Understanding consent in clinical negligence

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Introduction

1. The need for a patient’s appropriately-informed consent to a proposed investigation or treatment is fundamental to the practice of medicine. It is a source of heated and recurring controversy and debate. For instance, in the week this webinar is recorded a Department of Health-commissioned review panel has reported on the Liverpool Care Pathway end-of-life protocol, concluding that it has often been used inappropriately and should be phased out.

2. An analysis of the entire law of consent is well beyond the scope of this presentation. My aim is to summarise and illustrate the main principles and key decisions which are relevant to clinical negligence practitioners. For a wider exposition I recommend a text such as Lewis and Buchan: Clinical Negligence (7th edition, 2012).

The basic need for consent

3. Any hands-on treatment of a patient by a doctor requires valid consent if it is to be lawful. Without consent, the doctor’s touch is like anyone else’s - a
criminal assault and a civil battery, actionable as of right. Every adult of sufficient mental capacity has the right to decide whether or not she will accept medical treatment even if refusal might risk permanent injury or death to her or her unborn child. That patient’s refusal of consent may be bizarre, irrational or immoral; but without it, her treatment is unlawful, and cannot be legitimised by detaining her as a mental patient: *St George’s Healthcare NHS Trust v S; R v Collins and others, ex parte S* [1998] 3 WLR 936. A patient who has the necessary capacity to make her own treatment decisions may refuse continued life support, even when this guarantees her death: *B v An NHS Hospital Trust* [2002] 2 All ER 449.

4. In practice, successful cases for battery against medical practitioners are rare; and the courts will generally be reluctant to find that a doctor acting in good faith has committed a trespass against the person (see for example *Chatterton v Gerson* [1981] QB 432). I will focus more on the situation where a patient undergoes treatment without being adequately informed of the risks of that treatment. Where the treatment causes injury, or the risk eventuates, the patient may have a claim in clinical negligence, or for breach of the Human Rights Act. The most frequent difficulty encountered by claimants lies in proving causation – that with sufficiently informed consent, they would not have proceeded with the injurious treatment.

**Giving and evidencing consent**

5. The General Medical Council’s online guide, *Consent: patients and doctors making decisions together* (‘the GMC Guide’) gives valuable guidance as to what the consent process requires. Although it sets regulatory standards rather than the standard of care in negligence, as the authoritative guidance of the relevant regulatory body it informs the common law too. Thus it should be considered by expert witnesses when addressing possible breach of duty in a consent context. The Guide
correctly points out that doctors should see getting a patient’s consent as an important part of the process of discussion and decision-making, rather than as something that happens in isolation. The more complex and risky the treatment, the more detailed the discussion will need to be, often involving different practitioners (for example, the operating surgeon to explain surgical risks and intended benefits; the anaesthetist to explain the risks associated with general anaesthesia and life support).

6. The GMC Guide advises that if patients have capacity to make decisions for themselves, a basic consent model applies:

   (a) *The doctor and patient make an assessment of the patient’s condition, taking into account the patient’s medical history, views, experience and knowledge.*

   (b) *The doctor uses specialist knowledge and experience and clinical judgment, and the patient’s views and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice.*

   (c) *The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one. They also have the right to accept or refuse an option for a reason that may seem irrational to the doctor, or for no reason at all.*

   (d) *If the patient asks for a treatment that the doctor considers would not be of overall benefit to them, the doctor should discuss the issues with the patient and explore the reasons for their request. If, after discussion, the doctor still considers that the*
treatment would not be of overall benefit to the patient, they do not have to provide the treatment. But they should explain their reasons to the patient, and explain any other options that are available, including the option to seek a second opinion.

