BJPsych Advances (2017), vol. 23, 63–72 doi: 10.1192/apt.bp.116.015990

After a prolonged gestation and difficult labour, informed consent is safely delivered into English and Scots law

ARTICLE

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SUMMARY

It is over 40 years since the principle of informed consent was accepted in the USA and it has been long established in other common law jurisdictions. But for decades English law has been constrained by the *Sidaway* case, which effectively perpetuated a form of medical paternalism. Nevertheless, a patient-centred approach can be traced to one of the judgments in that case, and in the case of *Montgomery* the Supreme Court has now adopted an approach to consent which is based on self-determination and autonomy and is more closely aligned to professional practice. It calls for a dialogue between doctor and patient, recognition of the patient's right to make a choice and recognition by the doctor of their duty to provide the comprehensible information necessary for the patient to exercise choice, having regard to what a prudent patient, in that patient's circumstances and with that patient's characteristics, would want to know.

LEARNING OBJECTIVES

- Understand how the principle of informed consent has emerged in UK law
- Understand the principle of informed consent
- Know how to apply the principle of informed consent to the practice of psychiatry

DECLARATION OF INTEREST

None

> 'Until very recently, conscientious physicians were actually trained to act paternalistically toward their patients, to treat patients according to the physician's own judgement about what would be best for their patients, with little regard for each patient's own perspectives or preferences. The problem with this arrangement, however, is […] that it is difficult for anyone other than the patient to make choices that will be compatible with the patient's personal value system' – Susan Sherwin (1998: p. 21).

There is a cruel irony in that the case which has confirmed the safe delivery of the principle or doctrine of informed consent into the law of England and Scotland (and by implication the rest of the UK) is the tragic case of a child born with severe disabilities following a complicated delivery as a result of what was found to have been a negligent failure to advise his mother of the risks of a vaginal delivery (*Montgomery v Lanarkshire Health Board (Scotland)* [2015]).

This article sets out the details of this landmark case, identifies the origin of informed consent, and traces the long gestation of the principle in English law back to Lord Scarman's judgment in the leading case of *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985]. It then describes how *Sidaway*'s grip gradually weakened, identifies the principles that can be derived from *Montgomery* and suggests their implications for psychiatric practice.

Nadine Montgomery's case

The case at first instance

Box 1 sets out the facts of Mrs Montgomery's case. Her evidence before the Outer House of Scotland's Court of Session was that, if she had been told of the risk of shoulder dystocia during delivery, she would have wanted the obstetrician to explain what it meant and what the possible risks were. If she had considered that it was a significant risk, which she would, she would have asked for a caesarean section. It was contended that she ought to have been given advice about the risk of shoulder dystocia in vaginal birth and of the alternative of an elective caesarean section.

This contention was rejected on the grounds that the approach was to follow *Sidaway* and apply the Scottish test for negligence (*Hunter v Hanley* (1955) or the equivalent English Bolam test (*Bolam v Friern Hospital Management Committee* [1957]) (Box 2) to the provision of advice.

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https://doi.org/10.1192/apt.bp.116.015990 Published online by Cambridge University Press

BOX 1 Nadine Montgomery's case – the facts

Nadine Montgomery had a BSc in molecular biology and worked as a hospital specialist for a pharmaceutical company. Her mother and sister were general practitioners. She was described in court as 'a clearly highly intelligent person'.

At her 36-week antenatal appointment Mrs Montgomery expressed concern about the size of the fetus and the risk that the baby might be too big for vaginal delivery. The obstetrician stated that Mrs Montgomery had not asked her 'specifically about exact risks'. Had she done so, she would have advised her about the risks of shoulder dystocia and cephalopelvic disproportion. In the absence of such specific questioning, the obstetrician had not mentioned the risk because it was her view that the risk of serious injury to the baby was very slight.

(*Montgomery v Lanarkshire Health Board (Scotland)* [2015])

The first appeal to the Inner House of the Court of Session

Mrs Montgomery then appealed to the Inner House of the Court of Session. Her appeal was rejected. Her argument was that there had been, in recent judicial authority (in particular, *Pearce v United Bristol Healthcare NHS Trust* (1999)), a departure from *Sidaway* so as to require a medical practitioner to inform the patient of any significant risk which would affect the judgement of a reasonable patient.

BOX 2 Nadine Montgomery's case – the judgment of the Inner House of the Court of Session

The court followed the approach of the majority in *Sidaway* and based its decision primarily on expert evidence of medical practice: other ordinarily skilled obstetricians acting with ordinary care would have advised Mrs Montgomery as her obstetrician did. The court decided that, according to *Sidaway*, whether a doctor's omission to warn a patient of inherent risks of proposed treatment constituted a breach of the duty of care was normally to be determined by the Scottish test for negligence (*Hunter v Hanley* (1955)) or the equivalent English Bolam test. It therefore depended on whether the omission was accepted as proper by a responsible body of medical opinion.

