

How to avoid being sued in clinical practice

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Challenges to clinical management are a fact of professional life. Every doctor must expect to become embroiled in complaints and claims from time to time and be prepared to justify why they managed a particular case in the way that they did. Good medical practice is defensible practice, which depends upon staying within the limits of your own expertise, keeping up to date and conducting audit, ensuring your administration is effective and that patients are not allowed to slip through the net, that you communicate effectively with patients, their carers and colleagues, and that medical records recall all salient facts relating to the patient.

If things go wrong, be open, investigate the facts, explain the situation fully to the patient, and do not be afraid to apologise.

Since New Labour came to power in 1997, quality has been at or near the top of the NHS agenda. In the past six years, there have been a number of initiatives aimed at setting standards, ensuring local delivery, and effective external monitoring.

Despite these initiatives, the cost of clinical negligence claims to the NHS continues to rise. That, combined with figures suggesting that 10% of all patients admitted to hospital—amounting to 850 000 per annum costing an estimated £2 billion in additional hospital stays alone¹—suffer avoidable harm during their stay, might appear to suggest that the government's initiatives have yet to bite.

Clinical standards continue to improve but the complete eradication of error is an unattainable goal. For individual clinicians, there is no fool-proof method of avoiding being sued (short of deserting clinical practice altogether) but attention to a few basic risk management principles reduces the risk and in the event of a claim, renders a successful defence more likely.

CLINICAL NEGLIGENCE

Claimants in clinical negligence actions have to demonstrate first that they were owed a duty of care by their health care provider, second that there was a breach of that duty, and third, that they suffered harm as a result.

The duty of care is established as soon as any medical advice is proffered or provided. So the first hurdle for the claimant is easy to overcome.

The second requires demonstration that the care provided fell below an acceptable standard. This in England and Wales is judged by the

Bolam test which, in essence, states that care must be provided in accordance with accepted medical practice, as determined by experts in the field.

This sounds simple in practice but involves poring over each element of clinical management to determine if it was reasonable or not.

The third hurdle is demonstrating that the harm suffered by the patient was due to substandard care or, to put it another way, harm that would have been avoided if adequate care had been provided. Compensation is awarded only for pain and suffering and specific losses attributable to identified avoidable harm.

The key issue for clinical staff involved in clinical negligence claims revolves around the Bolam test and whether, in the circumstances, their clinical management was acceptable. In many units there are standard protocols or guidelines for dealing with particular conditions. Where guidelines exist but are not followed, claimants are likely to plead that failure to do so proves the negligence of their doctors. That is not so, but healthcare professionals who do not follow unit guidelines must be prepared to justify their own management, again by reference to a responsible body of medical opinion.

INDEFENSIBLE CASES

Individual claims may be deemed indefensible on several grounds. First, there is a clinical error leading to harm. Many of these cases are borderline. Case reports in the Medical Protection Society *Casebook* and the new NHS Litigation Authority journal are published to illustrate particular points and tend to be cases where there is no argument about whether or not the care was negligent. Clear cut and appalling cases do occur but in many settled cases the dividing line between negligent and non-negligent care can be very fine, leading to lengthy debate among the experts.

Secondly, clinical negligence cases are won on the evidence, not the facts. Inadequate notes, lost records, failing or muddled memories may all lead to an inability to rebut the claimant's case. Consequently, cases which should be defensible are sometimes lost for want of evidence.

AVOIDING BEING SUED

Good medical practice is defensible medical practice and the first rule of avoiding being sued must be to keep within the limits of your own expertise, which may sound self evident but there have been a variety of cases where people who thought they knew what they were doing clearly did not. In one example, a gynaecologist in the private sector agreed to remove a number of moles from a patient's body when she was anaesthetised for dilatation and curettage. The

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patient was left with ugly scars and sued. The technique employed by the gynaecologist was not, when reviewed by experts, considered appropriate and consequently, the claim was settled.

