Montgomery A Year Later: Informed Consent Revisited

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Complete List of Authors:	Tulloch, Ed; University of Edinburgh Chan, Sarah; University of Edinburgh, Usher Institute for Population Health Sciences and Informatics Smith, Andrew; Compass Chambers Wojcik, Wojtek; Royal Edinburgh Hospital Norman, Jane; University of Edinburgh, Department of Medicine
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The Montgomery *case in 2015 was seen as a landmark for informed consent. One year later, we ask: what have its effects been in practice?*

Introduction

The *Montgomery v Lanarkshire* case of March 2015[1] drew fresh attention to the issue of informed consent. The case concerned Nadine Montgomery, a diabetic woman of small stature. Her son was delivered vaginally and suffered complications as a result of shoulder dystocia, resulting in hypoxic insult with consequent cerebral palsy.. Her obstetrician had not disclosed the increased risk of this complication in vaginal delivery, despite Mrs Montgomery asking if the baby's size was a potential problem. Mrs Montgomery sued in negligence, arguing that, had she been informed of the increased risk, she would have requested a caesarean section. The Supreme Court announced judgment in her favour in March 2015.

The key issue in *Montgomery* was what doctors must disclose to their patients to satisfy the standards of informed consent. The ruling overturned a previous House of Lords decision which had been law since the 1980s.[2] *Montgomery* established that, rather than being a matter for clinical judgment, to be assessed by reference to professional medical opinion, what a patient should be told depends upon what the individual patient wishes to know and not what the doctor thinks they should be told.

Responding to the *Montgomery* decision, some argued (in particular the General Medical Council who intervened to make submissions in the case) that it had simply enabled UK law to catch up with current GMC guidance; others hailed it "the most important UK judgement on informed consent for 30 years."[3] Doctors expressed concerns over the potentially radical impact on patient care and clinical practice.[4] A public debate we held last year, involving doctors, lawyers and medical students, highlighted renewed tension between doctors' professional discretion and patient autonomy.[5] But what are the actual implications for doctors' practice and their legal liability? A year after the Supreme Court's decision, we examine the impact of *Montgomery* in practice.

Legal Consequences for Doctors

Some clinicians have sounded alarm bells for clinical practice and medico-legal liability, suggesting that the new standard "will burden most patients with 'information overload' for the sake of benefiting a minority"[4] and that the retrospective application of the judgment may "open the floodgates" for claims in relation to doctors' past actions[6].

Legal opinions have been more reserved, describing the ruling as "the belated obituary, not the death knell, of medical paternalism."[7] Some argue that the standard imposed by *Montgomery* merely reflects what is already seen as good practice in medical decision-making,[8] supported by current GMC guidance[9, 10]. While this suggests that *Montgomery* should not demand changes to practice, it may nevertheless have an impact on doctors' behaviour and on other potential cases.

The significance of *Montgomery* was to redefine the standard for informed consent and disclosure: previously, the *Bolam* test[11] (in England) and the *Hunter v Hanley* test[12] (in Scotland), which ask whether a doctor's conduct would be supported by a responsible body of clinicians, had been used to determine what should be disclosed. The application of *Bolam* to consent cases had been affirmed in *Sidaway v Bethlam Royal Hospital Governors and others*;[2] the ruling, however, was not unanimous, with the judges placing different weight on the patient's right to make informed treatment decisions versus the doctor's professional judgment in disclosing information. *Montgomery* soundly rejected the application of *Bolam* to consent, endorsing instead the minority opinion of Lord Scarman in *Sidaway* and establishing a duty of care to warn of material risks: "The test of materiality is whether… 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."[1]

It has been suggested that this formulation of this duty is "the nail in the coffin for Bolam" regarding consent cases.[13] The solicitor representing Mrs. Montgomery spoke of the decision as having "modernised the law on consent and introduced a patient-focused test to UK law… [T]he court has stated very firmly that medical paternalism no longer rules."[14]

Impact on Subsequent Cases

The question that many have been asking is this: does the decision in Montgomery work retrospectively, and if so might it trigger a flood of claims challenging past cases on the basis of consent? Some think *Montgomery* is unlikely to have this effect, however "excited the claimant law firms might become initially."[15]

Constitutionally, the Supreme Court cannot make new law; only Parliament can do so. All that the court can do is to state what, in theory, the law has always been. Doctors may have been treating patients as they understood the position in law to be, as per *Sidaway*; the Supreme Court, though, has told us not only that *Sidaway* was wrong, but anyone who practised according to its terms was also wrong.

