

# Documenting the process of patient decision making: a review of the development of the law on consent

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## ABSTRACT

The doctor's role involves helping patients to understand their condition, including the anticipated benefits and risks of proposed treatments or omissions to treat. In order to treat, doctors require consent from patients but the duty to advise is equally strong if conservative management is appropriate. The recent judgement in the case of *Montgomery* has set a precedent for patient autonomy. However, doctors are still required to judge what risks they should disclose in their reasonable assessment of that patient and their specific situation. The General Medical Council reflects a consensus that the empowered autonomous patient is more likely to be satisfied with their clinical outcome than the passive victim of medical paternalism. Doctors, regardless of specialty, must counsel their patients adequately, paying particular attention to identifying material risks that are likely to be significant to their case.

**KEYWORDS:** Medical and shared decision making, decision records, law on consent, patient autonomy

## Introduction

The informed consent process has traditionally been used to describe the process by which patients give authority to perform invasive treatment. In counselling patients, healthcare professionals have been guided by the four principles of medical ethics: 'autonomy', 'beneficence', 'justice', and 'non-maleficence'. Patient autonomy, in particular, has taken precedence recently, a significant shift from the beneficence that often led to paternalism in medical decision making. In the current digital climate, patients have the potential to be better informed than before and this places an increased responsibility on doctors to recognise individual patient priorities and tailor information to their needs. The recent case of *Montgomery v Lanarkshire Health Board* [2015] delivered a further blow to medical paternalism, but whether it provided a new platform

for information sharing or simply articulated a position already set out in the General Medical Council's (GMC) *Good Medical Practice* (GMP) is a matter for debate.

The role of consent to treatment is grounded in the principle of the individual's right to decide what is done to their body.<sup>1</sup> Consent creates a defence to the tort and crime of battery, which is defined as touching without effective consent be it implied or explicit. Negligence occurs whenever a healthcare professional breaches the duty of care they accept when counselling patients.<sup>2</sup> They may fail to provide sufficient information; they may fail to present the information in the right way or at the right time. No consent means battery; bad counselling does not, but it may be negligent.

Consent is the culmination of an informed decision-making process. It is not helpful to describe it as having been 'obtained' and it is positively wrong to state the patient has been 'consented' because it describes the decision taken by the patient rather than something 'done' to a patient. What the doctor does is to counsel or advise, preferably well before the decision is taken, and then to record the decision of the patient. Using the correct terminology ensures that the process of consent remains patient centred. The process requires time and patience, more than is normally available during routine clinic appointments, and should be completed before the patient commits themselves by attending for the procedure, often in a state of high anxiety.

Doctors must work in partnership with patients and give them the information required to make decisions in order to ensure full understanding of the proposed treatment.<sup>3</sup> Discussions should include an explanation of the diagnosis, the prognosis with and without treatment, the purpose of the intervention, the range of likely outcomes, risks, alternative treatment options and follow-up implications.<sup>4</sup> Failure to counsel a patient adequately compromises their autonomy and reduces their ability to take charge of their own healthcare.<sup>5</sup>

Conventional documentation has been criticised for failing to record alternative options and negative decisions. Where there is no intervention, typically there is no record of the patient's decision. GMP requires that the practitioner use the patient's medical record or a consent document to record the discussion.<sup>6</sup> Because traditional consent documentation has been created to provide a defence for the practitioner charged with battery rather than a record of the decision taken by the patient, it has evolved a shorthand that bears little semblance to a record of decision. It often uses abbreviations that the

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decision taker could not construe. The demand that doctors become teachers and advisors mandates a fundamental change in the records that are employed. This places extra demands on clinic appointments that will be difficult to meet at a time of constrained resources. Additional demands are made by patients with learning difficulties or language barriers. Innovation is therefore required to support clinicians in providing the information required to empower patients.

