

Medico-Legal Considerations in the Sphere of Intravenous Therapy

Speaker:

Ms Penny Maudsley, Barrister
(Qualified Nurse, Qualified Midwife)

and/or

Mr Lee Gledhill, Barrister
(Qualified Nurse)



Nurses Defence Service
London, Manchester, Telford, Cardiff
enquiries@nursesdefenceservice.com
0800 01 22 506
www.nursesdefenceservice.com

Introduction

1. Speaker Penny Maudsley has practised as a barrister in various areas of law for the past 15 years, including medical and regulatory law. She regularly defends nurses and midwives before the NMC in fitness to practise proceedings. Penny also practised as a nurse and midwife in her previous career. She is Deputy Head of Chambers at Alexander Chambers.
2. Speaker Lee Gledhill has practised as a barrister in criminal law, civil law, and medico-regulatory law, for the past 15 years. He has represented several hundreds of nurses in NMC cases, inquests, and other legal cases. He also represents doctors at the GMC. And has defended clients in homicide cases in the Central Criminal Court. He practised as a nurse in his previous career. He is Head of Chambers at Alexander Chambers.
3. The speaker has been invited to give a presentation on:
 - (A) professional accountability and the law
 - (B) meeting quality statement 4 of the new NICE guidance – ensuring any consequences of fluid mismanagement are reported as critical incident
 - (C) advanced nursing practice: making autonomous decisions
 - (D) issues around gaining valid consent for IV Therapy
4. In covering the above, this presentation will look at: Product Liability, Gross Negligence Manslaughter, Consent, Giving Advice and Guidance, Nice Guidelines / Quality Standards, NMC Policies, NMC Misconduct and Competence Cases. This presentation does not claim to be comprehensive. These are some of the speaker's trigger notes.

(A) PROFESSIONAL ACCOUNTABILITY AND THE LAW

Product Liability

5. You will have read from time to time about clinical products causing harm to patients, sometimes leading to death. IV therapy can cause great harm if not performed correctly, using safe products that are fit for purpose.

What is the law of product liability in relation to IV therapy?

Common Law

6. Should people be compensated where the product has been found to be defective? The civil courts back in the 1930s were tasked with that very question, in the common law ('judge made law') case of Donoghue v Stevenson [1932] AC 562.
7. Mrs Donoghue purchased a bottle of ginger beer, which unfortunately also contained a decomposing snail. Having consumed some of the contaminated ginger beer she became unwell. She subsequently sued the manufacturer, in negligence. The manufacturer denied liability. The appeal court held that the manufacturer was liable for their failure to manufacture a safe product – free from decomposing snails. Mrs Donoghue recovered

damages (compensation). The case of Donoghue and Stevenson became a seminal case. It held that someone must take reasonable care in all of the circumstances, so as to ensure that a product is safe.

8. For further coverage of this case, see: http://en.wikipedia.org/wiki/Donoghue_v_Stevenson
9. Since that time, the UK government has implemented various legislation to put certain aspects of product Liability on a statutory footing.

Statutory Framework

10. See by way of example the Consumer Protection Act 1987, which introduced into the UK the harmonisation of product liability law, which was being adopted across Europe: namely, liability without fault. There are some defences.
11. Claims must be brought within three years of the incident or knowledge of the incident. There is a pro-manufacturer safeguard that no claim under this product liability legislation can be brought after 10 years. This time limit is an absolute bar. The restriction within the legislative provision makes insurance more affordable to industry, in the longer term. If damage becomes known after the ten years, then the claimant could potentially sue in negligence.
12. Adverse reactions from medicines are common-place and mostly known. Most adverse reactions are trivial and short-lived, and would not lead to a finding that a product was defective. The Act sets out in section 3 what constitutes a defective product:

'there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect' (section 3a).
13. There then follows further definition in the same section, which you can read at: www.legislation.gov.uk/ukpga/1987/43 but it does not really make interpretation any easier. Clear as mud? It will ultimately be down to the courts to look at the various relevant factors when determining liability.
14. Defences for manufacturers can be found in the same linked webpage, in section 4. One defence reads as follows: *'It shall be a defence...that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered that defect if it had existed in his products while they were under his control'* (section 4(1)(e)).
15. Manufacturers will generally test their products before selling them, to ensure, insofar as is possible, that they are fit for purpose. They will also obtain product liability insurance, in case something goes wrong. Consumers are therefore afforded some protection and rights when things go wrong. Pure economic loss falls outside of the scope of the Act but personal injury and damage to property is included.
16. A claimant still has to prove damage to be able to recover compensation. This may be difficult for a patient who is already ill, with a multitude of symptoms. How does one prove damage was caused by the defective product? It would turn on expert evidence. But there would be many hurdles for a patient to convince an expert that it was a medicinal product that was at fault rather than just their own illness. Very few claims are actually brought in product liability, for damage caused by defective medicines. Could this be one of the

reasons?