It ought to be obvious, however, that in practical terms the retrospectivity of *Montgomery* is at least back to 1999, when Nadine Montgomery attended her obstetrician. Guidance in effect at that time from sources such as the GMC[16], BMA[17], NHS and the Scottish Office[18] supported the existence of a doctor's duty to disclose relevant information and risks. It can be said with some confidence therefore that the *Montgomery* principles have been known or ought to have been known to doctors for many years.

Since *Montgomery*, there have been several attempts to introduce a consent-based claim to cases which were underway prior to the decision. One in Scotland has so far been unsuccessful[19]. Two English cases were heard where consent cases were in fact allowed to be added to the claims after the *Montgomery* decision[20, 21]. Some cases have succeeded on a *Montgomery* basis[22]; others are understood to have settled before litigation ever commenced or was concluded, as the claims were unanswerable in the light of *Montgomery*.

Examining some of the cases in which *Montgomery* has been considered illustrates its interpretation to date. In *Spencer v Hillingdon NHS Trust* (April 2015)[22] the patient suffered from bilateral Pulmonary Emboli (PE) following a hernia operation; he had not been advised of the risk of Deep Vein Thrombosis or PE, or of symptoms that might indicate these complications, and hence did not seek treatment immediately. The judge considered *Montgomery*, framing the test as "Would the ordinary sensible patient be justifiably aggrieved not to have been given the information at the heart of this case when fully appraised of the significance of it?" On this basis, the failure to inform the patient of the symptoms of DVT and their significance was held to breach the duty of care, and the defendants were found liable.

Shaw v Kovac (October 2015)[23] concerned a patient who died in 2007 after a transaortic valve implantation (TAVI), a new procedure that was then still the subject of clinical trials and not fully approved. The claimant's argument sought to interpret *Montgomery* as establishing a right to informed choice about treatment that would ground a claim for "damages for the loss of life without having been given informed consent." The court rejected this, holding that *Montgomery* did not go so far as to create a right to informed consent as "a new and free-standing independent cause of action", but simply set a new legal standard for the duty to disclose.

In *Mrs A v East Kent Hospitals University NHS Foundation Trust* (April 2015),[24] the claimant's baby was conceived using intracytoplasmic sperm injection. The baby suffered from chromosomal abnormality and Mrs A alleged that the Trust was negligent in failing to advise of this possibility. The court, in finding for the defendants, applied the Montgomery test to decide that this risk was not material, since neither a reasonable patient, *nor the patient herself*, would have attached significance to it. This case demonstrated that a patient-focused test does not make doctors liable for every omission of disclosure to which a patient later objects; *Montgomery* "is not authority for the proposition that medical practitioners need to warn about risks which are theoretical and not material."[24]

These cases, illustrating how *Montgomery* has applied so far, may perhaps dispel some fears. The legal test for consent is now patient-focused, but this does not subject doctors to infinite liability for every possible non-disclosure; paternalism may no longer rule, but then it has not for quite some time.

Clinical concerns and ethical arguments: revisiting informed consent

At the public debate we held[5], three main issues were raised regarding the effect of *Montgomery* on clinical practice.

First, some feared *Montgomery* would compromise patient care by removing doctors' discretion over what to disclose. More stringent disclosure requirements could risk overwhelming patients with information, causing distress or leading them to make poor decisions; meanwhile doctors' time would be taken up with endless explanations, creating a drain on healthcare resources.

