjects and found widespread deficiencies.

On July 19, 2001 the office suspended all federally supported research projects at Johns Hopkins and several affiliated institutions — not because of Roche's death but because of the additional problems that had been identified.

Story by Robert Steinbrook, M.D.

716 · N Engl J Med, Vol. 346, No. 9 · February 28, 2002 · www.nejm.org
http://content.nejm.org/cgi/content/extract/346/9/716

The Johns Hopkins response was initially combative, but became co-operative some time later and major changes were implemented. This incident shows how an initial, single event can sometimes provoke subsequent crises as investigation proceeds and new problems are revealed.

Chapter 2

ACTION: THE FRAMEWORK FOR PLANNING

A QUICK OVERVIEW

The following material offers a step-by-step guide to the planning process. Each stage is dealt with in detail in Chapter 5. References are to sub-sections within that chapter.

What we want to achieve

In the overall pursuit of effective crisis management, there are two distinct areas of activity:

- The identification and management of risks and vulnerabilities within or outside an organisation, its activities or relationships where there are *smouldering** problems which could lead to crises, and which are amenable to immediate management action: this is proactive crisis management designed to anticipate and prevent crisis. This includes scanning for early weak signals of trouble and assessing them quickly
- The identification of potential, sudden crises and planning for the prevention or management of them

The former essential activity appears as part of the whole process recorded here and in later chapters, including the identification of early warning signs of trouble.

Establish a strategic crisis planning team 5.2

List and publish: Names
Roles
Departments
All communications details (including out-of-hours)
Named deputies

Review state of crisis-preparedness and previous crisis management experiences (if relevant) 5.1

- Review the current state of crisis-preparedness throughout the organisation
- Examine and record principal learning points from previous crises (or the crises of others) and incorporate in the planning process.

Gather intelligence 5.3

- What is your reputation and profile?
  - List all known myths, perceptions and expectations and realities about your organisation, along with relevant individuals or organisations which are supportive or known to be a real or potential threat
- Who are your audiences and stakeholders?
  - List all individuals and organisations with key contact names, communications details, special interests, sensitivities, status of relationships and any action to be taken to develop them
- What risks and threats are there inside and outside the organisation?
  - List the entire range of risks and threats in a free-wheeling brainstorm process. Think the 'unthinkable'; expect the very worst, however extreme it may seem (see stories on p. 62)
  - Distinguish between current risks which can be reduced by management action internally and potential sudden crises arising internally and from the external world
- Meet and discuss risks and threats with key audiences and stakeholders
  - Check out the list with key stakeholders (e.g. clinicians, pharmacists, journalists, ministry officials, patient groups, employees) and seek their contributions

*'Smouldering' is the stage before a fire actually breaks out; where there is heat and maybe smoke, but no flame. Smouldering often goes unnoticed or is hidden during the time before it bursts into flame. A camp fire which is not extinguished properly may smoulder before being roused again to flame and then, maybe, causing a forest fire.

Complete a formal general risk assessment 5.4 and Chapter 6.

- **Identification** (what are the vulnerabilities, risks and threats?)
  - Produce a definitive list following brainstorming and consultation, distinguishing between risks which can be reduced by current management action and potential sudden crises
- **Estimation** (how probable are they?)
- **Evaluation** (how serious are they?)
- **Prioritise** the list taking account of the variables of probability and seriousness

Produce plans to address vulnerabilities and reduce risks 5.5

- **Planning**: agree actions and responsibilities for all vulnerabilities and risks
  - Identify management action to be taken to reduce current and potential vulnerabilities and risks, and allocate roles and responsibilities
  - Examine prioritised sudden crisis scenarios and identify crisis team action to be taken in the event of their occurring
- **Resourcing**: identify and allocate human and other resources to fulfil plans
  - Check the availability and performance of allocated staff and their deputies and physical resources over time (consider identifying a crisis command centre)
  - Check the availability and effectiveness of data-gathering resources and communications capability
- **Monitoring**: examine and measure effects and outcomes
  - Check what effects risk-reduction activities are having
  - Ensure that crisis planning is taking place and is regularly reviewed and updated
- **Controlling**: take remedial action where necessary

Define authorisation procedures and threshold criteria for declaring a crisis 5.6

List and publish names, communications details (including out-of-hours) and deputies

- who to contact in a crisis
- who declares a crisis
- who authorises an initial public response

Establish tactical crisis management teams for all categories of identified potential crisis situations 5.7 and 5.9

- Management and co-ordination team

  This team provides the 'Command Post' for any crisis and should have a designated leader and deputy (always important, but especially so in multi-site organisations) 5.9.1
- Operations (technical) team 5.9.2
- Communications team 5.9.3

List and publish for each team for each situation: Names
Roles
Departments
All communications details (including out-of-hours)
Named deputies

Allocate roles, responsibilities and resources (including contingency budgets) for all situations, building on work done at earlier planning stage 5.8

Develop detailed plans for each crisis situation 5.9

- **Management** 5.9.4
  - Decision-making and co-ordination
  - Mobilising teams
  - Intelligence gathering
  - Information processing
  - Legal team
  - Prepare for internal and external communications
  - Pre-approved templates, messages and live or dark website content
  - Manage contingency budget
  - Liaison with chief executive and board
- **Operations** 5.9.5
  - Technical team (problem solving; emergency procedures)
  - Intelligence gathering
  - Briefing management team
  - Liaison with first responders and outside experts
- **Communications** 5.9.6
  - Spokespersons
  - Hotline team
  - Internal communications
  - External communications
  - Briefing management team
  - Monitoring external responses

Produce organisational contact charts 5.10

Publish plans and conduct training 5.12

Seek comment and involvement of all key stakeholders; involve and train staff

Test, review and rehearse plans 5.13

Rehearse the plan and conduct simulations; modify plans in the light of experience

As a continuing management objective:
Promote a crisis-prepared culture 5.11