17. Suppliers, too, may also be caught by the Act. Is the NHS a supplier? Is a private hospital or clinic a supplier? Is a nurse a supplier? They often will be. A pharmacist is a supplier. A doctor or a nurse could be a supplier, if they provide (dispense) the medicine rather than giving their patient a prescription to be dispensed by a pharmacist. The need for appropriate insurance for certain types of clinicians is obvious. [The NMC has now made it mandatory that all nurses carry indemnity insurance. www.nmc-uk.org/Registration/Professional-indemnity-arrangements/ Some will be covered by their employer's liability, while others will have to arrange their own, perhaps through a union, or by buying a bespoke product direct from an insurer.]
18. An error in the workplace may make the nurse or midwife liable personally, or their employer vicariously liable, for any damage that is sustained.
19. Pursuant to the Act, a supplier might also be liable if they cannot identify the manufacturer. Records should therefore be kept for at least ten years. A supplier and a manufacturer cannot exclude liability under the Act: Section 7.
20. What is a product? A medicine is a product. A medical device is a product. It appears that human tissue and human fluids can also be products: A v National Blood Authority [2001] 3 All ER 289. Therefore, all intravenous therapies are likely to be found (by the courts) to be products that fall within the scope of the Act.
21. The NHS issues product recall notices from time to time, as do manufacturers. In the private-sector, where products may be used that are not in the NHS, there is a need for vigilance, and good lines of communication with suppliers. Product recalls need to be acted upon promptly, taking out of circulation any contaminated or defective products. If defective products have been used on patients, they may well need to be followed up.
22. This element of this presentation should have shown you that good record-keeping and record-retention are essential in clinical practice, as is having appropriate indemnity cover, sourcing reputable medicinal/IV products, checking that they appear to be in good order before use (no fish!), record the batch number and manufacturer, also ensuring that all NHS and other product recall notices are scrutinised and acted upon.

*

Prescribing Nurses, Dispensing Nurse: Liability in Negligence/Contract

23. In ***Prendergast v Sam and Dee Ltd - Times, March 24, 1988 : Independent, March 17, 1988 : Guardian, March 19, 1988*** Mrs Prendergast had consulted her GP. Mrs Prendergast was asthmatic. Her GP wrote a prescription that was illegible. The dispensing pharmacist, as a consequence, misread the prescription and dispensed a different drug. The drug was taken by the patient in accordance with the instructions on the bottle. An unintended overdose occurred and the patient suffered brain damage. The doctor was held (in negligence) to be 25% liable, while the pharmacist was found to be 75% liable. The doctor should have issued a clearly legible prescription, while the pharmacist should have recognised that the patient would not have been prescribed the type of drug the pharmacist believed the prescription to be stating. Also, the dosage should have been seen as being inappropriate.
24. The case demonstrates the importance of making clear and accurate records. Especial care

should be taken when writing a prescription. Nurses who write prescriptions need to ensure that their handwriting is accurate and that the dosage is correctly set out. A nurse who dispenses medicine in accordance with a prescription needs to ensure that they can read the prescription. They must check that the dosage falls within an expected range. They must take care to look out for prescribing errors. If there is any doubt the dispensing nurses must check with the prescriber. This applies equally to all medicines, including intravenous therapies.

Negligence

25. *So what is negligence? or clinical negligence*

Negligence:– Duty, Standard, Breach, Causation, Damage (& remoteness of damage)

26. The courts have developed the common law over many years. In essence, clinical negligence will likely be found where a nurse is found to have had a duty of care to deliver a particular standard of care, but has breached that duty (and in so doing, fallen below the standard of care that could reasonably have been expected to be in place), so causing harm to a patient. Such harm attracts an award of compensation in most instances.

BREACH OF DUTY / STANDARD / CAUSATION

27. In Bolam v Friern Hospital Management Committee QBD 1957 the test to be applied by the courts is the standard of care that the ordinary skilled [clinician] exercising and professing to have that special skill must exercise. McNair J opined:

"The test is the standard of the ordinary skilled man exercising and professing to have that skill. A man need not possess the highest skill at the risk of being found negligent. It is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art.

...I myself would prefer to put it this way, that he 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. I do not think there is much difference in sense. It is just a different way of expressing the same thought. Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view. At the same time, that does not mean that a medical man can obstinately and pig-headedly carry on with some old technique if it has been proved to be contrary to what is really substantially the whole of informed medical opinion. Otherwise you might get men today saying: "I do not believe in anaesthetics. I do not believe in antiseptics. I am going to continue to do my surgery in the way it was done in the eighteenth century." That clearly would be wrong.

28. The principles set out in Bolam were approved by the House of Lords (now the Supreme Court) in Whitehouse v Jordan [1981] 1 WLR 246. [For more information on the Bolam case see: http://en.wikipedia.org/wiki/Bolam_v_Friern_Hospital_Management_Committee]

29. As the above case discloses, nurses must work within a reasonable body of opinion or knowledge, as well as demonstrating the appropriate level of skill. There is a duty on nurses to keep up to date and avoid out of date practices. There may be more than one way of doing things and so long as the nurses falls within one of those reasonable approaches then they

will have acted competently, without negligence.

