Implementing Risk Management

Essentials of clinical risk management

Roger V Clements

Aims of clinical risk management

Risk management may broadly be defined as the reduction of harm to an organisation, by identifying and, as far as possible, eliminating risk. The aims of clinical risk management are (a) to reduce the frequency of adverse events and harm to patients, (b) to reduce the chance of a claim being made, and (c) to control the cost of claims that are made. The primary focus is on malpractice, which causes financial losses but also affects the reputation and morale of a trust and its staff. Clinical risk management also involves the continuing care of the injured patients and swift settlement of justified claims. Proper analysis of risk management reporting systems and an audit of clinical complaints also offer invaluable opportunity to improve quality in a way which is securely focused on the welfare of the patient. Improvement of quality must be the highest priority, for only by this means can the exposure to litigation finally be eliminated.

Aims of clinical risk management

- Reducing and, as far as possible, eliminating harm to the patient
- Dealing with the injured patient:
 - Continuity of care
 - Swift compensation for the justified claimant
- Safeguarding the assets of the organisation:
 - Financial
 - Reputation
 - Staff morale
- Improving the quality of care

In the new National Health Service (NHS) emphasis is rightly on both quality and price. When malpractice results in harm to patients quality is obviously affected, but malpractice also affects the overall cost of care. The provider unit must, firstly, recoup the cost of medical malpractice through its contracts, and therefore successful claims will skew prices. But in a more subtle way poorly handled medical malpractice may damage the reputation of the provider unit, affect the willingness of local practitioners to refer patients, deter patients, and ultimately reduce the size of contracts that are offered. A unit with an effective risk management system, on the other hand, will save money and enhance its reputation. Money is saved not only by improvement of quality but also by early settlement of claims which cannot be resisted, thus keeping money out of the hands of lawyers. The early reporting of adverse

events makes possible an economic defence where there is no fault.

Implementing risk management

The principles of industrial and commercial risk management (see Dickson, p 75¹) can be applied to the clinical arena:

- Identification
- Analysis
- Control
- Funding.

Funding is at present largely outside the control of individual provider units, though the creation of a central fund (see below) may go some way towards providing the opportunity for prudent financial management. However, identification and analysis of risks and the steps taken to reduce and control risks are at the heart of clinical risk management.

Several key issues must be addressed when a risk management system is established, and these will be discussed in turn:

- Leadership and responsibility
- Developing a risk management team
- Practical issues of implementation
- Cultural changes required
- Continuing care of the injured patient
- Ethical dilemmas
- Support for staff involved in litigation.

LEADERSHIP AND RESPONSIBILITY: ROLE OF THE MEDICAL DIRECTOR

In most large provider units the broader aspects of risk management (financial aspects, commercial aspects, fire, buildings, etc) will be the responsibility of a steering group led by the finance director. That group is not appropriate to deal with clinical risk, which should have a separate management group which liaises both with the general risk management group and with other quality initiatives within the provider trust.

Risk management must have a high profile in the perspective of the management board. There must be commitment to the concept of clinical risk management at board level, backed up by a written strategy. There must be an executive director of the board charged with personal responsibility for risk management. This will almost certainly be the medical director, whose role is to provide a medical perspective to board decisions, who should be in a position to influence the medical environment both within and outside the provider unit in line with those board decisions. In the NHS Management Executive's document on risk management² the medical executive director is

not once mentioned. Nevertheless that person can influence complaints monitoring, quality initiatives deriving from complaints, risk management, clinical audit, and claims management. Clinical risk management will therefore primarily be the responsibility of the medical director, although the directors of finance, nursing, and quality will work closely with him or her. Representatives from the clinical directorates may be incorporated in a risk management steering group, although this can make the group rather cumbersome. However the directorates link in with the central department, the role of the clinical director is paramount.

Just as within the trust as a whole the medical director's role is unique and central, so in each directorate the lead clinician must take responsibility for clinical risk management. Otherwise the programme will never carry sufficient weight and acquire the credibility to become effective. Unless the clinical director owns the responsibility for clinical risk management, the directorate will not buy into the process.

DEVELOPING A RISK MANAGEMENT TEAM

Two new roles need to be created, that of a claims manager and a risk management coordinator. These roles are very different but in small organisations they may effectively be combined in the same person.

Claims manager

The claims manager is the liaison with the solicitor and the person who effectively instructs solicitors on behalf of the trust. It is the claims manager's responsibility to see that the day to day conduct of legal business suits the trust's agenda. Major decisions about settling or defending claims will be communicated to the solicitors through the claims manager, although he or she will not usually be the person making the decisions. The decision to defend or settle a claim must be a board decision, usually delegated to the medical director. The medical director and claims manager must therefore work closely together in making sure that the solicitors act in the best interest of the trust.

