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Informed consent

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OVERVIEW

Hippocrates had no time for such ideas as informed consent:

> 'perform (your duties) calmly and adroitly, concealing most things from the patient while you are attending to him...turning his attention away from what is being done to him...revealing nothing of the patient's future or present condition.'

THE CLAIM IN NEGLIGENCE

Practising medicine without consent may constitute assault, actionable without proof of physical damage. However, for the most part, courts have restricted the use of the term 'battery' to circumstances where there is no consent whatsoever, rather than merely where the medical practitioner has given insufficient information upon which the patient can base consent.

This may arise when the treatment is entirely different to the one agreed or in a case such as Appleton and Garrett (1996) PIQR P1 where a dentist who carried out totally unnecessary treatment for financial gain was found liable for battery (the term 'assault' is used in Scottish Law).

The dentist concerned was struck off the dental register for gross overtreatment between 1981 and 1988. Some 80% of his previous patients had commenced proceedings. In eight of the cases the defendant admitted negligence. The claimants recovered damages for negligence and assault and battery, as the evidence established that none of the claimants were given any information on which to base a suitably informed consent. Damages recovered included the cost of treatment and subsequent remedial treatment and for loss of amenity such as loss of teeth, eating difficulties and halitosis, and for psychological injury including anxiety and distress.

Issues of consent will arise in negligence actions. A negligence action will require proof by the claimant of three elements:

- that there was a duty of care
- that the duty was breached
- that the breach caused damage

In the modern law of negligence the existence of a duty of care between doctor and patient to provide such information as appropriate is not in any dispute. The contentious issues discussed here therefore arise in relation to breach of duty and causation.

BREACH OF DUTY

The question of breach of duty relates to the issue of what level of information the doctor needs to provide to the adult patient in order to meet the required standard of care.

Before examining that question, however, it should be noted that there are clearly circumstances where a doctor can proceed to treat without obtaining consent. Primarily this will be where the patient is unable to give consent, perhaps because they are unconscious, and the treatment is required as a matter of urgency. If there are family members available it is good practice to discuss matters with them if that is feasible, but there is no law that empowers next of kin or any other family member to give legally valid consent on behalf of an adult patient just because he or she is unconscious. In such circumstances the doctor should do no more than is necessary, although it is highly unlikely that most patients are ever going to complain, and the courts would be sympathetic to the treating doctor.

Outside of emergency situations the issue of how much information a doctor is obliged to give a patient is, like much else in the law of negligence, a matter of degree. What is clear is that a doctor must inform a patient about risks that are material or significant.

The basic question that is not fully resolved, and is perhaps still evolving, is whether the doctor's duty is to be governed by a patient-orientated standard or by a professional-orientated standard. Much academic ink has been spilt over this distinction. However, in practice, the issue in case law has not been about whether information ought to have been given about a particular risk but, rather, the evidential question of whether it was given. It is true, however, that the two standards may produce different results.

THE PROFESSIONAL STANDARD

In essence, this is as follows.

A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in their particular art (The 'Bolam' test, referring to the case of Bolam v Friern Medical Committee (1957): Mr Bolam was advised by a consultant to undergo electroconvulsive therapy. He was not warned of the very small risk of fracture nor given relaxant medication. He sustained a hip fracture. This is consistent with the Scottish decision of Hunter v Hanley (1955). In that case Lord Clyde stated: 'In the realm of diagnosis and treatment there is ample scope for genuine differences of opinion…the true test is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty if acting with ordinary care'. In Moyes v Lothian Health Board (1990) the court accepted that a failure to disclose specified risks of an angiography procedure was not negligent as in 1981 it was consistent with responsible medical practice to give no warning at all.

THE PATIENT STANDARD

By contrast, this asks what the patient would think was significant or material, rather than what the doctor believes it to be. This in turn can be subdivided further into an objective standard: What would a reasonable patient want to know?; or a subjective standard: What would this particular patient want to know?

This may be an esoteric academic debate because very often any of these tests will produce the same answer. The position of the English courts is worth analysis. The House of Lords decision in Sidaway v Bethlem Royal Hospital (1985) AC 871 remains an important starting point although, to a degree, the world has moved on since then.

FACTS

This case involved a patient who was not told about a small risk of damage to her spinal column from spinal surgery, estimated to be approximately 1–2%. The patient claimed that if she had been warned she would not have had the operation.

The claimant lost. Four out of five judges in the House of Lords considered the duty to disclose as a component of the ordinary doctor's duty of care and so, largely, governed by a Bolam test. Lord Scarman, who concurred as to the outcome, dissented as to reasoning and staked out something more akin to a patient-orientated approach, albeit an objective one: 'The court should ask itself whether the risk was such that a reasonably prudent patient would think it significant'.

There has been inconsistency in the courts' approach over recent years but there has been a gradual drift towards applying at least a patient element to the decision. There is broad agreement that doctors must warn of risks that are 'significant' or 'material'. Whether this means significant to the doctor or patient is unclear.

