

2

LEGAL AND PROFESSIONAL ACCOUNTABILITY FOR NURSE PRESCRIBING

THE LEGAL FRAMEWORK FOR NURSE PRESCRIBING

This chapter aims to explain the legal framework of nurse prescribing in order to increase awareness of and reflection on the legal background of nurse prescribing and the implications for personal accountability. Frequent reflection on practice is an implicit element in the United Kingdom Central Council (UKCC) *Scope of Professional Practice* (UKCC, 1992a). For nurse prescribers, this reflection will encompass all aspects of their new role and in particular their legal and professional duty of care for ensuring safe practice. This in turn requires the nurse to assess where potential breaches of duty may occur in prescribing and to take appropriate steps to minimise risks to patients. Failure to do so may make the nurse professionally and legally vulnerable in any allegation of negligence. Therefore, a basic knowledge of the law of negligence is essential for nurses prescribers practising in an increasingly litigious society. It is certainly the case that ignorance (of the law) is no defence.

The UKCC makes it clear that each nurse is personally accountable for actions taken and it is also evident that the law imposes the same standards

CURRENT ISSUES IN NURSE PRESCRIBING

of care on those in a trainee or inexperienced capacity. This may include nurses taking on new roles such as prescribing. In *Nettleship v Weston (1971)* cited in Tingle and Cribb (1995), it was held that 'a learner driver would be liable in negligence if he failed to drive as well as a reasonably competent driver'.

This chapter examines:

- the background to nurse prescribing
- relevant legislation
- the law of negligence
- areas of potential breaches of care in prescribing.

THE BACKGROUND TO NURSE PRESCRIBING

Healthcare practice does not exist in a vacuum; it occurs within the legal frameworks created by society. Just as society itself is constantly changing, so too does the law in order to reflect the needs of society. Within this context, nursing developments may require the drafting of new legislation or the amendment of existing legislation to ensure that nursing practice is founded on sound professional principles within a legal framework. The implementation of nurse prescribing required new legislation in the form of the *Medicinal products: Prescription by Nurses etc Act 1992*. In addition, amendments to the *Medicines Act 1968* and the *Pharmaceutical Services Regulations 1994* were necessary before nurses could legally prescribe.

Amendments to existing legislation

The Medicines Act 1968 governs the prescription, supply and storage of medicines. Under this Act, it is unlawful for anyone other than an 'appropriate practitioner' to prescribe drugs. Doctors, dentists, veterinary surgeons and veterinary practitioners are the appropriate practitioners defined in the Act. Section 58 of this Act was amended to include 'registered nurses, midwives and health visitors' in the list of appropriate practitioners.

The *Pharmaceutical Services Regulations 1994* were also amended to allow pharmacists to dispense from prescriptions written by nurses.

THE MEDICINAL PRODUCTS: PRESCRIPTION BY NURSES ETC ACT 1992

The Act permits appropriately qualified nurses to prescribe from a list contained in the Nurse Prescriber's Formulary (NPF), a subsection of the British National Formulary. The NPF contains items such as analgesics, laxatives, skin treatments, dressings, etc. (see Box 1.1).

Although this Act was passed in 1992, the necessary secondary legislation Medicinal Products; Prescription by Nurses etc Act 1992 (Commencement No 1) Order did not come into effect until 1994. An Order is a legislative document that enables the powers in an Act to be implemented and in addition, gives the legal definitions of the terms used within the Act. This Order specified the conditions which would have to be met before a nurse could prescribe and Section 2 states that an appropriate practitioner who is permitted to prescribe is a nurse:

- registered in Parts 1 or 12 of the UKCC Register a Registered General Nurse (RGN) who holds a current district nurse qualification and is a district nurse
- registered in Part 10 of the UKCC Register (a midwife)
- registered in Part 11 of the UKCC Register (a health visitor).

In addition, the authority to prescribe is limited to nurses who are employed by a district health authority or an NHS trust and who have completed the necessary educational preparation approved by a national board to the UKCC's standards.

The conditions specified in the legislation exclude nurses working in non-community settings. It could be argued that this is discriminatory and undermines not only the UKCC *Scope of Professional Practice* (UKCC, 1992b), but the work undertaken by many clinical nurse specialists.

