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■ ANNOTATION

Informed consent in spinal surgery

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Informed consent is a very important part of surgical treatment. In this paper, we report a number of legal judgements in spinal surgery where there was no criticism of the surgical procedure itself. The fault that was identified was a failure to inform the patient of alternatives to, and material risks of, surgery, or overemphasizing the benefits of surgery. In one case, there was a promise that a specific surgeon was to perform the operation, which did not ensue. All of the faults in these cases were faults purely of the consenting process. In many cases, the surgeon claimed to have explained certain risks to the patient but was unable to provide proof of doing so. We propose a checklist that, if followed, would ensure that the surgeon would take their patients through the relevant matters but also, crucially, would act as strong evidence in any future court proceedings that the appropriate discussions had taken place. Although this article focuses on spinal surgery, the principles and messages are applicable to the whole of orthopaedic surgery.

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As with all surgery, spinal operations are accompanied by risk, particularly to neurological structures. Complications can be life-changing and difficult for patients to fully understand without time and effort being taken by surgeons to explain the risks in understandable terms. In the context of a busy surgical schedule, this makes fully informed consent, taking into account the terms of the Montgomery v Lanarkshire Health Board[1] judgement, difficult. This may have contributed to the increase in the number of negligence cases brought against surgeons and hospitals during the last decade.[2,3] The costs resulting from the increasing number of negligence claims fundamentally threaten the future of elective spinal surgery.

In several legal cases since the turn of the century, the complications were not a consequence of negligent surgery. Claims succeeded because of a failure in the consenting process. Informed consent is now based on a rights-centred approach reflecting the autonomous right of patients to determine what will happen to their body.[4] There are specific requirements for consent that must be applied to all patients and the surgeon must be able to demonstrate that these requirements have been fulfilled. A detailed checklist that builds on established professional practices is proposed that will help spinal surgeons to demonstrate that the necessary steps in the consenting process have been achieved.

Montgomery (1). The Montgomery judgement in 2015 finally laid to rest surgical paternalism and firmly put the patient and their needs at the centre of the treatment partnership, but the scene had been set by Chester v Afshar.[5] In 1994, a neurosurgeon performed multiple lumbar laminectomies for spinal stenosis. An injury to the cauda equina, the risk of which had not been explained to the patient, occurred. It was found that if the claimant had been warned of this risk, she would not have had the operation at that time and, if the operation had been deferred, the complication would not have occurred. The judgement hinged on the autonomy of patients to decide whether and/or when to have an operation. Surgeons must ensure that all information about the risks of surgery is put to the patient preoperatively. If there is a significant risk that would affect the judgement of a reasonable patient about whether or not to undergo a surgical procedure, the surgeon must explain that risk. This is hardly controversial. The most common deficiency is the failure to record a risk that subsequently occurs.

The United Kingdom has come to this position rather later than other countries, particularly the United States, Australia, Canada, and New Zealand.[6,7] Many spinal units in the United States use patient-centred informed consent in this process, with patients playing an active role in their healthcare decisions.[8] However, for clinicians to be effective in an informed choice partnership, they need to be able to deliver evidence-based information to the patient that describes all the reasonable options of treatment for the condition.[9-11] This must include the probabilities of benefits and harms, not just as a list of percentages, but in a format that respects the patient's values about what matters most to them. Any alternatives to surgical treatment must be fully explained.

Patient autonomy and material risks. The case of Thefaut v Johnston[12] involved a consultant neurosurgeon who recommended conservative management for back pain to a female patient. Two months later, she developed bilateral leg pain and

