Peter H. Worlock *DM, FRCS*
Consultant Orthopaedic Trauma Surgeon, Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne NE1 4LP, UK.
Email: peter.worlock@nuth.nhs.uk

Consent: where are we in 2016?

In 2015, the Supreme Court gave their decision on a case involving the issue of informed consent for an obstetric procedure.[1] That judgement (referred to hereafter as 'Montgomery') has implications for all doctors practising within the United Kingdom.

FACTS OF THE CASE

The claimant was a small, diabetic woman with a large foetus. The risk of shoulder dystocia was estimated to be between 9% and 10%, but the mother was not informed of this because her consultant considered the risk of a 'grave problem' for the baby to be "very small" (in the event of shoulder dystocia occurring, there was a 0.2% chance of brachial plexus injury and a 0.1% chance of prolonged hypoxia). The option of planned caesarean section (CS) was not discussed with the claimant, and induction was planned for 39 weeks. During delivery, there was occlusion of the umbilical cord resulting in a hypoxic brain injury.

Subsequently, the mother claimed that she should have been warned of the risk of shoulder dystocia and the potentially catastrophic consequences, and of the alternative of planned CS, in which case she would have opted for CS. At both the initial trial and on appeal, the defendant's experts stated that the "risk of grave problems was very small", but also that "if such women were warned, most would opt for CS". Both courts concluded that to not warn the patient was accepted as proper by a responsible body of medical opinion.

The Supreme Court accepted that the consultant's decision accorded with a reasonable body of opinion, but that patients have rights and are not passive recipients of the care of the medical profession. A person is entitled to decide which, if any, of the available forms of treatment to undergo. The Supreme Court accepted that, if appropriately warned, the claimant would not have agreed to undergo the procedure of induction of labour and thus was entitled to damages.

THE MONTGOMERY DECISION

The judgement from the Supreme Court runs to 37 pages (a total of 117 paragraphs), and paragraphs 74-93 (inclusive) are instructive reading for all doctors. The two paragraphs below summarise the key points in the judgement.

The doctor, therefore, has a duty to take reasonable care to ensure that the patient is aware of any material risks involved in the recommended treatment, and of reasonable alternative 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 whether the doctor is (or should be) aware that the particular patient would be likely to attach significance to it. The assessment of whether or not a risk is material cannot be reduced to percentages. It is fact-sensitive in relation to individual patients. The doctor's duty is not fulfilled by bombarding the patient with technical information which they cannot reasonably be expected to understand, let alone by routinely demanding a signature on a consent form.

The doctor is, however, entitled to withhold from the patient information regarding a risk if he/she reasonably considers that its disclosure would be seriously detrimental to the patient's health (the so-called 'therapeutic exception'). Nevertheless, this therapeutic exception is a limited exception to the principle that the patient should make the decision on whether to undergo treatment. The doctor is also excused from conferring with a patient in circumstances of necessity, as, for example, where a patient requires treatment urgently but is unconscious or otherwise unable to make a decision.

The issue of what should be discussed with the patient is now a matter of law, not of professional practice. In pleading a case of lack of consent, it is not a matter of expert medical opinion. *It is for the courts and the law to determine, not doctors.*

THE PROFESSIONAL POSITION

The decision of the Supreme Court in this case should not have come as a surprise to anyone. It is in line with the dissenting judgement of Lord Scarman in the Sidaway case of 1985,[2] with the case of Pearce v United Bristol Healthcare NHS Trust in 1999[3] and with the case of Chester v Afshar in 2005.[4] While it may be thought unreasonable for all doctors to be familiar with these legal judgements, they should be aware of the position of the General Medical Council (GMC) and the Department of Health (DoH).

In 2008, the GMC issued their guidelines in a booklet entitled 'Consent: patients and doctors working together'.[5] This booklet has been circulated to all doctors registered in the UK. It is essential reading and very clearly states that there are four steps in the basic model for obtaining informed consent:

1. The doctor and patient make an assessment of the patient's condition, taking into account the patient's medical history, views, experience and knowledge.
2. The doctor uses his/her specialist knowledge/experience/clinical judgement to identify which investigations/treatments are likely to benefit the patient.

