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Montgomery v Lanarkshire Health Board: transforming informed consent

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The landmark decision of the Supreme Court in *Montgomery v Lanarkshire Health Board* has confirmed that a patient's right to self-determination in treatment decisions triumphs over medical paternalism.[1] The practical effect is that patients with full mental capacity must be properly advised about their treatment options and the risks associated with each option so that they can make informed decisions when giving or withholding consent to treatment. In other words, the principles of shared decision-making must become the norm.

The case of *Montgomery* marks the culmination of a battle between two strands of law: the defensive 'Bolam test'[2] that allows the medical profession to be judged by its own standards of behaviour and a rights-based approach for the patient. For more than 50 years, the case of *Bolam* has dominated the law on the standard of care that doctors should provide to their patients. Care conforming to the practice of a responsible body of fellow practitioners gave rise to no claim.

Nevertheless, the *Bolam* standard has been chipped away at. In the 1985 case of *Sidaway*, the House of Lords held that a qualified Bolam test should apply when obtaining consent.[3] Doctors were under a duty to warn patients of material risks of grave adverse consequences, even if it were

not medical practice to do so. Every adult patient has a right to bodily integrity unless he or she consents to treatment. The law protects this right and it is an assault to administer treatment without consent. How doctors obtained such consent was judged by the Bolam test, as qualified in *Sidaway*.

However, the case of *Montgomery* goes much further. The battleground has been the amount of information a doctor should give before consent to treatment is regarded as valid in law to protect the doctor against claims of assault or negligent injury. The facts in *Montgomery* illustrate that battle.

The patient had a high-risk pregnancy due to her diabetes and small stature. Her obstetrician advised she was having a larger than usual baby but she should deliver vaginally. The obstetrician did not warn of a 10% risk of shoulder dystocia, nor did she offer an elective Caesarean section delivery. She withheld this information because it was her opinion that, even if shoulder dystocia occurred, the risk of a grave problem for the baby was very small. The obstetrician also thought that if she did mention shoulder dystocia, most patients would opt for a Caesarean section, which she considered to be against their best interests. The complication of shoulder dystocia arose. The baby became stuck and sustained severe brain damage during vaginal delivery. A claim was brought on behalf of the child alleging a negligent failure to inform of the risks from vaginal delivery and the option of Caesarean section.

The Supreme Court upheld the claim. It attached weight to the General Medical Council's guidance on consent and the doctor–patient relationship. *Good Medical Practice* states: 'Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions with you about their treatment and care.'[4]

This guidance encapsulates the *Montgomery* decision. In recognising and upholding a patient's right to self-determination in healthcare decisions, the Supreme Court observed that social and legal developments have moved away from medical paternalism. Patients are decision makers exercising choices. They often seek information (of variable quality) about their condition from the internet, patient support groups and healthcare leaflets. The doctor's duty is to ensure that they are properly informed about their condition, the range of treatment options and associated risks before treatment is given.

The effect of the Montgomery decision is to require shared decision-making between a doctor and patient. Shared decision-making is a process in which clinicians and patients work together to select tests, treatments, management or support packages, based on clinical evidence and the patient's informed preferences.[5] It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a systematic approach to recording and implementing patients' preferences.

An adult patient of sound mind is entitled to decide which (if any) treatment option to undergo. The patient's informed consent must be obtained before treatment is given; otherwise the doctor is guilty of assault. In order to obtain effective consent, a doctor must enter into a dialogue with the patient, providing information, listening to their concerns, and eliciting their values and preferences. The purpose of this dialogue is to ensure the patient understands the medical condition, the benefits and risks of the proposed treatment, and any reasonable alternative so that the patient can make an informed decision.

The doctor's duty is to take reasonable care to ensure the patient is aware of any material risks involved in the recommended treatment and of any reasonable alternative treatment options. The dialogue needs to be focused on the individual to ascertain what risks are or are not acceptable to that individual's circumstances. Non-medical considerations may influence a patient's choice. What is not a material risk for one patient may be a material risk for another. For example, a small risk of injury to a little finger may not be of much significance to most patients but may be highly important to a musician. This can only be established by discussion and the sharing of information between a doctor and patient.

A doctor must provide information in a comprehensible way and ensure it is properly understood. The doctor's duty is not discharged by bombarding a patient with technical information or by simply obtaining a signature on a consent form. The Supreme Court recognised its decision would have an impact on medical practice, noting that 'even those doctors who have less skill or inclination for communication, or who are hurried, are obliged to pause and engage in the discussion that the law requires.'[1]

Shared decision-making is often perceived as a time-consuming exercise. However, it need not be so. Tools to support decision-making are available to enable the doctor and patient to share information in an efficient and comprehensive way. Patient decision aids are information packages designed to inform patients about their treatment options and help them determine which they would prefer.[6] They can take a variety of forms, from one-page sheets to more detailed leaflets as well as computer programmes, DVDs and interactive websites. Some are designed for use by patients at home whereas others are intended to guide discussions in medical consultations.

