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Education

Getting informed on informed consent: a guide for medical students

EDUCATION

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ABSTRACT

Summary

This paper provides guidance on the law surrounding informed consent, pitched at a medical school level. It will differentiate basic consent from informed consent, examine the surrounding case law (in particular Montgomery v Lanarkshire Health Board [2015]), providing the facts of key cases and the significant consequences of the judgements in order to ground abstract legal principles in practical examples. It makes suggestions on how to tailor practice to ensure that an informed consent is obtained.

Relevance

It is apparent that an understanding of law surrounding clinical practice is highly applicable to medical students and is often a dedicated learning outcome on the syllabus. 'Consenting a patient' is a process that takes place many times every single day and is a prominent part of any doctor's career, from every time they take blood to perform major surgery. It is vital that students understand the laws surrounding this process and what is required of them both now and in the future.

Take Home Messages

The case of Montgomery legally enforces a process of enabling autonomous decision making by the patient rather than paternalistically determining the direction of management. Informed consent requires that material and relevant risks be disclosed to the patient for both the recommended and alternative treatment plans. To achieve this, and determine what is material for that patient, obtaining informed consent requires a dialogue between doctor and patient.

mended management plan and thus, the interventions required, as well as those of reasonable alternative courses of actions. Legally, the courts will ask two questions to determine if an 'informed consent' is reached. Firstly, given the circumstances of this patient, would a reasonable person in that position attach significance to the given risk? Secondly, should the doctor have reasonably been aware that the patient would attach significance to it? (8)

Other cases provide further guidelines to form a complete definition of informed consent.

In the case of A v East Kent Hospitals [2015], it was held that the chance of Mrs A's child being born with chromosomal abnormalities was 1 out of 1000, this was determined to be "theoretical, negligible, or background" and thus immaterial. It was also considered whether the claimant would have further investigated or terminated the pregnancy had the abnormality been found. (9) However, it is insufficient to rely purely on the numerical chances of something occurring.

Whether a risk is significant or not is determined by factors such as the severity of its consequence, the potential impact it would have on that patient, the nature of the harm, and the potential benefits. This was reflected in the case of Spencer v Hillingdon Hospital NHS Trust [2015] where following an operation on inguinal hernias, a patient developed bilateral pulmonary emboli. Although the risk of this was much smaller, 1 in 50 000, given the potential severity of the outcome it was a material risk. (10) The potential severity of a risk to that individual is also a key determinant in what is material. A 1 in 1000 risk of damage to the hand could be much more relevant to a patient who was a concert pianist than an average member of the public.

In cases where patients rely on incorrect knowledge, a doctor will be liable if they either hold responsibility for this misunderstanding, or, they should have realised the misunderstanding has occurred but took no steps to rectify it. (11) This was shown in the case of Worrall v Antoniadou [2016]. In this case, the claimant had breast augmentation surgery for her wedding. She was then advised a secondary procedure (a mastopexy) would be required within 10 months of the surgery. The claimant believed she would not require a procedure for 5 to 10 years, whereas the defendant had stated she would need another procedure 'sooner or later'. The case hinged therefore on whether the defendant was firstly responsible for the incorrect belief, and whether the defendant had taken sufficient steps to dispel the claimant's incorrect belief.

The rationale behind this can help to clarify what Montgomery is trying to achieve. Initially it involves recognising the importance of patient-centred care and treating each person as a distinct individual. Secondly, it recognises clinical decision making is not to be taking place behind closed doors. The General Medical Council wish for doctors and patients to engage in determining treatment options. The patient is the autonomous individual to decide which treatment path is best suited to their life, and what for them would be the optimal outcome. However, the patient is reliant on the doctor to shed light on those paths. Thus, there is a reciprocal relationship required. Since it is of no benefit to bombard a patient with every single possible risk and overload them, it is required for the doctor to exercise discretion as to which potential risks and benefits are most important for that patient's goals. The doctor is there to facilitate the patient's decision making. Only by providing that information is the patient able to make an educated decision on the path they wish to pursue, and thus, provide consent for what is going to happen to them. (12, 13)

Practicalities of Obtaining Informed Consent

The key takeaway from Montgomery is that to obtain informed consent, one must enter a 'dialogue' with the patient. It is helpful to set certain goals to have been reached by the end of this dialogue for both the patient and the doctor. The patient should understand the extent and severity of their condition. They should understand the expected benefits and inherent risks of the proposed method of management. They should be aware of other management options, how they differ and compare to the recommended one.

On the other hand, the doctor should feel the patient is sufficiently informed of the above to make a personalised decision. They should appreciate what the patient would consider a good outcome. They should understand what risks are important to that patient. They should have taken the opportunity to apply these factors to their recommended management plan. They should understand why a patient has come to a particular decision.

The content of this dialogue is not purely limited to medical factors. (14) It includes the particular values, needs, interests, and circumstances of that patient in a medical and social context. The doctor should understand how the patient hopes to see their quality of life being improved with a holistic approach rather than a simply biological one. This is because the concept of 'risk' is relative. An acceptable or unacceptable risk varies from person to person; and a doctor must not subjugate their perspective onto that of their patient.

The doctor should determine how much information a patient wishes to receive, and how they wish to receive it. (15) The information should then be conveyed in a manner which is appropriate for that patient. As expressed in Montgomery "routinely demanding [her] signature on a consent form" is insufficient. The adequacy of communication is more important than the method. This may take the form of leaflets, hand-drawn diagrams of physiology and interventions, or through signposting to useful educational resources. (16) Sufficient de-jargoning should have taken place. Given how little information may be retained in a singular consultation, it may be useful to write down the key concepts for the patient to come back to. The burden of explanation is explicitly placed on the medical professional to be forthcoming with the required information, rather than expecting the patient to ask the correct questions. (17) Patients should be encouraged and enabled to ask the doctor questions and clarify issues. An opportunity to do so should be provided at regular intervals. Comprehension should be ensured at the end of the consenting process; for example, this could be through asking the patient to explain back to you what you have told them. Finally, the patient should have been provided adequate time and space to process and determine their wishes before the procedure takes place. In practice, this suggests it would be bad practice to consent someone in the anaesthetics room before an operation since they could feel rushed or pressured to accept the proposed operation rather than consider the alternatives thoroughly. In line with the Royal College of Surgeons of England, better practice would involve consenting a patient in clinic. This allows time to discuss the surgery and the patient can reflect on the discussion. Confirming consent on the day of the procedure ensures that nothing has changed in that period. (18)

The importance of surgery consent can be illustrated by the case of Thefaut v Johnson [2017]. In this case, Mrs Thefaut underwent an elective discectomy, unfortunately resulting in nerve damage, pain, and a loss of function in her lower half. The consenting process for this case took place via a 5-minute telephone consultation, a follow-up letter, and a conversation immediately prior to the surgery. There were also concerns that the letter overestimated the benefits and underestimated the risks. It was held that this did not demonstrate the required 'time and space' for a reasonable dialogue to meet the Montgomery informed consent threshold. (19)

CONCLUSION

A real consent protects a medical professional from liability from battery. However, the standard of informed consent to avoid negligence is significantly higher. Informed consent requires doctors to make sure that patients are aware of material risks. It places an emphasis on the nature of that patient and what benefits and risks are of most significance to them. To obtain informed consent, one must enter into a dialogue with the patient. This is to facilitate a joint decision-making process which steps away from previous paternalistic approaches. The process of consenting a patient should be done in good time, in a manner which suits that patient, and enables a good working relationship where patients are empowered to ask questions and determine their own futures.

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