Inpatient safety I

Challenges in the care of the acutely ill

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Health care providers, hospital administrators, and politicians face competing challenges to reduce clinical errors, control expenditure, increase access and throughput, and improve quality of care. The safe management of the acutely ill inpatient presents particular difficulties. In the first of five *Lancet* articles on this topic we discuss patients’ safety in the acute hospital. We also present a framework in which responsibility for improvement and better integration of care can be considered at the level of patient, local environment, hospital, and health care system; and the other four papers in the series will examine in greater detail methods for measuring, monitoring, and improving inpatient safety.

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Through other industries have been implementing error analysis for decades. Error-reduction efforts in health care have focused on the doctor-patient interface that might seem to casual observers to be the most obvious cause of medical accidents. Although failures by clinicians do contribute to unsafe acts, efforts to correct the performance of individual health-care providers seldom contribute to a general improvement in patients’ safety throughout a health-care system.

Studies of human error in industrial and transportation accidents have refocused our understanding of clinical errors as a systems problem that requires systems-oriented solutions. Latent failures embedded in organisational design set the stage for unsafe practices. Failures such as poorly designed equipment and monitoring alarms, paper records with illegible physician orders, and work conditions that promote fatigue and inattention lie dormant within organisations’ structures until a fatigued clinician with poor handwriting, for example, or a high patient turnover triggers error. Heinrich surveyed industrial accidents in the 1940s and estimated that for every major adverse event there were 29 minor ones and 300 non-injury accidents (near-misses). If similar proportions relate to health care, latent failures represent a tremendous opportunity to improve patient safety.

Even though errors of omission outnumber errors of commission by two to one, organisations respond more readily to errors of commission—for example, by addressing the risk of administering highly concentrated potassium solutions intravenously while overlooking failure to correct hypokalaemia, which affects 20% of inpatients and promotes life-threatening cardiac

Search strategy

We focused our review on patients’ safety and the management of the acutely ill hospital patient. To retrieve information about the health care environment, we also searched for publications about health care organisation and emergency services. We used MEDLINE, EMBASE, and Google, to access government publications and “grey” literature, using singly and in paired combination the terms safety, medical error, postoperative complications, emergency medical services, critical care, and intensive care. We discussed the themes extracted from this process with other authors in the series and with professional colleagues worldwide.
Arrhythmias.\textsuperscript{14} Health services need to find novel ways of avoiding errors of omission. Routine necropsy provides one opportunity for identifying diagnostic and therapeutic errors but they are less common than they used to be.\textsuperscript{16} Although a systems approach has improved safety in the aerospace and airline industries by identifying and correcting latent errors, systems engineering remains largely untested in health care.\textsuperscript{19}

Definitions
Disagreement exists not only about the precise scale of medical error,\textsuperscript{18–21} the degree of public disclosure required to stimulate safer medical practices,\textsuperscript{20} and the extent to which errors can be eliminated in complex systems,\textsuperscript{21} but also about the terminology.\textsuperscript{17,23} The IOM used an outcomes-based definition: "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."\textsuperscript{21} Others define error as latent failures at the systems level that include human, organisational, and technical constraints on performance,\textsuperscript{17} whether there are adverse consequences or not. "Lumpers" include any instance of underuse, overuse, or misuse of medical care\textsuperscript{23} whereas "splitters" confine the definition to failed processes that have been proved to cause adverse outcomes.\textsuperscript{17}

These competing taxonomies mesh poorly with the definitions of health care quality on which efforts to improve organisational performance are based.\textsuperscript{25–29} Definitions of quality incorporate concepts of causation, attribution, preventability, and near-misses, which are absent from definitions of medical error. Communication is hampered too; so is research; and the identification and correction of unsafe practices before an adverse event occurs are delayed. The medical errors movement has yet to take full advantage of the principles of outcomes research. For instance, no investigators have comprehensively and prospectively looked at the frequency of clinical errors using a priori definitions to establish causative links between errors and outcomes.\textsuperscript{32}