Risk management coordinator

The risk management coordinator has a broader function, including the day to day responsibility for the clinical incident reporting system and collecting data from it. These data must be fed back to the directorates if they are to improve quality. The risk management coordinator should also have a key role in maintaining the standards of the health records. Administration of the complaints procedure might appropriately be delegated to either the claims manager or the risk management coordinator. In most district general hospitals of modest size (£50m turnover) these roles can conveniently be assumed by one senior manager, directly responsible to the medical director.

Both the claims manager and the risk manager will work most closely with the

medical director. This small group would administer the reporting system and would rely on the medical executive director to liaise with each of the clinical directorates and with other board members. Although the clinical director must be responsible for effecting the culture change and for driving the initiative, he or she will depend on his service manager for the day to day running of the reporting system.

PRACTICAL ISSUES OF IMPLEMENTATION: REPORTING SYSTEM

Central to any clinical risk management system is an adverse outcome reporting system which has the confidence of all members of the organisation. Adverse events are identified from staff reports, though this process may be supplemented by a systematic screening of records. Reports of serious incidents are made before claims are initiated, and while memories are still fresh. The reports are used to create a database to identify common patterns and prevent future incidents. Ideally, patients and relatives are also informed about adverse incidents and action is taken to minimise both the physical and psychological trauma.

Key elements in risk management programmes are educating clinicians about their role in risk management, formalising channels of communication to enable early intervention with patients and their families after adverse incidents, and establishing a strong organisational structure for dealing with the findings of reviews of adverse events. The involvement and personal commitment of senior clinicians are crucial. A first step must therefore be to introduce a reporting system, but alongside must be an educational programme which will secure interest and ultimately ownership.

Implementation is best achieved by the following steps.

(1) Identify key risk areas

In any provider unit the key risk areas will usually be self evident. In a district general hospital they are likely to be the accident and emergency department (by volume the biggest risk area); obstetrics, particularly in the labour ward (by quantum the biggest risk area); and the operating theatres.

(2) Take the message to those key areas

The risk management team takes the programme of education to the risk area. For instance, a half day seminar arranged in the accident and emergency department is attended by the key healthcare providers (consultant staff, junior medical staff, senior nursing staff, and main users – for example, orthopaedics, gynaecology, paediatrics, etc). The principles of risk management are explained with due emphasis on the advantages to the quality of care which will accrue.

(3) Allow the healthcare providers to identify trigger events

During the seminar the healthcare providers create their own trigger list of incidents which they think are worth reporting to a risk management system. (If members of the department are

to have ownership of the system they must create their own list, then they are likely to respond to it.) They would also be encouraged to modify it with experience so that the list constantly changes. The same process is repeated in the labour ward and in the operating theatres. The box shows the kind of list of trigger events which might result for an average labour ward. Imposition of this list on any labour ward is not intended; it is given only as an example.

Trigger events in a labour ward

Apgar score ≤ 5 at 5 minutes
 Fetal malformation undiagnosed before birth
 Injury to the baby at time of birth
 Blood transfusion >3 units
 Caesarean section: decision to delivery interval >40 minutes
 Third stage or emergency hysterectomy
 Failed forceps delivery
 Unscheduled return to operating theatre
 Stillbirth or neonatal death
 Unexpected or late admission to special care baby unit
 Third degree tear

(4) Institute a reporting system

Having established a list of the trigger events likely to give early warning of patient harm, the risk management department introduces a system of reporting, which above all, must be simple.

For example, one particular hospital uses a double sided printed A4 sheet. It avoids large numbers of boxes to tick and it avoids difficult questions, simply requiring the identification of the incident, the carers, and the onlookers, with a small space for free script to allow the reporter the opportunity to describe what happened. The form is constantly under review, has recently been modified, and will continue to be modified. Anyone can use the form. Staff of all grades and of all disciplines from every profession are encouraged to report adverse outcomes. This inevitably leads to much over-reporting of trivial incidents, which is not discouraged. Nobody is dissuaded from making a report.

Non-medical staff quickly see the advantages of the adverse outcome reporting system and seldom need much encouragement to implement it. Without the doctors the risk management programme will not be effective, and it is essential that the medical staff should understand what is in it for them. Reporting adverse outcomes or near misses to a risk management reporting system should be associated with reward not punishment.

