JTO Medico-Legal Features

Orthopaedic Practice and Consent

Gerard Panting

Negligence claims in orthopaedic surgery fall under four broad categories:

1. Delayed diagnosis or treatment 2. Failure to warn about potential complications of surgical or other treatment

3.Adverse events during surgery 4.Outcomes that fail to meet the patient's reasonable or unreasonable expectations

A robust consent process reduces the risk of facing a "failure to warn" claim and helps manage patient expectations over outcomes. A forensic assessment as to the adequacy of the consent process will depend on the physical evidence of what happened, not what actually happened. Unless clinicians are able to demonstrate by reference to notes, correspondence, fact sheets, consent forms and other documentation that appropriate advice was provided, the prospects of a successful defence decrease.



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What do the courts expect of surgeons when it comes to consent?

To be valid, a competent patient must have sufficient information to make an informed choice about their treatment options so that they can decide which to accept or reject, without being pressurised into a decision. For elective surgery the patient must have sufficient time to consider the options, including doing nothing.

In practice the emphasis during the consent process is rightly on the information provided to the patient, because that's where most of the problems occur. Occasionally, competence to consent and whether or not consent was given freely are the key areas of contention.

Competence is nothing to do with age but all about understanding. The formal test of competence requires the patient to be able to understand the treatment information, to believe it, weigh it in the balance to arrive at a choice and then be able to convey their decision to the clinicians involved. Generally, it is assumed that adult patients are competent. Unless they make a decision which appears to be irrational, it is unlikely that anyone will question their ability to decide for themselves. Making a bad choice may make you question the patients' competence but is not proof in itself. A proper assessment, which may involve psychologists, interpreters or other, is required before the patient is condemned as incompetent. Even then the law requires the patient to be involved in decision making in so far as that is possible.

Competence is not an all or nothing phenomenon and may vary: it depends on the specifics of the situation and the proposed treatments. The classic case is *Re C* where a patient detained under the Mental Health Act developed a gangrenous foot. The surgeons called to see him wanted to amputate the foot but he refused consent and having been found to be competent by the court was granted an injunction preventing the proposed surgery.

The idea of a claim being based on consent not being given freely may seem far-fetched, but if patients feel pressurised into a decision which they later regret, it can occur. In one case a patient underwent a discectomy, and subsequently suffered cauda equina syndrome. The patient claimed he had not been warned of the risk, the surgeon said he had been warned on the day of surgery. The judge found that even if CES had been discussed on the day of surgery, this did not represent valid consent as the patient would not have had sufficient time to digest and reflect on the new and material risk. Except in exceptional emergency situations consent on the day of surgery may be deemed to be under duress.

The most frequent consent claims are "failure to warn" cases. Unfortunately, the leading legal cases are following spinal surgery. Since 1999, the General Medical Council has published guidance on taking consent. It has been updated over the years, but has always emphasised the degree of information that should be provided to patients.

This includes:

 Details of the diagnosis and prognosis, and any uncertainties
Options for treatment or management of the condition, including no treatment
The purpose of a proposed investigation or treatment
Details of the procedures
How to prepare for the procedure
Common and serious side effects and serious or frequently occurring risks
The probability of success
A range of other issues, including the patient's

including the patient's contribution to their own care before and after surgery.

In the case of *Chester v Afshar*¹, decided by the House of Lords in 2004, a patient suffering from a long history of low back problems, was advised to have surgery but was not warned about an unavoidable risk, of between 1 and 2%, of cauda equina syndrome, which unfortunately did occur. The law lords held that 'as a result of the surgeon's failure to warn the patient, she cannot be said to have given informed consent to the surgery in the full legal sense' and as a result she was awarded damages.

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Cases like this give rise to the myth that there is no need to warn about complications with a frequency below 1%. This is completely untrue: the requirement is to inform the patient about all information material to their decision, which should include the low risk of a serious complication such as paralysis.

