

Transforming Nursing Practice

# THE RESIDENCE OF THE PARTY OF T **Patient** Safety and Managing Risk in Nursing

Melanie Fisher Margaret Scott

Series editors: Shirley Bach and Mooi Standing



# Patient Safety and Managing Risk in Nursing

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# Patient Safety and Managing Risk in Nursing

Melanie Fisher and Margaret Scott









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### Foreword

An essential component of nursing care is to ensure that patients' health improves and is maintained and that optimum health is achieved. This concept of nurses' caring is being extended by the current debate about patients who are suffering harm in our healthcare institutions. The shocking disclosures of the reports from the Mid Staffordshire NHS Foundation Trust Public Inquiry into conditions in hospitals have shone a disturbing light on patient safety in our healthcare systems. Nurses can no longer only ensure that their patients achieve optimum health: they also have a responsibility to make sure that their patients suffer no harm.

This new text in the *Transforming Nursing Practice* series provides students and qualified staff with a concise account of the responsibilities and roles of healthcare professionals in ensuring patient safety. It is timely and highly relevant to contemporary nursing practice. The concept of patient safety is examined in the context of the patients' needs in the twenty-first century. This book provides an excellent guide to understanding how mistakes occur and how, as professionals, we can address them.

By taking a journey through the history of patient safety and risk management the reader will see how a transparent and proactive approach has been developed to minimise safety incidents. The text looks at evidence-based research and policy drivers in relation to managing risk and applies this to practice scenarios. Error prevention models and root cause analysis are discussed, and safety and medicines administration errors examined thoroughly through the lens of the professional codes of conduct and responsibility.

Melanie Fisher and Margaret Scott, with John Unsworth, introduce the reader to the concept of safeguarding and raising concerns. These are issues that have not always featured in nursing courses and do need to be addressed from a wider perspective and applied to all healthcare settings. The authors introduce the reader to the role that human factors play in 'error'. This includes exploring the relationship between technical and human error. Measuring safe care can be challenging. The methods that can be used effectively are discussed and this includes the role of patients' complaints. From an organisational point of view consideration is given to the role culture plays in relation to patient safety and how leadership, at all levels of the organisation, can shape and ensure a positive and common culture.

Patient safety is an emerging healthcare discipline that underlines the importance of reporting, analysing and preventing harm to patients. This text will provide readers with a comprehensive insight into this subject, and how individuals can play a part in preventing and reducing patient harm as an integral part of their nursing responsibilities.

Shirley Bach Series Editor

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## Introduction

# What is *Patient Safety and Managing Risk* in *Nursing* about, and who should read it?

This introduction provides information about who should read the book, what it is about, why it is important and how it is structured. A brief overview of learning activities and NMC standards is also given.

The purpose of this book is to introduce the reader to the concept of patient safety and managing risk in today's twenty-first century healthcare service. It is particularly timely as safety in our health service is never far from the attention of the media and public scrutiny. It is ideal for nursing students of all fields but is equally accessible for the new registrant and other healthcare professionals who wish to learn more about safety and risk. The book takes a look at how patient safety and risk management has developed over the years to where it sits today. We examine some of the factors that compromise patient safety and explore strategies to subsequently manage it.

#### **Book structure**

Chapter 1 introduces the reader to patient safety and explores what it means. We look at how patient safety was traditionally viewed in the last century to how it is received now. We provide an overview of issues in patient safety that will later be explored in subsequent chapters, such as the nature of error, policy drivers, reporting systems and the quality agenda. As throughout the rest of the book, there are a number of activities and case studies to help readers consider what safety means to them and relate this to their own practical experience in their clinical settings.

Chapter 2 discusses risk in healthcare and examines some of the strategies designed to assess and manage risk, for example checklists. We look at evidence-based research and policy drivers in relation to managing risk and apply this to practice scenarios. We consider ways of managing risk in our own practice by drawing on case studies and incidents where harm has occurred or could potentially occur.

Chapter 3 examines the kind of things that may go wrong and that lead to accidents and incidents. We discuss error prevention models and root cause analysis. In addition, we discuss the process of reporting incidents and mistakes, but we also acknowledge some of the barriers that may prevent healthcare professionals from admitting to errors.

Chapter 4 looks more specifically at safety and medicines administration errors. We discuss a wide range of causative factors and prevention in medicine errors. We focus on insulin administration as an example of transferable practices, which can promote safe administration of different types

of medicines. We specifically look at the nurse's role in the safe administration of medicines and guide readers to policies and standards to promote their own safe practice.

