Quality in Health Care 1995;**4**:90–96

Clinical risk management: experiences from the United States

Don Harper Mills, G E von Bolschwing

While a major goal of clinical risk management today is to improve patient care, the concept and development of risk management generally have evolved out of the litigation process and continue to do so. How should injuries that lead to litigation be compensated, managed or prevented, or both? The answers depend on the risks involved: What is the risk of injury? How severe are injuries when they occur? Can they be modified once they occur? Do the modifications impart cost savings? Can the injuries be prevented in the first place? Does the cost of prevention exceed the value of the injuries themselves? Do social costs have to be considered? These questions apply to any industry in which injury litigation is a recurring theme. Health care is a prime example. Studies in California[1] and New York state[2] have shown that injuries and adverse outcomes from health care occur often enough to warrant concern even without litigation: about 4% of patients in acute care hospitals incur injuries and adverse outcomes of medical and clinical management sufficient to cause substantial financial impact through prolonged hospital stay, readmission, surgery, reoperation, special clinical treatment, or even death. About a quarter of these outcomes occur under circumstances that could lead to successful litigation in the United States should the affected patients or their relatives decide to sue. That only a small percentage of them actually sue (about 10%) is of little solace, because the cost of their lawsuits is already a social burden, and the situation could get worse. Since we cannot always change or control social structure, including the tendency to sue, solutions will have to be found in antecedent factors, hence the need for risk management.

Published technical books describing standard risk management structure and function abound. We will not duplicate those efforts; rather, we want to tell of our personal experiences as we have participated in the growth and development of risk management related to health care in the United States. Most of these experiences have not previously been published, and we feel they may be particularly germane to the United Kingdom at a time when risk management is just beginning to become an important factor in health care.

Professional Risk Management Group, Long Beach, CA 90815, United States
Don Harper Mills, director
G E von Bolschwing, attorney

Correspondence to:
Dr D H Mills, Professional Risk Management Group, 911 Studebaker Road, Suite 250, PO Box 15398, Long Beach, CA 90815, United States

History of risk management in the United States

We found that the focus of risk management at any time depends greatly on the content of current lawsuits. Before the 1960s most litigation concerning medical injury involved complaints against hospitals and their nursing staff (as opposed to their medical staff). Doctors were rarely the primary targets because the legal profession was not sufficiently sophisticated to confront the judgmental decision making that forms the basis of clinical management. Thus, when a risk management programme was developed for the hospital industry in the mid-1950s attention was directed towards patients' falls, treatment errors, patient misidentifications, retained operative sponges, and the like.[3] Since the largest hospital litigation losses at that time arose from retained sponges, initial efforts were devoted to that problem. Analysis indicated that the methods of counting sponges during surgery was ineffective, even though universally followed. A third sponge count at the time of skin closure was recommended and adopted and was followed by a precipitous drop in retained sponges and resultant claims. Interestingly, a similar analysis of instrument counting procedures concluded that, although adding a terminal count might prevent retention of some instruments, prolonging surgery unduly would be counterproductive. Balancing risks and benefits therefore became a key element in the development of clinical risk management.

INCIDENT REPORTING SYSTEMS

Except for reported claims, there was no database to help to determine where the management problems lay and which of these was important. One of the first incident reporting systems was inaugurated for the California Hospital Association. It merely asked nurses to report unusual events occurring to and around patients – that is, events that were inconsistent with good nursing management. The resulting database disclosed that patients' falls out of bed were much too frequent. Bed rails were purchased, but these proved more of a hazard than a solution. Patients determined to get out of bed would do so anyway, only to find that the drop to the floor was much farther than before, producing more severe injuries. Lowering the beds so that the falls would be less severe only aggravated the nurses, who had to care for patients in stooping positions. Nurses' complaints of back strain led to the creation of high-low beds, which allowed the nurses to crank up the beds for attending to patients and then crank them down to avoid excessive injuries from falls. This development was the forerunner of the electrically controlled beds we have today.

