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The evolution of consent in clinical negligence

from 'Doctors know best' to 'Patient Autonomy'

Nearly all treatments carried out by healthcare professionals carry a risk and it is therefore helpful to understand what the legal position is where the treatment itself was carried out with skill and care, but the patient suffers harm from an inherent risk with such treatment. These types of claims, in respect of informed consent, are arguably one of the most complex given the difficult arguments that can arise from breach of duty and causation i.e. the patient claims that they would not have had the treatment had they known about all the risks (no matter how low that risk was) and would therefore not have suffered harm.

Case law throughout the years has evolved in respect of patient consent, with two seminal cases being influential in clinical negligence claims. This article will look at relevant case law, with particular focus on the 2015 Supreme Court Judgment in Montgomery v Lanarkshire Health Board[1] (**"Montgomery"**) and whether the standard of care test set out in Bolam v Friern Hospital Management Committee[2] (**"Bolam"**) still has relevance in light of Montgomery.

What is consent?

Consent is a fundamental legal and ethical principle. Shared decision making and consent are vital to good medical practice. For many years guidelines such as the National Institute for Health and Care Excellence (NICE) and General Medical Council (GMC) have helped support healthcare professionals in sharing the information their patients need to make decisions that are right for them.

Obtaining consent should involve a discussion between the healthcare professional and the patient as to the risks and benefits associated with each option available, so that the patient can weigh up the options and decide what they want to do – including the option to have no treatment at all. A discussion should, where appropriate, be supported by making available written materials, and should take place allowing sufficient time for the patient to reflect on the information given before being asked to give their consent.

If a healthcare professional fails adequately to obtain the patient's consent and the patient agrees to undergo a procedure that they would not have done had they been informed of all risks/alternative treatments - and suffers harm because of those risks - then the patient has cause to raise an action for damages against the healthcare professional.

Consent and Capacity

Patients must have the necessary capacity to give consent. In England and Wales, the Mental Capacity Act 2005 (**"MCA"**) is the basis to help determine whether a patient has such capacity and sets out a test which states that for a patient to be able to make a decision they must be able to:

1. Understand information relevant to the decision;
2. Retain that information;
3. Use or weigh it up as part of their decision; and
4. Communicate their decision effectively, by any means.

One of the main principles of the MCA is that a person must be assumed to have capacity unless it is established that they lack capacity. Similar statutes exist in Scotland (Adults with Incapacity Act (2000)) and Northern Ireland (Mental Capacity Act (Northern Ireland) (2016)) although the latter is only partially commenced.

1. [2015] UKSC 11, [2015] All ER (D) 113 (Mar)
2. [1957] 2 All ER 118

‘Doctors know best’

In the 1957 Judgment of McNair J, the well-known ‘Bolam test’ set out the framework for the assessing of the standard of care for a healthcare professional.

Bolam concerned a patient who sustained serious fractures during electro-convulsive therapy (ECT). Mr Bolam brought a claim alleging that his doctor had been negligent because:

1. He had not been administered with muscle relaxant prior to the procedure;
2. He had not been restrained during the procedure; and
3. He had not been warned of the risks involved.

In defence of the claim, it was argued that it wasn’t routine to give patients muscle relaxants during ECT, there were concerns among many doctors that restraining patients might increase risk of fracture and it was not common practice to warn patients about relatively small risks surrounding ECT unless they asked the specific question.

In his summing up to the jury, McNair J. stated that the jury had to decide “whether it has been proved to your satisfaction that when the defendants adopted the practice they did…they were falling below a proper standard of competent professional opinion on this question of whether or not it is right to warn”. McNair J. also highlighted that Mr Bolam had not been asked as to whether he would have undertaken ECT had he been warned of the risk of fractures and commented that, *“you might well take the view that unless the plaintiff has satisfied you that he would not have taken the treatment if he had been warned, there is really nothing in this point”.*

The jury, perhaps somewhat unsurprisingly based on McNair J.’s comments, found in favour of the defendant. McNair J.’s judgment then set out the test for breach of duty in which he stated:

> *he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a reasonable body of medical men skilled in that particular art. Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view.*

To put it simply, McNair J. considered that a patient was only required to know what a healthcare professional thought they should know and did not need to be informed of all the risks and options surrounding their treatment – effectively a ‘doctor knows best’ scenario.

In the case of Sidaway v Board of Governors of the Bethlem Royal Hospital[3] (**“Sidaway”**), the House of Lords applied the Bolam test but also determined that it applied to issues surrounding consent in that they considered the decision as to what a patient should be told about was a matter of clinical judgment. Such clinical judgment was to be decided based on evidence from other healthcare professionals in the same field i.e., a responsible body of professionals as set out in Bolam.