30. See also the case of Bolitho v City and Hackney Health Authority [1997] HL, in which a doctor who failed to promptly attend a child patient, having been bleeped, was sued in negligence. The negligence claim was that the doctor had caused brain damage to the child because of the delay in attending, so delaying intervention. It was claimed that the child suffered brain damage as a consequence of a failure to intubate. The defence mounted a challenge to that assertion. The defence claimed that even if the doctor had attended, the doctor would not have intubated the patient. The patient would or could have suffered hypoxia in any event, and that it was not a negligent act on the part of the doctor, because they fell within a reasonable approach. The court held that to be a logical and defensible approach, which was sustainable under judicial enquiry. To read the case of Bolitho, see www.publications.parliament.uk/pa/ld199798/ldjudgmt/jd971113/boli01.htm
31. The Bolam/Bolitho cases, as applied to the role of a nurse, could be stated as follows: a nurse who prescribes or administers intravenous drugs must do so with the reasonable care and skill of any nurse (or of a nurse also working at a similar specialist level), while at the same time working within a reasonable body of knowledge and opinion.
32. For further reading, see: Marriott v West Midlands RHA [1999] Lloyd's Rep Med 23; and Reynolds v North Tyneside Health Authority [2002] Lloyd's Rep Med 459; Maynard v West Midlands 1 WLR 634.
33. Some cases you can view online if you do a search for the name of the case. Try also www.bailii.org

*

DAMAGE

34. Some harm may be trivial, while some harm may cause catastrophic injury. Midwifery negligence could, by way of example, lead to the insurers of a midwife or their employer (under principles of vicarious liability) or their insurers, paying out compensation of several millions of pounds for life-time care of a new born child. The damage sustained must not be too remote. It should be reasonably foreseeable, and naturally flow from the negligent act or omission.

DISCUSSION

35. A nurse has a duty to their patients to look after them. They must also provide a standard or level of care that is appropriate, and ensure that the care delivered falls within a reasonable body of opinion.
36. If the nurse cannot demonstrate that they worked in accordance with a reasonable body of nursing/medical opinion, when they undertook or omitted to undertake a particular intervention, then they would be likely to be found negligent.
37. Good record-keeping and proper care planning are essential tasks for a nurse, so that they can reconstruct what has occurred at a given time. Far too many nurses make scant or no notes at all.

Gross Negligence Manslaughter

38. Each year many clinicians, including nurses, are interviewed under caution at a police

station. The precise numbers are not known. The UK police investigate unusual and unexpected deaths in hospitals and the community, where the standard of clinical care may have contributed to or caused death. Very few prosecutions follow. By way of example, this author knows of two cases where the CPS did not prosecute nurses. One concerned a proved IV overdose of heparin to an infant, the other a patient in diabetic coma that was not picked up.

39. The leading case in gross negligence (involuntary) manslaughter cases is that of the Crown v Dr Adomako. [For further reading, see http://en.wikipedia.org/wiki/Manslaughter_in_English_law#Manslaughter_by_gross_negligence]
40. Dr Adomako was an anaesthetist. He failed to observe (during surgery in theatre, when the patient was under a general anaesthetic) that oxygen was not reaching the patient via the endotracheal tube, due to a disconnection. Even after the resuscitation was commenced he had failed to check for a disconnection. The patient died.
41. The police charged Dr Adomako with manslaughter by gross negligence. The Crown's case was that there would have been signs of problems before the patient arrested, including the lack of chest movement and the patient turning blue. Dr Adomako was convicted by a jury of gross negligence manslaughter. He appealed. The court dismissed the appeal.
42. The court held that ordinary concepts of negligence would apply to cases of this type. The jury would then have to ascertain to identify but also held that the negligence would also have to be sufficiently gross such that it should be classed as a crime. The ultimate issue being left to the jury to decide. The criminal standard of proof applies (the jury must be 'satisfied so that it is sure', or 'beyond reasonable doubt'), whereas in civil cases, in contrast, the balance of probabilities is the standard of proof.
43. Some clinicians may be jailed, though a suspended sentence may well be more likely by way of disposal.

*

NHS local reporting of adverse incidents

44. The NHS has its own protocols for reporting and monitoring adverse incidents, some of which are a requirement under health and safety law. This particular topic will not be explored in any depth here. In the NHS's *Serious Incident Framework* (2013) document it is stated that:

“Governance principles for serious incidents

Both commissioning and provider organisations, whether in primary, secondary or tertiary care, are accountable for effective governance and learning following a serious incident. The precise split of responsibilities between organisations varies with the type of provider and commissioner, and the particular circumstances of each serious incident.”

45. The same document explains (at page 11): **What is a serious incident?**

- Serious incidents requiring investigation were defined by the NPSA’s 2010 *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*. In summary, this definition describes a serious incident as an incident that occurred during NHS funded healthcare (including in the community), which resulted in one or more of the following;

- unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
- a never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death. (See *Never Events Framework*);
- a scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population; allegations, or incidents, of physical abuse and sexual assault or abuse; and/or loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

46. For further reading, see also the 2014 guidance at: www.england.nhs.uk/2014/03/20/med-devices on reporting adverse incidents concerning medicines and medical devices.

47. This leads us 'nicely' into a short discussion of the new approach to IV therapy, adopted by NICE.

*

(B) MEETING QUALITY STATEMENT 4 OF THE NEW NICE GUIDANCE – ENSURING ANY CONSEQUENCES OF FLUID MISMANAGEMENT ARE REPORTED AS CRITICAL INCIDENT

NICE Guidelines

48. NICE has produced many guidelines as to what the organisation considers good practice. By way of example, consider the NICE Clinical Guideline 174 (December 2013): *Intravenous Fluid Therapy in Adults in Hospital Settings [NICE guidelines [CG174]]* www.nice.org.uk/guidance/cg174/resources/guidance-intravenous-fluid-therapy-in-adults-in-hospital-pdf

49. The NICE authors of the above guidelines observe that:

'Errors in prescribing IV fluids and electrolytes are particularly likely in emergency departments, acute admission units, and general medical and surgical wards rather than in operating theatres and critical care units.'

