Evolution of the objective-subjective test for material risk in consent

Simon Britten

The Supreme Court's unanimous judgment in *Montgomery* recognised the importance of respect for patient autonomy and consigned to history the *Bolam* test when assessing standards of risk disclosure[1]. The judgment emphasised the importance of time and dialogue between patient and doctor in the consent process to discuss all material risks, and provided some clarity to the objective-subjective test for materiality of risk.

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The case has been prominent in the medical press and journals, commentators noting that *Montgomery* has aligned the legal and ethical standards in risk disclosure. This article considers the development of the concept of the objective-subjective test for material risk from *Bolam* to the present day.

In cases of risk disclosure, surgeons will be judged by the court on the basis of whether they identified and communicated the material risks of a procedure, rather than behaving as a reasonable group of their peers would have done by application of the *Bolam* test.

Recent case law discussed by Mike Foy in this journal[2] demonstrates how themes of autonomy, material risk, and dialogue are important in the consenting process as opposed to information transmission alone as was highlighted in *Montgomery*. Interpretation of the decisions and reasoning in this Judgement continue to evolve. In applying *Montgomery*, the courts are increasingly emphasising the need to provide an accurate risk-benefit profile in the consent process, and to allow adequate time and space for the necessary dialogue.

Surgeons are professional takers of risk and also bearers of responsibility. Lord Denning stated – "Every surgical operation is attended by risks. We cannot take the benefits without taking the risks."[3] An individual's autonomy includes their right to make choices and decisions for themselves, free from control or interference from others[4]. Taking or rejecting such choices in terms of medical treatment manifests itself in the weighing up of potential risks and benefits as noted by Lord Denning, and as a result giving or withholding consent to surgical or other treatment.

So what constitutes 'material risk'?

At the time of *Bolam* in 1957 the concept of risk disclosure was rudimentary at best. A psychiatric patient sustained acetabular fractures as a complication of ECT. They had not been warned prior to the procedure of the small risk of such a significant complication. With regard to risk disclosure, the expert instructed by the plaintiff (claimant) said – *"I think it is not right to give no warning of the risks to a patient who can understand the import of the warning."*[5] He qualified his evidence with the concern that at times warnings of the potential risks may not be of benefit to the patient.

The experts instructed by the defendants were clear – ordinarily they would not disclose risks of treatment which might deter a patient from accepting treatment from which they were likely to benefit. There was a caveat, that in circumstances where the patient enquired of any risks, then the treating doctors would provide a truthful explanation.

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By the early 1970s in the United States a prototype description of material risk was set out in *Canterbury v Spence*[6]. The court's view was that a risk should be disclosed "when a reasonable person, in what the physician knows, or should know to be the patient's position would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy."

In 1985 in the case of *Sidaway*, Lord Scarman set out the concept of 'material risk' which doctors must disclose and defined it as – "The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person would be likely to attach significance to the risk …"[7] Other judges in considering the case referred to the concept of "substantial" and "grave" risks, but at that time it was ambiguous as to who decided whether a particular risk was 'substantial' and 'grave' – the treating surgeon, expert medical evidence, the court or the patient.

At that time, Lord Scarman recognised the need for a duty of disclosure for the objective or reasonable patient, but he did not take into account the individualities of patients, only finally catered for by the endorsement of a subjective arm for the test of materiality in *Montgomery*[8].

By 1993, the emphasis in defining material risk shifted away from any quantitative considerations, towards purely qualitative considerations in the Australian case of *Rogers v Whitaker*[9]. A patient blind in one eye was not warned of the possible 1:14,000 risk of surgery on her bad eye causing sympathetic ophthalmitis, which in turn might cause blindness in her good eye, which unfortunately developed. In this case, material risk was defined as – "a reasonable person in the patient's position, if warned of the risk would be likely to attach significance to it." Even if a risk is extremely rare, it may be of sufficient severity – e.g. going blind – that a reasonable person would most certainly want to know this to assist them in deciding whether to opt for surgery or not. Numerical percentage point risks are of no relevance in defining material risk.

By 2003, in *Wyatt v Curtis*, increasing consideration was made of the specific patient's view of what constituted material risk – "… what is substantial and what is grave are questions on which the doctor's and patient's perception may differ, and in relation to which the doctor must therefore have regard to what may be the patient's perception …"[10]

In *Chester* in 2004 Lord Steyn stated – "…In modern law medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small, but well established, risk of serious injury as a result of surgery"[11]. Lord Steyn left it open as to whether appreciation of seriousness of risk was from the point of view of the doctor or patient, although given his 'end to medical paternalism' approach, it can be presumed that he felt it was the patient's perception that was important.

