HEALTH POLICY REPORT

PATIENT SAFETY

Understanding and Responding to Adverse Events

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An adverse outcome for a patient is difficult, sometimes traumatic, for all concerned. Such incidents pose considerable challenges to an organization, both in terms of the need to respond intelligently to their occurrence and in terms of the need to deal with their aftermath. The challenge is to find a way forward that provides the necessary support for the people involved while ensuring that the lessons of the incident are learned both by individual staff members and by the overall organization. In this article, I address two broad themes: first, how to investigate clinical incidents and learn useful lessons from them, and second, how to support the patients, families, and staff members who are involved.

HUMAN ERROR AND SYSTEMS APPROACHES IN MEDICINE

In most high-risk industries, learning from accidents and near-misses is a long-established practice and a cornerstone of safety analysis and improvement. Aviation accidents, for instance, are exhaustively investigated, and the lessons learned are disseminated widely, with important changes made mandatory by regulatory authorities. In contrast, learning within the health care sector, with some notable exceptions, has generally been fragmentary and uncertain.[1,2] There are a number of methods of investigation and analysis available in health care, but they tend to be underdeveloped in comparison with the methods available in industry. In the United States, the most familiar is the approach of root-cause analysis, developed by the Joint Commission on Accreditation of Healthcare Organizations, an intensive process with origins in "total quality management" approaches to health care improvement.[3] The Veterans Health Administration has developed a highly structured system of triage questions that is being disseminated throughout the system.[4] In Britain, my colleagues and I have developed a method based on James Reason's model of organizational accidents and a framework of contributory factors.[5,6] The protocol describing this method provides a step-by-step guide to the systematic investigation and analysis of any clinical incident.

The purpose of such analyses is often framed as the need to find the root cause of an adverse incident, tracing it back over a series of events to some fundamental problem. However, this perspective is misleading in two important respects. First, it implies that the incident has a single root cause, or at least a small number of causes, but this is an oversimplification. Usually, a chain of events and a wide variety of contributory factors lead up to the event. Second, it implies that the purpose of the investigation is simply to find out what caused the incident. However, while determining a cause is important, it is not the final goal. The real purpose is to use the incident to reveal gaps and inadequacies in the health care system. From this perspective, the investigation is proactive and forward-looking. For these reasons, we prefer the approach called "systems analysis" over "root-cause analysis."

ANALYSIS OF CLINICAL INCIDENTS

Studies of accidents in industry, transportation, and the military have broadened the understanding of accident causation, reducing the focus on the individual persons who may have made an error and aiming it instead on preexisting organizational factors. The theory underlying the approach described here is based on Reason's organizational-accident model.[7] Reason's essential insights are as follows. Incidents and accidents are usually preceded by some kind of "unsafe act," in which a person makes an error or mistake. However, to understand how this mistake occurred, it is necessary to look further, back to the "error-producing conditions" that led to the unsafe act and to "latent failures," or the decisions made by management and others that may have had a bearing on the outcome. We have extended and adapted Reason's model for use in health

care by developing a broad framework of contributory factors that can affect clinical practice and that includes both error-producing conditions and latent failures[8] (Table 1). The framework essentially summarizes the major influences on clinicians in their daily work and the systemic contributions to adverse outcomes, or indeed to good outcomes.

CARE-MANAGEMENT PROBLEMS

IDENTIFICATION

Once the sequence of events is clear, there are three main considerations: the care-management problems identified among the events, the clinical context of each of these problems, and the factors contributing to their occurrence.

The first step in any analysis is to identify "care-management problems," which broadly speaking are the health care equivalent of Reason's unsafe acts. Care-management problems are actions or omissions by staff members in the process of care. They may be simple mistakes, such as picking up the wrong syringe; lapses of judgment; omission of a procedure because of forgetfulness; or, in rare cases, deliberate departures from safe operating practices, procedures, or standards (Table 2). Care-management problems have two essential features: first, they involve care that deviates from safe limits of practice, and second, the deviation leads, directly or indirectly, to an adverse outcome for the patient.