3. The doctor explains options to the patient, setting out potential benefits, risks, burdens and side effects of each option (including the option of no treatment).
4. The patient weighs up the potential benefits, risks and burdens of the various options. The patient decides whether to accept any of the options and, if so, which one.

The GMC further stated that the discussions with patients should focus on their individual situation and the risks to them. Doctors should discuss and find out the patient's individual views about the adverse outcomes that most concern them. Doctors must tell patients of any serious adverse outcome (even if the risk is small) and of any less serious side effects or complications, if frequent.

With regard to the question of who should obtain consent, the GMC states that this is the responsibility of the doctor undertaking an investigation or providing treatment. If this is not practical, this doctor may delegate responsibility providing they ensure that:

- The person obtaining consent is suitably trained and qualified.
- The person obtaining consent has sufficient knowledge of the proposed investigation or treatment and understands the risks involved.

If responsibility for obtaining consent is delegated, the treating doctor is still responsible for ensuring that the patient has given informed consent before any investigation or treatment is undertaken.

The position of the GMC was reinforced by the DoH in 2009.[6] The DoH guidance also emphasised that the discussion should focus on the patient's individual situation and the risks to them. Doctors were told to inform the patient of any "material" or "significant" risks or unavoidable risks (even if small) in the proposed treatment, any alternatives to the proposed treatment and the risks incurred by doing nothing. The DoH stated that doctors should provide balanced information about procedures/risks and check that patients had understood. A record of the information given should be made in the notes.

With regard to the issue of who should obtain consent, the DoH stated that the clinician providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment is administered, and that the consultant overseeing the patient's care is ultimately responsible. Doctors were advised that inappropriate delegation could mean that the consent obtained was not valid.

The position of the GMC and DoH on informed consent has therefore been quite clear since 2008/09. Indeed, the GMC was so concerned about the Montgomery case that it took the unusual step of asking the Supreme Court if it could intervene and present evidence to the Court. This application was granted and the GMC gave evidence on their professional position. After the judgement, the GMC stated:

> "Today's judgement is very helpful and it justifies our decision to intervene in this case... We are pleased that the Court has endorsed the approach advocated in our guidance on consent. 'Good Medical Practice' and 'Consent: patients and doctors working together' make it clear that doctors should provide patient centred care. They must work in partnership with their patients, listening to their views and giving them the information they want and need to make their decisions."

While, in one sense, the Montgomery judgement simply brings the law into line with the professional position of the regulator (the GMC) and the ultimate employer of most doctors in the UK (the DoH), all doctors need to be aware that the situation has changed. Although there is no new legislation, the Supreme Court's interpretation of the existing law means that (as stated above) the issue of what should be discussed with the patient is no longer a matter of professional practice: it is a matter of law. The judgement means that it will be possible to look back and raise the issue of lack of informed consent in cases preceding 2015. Given the guidance issued by the GMC and DoH in 2008/09, it seems reasonable to work on the basis that claims pleading the lack of informed consent could now be made on any case from 2008/09 onwards. Perhaps the floodgates are about to open?

It is interesting to note that the senior barrister for the claimant in the Montgomery case (James Badenoch QC) was surprised at the earlier judgements and critical of the ferocity with which the defendants resisted the claim. He made the point, "It can therefore be said with certainty that the defendant's legal advisers were, by their approach to this case, personally responsible for the ultimate reversal of the legal principle on which they placed such misguided reliance. Only they can explain how lawyers experienced in medical law came to espouse and assiduously to pursue arguments on the facts and the law which were so devoid of merit."[7]

WHAT SHOULD YOU DO NOW?