The court accepted that, where the proposed treatment involved a substantial risk of grave adverse consequences, such a patient's right to decide whether to consent to the treatment might be so obvious that no prudent medical practitioner could fail to warn of the risk. However, the court considered that, in order to be significant, a risk must be a substantial risk of grave adverse consequences. It held that the circumstances of the present case did not fall within the scope of that exception. Although there was a significant risk of shoulder dystocia, that did not in itself require a warning, since 'in the vast majority of […] cases […] shoulder dystocia was dealt with by simple procedures and the chance of a severe injury to the baby was tiny'.

(*Montgomery v Lanarkshire Health Board* [2010])

The appeal to the Supreme Court

Finally, Mrs Montgomery appealed to the Supreme Court, which was invited to depart from the majority decision of the House of Lords in *Sidaway* and to reconsider the duty of a doctor towards a patient in relation to advice about treatment.

The long gestation

The origin of informed consent

Informed consent as a legal concept originated in 1972 in the US case of *Canterbury v Spence*. The term can be traced further back to a letter sent on behalf of the US Atomic Energy Commission advising a researcher about the requirements for research involving humans (Maclean 2004). It was eventually endorsed everywhere in the common law world except for the UK. In Canada *Reibl v Hughes* [1980] led to the courts coming down firmly in favour of the reasonable patient, who has a right to know what risks are involved in undergoing or forgoing certain surgery or other treatment. In Australia in 1992 the High Court held in *Rogers v Whittaker* that it would be illogical to hold that the amount of information to be provided could be determined from the perspective of the medical practitioner alone or, for that matter, of the medical profession, and the more recent case of *Rosenberg v Percival* (2001) confirms this approach. In 1994 in South Africa in *Castell v De Greef* the 'reasonable patient' test in *Rogers* was adopted.

Mrs Sidaway's case

The seeds for the Supreme Court's judgment in *Montgomery* can be traced back to the judgment of Lord Scarman in *Sidaway* (Box 3).

Mrs Sidaway claimed damages for negligence and relied solely on the alleged failure of the surgeon, who was by then dead, to disclose or

BOX 3 Amy Sidaway's case – the facts

Mrs Amy Sidaway had suffered recurrent pain in her neck, right shoulder and arms following an accident at work. In 1974, aged 63, she underwent an operation which was performed by a senior neurosurgeon at the Maudsley Hospital, London. The operation, even if performed with proper care and skill, carried an inherent, material risk, which was put at between 1 and 2%, of damage to the spinal cord and the nerve roots. The risk of damage to the spinal cord was substantially less than to a nerve root, but the consequences were much more serious. Although the operation was not carried out negligently, spinal cord damage occurred and Mrs Sidaway was left severely disabled by a partial paralysis.

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explain to her the risks inherent in, or special to, the operation advised. The court found that the surgeon did not tell her that the operation was one of choice rather than necessity; that although the surgeon had told her about the possibility of disturbing a nerve root and its consequences, he did not mention the danger of spinal cord damage; that in not so informing her he was following a practice which in 1974 would have been accepted as proper by a responsible body of skilled and experienced neurosurgeons; and applying the Bolam test the court dismissed her claim. The Court of Appeal agreed.

Mrs Sidaway then appealed to the House of Lords,[a] where four Law Lords dismissed her appeal on the basis that she had failed to prove that the surgeon had been in breach of any duty of care owed to her in failing to warn her of the risk inherent in the treatment. However, Lord Scarman sowed some of the seeds of the principle of informed consent.

Lord Scarman – 'The prudent patient test'

Lord Scarman regarded the primary concern of the court as 'the patient's right to make his own decision, which may be seen as a basic human right protected by the common law' (*Sidaway* [1985]).

His position, as summarised in *Montgomery*, was that if

> '(1) the patient suffers damage, (2) as a result of an undisclosed risk, (3) which would have been disclosed by a doctor exercising reasonable care to respect her patient's right to decide whether to incur the risk, and (4) the patient would have avoided the injury if the risk had been disclosed, then the patient will in principle have a cause of action based on negligence'

or, to be more precise, negligent pre-intervention non-disclosure.

Lord Scarman pointed out that the decision whether to consent to the treatment proposed did not depend solely on medical considerations, but on 'circumstances, objectives, and values which [the patient] may reasonably not make known to the doctor but which may lead him to a different decision from that suggested by a purely medical opinion'.