(5) Monitor and analyse results

The forms are sent initially to the manager at local level – the service manager or equivalent. The service manager has the discretion to decide whether the incident is trivial and of no consequence, when no further action need be taken. If the incident seems to be an important

indicator of a quality issue but is unlikely to have harmed a patient on this occasion the manager will take local action but may not forward the form. Only those incidents which relate to harm which might potentially lead to litigation need be sent to the central risk management department. There they are scrutinised again. Some will be rejected as being important to quality but not to the risk of litigation. Only those important for the risk of litigation will be entered on to the database.

The advantages of such a simple system are that it allows:

- The local manager to assess quality issues
- Identification of clusters
- Fuller investigation of the real exposure to litigation.

If the effect on quality is to be maximised the adverse outcome reporting system inherent in any clinical risk management programme must feed in to the other quality initiatives of the trust. Unless the adverse reporting system is an effective part of clinical audit it will not have its maximum effect on quality. Identifying a cluster of adverse outcomes may lead to the correction of a system or the counselling of a staff member. It should not be used for discipline.

(6) Investigate, when appropriate

When an incident is sufficiently important to be entered on to the database a full investigation will take place. The risk management department will require local managers to obtain statements from all healthcare providers involved with the patient. This enables the clinical director and the medical executive director to take an early view on whether an action, if brought by the patient, could be defended. When, months or years later, the “letter before action” arrives, the risk management department can instruct solicitors in an effective and timely manner without the unseemly and usually fruitless search through the archives for members of staff who have long since left not only the trust but usually the country.

CULTURAL CHANGE AND DIFFICULTIES OF IMPLEMENTATION

A risk management reporting system will inevitably be resisted by doctors. Doctors perceive adverse outcome reporting as a threat to their reputation and their professional integrity. To assure an effective clinical risk management programme a major cultural change will be needed to achieve *acceptance* by clinicians.

Conversely, patients’ organisations perceive risk management as a way of covering up when things go wrong. It is therefore important to establish, from the very beginning that risk management:

- Does not concern discipline
- Does not lead to covering up when things go wrong
- Does not encourage “defensive” medicine
- Does not involve creating complex causation arguments to defeat the plaintiff.

Risk management is about avoiding litigation – not about evasion.

In order to convince clinicians that risk management works, the medical director initially (and subsequently each clinical director) must explain to colleagues the advantages that a risk management programme can bring in quality and price to the organisation. It is essential to eliminate the fear which adverse outcome reporting naturally generates. Doctors need to be reassured that they will not be disciplined for reporting adverse outcomes even if fault is established. They need further to be reassured that one of the main advantages of a satisfactory risk management programme is that their reputations can more effectively be protected when they are not at fault.

Convincing the doctors is not easy; much depends on the individual leadership of clinical directors and the personalities of the senior doctors concerned. For instance, it may be relatively easy in the women's and children's directorate, perhaps because they are already familiar with the threat of litigation and the need to change practice in order to avoid it, and in the accident and emergency department, the high volume part of the industry where errors seem to be more frequent, for a variety of understandable reasons, not least the pressure of work out of hours. Difficulty may be encountered in the directorate of surgery. Part of the mythology of surgery is that the surgeon is in complete control of the operation and therefore completely responsible for everything that happens. Surgeons may feel particularly threatened by the idea that a member of the nursing staff should report an untoward incident – causing them to be brought to account. The pattern of response may vary but, whatever the personalities involved, it is essential that at the beginning key staff in the major areas are targeted and persuaded of the benefits, otherwise the programme will fail.

CONTINUING CARE OF THE INJURED PATIENT

An injured patient requires more, not less, care than patients with a successful outcome. Paradoxically, it is precisely at the moment when an accident happens that the caring seems to stop. At least that is how the patient perceives it.

Risk management means caring for the patient after the injury. Care includes the following:

- Continuing to treat – or sometimes arranging for alternative care if trust has broken down
- An explanation of what happened
- An explanation of *why* it happened
- Remedial action where possible
- Compensation when appropriate.

Thus the advantages for the patient are clear cut: early investigation of the cause of harm; if no fault, a clear explanation; and if fault, a clear explanation and early settlement.

A good clinical risk management system does not disadvantage a patient with a justified claim. It does of course withhold the payment of damages from those who are not entitled to them. That is only right. But it is also right that those patients should receive a full and early explanation as to *why* they are not entitled to damages. Conversely, the patient who is

entitled to damages receives an early settlement without money needlessly passing into the pockets of lawyers.

A good provider unit should establish a reputation for frank explanation and early settlement of cases with fault. A trust with such a policy would quickly gain the reputation for vigorous and successful defence where there was no fault, and the incidence of litigation against it would fall. Litigation is in the interest only of lawyers. The plaintiff wants an early explanation and settlement (when appropriate); good clinical risk management achieves this.