This exclusion was reviewed in *the Review of Prescribing, Supply and Administration of Medicines Report* Department of Health (DoH 1999), the recommendations of which were accepted by the government in March 2000. The report recommended that nurse prescribing be extended in the future to include nurses 'beyond currently authorised prescribers' and to allow prescribing by other healthcare professionals registered with a recognised regulatory body.

The report recommends the creation of two types of prescribers, 'independent' and 'dependent' prescribers, and the establishment of a New

Box 2.1 – The existing and new legislation required for nurse prescribing

- Medicines Act 1968
- Pharmaceutical Services Regulations 1994
- Medicinal Products; Prescription by Nurses etc Act 1992

Prescribers' Advisory Committee (NPAC) (see Chapter 1). It is not yet clear who will be empowered to be independent or dependent prescribers, nor is it clear what they will be permitted to prescribe. It is hoped that further consultations with appropriate professional groups will address these issues and the secondary legislation needed to establish this and to expand nurse prescribing is expected to be in place by 2001.

THE LAW OF NEGLIGENCE

The following explores Nurse Prescribing in relation to the law of negligence and includes:

- definition of negligence
- the duty of care in prescribing
- professional and legal definitions of standards of care
- potential breaches of duty of care prescribing.

Definition of negligence

In *Blyth v Birmingham Water Works (1856)* negligence was defined as 'the omission to do something which a reasonable man, guided upon these conditions which ordinarily regulate the conduct of human affairs would do or to do something which a prudent and reasonable man would not do'.

Duty of care

In law, NHS-employed doctors or nurses owe their patients a duty of care. This duty entails taking care and practising to a standard which will ensure that, as far as is reasonably practicable, patients are not caused harm or

damage. If, however, this duty of care is breached and the patient can prove that any subsequent harm or damage is due to the breach, then they will have a right to sue for negligence. All three elements have to be proven, i.e. that a duty of care existed, that the duty was breached and that subsequent harm or damage was directly related to a breach of the duty of care. Nurses need to be aware of the nature of the duty of care they owe to patients.

The legal definition of duty of care was defined in *Donoghue v Stevenson (1932)* and is cited by Dimond (1995). The case involved a manufacturer being held liable for the existence of the decomposed remains of a snail found in one of its beer bottles. In this case, Lord Atkin stated that 'You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour'. He defined 'neighbour' as '... Persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question'. It is evident from this definition that patients come into the category of 'neighbours' as far as nurses are concerned, i.e. persons to whom a duty of care is owed. The legal definition of duty of care is an integral part of the UKCC *Code of Professional Conduct* (UKCC, 1992b), which is not in itself a legal document but does affirm the principles of professional accountability. Nurses are accountable to the patient, the public, the profession and the employer. The nature of a nurse's legal duty of care to patients lies in their professional accountability for ensuring that patients are protected, have been given relevant and sufficient information before consenting to treatment and that they receive safe, quality care. Tingle (1990) states that 'However accountability is defined, and whatever the value of ethical codes, it is important to remember that the courts are the final venue for the resolution of disputes in medicine and nursing'.

In accepting new and expanded roles, nurses must be clear about their accountability and responsibility to determine whether their skills are relevant and up to date. They should also fully understand the nature of the tasks/responsibilities assigned to them. Additionally, Rieu (1994) stated that nurses must consider their competency before undertaking activities considered to be doctor's duties. This is particularly relevant to nurses undertaking prescribing responsibilities. It is clear from the *Scope of Professional Practice* (UKCC, 1992b) that nurses have a duty to acknowledge any limits of personal knowledge and skills and should not undertake activities which are outside their present level of competence. The nurse should compile a personal development plan to gain the required

competence. Nurses should also determine the means by which the new skills are acquired and updated, in order to lessen the risk of breaches of duty of care.

Professional and legal standards of care

Any examination of alleged breaches of duty of care in prescribing will involve a comparison with accepted standards. The *Scope of Professional Practice* document states the broad principles for standards of professional practice. The law expects standards which do not result in patient harm and which are defined in terms of compatibility with other practitioners operating at that level of care. The standard of care was stated by McNair (cited in Kennedy and Grubb, 1989) as 'the standard of the ordinary skilled man exercising and professing to have that special skill'. The leading case for assessing the standard is ***Bolam vs Friern Barnet Hospital Management Committee (1957)*** which established the so-called 'Bolam principle' or 'test'. This is that 'A doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion'. It is evident that this principle can also be applied to nursing and nurse prescribing.

