Four Years On, Do You Have Consent?

INCISION

Part 1 – Letter of the Law

Obtaining valid patient consent is one of the most fundamental pre-operative responsibilities of surgeons. In 2015 there was an important development in the UK case law – the now well-known Montgomery decision - which resulted in a sharp increase in claims against healthcare professionals generally arising from the consenting process.

Since then we have been carefully monitoring legal and practical developments and gathering real-life case studies from Incision members and other specialist surgeons. Understanding the current legal landscape and the practical challenges will help surgeons keep their processes updated to promote good practice in obtaining consent. In turn, this should help prevent unnecessary claims or regulatory proceedings from arising in the first place and, provided it is properly documented, will make it easier to defend any claims that do arise.

This short series of four guidance notes is intended to help busy Incision members by:

- Providing a recap and refresher on 'where we have got to' in legal terms over the past few years;
- Providing an in-depth reminder of the practical challenges that the legal developments have thrown up, with suggestions of how those challenges can be addressed;
- Providing 'food for thought' suggestions to help surgeons optimise any standard or template forms they may already use to support the process of good consent-taking;
- Providing information about real-life situations faced by Incision members and other specialist surgeons to illustrate the potential pitfalls and how to avoid them.

We think that this series is worthwhile even now, nearly four years after Montgomery was decided. We still regularly come across current examples via the medico-legal helpline service of surgeons misunderstanding their obligations. We have assisted in recent cases where the surgeon simply omitted to warn of or consent for certain risks because they 'didn't want to worry the patient', or thought that a risk was 'pretty unlikely' to manifest. All these matters required notification to the insurers, and some required fee refunds or compensation payments to resolve them, because the surgeons mistakenly used an approach to consent that is no longer legally acceptable.

What is the current UK law?

In 2015 the UK Supreme Court decided that 'informed consent' is now the correct approach. There is no higher court in the UK than the Supreme Court, so there is no prospect of any big departure from this key principle for the foreseeable future. Montgomery v Lanarkshire Health Board [2015] UKSC 11 ("Montgomery") clarifies that healthcare professionals have a duty to discuss with the patient the "material risks" involved in the proposed treatment and any alternative treatment options.

'Materiality' is to be judged by reference to the individual circumstances of the patient. A risk of the procedure is 'material' if a reasonable person in the patient's position would be likely to attach significance to the risk, or if the doctor is or should be aware that the particular patient would be likely to attach significance to it. This requires consideration of the patient as an individual – a holistic approach.

There will be situations where it is not possible to obtain informed consent before treatment, for example where the patient lacks the capacity to provide consent, where emergency treatment is to be provided or where disclosure of risks would be seriously detrimental to the patient's health. However, those situations will be rare.

There has been a small amount of case-law to help understand what 'materiality' means. For example, in A v East Kent Hospitals University NHS Foundation Trust (2015) the judge found that a risk that was "theoretical, negligible or background" did not have to be communicated to a patient. In that case expert evidence in that case had estimated the particular risk under consideration at 1:1000. In another reported case that same year, Tasmin v Barts Health NHS Trust (2015), the judge made a similar point that a 1:1000 risk is 'too low to be material'.

These cases give some comfort to surgeons that they will not always be obliged to waste valuable consulting time providing reams of information about every 'theoretical, negligible or background' risk that might exist. However, we would strongly caution against taking these two cases literally. Surgeons should not assume that they never need to mention risks that are below a notional 1:1000 threshold.

This is because the test will always be as stated in Montgomery - "…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". This means that there will be patients whose particular individual position means that they would be unwilling to take even a 1:1,000,000 chance of a particular adverse outcome.

The practical challenge that this throws up for busy surgeons is how to remain alert to 'outlier' patients who will need to be counselled in relation to very marginal risks as well as all the more likely ones. In the next guidance notes in this series we suggest some approaches to help surgeons identify the instances where they do need to go into more detail with a patient on remote risks.

What does this mean for surgeons?

A risk that is material for one patient may not be so for another. Therefore a 'one size fits all' approach to advising patients is no longer safe or appropriate. Surgeons will need to update their practice to ensure they obtain informed consent from every patient for every intervention or procedure.In our view, following Montgomery, it is vital to think of consent as a process rather than a single event. The process of consent will often be best approached in these broad stages and further commentary on each is provided in the next guidance notes in this series:

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- Obtaining the patient's medical and social history;
- Obtaining consent for ancillary matters, such as clinical photographs;
- Consulting with the patient, including providing patient information leaflets;
- Final consent to go ahead with the intervention/treatment.

Ideally, and particularly for elective surgery, there should be sufficient time between each stage for the patient to think about the risks and a realistic opportunity for them to pull out of surgery entirely at each stage. The potential risks of patients who feel 'committed' to a procedure before they have had a chance to evaluate the full implications are analysed in a later guidance note in this series.