50. This speaker understands that the substance of the NICE recommended clinical approach to IV therapy is being covered by another speaker, within this study day. However, the above document will also be relevant to the discussion below.

51. Suffice it to say that the contributors at NICE are well aware that many errors are occurring in this area of practice. NICE is therefore seeking to educate clinicians and in turn improve the standards of care delivered.

52. The new NICE **quality standards** statement [QS66] (consisting of 4 quality statements on) *Intravenous fluid therapy in adults in hospital [see link below]* states that all organisations should have:-

1. an identifiable person who has responsibility for 'training, clinical governance, audit and review of IV fluid prescribing, and patient outcomes' (**Quality Statement 1**).

2. Nice also recommends that all: 'Adults receiving intravenous (IV) fluid therapy in hospital are cared for by healthcare professionals competent in assessing patients' fluid and electrolyte needs, prescribing and administering IV fluids, and monitoring patient response' (**Quality Statement 2**);

3. Further, nice recommends that: 'Adults receiving intravenous (IV) fluid therapy in hospital have an IV fluid management plan, determined by and reviewed by an expert, which includes the fluid and electrolyte prescription over the next 24 hours and arrangements for assessing patients and monitoring their plan' (**Quality Statement 3**)

4. NICE has now developed its own recommended guidelines (**Quality Statement 4**) for reporting (internally, within a hospital or other institution) adverse incidents in the area of area of IV therapy, so that prompt action can be taken to improve patient care. It reads: '*For adults who receive intravenous (IV) fluid therapy in hospital, clear incidents of fluid mismanagement are reported as critical incidents.*' Quality statement 4 feeds back into the previous 3 quality statements.

53. (See the above link to view the document that is referred to in the following document. [QS66]).

54. For the quality statements [QS66], see: www.nice.org.uk/guidance/qs66/resources/guidance-intravenous-fluid-therapy-in-adults-in-hospital-pdf

55. In stated rationale behind the guidelines reads:

'There are a number of potential adverse consequences of IV fluid therapy, including unnecessarily prolonged dehydration, over hydration or significant electrolyte imbalance, which may be identified by clinical and biochemical monitoring. Not all adverse consequences of IV fluid therapy are due to fluid mismanagement, but clinically significant problems caused by IV fluid mismanagement should be reported as critical incidents. By routinely reporting these events, even when they are well-managed, hospitals will increase learning, improving the likelihood of better patient outcomes.'

56. The quality statement lists the adverse incidents that should be reported, pursuant to the above protocol, and the time-frames in which to do it:

Consequence of fluid mismanagement	Identifying features	Time frame of identification
Hypovolaemia	<ul style="list-style-type: none"> • Patient's fluid needs not met by oral, enteral or IV intake and • Features of dehydration on clinical examination • Low urine output or concentrated urine • Biochemical indicators, such as more than 50% increase in urea or creatinine with no other identifiable cause 	Before and during IV fluid therapy
Pulmonary oedema (breathlessness during infusion)	<ul style="list-style-type: none"> • No other obvious cause identified (for example, pneumonia, pulmonary embolus or asthma) • Features of pulmonary oedema on clinical examination • Features of pulmonary oedema on X-ray 	During IV fluid therapy or within 6 hours of stopping IV fluids
Hyponatraemia	<ul style="list-style-type: none"> • Serum sodium less than 130 mmol/l 	During IV fluid therapy or within 24 hours of stopping IV fluids

	<ul style="list-style-type: none"> No other likely cause of hyponatraemia identified 	
Hypernatraemia	<ul style="list-style-type: none"> Serum sodium 155 mmol/l or more Baseline sodium normal or low IV fluid regimen included 0.9% sodium chloride No other likely cause of hypernatraemia identified 	During IV fluid therapy or within 24 hours of stopping IV fluids
Peripheral oedema	<ul style="list-style-type: none"> Pitting oedema in extremities and/or lumbar sacral area No other obvious cause identified (for example, nephrotic syndrome or known cardiac failure) 	During IV fluid therapy or within 24 hours of stopping IV fluids
Hyperkalaemia	<ul style="list-style-type: none"> Serum potassium more than 5.5 mmol/l No other obvious cause identified 	During IV fluid therapy or within 24 hours of stopping IV fluids
Hypokalaemia	<ul style="list-style-type: none"> Serum potassium less than 3.0 mmol/l likely to be due to infusion of fluids without adequate potassium provision No other obvious cause (for example, potassium-wasting diuretics, refeeding syndrome) 	During IV fluid therapy or within 24 hours of stopping IV fluids

Cited from Nice Quality Standards [QS66] (2014), and NICE Clinical Guideline 174 (2013)

57. The quality standards presumably anticipate that hospitals and other care facilities will have a 24 hour system in place for experts higher up the chain of command to promptly respond to these adverse situations. Some hospitals already have such a protocol in place, contained within Early Warning Score protocols. There are of course funding issues to provide this level of expertise 24 hours a day (over and above the SHO on duty) and to set up a reporting process. Records will need to be kept centrally of all reported critical incidents.
58. It will be interesting to see whether this new quality statement has the desired effect of reducing the incidence of complications from IV therapy.
59. This speaker does not represent NICE and so we can only give an outsider's brief view on the framework, which was set to be implemented in August 2014. Guidelines are (arguably) just that. However, if an organisation intends to depart from the guidelines then the organisation should identify and record the reasons for doing so, so that it can justify their position in court.
60. *What is the status of a quality standard?* NICE states, in its online FAQs commentary (<http://www.nice.org.uk/Standards-and-Indicators/Developing-NICE-quality-standards-/NICE-quality-standards-FAQs>) that:

"The Health and Social Care Act (2012) makes it clear that the Secretary of State, in discharging their duty to improve the quality of services, "must have regard to the quality standards prepared by NICE".