Most of the studies used for the IOM report were not designed primarily to detect errors, assessors were not masked to outcomes, and the reliability of the measures were not provided. Because trained investigators have poor interobserver agreement in identifying clinical errors from medical record reviews,\textsuperscript{23,30} clinicians justifiably expect prospective, masked, outcome-based studies to determine the dimensions of the problem, identify methods for correcting it, and describe the quality of acute care.\textsuperscript{31}

Cultural context
The causes of error are diverse, often complex, and rarely attributable to single actions, events, or individuals. The causes are usually rooted in unsafe systems rather than individual caregivers. The final common pathway, however, is the interaction between practitioner and patient. This relation has undergone a profound change in the past 50 years. Previously paternalistic, personal, trusting, limited in therapeutic potency and low in expectation of results, patient-clinician interactions have become more equal, transparent, team-based, and contractual. Patients want doctors to communicate more effectively and devote more time to them. Treatments have become more effective and have a correspondingly greater capacity to harm if misused.\textsuperscript{14}

Increasingly, the public expects medical services to deliver the anticipated results, and on time, and if the outcome is not as anticipated, a culprit must be sought and retribution exacted. In a telephone survey of members of the public in the USA, 50% believed that suspension of licences to practise would be an effective way to prevent clinical error.\textsuperscript{32} Substantial cultural differences also seem to exist between medical disciplines\textsuperscript{33} and between countries\textsuperscript{34,35} in attitudes to error. A reduction in professional authority might have contributed to a lessening of physicians’ sense of personal responsibility for the duration of their patients’ care. Methods for reducing error need to take into account changing doctor-patient relationships and cultural differences.

Comparisons with industry
The safety and error-prevention record for health care services is often compared unfavourably with that of aviation, banking, chemicals, manufacturing, and military services in peacetime, the best of which have highly developed strategies to protect workers and clients. These strategies include a safety culture that emphasises the importance of safe practices, commitment of management to safety, and non-punitive and simplified reporting of errors with feedback of error analyses. Aviation has focused on the importance of working in teams, and lessons learned from crew resource management are starting to be applied to health care.\textsuperscript{36}

Industries with successful safety records emphasise standardisation of practices combined with flexibility to address unique circumstances. They also invest in safety training and research. This strategy has resulted in substantial reductions in errors and adverse outcomes, with some industries reporting no serious workforce injuries for many years. The IOM has adopted the viewpoint of groups that study "high reliability organisations" (nuclear aircraft carriers, nuclear power plants, and air-traffic control) that successful systems engineering for high levels of safety is achievable.\textsuperscript{37–39}

Health services have, therefore, been encouraged to align their safety efforts with those of industry\textsuperscript{40} and aim for an error rate of less than 3-4 per million events.\textsuperscript{41} This is known as "six sigma quality" because it lies outside six SDs of a normal distribution. Anaesthesia has made substantial contributions to patients’ safety through concerted efforts by practitioners and equipment manufacturers to standardise processes. The IOM report states that deaths attributable to anaesthesia have fallen to 5-4 per million, which approaches five sigma, although the validity of the data that support this observation has been questioned.\textsuperscript{42} The persistence of a steady rate of fatalities in aviation\textsuperscript{22} or road transport\textsuperscript{43} despite increased traffic volume suggests that benefits of safety efforts could be counterbalanced by competing risk factors, such as high throughput, seriously ill patients, and complex interventions.

Although industrial experience provides valuable insight into potential solutions for clinical errors, the extent to which it applies to health care remains uncertain. Health care is characterised by highly complex processes, unique problems and needs of individual patients, loosely knit teams, multiple outcome measures, incomplete evidence for many health care decisions, and varying layers of responsibility. In hospitals, unpredictable workloads and uncertainty about individual patients’ outcomes are additional factors. A more appropriate industrial analogy for safe care of the acutely ill patient would be the armed forces contending with the uncertainties of warfare, friendly fire, and "collateral damage", a distinction which governments seem willing to apply to safety of military personnel.\textsuperscript{44} Health services should learn from other industries but they need models that address the unique challenges of the acute hospital setting.
Error and environment