The authority of Sidaway would suggest this is to be determined by the Bolam test and so the question would be whether the information would be significant to the reasonable doctor, but a number of decisions suggest that there is at least a tendency to modify the approach to include some consideration of what is significant to the patient. There is no clear and uniform guidance of what kind or level of risk is 'significant'. Some are obvious, but inevitably will be fact-specific. It is impossible to say that a 2% risk will always be significant while a 0.5% risk never will be. Significance straddles both incidence of risk and severity.

The duty does in most cases extend beyond providing information merely about the procedure. And will normally require information about the consequences, as well as alternatives. In Birch v UCL Hospitals (2008) EWHC 2237, the patient was warned of a 1% risk of stroke associated with catheter angiography but was not told that there was an alternative, albeit less precise, diagnostic technique that carried no risk at all. The judge held that the duty extended to explaining comparative risks associated with the alternatives.

UNDERSTANDING

Regardless of what the doctor has to tell the patient, there is the question of whether that duty is discharged merely by giving the information or does the doctor have a further duty to ensure that the information is understood? It has never been suggested that the duty can be fulfilled in a technical manner and it must, at the least, be reasonable for the doctor to assume

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that the patient understands in general terms the information being provided. Patients anxious and in pain may not easily be able to absorb information. The case of Al Hamwi v Johnston (2005) EWHC 206 considered this issue.

The question of understanding arose because the claimant's first language was not English. The judge, at first instance, held that a doctor's duty was to take reasonable care to ensure that the patient had understood the information but rejected extending the duty to 'ensuring' that the patient had understood. It was not appropriate for the doctor to cross-examine the patient about their level of understanding. However, again, what is reasonable will always be fact-specific.

THE QUESTIONING PATIENT: THE GOOGLE EXPERT

What about the patient who is inquisitive? Does that modify the duty?

The issue does not appear to have come up for decision in the English courts but in Sidaway, three of the judges (Lords Diplock, Templeton, and Bridge) all expressed the view that a doctor was under a duty to answer truthfully any question the patient put to them. In Pearce v United Bristol Healthcare (1998) 48 BMLR 118, Lord Woolf commented: 'If a patient asks a doctor about the risk then the doctor is required to give an honest answer'. The GMC guidance reflects this case law recommending: 'You must answer patients' questions honestly and, as far as practical, answer as fully as they wish'.[1] It may be appropriate in some instances to consider providing patient information leaflets.

THERAPEUTIC PRIVILEGE

All the judges in Sidaway agreed that the duty to provide information was subject to an exception called therapeutic privilege. This means that the doctor does not need to provide information which might be positively harmful to the patient.

The extent of this exception has never come before the higher courts but it is likely to be given a restrictive interpretation. In any case, the exception is highly unlikely to encompass a doctor withholding information merely because it might lead the patient to decline treatment that the doctor believes the patient should have.

PROFESSIONAL GUIDANCE

The guidelines of professional bodies, like the GMC, have in many respects gone beyond the common law duty. In relation to the standard of the obligation to inform, GMC guidelines come down pretty firmly on the side of the patient-orientated approach, stating:

'the amount of information about risk that you should share with patients will depend on the individual patient and what they want or need to know. Your discussions with patients should focus on their individual situation and the risk to them'.[2]

It might be thought that this would mean a shift in the professional-orientated standard. Alternatively, it might be interpreted as a cautious approach to ensure that the risk to the doctor is minimised.

ORAL OR WRITTEN CONSENT?

The GMC guidance is clear that written consent is required where:

- The investigation or treatment is complex or involves significant risks
- There may be significant consequences for the patient's employment or social or personal life
- Providing clinical care is not the primary purpose of the investigation or treatment
- The treatment is part of either a research programme or is an innovative treatment designed specifically for their benefit
- Fertility treatment

Consent forms are not contracts that guarantee a defence: a patient may still sue for negligence on the basis of lack of informed consent having signed a consent form if, for example, they can establish that they did not understand the form, or had not been given time to digest its meaning, or that they signed when their capacity to understand was temporarily compromised (perhaps due to their illness, pain, or drugs).

CONSENT FORMS

The fact that the information in a consent form is often illegible, and/or rushed, and/or prepared in advance of or immediately pre-surgery, and infinitely variable surely needs to be addressed?

Best practice would suggest that, in the age of NICE guidelines, a standardised national format should be devised. A printed section would set out the name of the procedure and the known risks. This would be followed by an optional handwritten section for completion by the treating medical practitioner.

What is key to many litigated cases is the failure to explain and communicate, and to record discussions with the patient effectively in the notes. It is well recognised that patients, under what can be stressful circumstances, may fail to recall some or much of what

was discussed. Consent forms are written evidence of the end result of what should be 'a discussion process' and hence the importance of recording the consent interview itself. Given that the duty of candour is seen to be the way ahead, could and should the consent interview be recorded and handed to the patient as a contemporaneous record of what was said?

In this internet age, the issue of consent in medical practice is ripe for overhaul.

References

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2 GMC. *Consent guidance: Discussing side effects, complications and other risks*. http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_discussing_side_effects_and_complications.asp

Further reading

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2 Appleton and 7 others v Barry Richard Garrett (1996) PIQR P1
3 Bolam v Friern Hospital Management Committee (1957) 2 All ER 118
4 Hunter v Hanley (1955) SLT 213
5 Moyes v Lothian Health Board (1990) 1 Med LR 463
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