Framework for analysing risk and safety in clinical medicine

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Adverse events are incidents in which a patient is unintentionally harmed by medical treatment. Awareness that these events lead to injuries, deaths during surgery, and missed cases of meningitis is tragic for both patients and staff, and may lead to complaints or litigation. Investigations usually focus on the actions of individual doctors and seldom examine the background to these events.

In a recent case of a patient whose bowel was perforated during surgery, examination of the medical records led to criticism of the surgeon. Only later did it emerge that the operation had been carried out in near darknes because of several equipment and power problems. Adverse events usually originate in a variety of systemic factors, including equipment, the task, the team, the environment, psychological factors, and the organisation. We present a framework that aims to encompass the many factors influencing clinical practice. It can be used to guide the investigation of incidents, to generate ways of assessing risk, and to focus research on the causes and prevention of adverse outcomes.

Adverse events

In spite of increased attention to quality, errors and adverse outcomes are still frequent in clinical practice. The risk of iatrogenic injury to patients in acute hospitals remains high, with studies reporting rates of 4-17%. A recent American observational study found that 45% of patients experienced some medical mismanagement and 17% suffered events that led to a longer hospital stay or more serious problems.

Even with the advent of clinical audit, comparatively few studies focus directly on the causes of adverse events. Notable exceptions include the confidential inquiries into maternal and perinatal deaths. Loachi argues that more attention must be paid to psychological and human factors in the nature, mechanisms, and causes of error—particularly the fact that liability to error is strongly affected by the context and conditions of work. Critical incident and organisational analyses of individual cases have illustrated the complexity of the chain of events that may lead to an adverse outcome. The root causes may lie in several interlocking factors, such as the use of locums, communication and supervision problems, excessive workload, and training deficiencies. Some fundamental features of a unit, such as poor communication within a team, may be implicated in a range of adverse clinical events.

Analysis of accidents

"Human factors" approach

Analyses of accidents in medicine and elsewhere have led to a much broader understanding of accident causation, with less focus on the individual who makes an error and more on pre-existing organisational factors that provide the conditions in which errors occur. This "human factors" approach, as it is called, is a hybrid discipline that focuses on the human component within complex sociotechnical systems. The assessment of accidents in large scale systems has acquired a high profile in industry, after such disasters as the fire at King's Cross underground station, Chernobyl, and the Piper Alpha platform. Reason's
model of organisational accidents was originally developed for use in complex industrial systems, and has now been adapted for medical settings.10-14 The method is essentially to examine the chain of events that leads to an accident or adverse outcome, consider the actions of those involved, and then, crucially, look further back to the conditions in which staff were working and the organisational context in which the incident occurred.

Active failures

Human decisions and actions play a major part in nearly all accidents. They contribute in two main ways—through active failures and latent failures.15 Active failures are unsafe acts or omissions committed by those whose actions can have immediate adverse consequences—pilots, air traffic controllers, anaesthetists, surgeons, nurses, etc. The term active failures includes:

- Action slips or failures, such as picking up the wrong syringe
- Cognitive failures, such as memory lapses and mistakes through ignorance or misreading a situation
- "Violations"—deviations from safe operating practices, procedures, or standards.

In contrast with errors, which are primarily from informational problems (forgetting, inattention), etc., violations are more often associated with motivational problems such as low morale, poor examples from senior staff, and inadequate management generally.

In industry, and to a lesser extent in medicine, defences exist to guard against human error and aid recovery from potential problems. In industry, this might be a fail-safe device to shut down a reactor; in medicine the warning sound of a monitor alerting an anaesthetist to falling blood pressure. A full account of these distinctions can be found in Reason's book.19

Latent failures

Latent failures stem from fallible decisions, often taken by people not directly involved in the workplace. In medicine, latent failures would be primarily the responsibility of management and of senior clinicians at those times when they are taking decisions on the organisation of their unit. Latent failures provide the conditions in which unsafe acts occur; these work conditions include:

- Heavy workloads
- Inadequate knowledge or experience
- Inadequate supervision
- A stressful environment
- Rapid change within an organisation
- Incompatible goals (e.g. conflict between finance and clinical need)
- Inadequate systems of communication
- Inadequate maintenance of equipment and buildings.