By the time of *Montgomery* in 2015, the Supreme Court noted that the most recent GMC guidance had treated *Chester* as the standard in risk disclosure[12]. Lord Kerr and Lord Reed set out the two-armed test for materiality in risk disclosure as follows – "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."[13]

The test is not 'what the patient thinks is important plus what the doctor thinks is important to the patient'. It is more subtle than that. The test combines a general objective arm – what the reasonable patient in that position would need to know, with a subjective arm tailored to the individual – what risks in the doctor's view the *particular* patient would consider important.

It can be argued that the second arm of the test is doubly subjective, given that it relies on what the treating doctor thinks (subjective) the particular patient (subjective) would wish to know.

Material risk is not simply an objective matter of a percentage risk or severity of a given potential complication which would concern the reasonable patient, it is also a subjective test which at its simplest is anything which the particular patient thinks is important. This subjective component of the test of materiality will vary from individual to individual and the doctor is obliged through discourse with the patient to ascertain their concerns.

The subjective arm was considered by Badenoch (Mrs Montgomery's counsel) as the need to personalise the dialogue with the particular patient during the consent process to include consideration of factors such as "age, intellectual ability, nature and demands of employment, family and other responsibilities, social and other problems, prospects if untreated."[14] I suggest adding the individual patient's personal views, hopes and fears, eccentricities and religious views.

The need to satisfy the subjective arm of the test is the reason why providing a Patient Information Leaflet [PIL] alone will never be sufficient to ensure adequate consent. A standardised leaflet cannot make provision for the concerns of the particular patient.

Recent work by Seewoonarain, reviewing the readability of PILs from leading UK orthopaedic institutions, concluded that orthopaedic-related PILs do not comply with recommended

reading ages, with some requiring graduate-level reading ability.[15] On this basis, PILs do not appear to satisfy the objective arm of the test either, as in many instances the reasonable patient will be unable to comprehend the literature provided.

The subjective arm of the test can be seen to be very pro-patient rights, well-illustrated in *FM v Ipswich Hospital NHS Trust*, like *Montgomery* a shoulder dystocia case, in which the judge noted that while the disclosure of risk may not have altered the final decision made by the majority of patients, it would have affected what the *specific* mother would have done.[16]

Wheeler has expressed several practical concerns in risk disclosure. A difficulty for clinicians to know when to draw the line, identifying the point at which the foreseeability of risks becomes too theoretical while navigating the "branches and twigs of complications that arborise from only one of several alternatives".[17]

Wheeler also touched on the subject of emergency surgery, with the scenario of a patient in significant pain, fearful both of receiving a grave diagnosis and of impending surgery. He argued that in such a circumstance a full and detailed discussion may be impractical and unreasonable and may have to be slimmed down to a simple nugget which the patient is able to comprehend. With regard to deciding what to say to the patient he notes – "Plainly this is an exercise in clinical judgement, no different from choosing the relevant investigations and antibiotics that the patient requires." Are risk disclosure, diagnosis and treatment all part of exercising clinical judgement? Bring back Bolam! Perhaps the surgeon should decide what to tell the patient after all?

In *Jones v Royal Devon and Exeter NHS Foundation Trust* it was argued successfully that when applying the subjective arm of the test for materiality, the identity of the operating surgeon was of importance to the patient – the experienced consultant rather than the less experienced fellow. This despite the fact that six days prior to surgery she had signed a consent form which stated "I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience".

When a recognised complication arose, the court found that while surgery had not been performed negligently, on balance the claimant had been led to understand that her operation would be performed by the more experienced surgeon. Expert evidence given was that the seniority and experience of the operating surgeon had an effect on the likely rate of complications. The judge concluded that the claimant's "right to make an informed choice as to who would operate on her" had been infringed, thereby denying her autonomy and dignity. On the basis of *Montgomery*, being informed of the change in surgeon virtually as she was being wheeled to theatre did not give her time to consider whether to proceed or not.

If the floodgates open on a proliferation of cases in which surgery is performed in non-negligent fashion, a non-negligent complication arises, and yet the patient successfully sues in negligence on the basis that they would not have had surgery had the consent process been adequate, it remains to be seen whether the NHS will be able to afford the spiralling negligence bills.[18]

The evolution of the objective-subjective test for materiality in consent has been described. While carefully written PILs may satisfy the objective arm of the test – what the reasonable patient needs to know – careful dialogue with the particular patient during the consent process is necessary to try to identify any subjective concerns specific to the individual. Consultant orthopaedic surgeons will still have a role to play giving expert medical evidence in clinical negligence cases involving consent, but it will not be to give their opinion on whether the standard of risk disclosure was reasonable or not. Rather it will be to advise the court on the potential benefits and known risks of the specific procedure under consideration, and any alternative treatments of which the court should be aware. It will then be for the court to determine which of the known risks pass the test of materiality, and to determine whether all material risks and alternative treatments were satisfactorily disclosed. ■

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References

References can be found online at *www.boa.ac.uk/publications/JTO* or by scanning the QR Code.

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