This was regarded by the Supreme Court in *Montgomery* as important:

> 'Countless […] examples could be given of the ways in which the views or circumstances of an individual patient may affect their attitude towards a proposed form of treatment and the reasonable alternatives. The doctor cannot form an objective, "medical" view of these matters, and is therefore not in a position to take the "right" decision as a matter of clinical judgment' (*Montgomery v Lanarkshire Health Board (Scotland)* [2015]).

Lord Scarman held that the trial judge and the Court of Appeal had erred in law in holding that, where the alleged negligence is a failure to warn the patient of a risk inherent in the treatment proposed, *Bolam* applied (Box 4).

Notwithstanding this exegesis of the law, Lord Scarman, with profound regret, then concluded that Mrs Sidaway had failed to prove her case. This was because the issue could not be settled positively without knowing what advice, including any warning of inherent risk in the operation, the neurosurgeon gave Mrs Sidaway and what his assessment was of her mental, emotional and physical state. The trial judge had derived no help from the evidence of Mrs Sidaway, the neurosurgeon was dead, and the medical records afforded no sure guide.

The Supreme Court in *Montgomery* said that it followed that medical evidence would normally be required as to what Lord Scarman identified as two critically important medical factors: the degree of probability of the risk materialising and the seriousness of the possible injury if it should occur. He also identified the 'character' of the risk, such as whether it was a risk common to all surgery or specific to the operation under consideration. Medical evidence would also be necessary to decide whether the 'therapeutic exception' was justified. Here, this term refers to how a doctor can avoid liability for injury resulting from the occurrence of an undisclosed risk if they can show that they reasonably believed that communication to the patient of the existence of the risk would

a. The Appellate Committee of the House of Lords was the forerunner of the Supreme Court of the United Kingdom.

BOX 4 Lord Scarman and 'The prudent patient test'

'Ideally, the court should ask itself whether in the particular circumstances the risk was such that this particular patient would think it significant if he was told it existed. I would think that, as a matter of ethics, this is the test of the doctor's duty. The law, however, operates not in Utopia but in the world as it is: and such an inquiry would prove in practice to be frustrated by the subjectivity of its aim and purpose. The law can, however, do the next best thing, and require the court to answer the question, what would a reasonably prudent patient think significant if in the situation of this patient […]

'To the extent that I have indicated I think that English law must recognise a duty of the doctor to warn his patient of risk inherent in the treatment which he is proposing: and especially so, if the treatment be surgery. The critical limitation is that the duty is confined to material risk. The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk. Even if the risk be material, the doctor will not be liable if upon a reasonable assessment of his patient's condition he takes the view that a warning would be detrimental to his patient's health.'

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(*Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985])

BOX 5 Lord Diplock and 'The responsible doctor test'

Lord Diplock considered that the Bolam test should be applied when determining an alleged breach of a doctor's duty of care towards their patient, whether related to diagnosis, treatment or advice, and it was on this basis that he found against Mrs Sidaway. He relied on that fact that the expert witnesses all agreed that there was a responsible body of medical opinion that would have undertaken the operation at the time the neurosurgeon did and would have warned the patient of the risk involved in the operation in substantially the same terms as the trial judge found on the balance of probabilities that the neurosurgeon had done, i.e. without specific reference to risk of injuring the spinal cord.

However, Lord Diplock did make a distinction between patients like Mrs Sidaway and 'a highly educated man of experience', as he described himself, who would naturally and correctly want to be 'fully informed of any risks' so as to form his own judgement as to whether to refuse the advised treatment or not. He also suggested that volunteering unsought information about the risks of failing to achieve the result sought, or making the patient's physical or mental condition worse rather than better, could have the effect of deterring the patient from undergoing the treatment that, in the expert opinion of the doctor, it was in their interests to undergo.

(*Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985])

have been detrimental to the health (including the mental health) of the patient.

In addition to Lord Scarman, Lord Diplock (Box 5) and Lord Templeman (Box 6) gave judgments and Lord Bridge (Box 7) gave a judgment with which Lord Keith agreed. All agreed that it is part of the doctor's ordinary duty of care to disclose information, but they differed significantly in their approaches, with Lord Scarman at one end of the spectrum and Lord Diplock at the other.