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urinary frequency. There was a four- or five-minute telephone conversation with the surgeon backed up by a letter. She was told that it was reasonable to recommend surgery with at least a 90% chance of ridding her of leg pain and every chance that back pain would settle as well. There was a 0.1% chance of nerve damage leading to weakness of the left ankle and a 2% chance of a leak of spinal fluid. No other risks of surgery or alternatives were discussed, and the patient was not seen preoperatively until the day of surgery when a consent form was signed. A left L4/5 microdiscectomy was performed, followed later by a revision operation carried out by another neurosurgeon. The patient developed cauda equina syndrome with persisting low back pain, leg pain, numbness, and weakness, with sexual and bladder dysfunction. There were two key aspects of the judgement: patient autonomy and the material risks that need to be explained to patients. A material risk is one that would be regarded by a reasonable patient as significant in making the decision to accept or reject surgery. Surgeons are obliged to tell patients of both material risks and any other risks that they believe are significant. A material risk is a mixture of subjective and objective matters. Objective matters include the known and usually quantifiable risks of surgery. Subjective factors might include a patient's tolerance to pain, a desire to return to work, or a recent bereavement. The reasonable surgeon must directly ask the patient whether there are subjective factors that could be contraindications to surgery. The judge emphasized that material risks cannot be reduced to mere percentages. Risks are sensitive to the facts and also the characteristics of the patient. There must be adequate time and space for appropriate communication and dialogue between the doctor and the patient. The dialogue must not contain jargon. The surgeon's duty is not fulfilled by bombarding the patient with technical information, and the presence of a signature on a consent form does not by itself mean anything in terms of consent. In this case, the four- or five-minute telephone call and the letter received by the patient did not provide adequate time and space to correct the deficiencies in that letter. The immediate preoperative discussion, when the consent form was signed, was too late to correct the defects in terms of consent, because the pressures of imminent surgery meant that there was no time for a sensible dialogue and free choice could not be exercised. If the benefits and risks of the operation had been properly explained, the patient would not have gone ahead with surgery at that time and she would have avoided the non-negligent complication of surgery. An accurate and detailed explanation of the benefits and risks of surgery, or of doing nothing, must be explained to the patient with sufficient 'time and space' to achieve a dialogue.

Communication and the expectation gap. A surgeon might be technically gifted, but there should be no assumption that she or he is an excellent communicator and, therefore, specific training in the techniques of consent is warranted.[13,14] This would potentially reduce claims that arise from the poor management of wide expectation gaps. Toyone et al[15] assessed the expectations of the outcome of surgery in 98 patients undergoing discectomy or laminotomy for stenosis. Expectations of a successful outcome, up to and including complete relief of lower limb symptoms and a restoration of unlimited mobility, were high in both groups. However, positive expectations were associated with better outcomes only in the discectomy group, and 86% stated that surgery had met their expectations. The patients with spinal stenosis reported a lower rate of satisfaction and only 71% of the group felt that the surgery had given them the expected benefit. Similarly, Yee et al[16] found that the expectations of elective spinal surgery were met in only 81% of patients and that those who had lower mean 36-Item Short-Form Health Survey (SF-36)[17] quality-of-life outcome scores before surgery were more likely not to have their expectations met. Even if the clinical expectations are met, some patients will still be dissatisfied, particularly those with more chronic conditions such as spinal stenosis. Surgeons therefore need to be aware that they should have training in actively managing expectations as part of the process of informed consent. This training should allow surgeons to become familiar with, and be able to use, shared decision-making tools including appropriately written information, balanced stories of others' experiences, and multimedia presentations to improve patients' knowledge of the treatment proposed and understand the range of outcomes, both good and bad, therefore limiting the extent of unrealistic expectations.[18] The anticipated outcome of elective spinal surgery may be quite different depending on whether the perception is from the point of view of the surgeon or of the patient. The process of informed consent has to include realistic descriptions of the potential outcomes of the treatment that are meaningful to the patient. This includes an honest description of the alternatives to surgery.

In Hassell v Hillingdon Hospitals NHS Foundation Trust,[19] a patient had a painful left C6 radiculopathy caused by a C5/6 foraminal disc prolapse and stenosis without objective neurological deficit, which did not respond to a left C6 nerve root injection. There was limited impairment of function, some left-sided arm pain on driving, and some limitation of movement of the neck. However, she was working normally and was able to look after her three children. A consultant orthopaedic spinal surgeon recommended a C5/6 anterior cervical decompression plus either a disc arthroplasty or a fusion. The patient was not informed of alternatives to surgery and there was no warning of spinal cord injury. A standard C5/6 decompression was performed. During the anterior part of the discectomy, spinal cord monitoring potentials were lost and the patient awoke quadriparetic. A postoperative MRI scan showed damage to the anterior spinal cord. The surgeon said that he thought that the patient had had conservative treatment including physiotherapy and she was given the option of further injections, but she had never had physiotherapy for her neck problems. The judge found that the surgeon had not had an appropriate dialogue with the patient preoperatively; he had not advised about conservative treatment or further injections and he had not warned about a risk of paralysis. The operation was carried out to an appropriate standard and the cause of spinal cord injury was not identified. The judge said that if the patient had been informed of the risk of spinal cord injury, and also been informed of the possibility of further conservative treatment, she would not have had the operation at that time and spinal cord injury would have been avoided. This judgement emphasized the primacy of a full dialogue preoperatively to include a discussion of the risks, benefits, and alternatives to surgery and also of recording this clearly and fully.

