

# Patient safety: the need for an open and fair culture

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**ABSTRACT – Intermittent failures of healthcare delivery culminating in patient safety incidents are an international problem. Collecting information on incidents and where necessary analysing causes allows problems to be identified which, when resolved, can prevent future errors and incidents. To support incident reporting, it is vital to have an effective data collecting system and, in addition, an open and fair culture where those who report are supported and not punished. Where this has been introduced, large numbers of incidents are identified and solutions that improve patient safety can be implemented.**

**KEY WORDS:** adverse event reporting, medical error, open and fair culture, patient safety, safety culture

In 1999, the Institute of Medicine produced its report, *To err is human*,<sup>1</sup> which identified the scale of human error in US medical services. The reported deaths due to error cited in a report were between 44,000 and 98,000 per year. In his evidence to Congress, Dr Lucian Leape of Harvard Medical School said that the greatest impediment to error prevention was that 'we punish people for making mistakes'. This article asks whether there is a middle way between a punitive culture in which error is hidden and thus improvement precluded and, at the other extreme, a blame-free approach or 'a blunderer's charter' and consequent loss of public confidence in health services.

## Patient safety in the UK

Patient safety problems in the UK are similar to those in the USA. Approximately 10% of admissions to acute hospitals are associated with some form of

adverse event, half of which have a preventable element and one-third of which lead to serious morbidity or mortality.<sup>2</sup> In primary care, medical error occurs between five and 80 times per 100,000 consultations, and prescribing errors occur in 11% of all prescriptions.<sup>3</sup> The problem of error has been addressed in two Department of Health publications,<sup>4,5</sup> and culminated in July 2001 in the creation of the National Patient Safety Agency (NPSA)<sup>6</sup> which has a duty to collect data on adverse events and put in place safety solutions in the NHS in England and Wales.

To test the hypothesis that staff in the NHS would report when things went wrong, the NPSA conducted a pilot study on 18 NHS trusts over a six-month period. Staff were encouraged to notify adverse events and data were collected and analysed by the NPSA. A total of 28,998 incidents were reported (Fig 1),<sup>7</sup> the vast majority of which were 'near misses' in which no direct harm was done to patients. However, there were 100 incidents with a catastrophic outcome and 179 with major adverse outcomes. The extent to which the incidents had preventable elements was variable. Incidents occurred in many clinical areas and there were differences in the types of incidents reported in acute and mental health trusts.

The data suggest that if staff are supported in reporting incidents, a large number can be identified, creating the possibility for learning and the introduction of safer systems. Error is rarely an isolated event, but more often one element of a problem with the system.<sup>8</sup> Analysis of adverse events and the surrounding management arrangements by techniques such as root cause analysis has allowed system problems to be identified and changes to be implemented. An example of this has been the introduction of the NPSA's first Patient Safety Alert, requiring vials of concentrated potassium chloride to be removed from general ward areas and used only under highly regulated arrangements in high-dependency areas.<sup>9</sup> This system-wide solution prevents human error occurring on a general ward where vials of potassium and sodium chloride might otherwise be confused. Subsequent audit has shown wide uptake of this alert with a consequent decline in national sales of potassium chloride concentrate and an increase in the NHS purchase of pre-diluted solutions.

## Key Points

The collection of information on patient safety incidents is vital to identify failures and errors, which can subsequently be prevented

NHS staff will report incidents. Vital to this process is an efficient electronic data collecting system and an open and fair culture, which supports rather than punishes those who report

There is evidence from other industries and from healthcare in the USA and UK that data on incidents can be collected and safety improved

