Contemporary interpretation of informed consent: autonomy and paternalism

The Supreme Court's decision in the Montgomery case has questioned what is meant by 'informed consent'. Clinicians must establish who is a reasonable patient and exactly what they want to know. Obtaining informed consent requires a relationship to be built between patient and clinician and must respect patient autonomy.

In light of the decision of the Supreme Court in Montgomery v Lanarkshire Health Board (2015) the degree of information that clinicians must provide to patients has moved from being measured by consensus of the medical profession to being what a reasonable person would want to know (Boyd, 2015). The judgment included the following:

> **'The doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and or any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should be reasonably aware that a particular patient would be likely to attach significance to it.' (Montgomery v Lanarkshire Health Board, 2015)**

Montgomery v Lanarkshire Health Board (2015) has already been cited in a successful lawsuit where the claimant argued negligence after he suffered a deep vein thrombosis following an inguinal hernia repair (Spencer v Hillingdon Hospital NHS Trust, 2015). The patient, Mr Spencer, was considered to be low risk for a deep vein thrombosis and so he had not been given specific instructions about the signs and symptoms of deep vein thrombosis. When he developed a deep vein thrombosis he did not present to hospital in a timely manner and hence suffered bilateral pulmonary emboli. The judge posed the question:

> **'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?' (Spencer v Hillingdon Hospital NHS Trust, 2015)**

The question this poses to the clinician is how is a reasonable patient defined and how does the clinician elucidate what the reasonable patient would want to know? In the Montgomery case, Dr McLellan's defence for not discussing shoulder dystocia before delivery was that if she had done so the patient would likely have opted for a caesarean section, which would not be in the best interest of the mother (Montgomery v Lanarkshire Health Board, 2015). The concept of not discussing the risks associated with vaginal birth in a diabetic patient because they would lead to a woman requesting a caesarean section could be said to be paternalistic. The concern for clinicians in the face of these cases is how to know exactly what a reasonable patient needs to know to provide informed consent and how does a clinician recognize such a patient?

Dr Louise Robertson is ST6 in Obstetrics and Gynaecology in the Department of Obstetrics and Gynaecology, Liverpool Women's NHS Foundation Trust, Liverpool L8 7SS (louiserobertson5@nhs.net)

A brief history of informed consent

Consent derives from the Latin *can sentire*, which translates to feel together (Maclean, 2013). The concept of seeking consent started in the wake of the Second World War when it came to light that medical experiments had been performed on prisoners by the Nazis against their captives' will. The Tuskegee syphilis studies, started in 1932, where patients were not fully informed about the nature of the trials nor offered the cure of penicillin when it was discovered (Centers for Disease Control and Prevention, 2016), added further concerns about consent. This led to the Nuremberg code that was produced in 1947. It states:

> **'The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision' (Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, 1949).**

Informed consent originated in America in the 1950s, requiring doctors to disclose risks and alternatives of treatment (Silverman, 1989), and has been in contention

ever since. In the UK the case of Bolam in the 1950s was the starting point for the history of informed consent (Bolam v Friern Hospital Management Committee, 1957). Mr Bolam suffered fractures after undergoing electroconvulsive therapy. He claimed this was negligence, as he had not been given relaxant drugs, had been inadequately restrained and had not been informed of the risk of such fractures before the procedure. The judge found that his doctor had not been negligent as his practice was supported by a responsible body of opinion; although there was a similar body of opinion that held a contrary view, this was insufficient to prove negligence (Bolam v Friern Hospital Management Committee, 1957). This led to the 'responsible body of opinion test' for all negligence cases; effectively, to defend a practice a doctor need only find a supporting opinion and the courts would rule in the doctor's favour.

The case of Patrick Bolitho in 1998 was heralded as a new dawn with regards to medical negligence (Bolitho Appellant and City and Hackney Health Authority Respondents, 1998). In this case a 2-year-old boy died as the result of a respiratory arrest while in hospital. The doctor had been called to review Patrick twice before his final respiratory arrest but had failed to attend. Although the hospital admitted negligence in that he was not reviewed it maintained that even if he had been reviewed the attending doctor would not have intubated him and it would only have been this that would have prevented his death. The question in the case then became whether the doctor should have intubated him. There was expert opinion in support of both options and the Court of Appeal asked whether the court is bound to accept evidence from experts without question. The answer was a resounding no. Lord Browne-Wilkinson's speech is often quoted:

> **'If, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.' (Bolitho Appellant and City and Hackney Health Authority Respondents, 1998)**

The claim from the Bolitho case was that it returned Bolam to its proper limits and that it is the courts and not doctors who decide medical negligence cases (Brazier and Cave, 2011). However, the inclusion of 'rare' in Lord Browne-Wilkinson's speech has been considered as a get-out clause and many feel that it will have little impact upon the judgments in many cases (Maclean, 2002).