Although most large safety studies have been in acute care settings, few distinguish between elective admissions and emergency admissions or emergencies during planned treatment. Elective admissions and procedures have well-defined care pathways which facilitate analysis of deviations; emergencies tend to be less predictable. In our view emergency care needs to be seen as a separate entity with a focus on patients' safety that cuts across disciplines and departments. In view of the pressures to accelerate patient throughput, improved safety will also require better integration of community health care with discharge planning, especially since preventable adverse events might affect 6% of patients after hospital discharge.42

Error in acute care

The risk of adverse events is higher for patients admitted to emergency departments3, 46–48 and general medical wards than for those admitted for elective surgery.4,41 Clinical errors most commonly affect the elderly,7 who account for most emergency admissions10 and have the highest risk from emergency surgery.11 The risk of error increases when such care is provided, as it often is, by inexperienced clinicians and unsupervised trainees.12–14 The risk of an adverse event increases by about 6% per day for patients admitted as emergencies,15 and is especially high for those needing lifesaving invasive interventions.16

Critical illness increases the opportunity for clinical error17–19 because of the complexity of patients' problems and the frequency of invasive interventions. The intensity of monitoring in critical care units means that errors are more likely to be detected. Iatrogenic complications are a common cause of admission to intensive care,20 and previously suboptimal care is associated with an increased mortality in the intensive care unit.21 Cardiopulmonary arrest in hospital is frequently preceded by warning signs22 and can be prevented by interventions to identify and manage patients earlier.23 Premature discharge from intensive care is associated with increased in-hospital mortality.24 These factors confirm the need for a systems approach to error prevention.

Effect of case-mix

The greater risk of clinical errors in emergency admissions is especially alarming because of the increasing demand for emergency care.25,26 In the USA, emergency admissions constitute more than a third of all hospital admissions, 41% of admissions of children, and 55% of admissions of patients older than 80 years. 54% have at least one comorbid condition and a third have two or more.27 Age and comorbid disease add to the risk of adverse events28 either from limited physiological reserve or because of exposure to more interventions. In the UK, about 60% of hospital admissions are emergencies, and the proportion has been increasing yearly by 2.1% since 1989, when data were first collated. For patients older than 65 years, the annual increase is 3.3%.29

Changes in service provision

In many developed countries the need for emergency services has been growing in parallel with pressures to reduce length of stay and numbers of beds.30 For example, day-cases account for an increasing proportion of elective admissions. In the UK, the number of National Health Service beds fell from 480 000 in 1948 to 190 000 in 1998, throughput and occupancy have increased, and length of stay has shortened.31 Many regions in the USA have shortages of beds and face the need to replace old hospitals, and increasingly crowded emergency departments have a statutory obligation to provide care for the 46 million Americans who carry no health insurance. These pressures can represent a substantial hindrance to efforts to improve safety.

Poor integration of acute hospital services can also contribute to error. Market forces in the USA promote competition between neighbouring facilities, often resulting in redundant services. In the UK, however, a desire for convenient local access causes acute hospitals to proliferate, preventing economies of scale when nearby hospitals replicate specialist services, a tension reflected in abrupt changes in governmental planning.32 This lack of integration dilutes professional experience, including operative procedures, and lowers competency and quality of outcomes.

Working hours

To provide safe acute care means employing adequate numbers of trained staff, which is increasingly difficult in the European Union because the Working Time Directive, from August, 2004, limits the working hours for trainee doctors to 56 per week and to an average of 48 for all employees by 2009. “Work” is defined as “required to be present at the health centre” regardless of the activities being undertaken. This ruling has important implications for out-of-hours and emergency care33 since being asleep in an on-call bedroom will still count as work. In the USA, resident physicians in training have, since July, 2003, been limited to an average of 80 h a week.34 Comparison of the effects of the European and American regulations should prove useful, in view of evidence that fatigue from long hours of work impairs patient safety.35

Concerns have been expressed that these constraints may adversely affect training and acquisition of skills.36 They will certainly strain services in countries that have a physician shortage. It will not be possible to train enough extra doctors in the UK to fill the gap created by the European directive before 2015. Reliance on non-physician care-givers may improve the delivery of preventive medicine and enhance performance of specific tasks but does not seem to improve acute care.37 Moreover, the worldwide shortage of nurses38 restricts the large-scale transfer of traditional physician duties. A more constructive approach for maintenance of patients’ safety in acute care would be to focus on models of team-working rather than transferring work to other groups.