Many legal experts and authors express concerns as to whether Bolam is still relevant in the healthcare services of the 21st century since it effectively allows the medical profession to state the standard on which they will be judged. Simanowitz (1997) suggests that the validity of the Bolam test needs to be continuously 'attacked' by lawyers. He cites an Australian case, ***Rogers v Whitaker (1992)***, where a doctor was being sued following recanalisation after vasectomy that resulted in the patient's wife becoming pregnant. The defendant stated that he normally warned patients of the risk of recanalisation but omitted to do so, due to an oversight. Nevertheless, the doctor appealed to the Bolam principle, saying that a responsible body of doctors would not have informed patients of the risk. The court found in favour of the plaintiff, stating that 'The risk was so serious that the patient should have been warned'. Simanowitz concludes by stating that 'The Bolam principle provides a defence for those who lag behind the times'.

Stauch (1997) also supports the view that the courts appear to be taking a 'more critical' stance to doctors and cites the case of ***Bolitho v City and Hackney HA (1993)*** in which Lord Justice Farquharson suggested that

LEGAL AND PROFESSIONAL ACCOUNTABILITY

‘Ultimately, the judge must decide whether a particular clinical practice, even one endorsed by a body of doctors, puts the patient unnecessarily at risk. Thus, while compliance with approved practice may make it unlikely that a doctor is guilty of negligence, it does not settle the matter’. Stauch refers to this development as the ‘new Bolam’.

As stated, the Bolam test defines the standard as that of the reasonable person professing to have that same skill. However, what is not clear is whether the nurse taking on a role hitherto undertaken by doctors will be judged against the reasonable doctor or the reasonable nurse test. It may be that nursing and medical guidelines and standards would need to be referred to in attempts to determine the nature of the harm.

It appears that the law will focus on whether, in the performance of the role, the nurse achieved the level of competence demanded by the role. It is unlikely that the UKCC or the legal profession will accept as a defence that professional (nursing) accountability can be denied because the role was once a medical one. According to Bolam, it appears sufficient if the nurse exercises an ordinary level of care.

However, whilst this basic level of competency may satisfy the law, it is important for nurses to realise that in any scrutiny of professional standards, the UKCC may demand more than basic competence and may independently proceed against the nurse. Appropriate disciplinary action will be taken where the standards have, in the UKCC’s view, not reached an acceptable professional level.

Elliott Pennels (1997) highlights that it is important to remember that the standard of care is related to ‘the post and not to the individual ... that is, it is related to the skills that are needed for the job, not what skills the individual doing the job can offer’.

In the case of *R v Bateman (1925)* cited in Kennedy and Grubb (1989), Lord Hewart stated ‘If a person holds himself out as possessing special skill and knowledge ... by or on behalf of a patient ... he owes a duty to the patient to use diligence, care, knowledge, skill and caution in administering the treatment’.

Whilst the legal principles discussed so far relate to doctors, the same principles would apply to nurses and nursing standards. This has particular significance for those who, like nurse prescribers, are undertaking roles traditionally performed by doctors.

POTENTIAL BREACHES OF DUTY OF CARE IN PRESCRIBING

It is essential that nurse prescribers, through continuous reflection on their prescribing role, identify areas where potential breaches of duty may occur. Potential breaches of duty could occur in:

- prescribing
- product liability
- consent
- communications.

Box 2.2 – Duty of care for the nurse prescriber involves personal accountability for:

- being adequately prepared for the role including attending an approved nurse-prescribing programme
- abiding by professional standards of care including the UKCC standards for the administration of medicines
- understanding the legal and professional basis (including the 'Bolam test') for determining the standard of care for safe prescribing and take appropriate actions to reduce that risk.

Prescribing

Areas of Prescribing which could potentially render the Nurse Prescriber vulnerable include:

- prescription writing
- preferential prescribing
- security of prescription pads.

