CHAPTER 1

The Scope of the Problem

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OVERVIEW

- Many patients are harmed by healthcare, both secondary and primary, and often this harm is preventable
- The frequency and nature of threats to patient safety depend on the method of identification and classification
- Adverse drug events are the commonest threat to patient safety in secondary care
- Failure and delay in diagnosis is the commonest threat to patient safety in primary care

Patient safety is a major concern for all healthcare providers. It appears perverse that patients can suffer harm when they are being treated and cared for. However, healthcare is complex and its outcome is influenced by many factors. It is inevitable that within any healthcare system patients will be harmed, and in every encounter there is the potential for harm to occur. This has been recognized since the time of the physicians of Ancient Greece and Rome – 'First, do no harm.'

How frequent are threats to patient safety?

In the 1970s, research identified that as many as 36% of admissions to a general medical unit and 13% of admissions to intensive care units followed adverse events in which patients had been harmed, most often as a result of medications (Fig. 1.1). However, it was the publication of the Harvard Medical Practice Study (HMPS) in 1991 that highlighted to healthcare providers and policy-makers the extent of harm. Patient safety was now in the public eye, not only in the USA but throughout the world.

The HMPS analysed more than 30 000 randomly selected medical records of recently discharged patients from a random selection of 51 hospitals in New York State. Adverse events, defined as extended hospitalization, disability at the time of discharge, or death resulting from medical care, were identified. The proportion of hospital admissions experiencing an adverse event was 3.7%. The proportion of adverse events that were preventable was 58%. These findings were confirmed in a similar study of acute care hospitals in Colorado and Utah, with 2.9% of admissions experiencing an adverse event, of which 53% were preventable. The Quality in Australian Health Care Study also analysed medical records, and found that 16.6% of hospital admissions experienced an adverse event (Table 1.1). Extrapolation of the results of both US studies implies that in 1997 between 44 000 and 98 000 US citizens died in hospital as a result of preventable adverse events. If these rates are typical of secondary care in the UK, then at least 850 000 admissions will experience an adverse event.

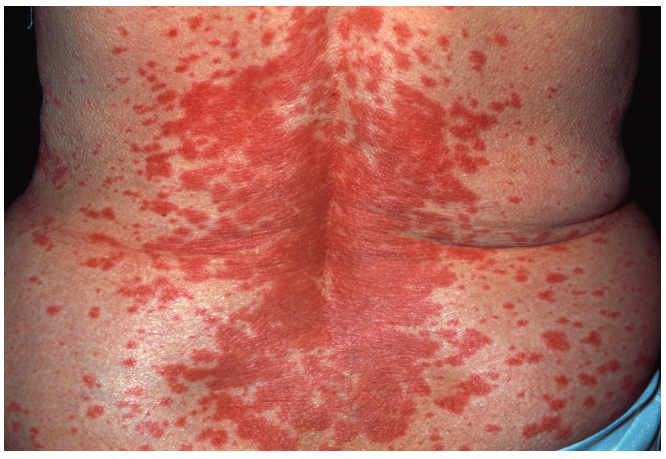

Figure 1.1 Rash on the back of an 80-year-old man caused by an allergic reaction to the antifungal drug terbinafine. (Reproduced by courtesy of Dr P. Marazzi, Science Photo Library.)

No similar research using systematic review of medical records has been performed in primary care. However, studies have used incident reporting in an attempt to estimate adverse events in primary care. One of the largest studies was performed in Australia, with 805 incidents from 324 general practitioners being analysed. The esti-

Table 1.1 US and Australian research into adverse events in hospitals

	Harvard Medical Practice Study, 1991	Quality in Australian Health Care Study, 1995
Proportion of inpatient episodes leading to harmful adverse events	3.7%	16.6%
Proportion of inpatient episodes resulting in permanent disability or death	0.7%	3%

mated rate of adverse events was 40–80 per 100 000 consultations, of which 76% were considered preventable and 27% had the potential for severe harm. In a study of prescriptions that had been issued by general practitioners in the UK and then reviewed by community pharmacists, a potential adverse drug reaction was identified in 0.13% of all prescriptions. These rates may initially appear to be insignificant, but it is important to consider that in the UK there are over one million general practitioner consultations each day, and 1.5 million prescriptions are generated daily.

What are the types of threat to patient safety?

Adverse drug events, defined as injuries resulting from medical intervention related to a drug, are the commonest threat to patient safety in secondary care. However, not all adverse drug events are preventable, such as an unexpected allergic reaction. In a review of 4031 adult admissions to 11 medical and surgical units at two hospitals in the USA, there was an event rate of 6.5 adverse drug events per 100 admissions, of which 28% were judged preventable. Adverse drug events are also common in primary care, with 13–51% of all reported adverse incidents related to medication. In two recent UK-based studies of admissions to hospital, about 6% were regarded as being the result of a preventable adverse drug event (Fig. 1.2).

In hospitals, other common types of adverse event are preventable infections, surgical and diagnostic mistakes, and events involving medical equipment (Fig. 1.3).

The medico-legal database of the Medical Protection Society (MPS) provides a useful source of information concerning 1000 consecutive formally registered claims that had been made against general practitioners in the UK, and is highly relevant to primary care. The largest category was Investigation and Treatment (63%), followed by Prescribing (19%). In the Investigation and Treatment category, the main types were failure or delay in diagnosis and referral to secondary care. The largest group was related to malignancy, followed by diseases of the circulatory system and injuries. In Prescribing, the main types were failure to warn or recognize drug side effects, followed by medication error. This is an error at any stage of the medication process, including prescribing, dispensing, administering and monitoring. The main groups were related to the use of steroids in disease management and allergic reactions when antibiotics were prescribed. Administration problems were noted in 4.8% of claims, the main types being poor records, communication difficulties between members of the practice, and errors made by receptionists or other employees of the practice. Practice nurses were noted in 3.2% of claims, with the main types related to performing an injection or blood test, undertaking a procedure, and inappropriate advice.