Chapters 5 and 6 introduce readers to the concept of safeguarding and raising concerns. Patient safety is not solely about avoiding errors in care and treatment, it is also about promoting safety and recognising those who are vulnerable. Chapter 5 was included in the book because safeguarding is an important area in healthcare delivery and sits comfortably with risk management and raising concerns. Chapter 6 looks more specifically at raising concerns and professional regulation. The chapter defines the nature and scope of professional accountability and regulation as applied to nursing. It explains how professional regulators can hold practitioners to account and maintain professional standards.

Chapter 7 introduces readers to the role that human factors play in 'error'. We explore the relationship between technical and human error, and take a further look at the skills required to prevent errors. We look more closely at the nature of errors and we consider lessons taken from high-reliability organisations, such as aviation and the military, to help us avoid errors.

Chapter 8 considers the way in which we measure safe care and how this can be challenging. We will briefly consider how measuring mortality is used as an indication of the quality of care provided by hospitals. We explore how the number of complaints received by patients or carers, or the numbers of accidents and incidents that have occurred over a given period of time, are often used to measure how safe the care is that we deliver. Key aims of the Commissioning for Quality and Innovation (CQUIN) framework and the NHS Safety Thermometer tool will be explored, and the benefits for both practice and patients.

Chapter 9 looks at how personal values and beliefs can influence the ways in which we behave. We then move on to explore values and beliefs from a professional perspective and how cultures and subcultures emerge within large, complex organisations, such as the NHS. Consideration will be given to what role culture plays in relation to patient safety and how leadership, at all levels of the organisation, can shape and ensure a positive and common culture throughout. Your role as a leader of care and the leadership traits that you already demonstrate, but might not be aware of, will be identified and explored.

Chapter 10, the concluding chapter, is where we consider the way forward in patient safety and quality care. The report of the Mid Staffordshire NHS Foundation Trust Public Inquiry is discussed further with emphasis on some of its recommendations. We consolidate some of the skills required of healthcare professionals in order to prevent errors occurring, and ask readers to reflect on their own responsibilities and learning needs in order to develop as safe and professional practitioners.

# Requirements for the NMC Standards for Pre-registration Nursing Education and Essential Skills Clusters

The Nursing and Midwifery Council (NMC) has established standards of competence that have to be met by applicants to different parts of the register. The standards are necessary for safe and effective practice. As well as these standards the NMC has also identified specific skills students must acquire at various points of their educational programme. These skills are known as Essential Skills Clusters (ESCs). This book is structured in a way that will help you understand and meet some of these competencies required for entry to the NMC register. The boxes refer to the latest NMC Standards, taken from *Standards for Pre-registration Nursing Education* (NMC, 2010a).

### Learning features

Learning about topics such as safety and risk is not always straightforward and is often dependent on your personal experience and stage in your learning or career. In order to help you contextualise and connect with the subject matter, there are a number of features in this book designed to help you to participate in your own learning. The chapters contain activities, case studies, scenarios and exercises to help you reflect, think critically and develop your own learning style. Each chapter has suggested further reading and websites to help you explore the topic further. There is also a glossary of terms at the end of the book that provides an interpretation of terminology (in **bold**) with which you may be unfamiliar. The activities are designed to allow you 'time out' from reading so that you can reflect on your own knowledge and practice experience. You may do this either by engaging in further reading and searching or discussing with a peer. Some of the activities provide an outline answer at the end of the chapter but others require you to reflect personally. You may wish to use some of these activities as part of your personal development plan (PDP). You could write them up for your PDP or personal portfolio as part of your studies and use them later to reflect upon. Some of the further reading has been highlighted as beneficial for those of you preparing for interview.

The book is designed to be read from cover to cover or to 'dip in' and 'dip out' of. It is an introductory text but is useful as a springboard to further reading and understanding.

### Chapter 1

## Patient safety and quality

#### NMC Standards for Pre-registration Nursing Education

This chapter will address the following competencies:

#### Domain 1: Professional values

- All nurses must understand the roles and responsibilities of other health and social
  care professionals, and seek to work with them collaboratively for the benefit of all who
  need it.
- 7. All nurses must be responsible and accountable for keeping their knowledge and skills up to date through continuing professional development. They must aim to improve their performance and enhance the safety and quality of care through evaluation, supervision and appraisal.