### The development of the law on consent

Most legal systems outside slavery recognise the individual's interest in what happens to their body. In English common law, the importance of taking adequate consent was recorded as early as 1767 when charges of negligence were upheld against surgeons performing surgery without explicit consent.<sup>7</sup> In 1957, the *Bolam* principle saw the consent process as a matter of clinical judgment to be evaluated purely by the evidence of experts. *Bolam* stated that a doctor would not be 'seen as negligent if he has acted in accordance with practice accepted as proper by a responsible body of medical men'.<sup>8</sup> *Bolam* was upheld by the House of Lords in *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985]; however, Lord Scarman suggested the patient should be told of everything that a 'prudent patient' would want to know and that doctors have a duty to discuss substantial risk of injury.<sup>9</sup> In the case of *Bolitho v City and Hackney Health Authority* [1997] Lord Browne-Wilkinson stuck to *Bolam*, but said that an opinion that did not 'stand up to analysis, in the sense of being demonstrably wrong on the basis of the then present state of the art would not be a reasonable school of thought, however widely endorsed'.<sup>10</sup> Since then it has been hard to persuade the courts that a failure to mention a risk, or a safer alternative mode of therapy, is reasonable where the patient insists that they wish they had been warned. Lord Justice Sedley, in the case of *Wyatt v Curtis* [2003], stated that 'there is arguably something unreal about placing the onus of asking upon a patient who may not know that there is anything to ask about'.<sup>11</sup> In its 2008 guidance, the GMC is clear that doctors should not make assumptions about the information a patient might want or need, or the clinical factors that the patient might consider significant,<sup>6</sup> recognising that such decision making is highly personal and clinicians cannot be confident about what an individual patient will decide to do.

### Montgomery v Lanarkshire Health Board

Mrs Montgomery, a woman with type 1 diabetes argued that she was not offered an elective caesarean section and had she been cognisant of the risks of shoulder dystocia associated with vaginal delivery in a diabetic mother, she would have opted for this. Her obstetrician stated this was not offered because of there being only a 9–10% risk of shoulder dystocia occurring during the delivery of an infant to a diabetic woman, with subsequent low risk of harm to the baby. Her obstetrician said she had not mentioned the risk because if given the option, every female with diabetes would opt for caesarean section, which would not be in their best interests. Despite initially being acquitted in the Scottish Courts, the UK Supreme Court (UKSC) declared that the doctor–patient relationship had evolved. The key points were that 'patients have rights, and

should be viewed as consumers exercising choices' and that 'doctors have a duty to ensure patients are aware of any material risks involved in any recommended treatment and of reasonable alternative treatments'.<sup>12</sup>

The test of materiality is now 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, aware that the particular patient would be likely to attach significance to it.<sup>13</sup> The UKSC stated 'whether a risk is material cannot be reduced to percentages, the significance of a given risk is likely to reflect a variety of factors besides its magnitude', eg the effect of its occurrence on the patient's life and the importance to the patient of the benefits of the treatment.<sup>14</sup> *Montgomery* confirms that doctors need to focus on the specific concerns of each patient in order to counsel them adequately and thus obtain valid consent.

### The implications of patient-specific consent

*Montgomery* is an important decision in favour of autonomy, but it also confirms what the law has been for a long time.<sup>15</sup> *Bolam* is very much at a discount with the (medical) professional yardstick displaced by the judicious patient. However, the concept of doctors as guides and teachers reflects a secular change in clinical practice. Doctors know they must form relationships with patients to identify risks that may be material but are sometimes less careful in analysing what the patients want to know. Routine counselling in cases we encounter rarely deals with the post-procedural course in detail. For example, how often in routine counselling is the post-procedural course discussed in detail? Patient expectations may be radically different from the realities of a procedure and the course of events anticipated. While long-term risks may be rare, there is an inherent risk of short-term disability following the insertion of central lines, urinary catheters, drains and infusions pumps and often these are not clearly explained.<sup>16</sup>

Written consent forms exist purely for the purpose of ensuring the consent process is followed and to provide evidence that a discussion has taken place. There is no legal threshold as to when consent should be signed by the patient and when other means of documenting the decision will be effective. However, the onus is on the clinician of record to ensure the patient is fully informed of a procedure and its consequences, including the short-term disability caused by insertion of devices.