7. In the context of a routine low-risk examination, whether in a primary care or hospital setting, consent is usually sought orally (e.g. ‘Let’s have a look at your chest’) and given orally or by implication (e.g. partially undressing). As a matter of good practice, consent to more complex and riskier procedures should always be obtained in writing on a printed consent form. That said, there is no absolute requirement for written consent under the common law (in contrast, for example, to the position governing the use of human gametes under the Human Fertilisation and Embryology Act 1990, or the use of organs and tissues under the Human Tissue Act 2004 where the donor is deceased).

8. Nevertheless the consent form will be important evidence if an issue arises over the fact or scope of the consent, or the duty to warn of risks. Indeed, the absence of a properly-completed consent form may itself raise questions as to level of care and competence exercised. And absent such a record, it will be difficult for the doctor to dispute from recollection that due consent was missing. As Smith J observed in Rhodes v Spokes and Farbridge [1996] 7 Med LR 135, a doctor has to remember one case out of the hundreds which occupied his mind at the time, while the patient has only to remember their own. The consent form will contain standard information, such as the patient's name, the proposed procedure plus any additional procedures which become necessary (e.g. ‘colonoscopy +/- excision of polyps’), the main risks (such as bleeding, infection, or nerve damage), and the signatures of doctor and patient to confirm that the risks have been explained and accepted, respectively.
Consent: how informed must it be?

9. How much does the clinician have to tell the patient to make the patient’s consent validly given? English law has been dogged by the disparity between the minimum standard of information required by the law of negligence, and the higher standard objectively necessary for genuinely informed consent. As we will see, however, the gap has been closing.

10. In Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital [1985] AC 871, the claimant consented to an operation on her cervical vertebrae. The operation carried a small risk (2%) of damage to her nerve roots (affecting movement or sensation in the patient’s arms) and a smaller risk of more serious damage to her spinal cord (less than 1%). The neurosurgeon warned her of the root damage risk but not of the cord damage risk. The operation left her paralysed. The patient sued, claiming lack of consent. By a majority the House of Lords considered that the decision as to what to tell the patient was a matter of clinical judgment, not of informed consent. So if sufficient information on the risks had been given according to the expert evidence of other neurosurgeons, that was enough. In short, the majority applied the Bolam standard: a responsible body of neurosurgical opinion sufficed. On this basis, to succeed in defending such an allegation all the surgeon has to do is get an expert in his area of practice to give evidence that no more information was required.

11. However, more recent appellate decisions have paid greater respect to the requirements of patient autonomy, and less to medical paternalism. One factor at work has been the more patient-centred approach taken by courts in other common law jurisdictions. Another has been the increasing awareness of relevant European human rights jurisprudence. As Lord Bingham observed in Van Colle v Chief Constable of Hertfordshire Police [2009] 1 AC 225 at para 58, one would ordinarily be surprised if conduct which violated a fundamental right or freedom of the individual under the
Convention did not find a reflection in a body of law as sensitive to human needs as the common law.

12. In *Bolitho v City and Hackney HA* [1998] AC 232 the House of Lords excepted the question of disclosure of risk from its analysis of why treatment could be held negligent despite being sanctioned by a responsible body of opinion. More striking was the Court of Appeal’s decision in *Pearce v United Bristol Healthcare NHS Trust* [1998] PIQR P53, where the claimant complained of a failure to warn of the additional risk of waiting to deliver her child two weeks after the due date. Sadly the child was stillborn.

13. Lord Woolf MR held:

..that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.

14. This was reinforced by the House of Lords’ decision in *Chester v Afshar* [2005] AC 134, which concerned the defendant’s failure to warn of the small risk of paralysis arising from lumbar surgery. The risk materialised through no surgical fault of the defendant. Nevertheless the trial judge upheld the claim, finding that the claimant, had she been warned of the risk of paralysis, would have declined to have the operation at that time. Rather, she would have sought a second opinion, or even a third. The House of Lords affirmed the judgment by a majority. Their reasoning on causation broke new ground, and is considered below at para 18. But also notable is the tacit judicial acceptance that *Sidaway* belonged to another age. Lord Bingham stated (para 16):

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 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.