#### NMC Essential Skills Clusters

This chapter will address the following ESC:

#### Organisational aspects of care

18. People can trust a newly registered graduate nurse to enhance the safety of service users and identify and actively manage risk and uncertainty in relation to people, the environment, self and others.

#### Chapter aims

After reading this chapter you will be able to:

- define what is meant by the terms 'patient safety', 'harm' and 'error';
- begin to understand how patient safety has developed in the UK and beyond;
- identify some of the key organisations involved in promoting and monitoring patient safety;
- demonstrate an understanding of the role nurses play in promoting the safety of others.

#### Introduction

It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm.

(Florence Nightingale, 1860/1969)

Over 300,000 incidents in healthcare within the UK were reported to the National Reporting and Learning Service between October 2003 and June 2011.

(NPSA, 2011c)

This chapter aims to introduce you to the concept of **patient safety** in healthcare provision in the twenty-first century. In order to understand how mistakes can and do occur and subsequently how we can address them, it is beneficial for you to have some understanding of the terminology used when discussing patient safety, and the nature of incidents that occur and compromise patient safety. The chapter is also designed to encourage you to consider your roles and responsibilities in preventing harm and managing risk. We can see from the above quote from Florence Nightingale that the importance of safety was acknowledged in the early days of healthcare provision. However, it will become apparent that patient safety management has not always been accomplished in the last two centuries and until more recent times was conveniently disregarded when things went wrong.

It will be useful to glean some knowledge and understanding of the history of patient safety, which has led to the more transparent and proactive approach to minimising safety incidents today. This will help you to understand where safety sits in modern healthcare practice. We will examine why patient safety is high on the agenda in healthcare and explore some of the policy drivers underpinning safety initiatives, focusing upon the UK but also touching upon some other parts of the world. We will also provide some case studies to enable you to identify patient safety issues that may arise in your own practice and allow you to reflect on them. The World Health Organization (WHO, 2011) advises that students of healthcare need to understand how different systems impact on the quality and safety of healthcare. By systems we mean tools and processes to monitor and learn from safety incidents, and we will touch upon these in this chapter and throughout the book. The management of patient safety fits closely within the framework of **clinical governance** and the quality agenda and we will briefly explore this relationship.

Patient safety is not a stand-alone discipline but rather one that is integrated into all aspects of healthcare. It is the responsibility of all who come into contact with the individual in a healthcare setting, from the porter to the surgeon. It is a theme that runs through all nurse education courses (and other healthcare professional programmes) and it is embedded in mandatory training for staff at all levels. Because it is such an important concept, it is imperative that student nurses are introduced to the concept early and that it is at the foundation of everything you learn and practise. We are fortunate that we can learn from hindsight and ironically through the mistakes of others. Nursing undergraduates and graduates reading this book should dismiss any fears of making mistakes out of context, because to err is human. Instead they should embrace the wisdom to avoid the mistakes of others, and practise with confidence and evidence-based knowledge.

### Hospitals do the sick no harm?

Patient safety is at the heart of quality care and the fact that care may fall short of this fills people with horror. Imagine if you or your loved one came to harm while undergoing treatment or care in hospital or in the community. In recent years there have been a number of reports of patients being harmed through medical or nursing **errors**, some of which are tragic and others at the very least **negligent**. Whether this is a reflection of worsening substandard practice or more robust reporting and data collection is a subject of debate and will be the subject of discussion in subsequent chapters.

#### Case study

Norma is a 40-year-old school teacher with two school-age children. She has been awaiting a date for surgery to remove her gall bladder. When she finally does receive the letter inviting her for the procedure, although relieved that her problem will be treated, she also feels apprehensive. She is very worried about the procedure, which will require an anaesthetic. She has only ever been admitted to hospital for the birth of her two children and although this was uneventful she has a morbid fear of hospitals. She has heard stories from colleagues and the media about 'things going wrong' and she is terrified that this will happen to her.

Activity 1.1 Reflection

- Make a list of the things Norma may be anxious about.
- If you were to be admitted to hospital for an invasive procedure, is there anything that you would be afraid of? If yes, make a list.

An outline answer is provided at the end of the chapter.

The case study above was designed to get you to think about safety from a patient perspective. Perhaps your list in response to Activity 1.1 may be influenced by stories and reports in the media, television documentaries, your own experience or experiences of those close to you. It could be influenced by your experience of working in healthcare and insider knowledge. Perhaps you are aware of statistics regarding **adverse incidents** made available by government bodies.