Another problem at the time was losing patients when they were transported to radiology, surgery, or some other specialised care unit. Patients became separated from their

charts (medical records), and, because they were often sedated no one could determine where they belonged. The frequency of lost patients was recorded by the incident reporting system and led to the introduction of wrist band identifiers. But patients going to surgery still became lost occasionally because anaesthetists would cut off the wrist bands to facilitate vascular access. The bands were subsequently loosened to avoid that necessity, and anaesthetists were counselled on the need for retaining them.

The incident reporting system also became a product of litigation in the United States, serving as an early warning system for potential claims, as well as for finding problems before they were bad enough to cause claims. Injuries sustained by patients falling out of bed prompted lawsuits and solutions. Losing patients in the hospital rarely caused injuries but needed to be avoided; similarly, treatment errors rarely caused injuries, but they too needed to be avoided just to prevent an unusual toxic or allergic reaction. From unpublished data in our files for 1980–2, the incidence of treatment errors was 0·54/100 patient days in participating California hospitals whereas that of actual treatment reactions was only 0·03/100 patient days. According to the medical insurance feasibility study in California in 1977, 85% of drug reactions were transient in nature.[1]

As malpractice litigation increased during the '60s and early '70s, attorneys representing patients became more experienced in managing issues of clinical care and the emphasis on liability shifted from the hospital and nursing staff to primarily doctors. But during this transition, risk management programmes lagged behind, continuing to address problems associated with hospitals and nursing and rarely focusing on those associated with doctors. Doctors allowed hospitals to accumulate data about non-clinical issues but often resisted the development of information about their own clinical conduct, even though they had functioning tissue committees and surgical case review committees. (These committees of medical staff review appropriateness of medication for surgery and complications.) It was not until the mid-1970s, with the California medical insurance feasibility study,[1] that the development of databases involving clinical problems became a reality. The concept that generic screens could flag adverse outcomes made this transition possible. This study measured the frequency of patients' injuries and adverse outcomes arising from healthcare management, much as did the New York study in the late '80s.[2] To facilitate the search for these injuries and outcomes special criteria were developed to screen patients' charts. Of the 20 original criteria, only 11 proved necessary to identify virtually all of the injuries and outcomes: criterion 1, admission in the previous six months; criterion 3, admission for conditions suggesting prior failure or adverse result of treatment; criterion 4, trauma incurred in hospital; criterion 8, return to surgery; criterion 10, unplanned removal of an organ or part during surgery; criterion 11, acute myocardial infarction during this admission; criterion 12, wound infection; criterion 13, neurological deficit occurring during admission; criterion 14, death in hospital; criterion 15, length of stay exceeding the 90th percentile for the region; and criterion 20, any other unlisted complication of clinical management.

Generic screens were intended to serve as indicators for the possibility that adverse outcomes from medical or clinical management had occurred. That is, if a patient was returned to surgery, that chart needed to be examined to see what adverse outcome, if any, was responsible (such as postoperative infection, postoperative haemorrhage, or some other complication related to the previous surgical management). Also, the transfer of a patient from a non-intensive unit to an intensive care unit creates the presumption that something might have gone wrong; therefore, the chart should be examined to see what diverse outcome, if any, was responsible. That a patient's chart was flagged by a generic screen, therefore, did not mean that an actual adverse outcome had occurred; it merely meant that certain outcomes might be present and the chart needed to be examined for those possibilities. Yet a tendency developed in the United States to regard return for surgery and unanticipated transfers to intensive care units as ultimate adverse outcomes.[4] In our opinion this was accumulation of ineffective information. These criteria identified 16 486 occurrences (79%) in 20 864 charts; yet, only 7% of these occurrences were shown by peer review to represent clinically caused injuries and adverse outcomes. Such a high sensitivity/low specificity may be good enough for research to establish baselines, but it is not efficient enough for prospective risk management. If a patient returned to surgery for peritonitis after an appendicectomy the return would be reported first on the generic screen, later followed by an examination of that chart to see if an adverse outcome was responsible. Taking the case that it was a burst appendiceal stump, the case should be added to other similar cases which could later be reviewed as a group. If this hospital had only one burst stump over 12 months, that episode would not be considered important in terms of quality management. However, if there had been six such occurrences a surgical problem probably existed and deserved attention with a view to prevention. The development of this scenario required three stages: a flagging system, a chart analysis for adverse outcomes, and the audit of the group of adverse outcomes. Today, with the utilisation of more refined indicators by departments, the data gathering can be simplified by combining the first and second stages into a

Doctors ... often resisted the development of information about their own clinical conduct ...

single outcome measuring system. The initial flagging system should have identified the burst stump directly.