In a similar case, Rodney Crossman v St George's Healthcare Trust,[20] a 64-year-old man had bilateral C5 and C6 radiculopathies secondary to foraminal stenosis. A consultant neurosurgeon recommended physiotherapy, review three months later, and, if the patient was no better, surgery. There was an administrative error and physiotherapy was not arranged. The patient was admitted for surgery and bilateral posterior foraminotomies were performed. Postoperatively, there was a severe right C5 nerve root lesion that did not recover. Following admission, three treating doctors were aware that physiotherapy had not been tried but, even so, the operation went ahead. The failure to organize the proposed physiotherapy was accepted to be in breach of duty of care. Even if the decision not to give physiotherapy was planned (which it was not), the surgeon had a duty to explain the change in treatment. If there is a deliberate change in the treatment plan, the patient must be informed why there has been such a change and if a mistake had been made, it should have been corrected. The patient is not at fault for failing to question why the treatment plan has changed. If physiotherapy had been given, surgery may not have been required and the nerve root injury would not have occurred. The court found that if surgery had taken place on a different occasion, three months later, the C5 nerve root injury would not have occurred.

Trust in the surgeon. Expectations of the outcomes of treatment are not only related to harms and benefits. Risks that are explained by a surgeon to the patient are theoretical concepts, since the patient has no reason to understand the full implications of data from the literature. Therefore, an important part of the consent process, from the point of view of the patient, is vested in trust of the treating doctor. If a surgeon promises to perform an operation and then, for reasons they cannot control, is unable to do so, patients need to go through the full process of informed consent with the replacement surgeon so that trust can be established. It is reasonable for a patient to refuse surgery by a surgeon they neither know nor trust, as shown in the Kathleen Jones v Royal Devon and Exeter NHS Foundation Trust case.[21] Mrs Jones had spinal stenosis at L4/5 causing bilateral radiculopathy. She sought the advice of a consultant orthopaedic spinal surgeon who had an excellent reputation. She was offered a bilateral L4/5 decompression and understood that surgery would be carried out by that consultant. She subsequently contacted the Trust because her symptoms had worsened, and she was told that her original surgeon was on compassionate leave but an operation could be expedited, although it would be carried out by another surgeon. She declined and opted to wait for her original surgeon to return to work. Mrs Jones was then seen in a consent clinic by another surgeon who was a fully trained spinal surgeon awaiting appointment to his first consultant post. She was admitted to hospital for surgery and found, almost at the door of the operating theatre, that her surgery was to be carried out by the second, not the original, surgeon. The Court found that because Mrs Jones became aware that her original consultant would not be undertaking her operation at the door of theatre, her acceptance of the new surgeon was a decision that was not taken freely and there was no valid consent to the new surgeon. There was a breach of her right to make an informed choice as to whether – and if so, when and by whom – to be operated on. She developed cauda equina syndrome postoperatively with severe neurological deficits, including bladder and bowel dysfunction, sensory loss, motor weakness, and disturbed balance. The judge found that if the operation had been carried out by the original, much more experienced surgeon, neurological injury would not have occurred. If the patient believes that a particular surgeon will be carrying out the operation, either because that has been explicitly agreed or it is implied, there must be specific consent for a change in the operating surgeon.