Although these standards principally set out aspirational but achievable care and are not targets, the care system should also have regard to them in planning and delivering services, as part of a general duty to secure continuous improvement in quality.

The primary purpose of NICE quality standards is to describe high-priority areas for quality improvement, which are aspirational but achievable, in a defined care or

service area. NICE quality standards do not provide a comprehensive service specification. They define priority areas for quality improvement based on consideration of the topic area.'

61. *Is a quality standard a guideline?* The civil courts are now taking into account NICE guidelines, when seeking to determine reasonable bodies of opinion, in negligence cases, and other medical law cases. See, by way of example Richards v Swansea NHS Trust [2007] EWHC 487 (QB), where the court rejected an expert's opinion, as it did not accord with the NICE/RCOG guidelines. [The guidelines may not have had the same force if the Royal College of Obstetricians and Gynaecologists had not co-authored the guidelines.] Will the courts also take into account quality statements?
62. This reliance by the courts on guidelines may come as a surprise to some, because guidelines should be just that: guidelines. (NB. Only NICE 'appraisal category' statements must be implemented within three months.)
63. The NICE guidelines were not intended to impact on clinical discretion, were they? Were they not meant to be a tool to achieve consistency? The quality statement [QS66] states:

'Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.'
64. As mentioned above, on occasions the guidelines appear to be given greater weight by the courts than was probably anticipated. This speaker has also noticed this trend in regulatory law cases (NMC, GMC, FTP law): particularly in weight loss drug therapy cases. Further, coroners will also have regard to NICE guidelines when looking at the standard of care that should have been in place when a patient died.
65. This trend of the courts to rely on the guidelines may in turn have an impact on the private-sector. While the private sector falls outside of the NICE/NHS framework, can they afford to do so if the courts will take them into account when assessing negligence. CQC makes reference to the guidelines when determining whether to report clinicians to their regulators (GMC, NMC).
66. NICE is of the view [QS66 document] that over time the reporting of critical incidents will improve the delivery and monitoring of IV therapy. NICE also anticipates that the data recorded will be taken into account by commissioning groups:

Commissioners

(clinical commissioning groups and NHS England area teams) [will be able to] ensure that they commission services for adults receiving IV fluid therapy in hospital from providers that report clear incidents of fluid mismanagement as critical incidents. This can be achieved by ensuring that providers share lessons learned from critical incident investigations.