Detailed counselling of patients about the post-procedural course of events is good medicine, as well as being good manners; it creates fewer disappointed patients, results in less postoperative analgesia and reduces length of stay.<sup>17</sup> However, counselling takes time, effort and sometimes great skill. In order to meet this challenge, sophisticated documentation and visual aids that streamline information, are likely to be needed.<sup>18</sup>

### Uncertainty about the therapeutic exception

One uncertainty that remains following *Montgomery* is the role of the therapeutic exception. This allows doctors to decide that it would be detrimental to the health of the patient to explain what is involved in a procedure, or the reasons for their advice.<sup>19</sup> Some doctors may not wish to scare patients with details of treatment; however, the UKSC is clear that the

therapeutic exception must be used very sparingly. It is likely that legal challenges will flow from the exception as patients dispute a doctor's ability to determine what information is detrimental to their health.<sup>15</sup>

There are, of course, exceptions to the simple rule in *Montgomery*. These include life-saving emergency interventions and those where patients with capacity decide that they do not wish to be informed of the risks of treatment. *Montgomery* acknowledges that clinicians are not obliged to discuss the risks inherent in treatment with a person who makes it clear that they would prefer not to discuss the matter.<sup>19</sup> However, the tide of legal history is flowing against a mode of consultation that may in future be stigmatised as paternalistic. The GMC is clear that clinicians should respect patient wishes as far as possible, but that patients must be given the relevant information needed to give their consent to a proposed investigation or treatment. If the patient insists they do not want this information, the potential consequences of them not having it, particularly if it might mean that their consent is not valid, must be explained. It is imperative that a record of this discussion is maintained if the patient has declined to receive information and it must be made clear they can change their mind at any time.<sup>6</sup>

## The problem

Informed consent is an oft-used term but a poorly studied phenomenon. There is currently no consensus of what good counselling should look like in clinical practice. Fear of litigation has led to the development of consent documentation that does not serve as an educational tool so much as illusory protection for the clinician, including waivers of liability that overlook patient autonomy. Patients perceive the act of signing such forms as paternalistic, legalistic, and part of a process that detracts from active participation in their own care.<sup>1</sup> It is widely believed that a signature proves validity of consent, whereas the signature itself only records that the patient had decided to proceed and records little about what information was provided and, where counselling is deficient, the decision cannot be defended.<sup>20</sup>

Traditional consent forms are not fit for purpose as the reading material and language is often complex and poorly understood by patients.<sup>5,21</sup> A review of documentation for urological procedures concluded that a significant proportion of non-standardised consent forms exhibited deficiencies in information provided.<sup>22</sup> Approaches such as using a 'Medical Decision Worksheet' have facilitated patient participation in dynamic processes to educate with consideration of person-specific, cultural and value-based denominations.<sup>23</sup> A randomised trial using a 'Repeat Back' tool assessed patient understanding by asking patients to recount information given during their discussions with surgeons; this resulted in improved comprehension of information via consolidation and clarification.<sup>24</sup>

## Decision records

Currently only positive decisions involving intervention are recorded on consent forms; no formal documentation exists for patients who decide not to proceed. Rarely is there a formal consent record of decisions either to commence or cease medical therapies. This information could be entered onto a decision-making record (DMR) based on the GMC guidance, which states doctors should record discussions, decisions made

and actions agreed.<sup>3</sup> A Cochrane review has demonstrated that DMRs improve knowledge about options and enable individuals to make more informed decisions.<sup>25</sup>

Many authors recognise it is difficult to achieve a meaningful decision-making process in the inpatient setting or within scheduled time slots in outpatient clinics.<sup>16,26,27</sup> Limited research has explored the different roles of documentation and discussion with patients; both are meaningful and detailed but ineffective in isolation.<sup>28</sup> One way of enhancing this process is to have pre-populated forms full of information written in an easily understandable format. Such documentation may include anatomical images, investigations, post-procedural course of events, risks, benefits and a free text part that could list any person-specific material concerns.<sup>16</sup> DMRs should also include a description of the health problem and proposed intervention; currently patients may just read 'oesophagogastroduodenoscopy' or 'upper GI endoscopy', but with no adequate record of the context, such as why they are undergoing the stipulated intervention.<sup>29</sup> A systematic review of the quality of interventions to increase patient understanding of medical decision making found consistent evidence that additional written information, audiovisual/multimedia programs, extended discussions, and test/feedback techniques improved patient comprehension of the treatment and risks.<sup>5</sup>

The development of better information technology would significantly enhance DMRs. Such records could also be used for future audit and research to ensure continuous quality improvement.<sup>30</sup> The advice contained in these documents should be standardised based on current guidance. In particular for physicians, decisions to commence pharmacological therapies, such as anticoagulation, should also be recorded in this way. Clinicians need to evolve from reserving consent forms for invasive intervention to utilising DMRs for any form of treatment in order to educate and empower patients, as well as maintain clinical standards.