In another case, a junior surgeon injecting piles injected the prostate gland with phenol, resulting in prostatitis. The technique employed by the surgeon was inadequate and consequently the claim had to be settled.

The competence issue extends to delegation. When delegating tasks to others, whether or not medically qualified, the delegating doctor should always check that the individual is competent to a reasonable standard. Equally, delegated duties should not be accepted unless you are competent of completing them to a reasonable standard.

In another case, a young child presented to a local hospital with symptoms suggestive of appendicitis. The surgeon arranged to operate straightaway. On entering the abdominal cavity, turbid fluid was encountered so that the appendix was not easily visible. The surgeon then identified the tubular structure that was indurated attached at its base to a pinkish structure identified as the caecum. The histology report revealed that the excised structure was in fact a fallopian tube, not the appendix. Subsequent analysis by experts threw doubt on the accuracy of the diagnosis of appendicitis and concluded that there was no excuse for the error that had been made.

Keeping up to date is another important and related issue. Medical practice is constantly evolving. Using outdated techniques inevitably makes practitioners vulnerable to criticism. Having the right facilities and necessary help to hand is another prerequisite for providing adequate care. Any shortfall should lead to delaying the procedure unless doing so would jeopardise the patient's wellbeing.

AUDIT

Audit is now an integral part of medical practice. This is what the General Medical Council has to say about it—'You must work with colleagues to monitor and maintain the quality of the care you provide and maintain a high awareness of patient safety. In particular, you must:

- Take part in regular and systematic medical and clinical audit, recording data honestly. Where necessary you must respond to the results of audit to improve your practice, for example by undertaking further training.
- Respond constructively to the outcome of reviews, assessments or appraisals of your performance.
- Take part in confidential inquiries and adverse event recognition and reporting to help reduce risk to patients'.²

ADMINISTRATION

Administration is not just for administrators. Unless basic systems are in place to deal with patient referral, follow up, completion of clinical records, clinical correspondence, reviewing test results and acting appropriately on abnormalities, all sorts of things can and do go wrong with potentially catastrophic effects for patients. Here is one example.

A woman in her early 40s attended her general practitioner complaining of intermenstrual bleeding. In preparing the referral letter, the doctor came across a cervical smear test taken two and a half years before which showed some abnormal cells and advised a repeat smear. Although that report was signed as having been seen, no action had been taken and the patient's condition had been left to deteriorate over the intervening period.³

COMMUNICATION

The temptation is always to think of communication as a process taking place between doctor and patient, in particular

in relation to consent. That is very important and box 1 sets out the information that patients ought to know before their consent is sought for treatment.⁴

But to ensure continuity of care, good communication within teams and between teams and in particular between primary and secondary care is essential. *An Organisation with a Memory* sets out in detail the chronology of a tragic case in which vincristine was given intrathecally (see table 1).⁵ The chronology identified a series of events leading to this disaster, many of which were communication failures.

MEDICAL RECORDS

Medical records do not simply recall what has happened to patients for posterity but should be a running dialogue between involved clinicians on the patient's management and progress so that anyone coming fresh to that patient's care can pick up where other colleagues have left off. It is, therefore, essential that each patient contact is adequately recorded so that all clinical developments are noted together with investigations undertaken, action on results and notes on future management, referral, and follow up (see box 2 for full details).⁶

Box 1: Information that patients should know before consent to treatment⁴

The information which patients want or ought to know before deciding whether to consent to treatment or an investigation may include:

- Details of the diagnosis and prognosis, and the likely prognosis if the condition is left untreated.
- Uncertainties about the diagnosis including options for further investigation before treatment.
- Options for treatment or management of the condition, including the option not to treat.
- The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patients should prepare for the procedure; and details of what the patient might experience during or after the procedure including common and serious side effects.
- For each option, explanations of the likely benefits and the probabilities of success; and discussions of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment.
- Advice about whether a proposed treatment is experimental.
- How and when the patient's condition and any side effects will be monitored or reassessed.
- The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team.
- Whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment.
- A reminder that patients can change their minds about a decision at any time.
- A reminder that patients have a right to seek a second opinion.
- Where applicable, details of costs or charges which the patient may have to meet.