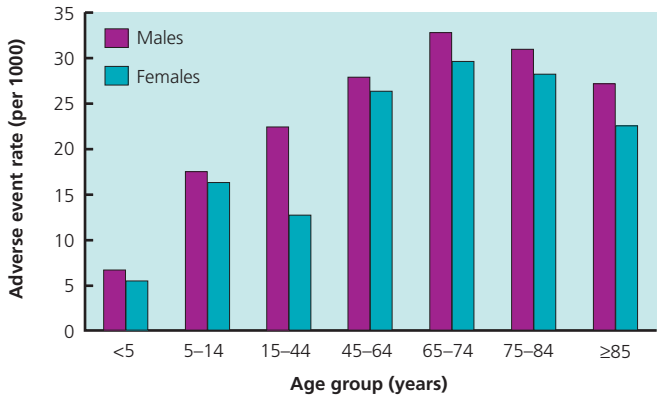

Figure 1.2 Rates of adverse events by age and sex. (After Aylin P, Tanna S, Bottle A, Jarman B. How often are adverse events reported in English hospital statistics? *Br Med J* 2004;**329**:369.)

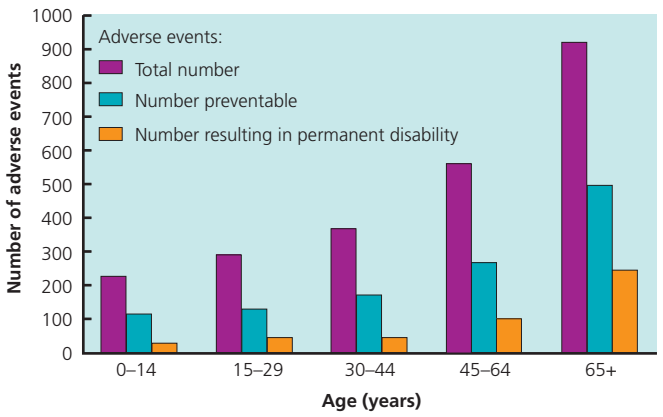

Figure 1.3 Numbers of adverse events, preventable adverse events, and events resulting in permanent disability, by age. (Adapted from Wilson RM *et al.*, 1995.)

Perspectives from patients and healthcare professionals

In a telephone survey of 1513 adults in the USA, 42% reported that they or a family member had experienced harm as a consequence of interacting with the healthcare system. This is supported by other studies. One-third of US physicians reported harm to themselves or their family as a consequence of healthcare, and in another study 16% of patients had experienced a medication error.

What is the cost of threats to patient safety?

In the USA, preventable adverse events have been estimated to cost $17–29 billion a year. This includes litigation costs and the resultant increased healthcare costs. The total economic impact, including lost income and disability, has been estimated to be $38–50 billion a year. In the UK, adverse events in hospitalized patients have been estimated to cost at least £2 billion each year for the additional days required in hospital.

In addition to these economic costs there are other consequences. The aftermath of an adverse event in which a patient has been harmed will have an impact on the psychological and social well-being of all who are involved in the incident, whether patient, family or healthcare professional. There are also wider aspects, with loss in public trust in the healthcare system.

Differences between studies

It is immediately apparent that there are wide differences between the various studies, and this is not only between secondary and primary care. When comparing studies it is important to consider the following points.

- **Purpose of data collection.** Studies have been performed for a variety of purposes. Some studies have had the main aim of identifying the frequency and nature of adverse events, but some have reviewed administrative and medico-legal databases. Such databases are more likely to include complaints that are unproven, contain details about more serious events, and not include events that have the potential to cause harm.
- **Settings.** There has been little extensive work from the UK, and most studies have been performed in the USA and Australia. These countries have differing approaches to healthcare, and comparison between countries with different healthcare systems may be inappropriate.
- **Definitions.** The definition of an 'adverse event' will determine what is identified, and what constitutes an adverse event varies considerably across various studies. Some studies have used a wider definition that encompassed actual and potential harm to patients whereas others considered only those that caused actual harm, including those resulting in medico-legal action. The classification of harm has often been made by a variety of people, ranging from individual doctors to administrative staff.
- **Method of data collection.** The identification of the true frequency requires a systematic process, similar to a mass screening programme for disease identification. Surveys have tried to capture the frequency in a hospital population, often by targeting specific groups, such as those receiving medication. However, such surveys are highly resource dependent, and opportunistic programmes have been more widely introduced, including primary care. Incident reporting, a type of opportunistic screening, does not give a true population frequency because it is limited to only those incidents that are reported. Most studies have been opportunistic, relying on the identification of incidents by self-reporting.
- **Classification.** The depth of understanding of threats to patient safety varies across the studies. Most studies have used simple classifications, such as prescribing, but this may oversimplify the cause.

It is easy to argue about the absolute frequency, types and cost of threats to patient safety, but the main message still stands: many patients are harmed by healthcare, both secondary and primary, and that harm is often preventable.

Further reading

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Further resources

National Patient Safety Agency (NPSA). Publications and more information are available from their website www.npsa.nhs.uk.

National Patient Safety Foundation (NPSF). Publications and more information are available from their website www.npsf.org.