## What is required on the professional's part?

Clinicians must inform their patient of reasonable alternative treatments. However, not all hospitals offer every possible treatment modality that a patient might wish to consider. This represents a challenge during discussion and recording decisions about other treatments that some centres may not offer. In this context, greater professional collaboration is required. For example, a cardiologist and a cardiothoracic surgeon may offer different treatments for ischaemic heart disease: percutaneous stenting of coronary vessels and an open bypass grafting may both be appropriate in different cases, but the law may demand that patients are given the same evidence-based advice wherever they present.

Clinicians must respond to the difficulties faced by patients trying to understand and retain information regarding their proposed procedure. Evidence suggests that, while the overwhelming majority of patients were satisfied with the information received in an outpatient setting, they were unable to describe the nature of the surgery that had been advised or the specific complications they should consider.<sup>31</sup>

Furthermore, patients do not want to have the responsibility for making the exact treatment decision, whereas it seems they do want information from clinicians to enable them to understand and make an informed choice. A consensus

is required to ensure a shared understanding of the issues concerning a particular intervention.<sup>1</sup> Once this common ground has been determined, the responsibility can be shared between both parties. Only an active discussion, with the provision of understandable information in a form and at a time when a patient will be best able to absorb and work with it, will empower patients.<sup>32</sup> The standard model of communication will require modifications to cater for the precise case. However, if there is no standard model, or if it is deficient in design, the clinician has even less chance of getting it right. Proper detailed, legible documentation of the process is essential if the doctor's role is to be defensible in a court of law.

The logistics of determining whether your patient has made an informed choice may be difficult when faced with pooled procedural lists. It is common for patients attending for endoscopy to meet the operator for the first time on the day of the procedure. It may be difficult for the clinician to decide whether it is necessary to repeat part of the counselling given by others. The guidance from the Royal College of Surgeons England stipulates that the person undertaking the treatment or someone actively involved in the patient's care must ensure consent is received, which means they have to know the patient has been properly counselled.<sup>4</sup> Healthcare will have to evolve to facilitate this process. Clinicians and others concerned about the allocation of scarce resources should be concerned about the impact on busy outpatient clinics and it may be that a great deal of this work will have to be taken elsewhere. Patients undergoing routine procedures, such as angiography, endoscopy or pacemaker insertion, could be provided with information videos or attend a group learning session after their consultation. They could then be given the opportunity to go away and consider this information together with lists of other documents that they are advised to consult. Furthermore, clinicians may wish to dictate an email or letter to the patient in the consultation room so that they hear a summary of the discussion. In some cases, where the decision is finely balanced, patients may be required to complete a questionnaire to demonstrate their awareness of the treatment.

## Conclusion

It is clear that the medical profession no longer solely determines which risks are material. *Montgomery* has marked a milestone in the progress towards patient autonomy: it may contain little or nothing that was not implicit in guidance already issued by the GMC, but it has triggered a debate within the healthcare profession that has brought these issues to the fore. It is now clear that:

- > the autonomous empowered patient is not a soft option
- > the NHS will have to redesign services to ensure that patients are counselled in a language and a fashion that they understand before taking any decision
- > the onus is on the clinician to make sure patients are appropriately counselled, even though much of it may have to be done on their behalf outside routine clinics
- > the duty to counsel about alternatives available is one that applies to all clinicians regardless of specialty and includes medical and conservative choices
- > there is an obligation to create an accessible record of such discussions.

Patients frequently sue their doctors for failure to mention risks; soon they will be suing for having been given the right information at the wrong time or in the wrong way. There is no 'one-size-fits-all' solution because the needs of patients in a diverse population from a variety of cultural backgrounds will invariably differ. Bespoke consultations are essential and healthcare organisations will need to recognise the practicality of delivering this service and creating records of what has been said and done. Doctors who hurry or have less inclination for communication bear the same obligation to pause and engage in discussion and to create a record of that discussion. The courts have rightly sought to restore balance to ensure GMC advice is followed. The decision in *Montgomery* may cause litigation to increase over the next few years but it represents recognition of a secular change in the role of medicine that has been going on for many years. ■

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