Decision aids have been developed for a variety of surgical conditions, including coronary heart disease, osteoarthritis of hip and knee, gallstones, cataracts, menorrhagia, inguinal hernias, lower urinary tract symptoms, glue ear and various types of cancer. Use of these tools has been shown to improve patients' knowledge and ability to participate in decisions about their care, improving the quality and appropriateness of clinical decision-making.[7] Interestingly, patients who are well-informed about their options tend to make more conservative choices, all else being equal.[8–10]

Shared decision-making is not a new idea. Studies and demonstration projects have been carried out in the UK since the mid-1990s but the US has an even longer history of advocating this practice. The UK can learn from the American experience. In 1982 President Carter appointed a commission that examined the legal and ethical implications of informed consent. The commission concluded: 'Ethically valid consent is a process of shared decision-making based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.'[11]

Approximately half of the American states have now adopted a 'patient-based' standard and Washington state has recently taken a further step towards making shared decisions the accepted standard for informed consent. In 2007 legislation was enacted there to establish that a practitioner who engages in shared decision-making with a patient, including the use of a 'certified' patient decision aid, will be deemed to have met the requirements for informed consent.[12] The presumption of informed consent can then only be rebutted by clear and convincing evidence to the contrary.

Washington State is currently developing a certification process for patient decision aids, based on the widely recognised International Patient Decision Aids Standards criteria,[13] to ensure that the information provided is balanced, reliable, evidence-based and comprehensible to patients. This type of decision support has been integrated successfully into routine clinical care in several health systems in the US, with excellent results.[14,15] Moreover, a survey from 2013 of more than 2,200 patients underscored that the process of shared decision-making helps patients understand their treatment choices and prepares them for their informed choice discussion with their care providers.[16]

Evidence shows that it is possible to inform and engage patients of all ages, from all walks of life and educational backgrounds, if they are provided with well-designed information materials and given appropriate decision support by well-trained staff. Indeed, people from disadvantaged groups tend to benefit more than others, perhaps because they have more to gain in terms of knowledge about their options and encouragement to participate.[17]

Informing and involving patients in this way need not be too time-consuming if pathways are well-designed, with decision points identified and appropriate information readily available. However, provision of decision aids is not sufficient on its own. Shared decision-making depends on effective dialogue between patients and clinicians. In order to facilitate this, clinical staff should be offered training in risk communication, options appraisal, decision support and preference elicitation.

There is a limited therapeutic exception to the Montgomery duty of disclosing information. There is no duty to explain risks if the doctor reasonably decides it would be seriously detrimental to that patient's health. Furthermore, shared decision-making does not apply where patients lack capacity to give informed consent (for example, where the patient is a child or mentally incapacitated adult) or in emergency treatment situations where the patient is unconscious. These exceptions aside, there are strong professional, ethical and legal reasons why shared decision-making should replace the traditional methods for gaining informed consent in surgical practice.

References

1. Montgomery v Lanarkshire Health Board Scotland [2015] UKSC 11.
2. Bolam v Friern Hospital Management Committee [1957] 1 WLR 583.
3. Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 1 All ER 643.
4. General Medical Council. *Good Medical Practice*. Manchester: GMC; 2013.
5. Coulter A, Collins A. *Making Shared Decision-making a Reality*. London: King's Fund; 2011.
6. Barry MJ, Edgman-Levitan S. Shared decision making – the pinnacle of patient-centered care. *N Engl J Med* 2012; **366:** 780–781.
7. Stacey D, Légaré F, Col NF *et al*. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2014; **1:** CD001431.
8. Kennedy AD, Sculpher MJ, Coulter A *et al*. Effects of decision aids for menorrhagia on treatment choices, health outcomes, and costs. *JAMA* 2002; **288:** 2,701–2,708.
9. Arterburn DE, Westbrook EO, Bogart TA *et al*. Randomized trial of a video-based patient decision aid for bariatric surgery. *Obesity* 2011; **19:** 1,669–1,675.
10. Arterburn D, Wellman R, Westbrook E *et al*. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. *Health Aff* 2012; **31:** 2,094–2,104.
11. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Making Health Care Decisions*. Washington DC: US Government Printing Office; 1982.
12. Shared Decision Making. Washington State Health Care Authority. http://www.hca.wa.gov/hw/Pages/shared_decision_making.aspx [last accessed May 2016].
13. Elwyn G, O'Connor AM, Bennett C *et al*. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). *PLoS One* 2009; **4:** e4705.
14. Fowler FJ, Levin CA, Sepucha KR. Informing and involving patients to improve the quality of medical decisions. *Health Aff* 2011; **30:** 699–706.
15. Hsu C, Liss DT, Westbrook EO, Arterburn D. Incorporating patient decision aids into standard clinical practice in an integrated delivery system. *Med Decis Making* 2013; **33:** 85–97.
16. King J, Moulton B. Group Health's participation in a shared decision-making demonstration yielded lessons, such as role of culture change. *Health Aff* 2013; **32:** 294–302.
17. Durand MA, Carpenter L, Dolan H *et al*. Do interventions designed to support shared decision-making reduce health inequalities? A systematic review and meta-analysis. *PLoS One* 2014; **9:** e94670.

Further information

More information about shared decision-making and patient decision aids is available from:

- Informed Medical Decisions Foundation (www.informedmedicaldecisions.org/)
- Health Foundation (http://personcentredcare.health.org.uk/)
- Option Grids (www.optiongrid.org/)
- Ottawa Hospital Research Institute (http://decisionaid.ohri.ca/)
- Right Care (http://sdm.rightcare.nhs.uk/pda/)