Do You Have Consent?

INCISION

Part 3 – Consultations and Information Leaflets

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. 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.

A recap on the current UK law was provided in Part 1 of this series. The upshot of the legal changes is that the process of consent will often be best approached in these broad stages:

- Obtaining the patient's medical and social history (covered in Part 2 of this series);
- 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.

In this note we focus on the practicalities of consultations with patients, providing patient information leaflets to support that process, and obtaining the final consent to go ahead.

Consulting with the patient and providing patient information leaflets

In this stage, the patient is given information about the nature and purpose of the proposed intervention or procedure and the potential risks. Depending on the exact procedure, this could be a lengthy and complex discussion and it is important that wherever possible the discussion is led, and documented, by the surgeon who will actually performing the procedure. The risks of 'delegating' parts of that process are reviewed in a later note in this short series.

It is very important indeed that the process includes a detailed discussion about any potential alternative treatment options, and the relative merits of such options. This includes alternatives that the surgeon may not consider to be the most appropriate, as well as the option of not proceeding with any form of treatment at all.

Failure to advise of alternatives is a particularly common allegation in consent claims. For example, where a patient who was consented for surgery alleges that he or she was not appropriately informed of the option of conservative treatment.

Obtaining effective consent depends on ensuring that the patient receives all of this information in a format and manner that makes it comprehensible to them. Each surgeon needs to give careful thought to what information the patient needs about each procedure they offer. They also need to design an effective process for ensuring that all of the information is provided to the patient and that records are kept.

Therefore, any template forms used for consultations should be individually drafted to deal with each type of procedure offered. The template forms should also have enough flexibility to be adapted to the particular situation of each individual patient.

While conveying all the potential 'material' risks and the pros and cons of all the alternatives is necessary for all types of surgery, even those where the only alternatives would inevitably lead to death or serious disability, the process is perhaps particularly important for the following types of surgery:

- Medically necessary, but not urgent and can be deferred for some time. In these cases the issue for the patient might not be so much whether to accept the risks of surgery, but when to go ahead so as to manage the potential complications best. For example, if a risk of surgery is slow healing leading to a long recovery period, a patient who is a parent of small children might find that risk easier to accept if the surgery is delayed until the children are all in school. Similarly, if a risk of the surgery is that the patient might not be able to drive for a time after surgery, and the patient's job is dependent on them being able to drive, the patient may wish to defer the surgery until after retirement.
- Not strictly medically necessary, purely elective. The classic examples include aesthetic surgery and some types of eye surgery, but examples exist in most surgical specialisms. In these cases the consenting process can be especially difficult because the very factors that give the patient the desire for the surgery might make the inherent risks more 'material' for that patient. For example, a patient who is so concerned about his aesthetic appearance that he is willing to pay privately for aesthetic surgery is inherently less likely to be able to easily accept the risk that the surgery might in rare cases leave him with a worse aesthetic appearance. Similarly, a patient whose job or hobbies mean that they would like to be able to dispense with spectacles, might be least able to cope if rare complications manifest that adversely affect their vision.

After Montgomery, surgeons simply must ensure that sufficient information is provided to each patient to allow the patient to make a fully informed decision about whether to go ahead. Particularly, bearing in mind any risks that are particularly 'material' to them personally.

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I have heard surgeons quibble with that on the basis that too many patients will be put off from going ahead with surgery that might benefit them. It is fair to say that if a surgeon does the consenting process properly, some patients will certainly be put off from the procedure entirely, or will elect to defer it for a long time. The surgeon might not agree with or understand the patient's rationale – they may even find the patient's decision irrational - but that is the upshot of Montgomery. The 'paternalistic' model no longer holds good and the patient must be given all the necessary information about the risks they will be running, so that they can make their own subjective decision about what risks are acceptable to them.

Surgeons must also document the advice and information they provided. This is partly to help ensure that a surgeon has a record to use in follow up or future treatment. It is also necessary in order to be able to defend the surgeon in the event of a complaint or claim.

Are patient information leaflets helpful?

Depending on the type of procedure, and particularly whether it is an elective procedure, it may be appropriate to provide the patient with information leaflets about the proposed procedure.

Good information sheets help the surgeon to present generic information about the procedure to the patient in a clear way. They are an important support and complement to the advice the surgeon gives the patient in consultation, especially as written information can allow space for the patient to reflect, often after the consultation, in a way that the face-to-face consultation may not.

By the time a claim is made, it can be difficult to prove whether an information sheet was provided to the patient at all, and if so which information sheet was provided. Therefore it is vital to find a robust way to record which information sheet each individual patient received.

Also, almost needless to say, information leaflets are only as helpful as the information they contain. If a leaflet contains incomplete or outdated information then it could arguably do more harm than good. If a surgeon decides to use information leaflets as part of the standard consenting process, then the surgeon must accept that this will entail investing time every so often in reviewing and updating those documents.

I know of some surgeons who have ceased using physical leaflets and instead direct their patients to their websites, which contain regularly updated information about the procedures they offer. The benefit of using a website rather than physical leaflets is that the cost of printing physical leaflets is saved. Also, a website can be quickly and regularly updated for all the patients (indeed often the whole world) to see. The potential downsides are that even today not all patients can get online or are comfortable doing so. Also, it can be somewhat more difficult to ensure that the patient has actually gone to the website and read the right parts of it. In some cases the surgeon might need to print off the relevant pages for a patient who would not otherwise be willing or able to access them.

Final consent to go ahead

In this stage, the patient, having been provided with all the necessary information, records his or her final consent to go ahead with the procedure, usually by signing a form to that effect. Such a form is often referred to as 'the consent form'. Such terminology is unhelpful because it suggests that consent is an event that simply involves the signature of a form, when in reality obtaining consent is a process culminating in the signature of a form.

Templates and documents for the consultation stage

Often, a very convenient method for structuring a patient consultation and obtaining final consent is to use standard written documents. While a 'checklist mentality' is not necessarily helpful, well-designed forms can be a helpful aide memoire for a busy surgeon to help ensure that all the necessary material is covered with every patient, to give the best possible chance that the surgeon does give advice about everything that is 'material' to that patient.

The guides in the two appendices to this note are certainly not a prescriptive statement of what that documentation should contain. Instead it is intended as guidance and 'food for thought' to help you review your current documentation and assess whether improvements can be made to help protect you from complaints and claims.

In addition to thinking about the content of your template documents for use in the consultation process, you should also think about the layout and format. Even a form with a perfectly optimised set of questions could be rendered useless if there is so little space left for the answers that incomplete information is actually obtained or recorded.

Other steps in optimising your template or standard forms

We hope that this note contains helpful guidance about designing or optimising your template forms or documents for use in the process of taking a patient's medical and social history.

If you would like any general comments or feedback on your existing templates or documents, or to discuss the issues raised in this note, then please don't hesitate to call the medico-legal helpline on 0333 010 2826. Our general medico-legal guidance and feedback is of course free, as part of your Incision medico-legal service.

However, if after receiving general medico-legal comments and feedback you would like additional assistance in updating your documents, you have various options. We understand that various companies offer consenting 'systems' that aim to ensure that healthcare professionals use compliant consenting documents and processes. By way of an example only (we do not endorse this or any other provider), here is the website of one such provider https://www.eidohealthcare.com/.

Alternatively, if you would like more detailed and specific legal advice and recommendations on what changes you need to make to your own documents in the context of your particular practice, or would like specialist lawyers to revise your documents for you, then DWF LLP will be delighted to provide those services, at an additional fee that will be discussed and agreed with you in advance.

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