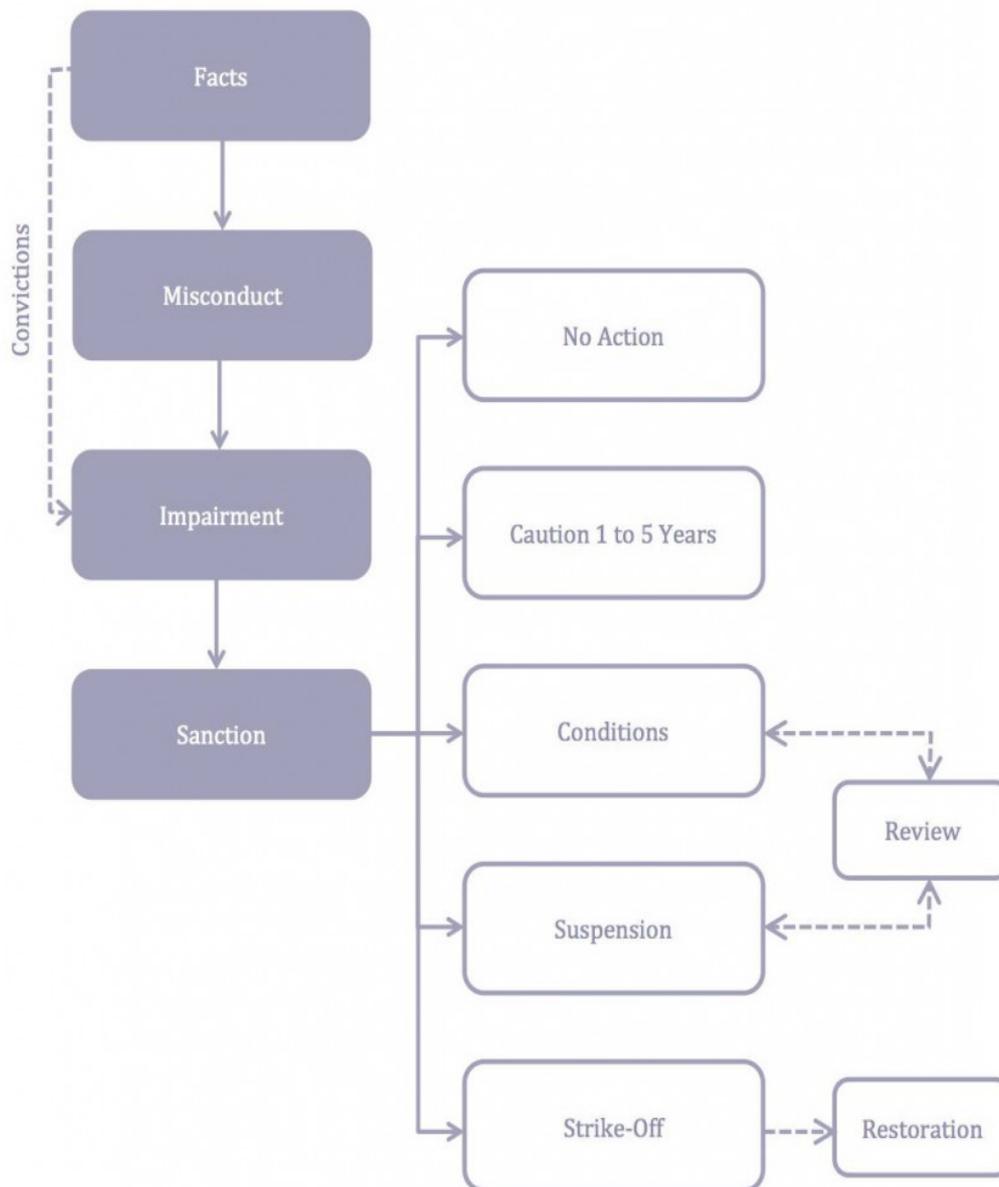
*

(C) ADVANCED NURSING PRACTICE: MAKING AUTONOMOUS DECISIONS

67. We have already explored aspects of civil and criminal law. The Nursing and Midwifery Council (NMC), the regulator of nurses and midwives, and the General Medical Council (GMC) the regulator of doctors, each provides guidance (on a number of subjects) on their respective websites (www.nmc-uk.org and www.gmc-uk.org) to clinicians. Some of the GMC's publications may well be relevant to nursing autonomy.
68. All nurses and midwives make autonomous ('independent') decisions on a daily basis, drawing on their experience and training, working within protocol or policy (acting, hopefully, within a reasonable body of opinion).
69. Nurses/Midwives regularly make autonomous decisions concerning IV therapy. They may prescribe IV therapy. They may administer IV therapy, following the prescription/script of another. They also teach others how to undertake these tasks, in order for them to become autonomous.
70. The words 'autonomy' and 'autonomous' are not mentioned in the 2008 NMC Code. Paragraph 38 of the code reads: *You must have the knowledge and skills for safe and effective practice when working without direct supervision.*
71. The code also requires a nurse/midwife to work collaboratively with others and ensure that any delegated task is properly delivered (paragraphs 29 to 31):
- 29 You must establish that anyone you delegate to is able to carry out your instructions.*
- 30 You must confirm that the outcome of any delegated task meets required standards.*
- 31 You must make sure that everyone you are responsible for is supervised and supported.*
72. The code also sets out a nurse's/midwife's duties where problems arise:
- 33 You must inform someone in authority if you experience problems that prevent you working within this code or other nationally agreed standards.*
- 34 You must report your concerns in writing if problems in the environment of care are putting people at risk.*
73. Paragraphs 33 and 34 are, sadly, not always observed by nurses and midwives. The longer they fail in this duty the more likely the problems will remain or get worse. Keeping one's head down, to have an easier life, does not accord with the code.
74. A nurse/midwife is accountable for their actions and omissions to their patients, the NMC, the courts in certain situations and, to a degree, their employers.
75. If things go wrong, a nurse or midwife (or other clinician) may be referred to their regulator.

For an overview of how fitness to practise processes operate, visit www.nursesdefenceservice.com/nmc-hearings and www.doctorsdefenceservice.com/gmc-ftp-representation

76. The NMC procedure is set out in the following diagram:



Facts determined on the Balance of Probabilities

Misconduct, Impairment, Sanction are a Matter of Judgment for the Panel

© Nurses Defence Service

77. Note that instead of misconduct a nurse may instead be charged with a lack of competence.

78. WHAT IS MISCONDUCT? There has never been a precise definition. Within the old statute (UKCC) it was said to be 'conduct unworthy of a nurse'. What is that exactly? Is it a fixed concept? Does it change over time?

79. What have the civil courts had to say? In *Roylance v General Medical Council* [1999] UKPC 16 (www.bailii.org/uk/cases/UKPC/1999/16.html) it was held that the standard of propriety may often be found by reference to the rules and standards ordinary required to be a registered practitioner. A registered practitioner must also conduct themselves in an appropriate manner outside of work:

'Professional misconduct extends further than [clinical work]. So it is not simply misconduct in the carrying out of medical work, which may qualify as professional misconduct. But there must be a link with the profession of medicine. Precisely what that link may be and how it may occur is a matter of circumstances. The closest link is where the practitioner is actually engaged on his practice with a patient. Cases here may occur of a serious failure to meet the necessary standards of practice, such as gross neglect of patients or culpable carelessness in their treatment, or the taking advantage of a professional relationship for personal gratification... Serious professional misconduct may arise where the conduct is quite removed from the the practice of medicine but is of sufficiently immoral or outrageous or disgraceful character.'

