Informed consent and Montgomery implications for clinical practice

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Abstract

Consent is central to the delivery of healthcare, and all healthcare professionals must obtain consent before proceeding with any interventions. The nature of informed consent allows the patient to fully participate in any proposed healthcare interventions. Informed consent requires high-quality information to be given that enables the patient to fully understand all the benefits as well as the risks associated with proposed interventions. This approach respects the right of the patient to self-determine what happens to their body provided they have the relevant capacity to understand the nature of the proposed intervention. Although consent may be seen as a procedural 'must', the importance of the dialogue that takes place between the patient and the clinician is what determines the validity of the consent as advocated by the Supreme Court ruling in Montgomery v Lanarkshire Health Board (Scotland) [2015]. It is noted that the number of legal cases related to consent has risen since the Montgomery decision.

Keywords Disclosure; informed consent; Montgomery ruling

Key points

- Obtaining informed consent is not just a process but a careful dialogue between patient and clinician; this requires documentation
- The clinician must consider whether a risk is material if a reasonable person in the patient's position would be likely to attach significance to it, and/or the patient in question would probably attach significance to it
- Patients must be made aware of reasonable alternative treatment options
- The clinician must make sure that the patient has understood the information provided
- The consent form in itself does not prove informed consent

Introduction

All healthcare professionals are familiar with the process of obtaining consent. It is an ethical, professional and legal obligation to obtain consent before proceeding with any clinical intervention. The legal obligations surrounding the nature of consent have been part of all healthcare curricula for decades, although it is worth noting and keeping up to date with recent judicial outcomes. The General Medical Council (GMC) has issued guidance on decision-making and consent (2020) (see Further reading) in line with the law and supports doctors to act within it. The seven principles advocated by the GMC provide an important approach that focuses on the right of a patient to be involved in the healthcare decision-making process.

Having said that, most healthcare professionals recognize that complex interventions can make the process of obtaining consent challenging given the vulnerability of the patient who may not be at their best or may not have the relevant medical knowledge to fully understand all the benefits or risks associated with a proposed clinical intervention. Nevertheless, there is an acceptance that supported decision-making reduces harm and waste. A focus on setting out treatment options in simplistic terms may minimize overtreatment as well as patients shouldering the responsibility of managing their own health that fits in with their own personal circumstances.

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The nature of informed consent

The right to self-determination is central to the notion of consent. To uphold this aspect, it is important to have a full understanding of what the law requires. In a nutshell, to satisfy the legal requirements, the patient must be of sound mind, must have been given all the materially relevant information, including risks, benefits, and alternatives, and must not have been coerced into making the decision. This simplistic formula, however, highlights the difficulties that clinicians can encounter. For example, how much information should the patient be given and are the clinicians content that the patient has fully grasped what is being proposed? What clinicians might consider to be appropriate may not be in line with what the law requires or with the patient's social circumstances. The doctrine of informed consent is a relatively new phenomenon because of legal changes.

A wealth of cases has dealt with consent, Bolam (1957), Sidaway (1985), Pearce (1999), Chester (2004) to name a few. The case of Montgomery v Lanarkshire Health Board (Scotland) (2015)[1] heralded an important change in the way the law deals with the materiality of information but, more importantly, has redefined the standard for informed consent and disclosure. The Supreme Court asserted here that it is for the individual patient to decide upon the materiality of a risk. The key issue for clinicians is to ask whether a reasonable person in the patient's position would attach significance to the risk associated with the intervention. In essence it is the meaning associated with the potential complication for the individual patient that is important.

It is therefore imperative to have meaningful and clear dialogues with the patient. It is not about giving out lots of information or covering every conceivable risk. There will be instances where clinicians may withhold information about a risk, for example where the disclosure might be detrimental to the patient. The Supreme Court, however, made it clear that the notion of therapeutic exception must be used sparingly. The

outcome of the Montgomery case has essentially introduced a patient-focused test in UK law. The next section looks at legal cases after Montgomery.

Post-Montgomery rulings

Webster v Burton Hospitals NHS Foundation Trust (2017)[2] was an obstetric case concerning the failure to notice antenatal abnormalities on ultrasonography. The first instance judge (before the Montgomery decision) applied Bolam and found against the claimant, in that it was reasonable to proceed with labour even after further abnormal scans. The claimant appealed. The Court of Appeal heard the case after the Montgomery ruling and overturned the judgment. The Court concluded that the increased risks of continuing labour in the presence of ultrasound abnormalities should have been discussed with the mother and the option of induction offered, which she would have accepted.

