Ten years post-*Montgomery*: fewer uncertainties with time?

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Refuting the established principles guiding informed consent in *Sidaway*,[1] the decision in *Montgomery*, 10 years ago, swung the pendulum to the opposite side of the physician-patient relationship.[2] The 'doctor-centred' approach (what 'doctors think is reasonable') has now shifted to a 'patient-centred' model (what 'patients need to know'). The decision-making process has become a shared one between doctors and patients, where patients are now regarded as the 'chief managers' of their own lives and fates.

The key legal principles established in *Montgomery*[2] were as follows:

1. A doctor must ensure that the patient is aware of any material risks associated with a treatment, as well as any reasonable alternative treatments.
2. Materiality is defined as whether a reasonable person in the patient's position would be likely to attach significance to the risk or whether the doctor should reasonably be aware that the particular patient would be likely to do so.

Doctors may be particularly challenged by the *Montgomery* principles, which diminish their authoritative status and impose additional burdens,[3] uncertainties, legal risks, and the potential for an increase in claims,[4] given the heightened standards of informed consent. There is now greater uncertainty regarding the concept of the 'particular patient', concerns that doctors may be expected to second-guess individual patients' wishes, a perceived obligation to provide excessive information to patients who may not want it, and a loss of clinical discretion when treating vulnerable patients.[5]

Common law is ever-changing with time. The *Montgomery* principles did not emerge 'all of a sudden'. When considering the judgement, the Supreme Court analysed several medicolegal cases spanning centuries, both locally and internationally,[6-8] which unanimously disagreed with the *Sidaway* principles. Although the landmark *Montgomery* case 'rectified' the standard of care in informed consent, legal uncertainties remain in certain areas, such as 'materiality' and 'alternative'. Subsequent case law post-*Montgomery* has introduced further refinements in these areas and provides important referential value for clinical practice.

Materiality: what and how?

Determination of materiality is a matter for the court, not medical professionals. Thus, the first uncertainty is: what constitutes 'material'? In *Duce v Worcestershire Acute Hospitals NHS Trust*,[9] a woman developed chronic pain after a gynaecological operation and claimed that the surgeon had failed to consider whether the risk of chronic persistent pain was 'material'. At the time of the consent process in 2008, the Royal College of Obstetricians and Gynaecologists and the general consensus among gynaecologists did not regard chronic or neuropathic pain as a well-recognised complication. Both the Court of First Instance and the Court of Appeal dismissed the claim. The test of causation established in *Chester v Afshar*[10]—if an injury was closely linked to a failure to warn, then the duty was owed and causation established—could not be fully applied in this case. The plaintiff still had to demonstrate that the injury would not have occurred if the doctor had warned her of the risk. This case clarified that: (1) the doctor's duty to warn of certain treatment risks applies only to those risks clearly associated with the intended procedure at the time of treatment; (2) the plaintiff must prove that she would not have chosen to undergo the operation had she been warned of that particular risk; and (3) the duty to warn in consent cases serves to assist the plaintiff in assessing risk acceptability, rather than to protect the plaintiff from injury. Therefore, it is unnecessary to be concerned that doctors must exhaustively list all risks to avoid omitting those that may be deemed 'material'. The determination of which risks are known (or should have been known) to be associated with a particular treatment is a matter for doctors, not the courts.

The second question is: How 'material' is 'material'? In *A v East Kent Hospitals University NHS Foundation Trust*,[11] a woman conceived through in-vitro fertilisation, and genetic test results for fetal abnormalities were negative. The baby was subsequently born with disabilities. The plaintiff claimed that if she had been informed of the possibility of disability, she would have chosen to terminate the pregnancy. The court held that, because the risk of genetic abnormalities was as low

as 1 in 1500, it was 'theoretical' or 'negligible' rather than 'material'—a reasonable person in the plaintiff's position would not have attached significance to that risk level.