Discontinuities in patient care

Hospital medicine has become increasingly compartmentalised, with blurred borders of responsibility and multiple transitions (“hand offs”) between different health care providers and teams.39 The benefits of reduced fatigue from restricted hours of work for medical staff may be offset by the discontinuities in care and personal isolation caused by shift-working, the greater risk of communication failures, and constraints on the delivery of clinical education. A clinical vignette illustrates the problems (panel).

This patient did not have just one illness and nor did she have a distinct medical error that resulted in a well-defined adverse event. She had several comorbidities, was exposed to high-risk interventions with known side-effects, and was treated in an acute care environment with insufficient safeguards against clinical error. Potentially avoidable adverse events were caused by faulty actions and inactions, suboptimal training, poor supervision, and inadequate service provision at local and national levels. However, establishing a root-cause would be difficult because of the varied, diffuse, and overlapping failures.
A 56-year-old woman was admitted on a Saturday evening to a university teaching hospital with progressive malaise, diffuse abdominal pain, and diarrhoea 1 week after chemotherapy for breast cancer. Ten years previously she had had cancer in the other breast and had undergone mastectomy with radiotherapy. She was on warfarin for an axillary vein thrombosis caused by a Hickman catheter and had a history of penicillin allergy. She was apyrexial, tachypnoeic, hypotensive, and oliguric; total leucocyte count of less than $0.1 \times 10^9/\mu L$, platelets $70 \times 10^9/\mu L$, serum creatinine $170 \mu mol/L$, and international normalised ratio 6.2. Blood culture produced gram-negative rods within 12 h.

She was treated by the resident medical staff in the emergency unit with piperacillin and gentamicin, inadequate intravenous fluids, parental non-steroidal anti-inflammatory analgesics, and diuretics. She had a head injury after falling unobserved from the commode where she had been placed by the nursing assistants, who then sat her in a chair despite a documented systolic blood pressure of 70 mm Hg. There were only two trained nurses on duty for this 28-bed ward. She was eventually seen by a consultant 24 h after admission, and was referred to intensive care in neutropenic septic shock with multiple organ failure.

Because no bed was immediately available in the intensive care unit, mechanical ventilation and cardiovascular support were started in the ward. Preparations for transfer to another hospital were cancelled when an appropriate bed did become free. Shortly after admission she developed a transient rash that was attributed to piperacillin, already discontinued. A CT scan showed a small subdural haematoma that did not need intervention other than correction of the coagulopathy. Renal replacement treatment was needed. During her 4 weeks in intensive care, she developed a ventilator-associated pneumonia and became colonised with meticillin-resistant Staphylococcus aureus. After being discharged to the ward, she developed bacteraemia from a central venous catheter that had been left in place several days longer than intended and needed a brief re-admission to intensive care.

She returned home 2 months later, weak but able to look after herself. Her husband confided that he was surprised by the contrast between the quality of care in the intensive care unit compared with that on the ward.

Vincent and colleagues have developed a structured approach for analysis of such episodes, combining the factors that affect clinical practice with Reason’s organisational model of error. We have adapted this model, bringing in elements from the quality literature (table), as a method for assessment safe care of the acutely ill patient.

Responding to the challenge

Our perspective is that safety and reliability are the most important components of quality in health care and that services need extensive restructuring to achieve an acceptable level of these characteristics of high quality care. The restructuring demands a systems approach. In the panel, we identify deficiencies in resources and organisation, processes and delivery of care, monitoring, clinical competence, communication, continuity of care, therapeutic interventions including prescribing, leadership and governance, and patient empowerment. We classify these deficiencies as occurring at the four levels of patient, microsystem, organisation, and environment, a classification that allows consideration of quality and safety issues from different perspectives. What follows is a summary of some of these issues. The next four articles in this Lancet series will go into more detail, looking at the monitoring of and improvements in safety for the acute inpatient, both from a local and a systems standpoint.