OVERCOMING RESISTANCE TO REPORTING

We encountered resistance in expanding risk management from hospital and nursing care to include outcomes of clinical management. Doctors not only became protective when their own information was being screened for quality analysis and management but they also tended to find many reasons for not reporting their own adverse outcomes. We therefore chose nurses to do this reporting. They were already proficient in reporting non-clinical problems on their old incident report, and since clinical reporting did not involve assessment, cause, or conduct they were fully capable of identifying current adverse outcomes sufficiently to comply with our reporting requirements. But knowing that doctors themselves tended not to report these outcomes, nurses complained that they were being required to do the work of others. They felt that doctors should do their own reporting. So we had to meet with doctors and nurses together to try to solve the riddle of data gathering on a reasonably concurrent basis. We established hotlines for reporting incidents by telephone. Doctors preferred this method to writing reports, particularly when the outcomes were serious. We found that doctors used the hotline primarily to find out what they should do. Thus we piggybacked the data gathering system on requests for information. Of course, additional time and effort are required for hospitals to maintain adequately trained staff to respond to such hotline calls, but where this has been done risk management has improved, both for the care of injured patients, and for developing information for protecting yet uninjured patients. Once the nurses realised that doctors were participating in the reporting system, albeit only orally, they became less reticient in complying with the written reporting requirements.

Managing injured patients

An injured patient is one who has experienced some form of injury or adverse outcome either as a result of custodial or nursing management or as a result of clinical practice. Once a mechanism to identify such patients is in place, the next action is to minimise the injuries. For example, if a patient fell and sustained a fracture we need to evaluate that fracture and ensure appropriate management; if a patient developed a postoperative deep venous thrombosis and a pulmonary embolism we need to ensure that appropriate anticoagulation has been undertaken to avoid the next, and possibly fatal, embolism. Someone should monitor the process of identifying and managing these adverse outcomes and, when necessary, obtain clinical consultation to ensure that appropriate action is taken. Many hospitals in the United States did not have ongoing systems to carry out these functions. As early as 1963 a review of 1000 malpractice cases disclosed that at least 5% of adverse outcomes were worsened by subsequent problems with management (such as inadequate management of postoperative wound infections).[6] These additional complicating factors have to be avoided.

In addition to minimising injuries, we need to tell patients what happened and what will be done. Whether an adverse outcome is a result of bad clinical care or merely a calculated risk of modern medicine, doctors tend to become silent and defensive when it occurs. They have been told over the years not to confess to patients for fear of litigation, and therefore they tend not to talk to patients at all about adverse outcomes. This is counterproductive. In the United States many injured patients go to lawyers simply to find out what happened – an unnecessary and costly investigative approach. It would be much better for doctors to sit with their patients and talk about what happened and what will be done medically and surgically. If liability is involved, now is the time to begin to consider some form of compensation. But the purpose of this communication is not for litigation, it is primarily to satisfy patients' clinical uncertainty. Yet, communications such as this will go far to preclude expensive litigation.

MANAGING MALPRACTICE CLAIMS

Decades ago all malpractice claims were defended with determination. Few claimants succeeded because attorneys representing them were incapable of ferreting out the real issues; obtaining medical advice and experts; and proving negligence, causation, and damages; but they have learnt well subsequently. Total resistance is no longer an appropriate manoeuvre for claims or risk management, particularly for public entities (county or state hospitals in the United States). These institutions may be embarrassed by such tactics taken against the very population they serve. Serious and meritorious claims can and should be resolved, often without entering into formal litigation.