Montgomery (2). Surgeons have long understood that, in proposing an operation, they have a duty to explain why surgery is needed, the benefits and risks of surgery, and any alternatives to the proposed operation. The legal approach to consent was set out in detail by the Supreme Court in Montgomery and all surgeons should read that judgement itself, or a review of it,[6,22] which set out the standards by which surgical practice will be judged. Briefly, these are summarized as:

1) Consent is based upon a rights-centred approach and every adult patient of sound mind has the right to decide what will happen to their body. The patient has an absolute right to reject surgery even if the decision will cause them harm or even death.[5] The surgeon's responsibility is to put the patient in the best position to make a fully informed decision, and this requires a dialogue that cannot be assumed and must be demonstrable. Surgeons should understand that if they do not record what was discussed in respect of consent, a subsequent statement that such a discussion was their usual, or standard, practice may not be accepted by the court.

2) The material risks of surgery are the risks that would influence the decision of a reasonable patient to undergo or reject surgery. These include common but usually unimportant risks, such as a haematoma, and rare but serious risks such as spinal cord injury or cauda equina syndrome.

3) The surgeon must take the individual patient into account. A single-parent mother may have an entirely different view of the risks of surgery than a retired policeman. The surgeon's duty is to explain all relevant matters and the patient is not expected to ask for answers to specific questions, because they may not know what questions to ask.

4) The risks of surgery are specific to both the condition and the patient, and quoting overall percentages of risk may not be the correct level of risk for a particular patient with a particular pathology.

5) The information given to a patient should be comprehensible and specific, and jargon must be avoided. To say that there is a risk of 'root' or 'cord' damage or 'cauda equina syndrome' means nothing to most patients. The risks need to be explained in terms that the patient can understand, such as 'paralysis'.

6) The patient should not be overwhelmed with technical data, particularly where an information sheet includes a discussion of many different pathologies and procedures. Any discussion and/or information sheet must be specific to this patient and their condition. An information sheet or website should contain the full details of risks, benefits, and alternatives to treatment.

Patient information and its limitations. The Ipswich model of consent, which has been adopted by the British Association of Spinal Surgeons (BASS) as the 'three-legged stool',[23] sets out three required components for successful informed consent.

Table I. Consent checklist for spinal surgeons

Checklist item
A description of the pathology requiring treatment
The recommended procedure (including side/level)
The natural history of the condition if left untreated
The benefits of surgery
The risks of surgery
Any alternative(s) to surgery
Is any treatment needed before surgery, such as physiotherapy?
Has the patient been asked what his/her expectations of the treatment are?
Has a specific surgeon been proposed?
Have any guidelines/websites been used (if so, record what/where)?
Has a further outpatient appointment been arranged to confirm consent?
Has a second opinion been requested and, if so, arranged?
Is there likely to be any complex postoperative management?
Is there anything specific to this patient that requires attention?

The first is the provision of information booklets that should be written and illustrated at a level that is understandable by all reasonable patients undergoing spinal surgery. These are crucial, shared decision-making tools that underpin effective communication between the members of the therapeutic partnership and must be easy to understand. Furthermore, the delivered information should be easy to retain. Considerable evidence from a range of surgical disciplines over the last three decades has demonstrated that neither of these two requirements are fulfilled in many cases.[9,18,24-41] Retention of information in the short-term and long-term is adversely affected by older age, lower IQ, depression, and cognitive impairment.[25,28]

The average reading age of the general population is an important metric that surgeons should be aware of when engaging in the process of informed consent. As many as 15% of the population of the United Kingdom are functionally illiterate, which is described as: "literacy levels at or below those expected of an 11-year-old. They can understand short straightforward texts on familiar topics accurately and independently, and can obtain information from everyday sources, but reading information from unfamiliar sources, or on unfamiliar topics, could cause problems."[42] The rates are similar in the United States and Canada.[43] Shared decision making and informed choice and consent demands that printed information should be understood, and the content retained by all patients, not just a proportion of them. The two United Kingdom surgical spinal societies (BASS and the British Scoliosis Society (BSS)) provide patient information leaflets for specific conditions and treatments. BSS leaflets were consistently found to be at the easier end of the reading scale than those from other British orthopaedic societies.[41] BASS had the third most difficult-to-read information leaflets, with a reading age close to undergraduate level (18 years). Reform of the information provided by professional societies supporting informed choice and consent, and the adoption of more creative solutions for the transfer of information, are urgently needed.[31,33] Failure to meet patients' literacy needs ensures that surgeons will continue to fall into the trap of believing they are Montgomery-compliant when the opposite might be true.