CLINICAL CONTEXT AND PATIENT-RELATED FACTORS

For each care-management problem identified, the investigator should record the salient clinical events or the condition of the patient at the time (e.g., heavy bleeding or decreasing blood pressure). The investigator also needs to record other patient-related factors that may have affected the process of care (e.g., great distress on the part of the patient or an inability to understand clinicians' instructions).

CONTRIBUTORY FACTORS

Having identified the care-management problem, the investigator should then consider the conditions in which errors may occur within the overall organ-

Table 1. Framework of Factors Influencing Clinical Practice and Contributing to Adverse Events.*

Framework	Contributory Factors	Examples of Problems That Contribute to Errors
Institutional	Regulatory context Medicolegal environment	Insufficient priority given by regulators to safety issues; legal pressures against open discussion, preventing the opportunity to learn from adverse events
Organization and management	Financial resources and constraints Policy standards and goals Safety culture and priorities	Lack of awareness of safety issues on the part of senior management; policies leading to inadequate staffing levels
Work environment	Staffing levels and mix of skills Patterns in workload and shift Design, availability, and maintenance of equipment Administrative and managerial support	Heavy workloads, leading to fatigue; limited access to essential equipment; inadequate administrative support, leading to reduced time with patients
Team	Verbal communication Written communication Supervision and willingness to seek help Team leadership	Poor supervision of junior staff; poor communication among different professions; unwillingness of junior staff to seek assistance
Individual staff member	Knowledge and skills Motivation and attitude Physical and mental health	Lack of knowledge or experience; long-term fatigue and stress
Task	Availability and use of protocols Availability and accuracy of test results	Unavailability of test results or delay in obtaining them; lack of clear protocols and guidelines
Patient	Complexity and seriousness of condition Language and communication Personality and social factors	Distress; language barriers between patients and caregivers

* The framework is based on Vincent et al.[8]

Table 2. Examples of Care-Management Problems.

Failure to monitor, observe, or act
Delay in diagnosis
Incorrect assessment of risk (e.g., risk of suicide or self-harm)
Loss of information during transfer to other health care staff
Failure to note faulty equipment
Failure to carry out preoperative checks
Deviation from an agreed protocol (without clinical justification)
Failure to seek help when necessary
Use of incorrect protocol
Treatment given to wrong body site
Wrong treatment given

izational context. These are the contributory factors. For each care-management problem, the investigator uses the proposed framework based on Reason's model (Table 1), both during interviews and afterward, to identify the factors that led to the care-management problem. A variety of factors may be relevant. Individual factors may include lack of knowledge or experience on the part of particular staff members. Task factors may include the unavailability of test results or protocols. Team factors may include inadequate supervision or poor communication among staff members. Factors related to the work environment may include heavy workloads, inadequate staffing, or limited access to vital equipment.

Any combination of these factors can contribute to the occurrence of a single care-management problem. The investigator should differentiate between contributory factors that were relevant only on the particular occasion in question and those that are long-standing features of the organization. For instance, a failure of communication between two midwives may have contributed to a care-management problem. If such a failure of communication seldom occurs, then it may not have any implications beyond the specific care-management problem in question and may not need to be considered further. If, on the other hand, such a failure is common, then the incident clearly reflects a wider, systemic problem that needs to be addressed.

THE INVESTIGATION PROCESS

Information can be gleaned from a variety of sources. Case records, statements from witnesses, and any other relevant documents should be reviewed. Structured interviews with involved members of the staff are then undertaken to establish the sequence of events, the main care-management problem, and the contributory factors, as perceived by each staff member. Interviews should include the following key questions: "What happened?" (which provides information on the outcome and chronology), "How did it happen?" (which helps identify the care-management problem), and "Why did it happen?" (which helps identify contributory factors).

Although a considerable amount of information can be gleaned from written records, interviews with the people involved are the most important method of identifying contributory factors. This is especially true if the interview explores these factors systematically and thus allows each interviewed staff member to collaborate in the investigation. In the interview, the story and "the facts" are just the first stage of information gathering. The investigator should also encourage the staff member to identify both the care-management problems and the contributory factors, an approach that greatly enriches both the interview and investigation. Of course, the incident should also be discussed with the involved patient and his or her family, and they should be informed of the results of the inquiry. The potential contribution of patients to such investigations has yet to be properly explored.