Total resistance is no longer an appropriate manoeuvre for claims or risk management

Managing claims before or during litigation requires risk managers to utilise in house consultations. For instance, cases involving adverse outcomes from fractures will almost always be decided by what the radiographs show. These should be gathered and delivered to the chief of the orthopaedic department for a review to describe the initial fractures, to determine how well they were managed, and to ascertain whether the outcomes should have been different. Although the chief might have an interest in protecting his or her staff, utilising this help in evaluating claims allows for both departmental interaction and the implementation of whatever preventive means might surface from the evaluation. This method therefore entails both awareness and participation of the institution in the claims management process. If the chief feels the case is "clean" the claims manager or risk manager

may still seek independent consultation that avoids conflicting interests to ensure that the assessment has been appropriate. This process should not be put in the hands of solicitors. They are not trained for this purpose and they may not know how to ask appropriate questions. Solicitors and barristers are trained to conduct litigation; they may not be good claims managers.

Risk managers need to view medical and legal issues in malpractice litigation in a way that makes sense to doctors. To talk about duty, breach of duty, and proximate cause often leaves doctors bewildered. Thus we have learnt to approach these concepts differently. In clinical negligence there are two types of adverse outcomes.

The first type of adverse outcome is a new abnormal condition (such as an allergic reaction) caused by doing something to or for the patient (such as prescribing a drug.) A set of medical issues pertain to this type of outcome, a breakdown in any one of which may result in liability for the doctor: (1) Was the drug or procedure calculated to be effective for its intended use for this patient (technology assessment, for example, North American Symptomatic Carotid Endarterectomy Trial Collaborators[7])? (2) Was it adequately indicated at this time (appropriateness, for example, McGlynn *et al*[8]). (3) Was the doctor competent to perform the procedure (credentialing, for example, Langsley[9])? (4) Was valid consent obtained from the patient? (5) Was the procedure or prescription properly performed?

Lack of valid consent ... is a frequent allegation in clinical negligence cases ....

The incident reporting system should disclose what procedures or drugs are causing undue problems, and the case analyses should identify which issues are involved. Groups of cases can then be subjected to clinical audit for quality improvement.

Lack of valid consent from the patient is a frequent allegation in clinical negligence cases in the United States.[10] It does not fit into the usual category of clinical negligence in that it is not a professional judgment or performance issue. Rather, it is a doctor-patient communication problem. Did the doctor disclose sufficient information for the patient to make a personal decision to proceed? Not only is the doctor required to balance risks and benefits in deciding to recommend the procedure (involving categories (1) and (2) above) but he or she must then allow the patient to make a similar judgment, though at a non-clinical level. The usual lawsuit in the United States stems from experiencing a complication of the procedure which the patient alleges he or she would have refused had the risk of that complication been adequately disclosed. Doctors in the United States have been slow to realise their obligations of disclosure, finding it difficult to switch from paternalism to accepting patients' autonomy. The duty to disclose the risks of a beneficial procedure sometimes seems antithetic to the desire to help the patient. Fortunately, we have been able to defend most lack of consent cases by emphasising the need for the procedure (benefit to the patient) and by establishing that most reasonable patients would have accepted the risks had these been disclosed. But we have not been able to cope successfully with consent cases based on misinformation (as opposed to lack of information) – that is, if doctors downplay the risks, they place themselves in an almost indefensible position should the patient sue, even though the sole intent was to benefit the patient.

The second type of adverse outcome is a worsening or prolonging of the patient's disease or condition caused by a lack of timely intervention (that is, a failure to do something). The medical or legal issues for such adverse outcomes are different. (1) Was the lack of diagnosis or misdiagnosis reasonable? (2) Did the doctor accumulate enough information before making a diagnostic or therapeutic decision? If the database was adequate the doctor may have a right to be wrong, but if it was insufficient the misdiagnosis is probably not defensible, medically or legally. Examples are (*a*) not performing a rectal examination in acute appendicitis (the patient went on to experience rupture of the appendix and died from sepsis) and (*b*) not performing a spinal fluid examination in acute meningitis (the patient developed severe, permanent neurological sequelae because of delayed treatment). We found that the audit for problems of misdiagnosis may be more fruitful if it is focused on the status of the database, rather than on the misdiagnosis alone.