**Resources and organisation**

**Emergency departments**

Safe emergency care needs prompt access to initial treatment for life-threatening emergencies, and hospitals cannot provide that if their emergency departments are overloaded by medical problems that could have been managed by a family practitioner or a pharmacist. Patients cannot obtain prompt treatment without either adequate local facilities or an efficient ambulance service. In large hospitals, parallel provision of primary and secondary care within the emergency department improves efficiency and focuses resources on sicker patients. Small and rural acute hospitals will need local solutions to professional staffing that include shared management of the emergency department by community practitioners, consultation available via telemedicine links, and appropriately staffed rapid transport to take more seriously ill patients to better-equipped centres. This hub-and-spoke integration is well-accepted for paediatric emergency care. Appropriate investment in training and career structures will also be needed to encourage practitioners—medical and non-medical—to develop team-based approaches to emergency care as a method for reducing errors and improving quality.

**Models for delivering acute care**

Future clinicians who provide core services in the acute hospital setting will need new skill sets, which will be transdisciplinary and especially suited to the range of health care needs of hospital patients. Physicians, nurses, pharmacists, and other health-care providers will develop team-based models of care that avoid gaps in knowledge and services. These gaps constitute an important risk for patient safety. Essential skill sets will draw on anaesthesia, internal medicine, surgery, accident and emergency medicine, basic sciences, and ethics whereas behavioural competencies will learn from aviation and crew resource management. Critical care medicine illustrates this development. Intensivists (ie, intensive care specialists) have become the general practitioners of acute care. They have adopted multidisciplinary collaboration, contributed to systems management within intensive care, and emphasised intervention at the first signs of clinical instability. Integrative models with well-organised systems within intensive care units have reduced mortality, and the appointment of intensivists is a key recommendation of the Leapfrog Group in the USA for improving hospital safety.

In the USA, acute hospital care has been developed into a professional track termed hospital medicine practised by the “hospitalist.” Australian hospitals have extended intensive care services and personnel into hospital wards by creating medical emergency teams. The UK has outreach care provided by critical-care-trained nurses for patients admitted to the wards. Such outreach detects early signs of clinical deterioration and improves communication between ward admitting teams and staff in intensive care units. Although there are no comparative data to favour one model over another, studies suggest that early intervention might reduce cardiac arrest rates, although there is the risk that the point of death could merely be shifted to the ICU. Better integration should also extend into post-hospital recovery. We are only just beginning to identify the safety...
issues of post-discharge care, though we know that the physical consequences of critical illness persist.

Processes and delivery of care
Providing evidence-based interventions in a coordinated and prompt manner to patients with complex health problems defies the human abilities of inpatient practitioners. With over 30 000 new publications entering the MEDLINE database each month, clinicians need knowledge pathfinders to assist their decision-making. Safe care of patients will need greater reliance on clinical pathways, clinical practice guidelines, and decision support tools. No longer “physician-centric”, transdisciplinary teams will undertake their clinical responsibilities in an integrated manner using guidelines and protocols. A team approach using treatment algorithms has achieved more rapid weaning of ventilator-dependent patients compared with physician-dependent approaches. Clinical practice guidelines, adapted to the local clinical setting, increase the likelihood of desired health-care outcomes.

Information management and communication
Failures of communication between health-care providers and between clinicians and patients are common causes of error and litigation. Training in communication skills will be especially important for multidisciplinary teams functioning in rapid-paced inpatient settings. The electronic medical record and computerised physician order entry (prescription system) offer opportunities to provide clinicians with an electronic platform that embeds decision support and knowledge resources to promote best practice. Computerised prescribing should improve patient safety by reducing documentation and by warning of potential drug interactions, contraindications, dosing adjustments, and allergies. Evidence is emerging for benefits from error reduction and improved decision making, and computer-assisted record keeping and prescribing are among the interventions recommended by the Leapfrog Group.