Patient safety is certainly an issue that is discussed in a more open and transparent way than it was some years ago. Incidents that affected patient safety more than two or three decades ago were often left unreported and at best dealt with 'in house' (Vincent, 2010). It was deemed not to be in the public interest to talk about 'such things' as the image of medicine would be tarnished and public trust would dwindle. Medicine and healthcare have inherently been concepts that carry a plethora of risks and nursing the sick is no exception. However, the concept of keeping patients safe during their trajectory of care is indeed the essence of care and for medical staff it is grounded in the Hippocratic Oath to 'do no harm'. With hindsight it seems obvious that care and cures were

sometimes worse than the illnesses themselves but, if harm did occur, it was usually unintended or accidental. There are of course some exceptions to this, notably nurse Beverly Allitt and Dr Harold Shipman, who were both convicted of murdering patients in their care. In addition, as healthcare technologies, knowledge and techniques develop, one can ask whether risk increases too. Vincent (2010) reminds us that the terms 'harm' and 'error' are sometimes equated when discussed in literature, but errors do not all lead to harm and not all harm is caused by error. It is important to keep this in mind and think critically about issues that involve risk and safety.

#### Harm and medical iatrogenesis

A term you may have encountered is **medical iatrogenesis**. This term is used to refer to disease or harm introduced by the physician. Translated, iatrogenesis comes from *iatros*, the name for a Greek physician, and genesis, meaning origin (Illich, 2002). Illich was a priest and philosopher who wrote prolifically on the subject, terming it 'medical nemesis'. His writings described the disabling impact of medicine and treatment upon health. Illich's controversial views implied that, by medicalising illness and health, doctors in particular have moved beyond their proper boundaries and by doing so have potentially caused harm. It is for individuals to arrive at their own conclusions about Illich's views. There is no doubt that, for some, treatment can be worse than the disease or illness itself. But the individual has to decide whether the outcome is worth it. Illich's thoughts are interesting but have to be balanced against the great benefits medical advances have brought over the past few decades. We mentioned earlier that not all harm is caused by error. Some treatments and interventions, for example chemotherapy, may cure cancer but, in the process, compromise the patient's immune system and induce severe nausea and vomiting, which is distressing and potentially harmful to some.

Activity 1.2 Reflection

 Think about some of the side effects patients may experience during the course of their treatment that are not caused by error but rather are an expected occurrence and outcome of established interventions.

An outline answer is provided at the end of the chapter.

#### **Errors**

Errors that do incur harm of course do happen in the delivery of care and can be **human errors** (caused by an individual or individuals) or technical errors (caused by device malfunctions). There has undoubtedly been an improvement in the way incident information is reported, recorded and disseminated in more recent years, so we have a greater understanding of the nature and trends that underpin patient safety events. In the later part of the last century, patient safety featured 'implicitly' in healthcare. Since the beginning of this century, patient safety is now 'explicit' and is linked to the quality agenda (as we explore in later chapters). There are a number of reasons for this, which will be discussed throughout the book. What, then, do we mean by patient safety and do all errors inevitably lead to harm?

#### Case study

Ahmed, an experienced community mental health nurse, visited James, a 32-year-old man with a long history of bipolar disorder. He spent some time discussing how James was feeling and he chatted to him about his new medication, which appeared to be having a positive effect on his mood. James had experienced behavioural problems in the past and his low mood and depression could be triggered by events that may seem trivial to others, but are meaningful to him. Ahmed left James to visit his next client, satisfied that everything was well. As he drove out of the road, he realised that he had mistakenly left James's case notes in the kitchen. His spine froze as he imagined how James may react if he was to read some of the records. Hurriedly he returned to the house and James was surprised to see him. He apologised to James that he had left something in the kitchen. James was unperturbed and said 'oh, no problem mate'. Ahmed retrieved the notes and bid him farewell. It appeared James was unaware his notes had been left and therefore had probably not read them. Ahmed was shaken at the thought of what may have potentially happened in this situation and became extra vigilant about managing case notes.

This was an error of judgement that thankfully had no serious consequences. However, had James accessed his notes, he may have read entries that could have been sensitive and triggered an exacerbation of his depression and anxiety.

So far we have discussed patient safety as a concept without defining it. As with the terms harm and error, it is not always clear exactly what it means. What, then, do we mean by patient safety?