What we have just described are forms of system errors that may be remedied if there has been adequate data gathering, analysis, and action. But episodic errors also exist. These are instances of clinical negligence that occur regularly but seem to defy prediction and therefore prevention. The problem has not been lack of analytical ability, but the failure to accumulate enough information about the occurrence of episodic errors. Lawsuits alone do not supply enough information to permit analysis of these episodes, so we have had to fold in the cumulative data from incident reports to establish trends and to permit auditing, which seems to be satisfactory, but only when the incident reporting system is equal to the task.

Few doctors know how to analyse clinical negligence cases well. They are not trained to appreciate the credibility factors or the types of evidence most meaningful to judges. Nor are they conversant with the types of system errors we have been talking about. Solicitors and barristers may have similar shortcomings unless they are extraordinarily skilled in this field. The risk or claims manager, therefore, has a role to oversee the evaluation of claims and to ensure that consulting doctors are focused appropriately. It is inefficient and insufficient for a solicitor or claims manager simply to provide

a medical record to a consulting reviewer without guidance. A factual determination of what happened in the case must be carried out before asking consulting experts to evaluate the defendant's conduct. This preparation often includes the use of in house consultation with departmental chiefs.

Preventing the next injury

In working on preventing adverse outcomes, risk management becomes a subset of quality assurance. As we found out in the mid-1970s, most adverse outcomes are not related to clinical negligence. In the sentinel California study 4·65% of patients in acute care hospitals developed adverse outcomes from their management, of which only 17% were caused by negligence.[1] In real numbers, out of three million admissions annually in California, 140 000 adverse outcomes occurred, only 23 000 of which were due to clinical negligence. Efforts at prevention therefore focused on a much greater population than the liability cases. But even so, this comprises less than 5% of admissions; this is an outlier population, and some people complain that focusing on this group is an inefficient way of improving quality of care.[11] Although we agree that continuous quality management is an appropriate route to improve the quality of care, we have to realise that when particular adverse outcomes lead to litigation they exact substantial expense. This alone deserves attention. Even if adverse outcomes are not a major quality problem they are certainly a cost control problem. Some episodes are eggregious enough to demand instant reaction whereas others may wait for trends to be identified. The degree of clinical responsiveness often depends on the points of view of the institution's administrator. In California some hospital administrators will hesitate to pay damages for an injury clearly negligently caused unless steps are in place to prevent such an episode from recurring. But the way to prevent recurrence may not be apparent from solitary episodes. The risk manager is therefore in a position of having to satisfy both the administration and the doctors. It is not often a good idea to delay settling a damage case just because we cannot immediately produce methods to prevent recurrence.

Prediction should be high in the vocabulary of risk managers.

PREDICTING PROBLEMS

Prediction should be high in the vocabulary of risk managers. They should be clinically aware of the progress in medical science to predict when and where problems may arise. Once closed chest cardiac massage proved effective in the early '60s, we began to worry about the concept of coronary care units, where patients could be salvaged from cardiac electrical failures. The first units were small and not all hospitals had them. We were concerned about the survival of patients with heart attack admitted to hospitals without such units (that alone prompted the rapid development of coronary care units in many hospitals). But we were more concerned about the small units that were in operation. How would decisions be made to discharge patients prematurely to make room for new patients who had greater priorities? Rather than wait to allow these problems to be decided ad hoc, we recommended the development of protocols which identified known criteria for admission, retention, and discharge from these units. Most hospitals developed these protocols early, and they proved effective. Although some patients who were excluded from continuous care owing to limited space in the units developed fatal cardiac arrhythmias in unmonitored rooms, we had very few lawsuits. Attorneys who represented the families of deceased patients admitted that the protocols contributed to the decisions for refusing their representation.