Table 1 Chronology of a case showing errors and communication failures

Sequence of events	Failures
A child was a patient in a district general hospital and due to receive chemotherapy under general anaesthetic at a specialist centre. He should have been fasted for 6 hours before the anaesthetic, but was allowed to eat and drink before leaving the district general hospital	Fasting error. Communication problem between district general hospital and specialist centre
No beds were available for the patient on the oncology ward so he was admitted to a mixed specialty "outlier" ward	Lack of organisational resources (that is, beds for specialised treatments). Patient placed in a environment lacking oncology expertise
The patient's notes were lost and not available to ward staff on admission	Loss of patient information
The patient was due to receive intravenous vincristine, to be administered by a specialist oncology nurse on the ward, and intrathecal (spinal) methotrexate, to be administered in the operating theatre by an oncology specialist registrar. No oncology nurse specialist was available on the ward	Communication failure between oncology department and outlier ward. Absence of policy and resources to deal with the demands placed on the system by outlier wards, including shortage of specialist staff
Vincristine and methotrexate were transported together to the ward by a housekeeper instead of being kept separate at all times	Drug delivery error due to non-compliance with hospital policy, which was that the drugs must be kept separate at all times. Communication error. Outlier wards were not aware of this policy
When the fasting error was discovered, the chemotherapy procedure was postponed from the morning to the afternoon list. The doctor who had been due to administer the intrathecal drug had booked the afternoon off and assumed that another doctor in charge of the wards that day would take over. No formal face-to-face handover was carried out between the two doctors	Communication failure. Poor handover of task responsibilities. Inappropriate task delegation
The patient arrived in the anaesthetic room and the oncology senior registrar was called to administer the chemotherapy. However, the doctor was unable to leave his ward and assured the anaesthetist that he should go ahead as this was a straightforward procedure. The oncology senior registrar was not aware that both drugs had been delivered to theatre. The anaesthetist had the expertise to administer drugs intrathecally but had never administered chemotherapy. He injected the methotrexate intravenously and the vincristine into the patient's spine. Intrathecal injection of vincristine is almost invariably fatal, and the patient died 5 days later	Inadequate protocols regulating the administration of high toxicity of drugs. Goal conflict between ward and theatre duties. Poor practice of expecting the doctor to be in two places at the same time. Situational awareness error. Inappropriate task delegation and lack of training. Poor practice to allow chemotherapy drugs to be administered by someone with no oncology experience. Drug administration error

WHEN THINGS GO WRONG

Inevitably in clinical practice, some things will not turn out as originally planned through error, unexpected findings, or some other cause. When things go wrong, the patient is entitled to a full explanation of what has happened and why. The General Medical Council provides this advice:

"Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response. This will include an explanation of what has happened, and where appropriate, an apology. You must not allow a patient's complaint to prejudice the care or treatment you provide or arrange for that patient.

You must cooperate fully with any formal inquiry into the treatment of a patient and with any complaints procedure which applies to your work. You must give, to those who are entitled to ask for it, any relevant information in connection with an investigation into your own, or another healthcare professional's, conduct, performance or health".²

Key points

- Claimants have to demonstrate first that they were owed a duty of care, that there was a breach of that duty, and that they suffered harm as a result.
- Inadequate notes, lost records, failing or muddled memories may all lead to an inability to rebut the claimant's case.
- Good medical practice is defensible medical practice.
- Keeping up to date is another important and related issue.
- Unless basic systems are in place to deal with patient referral, follow up, completion of clinical records, clinical correspondence, reviewing test results and acting appropriately on abnormalities, all sorts of things can and do go wrong with potentially catastrophic effects for patients.