We appreciate that, in some situations, all stages of the consent process will have to take place within one meeting between the patient and the healthcare professional. If the procedure is quite urgent, or the clinic very busy, there may not be much time for the discussion. Nevertheless, if surgeons keep these stages in mind they are more likely to obtain valid informed consent from their patient, even when they are working under significant time pressures. It is essential that each stage of the process is carefully documented in the patient's notes, as this will be vital evidence in defending any subsequent claim.

Does it have to be in writing?

Consent that is obtained orally and not recorded in writing is technically valid, so carrying out investigations or treatment based on oral consent only is not going to be a criminal assault.

However, from the legal perspective of defending compensation claims, there is simply no substitute for written records. We have assisted surgeons who believed that it was sufficient to have a clinic letter that stated, "all the potential complications were discussed", and their recollection of what their practice was at the time in terms of explaining potential complications to patients. It is not.

If there is no written record that a particular risk was warned of, then in a hypothetical trial the judge would be faced with a surgeon whose evidence is, 'I don't have a specific record, but I believe I must have warned of this' and a patient whose evidence is 'no he didn't'. The judge will virtually always prefer the evidence of the patient in that situation. The received wisdom is that the consultation will have been an unusual or significant event for the patient such that their recollection of the particulars is likely to be better than that of the surgeon, for whom this will have been a routine meeting very similar to dozens of others. Also, the judge will be unwilling to give a surgeon the benefit of the doubt when documentation of the meeting is always the surgeon's responsibility, rather than the patient's.

Well-designed template forms can help with the consent process and thereby reduce the risk of expensive complaints and claims arising in the first place.

For example, while a 'checklist mentality' is not necessarily helpful, a standard document can be a helpful aide memoire for a busy surgeon to help ensure that all the necessary material is covered with every patient. They can be particularly helpful as a prompt to mention newly-discovered or unusual risks of a procedure. They also help ensure that complete records are kept by providing a convenient and consistent way to make the necessary notes, which is vital in defending any claims which arise.

Effective forms are those that have been designed or adapted for the surgeon's particular practice. They should be regularly reviewed and updated to make sure they capture all the necessary information and to reflect any changes in the known risks for the procedure. They should be written in clear and straightforward language.

When designing or adapting forms, surgeons need to consider not just the content of the form but also the layout and format. For example, in my experience too few surgeons give sufficient thought in advance to whether their standard forms include sufficient space to record all the necessary details. Poorly designed forms often leave so little room for answers that important information is either not recorded or becomes illegible.

What if surgery would have been deferred, not rejected?

We have spoken to some surgeons who have gained the impression that if the surgery is essential and will certainly go ahead, then the consent process is less important because the patient is going to have to take the surgical risk. In our view, that is a potentially risky mischaracterisation of the legal position.

Even where a surgery is essential and will certainly go ahead, then there could still be a consenting issue over when exactly it goes ahead (except for emergency surgery, of course).

The difficulty arises because of a somewhat controversial case called Chester v Afshar. That case decided that in a situation where a patient was not adequately consented, the patient only has to prove that they would have delayed the surgery. If they do that they have demonstrated the legal causation between the inadequate consent and the injury suffered and are entitled to compensation. In other words, even if the patient would only have taken an extra day to think about the risks, the court has to 'deem' the causation of injury to be proven. This is a legal fiction of course, there is no reason why the adverse outcome would have been avoided if the surgery was delayed by a day but still went ahead. Unfortunately, that is the legal reality we are all stuck with. The patient does not have to prove that the surgery would never have gone ahead to be entitled to compensation.

While some patients would allege that if they had been warned about the risks more fully they would have taken an extra day or so to think about them, other patients might have actual practical reasons for delaying or deferring surgery. For example, a parent of small children might want to delay surgery until all the children are at school to better manage the recovery process and any risk of delayed healing. A patient facing surgery with a significant mortality risk might want to wait a few days to make a will. A patient facing surgery that could prevent them from driving afterwards might want to wait until they have changed jobs to one that does not rely on them driving.

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The practical upshot of the legal landscape for surgeons is that in the consent process they need to get the patient to think about not just whether they will ever have surgery, but if so when. There could be lots of practical reasons why a patient might want to delay or defer the surgery – whether for a short time or many years – until a point where they are better able to accept or cope with the risks that are material to them.

Final thoughts on the legal landscape

Surgeons care deeply about their patients. While most agree that driving up standards is essential, some feel frustrated that this has caused the growth in process-driven care that risks depersonalising patients. In this context, Montgomery should be considered a cause for optimism because it requires healthcare professionals to consider each patient from a holistic point of view and to understand how a proposed procedure will affect them personally.

Nevertheless, this case has created an increased risk for surgeons because it is now rare for a claimant's pleaded case to not contain allegations about a failure to obtain informed consent. Documentation is key and following the above processes will help protect you. If the documentation is lacking or does not exist at all, it will be impossible for your lawyer to defend you against such allegations.

If you want to discuss any of the matters issues raised in this note, please don't hesitate to call the medico-legal helpline on 0333 010 2826.

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