80. For other cases on this topic, see: www.doctorsdefenceservice.com/regulatory-case-law
Many of the cases are equally applicable to nurses cases before the NMC.

81. Is it a case of you know it when you see it? Inside and outside of work? Are alternative bodies of opinion a valid defence to this? Just how reasonable does an alternative body of opinion have to be?

82. The definition of misconduct on the NMC website (September 2014) states that misconduct is: Behaviour which falls short of what can reasonably be expected of a nurse or midwife. Is that any clearer? By what is it measured?

83. In fitness to practise proceedings, the panel will look at the NMC Code of Conduct (2008) for Nurses and Midwives, which sets out the standards that nurses should adhere to. (See www.nmc-uk.org/Publications/Standards/The-code/Introduction) The panel will cite paragraphs of the code that a nurse has breached, when determining misconduct.

84. But does the code help us to define the ambit of 'misconduct'? Not in isolation. National and local policies may be relevant, as will the opinion of an expert. The NMC often hears from nursing and other experts, to determine best practice or practice that falls within a reasonable body of opinion.

85. Some NMC publications to be familiar with when working in IV therapy:

- I. Standards for Medicines Management (2007): www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf
- II. Standards for Competence (2010): www.nmc-uk.org/Documents/Standards/Standards%20for%20competence.pdf
- III. Standards for Nurse and Midwife Prescribers (2006) www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-proficiency-nurse-and-midwife-prescribers.pdf

86. What about local, work-based policies? Do they set out the dos and donts of nursing practice? What about academic writings and peer articles? Seminars? Discussions in nursing journals and magazines?

87. When a nurse or midwife takes on roles and responsibilities that were once reserved for

doctors, the legal framework underpinning practice does not really change. The nurse or midwife does, however, have a greater responsibility to ensure that they are working within accepted parameters.

Accountability

88. Are we able to define 'accountability'? In 2004 the RCN published an ethnographic study which sought to explore the concept of 'accountability'. Researchers Savage and Moore recorded their findings in summary at the start of their report. The researchers concluded that:

'The study found that the meaning of 'accountability' was elusive and ambiguous for participants and that this ambiguity mirrored the 'catch-all' use of the term in current government policy. It was described by some as a retrospective explanation of actions, particularly as a way of apportioning or accepting blame. At the same time, accountability could be seen as something that motivates action and good practice and implies a readiness to take the consequences of action. In addition, accountability was used as a way of describing certain relationships, such as those between practitioners and clients, or between employers and employees. In general, participants found it difficult to articulate what accountability meant, and the more intent they became on pinning it down the more its meaning seemed to elude them.' (RCN: Savage and Moore 2004)

89. 'Accountability' is a term that is used often in literature. Take for example nurse and midwife revalidation, coming into effect from December 2015. The NMC declares that:

Nurses and midwives will have ownership of, and **will be held accountable** for, their own revalidation process. Every three years at the point of renewal of registration, nurses and midwives will need to demonstrate to the NMC that they continue to remain fit to practise in order to remain on the register.

90. Accountability (to the speaker) seems to include taking responsibility for what one does inside and outside of work; being able to justify the actions taken, or omissions to act, in the workplace, concerning patient care and the interaction with others; making good records; ensuring one is safe and working to an evidence-based, acceptable framework; acting with respect for diversity and difference of opinion, taking their clients wishes into account. What else can we add?

91. The NMC Code of Conduct (2008) states that a nurse is accountable for their actions and omissions. The preamble to the code reads:

As a professional, you are personally accountable for actions and omissions in your practice, and must always be able to justify your decisions.

You must always act lawfully, whether those laws relate to your professional practice or personal life.

Failure to comply with this code may bring your fitness to practise into question and endanger your registration.

This code should be considered together with the Nursing and Midwifery Council's (NMC) rules, standards, guidance and advice available from www.nmc-uk.org

(D) ISSUES AROUND GAINING VALID CONSENT FOR IV THERAPY

What is valid consent?

92. The NMC Code of Conduct (2008) states (paragraphs 13 to 17):

'Ensure you gain consent

13 You must ensure that you gain consent before you begin any treatment or care.

14 You must respect and support people's rights to accept or decline treatment and care.

15 You must uphold people's rights to be fully involved in decisions about their care.

16 You must be aware of the legislation regarding mental capacity, ensuring that people who lack capacity remain at the centre of decision making and are fully safeguarded.

17 You must be able to demonstrate that you have acted in someone's best interests if you have provided care in an emergency.'

93. **Giving Advice:** The NMC Code of Conduct (2008) states, at paragraph 36: *You must ensure any advice you give is evidence-based if you are suggesting healthcare products or services.*

94. **Providing Care:** Paragraph 35 of the Code states: *You must deliver care based on the best available evidence or best practice.*

95. So the NMC code is a starting point for the duties of a nurse or midwife, when obtaining valid consent. But what is valid consent?

96. **Providing sufficient information:** a clinician who fails to provide information to a client about care or treatment may face an action in tort or negligence. In tort law, a patient may bring a claim in battery for compensation. See, by way of example, the case of Chatterton v Gerson [1981] QB 432 (QB) in which the claimant alleged that she had not been given sufficient information about risks, so negating her consent to treatment when she encountered side-effects that she had not been told about. The court held that for consent to be real a clinician must inform the patient in "broad terms" about the nature of the procedure. The court considered that if someone went into hospital for a tonsillectomy but by mistake was circumcised, the cause of action would lie in trespass. The court was of the view that where a doctor has failed to inform a patient sufficiently, the cause of action would lie in negligence rather than battery. A similar view was expressed in The Creutzfeldt-Jakob Litigation [1995] 54 BMLR 1 (QB).

