

Chapter 1

Clinical error: the scale of the problem

The years since the Second World War have seen enormous progress in medical science. Unfortunately, the bright light of this success had blinded doctors and nurses to a dark subject that had, until recently, been completely overlooked.

Evidence is accumulating that harm to patients resulting from errors by healthcare professionals is a very significant problem. The consequential costs in litigation, wasted time, and extra treatment create a substantial drain on the resources of healthcare systems. The resources thus wasted are unavailable for the treatment of other patients.

The Harvard Medical Practice Study^{1,2} was a retrospective review of the records of over 30 000 randomly chosen patients who were admitted to 51 acute care, non-psychiatric hospitals in New York State in 1984. This study suggested that one patient in every 200 admitted to hospital died following an adverse event. This study was met with much incredulity. How could the rate of fatal adverse events be so high?

In the following years, however, further retrospective studies were carried out in six other countries, including the UK. If allowance is made for the differences in definitions used and the scope of the types of adverse events that these studies investigated, these studies confirmed that the results of the Harvard study were broadly correct. Indeed they suggested that the Harvard estimate of the frequency of adverse events was too conservative.

Across the seven different national healthcare systems 'covered' by these studies, some kind of adverse event occurred to approximately 1 in 10 hospital inpatients. Of these nearly half of all adverse events were assessed as 'preventable'. Approximately 6% of patients who suffered an adverse event were permanently disabled as a consequence of the adverse event. Approximately 8% of patients who suffered an adverse event died.

There was criticism that the retrospective study methodology was subject to bias. However, prospective studies observing clinicians at work in real time show rates of error in such activities as administering medications, communicating

clinical data, blood transfusions, etc., which are of the same order as those seen in the retrospective studies.

In Britain the cost of preventable adverse events is assessed as £1 billion per annum in lost bed days alone.³ The wider costs of lost working time, disability benefits paid to those injured by the adverse event, and the wider economic consequences add additional unmeasured costs. The Institute of Medicine report⁴ estimated that, in the USA, total annual national costs (lost income, lost household production, disability, healthcare costs) were between \$17 billion and \$29 billion for preventable adverse events and about double that for all adverse events.

The Harvard Medical Practice Study 1984^{1,2}

This study reviewed the patient records of 30 121 randomly chosen patients in 51 acute care, non-psychiatric hospitals in New York State in 1984. The goals of the study were

1. to establish the level of patient injury, and
2. to provide data for efforts to reform medical malpractice procedures.

As a consequence of the second goal only those injuries that could potentially lead to litigation (and thus represented injury due to substandard care) were measured. No attempt to detect ‘near misses’—errors that did not actually harm patients—was made nor were events that caused only minor physical discomfort counted. Terminally ill patients were excluded. Thus, adverse events in patients who were certain to have died were excluded from the study.

The results

1. Adverse events occurred to 1133 (3.7%) of the 30 121 patients in the study.
2. Of these 1133 patients, 74 were ‘permanently disabled’ by the event.
3. 154 (0.5%) patients died following a ‘clinical error’.

This equates to 1 in 200 patients dying as a consequence of an adverse event.

Of all adverse events, 47.7% were operative events (related to surgical care) and 17% of all adverse events were deemed to have been due to negligent practice, i.e. it was judged that the management had been substandard. The most common non-operative adverse events were adverse drug events (ADEs), followed by diagnostic mishaps, therapeutic mishaps, procedure-related events, and others.

Overall, 37.2% of the non-operative events were deemed to have been due to negligent practice. As one might expect, the most common sites for adverse

events were operating theatres followed by the patients' rooms, Accident and Emergency Departments, labour and delivery rooms, and ICUs.

Extrapolations from these data suggested that approximately 98 000 Americans would die each year following preventable adverse events. This would be eight times the number who die on America's roads.

The Quality in Australian Healthcare Study 1992⁵

The Quality in Australian Healthcare Study (QAHS) investigators based their study upon the Harvard methodology. However, as their goal was to gather data to improve 'quality' efforts, they were more interested in the 'preventability' of adverse events rather than 'negligence' in a medico-legal context.

They reviewed 14 179 randomly sampled records from patients in 28 hospitals in South Australia and New South Wales in 1992. As they focused on preventable events and included 'near misses' (where no harm to the patient resulted), the study uncovered a much larger number of adverse events than the Harvard study.