The next question follows: Was materiality primarily determined by the risk of occurrence? The answer is no, as illustrated in *Spencer v Hillingdon Hospital NHS Trust*.[12] The plaintiff underwent inguinal hernia repair but was not informed of the risk of deep vein thrombosis and pulmonary embolism. He subsequently developed acute pulmonary embolism. The defendant cited the risk of postoperative pulmonary embolism as 1 in 50 000. The surgical expert explained to the court that it was "impossible to either ask or give advice as to every possible complication that can occur… The list would be huge… [a] patient would not be able to take such a list in…" The court determined that the hospital was liable and suggested that disclosure would be favoured if: (1) the condition is potentially fatal; (2) the condition is treatable if diagnosed early; (3) the provision of information is straightforward; (4) relevant medical guidelines exist; and (5) a hospital policy for managing relevant conditions is in place.

What makes a discussion on alternative treatment options valid?

First, the risk and benefit profile of treatment options must be accurately presented. In *Thefaut v Johnston*,[13] the defendant surgeon recommended surgery, describing the likelihood of improvement in back pain and leg pain (eg, 'at least a 90% chance' of resolving the leg pain). The defendant also discussed the alternative of conservative management, during which the pain may improve without surgery within 12 months. The plaintiff chose surgery but subsequently developed debilitating postoperative neurological symptoms. Expert opinions indicated that the defendant had overstated the likelihood of recovery from back and leg pain while understating the risk that the pain might worsen after surgery. The judge concluded that, if the plaintiff had been properly advised, she would either have refused surgery or deferred it to seek a second opinion.

Second, doctors are required to discuss only those alternative options considered 'reasonable'. This principle originated in *Bayley v George Eliot Hospital*,[14] where the plaintiff argued that the defendant "failed to advise the plaintiff of all treatment options available to her deep vein thrombosis… including the risks and benefits of those treatment options… such advice should have included iliofemoral venous stenting to remove any occluded veins…" The court ruled that only reasonable alternative treatments needed to be disclosed—specifically, those that were known to clinicians, effective, and accepted practice at the time of discussion. A similar judgement was issued in *Malik v St George's University Hospitals NHS Foundation Trust*,[15] where the plaintiff experienced debilitating neurological damage after spinal orthopaedic surgery and alleged that the operating surgeon had failed to mention alternative options. The defendant explained that the proposed 'alternatives' (eg, oral analgesics and nerve root injection) were not viable. The judge in the Court of ppeal applied the *Bolam* principles to the discussion on 'reasonable alternatives'. Later, in *McCulloch v Forth Valley Health Board*,[16] the Supreme Court unanimously held that distinguishing between reasonable and unreasonable alternative treatments depends on professional skill and judgement (to which the *Bolam* principles apply, rather than the *Montgomery* principles).

Do we feel less uncertain now?

Stare decisis does not preclude ongoing reconsideration and optimisation, as evidenced by the case law non-exhaustively discussed above. The *Montgomery* case overturned the *Sidaway* decision after decades, and the *Montgomery* principles continue to be refined. The assessment of the materiality of risk is primarily fact-based. Literature and statistical probabilities are relevant but not the decisive factors. A risk with a low probability but serious consequences is likely important to most patients, particularly in cases of minor, elective, non-compelling, or purely cosmetic procedures. Conversely, a risk with a high probability but minor impact is unlikely to be important to most patients, especially when the treatment is urgent or strongly indicated. However, any risk, regardless of its likelihood, is likely important to patients whose life or quality of life would be adversely affected. The standard for the extent of disclosure is 'reasonable'. The amount of information to be provided should be context-specific and patient-specific, rather than exhaustive. A doctor is not expected to allocate excessive time to listing a long series of complications and alternatives, which may overwhelm the patient's analytical capacity and encroach on the doctor's working hours. Looking ahead, common law regarding informed consent will continue to evolve and address any remaining uncertainties.

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