In the case of Bolitho v City and Hackney Health Authority[4] (**“Bolitho”**), the House of Lords helped to clarify what was meant by ‘a responsible body’ by establishing that it was one that had a ‘logical basis’. Bolitho was a tragic case relating to a two-year-old boy who collapsed, went into cardiac arrest, suffered severe brain damage, and subsequently died following a failure by a senior paediatric registrar to attend to him despite being asked multiple times by a senior nurse to do so.

The evidence given concluded that the patient would have survived had he been intubated however the registrar gave evidence that she would not have intubated him even if she had attended him. Eight expert witnesses were called, five of which stated that any competent doctor would have intubated the patient and three of which stated that intubation was not appropriate.

The Judge in Bolitho determined that the registrar had not been guilty of negligence since a responsible body of medical opinion i.e., three experts, would also not have intubated him. Put simply, just because five doctors believed something to be reasonable, it did not mean that the judge had to agree with them.

3. [1985] 1 All ER 643
4. [1997] 4 All ER 771

Acknowledgement of Patient Autonomy

It wasn't until 2004 that there began a shift away from judgments favouring doctors and a move towards patients. In the case of Chester v Afshar[5] (**"Chester"**), the House of Lords took the majority view that the claimant should have been warned about an extremely low (1%) risk that lower back surgery could lead to compression of the nerves in her lower back. Whilst the claimant was unable to prove that, had she been told of the risk, she would not have undergone the operations (essentially satisfying the 'but for' test), she argued that had she been warned she would have had the opportunity to seek another opinion and consider matters further. Despite the claimant admitting that she would have likely undergone the surgery at a later date in any event, the House of Lords held that the principles of causation should be modified on the basis that the breach of duty, in failing to inform the claimant of the risk, had impaired her decision to consent. In the Judgment, Lord Hope stated:

> *...the function of the law is to protect the patient's right to choose. If it is to fulfil that function it must ensure that the duty to inform is respected by the doctor.*

In the more recent and widely publicised case of Montgomery, the claimant was regarded as a high-risk pregnancy as she was diabetic and of small stature. Diabetes in pregnancy results in over-production of insulin in the baby causing broad shoulders making shoulder dystocia more likely. During a natural birth, the claimant's son experienced complications due to shoulder dystocia resulting in cerebral palsy. The claimant's obstetrician had not disclosed the increased risk of this complication during a natural birth to the claimant.

The claimant sued for negligence and alleged that had she known of the increased risk, she would have requested a caesarean section. The claimant's case succeeded and, following two failed appeals by the defendant, the Supreme Court established that, rather than being a matter for clinical judgment to be assessed by professional medical opinion, a patient should be told whatever they want to know, not what the doctor thinks they should be told. Lady Hale in the ruling stated:

> *...it is not possible to consider a particular medical procedure in isolation from its alternatives. Most decisions about medical care are not simple yes/no answers. There are choices to be made, arguments for and against each of the options to be considered, and sufficient information must be given so that this can be done.*

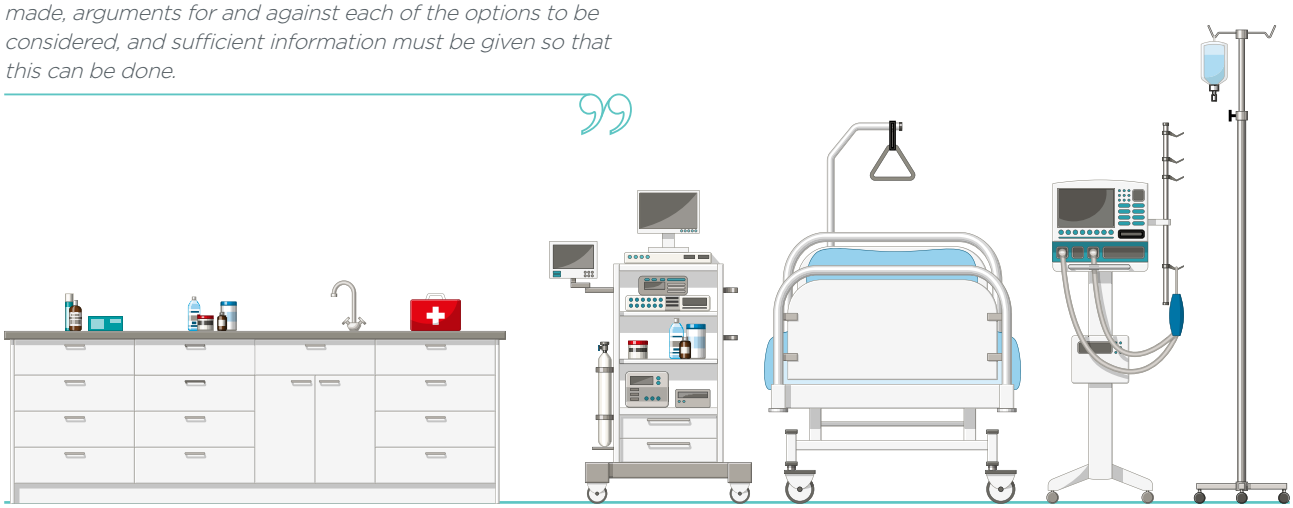
The judgment therefore means that healthcare professionals must share all such material risks, as well as any to which it would be reasonable for them to think the individual patient would attach significance. The Judgment in Montgomery set out helpful guidance as to what a patient may consider to be material risk:

> *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 case of Montgomery made it very clear that consent is principally an issue of patient's rights and doctors are under a clear obligation to not only discuss risks and alternative treatments but ensure that they understand the patient's concerns – a departure from the approach in Bolam in which the information to be provided by doctors about alternative treatments was judged by reference to the practice accepted as proper by a responsible body of medical professionals in the relevant field.

However, some would argue that Montgomery wasn't 'ground-breaking' in its assessment of consent, more-so catching up with the views and guidance that has been set out for years by the GMC and NICE guidelines. By 2008, the GMC's guidance with regards consent was extensive with the following sentence being particularly significant:

"You should do your best to understand the patients' views and preferences about any proposed investigation or treatment, and the adverse outcomes they are most concerned about. You must not make assumptions about a patient's understanding of risk or the importance they attach to different outcomes. You should discuss these issues with your patient."professional in question. Subsequently, whether those risks should have been conveyed to the patient by reference to whether they were material is a question for the court to decide.



5. [2004] UKHL 41, [2004] 4 All ER 587

Recent case law

The case of Duce v Worcestershire Acute Hospitals NHS Trust[6] (**"Duce"**) softened the approach set out in Chester, in that the Court held it was necessary for the claimant to plead and prove that if informed of the risk, they would have postponed the operation to another date or not had it at all.

The claimant had suffered from painful and heavy periods which resulted in lower back pain. She sought medical advice in relation to possible total abdominal hysterectomy. The clinical notes in respect of the claimant's treatment detailed this was a "major operation with associated risks." The claimant was also advised to try less invasive methods.

Whilst there was found to be no negligence in the surgery conducted, the claimant developed Chronic Post-Surgical Pain as a result of nerve damage. The question before the court was whether she was properly consented for the risk of post-operative pain.

The claimant's clinic notes recorded that "risks" were explained and the registrar had warned of post-operative pain but the claimant had not been warned about chronic or neuropathic pain following surgery. RCOG guidance did not detail the risk of chronic, long term or neuropathic pain and experts agreed that it was not common knowledge amongst gynaecologists at the time. On this basis, on applying the Bolam test, it was held there was no duty to warn of the risk of chronic or neuropathic pain.

The claimant appealed and argued that Bolam had been applied incorrectly and the correct test should have been materiality as set out in Montgomery.

It was held on appeal that the application of the Montgomery test is two stage. Hamblem LJ set out the test as:

1. "What risks associated with an operation were or should have been known to the medical professional in question. This is a matter falling within the expertise of the medical professionals; and
2. Whether the patient should have been told about such risks by reference to whether they were material. This is a matter for the Court to determine. The issue is not therefore the subject of the Bolam test and not something that can be determined by reference to expert evidence alone ".

The first limb of the test set out in Duce is clearly a homage to the Bolam test and medical experts in clinical negligence claims should still be instructed to deal with the risks that that should or ought to have been known by the healthcare professional in question. Subsequently, whether those risks should have been conveyed to the patient by reference to whether they were material is a question for the court to decide.

Comment

In terms of whether Bolam has been eclipsed in light of Montgomery, it is clear that the answer is no. The two cases remain influential in clinical negligence claims for distinct reasons with Bolam remaining at the forefront of what healthcare professionals should know with regards risks and Montgomery determining whether a patient should be fully consented to those risks.

Whilst views in cases such as Bolam and Bolitho in respect of 'doctors know best' have disappeared with regards consent and shifted towards a more rights-based patient approach, Montgomery doesn't alter the position in clinical negligence cases where a healthcare professional does something wrong or something that they should not do when treating a patient. Most negligence cases will still centre on the issue of the quality of care provided to patients including diagnosis, treatments and follow up and the standard of care will be assessed by the Bolam test.

A total move away from Bolam would likely lead to an inability for healthcare professionals to be able to treat patients in what they deem to be the best for the patient in fear of litigation should the treatment not be successful. Montgomery simply signalled the end of applying Bolam in informed consent cases. It has not considerably changed the law surrounding consent, simply brought it in line with practices adopted by healthcare professionals for years in recognising that respect must be given to patients making decisions about their own bodies.

Healthcare professionals should continue to ensure that they provide clear and concise information as to risks and ensure that patients are able to sufficiently understand the same, however technical they may be, whilst keeping in mind the principles set out in both Bolam and Montgomery.

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6. [2018] EWCA Civ 1307, [2018] All ER (D) 48 (Jun)

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