CONSENT

The current law and implications for clinical practice

The legal principles in outline

Following the Supreme Court decision in Montgomery v Lanarkshire Health Board [2015] UKSC 11 the concept of “informed consent” is now firmly embedded in English law. The court stated (at paragraph 87):

“An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken.”

The court went on to say that:

“The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.”

Their Lordships explained that:

“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.”

The facts of the case

To set this in context, the Montgomery case concerned a diabetic mother who was expecting her first baby. At 36 weeks gestation Mrs Montgomery expressed concern about the large size of her baby, but was advised that she would be able to deliver vaginally. She was not warned about the risks to herself or to her baby. Specifically, she was not offered the option of an elective Caesarean section, although if she had asked for one it would have been carried out. Unfortunately, the baby became impacted during labour. An emergency general anaesthetic was given so that a Zavanelli manoeuvre (to push the baby back into the uterus) could be attempted. The doctor then decided she had no option but to try to complete the delivery. She used "significant traction" to deliver the head, and attempted a symphysiotomy with partial success, eventually completing an instrumental delivery “with just a huge adrenalin surge.” Needless to say, these events were hugely stressful for clinicians and mother alike. The baby has Erb’s palsy and cerebral palsy of dyskinetic type affecting all four limbs due to lack of oxygen for the 12 minutes the umbilical cord was occluded during delivery.

In evidence, Mrs Montgomery told the court that if she had been told of the approximately 10% risk of shoulder dystocia, she would have requested an explanation of what that meant and the possible outcomes. Once she had learned what this was about she said she would have regarded the risks as significant and asked for a Caesarean section.
The doctor said that if she had thought that the baby was likely to weigh more than 4 kgs she would have offered Mrs Montgomery a Caesarean section, but as the assessment was that the baby would not exceed that weight limit no such offer was made. The doctor accepted that the 10% risk of shoulder dystocia was relatively high, but she didn’t mention it to Mrs Montgomery because in her opinion the risk of a grave problem for the baby resulting from shoulder dystocia was relatively small. She explained that “if you were to mention shoulder dystocia to every diabetic patient, if you were to mention to any mother who faces labour that there is a very small risk of the baby dying during labour, then everyone would ask for a caesarean section, and it’s not in the maternal interests for women to have caesarean sections.”

The Supreme Court has indicated very clearly that such an approach to the sharing (or withholding) of information with (from) patients is negligent.

Discussion of the legal principles

As noted above, and evident from the facts of the case, the courts have stated in the clearest possible terms that patients must be told about alternative treatments available, and about the “material” risks. What does this mean in practice?

In Montgomery the practical options were vaginal delivery or instrumental delivery (which many mothers would not regard as a form of vaginal delivery) or Caesarean section, which may be carried out either electively or as an emergency when other methods of delivery have failed. In other circumstances it may be appropriate, for example, to discuss the risks and benefits of no treatment, or of alternatives to surgery, or of different types of surgery.

It will almost never be enough (save in an emergency life-saving situation) to intervene without having first discussed the alternatives, and if necessary, advising the patient to seek advice elsewhere. For example, when the Abortion Act 1967 came into force some doctors, for reasons of personal conscience, declined to carry out legal abortions. The courts said that the doctor who declined also had a duty to advise the patient that another doctor might be willing to carry out the abortion, and to direct the patient elsewhere for further and timely advice.

The same principle applies today: if there are alternative treatments available which the doctor does not offer (or consider to be clinically appropriate) although his peers may do, then the patient should be advised to seek further information, perhaps by way of a second opinion, before making a final decision. It isn’t entirely clear where the line is to be drawn as this issue was not addressed by the court in Montgomery: should the doctor, for example, mention so-called “alternative therapies” or limit the discussion to conventional treatments, including those offered by the allied professions such as physiotherapists?

It is important to note that patients are not entitled to demand their treatment of choice regardless of the doctor’s views on what is clinically appropriate. The courts will not direct a doctor to carry out treatment which the doctor considers to be clinically inappropriate, or treatment considered to be futile. The implication of this is that it is only those treatments which are generally regarded as clinically appropriate which must be mentioned, but it is important to note that it is insufficient in law to limit the discussion to the doctor’s preferred option or to base advice solely on clinical grounds.
In relation to what is “material” the Supreme Court explained (at paragraph 89) that:

“…the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of other factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive to the characteristics of the patient.”

They went on (in paragraph 90) to state that:

“…the doctor’s advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision.”

Clearly a doctor cannot be expected to impart years of technical knowledge and experience in a relatively short discussion, but there is an expectation that a suitable distillation of the relevant information will be given to the patient. How much information is enough will obviously vary from one patient to another, as will the content of the discussion, and the depth of detail required by the patient. Thus, it may be appropriate for some patients to be referred to more detailed guidance available on the internet.