Prescription writing

The writing of a prescription implies an acceptance by the nurse prescriber of personal accountability for knowledge of the patient's current and past medical history, current medications and knowledge of the side effects and

contraindications for the products prescribed. 'The nurse who takes the original decision and writes the prescription is responsible in law for ensuring that the prescription is used in accordance with their instructions' (ENB, 1998: p. 2.2).

To ensure legal validity, the prescription must be legible, dated and signed. In addition, it must be appropriate, accurate, not contain any abbreviations and be based on products listed in the NPF. The prescriber is responsible for ensuring that all prescriptions are entered not only on the nurse or patient-held records but also in the General Practitioner GP-held records. If a decision is made not to prescribe, the reason should be recorded in the patient's records. The nurse prescriber also needs to be aware when it is more appropriate to refer a patient to the GP, rather than issue a prescription. If a nurse decides not to prescribe but recommends to the patient or client that they purchase the product over the counter (OTC), the nurse remains accountable for giving any relevant information concerning use and storage of the OTC product. The reason the nurse remains legally liable is because the advice is given within the therapeutic relationship existing between patient and nurse, which may influence the patient to preferentially purchase a particular product.

It is important that nurses should discuss prescribing role parameters with GPs to ensure that mutual agreement is reached on actions to be taken in the event of a disagreement over products prescribed. However, it is important to realise that 'In the event of a disagreement between professionals over treatment of a patient, the GP responsible for the care of the patient will, as at present, take the final decision' (DoH, 1989 cited in ENB, 1994).

Good record keeping in prescribing is not only essential to ensure safe continuity of care and identification of areas of risk for patients but also because, in the future, nurse prescribing could be one of the new developments assessed by the *National Institute of Clinical Effectiveness* (NICE). If the quality of record keeping is poor, it may prevent accurate assessment of the effectiveness of nurse prescribing in delivering an improved quality of service for patients. Poor record keeping may also hinder attempts to provide vital data should nurse prescribers in the future demand an extension of the NPF.

The quality of record keeping itself may be negatively affected by the repetitive data entries expected from nurse prescribers. Currently (and dependent on local procedures), many nurses are expected to separately enter details of the prescription in records held by the patient, the nurse, the

parents and the GP. Nurse prescribers and managers should discuss these issues and devise systems which are 'practitioner and patient friendly' and which accord with legal and professional standards for record keeping.

Preferential prescribing

Nurse prescribers need to be aware of external influences on prescription choices as they may find themselves targeted in sales promotions by commercial firms.

Commercial representatives may attempt to persuade nurses to preferentially prescribe their products. If a product is preferentially prescribed, the nurse remains responsible for the appropriateness of the prescription which should include checking the claims made for the product in any sales promotion. This will involve the nurse reading all the sales promotional literature and, in particular, any data relating to research studies on which claims for the product are based.

As in all other areas, nurses need to be aware of the UKCC *Code of Professional Conduct*, which states that nurses' 'professional judgement is not influenced by commercial considerations'. In addition, nurses need to abide by their employers' policies and procedures on accepting and declaring any inducements to prescribe preferentially.

Preferential prescribing may involve the nurse prescriber in ethical issues which, if unresolved, may not only compromise professional practice, but render the practitioner legally vulnerable. For a fuller discussion of ethical issues see Chapter 3.

Security of prescription pads

Security of the individual prescription pad remains the responsibility of prescribers, who should also ensure that they do not lend the pad to others. Dependent on the circumstances, for example failure to ensure that the pad was stored securely, loss of the prescription pad could constitute a disciplinary offence under the employers' procedures.

Each prescription pad will have a 'new unique nurse identifier' (ENB, 1998) which in many areas is the nurse's UKCC personal identification number (PIN). The UKCC advises that nurses should retain their PIN numbers securely and that in the event of loss, the UKCC should be informed.

Many nurse prescribers are concerned that maintenance of PIN security is impossible if the PIN is written on a prescription which is then given to

Box 2.3 – The duty of care in relation to the prescription could potentially be breached in these areas

- Prescription writing
- Preferential prescribing
- Security of prescription pads

patients. In addition, they express concerns that loss of a prescription pad containing the PIN could expose them to personal and professional risk, as it may be possible for anyone who gains possession of it not only to access information held by the UKCC but to fraudulently use the PIN to gain employment. Medical prescriptions do not include the doctor's professional PIN.

