

# Risk management The changing face of consent: past and present

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The law of consent is moving towards a more patient-centred standard of disclosure in order to safeguard the patient's autonomy and right to self-determination. The well-known Bolam principle upon which clinicians rely is now being challenged. This review looks at the law of consent as it currently stands and how it is evolving. All healthcare professionals should take these changes seriously and reconsider the way in which they practise. Sufficient resources — more time, in particular — are needed to train clinicians to communicate more effectively with their patients.

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## Introduction

The law relating to consent is evolving and becoming increasingly complex. It is now recognised both professionally and legally that it is the doctor's duty to reinforce the rights of patients to consent to or refuse treatment by providing them with appropriate information. Consent, and the need for it, is a legal reflection of the ethical principle of respect for the patient's individual autonomy. In a qualitative study by Habiba *et al.*<sup>1</sup> those women questioned perceived the process of consent for gynaecological surgery as ritualistic and bureaucratic, thus appearing to legitimise the decisions and actions of the doctor, rather than empowering the patient. Such a process is likely to impair trust and confidence between the doctor and patient.

## The cost and type of litigation

According to the NHS Litigation Authority, in 2003–2004 there were 6251 claims of clinical negligence, amounting to payments of £422.5 million in connection with these claims.

**Table 1** shows how these cases were settled. The estimate of total liabilities (the theoretical cost of paying all the outstanding claims immediately) is £7.78 billion for clinical claims. Obstetrics and gynaecology represents the greatest proportion of the total value of claims. In a study by B-Lynch *et al.*<sup>2</sup> of 500 cases involving medico-legal obstetric and gynaecological claims, 7% were the result of failures of communication. This failure to communicate, often resulting from inadequate consent, accounted for about £30 million in litigation claims in 2004.

Following the problems highlighted after the Bristol Royal Infirmary and Alder Hey inquiries,<sup>3–4</sup> the General Medical Council (GMC), Department of Health, British Medical Association and other professional bodies (including the RCOG) have issued specific instructions on the standard of obtaining consent, to which doctors and Trusts are expected to conform.<sup>5–8</sup> The GMC has the power to deregister any clinician who is in breach of these principles.

## What is consent?

Legally, patients can pursue a remedy in the civil courts for having been deliberately touched without consent (battery) or for not having

received enough information about the risks of the proposed procedure (negligence).

A valid consent therefore licenses what would otherwise be unlawful. Consent is only valid if:

- It is given by a legally competent person.
- It is real, i.e. the patient has been adequately informed. 'Adequate' information can be defined as sufficient to enable the patient to understand in broad terms the intention, nature and purpose of what is intended.
- It is given freely, i.e. voluntarily and not because of undue pressure or influence by another or by fraud.

The overall burden of proving lack of consent is upon the patient. In other words, intentional touching is not *prima facie* unlawful unless the patient can prove otherwise. The doctor can at least raise consent as a defence of invasive treatment. In Canada and Australia, the burden is reversed, such that the doctor has to prove consent. This is more in keeping with the patient's right to bodily integrity.

## What is capacity?

In order to give valid consent, the patient must have capacity. Capacity does not relate to the appropriateness of the final decision, but to the way in which the patient arrives at that decision. A patient can make an irrational decision and yet be deemed to have capacity. It is possible for someone who has a mental disorder to be legally capable of making a competent medical decision. Capacity is a legal concept. Patients who lack capacity can still be treated if it is deemed to be in their 'best interests', in which case a court order may be required. When treatment is proposed in the patient's best interests, it is still considered 'good practice'<sup>9</sup> or possibly a legal requirement<sup>10</sup> to apply to the court for a declaration that the treatment will be lawful. 'Best interests' means any treatment that is necessary to 'preserve the life, health or wellbeing of the patient and for the patient's welfare', such as dressing wounds, washing and feeding, etc. If this decision is later challenged, then the Bolam principle<sup>11</sup> could be used as a defence for the doctor, although it may not be available if a doctor comes to a decision which proves to be wrong and where the law requires referral to court. Relatives have no right to consent on behalf of an incompetent patient (Department of Health)<sup>12</sup> unless they have been given legal proxy as stated in the new Mental Capacity Act 2005.