97. In Chatterton the court opined that if information is withheld in bad faith then consent will be vitiated by fraud. In the case of Appleton v Garrett 34 BMLR 23 (QB) a dentist who undertook dental work that was not justified, for financial gain, was found liable in battery. Battery usually requires some physical touching that is not warranted.

98. **Negligence:** There is a duty of care to provide information to patients. But how much information should be given? In Sidaway v Board of Bethlem and Maudsley Hospital [1957]

WLR 582 a patient claimed that she would not have given consent to be treated if she had been told that there was a 1 or 2 percent possibility of damage to her spinal cord, which regrettably had occurred during her surgery. The court determined that a patient has “a right to be informed of the risks inherent in the treatment which is proposed” but found against the claimant in that case. The percentage of risk was considered too low to require disclosure. Yet the judgment makes it less clear the percentage of risk that is required before the information must be disclosed in a particular case. Contrast that case with the case of Chester v Afshar [2004] UKHL 41 Pt 2 in which the House of Lords held that a patient who was left paralysed from surgery should have been advised of the 1-2% risk of damage occurring, which was an unavoidable risk. Lord Bingham stated:

'A surgeon owes a general duty to a patient to warn him or her in general terms of possible serious risks involved in the procedure. The only qualification is that there may be wholly exceptional cases where objectively in the best interests of the patient the surgeon may be excused from giving a warning. ...In the modern law medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small but well established risk of serious injury as a result of surgery.' (Para 16)

99. **Providing care:** any care should be Bolam compliant. Namely, of a standard that reasonably skilled clinicians ought to provide.
100. **Capacity:** A patient who has capacity can refuse treatment, even if it results in their death: Re B (Adult, refusal of medical treatment) [2002] 2 All ER 449 Also, mental illness does not mean that someone lacks capacity: Re C (Adult, refusal of treatment) [1994] 1 All ER 819 See, also, Re MB (Adult, medical treatment) [1997] 38 BMLR 175 CA phobia of needles (fear and panic) found to have led to a temporary lack of capacity. See, further, Re T (Adult) [1992] 4 All ER 649 where the courts found that a 20 year old had been unduly influenced by her mother to refuse a blood infusion, while also being affected by medication, such that she lacked capacity to refuse blood. The blood transfusion was given. In Williamson v East London and City Health Authority (1998) 41 BMLR 85 the courts confirmed that unless there is a life or death situation, if a surgeon during surgery discovers that there is a far more serious health problem that needs surgical treatment, they should not proceed to deal with it there and then (unless the procedure has already been consented to). Finally, St George's Healthcare NHS Trust v S; R v Collins, ex parte S [1998] 3 All ER, in which it was held that a pregnant woman who has capacity can refuse treatment even if it would cause her or her unborn baby harm.
101. A patient who lacks capacity will require a best interests decision to be made. Local protocols should be in place to deal with this frequent occurrence. On occasions the family of the patient who lacks capacity may object to proposed treatment or interventions. Parents will often make decisions for their children. Children should be involved in the decision-making process, where possible. On occasions, a clinician may disagree with the parents approach. In both of these cases, an application may need to be made to the courts for a decision to be made or guidance be given.
102. **Gillick Competence:** a child of sufficient maturity and intelligence who can understand the nature and implications of treatment can consent if certain criteria are satisfied, in the absence of their informing their parents or obtaining their parents consent. Gillick v West Norfolk and Wisbech AHA [1986] AC 112
103. **Requests for treatment:** A clinician is not under any legal obligation to provide care to a patient if the clinician considers it not in their best interests Burke v GMC [2005] EWCA Civ 1003

104. **Records:** A good quality, and sufficiently detailed note should be made of the discussion with a patient. The more complicated the procedure or intervention the greater the depth of discussion may need to be. Some patients do not want to know the details or the risks, of course.
105. **Implied Consent:** When a patient permits a clinician to do an intervention, by raising an arm for bloods to be taken, or by cooperating with the clinician.
106. **Express Consent:** recorded in writing. The more significant the intervention or the risks the greater the need to obtain written/signed consent from the patient.
107. The GMC has compiled a guide (consisting of 64 pages) for doctors on obtaining consent, which is worth reading: www.gmc-uk.org/static/documents/content/Consent_-_English_0414.pdf Much of the content is equally relevant to nursing.
108. **Discussion:** How many times have you gone to a patient's bedside, when a doctor has written up a prescription for an IV drug, to be administered for the first time, where neither you nor the doctor has explained to the patient the purpose of their having the drug or the potential side-effects or risks? Is this not a common-occurrence? Is implied consent enough? What if the risks (say 5% risk) are such that the patient may become deaf from the IV drug to be administered? Does anyone have responsibility to discuss risks? If so, who should it be?

Closing Remarks

109. We have merely dipped our toes into these areas of law and protocol. Each and everything we do as clinicians is governed by policy and law to some degree. Keeping abreast of changes is not an easy task. We hope that this presentation will be of some assistance to you in your daily job.

PENNY MAUDSLEY
LEE GLEDHILL