Using their definition of an adverse event, QAHS researchers found that 16.6% of the patients in the study experienced an adverse event. When adjusted to count adverse events according to the Harvard Study definition the rate was 13%. Of all adverse events, 51% were judged to have been preventable if there had been better communication between clinicians and better standards of checking.

The higher rates of adverse events detected in the Australian study, over four times greater than that found by the Harvard study, is partly accounted for by the wider range of adverse events included (for instance, adverse events occurring outside hospital were included), the focus on quality of care rather than negligent care, and the inclusion of many more minor events in the definition of adverse events.

As with the Harvard Study, most adverse events were related to surgical procedures (50.3%) followed by diagnostic errors (13.6%), therapeutic errors (12.0%), and ADEs (10.8%). Permanent disability resulted from 13.7% of adverse events and death from 4.9%.

1 in 123 patients died following a 'clinical error'.

The Australian study also found that 34.6% of errors were related to technical performance, 15.8% to a failure to synthesize and/or act upon information, 11.8% from a failure to request or arrange an investigation, procedure, or consultation, and 10.9% due to lack of care and attention or failure to attend the patient.

Communication problems between clinicians were the single most frequently occurring factors contributing to adverse incidents that harmed patients and these errors were nearly twice as common as those due to inadequate medical skill or knowledge.

The University College London Study 2001³

This paper announced the results of a retrospective review of the medical and nursing records of 1014 patients in two acute hospitals in the Greater London area.

The study showed that 110 (10.8%) patients experienced an adverse event, with an overall rate of adverse events of 11.7% because several patients suffered more than one event. About half of these events were judged to be preventable with ordinary standards of care. A third of adverse events led to moderate or greater disability or death. Nine patients died.

This translated into 1 in 113 patients dying following an adverse event.

Danish, New Zealand, Canadian, and French studies

In addition to the three studies above, four others have been carried out in Denmark, New Zealand, Canada, and France. The results of all seven studies are summarized in Table 1.1. In aggregate, these latter four studies have an average adverse event rate of almost exactly 10%, which is very close to the rate in the UK UCL study.³

The frequency and costs of adverse drug events

One retrospective study¹⁰ examined the frequency and cost of ADEs at the University of Virginia Hospital. The authors used an automated monitor that looked for patterns in laboratory test results and/or orders for medications that may have indicated that an ADE had taken place. For instance, if a hospital patient was prescribed naloxone (a drug used to reverse the effects of opiates), this may have indicated that the patient had received an erroneous excessive dose of morphine or other opioid. Based on an analysis of these results it was estimated that between 1996 and 1999 ADEs occurred at a rate of 10.4–11.5 adverse events per 100 admissions.

About half of these events were assessed as ‘preventable errors’—roughly five events per 100 admissions. It was estimated that length of stay following a preventable ADE was extended by an average of 2.2 days per patient.

Table 1.1 The percentage of patients experiencing an adverse event (AE) in the Harvard, Australian, Danish, New Zealand, Canadian, French, and UK studies

Study	Number of hospitals (year)	Number of patient admissions	% of patients who suffered 'adverse events'	% of AEs that were 'preventable'
USA: (New York) Harvard Medical Practice Study (Brennan <i>et al.</i> 1991) ¹	51 (1984)	30 121	3.7 (study excluded non-preventable events)	Not assessed as the study only considered preventable events
Australia: Quality in Australian Healthcare Study (Wilson <i>et al.</i> 1995) ⁵	28 (1992)	14 179	16.6	51.0
Denmark (Scholer <i>et al.</i> 2001) ⁶	17 (1998)	1097	9.0	40.4
New Zealand (Davis <i>et al.</i> 2002) ⁷	13 (1998)	6579	11.2	37.0
UK (Vincent <i>et al.</i> 2001) ³	2 (1999)	1014	10.8	48.0
Canada (Baker <i>et al.</i> 2004) ⁸	20 (2000)	3745	7.5	36.9
France (Michel <i>et al.</i> 2004) ⁹	7 (2002)	778	14.5	Not reported

Accuracy of retrospective studies

The retrospective reviews upon which the above statistics were based, like any other research method, have their limitations and the findings of the studies have to be treated with caution because of their methodological limitations.

Graham Neale, the lead clinician in the British study, summarized the principal methodological problems, although he accepted that the level of adverse events revealed was broadly correct. Neale and Woloshynowych¹¹ pointed out, for instance, that the review process relies on the judgements of the doctors who reviewed the patient records.