If doctor-patient communication is appropriately handled, however, these should not be causes for concern. Those who envision doctors spending hours reciting complicated, effectively meaningless statistics about risk to befuddled patients are being inappropriately pessimistic. It is difficult to see how good communication could lead to patients being harmed by an excess of information: patients have a right to know relevant facts before making a treatment decision, but the doctor's duty to inform does not mean swamping them with irrelevant information.

A potentially difficult situation arises where certain information may lead the patient to a decision that the doctor thinks is not in their best interests. This was, as it happens, the situation in *Montgomery*. The doctor may feel that disclosure in this circumstance will result in harm. Ethically and legally, however, the position is clear: doctors may not withhold information simply because they disagree with the decision the patient is likely to make if given that information.

As far as the issue of doctors' time, making sure patients understand all the information they need to make a decision may occasionally take longer. Allocation of health resources, however, ought to be addressed at system level rather than within individual doctor-patient interactions. This is achieved by setting healthcare policy, for example over what treatments should be available, or how consent procedures should be handled, as the GMC has done[16]. The doctor's duty is simply to treat patients according to their interests, which may include being given more information than usual.

A second concern was that *Montgomery* would encourage "defensive medicine", shifting the focus from helping the patient to protecting the doctor: consent might become a bureaucratic exercise of self-preservation, rather than a process of communication. Doctors, however, ought already to be following the GMC guidance on consent, which highlights the importance of communication; *Montgomery* simply affirms this[8].

Finally, the emphasis on autonomy was directly criticised as an ill-judged attempt to give patients more power. This polarised view of autonomy versus paternalism is, however, something of a false dichotomy: the idea of the fully autonomous patient making choices completely independent of the doctor's input does not reflect the complex reality of medical decision-making, any more than does the caricature of the high-handed, paternalistic doctor running rough-shod over patients' objections.

We know that patients are not always clear about the facts of treatment in consent-related discussions[25] and are influenced by the way in which information is presented (the 'framing effect')[26]. The difficulties of conveying information about treatment and risks should not, however, be taken to indicate that patients are incapable of understanding medical information, or that talk of autonomy in patient decision-making is therefore meaningless. Instead it shows that the communication process has a strong influence on how patients understand, remember and weigh information – all factors essential to informed consent. The doctor's role is to ensure relevant information is presented so as to enable the patient to use it meaningfully.

Conclusions

Montgomery was framed by some as a clash of values: patient autonomy versus medical paternalism. In reality, medical decision-making involves a nuanced negotiation of information and roles involving doctor and patient: neither autonomy nor paternalism rules supreme, nor should they. Today's patients can expect a more active and informed role in treatment decisions, with a corresponding shift in emphasis on various values, including autonomy, in medical ethics.

Undoubtedly, the full implications of the case are yet to be felt, but *Montgomery* has clear relevance for medical law and ethics. In the legal realm, consent law has been clarified and aligns with current GMC guidance; the Montgomery test has already been applied in a number of cases. In ethical terms, it makes explicit an already-occurring shift towards a more cooperative approach in the consultation room. *Montgomery* has not radically changed the process of consent as some suggested; it has simply given appropriate recognition to patients as decision-makers.

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Contributors and Sources

The authors were organisers (ET, WW, JN) and participants (SC, AS) of an event in the Edinburgh Medical Debates series on the ethical and legal impact of the *Montgomery* case ("Patient Consent: Do doctors really know best?" University of Edinburgh, 22 September 2015). ET is a medical student at the University of Edinburgh and was primarily responsible for research and drafting of the manuscript; SC is a researcher in bioethics and was responsible for critical revisions, ethical analysis and part of the legal research; WW and JN are clinicians and were responsible for conceiving the idea for the manuscript and critical revisions; AS is a barrister and QC in both Scotland and England, specialising in medical negligence, and was responsible for legal advice and analysis. All authors approved the submission of the manuscript.

Conflicts of Interest

We have read and understood the BMJ Group Policy on declaration of interests and declare the following interests:
AS represented the GMC in the Supreme Court during the *Montgomery* case. Other authors: no competing interests declared.

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