



# AN ESSENTIAL GUIDE TO CLINICAL MANAGEMENT

ADVICE FOR THE UNITED KINGDOM



# INTRODUCTION

Most incidents leading to medicolegal problems fall into one of the following categories:

- Failure to appreciate legal and professional responsibilities
- Problems in clinical management
- Medication errors
- Administrative errors
- Failure of communication, including inadequate medical records



# PROBLEMS IN CLINICAL MANAGEMENT

Negligence is a legal concept. It does not mean neglect or wilful misconduct, but a failure to attain a reasonable standard of care. In cases of negligence, the claimant must prove all three of the following:

- They were owed a duty of care;
- There was a breach of that duty of care;
- Damage was suffered as a result.

## CLINICAL PRACTICE

The courts assess standards of clinical practice by the “Bolam test” (in England and Wales, though similar standards exist in Scotland and Northern Ireland). Bolam sustained fractures during electroconvulsive therapy carried out in the early 1950s. In the subsequent court case, experts for the claimant and defendant could not agree on whether Mr Bolam should have been given a muscle relaxant.

The judge set out the following test in his summing up to the jury: “A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art...putting it the other way round, a doctor is not negligent if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view.” (*Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.)

## ADOPT ACCEPTED PRACTICE

Accepted practice can be easy to define in some areas – prescribing in accordance with the recommendations of the *British National Formulary* will usually be regarded as accepted practice. Increasingly, proper practice has to be based on evidence (ie, determined by systematic methods based on literature review, critical appraisal, multidisciplinary consultation and grading of recommendations by strength of evidence).

Accepted methods of investigation and treatment are often described in clinical guidelines. Such evidence-based guidelines aim to improve the quality and consistency of clinical decisions, help replace outdated practices, provide a focus for audit of clinical practice, and provide benchmarks for clinical governance.

Guidelines are supposed to be an aid to clinical judgment, not a substitute for them. In theory, then, you may exercise your judgment and decide not to follow a particular guideline. In practice, however, you should only deviate from the accepted practice embodied in the guidelines if you have very good reasons for doing so. If your judgment is called into question, you will have to demonstrate why you were justified in not complying with the guidelines. Conversely, if you follow respected clinical guidelines and base your decisions on evidence, you will be in a very strong position if a complaint is made against you.

## **ACT WITHIN YOUR LIMITATIONS**

Although doctors are not expected to be infallible, the law requires that they exercise a reasonable standard of skill and care at all times.

- Never undertake a task that is beyond your competence except in a real emergency – when in doubt, seek help from a more experienced colleague.
- Ensure you have sufficient help and equipment available for any procedure you undertake, and for the management of foreseeable complications.
- Ensure that you are familiar with the equipment that you are using or expecting others to use and that it is in full working order before beginning any procedure.
- Always explain to the patient what you are intending to do and why<sup>3</sup> and obtain the patient's fully informed consent<sup>2</sup> after<sup>3</sup> why<sup>2</sup>.

## **DELEGATE APPROPRIATELY**

In the context of multidisciplinary and cross-agency teamwork, it can be difficult to distinguish between delegation and shared responsibility. The question is really one of accountability.

As a member of a clinical team, you will have ongoing responsibilities for the care of patients, some of which you might delegate to staff who do not belong to a registered professional organisation. In these circumstances you would be held accountable by the GMC for the actions of those staff members, so you must satisfy yourself that they are competent to take on the duties you are delegating to them and supervise them if necessary.

The matter is a little different when you delegate to a professional colleague. You would not be held accountable for the actions of another registered professional; however, you would still be expected to delegate appropriately (ie, to a colleague with relevant training and skills) and to have provided them with sufficient information to carry out the task assigned to them.

# MEDICATION ERRORS

Medication errors account for a high level of complaints, claims and patient safety incidents.

- Some causes of medication errors

- Wrong name
- Wrong drug
- Wrong dose
- Wrong frequency
- Wrong supply



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## WHEN WRITING PRESCRIPTIONS

- Be sure that the treatment is indicated;
- Check that the intended drug is not contraindicated and that the patient does not have a history of adverse reactions to it;
- Ensure that it will not interact with the patient's other medication and warn the patient about any potential interactions with over-the-counter medicines;
- Write legibly, taking special care if the drug name could easily be confused with another – use capital letters and give the generic rather than trade name;
- If you're not sure which of two similar sounding drugs you should be prescribing, check with a senior colleague and confirm the correct spelling in a national formulary;
- Write clear and unambiguous instructions for dosage, frequency and route of administration, avoiding abbreviations and leading decimal points (put a zero in front of it, eg, 0.2mg);
- Note the prescription and any other relevant information (eg, warnings given to the patient) in the medical record.