ETHICAL DILEMMAS

Occasionally, the caring team may become aware that the patient has been injured while the patient continues to believe that he or she has had the best possible care. Under those circumstances the provider unit is obliged to give the patient a full explanation, consistent only with the patient's best interest.

Lord Donaldson has several times drawn attention to the obligation placed on lawyers in such circumstances.³

Both branches of the legal profession have a salutary rule of professional ethics requiring them to advise their client to consult another practitioner if they consider that they may have been in breach of their duty of care and that this breach has led to loss or damage on the part of their client.

He goes on to plead for a similar frankness from doctors.

The position in relation to the medical profession is, or should be, in many respects the same. The duty of care does not involve the doctor in making a definitive judgement on his own professional conduct and communicating that judgement to the patient. Save in a clear case, he may be less likely than the lawyer to be the person best able to decide. But, in contrast to the position of the lawyer, he has a very special duty of disclosure.

Doctors who find themselves in such a dilemma should find support from their senior managers for a full and honest disclosure to the patient of the unsuspected accident. Caring does not stop when an accident occurs; part of that caring is to make sure that the patient understands what has happened and why.

SUPPORT FOR STAFF INVOLVED IN LITIGATION

In return for active participation in risk management, all clinical staff should feel supported and protected by the system; the programme must offer support to the doctor, who often feels vulnerable and isolated when a patient is injured. Few doctors cope well with the knowledge that they have harmed a patient. Practical help should include the following.

- An opportunity to talk through the experience with senior colleagues
- An inquiry process which is supportive, not confrontational
- Readily available legal advice – for example, before appearing in a coroner's court
- Shared experience with those who have had a similar experience.

Before crown indemnity, medical staff were used to relying on their medical defence organisations for such support. The defence

societies are still available to give informal advice to individual doctors, but they are no longer involved in litigation for hospital doctors and that role should be increasingly subsumed by the risk management department. Similarly nurses and midwives tended to refer to their unions for support in litigation. Although the unions were seldom involved directly in the litigation process, the nurse or midwife often felt protected by the union. A good risk management department should be able to provide just such support for all staff.

The interests of the individual will not necessarily always coincide directly with those of the provider unit. Nor did they in the days when doctors were “protected” by their medical defence organisations. There are countless examples of litigation conducted primarily for the benefit of the medical defence organisation, with doctors coming a poor second in the process, for they were never the first client of the lawyers conducting the action. Doctors tended to assume that the defence societies were exercising their paternalism benignly in the interests of the individual; often, though, the societies were acting either in their own interests or in what they perceived to be the interests of the profession as a whole.

So with individuals and provider units a conflict will occasionally arise. Doctors perceive this conflict most starkly where the trust might be inclined to settle a case which, in their view, can be defended. They would be offended by the admission of liability where they believe none exists. But whose reputation is stained thereby? Doctors need to be reassured that in these days of crown indemnity they are most unlikely to be named in any suit. In any event, in NHS practice an admission of liability is made on behalf of the provider unit, not by an individual. The doctors whose reputation is harmed by malpractice are those whose cases attract publicity. They are doctors who are defended in public – in the courts.

A settlement with or without admission of liability seldom attracts publicity in any personal sense. When doctors' names are published it is because the accusations have been made in open court and, substantiated or not, the accusations can be repeated by the newspapers without redress. The newspapers report the action on the first day of the trial, seldom later. Plaintiff counsel speaks on the first day of the trial cataloguing the misdeeds of the doctor. Even if the doctor is fully exonerated, even if the judge finds on the fourteenth day of the trial that no blame attaches, even if the decision goes for the defence, nobody gets to know about it because by then the newspapers have lost interest. “Doctor not guilty of negligence” is not news. So to safeguard the reputation of the medical staff, the simple answer is to keep them out of court. Doctors should be reassured that the discreet and early settlement of a case which might attract publicity, whether or not the court found for the plaintiff, may well be in the interest not only of the trust but of the individual doctor whose reputation is thereby protected.

Response to litigation

When a “letter before action” is received, the risk management team, led by the medical director, should determine the response of the trust. It will not always be appropriate to instruct solicitors. In many cases the matter is trivial, the issues are clear cut, and an offer of a very modest settlement may deflect a potentially costly legal action. It is important to remember the common experience of experts and plaintiff solicitors – namely, that often the injured patient seeks only an explanation and an apology and is not *primarily* motivated by money. Nevertheless, most “letters before action” will need to be forwarded to the trust's legal advisers so that the matter may be assessed and an appropriate response formulated. Under no circumstances should doctors ever be allowed to respond personally to a “letter before action.” The skill and responsibility of the claims manager, supported by the medical director, does not end with the handing over of the “letter before action”: it must include the proper *instruction* of solicitors.