Product liability

Nurse prescribers must be aware of their responsibilities for giving product information under the Consumer Protection Act 1987. This Act relates to the safety of products and creates strict liability for injuries caused by defective products. A defective product is defined by the Act as one which is '... not as safe as people are generally entitled to expect'. The concept of liability for products requires a complainant to demonstrate that a particular product is defective under the Act and that the product caused harm. Defective drugs come within the scope of the Act but 'a drug will only be "defective" where it can be shown that the risks associated with its use are so grave that they outweigh the potential benefits of treatment' (Korgaonakar and Tribe, 1995).

The Consumer Protection Act is drafted in such a way as to allow the complainant who is unable to identify the producer of the product to sue the person who supplied them with it. The definition of 'supplier' would include doctors, pharmacists and nurse prescribers.

The implications of this Act for nurse prescribers are that they are accountable for ensuring that information concerning the side effects and particular instructions regarding the product are given to the patient. Additionally, that information is given regarding the safe storage and disposal of prescribed products. It is good professional practice to record in the patient's notes that such information was given.

Consent

In law, any mentally competent adult has the right to consent to any touching of their person. Any non-consensual touching could result in a civil action for trespass to the person. Consent can be implied or expressed. An example of implied consent is where the patient's actions imply that they have given consent; for example, when a patient rolls up their sleeve on being informed that the nurse wishes to take their blood pressure. Expressed consent, given verbally or in writing, is an explicit consent to any invasive procedure or treatment or where there is a known risk element.

Nurse prescribers need to be aware of their professional and legal responsibility for giving sufficient information, on which a balanced judgement of whether to accept or refuse the treatment can be made. Expressed consent should be sought for any product which the nurse prescribes and intends to use invasively, e.g. urinary catheters. Where the patient is incapable of giving expressed consent, the nurse should advise relatives or carers of the reason for the prescription and treatment and record the information in the patient's records. Nurses should ensure that in the case of adults incapable of giving consent, decisions regarding any proposed treatment are made on the basis that it will be in the best interests of the patient. This decision may have to be justified at a later date.

Communicating with colleagues

The role of the nurse prescriber could potentially cause areas of disagreement or misunderstanding with other non-prescribing colleagues (including managers). Colleagues who do not fully understand the prescriber responsibilities may request prescriptions for their patients 'to save bothering the GP'. Such requests should be carefully considered. They involve prescribing for a patient who has not been assessed by the prescriber and they may have little or no knowledge of the patient.

It would be good practice for managers with staff who have successfully attended nurse prescriber courses to interview them on completion of the course to discuss these and other prescribing-related issues. Managers should be aware that vicarious liability may not be effective for nurse prescribers until they have been authorised in the role. Vicarious liability is defined in terms of the employer's liability for the negligence of employees acting in the course of their employment. Issues relating to aspects of the role should be fully discussed and role parameters clearly understood by

Box 2.4 – Areas in which breaches of the duty of care may occur**• Prescribing**

The prescription should be valid and used in accordance with the nurse prescriber's instructions

• Product liability

Information about side effects and particular instructions regarding the product should be given to the patient

• Consent

Sufficient information should be given to the patient on which a decision to accept or refuse the treatment can be made

• Communication

Nurse prescribers should communicate effectively with colleagues on all aspects relating to individual prescriptions

both parties. In taking on the new role, the manager and prescriber should also carefully examine existing standards and protocols which may need to be revised and updated to reflect the new responsibility.

Nurses should also discuss the new role with other prescribing colleagues and agree actions to be taken in the event of any concerns with products prescribed by another nurse prescriber. In addition, the nurse prescriber should be aware of the Primary Care Group or Trust position on issues such as prescribing patterns and budgetary limits for prescribing.

CONCLUSION

It is clear that nurse prescribers have a duty of care to patients to ensure that:

- they are adequately prepared for the role
- they understand the legal and professional framework for the role
- they are competent in the performance of the role
- the standards of their prescribing care meet with professional and legal requirements.