All orthopaedic surgeons taking responsibility for obtaining investigations and providing treatment for patients need to think carefully about delegating responsibility for obtaining informed consent to their trainees. If you do (and it is reasonable to do so providing the above criteria have been met), then you must be prepared to justify trainees' ability to obtain informed consent and the specific training they have had in obtaining consent in general and for any specific procedure. If a claim is advanced in respect of an alleged lack of informed consent, the Court may reasonably ask for written documentation that the individual obtaining consent had the necessary skills and expertise to do so. The basic model (as above) from the GMC[5] should be used as the template for the process of obtaining informed consent.

You must have made a formal assessment of the patient's capacity to give informed consent. Typically, there is lack of capacity for one of the following reasons:

- The patient is unable to comprehend and retain information material to the decision.
- The patient is unable to use and weigh up this information in the decision-making process.
- The patient is unconscious.

Lack of capacity may be permanent or temporary. You must record in the notes the details of why you consider the patient to be lacking in the capacity to consent and if it is likely to resolve. If you consider any lack of capacity to be temporary, you should record fully in the notes why the investigation or treatment cannot be delayed until the patient recovers capacity.

As in most cases of alleged clinical negligence, the quality of the medical notes is critical. You must expect sharp-eyed claimant solicitors to be scrutinising the notes for written evidence (or lack of written evidence) that you have followed the GMC guidance. The author suggests, therefore, that you:

- Make full and comprehensive (legible) notes on how you reached your diagnosis, on your decision-making process, on your recommended management plan and on the consent process.

- Document the alternative treatments (including no treatment) that have been discussed with the patient (and the risks/benefits of each).
- Make it clear that adequate time was set aside for a meaningful discussion with the patient (including multiple meetings if necessary).
- Make it clear and document the steps taken to ensure that the particular concerns and wider circumstances of the individual patient have been taken into account.
- Try to provide written documentation of a genuine dialogue between you and the patient.
- Document the potential risks, complications and adverse outcomes of the procedure(s) in the individual patient (amplify, rather than just using percentages).
- Document the risks of possible distressing, painful or dangerous intervening events.
- If exercising the therapeutic exception, document fully your reasons for doing so.
- Record if the patient appears to have fully understood the advice you have given them.

Where any investigation or treatment is planned as an elective procedure, then it should be possible to follow the GMC guidelines and document matters fully (although NHS employers will have to recognise the additional time this will take in busy out-patient clinics). The situation may well be different in an emergency.

The Supreme Court clearly recognised this, and Montgomery states that you are "excused from conferring with the patient in circumstances of necessity, as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision". You should, therefore act in the patient's best interests to save life and/or prevent serious harm to their health (and in accordance with any advance directive), and document fully in the notes what this best interest is and why. You should consult with colleagues (if time allows) and discuss what you propose with the patient's family or next of kin (recognising that, except in children, they cannot legally give consent).

All orthopaedic surgeons treating trauma will be familiar with this situation in unconscious patients and in elderly patients with Alzheimer's disease. However, the author has long had concerns about the validity of a signature on a consent form in patients with severe limb injuries (albeit conscious and with no suggestion of permanent cognitive impairment). It difficult to see how a patient in pain from, for instance, a severe open tibial fracture, after receiving considerable amounts of opiate analgesia, can be said to give 'informed' consent (as laid down by the GMC in 2008). In such a situation, he is prepared to act in the patient's best interest (having followed the procedure outlined above), document the situation fully in the notes and sign a NHS Consent Form 4.

Clearly, at the other end of the trauma spectrum are patients with (for instance) isolated wrist and ankle fractures, who are being assessed in the fracture clinic. In such a situation, it should be possible to proceed with the process of obtaining informed consent exactly as for a planned procedure, using the basic model of the GMC.

CONCLUSION

Although the law has not changed, the court's interpretation of it has changed with the Montgomery ruling; all practising doctors need to be aware of this. As Sokol stated in the BMJ,[8] "The law now demands a standard of consent broadly similar to that required by the professional guidance of the General Medical Council. Doctors who follow that guidance will not fall foul of the law."

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 DOI: 10.1302/2048-0105.53.360434