Information technology does need staged “bottom-up” development, pilot testing, and appropriate implementation into existing hospital cultures. Greater dependency on computerised systems creates new safety issues when the system fails. However, health services for the most part still depend on the oral transmission of information supported by handwritten records. It does seem logical to build on the progress with computerised prescribing, and develop an electronic patient record with modules for investigations, diagnosis, interventions, and outcomes.

Monitoring and analysis
Early warning systems
Traditional monitoring in the acute hospital often identifies adverse events only after they occur. Reactive systems, based on instructions to call a doctor if there are major changes in vital signs, should be replaced by proactive monitoring to identify early changes and empower ward staff to call for help and initiate further investigation to prevent or limit the magnitude of adverse events.

Adverse event and error monitoring
Adverse event reporting is essential for improving patient safety but current methods are unsatisfactory. Major events may be more reliably reported, but near-misses are likely to be ignored, deferred, or forgotten in the pressured environment of clinical work. Barriers include cumbersome and non-standardised paper formats; a litigious culture that deters open reporting and discussion; difficulty with identifying and reporting errors of omission; a long interval between intervention and adverse outcome (for example, nosocomial infection); deficiencies in information synthesis, analysis, and feedback; and failure of institutions to address improvements in processes of care. Whether incident reporting should be process or outcomes based remains unclear.
Hospitals need data collection systems that allow providers to enter information anonymously and easily. Intranet-based online systems with automated analysis and reporting to directors of patient safety and hospital executives should improve institutional responsiveness.\textsuperscript{103} Collation of institutional data by regulatory or governmental agencies should make it easier to detect patterns and recommend improvements. The US University Health System Consortium has an internet-based reporting system; the Joint Committee on Accreditation of Healthcare Organisations encourages voluntary reporting of sentinel events; and four agencies within the US Department of Health and Human Services are integrating their data systems on clinical errors or adverse events. These developments will increase the pressure for public disclosure of patient safety records but such data must accurately reflect the quality of care and the hospital's case-mix. So far, no such data collection systems exist.

**Competency-based training**

Many of our proposals need investment in new ways of training health care personnel. Traditional teaching has been specialty-based. Evidence of the trainee's success in making the transition to independent practitioner has rested on the completion of training of the required duration followed by a formal examination. This model has not facilitated horizontal integration of trainees across disciplines, and it has inhibited the sharing of knowledge and skills, and impeded collaboration and team building. The focus on knowledge assessment also produces a barrier within the curriculum and desirable educational outcomes. This is now starting to change with the development of competency-based training.

Competency-based training replaces time-based training. The process of defining areas of competence and mapping it to the core curriculum promotes integration of common elements across specialties. Patients' safety will become one such core competency. The UK has a competency-based training programme for multidisciplinary intensive-care medicine,\textsuperscript{104} and proposals are being developed for a similar approach across Europe. The US Accreditation Council for Graduate Medical Education has also restructured postgraduate medical education around competency-based “outcomes”.

The same educational principles must be applied in the undergraduate setting but undergraduate curricula remain largely silent on patients' safety.\textsuperscript{105} One method by which undergraduates can learn the basic principles of patients' safety and team-working in acute care is by provision of transdisciplinary peer-led tuition in resuscitation and emergency care, training senior students to act as tutors and role models in multidisciplinary groups.\textsuperscript{106}

**Governance: taking responsibility for change**

To achieve improvements in acute patient safety in the current climate and across different health care systems will take many years, but the process has started. Classen\textsuperscript{107} proposes four evolutionary stages: building awareness; development of organisational learning; proactive management of risk; and establishment and maintenance of high reliability organisations.\textsuperscript{108} Progress through these stages will need a multiplicity of approaches, from step-change at a local level to strategic planning at national and international levels. It will also need the establishment of common goals and shared responsibilities as we build partnerships between the public, practitioners, politicians, administrators, insurers, and educators.

Health care providers cannot be passive in this process but must lead it, if they are to show patients that they are worthy of public trust, and they must lead by example and from the front. This in turn requires commitment from the public, from politicians and from administrators to provide an infrastructure that facilitates safe care and to support those responsible for delivering it.

**Conflict of interest statement**

None declared.

**References**


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