So claimant experts must consider whether there are any small risks of serious injury mandating a warning, over and beyond risks of which any responsible body of opinion would require a warning.

15. It is not only the risk of serious injury which must be warned against, but the increased risks of one procedure over another. In Birch v University College London Hospital NHS Foundation Trust (2008) 104 BMLR 168, the claimant developed symptoms of vascular nerve palsy and was recommended a MRI scan to rule out an aneurysm. For want of available MRI slots she was transferred to the National Hospital for Neurology and Neurosurgery, Queen Square. There the neurosurgeons decided on a more invasive procedure, a cerebral catheter angiography. Complications ensued, resulting in a stroke. Cranston J held it was not negligent to use angiography rather than MRI. But the claimant was entitled to know of the comparative risks of the two investigations as part of the duty to inform her of those which were small but serious. Duly informed she would have selected the lower-risk MRI, so she succeeded on causation too.

Causation: what must patients prove they would have done if properly warned?

16. For a claim in negligence to succeed based on failure to warn of risks claimants must usually prove that, had they been fully informed, they would probably have refused the procedure altogether. Otherwise, so the
reasoning goes, the failure to warn has made no different to the outcome, and the claimant has lost nothing. This is why, as already mentioned, consent claims are notoriously challenging for claimant lawyers. Almost by definition, patients give consent for surgery or other risky investigations or treatments when they are disabled or unwell, and stressed by their conditions. Often they have run the gamut of more conservative treatments, and will be increasingly desperate. Against this background, it will often be difficult for a judge to accept that they would have declined the treatment in question after full and fair explanation. The more so when that explanation would naturally include the risks the other way - of the patient’s likely fate without the treatment.

17. The conventional route to causation success is illustrated by Birch (para 15 above). An opposite example is Gregory v Pembrokeshire HA [1989] 1 Med LR 81. The claimant gave birth to a child with Down’s syndrome following an amniocentesis. The judge held that the claimant should have been warned that the amniocentesis sample was inadequate, but that she failed on causation because she would have carried the pregnancy to term anyway, accepting what would have been her consultant’s advice - not to risk another amniocentesis. The Court of Appeal upheld the judge.

18. In Chester v Afshar the House of Lords blazed a new trail. They recognized that the application of normal principles of causation would defeat the claim – because Ms Chester could not prove that, duly warned, she would never have had the operation. However, the majority reasoned that on policy grounds, where a surgeon failed to warn of a significant risk and the risk eventuated, justice required the imposition of liability. Logically, there is an argument that where the risk is less than 1% - or even less than 50% - then on a future operative occasion the risk is unlikely to have eventuated, so causation is proven. This scenario was described in Chester as ‘bare “but for” causation’ – but for the negligence the patient would not have been in the way of harm on that occasion. But the argument runs up against the objection that to expose someone to a
risk to which that person is exposed whenever the operation is performed is not to cause anything at all (Lord Hope at para 81). What made the difference, reasoned Lord Walker at para 94, was that bare "but for" causation was powerfully reinforced by the fact that the misfortune which befell Ms Chester was the very misfortune which was the focus of the surgeon's duty to warn.

The scope of the consent

19. If the consent form contains a limitation on the treatment in question, the doctor must not breach it. Thus in the US case of Allen v New Mount Sinai Hospital [1980] DLR (3d) 364 a patient gave consent for an injection into his right arm and expressly forbade injection into the left arm. When the anaesthetist actually injected the wrong arm and caused an injury the court awarded damages for trespass to the person. Where the treatment is unnecessary and carried out in bad faith for the sole purpose of creating more work, that too is trespass to the person: Appleton v Garrett [1987] 8 Med LR 75.

Ancillary procedures

20. A clause giving consent to ancillary procedures does not give carte blanche authority to the surgeon to do whatever he wants. These clauses are usually construed by the courts purposively, so that only procedures connected with the target operation are covered, but the connection itself may be loose.