With regards to how these two cases shape how clinicians consent a patient, it is clear that there is no complete consensus on what information clinicians give. If the clinician has the support of a reasonable body of opinion that the information provided is acceptable, and that opinion is capable of withstanding logical analysis it would appear that the clinician could not be considered negligent. The crux in the Montgomery case is that the doctor herself argued that by telling Mrs Montgomery about the risk of shoulder dystocia associated with a normal vaginal delivery in a diabetic mother she anticipated that the patient would elect for delivery by caesarean section. She withheld this information and did not disclose to the patient the risk of shoulder dystocia, a risk that was considered to be significant and which, had it been disclosed, would have altered the course of action Mrs Montgomery took. Her management of this patient is therefore not capable of withstanding logical analysis.

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It has been claimed that the fear of litigation following the Bolitho case may strangle medical innovation as it may force clinicians to follow the path of least risk (Mason and Laurie, 2010). The Access to Medical Treatment (Innovations) Bill passed this year has been hailed as a way to allay such fears. Originally proposed as the Medical Innovation Bill it was designed to clarify the law on innovative treatment options and reduce the worry surrounding litigation (Hoppe and Miola, 2014). The bill was rejected in its initial form as it was argued that it added little to the original reading of negligence law with regards to innovative treatment (Hoppe and Miola, 2014). Innovative treatment is not indefensible as it may be the best option for a patient, provided the patient's best interests are considered and all options discussed. It is unlikely that a doctor would be considered negligent as such management would withstand the logical analysis set down in Bolitho. The bill that was passed in 2016 is a much scaled-down version of the original bill which forms more of a database of innovative treatment.

Autonomy *vs* medical paternalism

The implication that some could draw from the Montgomery verdict is that the ball is now firmly in the patient's court when it comes to deciding on treatment. As argued above this was not particularly the crux of the Montgomery case, it was more that the patient was not informed of all the risks associated with a vaginal delivery. The doctor was acting paternalistically in withholding such information and not respecting the autonomy of Mrs Montgomery.

To treat a human being as a person we must respect his/her autonomy to make a decision. The problem with this is that the true definition of autonomy is widely debated. In its basic form it is self-rule; an autonomous agent is not ruled by another person, institution or government and exercises such self-rule (Levy, 2014). It could be argued, however, that it is likely that no one is truly autonomous (Harris, 1985). There are barriers to autonomy such as defects in an individual's reasoning and/or defects in the information upon which he/she bases his/her choices

(Harris, 1985). Autonomy could be considered more of a concept that we should strive towards (Harris, 1985).

Human beings are bad reasoners. Their perception of the future is skewed – only half of 25–34-year-olds save for retirement and yet over 80% agreed that saving for retirement is important (Adams, 2010). A person's perception of how he/she will feel about something in the future is also questionable. People perceive that their satisfaction with life would be negative after suffering a disability and be overwhelmingly positive if they were to win the lottery, yet evidence shows that the opposite is true (Brickman et al, 1978; Lucas et al, 2003; Levy, 2014). Humans also are notoriously bad at recalling how a previous event made them feel, with bias placed towards how the experience ended – the more unpleasant the ending the more a person is likely to recall it as a bad experience regardless of the duration of the experience and what has gone before it (Levy, 2014). Humans also tend to stick to prior beliefs regardless of the information they have been given, known as the motivated reasoning effect – how humans respond to information is likely to be influenced by their own behaviours (Levy, 2014).

The other concern is the rationality of a person's beliefs. It has been argued that one's choices and actions should be rational in order to be regarded as autonomous (Savulescu and Momeyer, 1997). Does this call into question the capacity of an individual? The common example is of Jehovah's Witnesses refusal for blood transfusion. The refusal is based on a religious belief that is not responsive to evidence nor is it consistent with any other religious texts and yet it is considered an autonomous decision to reject blood transfusion on such grounds (Savulescu and Momeyer, 1997).