These are the factors that influence staff performance and may precipitate errors and affect patient outcomes.

Anatomy of an accident

The figure shows the anatomy of an organisational accident according to this scheme. The accident sequence begins with the negative consequences of management decisions and organisational processes. The latent failures thus created are transmitted along various organisational and departmental pathways to the workplace (operating theatre, ward) where they create the local conditions that precipitate errors and violations. The model presents the people who are directly involved as the inheritors rather than the instigators of an accident sequence, though this does not necessarily imply that blame is simply shifted "upstream."16

Organisational influences in medicine

In the above analysis a hierarchy of factors is involved in the cause, and therefore in the analysis, of adverse outcomes. To understand and prevent adverse events in medicine, it is necessary to delineate the conditions of work and associated latent failures. The oil, chemical, and nuclear industries have developed tools to analyse systematically organisational safety performance.17-18 Typically, there is a general framework with components specific to that industry. The background conditions that predispose to risk and unsafe practice are directly and routinely monitored to assess not the health of a patient but the health of a unit—the unit's vital signs. While there is certainly interest in organisational influences on medical practice, there is no current framework in medicine that attempts to integrate the whole hierarchy of factors and their components.

Framework for medicine

The framework described below was initially derived from Reason's model of organisational accidents.11-14 However, we also reviewed the major frameworks in use in the human factors field, such as the socio-technical pyramid of Hirst and Ratcliffe16 to ensure that all factors of potential relevance to medicine were included.17 Components for the major factors (see box) were primarily derived from medical publications on error, adverse outcomes, and risk management.11-15 Components for the major factors (see box) were primarily derived from medical publications on error, adverse outcomes, and risk management.11-15 Components for the major factors (see box) were primarily derived from medical publications on error, adverse outcomes, and risk management.11-15 Components for the major factors (see box) were primarily derived from medical publications on error, adverse outcomes, and risk management.11-15 The final framework incorporates many features that are of particular importance in medicine, such as patient characteristics, team working, and medicine's unique regulatory and economic context. The box shows the basic framework, and sets out the hierarchy of factors that may influence clinical practice.

Patients and staff as individuals

Clearly the condition from which the patient suffers is the most powerful direct predictor of clinical outcome. However, it has a further importance in this context in that adverse events are more likely when the patient is already seriously ill.18 Other factors, such as the patient's language and personality, may influence communication with staff and, in turn, the likelihood of
Factors that influence clinical practice

Institutional context
Economic and regulatory context
National Health Service Executive
Clinical negligence scheme for trusts
Organisational and management factors
Financial resources and constraints
Organisational structure
Policy standards and goals
Safety culture and priorities
Work environment
Staffing levels and skills mix
Workload and shift patterns
Design, availability, and maintenance of equipment
Administrative and managerial support
Team factors
Verbal communication
Written communication
Supervision and seeking help
Team structure
Individual (staff) factors
Knowledge and skills
Motivation
Physical and mental health
Task factors
Task design and clarity of structure
Availability and use of protocols
Availability and accuracy of test results
Patient characteristics
Condition (complexity and seriousness)
Language and communication
Personality and social factors

an adverse event. A number of staff factors, such as personality, experience, and training, may be influential. The confidence and assurance of staff may be of considerable importance, especially where junior staff are concerned; risk is attached to being nervous and unsure, and also to being overconfident and arrogantly self-assured.

Team, organisation, and community
Each staff member is part of a team, both within their unit and in the wider organisation of the hospital or community unit. The way individuals practise and their impact on the patient are constrained and influenced by other members of the team and the way the team members communicate with, support, and supervise each other. The team is affected in turn by management actions and by decisions made at a higher level in the organisation. The team’s environment is partly control-

led by senior clinicians and managers, although they too are constrained by a variety of circumstances. “Work environment” in our scheme includes such factors as staffing structures and levels, availability and maintenance of equipment, and education and training. The organisation, in turn, is affected by the external environment, including the commercial environment, financial constraints, external regulatory bodies, and the broader economic and political climate.

Specification of components
Each level of analysis can be expanded to provide a more detailed specification of the components of individual major factors. As an example (box), we have expanded the team level to show some of the characteristics that both published reports and analyses of individual events have found to be important in a team’s overall performance.