21. An obvious example of stepping over the line occurred in the Canadian case of Schweizer v Central Hospital [1974] 53 DLR (3d) 494. The patient gave consent to an operation on his toe but the surgeon carried out a back
operation as well. It was held that the ancillary procedure clause in the consent form did not cover that.

22. On the other hand, specific consent is not needed for every step in the operation. In *Davis v Barking, Havering and Brentwood HA* [1993] 4 Med LR 85 the patient consented to a cyst removal operation. She was only told she would have a general anaesthetic. The anaesthetist also did a caudal anaesthetic and the court held this was impliedly covered by the consent.

The emergency treatment defence: unconscious patients

23. What if the patient was unconscious when he arrived at the hospital? The general rule is that where the treatment was necessary to preserve the patient’s life or health, consent is implied or assumed.

24. In *Wilson v Pringle* [1987] QB 237 the Court of Appeal reasoned that, rather than resorting to the language of implied consent, it was better to say that an emergency operation on an unconscious patient was acceptable in the ordinary conduct of everyday life. But there are limitations on this acceptability. The treatment must be a necessity and no more than is reasonably required in the patient’s best interests: *F v West Berkshire HA* [1990] 2 AC 1, and *Re MB* [1997] 8 Med LR 217.

25. The emergency defence only applies in that limited circumstance, and not because it was merely convenient for the surgeon to do the second operation at the same time as the main one. In *Murray v McMurchy* [1949] 2 DLR 442 the patient had consented to a caesarean section birth and no more. The surgeon found fibroid tumours on her uterus and feared she was at risk in any future pregnancy so he tied her fallopian tubes. The court held this was not an emergency and amounted to a battery.
Children

26. The courts of England and Wales will, where necessary, step in and make treatment decisions on behalf of a child. Indeed, the court’s involvement at the instigation of one or other interested party may be mandatory where the treating doctors and the child’s family are at loggerheads: see for example *Glass v United Kingdom* [2004] 1 FLR 1019, ECHR.

27. For adolescents between the ages of 16 and 18, section 8 of the Family Law Reform Act 1969 deems that they can give valid consent to treatment. The position is more complex for children below 16. In *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112, the claimant mother sought a declaration that Government guidance to doctors allowing them to prescribe the pill to teenagers without telling their parents was a breach of the parents’ right to decide. The House of Lords held that the parents’ right terminated when the teenager achieved sufficient understanding and intelligence to enable her to decide for herself (hence ‘Gillick competence’). In *R (on the application of Axon) v Secretary of State for Health* [2006] QB 539, Silber J applied similar principles to sexual health counselling for under-16s, subject to ‘best interests’-type safeguards.

28. For younger children and those not Gillick competent, generally parental consent will suffice. Otherwise the wardship jurisdiction of the court will extend to those children who need treatment but whose parents refuse to consent to it on moral or religious grounds. Thus in *Re O (Medical Treatment)* [1993] 1 FLR 925 the court permitted a blood transfusion to a child where the parents refused.

29. *Re W (medical treatment)* [1993] Fam 64 concerned a child patient over 16 who had anorexia nervosa. The doctors wanted to give her treatment. She refused. The Court of Appeal held that where there was a probability of death or severe permanent harm, it had power to authorise treatment against the wishes even of a Gillick competent child, and did so.
Adult patients not of full capacity

30. The starting presumption for adults is enacted by the Mental Capacity Act 2005: a person must be presumed to have capacity to make the relevant treatment decision unless it is established that they lack it. As with any other decision, the Act requires that all practical and appropriate steps are taken to enable a person to make the treatment decision themselves, and the Code of Practice provides detailed guidance as to the assistance which may be needed. Healthcare professionals are themselves required by the 2005 Act to have regard to the Code of Practice. If and only if the relevant capacity is lacking may therapeutic concerns tilt the balance in the opposite direction to the views and desires of the patient. A patient lacks capacity to consent to treatment only if he is unable to appreciate the likely effects of having or not having the treatment: R (on the application of B) v SS and others [2006] 1 WLR 810, CA.