BOX 6 Lord Templeman and the 'The prudent doctor with a prudent patient test'

Lord Templeman (like Lord Bridge: Box 7), opted for the middle way. In proposing an objective test (the doctor decides if there are special or particularly great risks) and a subjective test (what the patient especially wants or needs to know and what danger might be special to the patient) that ensures that the doctor provides 'sufficient information to enable the patient to reach a balanced judgement', he does approach informed consent. In having regard to the subjectivity of the patient, Lord Templeman comes closer than his fellow judges to the patient-centred approach of Lord Scarman. He recognised that the patient was free to decide whether or not to submit to treatment, indeed free to make an unbalanced and irrational judgement, and so the doctor impliedly contracted to provide information that was adequate to enable the patient to reach a balanced judgement. But, as he put it, at the end of the day it came down to the doctor deciding what information should be given and in what terms it should be couched.

This could be called 'the prudent doctor with a prudent patient test'. However, he also 'took the view that a simple, general explanation […] would have made it obvious to Mrs Sidaway that damage to the spinal cord was possible [and] (f)rom her failure to question him about it, the surgeon was entitled to assume that she regarded the risk as sufficiently remote to be ignored'. This can also be called 'the blissfully ignorant patient test'. Nevertheless, his reference to 'balanced judgement' and to 'special risks' also anticipates the modification of *Bolam* by *Bolitho v City and Hackney Health Authority* [1998].

(*Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985])

Sidaway's weakening grip

'Trust me, I'm a doctor'

The effect of the majority in *Sidaway* – that is, excluding Lord Scarman – was to confirm the rule of medical paternalism, that the doctor knows best, albeit that close reading of the majority's judgments reveals shades of confirmation rather than complete endorsement. It is therefore not surprising that between 1984 and 1994, in 30 cases where informed consent was an issue, only 7 cases were successful (Jones 1999).

The tide turns?

But the tide was beginning to turn. In *Smith v Tunbridge Wells Health Authority* [1994] Mr Justice Morland found negligent a failure to disclose the risk of impotence that was inherent in an operation.

More significantly, in *Pearce* (1999) Lord Woolf moved away from the Diplock approach in *Sidaway*. He referred to the patient's right to be warned of any 'significant risk' and introduced the 'reasonable patient'.

Furthermore, more recently the English courts have generally treated *Pearce* as the standard formulation of the duty to disclose information to patients. Although *Sidaway* has remained binding, the lower courts have tacitly ceased to apply *Bolam* in relation to the advice given by doctors to their patients and effectively adopted Lord Scarman's approach. The problem for Mrs Montgomery was that, in her first appeal, the court rejected the argument that there had been a departure from Sidaway by the lower courts. So, as in earlier cases, the Court of Session applied *Bolam*, subject to qualifications derived from Lord Bridge's speech.

The onset of labour

Chester v Afshar [2004] involved a failure to warn a surgical patient of the 1–2% risk of cauda equina syndrome. The operation was not carried out negligently, but the claimant's case was that, if she had been warned, she would have delayed the operation to reconsider and take a second opinion. Giving judgment in her favour, Lord Steyn said that:

> 'In modern law medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small, but well established, risk of serious injury as a result of surgery.'

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Although not expressly endorsing the principle of informed consent, this heralds its introduction and illustrates how the tort[b] of negligence is not free-standing and gives practical expression to rights-based requirements.

The judgment of the Supreme Court

Seven Supreme Court justices heard Mrs Montgomery's case. Lord Kerr and Lord Reed gave the leading judgment, with which four other Law Lords agreed. Lady Hale gave a separate concurring judgment.

If the patient doesn't ask

Their Lordships found profoundly unsatisfactory the significance attached in *Sidaway* to a patient's failure to question the doctor:

> 'In the first place, as Sedley LJ commented in *Wyatt v Curtis* [2003] EWCA Civ 1779, there is something unreal about placing the onus of asking upon a patient who may not know that there is anything to ask about. It is indeed a reversal of logic: the more a patient knows about the risks she faces, the easier it is for her to ask specific questions about those risks, so as to impose on her doctor a duty to provide information; but it is those who lack such knowledge, and who are consequently unable to pose such questions and instead express their anxiety in more general terms, who are in the greatest need of information. Ironically, the ignorance which such patients seek to have dispelled disqualifies them from obtaining the information they desire. Secondly, this approach leads to the drawing of excessively fine distinctions between questioning, on the one hand, and expressions of concern falling short of questioning, on the other hand. Thirdly, an approach which requires the patient to question the doctor disregards the social and psychological realities of the doctor-patient relationship, whether in the time-pressured setting of a GP's surgery or in a hospital setting. Few patients do not feel intimidated or inhibited to some degree.'

Moving with the times

Their Lordships said that:

> 'since *Sidaway* it has become increasingly clear that the paradigm of the doctor-patient relationship implicit in the speeches in that case has ceased to reflect the reality and complexity of the way in which healthcare services are provided, or the way in which the providers and recipients of such services view their relationship. One development is that patients are now widely regarded as persons holding rights, rather than as being passive recipients of care. They are also widely treated as consumers exercising choices.'