Signing the consent form might seem to be the moment that the patient consents to treatment, but this is far too simplistic a view. The consent form itself is at best just one piece of evidence that the patient consented. When deciding whether or not valid consent to treatment was obtained, it is important to review all the discussions that took place about the diagnosis likely progression, options for management and potential problems that will have taken place during perhaps several consultations,

Numerous studies have shown how little some patients retain of the information they are given in outpatient appointments, so it's not surprising that there is often a conflict of evidence with the surgeon saying that various issues were discussed and the patient honestly replying that they have no recollection of any such issue being raised. So if there are clinical records which set out these details, letters to the GP copied to the patient providing this information, and information leaflets that are routinely given to the patient about the condition or procedure in question, it is no longer one man's word against another but a clear evidential trail setting out the thorough nature of the consent process.

Against this background the consent form itself becomes less important, so whilst it is required in most hospitals and adds some weight, it is not the one document on which claims are won or lost. Nevertheless when patients come to sign a consent form, they may have questions which have to be answered fully and honestly.

In the case of *Hatcher v Black²*, which came to trial in 1954, a patient suffering from thyrotoxicosis was advised to have surgery. The patient occasionally broadcast for the BBC was concerned about potential risks to her voice and specifically asked about this. She was assured that there was no risk to her voice even though the surgeon knew that this was not true. Her recurrent laryngeal nerve was damaged during surgery and her voice was affected and she never broadcast again. At trial the truth emerged, but it was accepted that the surgeon had lied 'for her own good.' The Judge said '...as far as the law is concerned, it does not condemn the doctor when he only does what many a wise man and good doctor so placed would do.' Consequently, Mrs Hatcher lost her claim. 60 years on the same would not be true – the case would never get to trial because it would be indefensible and if there was a complaint to the GMC the surgeon would be at serious risk of a warning or worse.

The GMC advise that 'You must answer patients' questions honestly and, as far as practical, answer as fully as they wish.'

Ideally, the surgeon undertaking the procedure should oversee the entire consent process. If this is not practical all or part of the process can be delegated to others. However, if delegated, the person taking consent must be in a position to provide all the necessary information about the procedure and potential complications and answer any questions.

A common question is when patients should be asked for consent. The issue here is that patients need to know the pros and cons of the proposed surgery well in advance so that they can go home and decide whether or not to go ahead. In practical terms at the clinic, prior to listing for surgery, is the optimal opportunity to take (and record) full and informed consent. Provided they have been given all the relevant information in the clinic, there is no problem with completing the consent form on the day of surgery. However, providing new and important information at the last moment is wrong as illustrated by the cauda equina case discussed earlier in this article.

In elective cases patients should have time to consider their options. but in emergencies there may be little or no time to spare and patients may be unconscious or in a severely compromised state. Consent cannot be glossed over in an emergency but the approach will be dictated by circumstance. If the patient is unconscious, necessary treatment can and should be provided unless there is a clear advance refusal of a specific therapy, such as a Jehovah's Witness not wanting to have a blood transfusion. Some adult patients will have granted lasting powers of attorney to trusted relatives and friends which can include consenting to treatment on the patient's behalf, but in an emergency, time cannot be wasted trying to find anyone in that position, so proceeding on the basis of necessity is the default policy. Any person with parental responsibility can give consent on behalf of a child, but otherwise you should do whatever is required to serve the child's best interests.

Even in elective procedures not everything goes to plan: there may be unexpected findings or complications requiring additional treatment. If additional treatment is required to ensure that the patient's

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condition is not jeopardised, it should be provided but where no urgent intervention is required for an unexpected condition, where the treatment options are different, the patient should be allowed to make their own decision once they have recovered from the anaesthetic.

The requirements for obtaining valid consent are onerous if viewed in isolation, but in practice providing all the necessary information is interwoven with the clinical care of the patient. Provided that in the event of a claim the care and attention taken in explaining all the relevant issues can be demonstrated by reference to the notes, letters and leaflets, allegations of "failure to warn" can be robustly defended.

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