The Continuing Saga of Informed Consent

Michael A Foy

It is unfortunate that we need to study cases that have reached the Courts to inform us of how we should be consenting our patients. There are guidelines from the GMC (2008) on the subject and these were widely quoted in the now famous Montgomery Ruling on informed consent in 2015. We have also outlined a proposal for obtaining consent in spinal surgery (Powell et al 2017). Despite all this, the issue of the adequacy of informed consent will not go away.

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Recent cases that have reached the Courts where consent has been a significant issue have been discussed elsewhere (Sokol 2016, de Bono 2017). Spinal surgery appears to be particularly vulnerable in this respect.

Another recent case, Hassell v Hillingdon Hospitals NHS Foundation Trust (2018 - spinal again I am afraid) is worthy of consideration and discussion for some of the important points and lessons highlighted therein.

Tracy Hassell was born in 1970 and had undergone lumbar spine surgery in 2009. She developed cervicobrachial neuralgia in 2011 and consulted the same surgeon who had carried out the lumbar surgery. An MRI scan showed a C5/6 disc protrusion that correlated with the clinical findings. Following failure of a CT guided C6 nerve root block a decision was taken to proceed to anterior cervical discectomy with either disc replacement or fusion. There is conflicting evidence about what was discussed between Mrs Hassell and the surgeon pre-operatively as far as the risks of surgery and alternative conservative treatments are concerned.

Mrs Hassell claimed that she was told that the only alternative available was to remove the disc and replace or fuse. She maintained that there was no discussion about the place of alternative painkillers or physiotherapy. She recalled being informed of the risks of infection, general anaesthesia and hoarseness. She said that she was not told the risks about spinal cord injury or paralysis. She said that had she known about the risk of paralysis she would not have had the operation.

The surgeon was adamant that he had discussed treatment alternatives including continued conservative treatment, physiotherapy and further nerve root block/s. He also outlined the risks that were discussed with Mrs Hassell including a one in 500-1000 chance of spinal cord injury/paralysis. It appears that the consent form was signed on the day of surgery. Unfortunately, during the operation, for reasons that were not entirely clear to the surgeon or any of the four eminent experts (two neurosurgeons and two orthopaedic spinal surgeons) spinal cord damage occurred and Mrs Hassell was left paralysed.

Mrs Hassell brought a case against the NHS Trust for damages, alleging a breach in the duty of care in performing the operation and she also alleged that she had not given informed consent to the procedure. She argued that had she been provided with adequate advice she would not have agreed to surgery. The case is interesting and instructive because it largely revolves around what the involved surgeon said, or rather didn't say in his correspondence before surgery, his witness statement and the evidence given at trial.

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When considering the quality of care in any case involving surgery it is essential to look at four areas in the assessment and treatment process:

1. The decision to operate
2. The quality of the advice given to the patient prior to surgery (including the consent process and bearing in mind GMC guidelines and the Montgomery judgement)
3. The performance of the surgery
4. Post-operative care.

There were differing opinions among the experts on whether they personally would have advised Mrs Hassell to have the operation. However, it was agreed that it was Bolam reasonable to do so.

With regard to the pre-operative advice and consenting process, when there is such an evidential difference between the two sides, as there was in this case, the judge has to take a view whose evidence is the most credible and is therefore preferred. Therefore it is really important to ensure clarity in recording what information was relayed to the patient in advance of surgery. It is also important to ensure that there is consistency, in the unfortunate event of a claim arising, in the recording and interpretation of matters surrounding the case in witness statements and in the witness box, should it come to that.

The judge decided in Mrs Hassell's case that she was not told about the risk of paralysis secondary to spinal cord injury and was not advised of other treatment options including physiotherapy and a further nerve root block. He concluded that the surgeon had not taken reasonable skill and care to ensure that Mrs Hassell was aware of the material risks of the operation and the alternative conservative options. Therefore he found that had she been given the appropriate information she would not have consented to the operation and the spinal cord injury would not have occurred. Mrs Hassell was awarded £4.4 million in damages for her residual tetraparesis. I must confess in consenting patients to this operation in the last 29-30 years I cannot recall a single patient refusing to go ahead with the procedure on the basis of a one in 4-500 risk of spinal cord injury (my figure). By definition if they are being offered surgery of this nature, they have significant pain/disability that has failed to respond to conservative treatment and after a proper risk/benefit analysis they accept the very small risk of cervical cord injury and other complications.

