



CONSENT AND PITFALLS

NICHOLAS BALDOCK

6 PUMP COURT, TEMPLE, LONDON EC4

Introduction and Overview

- 1 It is to be hoped that it is not in dispute that, with obvious exceptions such as emergencies, before any patient undergoes a surgical procedure informed consent should be obtained.

- 2 The aim of this paper / my lecture, is to give a practical guide as to the relevant issues and how they might be addressed. In so doing the following should be remembered:
 - 2.1 Nothing can stop a patient raising a complaint, for example to the relevant professional regulator (such as the General Medical Council) or through solicitors.

 - 2.2 Steps *can* be taken to make sure that a regulator disposes of the complaint

summarily or solicitors advise that any claim has minimal prospects of success thereby greatly shortening the process, reducing the cost and relieving the strain.

Brief Legal History

- 3 What follows is a very short resume of the recent history of the law relating to consent. With an understanding as to how the law relating to consent has developed, the current position can be better understood. Thus:
 - 3.1 For some time the same test was applied to the question of the adequacy of consent as was applied to negligent treatment; the so called *Bolitho* test¹. The test in short was such that, if a reasonable body of medical opinion would support the action taken by the Defendant clinician, no claim would be made out. Hence, it was not enough for a Claimant to prove that other doctors would not have acted as the Defendant did. The Claimant had to prove that no reasonable body of doctors would have done so even if such body would be in a minority.
 - 3.2 The above approach in relation to treatment not only made good law but also amounted to common sense. Were it otherwise, different opinions as to treatment would be tested in court with the Judge as referee between, for example, invasive and conservative treatment.

¹ Bolitho -v- Hackney and City HA [1998] AC 232

- 3.3 However, as time and the law moved on, the *Bolitho* test was considered to be less suitable for the determination of claims relating to consent.
- 3.4 In *Sidaway -v- Bethlehem Royal Hospital*² the House of Lords were asked to consider the issue of consent in the context of a patient who underwent surgery which damages her spinal cord.
- 3.5 In *Sidaway* the majority of the House of Lords decided that the *Bolitho* test should remain, although with some exceptions; for example where there was a grave risk that should be warned against or where patients asked for specific information. The difficulties thrown up by those exceptions only served to give increased support to the minority view.
- 3.6 The minority view (tacitly, increasingly applied) was that, in accordance with such principles as those set out in the *European Convention on Human Rights* a patient had a right to self determination. Further, their might well be legitimate non medical factors which a patient might want to take into account; such as the quantity versus quality of life as a result of the procedure. Therefore, patients had a right to be warned of material risks unless to do so would do harm.
- 3.7 In fact, that minority view reflected the profession's own view as expressed, for example, in *Good Medical Practice*³

² [1985] AC 871

³ General Medical Council - 2013 version which repeated previous versions

“The duties of a doctor registered with the General Medical Council”:

“Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients’ right to reach decisions with you about their treatment and care.”

- 3.8 Eventually, tacit acceptance of the minority view in *Sidaway* became express approval by the Supreme Court in *Montgomery -v- Lanarkshire Health Board*⁴. The conclusion of the Court can be summarised in the following quotation:

The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in Sidaway by Lord Scarman, and by Lord Woolf MR in Pearce, subject to the refinement made by the High Court of Australia in Rogers v Whitaker, which we have discussed at paras 77-73. 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 doctor is therefore 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 alternative or variant 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 the doctor is or should reasonably be aware that the particular patient would be

⁴ [2015] UKSC 11

likely to attach significance to it.

3.9 The obvious exceptions remained:

The doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient's health. 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. It is unnecessary for the purposes of this case to consider in detail the scope of those exceptions.

- 4 Overall, the key to understanding the concept of patient consent is that it is based on the patient's right to determine, for themselves, the treatment that they are willing to undergo. That decision is one in which the medical professional can and should play a key role.

Problems Raised by Montgomery

- 5 The Supreme Court in *Montgomery* were not blind to the fact that the decision could raise problems for the profession and dealt with them expressly:

- 5.1 *Measurement of the risk*: whether the risk is material, and therefore should be the subject of consent, is a question of judgment rather than a set formula or percentage. That leads to room for dispute.

- 5.2 *Nature of the explanation*: the doctor's advisory role is one of dialogue. The Court stated that the aim was to ensure that the patient understands the seriousness of his or her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives. At the end of the process he or she is then in a position to make an informed decision. The information provided must be comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which he or she cannot reasonably be expected to understand. Nor is a simple signature on a consent form enough.
- 5.3 *The Doctor's own views*; Risk to the patient him / herself is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment: a doctor cannot use this exception to prevent the patient from making an informed choice where he or she is liable to make a choice which the doctor considers to be contrary to that patient's best interests.

The Pitfalls and How to Guard Against Them

Identify the Risks

- 6 It is a statement of the obvious that any medical practitioner must keep themselves up to date with current thinking as to the risks of any particular treatment and its alternatives. It is impossible to see how a doctor could give a patient sufficient information if the doctor himself / herself is not up to date

with them.