Traditionally, medical malpractice has been handed over by doctors to their medical defence organisations and by health authorities to their legal advisors, with virtually no input thereafter. The matter was run at the speed convenient to the lawyers and the defence organisations with the inevitable result that actions were unnecessarily protracted and costs escalated. That is not in the interest of the provider unit, and it must be a priority of any risk management system to prevent it.

Instruction here carries the ordinary English meaning. The medical executive director should expect from his or her lawyers exactly what any individual instructing solicitor has a right to expect – namely, competent technical advice and compliance with the client's wishes. This means that when an in house investigation has determined that a matter is no longer defensible the lawyers should be instructed to settle it. Expert opinions can often be dispensed with when the in house opinion is clear and decisive. When the matter is to be defended the medical director should ensure that his or her clinical colleagues are involved in the choice of expert and are kept informed, throughout the conduct of the case, so that they can be of maximum help to the legal team. In some respects, this is the most difficult culture change to achieve, for it threatens traditional practices of two professions – the lawyers as well as the doctors! Although it is essential that defensible claims should be vigorously defended, the facts of medicolegal life must be clearly understood:

- Quantum (that is, damages) increases, in absolute terms, with time. The later a claim is settled or lost, the greater quantum is likely to be, leaving aside inflation and the costs of the action
- Failure to settle quickly an indefensible claim can only add further to the anger of the injured patient (or family) and so damage further the reputation of the trust
- Costs accumulate on both sides. If a claim is indefensible the plaintiff will continue to

incur costs (ultimately payable by the defendant) assembling evidence to prove liability until that liability is admitted

- The admission of liability at the door of the court almost always represents a massive waste of public money. Seldom have the facts of the case changed; seldom is there any *different* reason for assessing a case as indefensible on the day of settlement than on any of the preceding days, weeks, or months that have passed since the first intimation of a legal action.

Vacillation puts money into the pockets of lawyers. Incidentally, it usually increases, in real terms, the quantum paid to the plaintiff. An effective team of claims manager and medical director should have as their primary objective the prevention of *any* unnecessary costs paid to lawyers in both sides.

When claims should be settled

There will be times when it becomes clear to the medical director that the potential cost of defending an action will greatly exceed any possible quantum. It may be appropriate for him or her to advise the finance director that, even though there may be a chance of defending the action, settlement would be wiser. Settlements at the door of the court occur, mostly, because the defendants took a realistic view of the case only when their minds were finally concentrated by the need to produce evidence in court. The prospect of a lengthy court battle, only to lose, suddenly seems unattractive. Tragically, by the time that moment arrives many thousands of pounds in costs have already been spent by both sides, costs which will have to be borne by the provider unit. Not only that but (except in the Court of Appeal) costs orders against plaintiffs receiving legal aid are not enforced and success after many days in court may prove something of a pyrrhic victory if the costs incurred by the defendants exceed the plaintiff's (disappointed) expectations of quantum!

Care is required in these matters. The unit must not get the reputation for being an easy pushover, willing to settle any case where quantum is modest. Some cases have to be defended, if necessary in open court. In making such decisions the medical director and his or her trust board colleagues need to consider how best to preserve their assets, not only financial assets but also reputation and staff morale.

It has been suggested that creating a central fund may reduce the ability of local provider units to make such decisions in their own interests – may insist on cases where there is medical “merit” being defended even though it makes no financial sense to do so. This was strongly hinted at by Brian Marsden, deputy director of finance and corporate information, of the NHS Executive at the conference on prevention and control of clinical negligence at the Royal College of Surgeons in May 1994.

It is recommended that Trusts should have prime responsibility for handling the majority of claims. They would use solicitors from a nationwide panel approved by the Fund – with the Fund manager being consulted before a claim is settled and having discretion to take over management of any claim considered novel, or likely to create precedent, or to be costly.⁴

Interference, to prevent trusts settling small claims expeditiously and cheaply would be a mistake. Save only for the most exceptional circumstances, such decisions should belong to the local provider unit.

1 Dickson G. Principles of risk management. *Quality in Health Care* 1995;4:75–9.

2 NHS Management Executive. *Risk management in the NHS*. London: Department of Health, 1993.

3 Lord Donaldson. Foreword. In: Clements RV, ed. *Safe practice in obstetrics and gynaecology: a medicolegal handbook*. Edinburgh: Churchill Livingstone, 1994.

4 Marsden B. Funding clinical negligence claims in prevention and control of clinical negligence. *Clinician in Management* 1994;3(suppl 1):4.