The learning points from this case are the judge's reasons for preferring the evidence of Mrs Hassell and her family to that of the surgeon:

1. The surgeon admitted that he believed that Mrs Hassell had undergone physiotherapy treatment for the problem already, when in fact she had not. He concluded that this was evidence that there was not a clear/proper dialogue between surgeon/patient.

2. He concluded that the surgeon was "not a good communicator about the risks of operations", citing inconsistencies in what was told to Mrs Hassell in correspondence prior to surgery and the surgeons evidence in his witness statement and in the witness box. In a letter a few months before the operation the risk of hoarsenes was listed at one in a thousand but the surgeon said that this was the risk of spinal cord injury and the risk of hoarseness was two in a hundred. He also criticised failures to correct a significant error in the chief executives response to the complaint concerning a technical/ descriptive error in the operation record (see below).

3. The surgeon pointed out in a letter some months after the operation that he would have explained that the risks he would have outlined to Mrs Hassell would have been similar to those that existed with the previous (lumbar) spinal surgery. When the information provided before the lumbar operation was reviewed there was no mention of paralysis and the judge took this as evidence that the surgeon was therefore unlikely to have mentioned it to her prior to the cervical spine operation.

4. The surgeon told the court that he also directed patients to his website where there was a more detailed explanation of the risks and benefits of the procedure. When the website was consulted, there was no mention of paralysis as a risk of this procedure.

5. There was no mention of paralysis in a letter copied to the patient prior to surgery. The judge accepted that a risk of spinal cord damage was mentioned to the patient on the day of surgery (presumably, when the consent form was signed) but that warning on the day of surgery was not sufficient (as supported by the eminent experts).

Therefore, it appears that there were a whole series of poor communications and record keeping that led the judge to take the view that Mrs Hassel's evidence was preferred to that of the operating surgeon.

The judge discussed the performance of the operation itself and found that despite a poor operation record describing changes in the recordings of spinal cord monitoring intra-operatively part way through the discectomy (when in fact the monitoring became abnormal during the incision into the annulus of the disc) that the procedure was carried out to an acceptable standard despite the unexplained spinal cord injury. He believed that the surgeons approach to the operation itself was careful and measured. There was no criticism of Mrs Hassells' post-operative management.

As discussed, this is one of a number of cases exploring the implications of the Montgomery judgement. Montgomery requires the surgeon to take "reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it." It seems that spinal surgeons are particularly vulnerable in the area of consent. All three cases referred to herein were successfully prosecuted by the claimants.

The duty under Montgomery indicates that we must give the patients choice. We have to go further than just telling them about risks and benefits of a particular treatment/ operation. The failure to advise about conservative options was one of the factors that led to a successful claim in Thefaut v Johnston as well as in the Hassell

case. Significant risks given to the patient on the day of surgery are not acceptable. As in the Jones v Royal Devon and Exeter Trust (discussed by Sokol) the court found that a consent form signed on the day of surgery did not constitute informed consent. An eminent barrister informed me that all a consent form proves is that the patient can write their own name. Consent is a process and the details need to be carefully recorded. The personal injury lawyers are well aware that Montgomery can be applied retrospectively and when a client consults them with a complication of surgery they will, unfortunately, go through the records with a fine toothcomb to look for absence of any mention of the complication that occurred.

This is an area of clinical negligence litigation where witness evidence to fact is crucial. As can be seen from the above discussion, in the Hassell case the judge strongly favoured the claimant's evidence over that of the surgeon. The court considered expert evidence in relation to consent. Where consent is concerned Montgomery trumps both Bolam and expert evidence. Whether a risk is material or whether advice given was adequate is now a matter for the court to decide, not the medical profession. ■

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References

References can be found online at *www.boa.ac.uk/publications/JTO* or by scanning the QR Code.