They found that:

> 'Other changes in society, and in the provision of healthcare services, should also be borne in mind. One is that it has become far easier, and far more common, for members of the public to obtain information about symptoms, investigations, treatment options, risks and side-effects via such media as the internet (where, although the information available is of variable quality, reliable sources of information can readily be found), patient support groups, and leaflets issued by healthcare institutions. The labelling of pharmaceutical products and the provision of information sheets is a further example. It is of particular significance because it is required by laws premised on the ability of the citizen to comprehend the information provided. It would therefore be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent upon a flow of information from doctors. The idea that patients were medically uninformed and incapable of understanding medical matters was always a questionable generalisation, as Lord Diplock implicitly acknowledged by making an exception for highly educated men of experience such as judges like himself. To make it the default assumption on which the law is to be based was now manifestly untenable.'

The medical profession in step

These developments are already reflected in professional practice, as their Lordships noted. *Good Medical Practice* (General Medical Council (GMC) 2013) states, in the 'Duties of a doctor':

> '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.

BOX 7 Lord Bridge and 'The reasonably prudent doctor test'

Although the issue did not strictly arise in the *Sidaway* case, Lord Bridge said that a doctor had a duty to answer both truthfully and as fully as necessary a patient of sound mind who asked about the risks involved in a particular treatment that was being proposed.

The nub of Lord Bridge's judgment was that it was primarily a matter of 'clinical judgement' as to what degree of disclosure was best calculated to assist a particular patient to make a rational choice as to whether or not to undergo a particular treatment and how best to communicate to the patient the significant factors necessary to enable the patient to make that choice. Like Lord Diplock, he emphasised patients' lack of medical knowledge and their vulnerability to making irrational judgements.

Lord Bridge rejected the notion that a patient should be warned of all risks, but equally would not countenance the doctor being allowed to withhold, in the patient's best interests, so as not to alarm the patient, a warning of a grave and substantial risk. He gave the example of a 10% risk of stroke where 'no *reasonably* prudent medical man' [my italics] would fail to mention the risk unless there was some 'cogent clinical *reason*' [my italics] not to do so. There are parallels here with the later case of *Bolitho*, which explicitly qualified *Bolam* by adding the requirement that there had to be evidence that the course of action in question had a *reasonable* [my italics] basis and followed a consideration of the risks and benefits. So, by adding a requirement of the reasonableness of the decision not to disclose a risk, having regard to the nature and degree of the risk, Lord Bridge was applying a modified Bolam test.

(*Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985])

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b. Tort means a harm or wrong, and in this context it refers to a wrongful act or omission for which damages can be obtained; a tort can also be a breach of contract and many torts are also crimes, e.g. the tort of battery is the crime of assault.

- Respect patients' right to reach decisions with you about their treatment and care.'

Consent: Patients and Doctors Making Decisions Together (GMC 2008: pp. 6–7) describes a basic model of partnership between doctor and patient:

> 'The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice.
>
> The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one.'

In relation to risks, in particular, it advises that the doctor must tell the patient if treatment might result in a serious adverse outcome, even if the risk is very small, and should also tell the patient about less serious complications if they occur frequently. It is therefore clear that the GMC has for many years recognised the importance of informed consent without, probably deliberately, using the term.

Back to basics

One effect of the Human Rights Act 1998 has been for the courts to become increasingly conscious of the extent to which the common law reflects fundamental values. These include the value of self-determination as Lord Scarman pointed out in *Sidaway*, the value that also underlies the right to respect for private life protected by Article 8 of the European Convention on Human Rights. The resulting duty to involve the patient in decisions relating to their treatment has been recognised not only in judgments of the European Court of Human Rights, but also in a number of decisions of UK courts. Various international instruments also more specifically reflect this value.

The demise of medical paternalism

The social and legal developments that their Lordships mentioned point away from a model of the doctor–patient relationship based on medical paternalism. They also point away from a model based on a view of the patient as being entirely dependent on information provided by the doctor. What they point towards is an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors, treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks and living with the consequences of their choices.

Some practical implications

Their Lordships drew attention to three important points:

> '[Firstly, the assessment of] 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: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to them of the benefits sought to be achieved by the treatment, the alternatives available, and the risks these involve. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.
>
> Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role requires the information provided to be comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.
>
> Thirdly, it is important that the therapeutic exception should not be abused [...] it is not to permit a doctor to prevent a patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests.'