Spinal surgical checklist. Safety standards in the operating theatre have been dramatically improved by the widespread adoption of the World Health Organization surgical safety checklist,[44] resulting in lower rates of morbidity and mortality and potentially lower rates of litigation.[45,46] Orthopaedic surgeons and neurosurgeons carrying out preference sensitive treatment, such as elective spinal surgery for painful conditions, total hip arthroplasty, and total knee arthroplasty, also need a comprehensive checklist that should be deployed and, most importantly, documented fully before patients arrive in the hospital for surgery. This should ensure that everything that is required to be Montgomery-compliant has been fulfilled.[39,47-50] The BASS 'three-legged stool' partly addresses this need for spinal surgeons, and it is a very helpful mechanism to allow surgeons to approach Montgomery-compliance, but it does not fulfil all that is required.

In this article, five legal judgements in spinal surgery litigation have been reviewed. In all five, there was non-negligent surgery (i.e. the operation was carried out to an appropriate standard). In all cases, the claimant succeeded because of failures in the consenting process. There were failures to warn of spinal cord or cauda equina injury. One patient was referred to a website that did not contain the risk of spinal cord damage. There was a failure to treat with physiotherapy prior to surgery, as had been agreed. The benefits of surgery were exaggerated, and the risks were minimized in one case where there was also no time and space for a dialogue and/or reflection. In one case, a patient had understood that a specific surgeon in whom she had trust would perform the operation; there was the negligent substitution of another surgeon at the door of the operating theatre. A common theme in these cases is that the surgeons could not prove that the requisite legal tests had been satisfied. A solution to this is for all surgeons to record the dialogue in the medical records and a Spinal Surgery Consent Checklist may be helpful (Table I).

For routine elective surgery, the surgeon must have a proper dialogue with the patient and should record the following: 1) the proposed procedure (and level/side); 2) the natural history of the condition if left untreated; 3) the benefits, risks, and alternatives to surgery; 4) whether any other treatment has been recommended, and if so given, before surgery; 5) whether a specific surgeon has been offered; 6) any unusual or complicated postoperative management must be explained (such as, for example, the need for a halo); and 7) if a percentage chance of benefit is quoted, it must be accurate with reference to accepted literature and the surgeon's experience, which should be measurable through registry outcomes.[51]

It is extremely important that any alternatives of surgery are explained. For example, all patients with a posterolateral lumbar disc prolapse causing radiculopathy should be told that the natural history is frequently benign and if they can put up with a level of radicular pain for six to 12 weeks, with analgesia, it usually settles. The surgeon, can, and should, say what she or he recommends but not in a forceful or patronizing way. Signing a consent form is not necessarily evidence of informed consent and if new risks of surgery are discussed on the day of surgery, that is not informed consent.

The concept of a dialogue means that there is sufficient time and space for the patient to reflect upon the information they have been given and, if they wish, to ask further questions.

Private practice may be particularly vulnerable because there are usually shorter periods of time between the primary consultation and surgery compared with the NHS. For complex surgery, such as spinal surgery, a second outpatient consultation should be routine and a preoperative consent clinic is a good moment for that, as the BASS model recommends. In addition, for complex surgery, all patients should have the opportunity to access a second opinion in a timely fashion.

Summary. Some surgeons have not kept up with the new reality of informed consent, but they must. In the most recent case of operative spinal cord injury, the failure to take one or two minutes to explain and record this risk cost the public purse £4.4 million.[19] Surgeons must take great care with consent and must, by their actions and as recorded in the medical records, be able to demonstrate that they have achieved all that is now required.

Completing all the items in Table I for each patient would be powerful evidence that all aspects of consent were dealt with preoperatively and the case was Montgomery-compliant.

Take home message

- In all of the legal judgements reported in this paper, the faults were related to the consenting process, rather than to the surgical procedure itself.
- The authors propose a checklist that, if followed, would ensure that the surgeon would take their patients through the relevant matters but also, crucially, would act as strong evidence in any future court proceedings that the appropriate discussions had taken place.
- Although this article focuses on spinal surgery, the principles and messages are applicable to the whole of orthopaedic surgery.

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