Box 3: Record keeping⁶

Notes should include:

- *History*—relevant to the condition, including any answers to direct questions.
- *Examination of the patient*—any important findings, both positive and negative, and details of any objective measurements, such as blood pressure.
- *Diagnosis*—in clear, readily understood terms. It should be clear from your notes how you arrived at this conclusion. Include any uncertainties about diagnosis and steps taken to rule these out. Detail any further investigations you have arranged.
- *Information*—what you have told the patient, including any details of the risks and benefits of particular treatments.
- *Consent*—details of any consent the patient has given, together with the background or any discussion that led up to that consent.
- *Treatment*—detail the type and dosage of drugs, the total amount prescribed, and any other treatment you have organised.
- *Follow up*—include the arrangements for following up tests, future appointments, and any referrals made.
- *Progress*—how the patient responds to treatment, whether this is positive or negative.

Giving the patient all this information may be seen as an invitation to a writ but in fact the reverse is true. Doctors who prevaricate, appear evasive, or refuse to acknowledge fault are far more likely to push their patients towards litigation than those who explain exactly what happened and apologise for any shortcomings on their part. When patients do suffer significant loss due to negligence they are entitled to compensation, which should be provided swiftly and fairly.

CONCLUSION

Adverse incidents can be reduced in number but not totally eradicated through risk management. On an individual basis, this means practising within the limits of your own expertise, communicating effectively with patients and colleagues, ensuring systems are in place so that the patients and their results do not slip through the net and keeping comprehensive contemporaneous clinical records for continuity of care in the knowledge that if they are fit for that purpose, they will also be of substantial evidential value.

MULTIPLE CHOICE QUESTIONS (ANSWERS AT END)

1. The number of patients suffering avoidable harm during a hospital stay each year is:

- (A) 150 000
- (B) 250 000
- (C) 450 000
- (D) 550 000
- (E) 850 000

2. The following statements are true of clinical guidelines:

- (A) Guidelines are mandatory and must be followed no matter what the circumstances
- (B) Guidelines are of no consequence in legal proceedings

Key references

1. General Medical Council. *Good medical practice*. London: GMC, 2001.
2. General Medical Council. *Seeking patients' consent: the ethical considerations*. London: GMC, 1998.
3. Medical Protection Society. *Keeping medical records: a complete guide*. Dealing with negligence claims. London: MPS, 1999.
4. Report of an expert group on learning from adverse events in the NHS. *An organisation with a memory*. London: Stationery Office, 2000.

- (C) If you do not adhere to guidelines you must be able to justify your management according to an appropriate evidence base
- (D) There is no distinction between the terms "guidelines" and "protocols" in law
- (E) Failure to follow guidelines is clear cut evidence of negligence

3. According to the GMC's publication *Good Medical Practice*:

- (A) You must take part in regular and systemic medical and clinical audit
- (B) You must provide a prompt, open, constructive, and honest response to complaints
- (C) You must not allow a patient's complaint to prejudice his or her care
- (D) You must participate in confidential inquiries and adverse event recognition
- (E) You must respond positively to appraisals

4. Patients should be given the following information before deciding whether or not to consent to treatment:

- (A) Advice about whether the treatment is experimental
- (B) Uncertainties about the diagnosis
- (C) What it may cost them
- (D) The name of everyone participating in the procedure
- (E) A guarantee that the procedure will be undertaken

5. Medical records should include:

- (A) A rough pen picture of the individual to bring the clinical record to life
- (B) Follow up arrangements
- (C) Management plan, where applicable
- (D) The type and dosage of drugs prescribed
- (E) Full social history of all family members

ANSWERS (TRUE (T)/FALSE (F))

1. (E); 2. (A) F, (B) F, (C) T, (D) T, (E) F; 3. (A) T, (B) T, (C) T, (D) T, (E) T; 4. (A) T, (B) T, (C) T, (D) F, (E) F; 5. (A) F, (B) T, (C) T, (D) T, (E) F.

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6. Medical Protection Society. *Keeping medical records: a complete guide*. Dealing with negligence claims. London: MPS, 2003.