- 7 To use an analogy, if the Health and Safety Officer at a hospital has not kept up to date with the risks of allergic reaction posed by a brand of sanitiser, it is difficult to see how proper warnings could be given to users.

Assess the Risks

- 8 Having identified the risks, it is then important to assess them. That is a different process to simple identification.
- 9 Risk assessment is a process well known to those dealing with health and safety at work. A risk assessment of work at height will identify such dangers as falls from height and injury caused to those a ground level by falling materials. Risk assessments will consider both the likelihood of the risk arising *and* the severity of the outcome should it come about. The risk of a electrocution on a building site might be considered low but the severity of injury to be high were it to come about. The risks of mishap using a hammer in carpentry work might be assessed as being moderate, but the potential outcomes to be of low severity.

Match the Assessment to the Patient

- 10 So called *generic* risk assessments have a certain value; however, the risks have to be considered in relation to the particular patient to comply with

Montgomery. To take an obvious example, the risks of eye surgery to someone who has already lost the vision in one eye might be very different to the risks of the same procedure for someone with perfect binocular vision.

- 11 In *Montgomery* itself, the mother faced the recognised risks of dystocia associated with diabetes. However, those risks were magnified by the fact that the Claimant was of small stature and only just over 5 feet tall. That fact should have formed part of the risk assessment and explanation to the patient within the consent process.

Obtain Informed Consent

- 12 As set out above, there a number of factors which will determine the nature of the consent process. Those lead to the following wish list from a lawyer's perspective which, it is accepted, a clinician might deem to be an ideal world:
 - 12.1 Identification of material risks.
 - 12.2 Notification in a form which the patient can understand. That might involve such factors as the patient's age, command of English and level of intelligence. Social factors might have to be taken into account such as whether a partner is present who may be exerting an influence one way or another. Those risks might be enhanced, for example, in the field of cosmetic surgery.
 - 12.3 Taking care not to overburden a patient with worry whilst still covering all the

necessities. That might dictate the *way* in which any particular risk is explained, such as the warning in relation to general anaesthetics. Most patients would expect the warning about general anaesthetic to be given and discounted it. Others may come to it for the first time.

12.4 Taking enough time to ensure proper consent.

13 At the end of the process stop and think; would the consent that has been obtained be sufficient were the patient to be someone close to you and with the same characteristics as the patient?

Record the Consent

14 When faced with a complaint or potential claim arising out a consent issue, there will be two important issues for those advising you:

14.1 Whether a sufficient consent was obtained.

14.2 Whether it can be proved that a sufficient consent was obtained.

15 Whilst the above might seem to be evidence of a somewhat cynical view, it is borne out of experience from litigation across a wide range of fields. For example:

16 A driver who is speeding and fails to look at a junction will be at fault for any

ensuing crash. However, by the time the insurance form is filled in that driver may have persuaded themselves that they were within the speed limit and that he or she looked because that's how they always drive. Evidence of sight lines, distances and skid marks might well prove otherwise in court.

- 17 The issue of consent will involve a patient looking back and, often in the light of a serious outcome, considering whether they were properly informed. The patient's view may well be honest but inaccurate. A recent and pertinent example is that of *Diamond -v- Royal Devon & Exeter NHS Foundation Trust*.⁵ The case related to mesh repair. The Claimant insisted that she had not been properly informed of the risks in relation to any later pregnancy. The Claimant went on to assert forcefully that, if properly advised, she would have elected for a suture repair. The Judge at first instance (and the Court of Appeal did not interfere) said as follows:

But recalling specific events or conversations is markedly different from attempting to reconstruct what her response would or might have been if given certain information. Expert witnesses, lawyers and others are trained not to use the benefit of hindsight to inform their opinion of what might or should have happened. It is, however, human nature for people to permit that which eventuated to influence their thinking on what they might have done if warned about a particular risk. To my mind, it would be quite impossible for the Claimant to divorce from her thinking, the fact that she was subsequently told by Mr Jones that it would be inadvisable for her to become pregnant because

⁵ [2019] EWCA Civ 585

of the mesh and that, in the event, she has not had another child. Unquestionably, in my view, this sad outcome colours and informs her view of what she would have done if she had been appropriately warned.

- 18 Whilst, therefore, there are obvious benefits of standard consent forms for any particular procedure, they will not be conclusive evidence that consent was properly obtained. If, therefore, a particular matter was stressed, or explained in further detail, record that on the form thereby making it personal to that patient. Taking such steps as recording the time when the consent process began and ended may have the dual effect of proving how long it took and also being a measure at the time as to whether it seems sufficient.

Conclusions

- 19 Whilst the issue of consent may seem daunting, in fact, simple common sense steps, checks and balances can reduce, if not eliminate the stress.

Nicholas Baldock

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Nicholas.Baldock@6pumpcourt.co.uk

6 Pump Court

Temple

London EC4Y 7AR