Great efforts have been made to strengthen the accuracy and consistency of these judgements by training of observers, by the use of structured data collection, and by duplicate review.

Two factors may have an effect that might either underestimate or exaggerate the rate of adverse events in these retrospective studies.

Underestimation: failure to record erroneous acts

There is anecdotal evidence to suggest that, on occasion, doctors have chosen not to record accurately, or even at all, in the patient's medical notes an error that they have made in treating a patient. The researchers might not be able to detect such errors, although in some cases they might be inferred by subsequent treatment given to the patient. No study has attempted to gauge the extent of this underestimation problem.

Exaggeration: hindsight (outcome) bias

The principal criticism of the record review methodology used by the large-scale studies is that they may be prone to 'hindsight bias'. People tend to exaggerate in retrospect what they say they knew before an incident occurred—the 'I knew it all along' effect.

Hindsight bias might perhaps be better termed 'outcome bias'. When a clinical outcome is known to be bad, those looking back at the treatment of the patient are much more likely to be critical and more likely to define certain actions as errors. So, for example, Caplan *et al.*¹² asked two groups of physicians to review two sets of notes. The sets of notes were identical but one group was told that the outcomes for the patients were satisfactory and the other group was told that the outcome was poor for the patient. The group who believed the outcomes were poor made much stronger criticisms of the care, even though the care described was exactly the same. Thus we tend to simplify things in retrospect and tend to be more critical when the outcome is bad.

Kieran Walshe¹³ has concluded that the recognition of adverse events by record review had moderate to good face, and validity with respect to quality of care in a hospital setting.

Error rates revealed in retrospective studies are of the same order of magnitude as those found in observational studies

The negative and positive factors described above may have the effect of balancing each other out.

Although the methodology of the retrospective studies might be criticized, it is interesting to note that on the few occasions where observational studies have been carried out on clinicians performing their duties in real time, the rates of human error observed have appeared not to be greatly different from those reported in the retrospective studies.

An as-yet-unpublished prospective study (real time observations) at the Oxford Radcliffe Hospitals Trust found that 12% of patients suffered an adverse event (Simon Kreckler, personal communication). This rate is similar to the average of the rates (10%) found by the retrospective studies in Table 1.1.

Error rates according to type of clinical activity

Communication of safety critical data over the telephone

A study by Barenfanger *et al.*¹⁴ in the USA analysed the reliability of transfer of pathology laboratory results over the telephone from three pathology laboratories to doctors. These results were all urgent and in most cases the doctors would be providing immediate treatment based on the information received over the telephone. It goes without saying that it can be critical for the safe management of a patient that the *correct* result for the *correct* patient is communicated where conditions such as hyperkalaemia, or abnormal blood clotting, or a suspected myocardial infarction or pulmonary embolus is being managed. It is not too difficult to imagine that a fatal error could occur if the treating doctor bases the quantity of potassium infused into a patient on an erroneously communicated serum potassium level.

So what did Barenfanger and colleagues¹⁴ find? 822 telephone calls from the pathology laboratories were studied. In 29 cases (3.5% of the calls) the doctor had misunderstood or mis-transcribed the data. Many of these errors had the potential to seriously endanger the patient.

Verbal communication in the operating theatre

Lingard *et al.*¹⁵ reported an observational study of 42 surgical procedures in a Toronto hospital. During the 90 hours of observation there were a total of 421 verbal communications between members of the surgical team. Each communication was assessed with respect to 'occasion' (appropriate timing), 'content' (completeness and accuracy), 'purpose' (whether the message achieved its objective, or could have done), and 'audience' (whether the person addressed has the capacity to answer or whether key personnel were present).

One hundred and twenty-nine of 421 communications (30.6%) observed in the operating theatre 'failed' in one or more of these ways. Lingard *et al.*¹⁵ noted that 'a third of these resulted in effects which jeopardised patient safety'. They found that 'critical information was often transferred in an ad hoc, reactive manner and tension levels were frequently high'.

Bedside blood transfusion errors

A Belgian study¹⁶ assessed the frequency and nature of bedside transfusion errors in three hospitals in Brussels. Over a period of 15 months, 808 patients received 3485 units of blood. There were 13 serious errors (1.6% of all patients transfused), including seven cases where the patient received the wrong blood. This equates to *1 in 115 patients receiving the wrong blood*.