Prediction was again effective when the immune globulin to prevent maternal sensitisation in mother/fetus Rh incompatibility was developed. We knew this globulin was to be universally available in southern California by 15 June 1968; therefore, we flooded the medical media to prepare physicians and hospitals for this eventuality. Thereafter, only a few children developed erythroblastosis fetalis from lack of administration of immune globulin.[12]

Occasionally ethical dilemmas are deposited at the risk manager's doorstep. In the United States Jehovah's witnesses have the right to refuse blood transfusion, even if that refusal entails a risk of immediate death, and even if the patient is a pregnant woman. But some doctors feel morally and ethically impelled to override these refusals if transfusions would alter the outcomes. Other doctors feel that it is only ethical and moral to abide by the patient's wishes, with today's emphasis on autonomy. Neither group can be condemned, nor should they be. But the mere fact that both are "correct" prompts the recognition of a special obligation of that group which feels compelled to treat over objection. Since there are others who feel just as strongly the other way, the group that "must treat" needs to refer these patients elsewhere for management. Risk management is involved in developing lists of physicians who will accept patients under these circumstances.

Interpreting and implementing court decisions

Risk management in the United States must often interface between courts and the health-care system, and it has the obligation to be the caregivers' legal interpreter. The rules for civil liability, which includes clinical negligence, are controlled by the legislatures and courts of the individual states. Risk managers must therefore monitor legislative enactments and the state court opinions to interpret these for the hospitals and doctors in their particular state. In California we learnt in 1958 that doctors and nurses have the same direct obligation to

serve their patients.[13] This should not seem earth shaking, but it required nurses to intervene to protect patients from doctors' misactions. The appellate court opinion arose from a postpartum maternal death caused by exsanguination from a cervical laceration. The nurses were aware that the mother was not responding to the doctor's ministration but failed to intervene. The court held the doctor and the nurses responsible. This case accelerated the development of chains of command that now exist in most hospitals. Time and again risk managers had to explain to nurses and doctors that knowledgeable hospital staff have the duty to act. They cannot sit by knowing a patient may be injured. Their duty to intercede exceeds the rights of doctors to make mistakes, even non-negligent mistakes.

Many of the important court decisions affecting doctors' obligations arise from problems of communication. As we stated previously, doctors are not prone to be particularly informative to their patients. Courts therefore accepted the task of developing duties of communication for them. In Truman versus Thomas doctors were told that they had to warn patients of the downside risks when they refuse recommended procedures.[14] That case involved a woman who refused successive annual Pap (Papanicolaou) smears and developed advanced cervical cancer. She complained that the doctor should have told her why it was important not to refuse (and the court agreed). The impact of this case has been far reaching. Diabetic patients with infected foot ulcers must be told why they should not refuse admission for intensive care. Even patients who leave hospitals against medical advice must be warned of the consequences.

Various court decisions have affected doctors' duty to warn patients of the danger of driving motor cars while taking sedative drugs[15] or if they have brittle diabetes[16] and to warn an identified potential victim of a psychiatric patient's stated intent to harm that person.[17] The risk manager's task is not only to disseminate these principles but also to devise means to document warnings whenever given. Patients who drive under the influence of sedatives or tranquilising drugs who become involved in motor car accidents may claim that they were unaware of the dangers. Doctors have to prove that the warning was given, but they complain that they are already overburdened with menial recording tasks. However, in this case a stamp would suffice ("sedative warning given") if placed in an appropriate part of the chart at the time of the patient's visit.

One obligation for communication does not include patients directly. The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) requires doctors to talk with one another in evaluating and improving clinical care systems and in carrying out credentialling processes. These functions are enforced with varying degrees of success by hospitals seeking accreditation. Doctors have worried about these communications, fearing they may be developing information that patients' solicitors can use against them. These clinical care judgments are "built in" expert opinions that would greatly facilitate the prosecution of malpractice lawsuits. In the 1950s and early '60s we thought that judges would understand that quality assurance activities were essential to improving care and that, since communications about these activities were not directly involved in any particular patient's day to day care, they would be considered irrelevant and inadmissible in a malpractice case.[18] A California appellate court proved us wrong, and the floodgates were opened for patients' solicitors to go on fishing expeditions in the entire clinical audit system for whatever evidence or opinions might be beneficial to their claims.[19] Doctors threatened to close down the audits unless they were assured their activities would not rebound against them. There was a danger that medical audit would be reduced to examining non-threatening issues only. Risk management investigations into individual, potential lawsuits would not be impeded because of the attorney-client confidentiality and work-product rules; however, injury prevention and other programmes to improve clinical care would be devastated. The California Legislature responded by reversing the appellate court's decision with section 1157 of the California Evidence Code. This new law made proceedings and documents of quality care committees non-discoverable in legal proceedings. It has withstood attacks by the plaintiffs' bar,[20] and most other states have now followed suit. These legislative changes are now the mainstay of doctors' cooperative ventures into quality improvement.

