

TITLE: The Far-Reaching Implications of Montgomery for Risk Disclosure in Practice

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The Far-Reaching Implications of *Montgomery* for Risk Disclosure in Practice

The landmark decision of Montgomery set out a revised approach to risk disclosure which the courts have subsequently developed. The authors identify the legal trends and their implications for practice and the GMC's impending revision of its guidance on consent.

Abstract

The UK Supreme Court held in *Montgomery v Lanarkshire HB* (2015) that practitioners must take reasonable care to ensure patients are aware of any material risks involved in treatment. We reviewed all court decisions since *Montgomery* which deal with the case, to establish how this judgment is being interpreted by the courts and the implications of this for risk disclosure in practice. We found that *Montgomery's* application has been expanded in a number of ways: information about reasonable alternatives includes the provision of information about their risks and benefits; *Montgomery* applies to post- as well as pre-operative disclosure; and the timing of discussion with patients about risks is important. Conversely, there is evidence that the parameters of *Montgomery* are being curtailed, giving rise to questions about judicial commitment to patient autonomy. In some cases there is focus on the objective risks of procedures as opposed to patients' subjective concerns; in others, causation of injury is sometimes a factor that will defeat claims. There are also further questions about whether patients now should accept more responsibility for the outcome of decisions they make. We conclude that practitioners engaged in discussions about the risks of proposed treatments and their alternatives have been left in a position of uncertainty by the courts in relation to the obtaining of informed consent in practice. It is now critical that updated guidance is provided by the UK General Medical Council to give practitioners and service providers confidence that they are adhering to the law.

Keywords:

Informed consent; risk disclosure; professional guidance

Introduction

The landmark judgment of the UK Supreme Court in *Montgomery v Lanarkshire*¹ held that a doctor must take reasonable care to ensure that a patient is aware of any material risks involved in any recommended treatment, and any reasonable alternative or variant treatments. The test of materiality became 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”.² This test has been the subject of an evolving body of analysis,³ some from an international perspective,⁴ which considers its wider implications for the provision of modern healthcare.⁵ Broadly speaking the provisions of the case, which support patient autonomy, have been welcomed. This article, however, argues that despite the *apparent* clarity which the case brings to the question of risk disclosure, practitioners are left with insufficient certainty as to how they should help patients to realise their autonomy *in practice*.

This piece presents the findings of a project which considers the implications of *Montgomery* for practitioners and patients in the practical process of obtaining informed consent. To address this we analysed how *Montgomery* has been interpreted and applied by the courts in subsequent clinical negligence cases. Our findings demonstrate that, while the courts have provided some clarity on the application of *Montgomery*, there are a number of areas in which practitioners are left without firm guidance from either courts or regulators regarding the extent of their duty in practice. We therefore make a call for professional regulators to provide detailed, up to date guidance for the benefit of patients and practitioners.

Extending the Boundaries of *Montgomery*

The extent of *Montgomery*’s reach has been expanded in three distinct ways. First, while the principal focus of the judgment was on pre-operative risk disclosure, *Montgomery* has been interpreted to extend beyond a focus on the risks of the proposed form of treatment. To this end, greater emphasis has been placed on the need to discuss reasonable alternative treatments with patients. Similarly, in order to contextualise any associated risks, patients must also be informed of the *benefits* of a proposed course of action.⁶ This should not be confined solely to a particular treatment option favoured by the consultant, but ought to include information about the benefit versus risk ratio of the range of treatments that may be available. What is meant by ‘reasonable’ alternatives is far from clear though, and so far only sparse guidance has been provided by the courts.⁷ It would go beyond the concept of

reasonableness in negligence if the duty created an expectation that every conceivable alternative treatment must be discussed in detail with patients, so further elaboration is needed to ascertain how close 'reasonable' alternative treatments have to be to one another to require disclosure. If, as has been suggested,⁸ *Montgomery* places a duty on doctors to disclose the 'uncertainties' associated with a range of medical treatments, then the precise scope of the legal duty arguably remains poorly defined, leaving practitioners vulnerable to legal challenge depending on which approach they adopt.