These concerns about relying on autonomy as the essence of informed consent have led to debate about the role of medical paternalism. If patients hold irrational beliefs, clinicians have a responsibility not to abandon patients to their own decision-making but to educate and help patients deliberate more efficiently (Savulescu and Momeyer, 1997). This autonomy model of consent does not respect the complexity, confusion and difficulties associated with the relationship between clinician and patient (Smith and Newton, 1984).

Can humans ever give fully informed consent? It has been suggested (O'Neill, 2003) that wholly specific informed consent is an illusion. There can be no one size fits all approach as every situation is unique. Although a patient may consent to one procedure it does not follow that he/she consents to complications of or further consequences of a procedure (O'Neill, 2003).

Humans are all imperfect; they are influenced by external factors and are bad reasoners. Although it is imperative that clinicians do not pressure patients into making decisions, there is an argument for the supportive, advisory role that doctors have in obtaining consent and this is where the doctor's communication and relationship with patients is important.

The doctor–patient relationship

Although doctors do know the best clinical course of action for a disease it does not follow that they have higher authority in what is overall best for the patient (Keeley, 2005), so they need to develop a relationship with the patient in order to understand the patient's choices.

Maclean (2013) proposed that the relationship between health-care provider and patient is what is integral to the consent process. The concept of a relationship implies obligations and responsibilities from both sides. This relationship between a health-care provider and a patient is unique and is incomparable to any other relationship encountered in life. In order to have a relationship with each other both parties must recognize the other as an autonomous agent – through doing this both parties exercise their moral agency (Maclean, 2013). Enjoying a functional relationship between clinician and patient increases patient satisfaction and interaction (Speedling and Rose, 1985).

The balance of power in such a relationship will almost always be skewed towards the health professional, but the clinician's skill in communication and in building a relationship can reduce the importance of this issue. The process of consent is a mutual decision – to ask the patient alone to make the decision puts too much emphasis upon his/her self determination and does not reflect the importance of beneficence on the part of the health-care professional (Maclean, 2013).

There are times when a patient makes a decision that the clinician will disagree with and although the clinician must respect the decision if he/she believes that the patient has the capacity to make it, it is also prudent that the decision is explored and not simply taken at face value. It would fall under the doctor's duty of beneficence to ensure that the decision the patient has made is not subject to misgivings or misinformation. The clinician has to go beyond the surface and see what the root cause of a decision is, what the patient's values and goals are, and how they have influenced this decision (Maclean, 2013). It is also crucial that the clinician challenges such a decision and in some circumstances attempts to persuade a person otherwise. This reflects the positive and negative obligations faced when respecting autonomy – a doctor should not reject an autonomous decision and yet the doctor should ensure that such a decision is based upon sound information (Maclean, 2013).

The concept of persuasion goes against the grain of autonomy of the patient but it could be considered as part of the health-care professional's duty to provide holistic care to the patient. Persuasion is not to be confused with manipulation and coercion, which are wrong because they involve lying or twisting of the truth (Maclean, 2013).

The challenge in this theory of a balanced relationship is the role of the patient. Patients can be perceived to be in a difficult situation with many barriers to communication and understanding, such as the illness itself and lack of knowledge, and it is the duty of the health-care professional

to help a patient make an autonomous decision (Maclean, 2013). Although the drive is to increase the patient's involvement in decision making, responsibility still lies with the professional. The vulnerability of patients and the limitations on their ability to comprehend future events restricts the amount of responsibility they can share from their decision making (Keeley, 2005).

In an effort to find an objective standard of disclosure clinicians and lawyers have used statistics to attribute significance to risk (Heywood, 2009). Although this may help quantify risk it does not personalize the risk for patients and may not add to the conversation (Heywood, 2009).

Conclusions

The case of Montgomery may not necessarily change how clinicians obtain informed consent from patients. Doctors have always strived to ensure that patients are informed about their treatment options and as long as what doctors tell patients is capable of withstanding logical analysis this duty has been discharged. Striking the balance between medical paternalism and individual liberty – the right to pursue the good life without interference of others – is what is so challenging about medicine. Respect for a person's autonomy is a crucial part of mutual decision making but a patient's expression of his/her autonomy can be flawed. As clinicians it is our duty to support and educate our patients through good communication yet it is likely that, despite our best efforts, paternalism in some form will still exist. **BJHM**

Conflict of interest: none.

KEY POINTS

- Informed consent requires doctors to explore the wishes of their patient.
- In order to understand a patient's best interests the clinician needs to build a relationship with them.
- Although the Montgomery case has increased the scrutiny on informed consent the bar is still set at what is capable of withstanding logical analysis and what a reasonable person would want to know.

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