Conclusion

What we have described here has been drawn from decades of firsthand experience in medical and clinical risk management. We have not always succeeded, but we have found most of the essentials, as follows. (1) To succeed in the larger arena of clinical risk management, doctors must be involved, both individually and as a group. They need to participate in gathering data and finding problems; they need to improve their skills in analysing evidence; and they need to communicate more readily with their patients. (2) The risk manager has fundamental obligations (*a*) to control lawsuits in his or her jurisdiction (gathering evidence, seeking appropriate analysis, helping solicitors and barristers, but always keeping control over each claim); (*b*) to monitor injured patients, making every effort to minimise their injuries and keeping them informed; (*c*) to help in data gathering and analysis for preventing injury; and (*d*) to predict the clinical effects of new medical and legal changes in health care. Risk management is thus a complex endeavour.

Mr Jack J Fulton, hospital administrator and lawyer, was the first special representative for the California Hospital Association's risk management programme, beginning in the mid-1950s. He was responsible for most of the early examples cited in this paper, and we appreciate his review and guidance.

1 Mills DH, ed. *Report on the medical insurance feasibility study*. San Francisco: Sutter Publications, 1977.
2 Brennan TA, Leape LL, Laird NM, *et al*. Evidence of adverse events and negligence in hospitalized patients. *N Engl J Med* 1991;**324**:370–6.
3 Ludlam JE. A personal history of the California hospital association insurance program. In: Dunlap HB, ed. *Fifty years*. Glendale, California: Bright Publishers, 1991: 176–96.
4 Sanasaro PJ, Mills DH. A critique of the use of generic screens in quality assessment. *JAMA* 1991;**265**:1977–81.
6 Mills DH. Medical lessons from malpractice cases. *JAMA* 1963;**183**:1073–7.
7 North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. *N Engl J Med* 1991;**325**:445–53.
8 McGlynn EA, Naylor CD, Anderson GM, *et al*. Comparison of the appropriateness of coronary angioplasty and coronary artery bypass graft surgery between Canada and New York State. *JAMA* 1994;**272**:934–40.
9 Langsley DG. Medical competence and performance assessment, a new era. *JAMA* 1991;**266**:977–80.
10 Mills DH. Whither informed consent? *JAMA* 1974;**229**: 305–10.
11 Kritchevsky SB, Simmons BP. Continuous quality improvement, concepts and applications for physician care. *JAMA* 1991;**266**:1817–23.
12 Mills DH. Medical legal aspects of RhoGam. *Maternal and Child Health* 1968;**1**:18–9.
13 Goff v Doctors General Hospital of San Jose. *Pacific Reporter, Second Series* 1958;**333**:29 (California).
14 Truman v Thomas. *California Reporter* 1980;**165**:308.
15 Kaiser v Suburban. *Pacific Reporter, Second Series* 1965; **398**:14 (Washington).
16 Myers v Quesenberry. *California Reporter* 1983;**192**:583.
17 Tarasoff v Regents. *California Reporter* 1976;**131**:334.
18 Tissue committee of a hospital staff. *California Medicine* 1961;**95**:264–6. Judd v Park Avenue Hospital. *New York State Reporter, Second Series* 1962;**235**:843.
19 Mills DH. Medical peer review: the need to organise a protective approach. *Health Matrix, Journal of Law-Medicine* (Case Western Reserve University School of Law) 1991;**1**:67–76.
20 Mills DH. Protecting medical peer review, the case for confidentiality. *Los Angeles Lawyer* 1993;**15**:23–5.