It would seem that the *Montgomery* duty has also spread to *post*-operative disclosure. Recently, for example, liability was imposed where a patient developed bilateral pulmonary emboli after a double hernia repair.⁹ He was not provided with information about this risk and was therefore not alerted to its warning signs. Broadening the duty to situations such as this raises a number of questions. First, what causes a post-operative risk to be classified as significant and how, if at all, does a post-operative risk differ in nature to a pre-operative risk? Logic suggests that if a judge determined a risk to be significant post-operatively, then it should have been categorised as such pre-operatively for the purposes of obtaining informed consent. This was held not to be the case and so one is left wondering what it may take to transform the nature of any risk into being significant only after the operation. Such a requirement may place significant strain on the resources available for hospital discharge processes.

Finally, it is apparent that *Montgomery* has a variety of implications for the timing of discussions about treatment. It has been held that there can be a duty to inform the patient if there is a last-minute change of surgeon. The indication now is that if a patient initially consents to a medical procedure under the care of particular named consultant and that surgeon does not perform the operation due to a change in personnel, the patient must be informed of this switch in a timely manner. Failure to do so may result in the patient being able to recover damages should any subsequent harm occur.¹⁰ Such a change in personnel may have profound practical implications for whether the procedure can take place as planned. This is because the courts have also stressed that it is not appropriate for patients to have to make decisions immediately prior to surgery because '[t]here is no "adequate time and space" for a sensible dialogue to occur and for free choice to be exercised.'¹¹ This attitude reflects the idea that patients are now recognised as consumers, a central tenet of *Montgomery*,¹² but may mean that a delay is required to give such consumers the time and space needed to reflect on their choices. It has also been held that the post-operative information which may need to be given to patients should not be delayed without good

reason, and that it should be imparted as soon as the patient is well enough to participate in the discussion.¹³

These branches of *Montgomery* illustrate its capacity for expansion into unconsidered areas of discussion about risk with patients and highlight the need on the part of regulators for carefully considered updates to guidance provisions.

Clipping *Montgomery's* Wings

While the open-ended aspects of the judgment in *Montgomery* have allowed judges to adopt an expansive and claimant-friendly attitude to the ruling, there is evidence to suggest that the converse is also occurring. We have identified three examples of control mechanisms used by the courts that have potential to limit its significance.

The first key issue centres on how judges conceptualise risk. From whose perspective should the significance of risk be determined? *Montgomery* asserts that this should be assessed through the lens of patients, and thus demands a hybrid objective-subjective approach, focusing not only on what the *reasonable* patient may find significant in the circumstances, but also on what the *particular* patient may find significant. The inclusion of the subjective limb in the new disclosure test provides an added sting in the tail in its capacity to turn what most reasonable patients may class as an insignificant risk, into a subjectively defined material one. Despite this being capable of benefitting claimants, there are signs that some judges remain preoccupied with the objective element of the test. This can be seen in the reliance on medical evidence pertaining to percentage rates of occurrence that has been a feature of some of the post-*Montgomery* case law; undermining the ability of patients to bring their own experience, interests and preferences to the process of shared decision making. For example, in one case a risk of 1 in 1000 was held to be a theoretical and background risk and therefore not significant.¹⁴ Viewed objectively most would not disagree with that assessment, but this line of reasoning overlooked how this risk (of an unborn baby suffering from chromosomal abnormality causing severe disabilities) would have operated on the mind of that particular patient, both in terms of the severity of consequence should it have materialised and how she would have responded had she been informed of it. Excessive deference to statistics to resolve the issue of significance effectively permits the medical profession to dictate, or at least heavily influence, the legal standard of disclosure, which was the very position from which *Montgomery* intended to retreat.

