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Informed consent: where are we in 2015?

A recent ruling by the Supreme Court in the Montgomery *vs* Lanarkshire Health Board case (2015)[1] has rather moved the goalposts on the issue of informed consent. As orthopaedic surgeons, we need to be aware of it.

The case was heard on appeal by the Law Lords. It concerned the case of Nadine Montgomery, a diabetic lady who went through a vaginal delivery following which her son was born with severe disabilities because of obstructed labour secondary to shoulder dystocia. Apparently women with diabetes are more likely to have large babies and there is around a 10% risk of shoulder dystocia during vaginal delivery. The obstetrician in charge of Mrs Montgomery's care had a policy not to routinely advise patients of this risk as the likelihood of significant complications for the baby in association with it was very small, and she felt that if the risk was advised most women would opt for Caesarean section which was not necessarily in the mothers' best interest.

The original Court decision relied on application of the 'Bolam' test,[2] i.e. was the failure to mention the risk of shoulder dystocia, and its potential sequelae, supportable by a responsible body of medical opinion, together with the House of Lords' decision in the case of Sidaway (1985)[3] (modified in Pearce (1994)[4]) that in order for a risk to be significant it must carry a grave risk of substantial adverse consequences. On the basis of the application of these parameters, the original case was dismissed. The judge took the view that although the risk of shoulder dystocia was significant, it could, in the majority of cases be dealt with by "simple procedures" and the risk to the baby was "tiny."

At appeal this decision was reversed in the Supreme Court. The judgement (running to 38 pages) makes interesting reading. It refers at some length to legal precedent in earlier cases (some of which are alluded to above), with which many orthopaedic surgeons will be familiar. It reviews cases of a similar nature from other jurisdictions, particularly Canada and Australia. There is discussion (without definition) of what constitutes a substantial, significant or grave risk and how interpretation of these may differ between individual clinicians, and between clinicians and patients; it reflects upon the evolving nature of the doctor/patient relationship. It is noted that patients are widely regarded as consumers exercising choices, and no longer 'passive recipients' of the care of the medical profession. It considers how, in the 21st century, patients are able to access a wide range of data on their condition and treatment from the internet.

More importantly, the judgement focuses heavily on the publications of the General Medical Council (GMC) on consent (2008)[5], good medical practice (2013)[6] and the recommendations made therein. Paragraph 5 of the GMC consent document is quoted verbatim. The judgement goes on, "The doctor's advisory role cannot be regarded solely as an exercise of medical skill without leaving out of account the patient's entitlement to decide on the risks to her health which she is willing to run (a decision that may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a person's rights rests with the Courts, not with the medical professions."

The Supreme Court did not believe that the skill and judgement required for the provision of informed consent to a patient "are of a kind with which the Bolam test is concerned." Therefore it is no longer a defence of the quality of advice given to a patient ahead of a procedure to rely on the fact that a reasonable and competent body of similarly qualified/experienced practitioners would have given similar advice. The judgement goes so far as to state, "There is no reason to perpetuate the application of the Bolam test in this context any longer."

The conclusion of the judgement is that in a patient of sound mind, "The doctor is under a duty 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 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." Broadly speaking, most experienced orthopaedic surgeons would be working in and around these parameters in any case. However, it emphasises that advising an operation and discussing the risks and benefits at and prior to the consenting process requires quite detailed knowledge of the patient, their psyche and their social/occupational circumstances.

Three further points are made:

1. The doctor is entitled to withhold information if he believes that it would be detrimental to the patient's health. The 'therapeutic

exception', which should not be abused and should only very rarely be necessary.

2. It is not sufficient simply to reduce a risk to percentages. "The significance of a given risk is likely to reflect a variety of factors besides its magnitude."
3. The surgeon's role involves dialogue including a clear risk/benefit analysis of the proposed treatment and any reasonable alternatives that are available. "The doctor's duty is not fulfilled by bombarding the patient with technical information that they cannot be reasonably expected to grasp, let alone by routinely demanding their signature on a consent form."

It is conceded in the judgement that some patients would rather trust their surgeon than be informed of all the ways in which their operation may go wrong. It is not accepted that time constraints are a sufficiently good reason to fail to adequately warn patients of relevant material risks (even if this may not be palatable to certain health care providers). To support this, the judgement relies on the advice of the GMC publications referred to earlier. It also recognises that some surgeons are better communicators than others, and that the requirements outlined in the judgement may result in defensive practice together with increased litigation.

Fiona Godlee (2015)[7] editor of the British Medical Journal (BMJ), points out that our existing practices will "no longer do." She goes on, rightly in my view, "The days should be long gone when obtaining consent was left to the most junior trainee, tasked with getting the patients signature on a standard form, like a salesperson on commission." In the same publication Sokol (2015)[8] describes the judgement in the Montgomery case as a landmark decision. Sokol discusses the points made above with regard to the judgement, adding an additional point that all surgeons would be wise to ask themselves the question: Has my consent process been clearly and properly documented in the patient record?

What are we as orthopaedic surgeons to make of all this? Clearly we have to observe and follow the GMC guidelines on consent. As Lemaire (2006)[9] told us, there are varying approaches to provision of relevant information to patients prior to surgery. Equally, the retention of information by patients is variable. It is clear when reviewing patients' records that there are still great differences in the quality of information provided to patients in advance of surgery. Some surgeons and centres provide an exemplary level of pre-operative information, and the clarity and documentation of that information is excellent. There could be no criticism of it. In other centres, and with some surgeons, the level of information provided to the patient ahead of surgery appears (when reviewing records a few years down the line) very poor. In these latter circumstances it is difficult to defend the surgeon/hospital when Mr/Mrs X argues that, "If Mr Y had told me that Z could happen I would never have had the operation." Now that Bolam no longer applies, defence in such situations will be even more difficult, if not impossible.

Therefore it behoves us all to review our pre-operative information/consenting procedures to ensure that they would not fall foul of the criticisms levelled by the Law Lords in the Montgomery case. This is now the law.

REFERENCES

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