31. The GMC Guide directs that where patients are not able to make decisions for themselves, the doctor must work with those close to the patient and with other members of the healthcare team. The doctor must take into account any views or preferences expressed by the patient and must follow the law on decision-making when a patient lacks capacity. For example, this may entail involving an independent mental capacity advocate in serious treatment decisions. As regards a person incapable of making a decision for himself, section 1(5) of the 2005 Act requires his 'best interests' to be followed.

32. As to patients detained, or liable to be detained, for mental health reasons, the Mental Health Act 1983 defines the circumstances in which they may be treated without their consent. In this context too the courts have generally followed a best interests approach, although the needs of society may also be in point.

33. In R (on the application of B) v Ashworth Hospital Authority [2005] 2 AC 278 the House of Lords recognized that the objective of detention in a
mental hospital was the rehabilitation of the patient. That militated against an approach which ignored the overall scheme of the 1983 Act and imposed a threshold: treatment without consent could only be justified if necessary to stop the patient causing harm to others or to protect the patient from serious harm. However, a patient detained under the Mental Health Act 1983 who has the capacity to refuse consent can nevertheless be given antipsychotic treatment against his will, provided the proposed treatment was a medical or therapeutic necessity. If detention of a patient for treatment was justified on the ground that treatment was necessary for the protection of others, it was illogical to contend that a higher standard had to be applied to justify the administration of the treatment itself: *R (on the application of B) v SS and others*.

34. Notably, psychiatric opinion as to capacity is not always decisive, particularly as regards non-psychiatric treatment. In *Re SB (a patient: capacity to consent to termination)* [2013] EWHC 1417, the Court of Protection (Holman J) held that for the purposes of section 16 of the Mental Capacity Act 2005, a 37-year-old woman detained under the 1983 Act as a result of bipolar disorder did not lack the capacity to decide to have an abortion at almost 24 weeks' gestation. This was despite the psychiatric consensus that she did. Even though she had some paranoid and delusional thoughts, the judge held that she had given additional reasons for desiring a termination which were entitled to respect.

**Limitation**

35. There are no special rules here. As with other clinical negligence claims the primary limitation period will be three years from the date on which the cause of action accrued (usually the date of the injurious treatment or the materialising of the unwarned-of risk), or three years from the date of ‘knowledge’, if later: sections 11 and 14 Limitation Act 1980. Section 33
affords a secondary limitation period. Time does not run against children or other claimants under a disability: section 28.

**Human Rights Act claims**

36. The Human Rights Act 2000 has brought home a number of Convention rights which are relevant to consent issues - Article 3 (the right to freedom from inhuman or degrading treatment), Article 8 (the right to respect for privacy and family life) and Article 10 (the right to freedom of expression, which includes the right to hold opinions and to receive information). Under the HRA patients now have the possibility of additional recourse against public authorities such as NHS bodies.

37. Detailed analysis of these rights is outside the scope of this webinar, but there are some useful pointers in the existing European case law. For instance, in the right-to-die case of *Pretty v UK* [2002] 2 FLR 45, the European Court of Human Rights upheld the importance of personal autonomy under Article 8, although it held that laws prohibiting assisted suicide were within the UK’s margin of appreciation. By contrast, in *Glass* the European Court held that the treating doctors breached Article 8 by failing to seek early court authorisation for treatment which was strongly opposed by the child’s family.

38. HRA claims provide useful additional weaponry for claimant clinical negligence practitioners, particularly when there are evident failures of consent without obvious physical or mental injury in consequence. That said, they can never supplant claims in tort and contract – for one thing, HRA damages invariably fall far short of full restitution (when they are awarded at all). And the primary limitation period is only one year.

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