#### How do we define patient safety?

Patient safety is defined by Vincent as: the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare (2010, p31). There are many definitions in the literature but this is perhaps the most succinct. Interestingly, now that patient safety is recognised as a concept, it has developed its own terminology, which will be defined throughout the chapters and in the glossary.

#### **Activity 1.3**

#### Evidence-based practice

You listed your fears about what may potentially go wrong in healthcare in Activity 1.1.

 Now make a list or discuss with a fellow student, mentor or colleague the types of errors that actually occur and are reported.

An outline answer is provided at the end of the chapter. Further data and statistics will also be explored throughout the book.

Your discussion may have been based on your own experiences, observations or anecdotal evidence. You may have also given some thought to errors that compromised patient safety and those that did not result in harm.

# The development of safety in the UK and beyond

Patient safety is a concept that is acknowledged and addressed globally. The United States has long been aware of patient safety as an issue, in the main due to **litigation** and the financial cost of mistakes. Other countries, including the UK, have been quick to follow and the media have probably had some part to play in this. In the UK, the media are influential and court public opinion. Mistakes in healthcare that reach the headlines sell papers and boost viewings. The public are interested in what 'goes on' in hospitals, care homes and in social care, even though a good proportion of reports tend to highlight shortcomings in care delivery. The public have greater expectations when it comes to healthcare as they have greater access to information about illness, treatment and services via the media and internet technology. However, because not all information available to us is credible, this can cause confusion and lead to individuals being misinformed.

#### Activity 1.4 Critical thinking

Some newspaper headlines print statements such as: 'Patients are starving in our hospitals!' and 'Woman left to die in a corridor.' Think about the potential effect on members of the public reading this.

- · Do you think media reports are always factual?
- Do all journalists reporting these stories understand the context and complexities associated with healthcare delivery?

Outline answers are provided at the end of the chapter.

#### Raising awareness of patient safety

Culture in society and healthcare is changing; the days of 'doctor knows best' are diminishing.

While the notion of medical **hierarchy** is still evident in some communities, patients are much more likely to question health professionals and reject perceived substandard care. Perhaps the most influential catalyst to the development of patient safety was the publication of the US Institute of Medicine's 1999 report, *To Err is Human*. It raised political and public awareness in the United States. The Institute called for a national effort to address safety in healthcare and recommended that a centre for patient safety should be established within the Agency for Healthcare Research. This report and subsequent response from the Government spurred other governments to take action and, in 2000, Sir Liam Donaldson, the Chief Medical Officer for the Department of Health, led on the production of the UK's equivalent report: *An Organisation with a Memory* (OWAM; DH, 2000a).

In the UK, prior to the publication of OWAM, there had been some notable incidents that were starting to put patient safety into the spotlight. The Bristol Royal Infirmary 'scandal' was seen as a high-profile incident and catalyst for change in the way incidents are reported and managed.

#### Case study

Lack of openness and transparency masked the substandard practice of paediatric heart surgeons at the Bristol Royal Infirmary (BRI). In the late 1980s some clinical staff became concerned about the poor outcomes of children who underwent cardiac surgery, compared with the outcomes of other specialist units, and 'blew the whistle' (an unprecedented action for its time and one that will be discussed later in this book). An external enquiry was ordered and the case received a plethora of media attention. Some of the parents complained to the General Medical Council (GMC), which in 1997 examined the cases of 53 children, 29 of whom had died and 4 of whom had suffered brain damage. An enquiry was ordered and chaired by Professor Ian Kennedy and a report published in 2001 (BRI, 2001). Three doctors were found guilty of serious professional misconduct and two were struck off the register. The anaesthetist who blew the whistle left the UK for Australia.

#### Activity 1.5 Critical thinking

- Why do you think the substandard practice described in the BRI case study went on for so long before it was reported?
- Do you think the same situation would be reported earlier if it happened today?

One would hope that today an incident such as this would be intercepted earlier. The next few paragraphs outline why.

#### The role of the National Patient Safety Agency

Following the publication of OWAM, the Government responded to the need for safer care by setting up the arm's-length body, the National Patient Safety Agency (NPSA). The agency is responsible for leading and contributing to safe patient care by informing, supporting and influencing organisations and people working in the health sector. They have three divisions:

- National Reporting and Learning System (NRLS): concerned with identifying and reducing risks to patients receiving NHS care and leading on national initiatives to improve patient safety;
- National Clinical Assessment Service (NCAS): supports the resolution of concerns about the
  performance of individual clinical practitioners to help ensure their practice is safe and
  valued;
- National Research Ethics Service (NRES): protects the rights, safety, dignity and well-being of research participants who are part of clinical trials and other research in the NHS.