Team factors and their components

Verbal communication
Communication between junior and senior staff
Communication between professions
Communication between specialties and departments
Adequate handover

Written communication
Legibility and signatures of records
Adequate management plan
Availability of records
Quality of referral and discharge

Supervision and seeking help
Availability and responsiveness of senior staff
Clear definitions of responsibility
Willingness of junior staff to seek help

Structure of team
Skills mix of team
Balance of senior and junior staff
Balance of medical and nursing staff

Applications and development
The framework presented has a number of different uses with regard to the analysis of individual clinical events, the design and validation of risk assessment instruments, and in the design of studies to examine the relation of the many factors affecting clinical practice to the actual outcomes of patient care.

Formalising and extending analysis
Firstly, the framework enables researchers and risk managers to formalise and extend their analysis of adverse outcomes, or indeed of any incident that gives rise to concern. Instead of focusing simply on the actions of the staff involved and on patient characteristics, we can examine the whole gamut of possible influences. While this approach has already been applied productively by using interviews and checklists, much work still needs to be done to standardise procedures of data gathering and analysis and to validate the approach. The framework can be used to guide this process.

Systematic approach
Secondly, the framework enables a systematic and conceptually driven approach to the development of
organisational risk assessment instruments. Large scale organisational audit instruments cover many of the managerial areas of concern to us, but with comparatively little attention to the daily realities of clinical work and the lower level (but equally important) patient, task, staff, and team characteristics. They can also become increasingly unyielding, as they seek to cover every managerial process without trying to discern which factors are most important at a clinical level. The framework allows us to focus on key topics and also to consider what the most effective method of assessment might be.

The most important and most difficult problem to assess is the influence of these factors on patient outcome in empirical studies. Research on these broader factors on clinical practice does not exist, although several authors have pointed to the importance of systemic factors in organisational change.\textsuperscript{15} The extent, for instance, to which team performance and characteristics predict clinical outcomes has seldom been examined in formal studies, though team factors have been strongly implicated in studies of aviation safety and in some preliminary studies in medicine.\textsuperscript{15} 16

Error reduction strategies

The ultimate aim of every the most academic and theoretical approach is to help clinicians and patients to improve safety and the overall quality of care. Leape emphasised that safer practice can only come from acknowledging the potential for error and building in error reduction strategies at every stage of clinical practice.\textsuperscript{1} The framework enables the examination of the various influences on clinical practice at each stage, which in turn points to interventions and error reduction strategies of appropriate kinds. One reason for the limited impact of many quality and safety initiatives is that they rely on only one level of intervention—for example, staff training or tightening protocols—and give insufficient attention to other factors that influence clinical practice.

Safety needs to be addressed on the basis of a broad assessment of a system's health. Interventions may need to be targeted at several points in the hierarchy, an approach already followed in many industrial settings. Taking such a broad approach to the assessment and management of risk and the improvement of quality may seem difficult, even Utopian, but may be necessary if the level of iatrogenic injury is ever to fall below 4%.

We thank Jane Cartlidge, the late Anthony Hopkins, and Jonathan Seeker-Walker for comments on an earlier draft of this paper.

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Funding: The Clinical Risk Unit is funded by North Thames NHS Executive.

Conflict of interest: None.

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One hundred years ago
Puffin Island biological station

The days have long gone by when the accomplished naturalist was usually also a physician; yet the majority of medical practitioners still take a general interest in zoology and botany, and will be glad to have their attention called to the modest little report for 1896 and 1897 of the Puffin Island Committee for investigating the fauna and flora of the coast of North Wales, and for promoting the Sea Fisheries. The report, which is edited by Dr Philip J White, gives an account of the useful work which is being carried on with very slender resources by the writer and his friends. The greater part of the papers published in it deal with botanical subjects, but there are some notes on the Welsh fishery exhibits at the Imperial Institute, and a very interesting record of the excursions made by Mr Hughes in Ynys Seiriol (Puffin Island), while Sir William Turner describes a skeleton discovered there, which may perhaps be none other than that of St Seiriol himself. (BMJ 1896:526:742)