Justice for Mrs Montgomery

Their Lordships found that there could be:

> 'no doubt that it was incumbent on the obstetrician to advise Mrs Montgomery of the risk of shoulder dystocia if she were to have her baby by vaginal delivery, and to discuss with her the alternative of caesarean section'.

Although it was the obstetrician's policy to withhold information about the risk of shoulder dystocia from her patients because they would otherwise request caesarean sections:

> 'the "therapeutic exception" is not intended to enable doctors to prevent their patients from taking an informed decision. Rather, it is the doctor's responsibility to explain why she considers that one of the available treatment options is medically preferable to the others, having taken care to ensure that her patient is aware of the considerations for and against.'

The concurring judgment of Lady Hale

Lady Hale said that it could now be stated, to quote Grubb *et al* (2010), 'with a reasonable degree of confidence' that the need for informed consent was firmly part of English law. This case, she continued, had provided the Supreme Court 'with the opportunity, not only to confirm that confident statement, but also to make it clear that the same principles apply in Scotland'.

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She said that it is:

> 'now well recognised that the interest which the law of negligence protects is a person's interest in their own physical and psychiatric integrity, an important feature of which is their autonomy, their freedom to decide what shall and shall not be done with their body'.

She then quoted Herring (2012):

> 'the issue is not whether enough information was given […] but whether there was enough information given so that the doctor was not acting negligently and giving due protection to the patient's right of autonomy.'

An important consequence of this, she said, was that:

> 'it is not possible to consider a particular medical procedure in isolation from its alternatives. Most decisions about medical care are not simple yes/no answers. There are choices to be made, arguments for and against, and sufficient information must be given […] That is not necessarily to say that the doctors have to volunteer the pros and cons of each option in every case.'

Lady Hale said that a patient is entitled to take into account her own values, her own assessment of comparative merits, irrespective of what medical opinion may say, alongside the medical evaluation of the risks. She may be prepared to take risks. Unless she lacks the legal capacity to decide, the medical profession must respect her choice. But she cannot force her doctor to offer treatment which the doctor considers futile or inappropriate. And at least she is entitled to the information that will enable her to take a proper part in the decision-making.

BOX 8 Ten basic principles distilled from *Montgomery*

1. The right to accept or refuse treatment is a basic human right
2. The doctor has a duty to inform the patient of the material risks; the onus is not on the patient to ask
3. The threshold is lower for those who lack knowledge or express anxiety only in more general concerns
4. The doctor has a duty to provide sufficient information for the patient to make an autonomous decision
5. Frequently occurring but less serious outcomes may be as important to the patient as serious outcomes of which the risk is small
6. The doctor has a responsibility to explain which is the medically preferred option and why
7. The doctor must not assume that the patient is medically uninformed or incapable of understanding medical matters
8. Whether a risk is material is to be judged by what a reasonably prudent patient in the situation of the patient would regard as a significant risk; a material risk is not a matter of clinical judgement
9. The patient is entitled to take into account non-medical matters such as their circumstances, objectives and values
10. The doctor must respect the patient's decision even if it is not the medically preferred option

BOX 9 Putting the principles into practice

Decide whether the patient has the capacity to make the decision:

- Can the patient understand the potential benefits, risks, burdens and side-effects of each option (including the option of no treatment)?
- Can the patient understand the information relevant to these issues?

Allow sufficient time for the patient to make their decision

Create a consultation in which the patient does not feel intimidated or inhibited

Consider the patient's need for support, for example by an advocate, relative or friend

Decide whether communication of the risk(s) would be detrimental to the patient's health

Make sure you understand, so far as is reasonably possible, the patient's relevant circumstances, objectives and values; be sensitive to these and be prepared to probe the patient's priorities, preferences and concerns so that you can tailor your disclosure accordingly

Decide what a reasonably prudent patient in the situation of the patient would regard as a significant risk

Be familiar with, and able to discuss, the frequently occurring but less serious outcomes of the proposed treatment as well as the serious outcomes of which the risk is small

Use clear, simple and consistent language; if necessary, use an interpreter

Consider providing simple and accurate written information about the decision that is being made

Distilling the principles

Box 8 shows the ten important principles that can be derived from the Supreme Court's analysis of the law in *Montgomery*.

Implications for psychiatric practice

In mental healthcare, consent now means informed consent that stands up to the scrutiny to which a court might subject it in the light of *Montgomery* in the event of an action for negligent pre-intervention non-disclosure (Box 9). Informed consent is needed for drug therapy, psychological therapy, occupational therapy, electroconvulsive therapy (ECT) and psychosurgery.