Checking patients prior to blood transfusions

Turner *et al.*¹⁷ (National Patient Safety Agency data) analysed transfusions before and after the introduction of a bar coding system in a haematology outpatient clinic at a 1500-bed hospital in the UK. The study revealed that during the administration of blood, patients were not asked for their name in 93% of the 1500 cases, while their date of birth was not asked in 12%.

In 12% of the cases the patient was not wearing a wristband, and in 100% of the cases the patient ID on the wristband was not cross-referenced with the patient-stated ID. In 90% of the cases the special requirements on the blood pack were not cross-referenced with any requested on the prescription.

All of the checks were carried out at the bedside. During the collection of blood samples (30 observations) 43% of the patients were not asked for their name, while 50% were not asked for their date of birth; 90% of the patients were not wearing a wristband.

These statistics reflect a major and systemic failure of the checking culture.

Checking of anaesthetic machines

Mayor and Eaton¹⁸ surveyed the checking of anaesthetic machines and showed that up to 41% of anaesthetists performed no checks on their

equipment at all. This was a worrying statistic because Bartham and McClymont¹⁹ in the same edition of *Anaesthesia* found that 18% of anaesthesia machines had 'serious faults'.

Missing test results

A number of studies have sought to establish the incidence of missed test results. Delays in diagnosis constitute a common medical error and represent a significant threat to patient safety.

An important study conducted by Roy²⁰ examined clinician awareness of significantly abnormal test results that had been received by the clinical team after the patient's discharge from a large teaching hospital. The investigators found that clinically important missed results occurred in nearly 1% of patient discharges.

Deaths from adverse events

Blundering doctors 'kill 40,000 a year'

This was the main front-page headline of *The Times* newspaper on Friday 13 August 2004. The article beneath said that 'medical accidents and errors contribute to the deaths of 72,000 people a year, and they are directly blamed for 40,000.'

Media reports relating to medical accidents and errors in the USA have quoted a figure of 98 000 deaths a year there, based on the Harvard study.

The validity of these 'death rates' inferred from the Harvard and other retrospective studies has been questioned. It has been argued, following estimates of the death rate in hospital at the time of the study, that the patients who reportedly died from adverse events in the Harvard study were already severely ill and likely to die anyway.²¹ In a further challenge to the figures, Hayward and Hofer²² compared the findings with their own review of the standard of care of patients who died in hospital while having active, as opposed to palliative, care. They found that only 0.5% of patients would have lived longer than 3 months even if they had all had optimal care. Thus it seems that some deaths were possibly preventable but the great majority of these people were already very ill and would have died anyway. How important an extra few months of life is deemed to be no doubt varies from person to person according to their disease and circumstances.

In a reply to McDonald *et al.*'s²¹ criticisms, Lucian Leape,²³ one of the authors of the Harvard study noted that:

Some seem to have the impression that many of the deaths attributed to adverse events were minor incidents in severely ill people. This is not so.

First terminally ill patients were excluded from the study. A review of the cases in which the care was most deficient reveals two groups of patients: a small group, 14%, who were severely ill and in whom the adverse event tipped the balance; and a larger group, 86%, for whom the error was ... a major factor leading to the patient's death.

In July 2005 the National Patient Safety Agency (<http://www.npsa.nhs.uk/>) in the UK announced that they had received reports of 840 patient deaths following avoidable mistakes during the preceding year across the whole healthcare system (including GP's surgeries, ambulance trusts, and in community and mental healthcare). In its second report in August 2006, the agency stated that this total had risen to 2159 deaths. The higher rate in the second year undoubtedly reflects a greater level of reporting rather than a doubling of real adverse events.

Thus it seems that the true number of patient deaths from these causes lies somewhere between 2159 and 40 000.

Extra bed days as a consequence of error

The focus on the rate of patient *deaths* following adverse events has directed attention away from what is another very important consequence of clinical error.

Although 70% of patients who suffer an adverse event require no extra treatment, a small number require very prolonged treatment to recover from their adverse event. These few cases have the effect of substantially raising the overall average number of 'extra bed days'.

In one of the case studies in this book a patient who had the wrong kidney removed was judged to be unsuitable for a kidney transplant and, consequently, will require dialysis for the rest of her life. The average cost of treating a patient on hospital haemodialysis is £35 000 per year.

The UK, Danish, and Canadian studies assessed the consequences of those adverse events that had been detected in terms of the consequent extra bed days required to treat the patient. The three studies produced similar findings.