In 2010–11, the Government reviewed arm's-length bodies in an effort to drive down administration costs and reduce bureaucracy in the health service. It recognised the value of the NPSA's functions and recommended it should be abolished but with its functions continuing in different ways. The patient safety division will be incorporated into the new NHS Commissioning Board.

#### Patient safety incident data

The NRLS collects confidential reports of patient safety incidents across England and Wales through a national reporting system. Common themes and risks are analysed by safety experts and clinicians so that lessons can be learned and disseminated across healthcare organisations. This can be through safety alerts, tools to promote a strong safety culture and national initiatives in specific areas of high risk: Through its funding and monitoring of the three independent National Confidential Enquiries (patient outcome and death, maternal and child health, and suicide and homicide by people with mental illness), the NRLS can maximise the benefits of their in-depth research to better improve care (NPSA, 2008c, p19). An example of one initiative that developed as a result of such research was the adult patient's passport to safer use of insulin. This safety alert is aimed at improving patient safety by empowering patients to take an active role in their treatment with insulin through the use of patient-held records that will be shared with healthcare professionals involved in their care.

You may be aware of other organisations that collect and record data relating to patient safety incidents. It has to be said that reporting systems in healthcare can be confusing and daunting. You may get lost in the swamp of organisations, bodies and departments that you read and hear about. Vincent (2010) supports this view and suggests that, ironically, reporting systems lack cohesion and integration and duplicate functions, and that many organisations support multiple systems.

#### Other reporting systems

Reporting systems operate at different levels within the healthcare system. Some operate at local level through the hospital/Trust risk management and clinical governance framework. Incidents are reported locally using a standard incident form. Incidents that are reported are not always errors, but urgent action can then be taken to prevent harm to patients. Incidents can be used as triggers to allow for reflection and to improve and develop practice. Typical examples of incidents that nurses may have been required to report include medicines administration errors, patient falls and faulty medical devices. The information will be processed using organisation-specific systems and subsequent action will be determined by the nature and consequences arising from the incident. Other reporting systems operate at regional or national level and have different audiences depending on their level of operation. For example, the Medicines and Healthcare products Regulatory Agency (MHRA) is concerned with medical devices and medicine products that have contributed to error. Professional regulatory bodies (Nursing and Midwifery Council (NMC), General Medical Council (GMC) and Health and Care Professions Council (HCPC)) are interested in individuals on their registers who may be practising in a negligent manner. Incident reporting systems are reliant upon individuals but, as we will see in subsequent chapters, reporting systems are not a panacea for preventing harm.

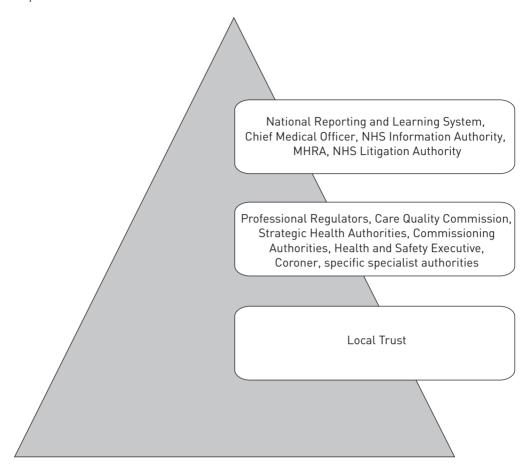


Figure 1.1: Examples of British authorities who may receive reports (these organisations change from time to time with NHS reforms)

In Scotland, patient safety is guided by Healthcare Improvement Scotland, a health body formed in April 2011 and concerned with quality and excellence in healthcare delivery. In Ireland at the time of writing, they too have their own national patient safety agenda (see www.patientsafety first.ie). Find out what systems your own healthcare placement provider feeds into. Figure 1.1 provides examples of authorities requiring safety incident information, but is by no means a complete list.

There are, of course, a number of strategies and tools to assist with the monitoring of data and management of safety incidents. We will explore these in later chapters.

# Clinical governance and the quality agenda

So far we have discussed the development of patient safety in the UK in relation to reporting patient safety incidents. Another key development in patient safety is the growth of clinical