- Ensure that the patient is aware of what is being prescribed, and why. Use patient information leaflets to augment your verbal instructions, and be particularly careful to warn patients about possible side-effects, adverse drug interactions (including herbal medicines), or potentially dangerous activities, such as driving while taking drugs that induce drowsiness.

## **PRESCRIBING FOR CHILDREN**

While all the foregoing advice on avoiding medication errors applies to both children and adults, special care is needed when prescribing, preparing and administering drugs to children. Drugs that are relatively innocuous in adults may have adverse effects in children. Variations in height, weight and body mass can make them more susceptible; or they may quickly accumulate toxic levels as a result of slower metabolism and excretion.

In many cases referred to MPS, errors occurred because the doctor failed to check the appropriateness of the drug and its route of administration in children or infants, or to prescribe the correct dose.

## **ADVICE FOR SAFER PAEDIATRIC PRESCRIBING**

- Limit the drugs you use to a well-trying few and familiarise yourself with their dosages, indications, contraindications, interactions and side-effects;
- Refer to a paediatric formulary when appropriate;
- When writing a prescription, include the child's age and write the exact dose in weight and (if liquid) volume required for administration;
- Always calculate doses on paper and, if possible, get a competent colleague to check your arithmetic;
- When writing dosage, take special care not to lead with a decimal point.
- Never abbreviate micrograms;
- For amounts less than 1 milligramme, prescribe in microgrammes to avoid confusion over the placing of decimal points;

- When prescribing for a child, it is particularly important to give the parents all relevant information such as:
  - The name of the drug.
  - The reason for the prescription.
  - How to store and administer the drug safely (if appropriate).
  - Common side-effects.
  - How to recognise adverse reactions.

Parents must always be warned about side-effects, particularly those that will be distressing to the child. It is also helpful to remind them of the importance of storing drugs in their labelled containers and out of the child's sight and reach.

## CASES

### TWO ILLUSTRATIVE CASES

1. A patient was seen on a Friday and was prescribed a loading dose of 1g of phenytoin, followed by a maintenance dose of 1g twice a day. The usual maintenance dose is around 300mg daily. Over the weekend, five 1g doses were administered; a pharmacist then screened the patient on Sunday and the incorrect dose was not picked up or queried with the medical team. The patient was not seen by any member of the medical team on Monday, and it was not until Tuesday morning that the wrong dose was noticed and crossed from the prescription. The patient died the next day.
  2. A patient was prescribed 62.5 micrograms of digoxin. On 27 January, 250 micrograms was erroneously dispensed, with the patient then feeling unwell for a few days. On 12 February, a family member noticed the error and contacted the pharmacy. The overdose was identified and a doctor examined the patient, advising the withholding of the next dose. However, the patient collapsed and later died in hospital.
- NPSA, *Safety in Doses: Improving the Use of Medicines in the NHS* (2009)

# FAILURES OF COMMUNICATION



## A FATAL MISCALCULATION

A doctor was deputising for a colleague absent on leave. After a particularly demanding night, he was asked, in the early hours of the morning, to see a premature infant with congestive heart failure. He was not normally responsible for the care of premature infants but he requested Digoxin to be given intramuscularly and calculated (by mental arithmetic) that the dose should be 0.6 mg.

Just as he settled down for a restorative nap, the nurse phoned to ask whether the dose shouldn't be 0.06 mg as she had had to open two ampoules. Without thinking he told her to "give it as I ordered". An hour later, he was called to the ward because the baby had suffered a cardiac arrest.

Underpinning good patient care is good communication, and this goes beyond establishing good relations with patients. In today's team approach to delivering healthcare, communication has to extend to more people and there are therefore more opportunities for it to fail.

## KEEPING EACH OTHER INFORMED

The divide between primary and secondary care is an area where communication can easily break down, particularly when patients are receiving long-term treatment. See the case overleaf:

# KEPT IN THE DARK

A diabetic clinic in a teaching hospital diagnosed TB in a diabetic patient with a history of weight loss. He was admitted to hospital and, on discharge, was prescribed three months' supply of ethambutol, rifampicin, pyrazinamide, isoniazid and pyridoxine.