In Spencer v Hillingdon NHS Trust (April 2015)[3] the patient developed bilateral pulmonary emboli after a hernia operation. He did not seek treatment immediately because he had not been advised of the risk of deep vein thrombosis or pulmonary embolism, or of symptoms that might indicate these. The judge considered the Montgomery ruling and found that failure to inform the patient was a breach of the duty of care.

In Shaw v Kovac (October 2015)[4] a patient died after a transaortic valve implantation, which was at that time still the subject of clinical trials and not fully approved. The claimant's argument sought to use the Montgomery ruling to ground a claim for damages for the loss of life without informed consent. The court rejected this, holding that the Montgomery ruling did not create a right to informed consent as an 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) (see Further reading), the claimant's baby, who was conceived using intracytoplasmic sperm injection, had a chromosomal abnormality. The claimant alleged that the trust was negligent in failing to advise of this possibility. The court applied the Montgomery test and decided that the risk was not material, because neither a reasonable patient nor the patient herself would have attached significance to it. Thus, although the test is focused on patients, doctors are not liable for every omission of disclosure to which a patient later objects.

Crossman v St George's Healthcare NHS Trust (2016)[5] demonstrates how, after the Montgomery ruling, the court may apply the 'subjective' element of Montgomery to determine a case. In this instance it was concluded that the claimant did not find it easy to express himself and was intimidated, such that it was the hospital's responsibility to communicate with him rather than the other way around.

Mills v Oxford University Hospitals NHS Trust (2019) confirms the need to advise on the availability of alternative treatments. In addition, Malik v St George's University Hospital NHS Foundation Trust (2021) (see Further reading) emphasizes the need to document the consenting process and any information given to the patient at the time.

Comment on Montgomery

Montgomery is a landmark case in healthcare law that emphasizes the importance of the disclosure of materially relevant risks and benefits. It signals a move away from a paternalistic approach to focusing on the autonomy of the individual to make informed choices about their own body. The Montgomery principle applies to all claims involving treatment advice from healthcare professionals and not just the consenting process. ◆

KEY REFERENCES

1 Montgomery v Lanarkshire Health Board (2015) SC 11 (2015) 1 AC 1430.
2 Webster v Burton Hospitals NHS Foundation Trust (2017) EWCA Civ 62.
3 Spencer v Hillingdon Hospital NHS Trust [2015] EWHC 1058 (QB).
4 Shaw v Kovac [2015] EWHC 3335 (QB).
5 Crossman v St George's Healthcare NHS Trust [2016] EWHC 2878.

FURTHER READING

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TEST YOURSELF

To test your knowledge based on the article you have just read, please complete the questions below. The answers can be found at the end of the issue or online here.

Question 1

A 35-year-old woman, living in the UK, with painful and heavy periods for some time sought medical advice for her troublesome lower back pain. She was seen in the clinic in relation to possible total abdominal hysterectomy. She agreed and the medical notes stated that this was a major operation with associated risks in broad terms. Surgery was undertaken and post operatively she developed chronic surgical pain because of nerve damage.

What information post-Montgomery v Lanarkshire Health Board (2015) should have been provided for her consent to be valid?

A. Provide her with information related to the intervention including all post operative complications.
B. Provide her with information about risks of which the doctor is aware and that is also widely known by their peers.
C. Provide her with basic information in broad terms without outlining alternatives or potential risks.
D. Provide her with alternative to surgical intervention without explaining why.
E. Provide her with written information outlining all the risks and asking her to sign the consent form.

Question 2

A surgeon in the UK was considering the amount of information that she should share with a patient about risks before an operation.

What best describes the risks that the *Montgomery v Lanarkshire Health Board* case indicated should be shared?

A All risks should be shared
B All serious risks should be shared
C The doctor should exercise their own professional judgement
D All risks to which a reasonable patient would attach significance
E All material risks should be shared as well as any risks to which a reasonable person in the patient's position would attach significance

Question 3

The law focusses on 'material risks' as an important component of the consent process for surgical intervention in the UK.

What is the best description of 'material risk'?

A. To discuss all risks and benefits even if they are not relevant to the patient's case.
B. To discuss frequent risks of which the doctor and colleagues are aware
C. To discuss risks associated with the intervention as well as risks to which the patient attaches significance.
D. To discuss reasonable alternative treatment and its benefits.
E. To provide written information with all risks and benefits associated with the proposed intervention.