The UK study found that patients who suffer an adverse event spend, on average, an extra 8.5 days in hospital. The Danish study found an average of seven extra bed days and the Canadian six extra bed days.

In the UK study the treatment of 1014 patients was analysed. The 110 patients who suffered adverse events required a total of 999 extra bed days. Of these 460 extra bed days (46%) arose from 'preventable' events.

A rate of 460 preventable extra bed days when treating 1014 patients would equate to *every* inpatient spending, on average, almost an extra half a day in hospital recovering from a 'preventable' adverse event.

Across the NHS this would total three million extra bed days a year at a cost of at least £1 billion. Other consequential costs may add a further £1 billion per year. Clearly, preventable adverse events produce a continuing and huge drain on NHS resources.

Belief in the reliability of the adverse event rate statistics

Robinson *et al.*²⁴ carried out a survey in the USA of 594 doctors and 500 members of the public in order to assess the level of credence in the rates of adverse events as reported by the various studies.

Only 21% of the doctors surveyed thought that healthcare was failing to match the safety records of other industries.

The general public was more likely than doctors to believe that the quality and safety of healthcare was a problem, that error reduction should be a priority and to support mandatory reporting of serious errors.

It appears, therefore, that a much higher proportion of the general public than of doctors is concerned about the safety of healthcare. Although the authors did not ascertain the reasons for this in their survey, they speculate that the public is unduly influenced by isolated but horrific accounts of medical errors in the media. Alternatively, they suggest, physicians do not seem to be as concerned about errors as they should be. It might be that the difficulty of defining and measuring errors and of determining their preventability has led physicians to underestimate their frequency or not to recognize them at all.

The cost to the NHS of adverse events

In November 2005 the National Audit Office in the UK issued a report into the costs of adverse events in the NHS.²⁵

A total of 974 000 clinical error events per annum were officially recorded, of which half were judged preventable. This figure did not include 300 000 hospital-acquired infections, of which 30% were judged preventable. One patient in 10 suffered harm as a result of a clinical error. Of those patients who were harmed, 19% suffered 'moderate impairment', 6% suffered 'permanent impairment', and 8% died. The report also revealed that there were 2081 clinical error deaths officially recorded in the year to March 2005, although it suggested that due to a culture of under-reporting the true total could be as high as 34 000 deaths per year.

The report repeated the calculation from the UCL study³ that the total cost of the extra bed days resulting from clinical errors is over £2 billion per year, of which one-half would be preventable.

In the year 2004–5 the NHS paid out £423 million in litigation costs. A further £50 million was paid to NHS personnel suspended on full pay during investigations into adverse events.

Criminal prosecutions for medical errors

A study reported in the *British Medical Journal*²⁶ showed that there had been an eightfold increase in the number of doctors charged with manslaughter during the 1990s compared with earlier decades. The report's author speculates that this might be because of 'a greater readiness to call the police or to prosecute, perhaps because the Crown Prosecution Service perceives that juries are readier to convict nowadays'.

In a later study, Ferner and McDowell²⁷ noted that of 85 prosecutions for manslaughter over a 20-year period, 60 (71%) were acquitted, 22 convicted, and three pleaded guilty. In 2005 there were 17 prosecutions of doctors for manslaughter in the UK. The rising trend of prosecutions continues.

Reliability: other industries

In civil aviation, European passenger railway and the nuclear power industries, the rate of catastrophic accidents in relation to the number of journeys or 'exposures' to the risk, is of the order of 1×10^6 or better.²⁸

Modern passenger aircraft are, in mechanical and structural terms, extremely reliable. However, significant risks in aviation still arise from unpredictable weather conditions, congested airports and airspace, hazardous passenger behaviours, terrorism threats, and human error by pilots, controllers, and engineers. In spite of this, the national airline systems of most first world countries have, in recent years, achieved almost a 100% reliability rate (virtually zero accidents) for many consecutive years.

Reliability: healthcare

Some specialties in healthcare do achieve high levels of reliability. In anaesthetics the rate of fatal adverse events has improved markedly in the last three decades and is now approximately 1 per 100 000 anaesthetics.²⁸ In contrast, the rate of adverse events in surgery has been reported as 1 per 1000. Certainly, the large-scale studies carried out in the seven different nations described above do seem to confirm this rate, or suggest that it is higher still.

How high reliability organizations have been able to achieve their impressive safety records is discussed later in this book. Many of the techniques they use could very easily be translated into the healthcare setting and so doctors—and their patients—could benefit by being aware of how high reliability organizations manage to achieve high levels of reliability.