The challenges to psychiatry are probably not very different in nature from those in other areas of medicine, but some may occur more commonly in mental healthcare. It will be a challenge to ensure that people with intellectual disabilities have treatment options explained to them with sufficient simplicity; this challenge will face all doctors, but it will arise more often for those working in intellectual disability services. In the case of patients whose mental health is already

compromised, it will be a challenge to decide whether or not the therapeutic exception applies and information should be withheld so as not further to damage their mental health; but this may apply as much to a surgeon who proposes to amputate a gangrenous foot as to a psychiatrist seeking consent for ECT. Where, in the past, a paternalistic approach may have led psychiatrists to restrict to a minimum the information provided to patients about the potential benefits, risks, burdens and side-effects of treatment, it may be that imparting significantly more information will reveal issues about understanding that call into question patients' capacity to consent. Although most mental healthcare is now delivered in the community and any institutional care for the mentally unwell is, for most, short-term, there are still many psychiatric patients in long-term hospital and other residential care where paternalistic attitudes may persist and there will be a challenge to ensure that such attitudes do not prevent the introduction of informed consent. Another challenge that will be understood by psychiatrists, but not limited to their practice, is that posed by a patient with a personality disorder; it is one thing to tailor disclosure of information to the reasonable person in the patient's position, but it may be quite another to tailor it to the unreasonable person in the patient's position.

Preparation

To obtain informed consent, mental health professionals must be familiar with the potential benefits, risks, burdens and side-effects of each treatment. This includes the less serious but frequently occurring side-effects, as well as the more serious but rarely occurring side-effects. It may be helpful to provide this information in written form, but the patient should not be bombarded with information or baffled with statistics. Providing, as already often happens, a patient information leaflet when prescribing a particular drug is not a substitute for a dialogue in which the doctor finds out what the patient wants to know, considers what the reasonably prudent patient would want to know and explains the information in language that the patient can understand.

Today's patients are now better informed. However, there is a great deal of misinformation, especially on the internet. The well-prepared mental health professional should be familiar with the readily available misinformation that may influence the patient's thinking.

It is also necessary to be familiar with the patient. This is a further argument for resurrecting, or reintroducing into the mainstream of mental healthcare, the formulation. Diagnosis is not enough. It is not a question of what to tell a patient with schizophrenia about the relative benefits of oral and depot antipsychotics. The patient's decision will be influenced by what the court calls their characteristics, circumstances, objectives and values. What to tell is no longer decided objectively by the doctor. It depends on the patient. It may not be possible to know all of the relevant characteristics, circumstances, objectives and values that may influence the patient's decision. However, it is reasonable to expect that a doctor, before seeking a patient's consent, will refresh their memory as to the salient aspects of their patient's formulation or construct a formulation, even if this requires additional history-taking or enquiry.

In any case of consent there is the issue of capacity to consent to treatment. This judgment does not alter the fact that consent is only valid if the patient has the capacity to consent. It is therefore a preliminary consideration whether or not the patient can understand and retain information about the potential benefits, risks, burdens and side-effects of the proposed treatment and use or weigh that information as part of the process of deciding whether to take the treatment or of deciding which treatment to take. If capacity is in doubt, allow sufficient time to address this at the beginning of the consultation.

The consultation

There should be sufficient time for the consultation. The patient should not feel pressured or hurried. Although the courts recognise the limitations imposed when staffing and resources are limited, it is clear that they will expect reasonable steps to be taken to ensure that there is sufficient time.

There is evidence that the involvement of relatives in decision-making helps the patient towards greater autonomy (Gilbar 2011). Consider what support may assist the patient.

Seeking informed consent is not about getting a signature on a form, however detailed may be the written explanation of the proposed treatment. It is a partnership. This means creating a dialogue. Find out what the patient knows, what they do not know and what they want to know. Be alert to, and seek to elicit, the unspoken questions that you would expect the reasonably prudent patient, in their circumstances and with their characteristics, to ask.

Provide a choice. Respect the choice. It is their choice and not yours. However, if there are good medical reasons for believing that it is the wrong choice, make those reasons clear.

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Do not assume that, perhaps as a result of their mental condition, the patient does not want to know what the treatment involves. It is no longer the case, as was said in *Bolam*, that 'you may well think that when dealing with a mentally sick man and having a strong belief that his only hope of cure is ECT treatment, a doctor cannot be criticized if he does not stress the dangers which he believes to be minimal involved in that treatment'. Remember that the patient who lacks knowledge, perhaps as a result of an intellectual disability, or expresses their anxiety about the treatment only in more general terms, may be in particular need of a dialogue that enables them to articulate their concerns and of sufficient information to allay anxiety and allow an informed choice.

Not more forms?