CURRENT ISSUES IN NURSE PRESCRIBING

As discussed earlier, the *Scope of Professional Practice* (UKCC, 1992a) expects that nurses should take appropriate steps to maintain role competence. This includes developing and maintaining their knowledge of 'pharmacology and the life sciences' (Courtenay and Butler, 1999).

Maintenance of competence and updating knowledge and skills can be done through a variety of mediums including:

- peer support
- auditing nurse prescribing
- reviewing prescribing patterns
- critical incident reviews
- clinical supervision
- keeping abreast with current prescribing literature.

Since the role of nurse prescribing is still relatively new, the new prescriber may experience a lack of peer support or clinical supervision. As this new role is traditionally a medical one, it may be appropriate for a doctor to act as clinical supervisor for the nurse prescriber, since they would be qualified to challenge the prescriber's decisions.

It is clear from the discussions in this chapter that nurse prescribers are professionally and legally accountable for every aspect of the prescribing process, including the knowledge base and practical skills. Nurses also need to be aware of social developments which may impact on prescribing practice; for example, their responsibility and accountability in prescribing for people such as those seeking political asylum who may not be registered with a GP. Equally, health visitors who run clinics for mothers and children who come from different geographical areas must be certain about their position in relation to prescribing.

As with any new development, nurses should be vigilant in reflecting on practice and attempt to identify the areas where patient safety may be compromised and, together with other prescribers and managers, devise appropriate procedures designed to reduce risk.

Box 2.5 – Some practice issues which nurse prescribers should consider

- How will performance in the role be assessed?
- Where and how will the patient's prescription be documented?
- How will the effectiveness of the prescription be evaluated?
- How will prescribing patterns be monitored?
- What actions should be taken in the event of needing to prescribe for patients
 - not registered with a GP?
 - not from the practitioner's catchment area?
- What is the procedure for adding a nurse-prescribed medicine to those already dispensed by a pharmacist in a sealed monitored dosage system?

Cases

Bolam vs Friern Barnet Hospital Management Committee (1957) 2 ALL ER 118
Medical Bolitho vs City and Hackney HA (1993)
Blyth vs Birmingham Water Works (1856) 11 Exch
Donoghue v Stevenson (1932) AC 562
Nettleship v Weston (1971) ALL ER 581; (1971) 3 WLR 370
R v Bateman (1925) LJKB 791, CCA
Rogers v Whitaker (1992) 3 Med LR 331

Statutes

Consumer Protection Act 1987
Medicines Act 1968
Medicinal Products: Prescription by Nurses etc Act 1992
Pharmaceutical Services Regulations 1994

References

Courtenay, M. & Butler, M. (1999). *Nurse Prescribing: Principles and Practice*. London: Greenwich Medical Media.

CURRENT ISSUES IN NURSE PRESCRIBING

Department of Health (1999). *Review of Prescribing, Supply and Administration of Medicines* (Crown Report). London: Department of Health.

Dimond, B. (1995). *Legal Aspects of Nursing*. London: Prentice Hall. P 28

Elliott Pennells, C. (1997). Professional negligence. *Professional Nurse* 13(1): Pages 50–53

English National Board for Nursing, Midwifery and Health Visiting (1998). *Nurse Prescribing Open Learning Pack*. Milton Keynes: Learning Materials Design. P 59

Kennedy, I. & Grubb, A. (1989). *Medical Law Text and Materials*. London: Butterworths. P 396

Korgaonaker, G. & Tribe, D. (1995). *Law for Nurses*. Cavendish Publishing. London. P 147

Rieu, S. Error and Trial, The Extended Role Dilemma. *British Journal of Nursing*, 1994 3(4) P 168–174

Simanowitz, A. Editorial AV-MA Medical and Legal Journal

Stauch, M. (1997). The legal concept of medical negligence, *British Journal of Nursing* 6(22): 1325.

Tingle, J. (1990). Accountability and the law: how it affects the nurse. *Senior Nurse* 10(2): 8–9.

Tingle, J. & Cribb, A. (1995). *Nursing Law and Ethics*. Oxford: Blackwell Science. P 143

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1992a). *The Scope of Professional Practice*. London: UKCC.

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1992b). *The Code of Professional Conduct*. London: UKCC.