A further limiting factor is the legal obstacle of causation, which asks, hypothetically: what would the patient have done had she been informed about the risk? If it is concluded, on

balance, that the patient would have proceeded with the operation anyway, her claim must fail. The courts have in the past been willing to relax causation principles in order to protect patients who can show that, had they been properly informed, they would have delayed the procedure even if they cannot prove they would have refused it altogether.¹⁵ Yet, post-*Montgomery*, the Court of Appeal has refused to extend this any further¹⁶, and a more conservative attitude prevails. This is particularly evident where the doctor has failed to inform the patient of a reasonable alternative: the patient bears the burden of proving they would have chosen the alternative and the court must be satisfied that the patient is not swayed by hindsight. In *Diamond*,¹⁷ for example, there was a breach of the duty to disclose information for a mesh repair. Whilst the claimant genuinely believed she would have chosen differently had she had the information, she failed to demonstrate that she would actually have done so. The lower courts in England and Wales do not yet appear to have followed their Australian counterparts by *fully* restraining the impact of the *Montgomery* standard of disclosure through causation.¹⁸ Indeed, some doubt that they ever will due to the Supreme Court's clear commitment to the principle of patient autonomy.¹⁹ This would be sensible, for caution is needed in using causation as a type of control device; it runs the risk of undermining all that *Montgomery* purports to bring in terms of a more sympathetic standard of disclosure. Yet, there is no doubt that since *Montgomery*, English courts have still become less generous to patients in the approach they have adopted to causation.

A final question is what responsibility, if any, should patients have regarding decisions they may make *against* medical advice? A key message from *Montgomery* is that it is no longer appropriate to view patients as 'passive recipients' of medical care, but to recognise that they should be actively involved in their healthcare choices.²⁰ To this end, it has been convincingly argued that patients also have obligations.²¹ As the body of post-*Montgomery* case law develops, it is possible that judges may remain more cognisant of this when assessing the question of fault. Where, for example, a patient is provided with detailed and relevant information and agrees to follow a designated care plan, what happens where the patient then ignores that care plan and agrees to undertake a risky operation earlier than advised? Where any scope for harm is exacerbated by the early performance of that medical procedure, then, irrespective of whether there has been a failure to disclose certain risks, it would not be wholly unreasonable for a judge to conclude that the patient contributed to her own harm and to adjust the level of damages accordingly. This point has recently been argued²² and while the patient was held not to be contributorily negligent in not following a plan for conservative management of degeneration of the spine, it is certainly possible that in

future assessing patients' conduct in the consent process could be a further way of mitigating against the harsher effects of *Montgomery*.

Implications for the Consent Process

The above developing legal trends give rise to a further practical dimension to consider: what will the effect of *Montgomery* be on the logistics of hospital consent processes and the resources needed to fulfil obligations? In particular, what role is the consent form going to play in the aftermath of *Montgomery*? A worrying consequence of the judgment could be that consent forms are now made more intricate and detailed, and that practitioners will spend more time listing every possible risk and alternative on the form in order to safeguard themselves against the threat of litigation. This poses the danger of detracting from consent being viewed as a shared-decision making process, in which the patient should be encouraged to participate. The net effect of *Montgomery* should not be to promote the rigorous filling in of a more elaborate consent form, but to encourage a dialogue between doctor and patient in order to help the latter develop a greater understanding of the nature of their illness and of the various options that are available to treat it. This may mean that consent procedures take more time than has historically been the case.

It is acknowledged that time is a precious commodity in the modern NHS. However, the implications of *Montgomery* and its subsequent interpretation are that it is expected that practitioners invest the time required, both to provide information about risks and benefits, and to obtain information from the patient which will enable them to do so in a meaningful way.²³ It is hoped that this will confer a number of benefits in the long run, not only as it may reduce the likelihood of doctors becoming the subject of a lawsuit, but also because it may facilitate improved communication between doctors and patients, encouraging levels of patient engagement which are recognised as contributing to their good health.²⁴ Any additional time and resource should not be channelled into ticking extra boxes and listing more risks, but to having an open and transparent discussion with the patient to ensure that they do not leave the consultation having grasped the wrong end of the stick.²⁵

Conclusions

We can reasonably expect the situations in which patient choice is protected to develop incrementally, but the courts are clear that failure to warn of risks does not give rise to a free-standing claim in damages.²⁶ We have outlined developing control mechanisms that limit any

potential rise in claims, but overzealous application would risk undermining advantages gained from the alignment of the law with principles of shared decision-making long espoused in practice. Yet the courts' application of *Montgomery* has served to ask as many questions as it has answered. This has profound implications for those practitioners engaged in discussions about the risks and benefits of proposed treatment, and may require significant changes to the processes and procedures currently in place to obtain and document patient consent. This is also of particular significance to the GMC, who will have to make sense of these complex issues when crafting the new version of their ethical guidance on consent.