Investigations based on this method have been conducted in hospitals, primary care settings, and mental health units. The protocol may be used in a variety of formats and may be used by individual clinicians, researchers, or risk managers or by clinical teams. In cases of serious incidents, a team of investigators with different skills and backgrounds may be assembled; otherwise, often only a risk manager or an individual clinician is needed. A clinical team may use the method to guide and structure reflection on an incident and to ensure that the analysis is full and comprehensive. The team approach is also useful for promoting understanding of the protocol itself and for introducing systems-oriented analysis. Although reading about systems analysis is helpful, actually analyzing an adverse incident brings the method to life.

The contributory factors that reflect general

problems in a unit should be the targets for change and systems improvement. When obvious problems are identified after a single adverse incident, action may be taken immediately; when more substantial changes are being considered, other sources of data (e.g., routine audits and outcome data) and the results of other incident analyses should also be taken into account. Recommendations may be made in a formal report, but it is essential that the people responsible for implementation are specified and that the recommendations are followed up with monitoring of the actions taken and of the outcomes.

THE EFFECT OF ADVERSE INCIDENTS ON PATIENTS AND FAMILIES

Patients are often in a vulnerable psychological state, even when the diagnosis is clear and the treatment goes according to plan. Even routine procedures and normal childbirth may produce posttraumatic symptoms.[9,10] Therefore, when patients experience harm or an unexpected event, their reaction is likely to be particularly severe. Patients and relatives may suffer in two distinct ways after an adverse outcome: they may suffer first from the incident itself and second from the manner in which the incident is subsequently handled. Many people harmed by treatment suffer further trauma if the incident is handled insensitively or inadequately. Conversely, when staff members come forward, acknowledge the damage, and take the necessary corrective actions, the overall effect on patients can be greatly reduced.

Medical injuries differ from most other injuries in two important respects. First, patients are unintentionally harmed by the people in whom they have placed considerable trust, so their reaction may be especially powerful and complex. Second, they are cared for by members of the same profession, and in some cases the same clinicians, as those who were involved in the injury itself. They may be very frightened by what has happened and have a range of conflicting feelings about those involved, even when staff members are sympathetic and supportive.[11,12]

A patient's initial reactions to a medical injury are most likely to be fear, loss of trust, and a feeling of isolation. Traumatic and life-threatening events produce a variety of symptoms in addition to any physical injury. Anxiety, intrusive memories, emotional numbness, and flashbacks are all common sequelae and are important components of posttraumatic stress disorder.[13] The full effect of most incidents becomes apparent only in the long term. A perforated bowel, for example, may require a series of additional operations and additional time in the hospital. The long-term consequences may include chronic pain, disability, and depression, with deleterious effects on family relationships and the ability to work. Whether a patient who has been harmed actually becomes depressed and to what degree depends on the severity of the injury; the support he or she has from family, friends, and health professionals; and a variety of other factors.[14]

When a patient dies, the trauma to his or her family members may be very severe, particularly if the death was potentially avoidable.[15] By analogy, many people who have lost a spouse or child in a road accident continue, for years afterward, to ruminate about the accident and about what could have been done to prevent it. They are often unable to accept, resolve, or find any meaning in the loss.[16] Likewise, relatives of a patient whose death is sudden or unexpected may find the loss very difficult to bear. If the death was avoidable, in the sense that poor treatment played a part in it, relatives may face an unusually traumatic and prolonged bereavement.

CARING FOR PATIENTS HARMED BY TREATMENT

The trauma to patients harmed by treatment can be greatly reduced if certain basic principles[12] are borne in mind. Clinicians should believe people who say their treatment has harmed them, at least in the first instance. Given the scale of potential harm from medical treatment, such a claim should at least be considered seriously. The patient may have information the caregivers lack. If the patient's concern is groundless, a complete and sympathetic explanation is essential therapy. Being ignored can be distressing to a patient and may delay remedial treatment. Caregivers should also be honest and open about the incident and about what is being done to prevent a recurrence. The lack of an explanation, and of an apology if appropriate, may be experienced by the patient as extremely punitive and distressing and may be a powerful stimulus to complaint or litigation.[17] Clinicians should ensure continuity of care and maintain the therapeutic relationship. After an injury, patients and families need more support, not less, although both patients and clinicians may feel a natural wish to distance themselves from one another after an adverse event.