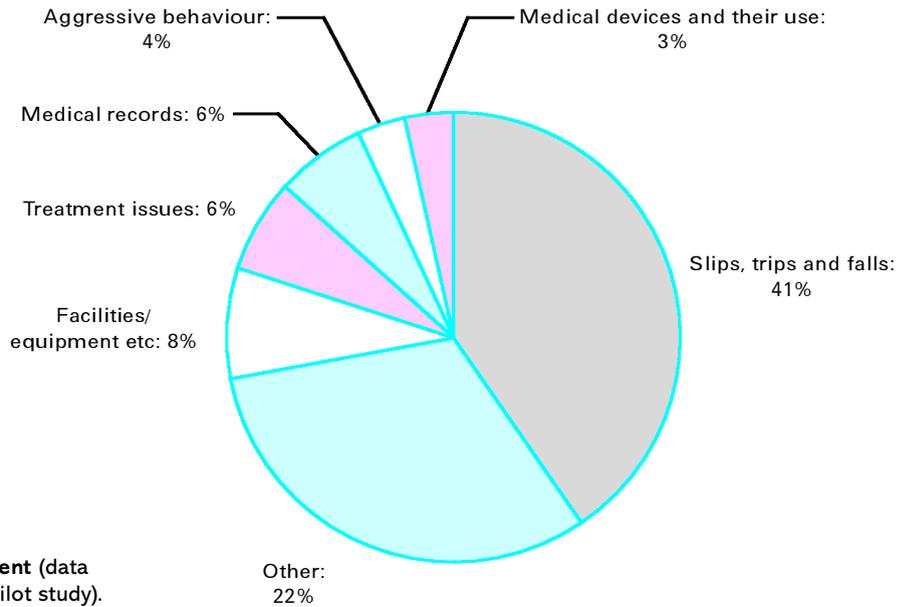


Fig 1. Categories of patient safety incident (data from the National Patient Safety Agency pilot study).

**An open and fair culture**

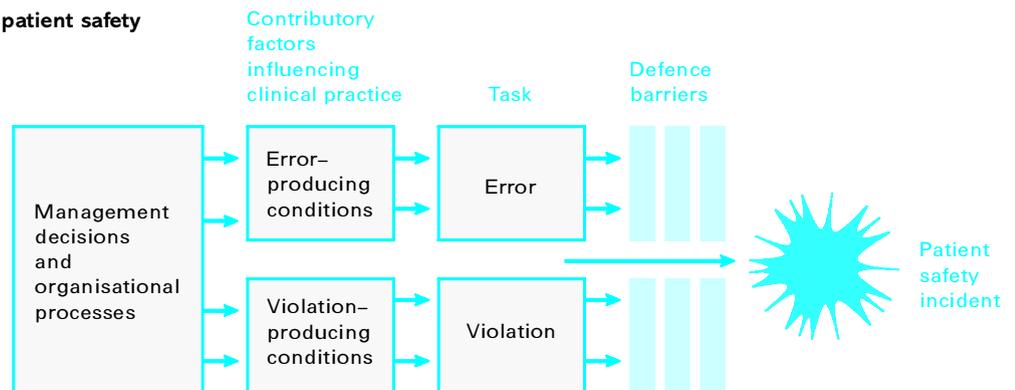
Any reporting system must operate within a culture that supports reporting, honesty and openness, yet reserves the right to use disciplinary processes in cases of malicious acts.<sup>10</sup> This ‘open and fair’ culture has the potential to create a virtuous circle in which more reporting occurs and consequently there is greater activity in service improvement to enhance safety. This in turn encourages further reporting, a progressive lowering in the tolerance of error and the raising of patient safety standards.<sup>11</sup>

The academic basis for this approach comes in part from an appreciation that individuals operate in a system which has inherent within it error-promoting conditions and circumstances which encourage violations of protocols, but has only variably effective back-up and safety net systems<sup>8</sup> (see Fig 2). Examples of such conditions include unsupported locum staff, perhaps working at night, or overbooked clinics. Under such circumstances errors and protocol violations occur. However, a catastrophic outcome is normally prevented by a defence