It is to be hoped that, as informed consent becomes embedded in mental health practice, it will not require the creation of more forms. However, there may be a case for making consent forms more detailed and providing patients with a copy. That said, a signature at the end of the form will be of questionable value if the patient did not read the form, if they do not understand the information on the form, if their signature was obtained under pressure of time, intimidation or in circumstances that call into question the validity of their consent. Obtaining a signature is not a substitute for a patient-centred dialogue about the proposed treatment.

There may be a case for obtaining written consent for certain treatments for which written consent has not hitherto been obtained. This should not be in order to seek to prove subsequently, if something goes wrong or a complaint is made, that informed consent was obtained. It may, but equally it may not, be accepted as evidence of such. The value is in providing the patient with a document that informs them about the treatment to which they have consented.

Conclusions

The legal approach to consent in the UK (Jackson 2016) most commonly engages the tort of negligence and only rarely the tort of battery. Complying with the duty to obtain consent prior to treatment protects against the tort of battery; actions for battery are rare because obtaining consent prior to treatment is routine. Complying with the duty to ensure that the patient has been given sufficient information to consent protects against an action for negligent pre-intervention non-disclosure. However, the concept of informed consent is inherently problematic as it immediately begs the question 'informed of what?' or 'what should be disclosed?' As Jackson (2016) asks: 'How much information is required in order to fulfil the doctor's duty of care?' *Montgomery* sets out in some detail of what a patient is to be informed, although that will vary from patient to patient and the responsibility rests with the doctor to take all reasonable steps to ascertain what a particular patient will want to know.

Although English (and Scots) law has come very late to an endorsement of what has been endorsed for many years in other common law jurisdictions, the fact that elements of the doctrine of informed consent have been promulgated for many years by the GMC with its partnership model of medical decision-making means that doctors do not face a dramatic change in their approach to consent. There is no reason to fear that it calls for such radical changes that clinical practice will implode or grind to a halt; this has not happened elsewhere in the common law world. *Montgomery* is not to be viewed only in positivist legal terms, as a change of practice enacted by the authority of the Supreme Court as it were, but as the expression or culmination of a gradual sea change in the approach to consent based on moral considerations, including rights-based requirements and, not least, the right to respect for autonomy. Indeed, the more closely the implications of *Montgomery* are compared with existing GMC guidelines, the more it begins to appear that what *Montgomery* has done is to align the standard of care in tort law with that in existing guidance.

No one would have wished on Nadine Montgomery a severely disabled son, but out of their tragedy informed consent has now arrived in the law of the UK. It is now incumbent on mental health professionals to put that law into practice, thereby enabling psychiatric patients to achieve greater autonomy and self-determination.

MCQ answers
1 e 2 a 3 b 4 d 5 e

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MCQs

Select the single best option for each question stem

1 Informed consent:

a is an example of medical paternalism
b was introduced into UK law in 1972
c is based on the Bolam test
d is exemplified by Lord Diplock's judgment in *Sidaway*
e is exemplified by the approach of the Supreme Court in *Montgomery*.

2 In the Sidaway case:

a Lord Scarman proposed 'the prudent patient test'
b Mrs Sidaway alleged that her surgery had been performed negligently
c Lord Scarman found in favour of Mrs Sidaway
d extreme positions were taken by Lord Bridge and Lord Templeman
e Lord Diplock made no distinction between patients according to their level of education.

3 The case of *Pearce*:

a had the effect of making the judgment in *Sidaway* no longer binding
b introduced the concept of 'the reasonable patient'
c introduced 'the blissfully ignorant patient test'
d stands alone in representing a departure from *Sidaway*
e was hailed as demonstrating that in modern law medical paternalism no longer rules.

4 Nadine Montgomery's case:

a was that her concerns about shoulder dystocia and cephalopelvic disproportion were disregarded by her obstetrician
b was unsuccessful in the first instance in the Outer House of the Court of Session, but successful on appeal to the Inner House
c provides a defence to a doctor who fails to disclose information about a material risk on the basis that the patient did not ask
d provides confirmation that informed consent is now firmly part of English law
e provides a basis for a patient insisting on treatment, however futile or inappropriate the doctor considers it to be.

5 When seeking informed consent from a patient:

a it is not necessary to take into account the patient's circumstances, as the standard is a medically objective one
b there is an onus on the patient to ask about the risks
c what is a material risk is a matter of clinical judgement
d it is important for the doctor not to indicate what is the medically preferred option
e the duty of the doctor is to provide sufficient information for the patient to make an autonomous decision.

BJPsych Advances (2017), vol. 23, 63–72 doi: 10.1192/apt.bp.116.015990