Patients should be asked specific questions about emotional trauma, especially with regard to any anxieties they may have about future treatment. Psychological treatment may be needed when reactions are severe. In addition, the institution should provide practical and financial help quickly. A relatively small sum of money can make a substantial difference after an injury when it is spent wisely on child care or disability aids or when it is used to alleviate temporary financial hardship.

The initiatives of individual clinicians and risk managers must be strongly supported by policies and directives at the institutional level. It is unreasonable to expect a clinician to be honest and open about problems that have occurred if he or she anticipates later facing sanctions from senior management. All health care organizations need a strong, proactive policy of active intervention and monitoring of patients who have been harmed by treatment. Clearly, there is an ethical imperative to inform patients of adverse outcomes, but the fear of legal action and media attention can act as a major disincentive to do so. Nevertheless, organizations that have followed the path of open disclosure have not been overwhelmed by lawsuits and have argued strongly for others to follow their example.[12,18]

THE EFFECT OF ADVERSE INCIDENTS ON STAFF

The aftermath of an adverse event can also have profound consequences on the staff members involved, particularly if an individual member is seen, rightly or wrongly, as primarily responsible for the outcome. After making a mistake, caregivers may experience shame, guilt, and depression; litigation and complaints impose an additional burden. In some cases, doctors or nurses may become very anxious about practicing clinical medicine, seek out a specialty with less direct patient contact, or abandon medicine entirely.[19,20] Wu expresses the typical reaction of the clinician in such a situation, whom he aptly describes as "the second victim," thus:

> Virtually every practitioner knows the sickening feeling of making a bad mistake. You feel singled out and exposed — seized by the instinct to see if anyone has noticed. You agonize about what to do, whether to tell anyone, what to say. Later, the event replays itself over and over in your mind. You question your competence but fear being discovered. You know you should confess, but dread the prospect of potential punishment and of the patient's anger.[21]

The reaction of the patient and his or her family may be hard to bear, especially if the outcome is severe and if there has been close involvement between the patient and the clinician over a long period. The reaction of colleagues, whether supportive or defensive and critical, may be equally powerful. Clinicians, like everyone else, vary in temperament, resilience, and attitude with respect to their own errors. To a highly self-critical person, errors and mistakes may be particularly disturbing. The high personal standards of excellent clinicians may in fact make them particularly vulnerable to the consequences of mistakes. This tendency is generally reinforced during medical training; the culture of medical school and residency implies that mistakes are unacceptable and, when serious, that they point to a failure of effort or character.[22]

SUPPORTING STAFF AFTER ADVERSE INCIDENTS

News of a major adverse incident spreads rapidly. Caregivers who are directly involved, in addition to feeling anxious and ashamed, may also feel isolated. With other staff members, too, a number of things can be done to limit the damage and support those involved.

Clinicians should be open about error and its frequency. Senior staff members' talking openly about past mistakes and problems is particularly effective. The need for support is not a sign of weakness. Clinicians are trained to be resilient, but almost all are grateful for the support of colleagues when a problem occurs. For a particularly profound reaction, perhaps, for example, to the death of a child, formal psychological intervention may be valuable.[23,24]

Clear guidelines for discussing errors with patients should be backed up by an institutional policy on open disclosure. In addition, the institution should offer training in the difficult task of communicating with patients and families in the aftermath of an adverse event.[25] Basic education in the law and the legal process surrounding medical incidents should also be offered and may reduce some of the anxiety about possible legal action.

CONCLUSIONS

The learning and organizational change that can follow the systematic and thoughtful investigation of an incident have not been given sufficient attention in health care. Such investigations are only one component of general quality and safety strategies, but they are a vitally important one. The patient's perspective has been neglected in patient-safety strategies,[26] and yet few things are more destructive to public trust and staff morale than the failure to respond positively to the patients and staff involved in adverse events. Systems analyses and support for patients and staff should be absolute priorities in any risk-management and safety strategy.

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