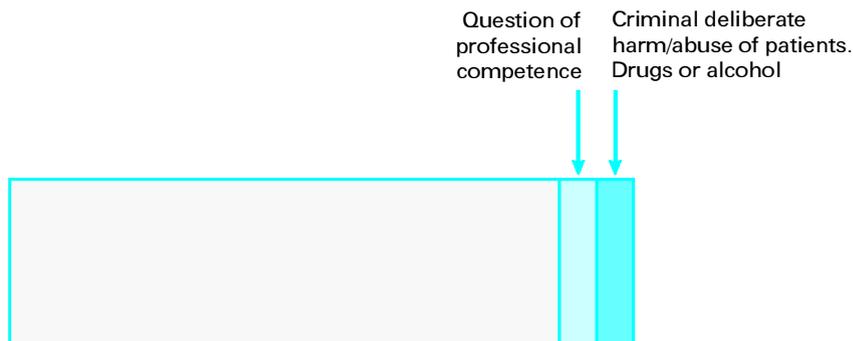
barrier, for example, a pharmacist checking a junior doctor’s prescription on the drug chart. On occasions, defence barriers fail and a patient safety incident occurs.

Even when it is clear that one person has made a mistake, professional incompetence is rare. The mistakes or errors by individuals can be of various types, ranging from the relatively common simple slip or lapse type of human error, through intentional rule violations with or without mitigating circumstances, to the much rarer occurrences of negligence where the expected standard of professional competence is not demonstrated, reckless conduct where significant risk is consciously disregarded, and finally to malicious or intentional acts of harm.<sup>12</sup> Embedded within all these categories may be occupational health factors such as undiagnosed alcohol abuse, or the consequences of historic failings in staff management (for example, a failure to address a dysfunctional team<sup>13</sup>). In NHS organisations policies are needed that differentiate the vast majority of simple errors from those of poor professional competence and those that cannot be treated in a blame-free manner but require discipli-

Fig 2. Factors that contribute to patient safety incidents (adapted from Ref 8).



**Fig 3. Categories of individual error**  
(reproduced from Ref 8).



nary processes (Fig 3). Such policies are illustrated by the Civil Aviation Authority statement of 2003 (Box 1).<sup>14</sup>

Policies need to take into account the disadvantages of traditional outcome-based disciplinary decision-making. With the outcome-based approach, a clinician who makes an error where no harm occurs is regarded as lucky, whereas a different clinician making the same error, but which culminates in patient injury, is considered blameworthy. Such disciplinary processes have a severity bias – the more severe the outcome, the more blameworthy the actor.<sup>15</sup> This approach risks punishing minor human error culminating in serious outcome more severely than reckless behaviour culminating in a near miss.

### Interrelationship of performance management processes

The successful creation of a fair and open culture requires alignment of many processes. Local disciplinary processes including suspension, protracted investigation and possible termination of employment have to become more sophisticated. There needs to be clear concordance with approaches taken by professional regulatory bodies, such as the General Medical Council, the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) and the Royal Pharmaceutical Society, as well as with wider bodies such as the police and crown prosecution service. The current arrangements for dealing with medical negligence are under review,<sup>16</sup> with one of the intended outcomes being to create a ‘culture of candour’. Government proposals on corporate manslaughter and corporate killing will also need to link in with the concept of an open culture in healthcare. The USA has attempted to address some of these issues by giving legal privilege to patient safety information.

One of the important influences on the culture is the response of the media. With the larger number of incidents reported to a national system and the regular publication of data on adverse events, a wider appreciation of the frequency of medical error and adverse events may make it possible to dilute the powerful nature of individual human interest stories associated with medical errors.

Professional bodies and the wider society can only be expected to support the approaches espoused in the phrase ‘open and fair culture’ if it is generally fair to all parties. Thus an

absence of blame is not synonymous with an absence of accountability. Individuals who make errors and report them need to be the first to strive to improve the system of care in which they function, to seek additional training and if necessary to relocate to an area of work more suited to their skills and competence. Patients and carers must also be informed and involved in investigation and solution finding.

