■ SPECIALTY UPDATE

Informed consent

WHERE ARE WE IN 2015?

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A recent Supreme Court ruling in the United Kingdom has significantly altered the emphasis of informed consent, moving from a historically 'doctor-focused' to a more 'patient-focused' approach, in line with the situation in other international jurisdictions.

The reasons for the change are discussed with some recommendations about how our attitudes need to change in the future.

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A recent ruling by the Supreme Court in the *Montgomery v Lanarkshire Health Board* case[1] has changed the position on the issue of informed consent in the United Kingdom. As orthopaedic surgeons we need to be aware of it.

The case was heard on appeal by the Law Lords. It concerned Nadine Montgomery, a diabetic woman who, following obstructed labour owing to shoulder dystocia, was delivered of a son with severe disabilities. Apparently there is a 9% to 10% risk of shoulder dystocia during vaginal delivery in diabetic mothers, who are more likely to have large babies. It was the policy of the obstetrician in charge of Mrs Montgomery's care not to advise patients of this risk routinely as the likelihood of significant complications for the baby was very small. The obstetrician felt that if the risks were described, most women would opt for caesarean section, which she considered not to be in their best interest.

The original court dismissed the case on the basis of the application of two principles. The first was the 'Bolam' test:[2] that the failure to mention the risk of shoulder dystocia, and its potential sequelae, was defensible if supported by a responsible body of medical opinion. The second was the House of Lords decision in the case of Sidaway,[3] modified in Pearce,[4] that in order for a risk to be significant it must carry a grave risk of substantial adverse consequences. With respect to the latter, the judge took the view that, while the risk of shoulder dystocia was significant, it could in most 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 with which many orthopaedic surgeons will be familiar, including those alluded to above. It also reviews cases of a similar nature from other jurisdictions, two of which are of particular interest. In the case of *Reibl v Hughes*,[5] the Supreme Court of Canada decided that the adequacy of consent before surgery should be judged on the "reasonable patient" standard rather than that of the "reasonable doctor". In the case of *Rogers v Whitaker*,[6] the High Court of Australia identified the basic flaw in approaching all aspects of the doctor's duty of care in the same way. It drew a distinction between the decision making process regarding the choice of treatment and the provision of information on risks before treatment, arguing (somewhat controversially) that, "no special medical skill is involved in disclosing the information, including the risks attending the proposed treatment". Skene and Smallwood[7] warned of what was on the horizon in their report on 'Informed consent: lessons from Australia', noting that tougher standards on consent were starting to be applied in England because of the ruling in the case of *Rogers v Whitaker*.[6]

The situation in the United States is much the same as in Canada and Australia and indeed has been established for much longer after *Canterbury v Spence* (1972).[8] Chalmers and Schwartz,[9] when analysing *Rogers v Whitaker*, discussed the conflict between the patient-orientated American rule on informed consent and the British rule which remained doctor-orientated.

In the Supreme Court ruling on Montgomery,[1] there is discussion (without definition) of what constitutes a substantial, significant or

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grave risk and how the interpretation of each may differ between clinicians and patients, or among clinicians. It reflects upon the evolving nature of the doctor/patient relationship. It is noted that patients are now widely regarded as consumers exercising choices and no longer as "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[10] and good medical practice,[11] and the recommendations made therein. Paragraph five of the GMC consent document, which outlines the basic model for consent in patients with the capacity to decide on their own treatment, is quoted verbatim. The judgement continues: "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".[10]

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". In this, they accepted the position taken by the High Court of Australia in *Rogers v Whitaker*.[9] Therefore, it is no longer a defence of the quality of advice given to a patient before a procedure to rely on the fact that a reasonable and competent body of similarly qualified and experienced practitioners would have given similar advice. Indeed, 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 with the capacity to consent for treatment, "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 before the consenting process requires quite detailed knowledge of the patient, their psyche and their social/occupational circumstances.

Three further points are made:

- The doctor is entitled to withhold information if he believes that it would be detrimental to the patient's health. This is the "therapeutic exception", which should not be abused and should only very rarely be necessary.

- 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".

- 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 reasonably be 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 warn patients adequately of the relevant risks, even if this may not be palatable to certain health care providers. In order to support this, the judgement relies on the advice given in 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,[12] editor of the *British Medical Journal*, points out that our existing practices will "no longer do". She goes on, rightly in my view, to say that "The days should be long gone when obtaining consent was left to the most junior trainee, tasked with getting the patient's signature on a standard form, like a salesperson on commission". In the same publication, Sokol[13] describes the judgement in the Montgomery case as a landmark decision. He goes on to discuss the points made above with regard to the judgement, adding that all surgeons would be wise to ask themselves the question: "Has my consent process been clearly and properly documented in the patient's records?"

What are we as orthopaedic surgeons to make of all this? Clearly we are obliged to observe and follow the GMC guidelines on consent. As Lemaire[14] discussed, doctors' approaches to the provision of pre-operative information vary, as does the capacity of patients to retain this information. It is clear when reviewing patients' records that there are still great differences in the quality of information provided to patients before surgery. In some cases, the level of pre-operative information is exemplary and the clarity and documentation of that information is excellent. In others, the level of information provided to the patient, when reviewing the records a few years later, is very poor. In these latter circumstances it is difficult to defend the surgeon or 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 more difficult, if not impossible.

Therefore, it behoves us all to review our practices in terms of the provision of information and the obtaining of consent before surgery. We must ensure that, in similar circumstances, our practices would not fall foul of the criticisms levelled by the Law Lords in the Montgomery case.

The law in the United Kingdom appears, somewhat belatedly, to have fallen in line with the standards applied on informed consent in other overseas jurisdictions.

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