Key messages

- 1: *Montgomery* establishes duties to disclose risks, benefits and reasonable alternatives but its subsequent interpretation by the courts leaves practitioners with uncertainty about how to fulfil these duties in practice.
- 2: The uncertainty surrounding what constitutes 'reasonable alternatives' and when post-operative risks should be disclosed pose challenges for clinical practice.
- 3: *Montgomery*'s pro-patient choice ethos might be restricted by the courts' reliance on statistical evidence and by the law of causation and contributory negligence.
- 4: *Montgomery*'s emphasis on the importance of dialogue and good record-keeping requires the adaptation of clinical practice, rather than wholesale change.

Declaration of Interests

The Authors declare that there is no conflict of interest.

¹ [2015] UKSC 11.

² *Montgomery*, at [87]–[88].

³ See Heywood R and Miola J, The changing face of pre-operative medical disclosure: Placing the patient at the heart of the matter. LQR 2017; 133: 296-321; Heywood R, R.I.P. *Sidaway*: Patient-oriented disclosure – A standard worth waiting for? Med L Rev 2015; 23: 455-466.

⁴ Smith MK and Carver T, *Montgomery*, informed consent and causation of harm: lessons from Australia or a uniquely English approach to patient autonomy? J Med Ethics Epub ahead of print 23 March 2018, doi:10.1136/medethics-2017-104273

⁵ See for example Herring J *et al.*, Elbow Room for Best Practice? *Montgomery*, Patients' Values, and Balanced Decision-Making in Person-Centred Clinical Care. Med L Rev 2017; 25; 582-603 and Chan S *et al.*, The law and informed consent: Where are we now? BMJ 2017; 357: j2224.

⁶ Herring et al, *ibid* at 20.

⁷ See *Holdsworth v Luton and Dunstable University Hospital NHS Foundation Trust* [2016] EWHC 3347 at [63].

⁸ See *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62 at [35].

⁹ See *Spencer v Hillingdon Hospital NHS Trust* [2015] EWHC 1058.

¹⁰ See *Jones v Royal Devon and Exeter NHS Foundation Trust*, Unreported, 22nd September 2015.

¹¹ *Thefaut v Johnston* [2017] EWHC 497 (QB) at [78]

¹² *Montgomery*, at [75].

¹³ *Gallardo v Imperial College Healthcare NHS Trust* [2017] EWHC 3147.

¹⁴ See *A v East Kent Hospitals University NHS Foundation Trust* [2015] EWHC 1038 at [84].

¹⁵ *Chester v Afshar* [2004] UKHL 41.

¹⁶ *Correia v University Hospital of North Staffordshire NHS Trust* [2017] EWCA Civ 356.

¹⁷ *Diamond v Royal Devon & Exeter NHS Foundation Trust* [2017] EWHC 1495 (QB).

¹⁸ See *Holdsworth*, above n 6 at [46] – [55]. See also *Jones*, above n 9 and Farrell AM and Brazier M, Not so new directions in the law of consent? Examining *Montgomery v Lanarkshire Health Board*. J Med Ethics 2016; 42: 85-88.

¹⁹ Smith MK and Carver T, *op cit* n.5

²⁰ *Montgomery*, at [75].

²¹ See Brazier M, Do no harm – Do patients have responsibilities too? CLJ 2006; 65: 397-422.

²² See *Crossman v St George's Healthcare NHS Trust* [2016] EWHC 2878.

²³ *Hassell v Haslingden Hospitals NHS Foundation Trust* [2018] EWHC 164.

²⁴ People and Communities Board, A new relationship with people and communities: Actions for delivering chapter 2 of the NHS Five year forward view. (February 2017)
https://www.nationalvoices.org.uk/sites/default/files/public/publications/a_new_relationship_with_people_and_communities_0.pdf

²⁵ See *Worrall v Antoniadou* [2016] EWCA Civ 1219 at [22].

²⁶ *Shaw v Kovac and University Hospitals of Leicester NHS Trust* [2017] EWCA Civ 1028.