A month later, he was seen in the diabetic clinic but there was no discussion of his TB treatment. He failed to attend his next appointment.

Three months after starting TB treatment, the patient began to complain of deteriorating vision and his GP made an urgent referral to the eye clinic. The GP had not yet received a discharge letter about the patient's last hospital admission for the treatment of TB, nor had the diabetic clinic informed him of the diagnosis so his referral letter to the eye clinic made no mention of the fact that he was taking ethambutol.

The patient attended the eye clinic several times over a month, but no history of TB or of treatment for TB was obtained, his visual loss being attributed to diabetes. However, his vision continued to deteriorate and by the end of this period he was only capable of counting fingers. A week later, the patient attended the diabetic clinic. Only then was the diagnosis of ethambutol eye toxicity raised.

The patient was seen immediately in the eye clinic where the diagnosis was confirmed and the ethambutol stopped, but by then he had sustained a permanent loss of 90% of his vision.

# COMMUNICATING WITH PATIENTS

Patients who are kept informed about their condition and are involved in deciding on the appropriate treatment are more likely to comply with the treatment you suggest, and less likely to complain if things go wrong.

It is particularly important that you tell patients about the possible side-effects of drugs or treatment you are ordering, and that they know what complications to look out for and what to do if they develop.

Warn patients about the risks before carrying out any procedures or prescribing medication.

If patients are receiving treatment, tell them when to return for review and what symptoms or signs of adverse effects or changes in their condition to report. If possible, give them an indication of when they might expect to see an improvement in their condition, and when to call you if it doesn't transpire within a certain timescale.

Document any advice you have given the patient. It is useful to document in the record any supporting literature or written information given to the patient.

## DUTY OF CANDOUR

You have a statutory duty to have systems in place that capture patient safety incidents. The regulation, or fundamental standard, is the **duty of candour**. The expectations of the GMC are laid out in the guidance *Openness and honesty when things go wrong: the professional duty of candour* (2015).

You must act in an open and transparent way and ensure you have:

- systems in place to capture notifiable safety incidents
- processes to inform patients and provide support.

Although the statutory duty applies to organisations, not individuals, an organisation's staff must co-operate with it.

## WHAT IS A NOTIFIABLE SAFETY INCIDENT?

The regulation states that there are two meanings of a notifiable safety incident; one for a health service body, the other for registered persons – registered persons being GPs and primary care dental practitioners.

According to the regulation: <sup>3</sup>In relation to a registered person who is not a health service body, <sup>3</sup>notifiable safety incident<sup>2</sup> means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional

- (a) appears to have resulted in the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days, changes to the structure of the service user's body, the service user experiencing prolonged pain or prolonged psychological harm, or the shortening of the life expectancy of the service user; or
- (b) requires treatment by a health care professional in order to prevent the death of the service user, or any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).



## An apology goes a long way in diffusing a situation, and is not necessarily an admission of liability

### WHAT SHOULD YOU DO?

After a notifiable patient safety incident has occurred, practices must:

- Inform the patient (or their representative)
- Provide an account of the incident and apologise
- Inform the patient what further enquiries are to be undertaken
- Provide support to the patient
- Keep a written record of all discussions.

### ACTION POINTS

Follow these steps to make sure you comply with the regulation. You should:

- Promote incident reporting and ensure that staff are aware of the reporting requirements.
- Make sure staff understand the consequences of non-compliance and that the duty sits alongside existing professional responsibilities.
- Ensure staff are able to raise concerns and understand the part they play.
- Have robust systems for investigating the causes of patient safety incidents, eg. using significant event audit and root cause analysis.

## ABOUT MPS

MPS is the world's leading protection organisation for doctors, dentists and healthcare professionals. We protect and support the professional interests of more than 300,000 members around the world. Membership provides access to expert advice and support as well as the right to request indemnity for any complaints or claims arising from professional practice. Highly qualified advisers are on hand to talk through a question or concern at any time.

Our in-house experts assist with the wide range of legal and ethical problems that arise from professional practice. This includes clinical negligence claims, complaints, medical and dental council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

Our philosophy is to support safe practice in medicine and dentistry by helping to avert problems in the first place. We do this by promoting risk management through our workshops, E-learning, clinical risk assessments, publications, conferences, lectures and presentations.

## HOW TO CONTACT US

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In the interests of confidentiality please do not include information in any email that would allow a patient to be identified.

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