#### Box 1. Extracts from the Statement on the Mandatory Occurrence Reporting Scheme by the Chairman of the Civil Aviation Authority of England.<sup>14</sup>

##### *Confidentiality of reports*

It is fundamental to the purpose of the Scheme that the substance of reports should be disseminated where necessary in the interest of flight safety. Without prejudice to the proper discharge of its responsibilities in this regard, the Authority will not disclose the name of the person submitting the report or of a person to whom it relates unless required to do so by law or unless, in either case, the person concerned authorises disclosure.

Should any flight safety follow-up action from a report be necessary, the CM will take all reasonable steps to avoid disclosing the identity of the reporter or of those individuals involved in the reportable occurrence.

##### *Assurance regarding prosecution*

The CM gives an assurance that its primary concern is to secure free and uninhibited reporting and that it will not be its policy to institute proceedings in respect of unpremeditated or inadvertent breaches of the law which come to its attention only because they have been reported under the scheme, except in cases involving dereliction of duty amounting to gross negligence.

##### *Possible action by employers*

Where a reported occurrence indicated an unpremeditated or inadvertent lapse by an employee, the CAA would expect the employer to act responsibly and to share its view that free and full reporting is the primary aim, and that every effort should be made to avoid action that may inhibit reporting. The CM will, accordingly, make it known to employers that, except to the extent that action is needed in order to ensure safety, and except in such flagrant circumstances as are described under the heading ‘Prosecution’ above, it expects them to refrain from disciplinary or punitive action which might inhibit their staff from duly reporting incidents of which they may have knowledge.

CM = Chairman.

## Improving patient safety

It is possible to identify high reliability organisations which have less than their fair share of accidents. They are characterised by the ability to recognise human fallibility. These organisations are constantly preoccupied by the possibility of failure and use a systems approach to avert errors.<sup>8</sup> Conversely, 'a vulnerable system syndrome' is a category of organisational pathology characterised by the self-perpetuating elements of blaming frontline individuals, denying the existence of systemic error provoking weaknesses, and the blinkered pursuit of productive and financial indicators.<sup>17</sup>

The link between fallibility and patient outcome has been illustrated in the specific area of paediatric cardiac surgery. In a human factors observational study, there was a close correlation between either a major adverse event, or the total number of minor events, and the patient-specific outcomes of death or near miss.<sup>18</sup> In this study there was an overall mortality of 6.6% with a death and or near-miss rate of 24.3%. This study suggests that focus on adverse events and near misses, as well as the human factors which contribute to them, is likely to save lives.

The ultimate proof of benefit of an open and fair culture will only come if large numbers of incidents are notified and if it can be shown that, over time, the number with a major or catastrophic outcome gradually declines. This will be hard to demonstrate since at least for a period there may be what is termed the 'confessional peak'. During this period, it is likely that there will be a rise in notifications of more serious events as confidence in the system grows. There is evidence to suggest that in the medium term safety will improve. Major airline reporting systems have found that, over a five- to ten-year period, there was an inverse relation between the growing number of incidents reported and a reduction in the number of serious incidents. Within healthcare, a very active monitoring system of adverse events in Wimmera Base Hospital in Australia demonstrated a fall in more serious events over an eight-year period.<sup>19</sup> The agreement in the USA to offer legal privilege for patient safety data has provided a major opportunity to improve patient safety there. The incident reporting systems at the Veterans' Administrations Hospitals have taken as their premise the maxim 'you can't fix what you don't know about'. These systems have resulted in a marked increase in reporting and incident investigation.<sup>20-23</sup>

## Conclusion

Traditional methods of intensive, very public investigation into specific incidents and costly medico-legal cases have had little systematic impact on improving patient safety across the NHS. The relatively novel concept of creating an atmosphere where staff volunteer information on adverse events and 'own up' when mistakes occur offers a unique opportunity for improving patient safety. The appreciation that individuals participate within a system of care allows managers and those experienced in process and system design to engage in improving safety. The human factors approach, which reviews how humans and the

system interact, can provide an opportunity for creative thought on how to minimise the scope for mistakes within the complex arrangements involved in delivering care.

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