References

- 1 Brennan TA, Leape LL, Laird NM, *et al.* Incidence of adverse events and negligence in hospitalized patients; results from the Harvard Medical Practice Study I. *N Engl J Med* 1991; **324**: 370–6.
- 2 Leape LL, Brennan TA, Laird N, *et al.* The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; **324**: 377–84.
- 3 Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *Br Med J* 2001; **322**: 517–19.
- 4 Kohn L, Corrigan J, Donaldson ME. *To err is human*. Washington DC: National Academy Press; 1999.
- 5 Wilson RM, Runciman WB, Gibber RW, *et al.* The Quality in Australian Health Care Study. *Med J Aust* 1995; **163**: 458–71.
- 6 Schioler T, Lipczak H, Pedersen BL, *et al.* Danish adverse event study. Incidence of adverse events in hospitals. A retrospective study of medical records. *Ugeskr Laeger* 2001; **163**: 1585–6.
- 7 Davis P, Lay-Yee R, Briant R, *et al.* Adverse events in New Zealand public hospitals I: occurrence and impact. *N Z Med J* 2002; **115**: U271.
- 8 Baker GR, Norton PG, Flintoff V, *et al.* The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *Can Med Assoc J* 2004; **170**: 1678–86.
- 9 Michel P, Quenon JL, de Sarasqueta AM, *et al.* Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *Br Med J* 2004; **328**: 199.
- 10 Einbender JS, Scully K. Using a clinical data repository to estimate the frequency and costs of adverse drug events. *J Am Med Inform Assoc* 2002; **9**(6): S34–8.
- 11 Neal G, Woloshynowych M. Retrospective case record review: a blunt instrument that needs sharpening. *Qual Saf Health Care* 2003; **12**: 2–3.
- 12 Caplan RA, Posner KL, Cheney FW. Effect of outcome on physicians' judgments of appropriateness of care. *JAMA* 1991; **265**: 1957–60.
- 13 Walshe K. Adverse events in health care: issues in measurement. *Qual Health Care* 2000; **9**: 47–52.
- 14 Barenfanger J, Sautter RL, Lang DL *et al.* Improving patient safety by repeating ('read-back') telephone reports of critical information. *Am J Clin Pathol* 2004; **121**: 801–3.
- 15 Lingard L, Espin S, Whyte S *et al.* 'Communication failures in the operating room: an observational classification of recurrent types and effects. *Qual Saf Health Care* 2004; **13**: 330–4.
- 16 Baele PL, De Bruyere M, Deneys V, *et al.* Bedside transfusion errors. A prospective survey by the Belgium SAnGUIS Group. *Vox Sang* 1994; **66**: 117–21.

- 17 Turner C, Casbard A, Murphy M. *Barcode technology: its role in increasing safety of blood transfusion* 2003. London: National Patient Safety Agency; 2003.
- 18 Mayor AH, Eaton JM. Anaesthetic machine checking practices. A survey. *Anaesthesia* 1992; **47**: 866–8.
- 19 Bartham C, McClymont W. The use of a checklist for anaesthetic machines. *Anaesthesia* 1992; **47**: 1066–9.
- 20 Roy CL. Patient safety concerns arising from test results that return after hospital discharge. *Ann Intern Med* 2005; **143**: 121–8.
- 21 McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA* 2000; **284**: 93–5.
- 22 Hayward R, Hofer T. Estimating hospital deaths due medical error. *JAMA* 2001; **286**: 415–20.
- 23 Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA* 2000; **284**: 95–7.
- 24 Robinson AR, Hohmann KB, Rifkin JI, *et al*. Physician and public opinions on quality of health care and the problem of medical errors. *Arch Intern Med* 2002; **162**: 2186–90.
- 25 National Audit Office/Department of Health. *A safer place for patients: learning to improve patient safety*. London: The Stationary Office; 2005.
- 26 Ferner R. Medication errors that have led to manslaughter charges *Br Med J* 2000; **321**: 1212–16.
- 27 Ferner RE, McDowell SE. Doctors charged with manslaughter in the course of medical practice. *J R Soc Med* 2006; **99**: 309–14.
- 28 Amalberti R, Auroy Y, Berwick D, Barach P. Five system barriers to achieving ultrasafe health care, *Ann Intern Med* 2005; **142**(9): 756–64.