The court has emphasised the importance of the information provided being comprehensible – otherwise consent cannot be properly “informed”. There has to be a sensible balance between giving sufficient information to enable the particular patient to make an informed decision, and simply blinding patients with science which they cannot reasonably be expected to understand or evaluate. However, a patient who is scientifically or medically trained may require a greater level of detail than a patient who has a learning disability before making what for that individual is an “informed” decision. Equally, regardless of their level of education, some patients need to know more than others before reaching a decision. The doctor’s task is to ascertain how much information is required for that individual patient to be able to make an informed decision, and to provide that level of information in terms that the individual is able to comprehend.

There are limited circumstances in which a doctor is entitled to withhold information from the patient, namely “if he reasonably considers that [...] disclosure would be seriously detrimental to the patient’s health.” The court in Montgomery was at pains to make clear that the so-called “therapeutic exception” (ie withholding information which may cause serious harm to the patient) must not be abused. The doctor is “also 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.”

The court declined to consider the detailed scope of the exceptions, but emphasised that they should not be used to circumvent the general principle of informed consent. They also said that the therapeutic exception:
“…is not intended to subvert [the] principle [of informed consent] by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests.”

Thus, the court said, it is insufficient in law to say that clinic time is too short for such discussions, or to attempt to protect patients from making poor decisions by withholding information. It is a basic tenet of the law that every adult of sound mind is entitled to make their own decisions, even if others (including their doctors) might consider those decision to be unwise, foolish, or eccentric. Only if a patient is assessed as lacking capacity to make the relevant decision at the time it needs to be made (noting that delay or assistance may enable the patient to regain capacity to make the decision) is it lawful to act in a patient’s best interests – and therefore without having given the patient an opportunity to make their own informed decision.

The Supreme Court did recognise that some patients don’t want to be burdened with a lot of technical information or, in some cases, the responsibility of making a decision about their own healthcare. The court said (at paragraph 85):

“…a doctor is not obliged to discuss the risks inherent in treatment with a person who makes it clear that she would prefer not to discuss the matter.”

In such situations, the doctor is expected to work out how best to explain the risks to the patient, even if good communication is not that doctor’s forte. If, despite every effort, the patient is adamant that she doesn’t want to pursue the discussion then a very careful note must be made in the patient’s records stating what was offered, and the terms in which it was declined. Bear in mind that you may need to rely on your notes to explain why a particular risk which has eventuated was not discussed beforehand.

Finally, the Supreme Court said that:

“...in so far as the law contributes to the incidence of litigation, an approach which results in patients being aware that the outcome of treatment is uncertain and potentially dangerous, and in their taking responsibility for the ultimate choice to undergo that treatment, may be less likely to encourage recriminations and litigation, in the event of an adverse outcome, than an approach which requires patients to rely on their doctors to determine whether a risk inherent in a particular form of treatment should be incurred.”

We have moved full circle since the 1950s approach of the Bolam test, by which doctors were required to warn their patients only about the risks that their medical peers usually mentioned. The focus now is on what the patient needs to know to enable that individual to make an “informed” decision. Paternalism is dead – long live informed consent!

**Practical implications of the decision**

- Every adult patient must be assumed to be capable of making an informed choice about their treatment - unless assessed as lacking capacity to make that decision at that time (e.g., life-saving treatment or other necessity).
- Patients must be told about alternatives to the proposed treatment, along with the risks and benefits of each option, including the option of no treatment.
• If an alternative treatment is available elsewhere then it may be appropriate to say so and/or to refer the patient for a second opinion.

• Risks and benefits are not about percentages: they must be explained in language which the particular patient can understand.

• What is a “material” risk is both fact- and patient-specific.

• What is material to the patient may not coincide with what the doctor regards as material – the doctor is required to ascertain and discuss the patient’s views on materiality of risk.

• Lack of time is not a good enough reason to avoid a proper (lawful) discussion with the patient.

• Use of patient information leaflets, references to internet resources, etc may be a good way of conveying basic information about common procedures so that clinic time can be used to discuss what is important to the patient, including specific risks relating to that individual raised by the doctor and specific questions raised by the patient.

• Consent is a process of dialogue over a period of time. How long or detailed the discussion needs to be will depend on the nature of the decision to be made, and on what the individual patient wants to know and understand so as to be able to make an informed decision.

• The signing of a consent form is not “consent” whether informed or otherwise, but is often no more than a tick box exercise carried out at the last minute. There should be nothing in a consent form which has not previously been mentioned to the patient and discussed at the level of detail desired by the patient.

• Where life-saving treatment is necessary it should be given in the patient’s best interests if it is not realistic to discuss it with the patient beforehand (subject to any Advance Decision the patient may have made which is valid and applicable to the current situation or to the views of a validly appointed Healthcare Attorney).

• If in doubt, please seek legal advice at an early stage. Training on the law on consent and its practical implications can be provided by the Head of Litigation on request.

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