Thus, patients having legal capacity would include:

**Table 1**  
Outcome of claims for clinical negligence against the NHS up until March 2004

Outcome	Percentage
Abandoned by patient	35
Settled out of court	43
Settled in favour of patient	1.5
Settled in favour of NHS	0.5
Outstanding	20
<b>Total</b>	<b>100</b>

- Individuals above 16 but under 18 years of age. They can give consent and they have the capacity to refuse consent, which can be overridden by a parent or a court.<sup>13</sup>
- Individuals who are under 16 years of age can give consent if, in the opinion of the doctor, they are capable of understanding the 'nature and possible consequences of the procedure'. Such people are deemed 'Fraser competent',<sup>14</sup> and can refuse treatment, but that refusal can be overridden either by a parent or the court.<sup>15</sup>
- Anyone over the age of 18 years with capacity.

To have sufficient capacity there must be (see **Box 1** for incapacity):

- An ability to comprehend and retain information.
- A belief in the information.
- An ability to balance the pros and cons of the proposed treatment in order to make a choice.

It, therefore, follows that patients must be able to understand the concept of probability information in relation to treatment risks and benefits. Fuller *et al.*<sup>16</sup> were able to show that, regardless of age, all patients had the potential to misinterpret probability information, which could impact on informed consent. In this study, 16% of patients thought that a one in five risk and a 5% risk were identical, and 27% confused one in 20 and 20%. These are worrying findings which cast doubt on the capacity of patients of all ages. Doctors must therefore be able to explain medical information in laymen's terms. Pictorial representation of probability may be a better tool with which to help patients come to a more meaningful decision prior to treatment or surgery.

## Types of consent

Consent can be 'express' or 'implied'. It need not necessarily be in writing to be valid in law, although it would be evidentially more certain when written. Implied consent could be inferred from the outward appearance and conduct of the patient, leading to the conclusion that the patient had consented to the procedure or treatment. A signature on a consent form prior to surgery does not in itself constitute a valid consent if the patient has not actually understood what is proposed. It is the actual state of the mind of the patient that is crucial. Consent that is expressed in form only is no consent at all. In *Pridham v Nash*<sup>17</sup> the Claimant consented to a diagnostic laparoscopy for pelvic pain and signed the consent form, which stated that she also agreed to 'additional or alternative procedures as may be necessary or

### Box 1

#### Legal definition of incapacity

A patient has incapacity when, if at the material time, she:

- is unable to understand relevant information
- is unable to retain the information
- is unable to weigh up the information and make a decision based on it
- is unable to communicate her choice because of unconsciousness or pain

medically advisable during the course of the procedure'. During the procedure the surgeon discovered pelvic adhesions and divided them laparoscopically. Unfortunately, the patient later developed peritonitis and sued the doctor for battery, claiming she had not consented to the adhesiolysis. The judge disagreed with her and concluded that the additional procedure was 'simple and minor' and thus fell within the words of the consent form. However, the judge went on to add that if during the laparoscopy the surgeon had discovered something more 'major' then the surgeon would not have been able to rely on the original consent.

Once consent has been given, the patient still has the right to withdraw it and thus to continue would be unlawful. However, withdrawal of consent can only be valid if the patient has the capacity in law to do so. Capacity can fluctuate; for example, when the patient is unconscious, sedated or in pain.<sup>18</sup> In *Mitchell v McDonald*<sup>19</sup> the Claimant's cry of 'for God's sake stop' while having a steroid injection, was regarded by the judge as a 'cry of pain' rather than an attempt to withdraw consent. In contrast, in *Nightingale v Kaplovich*<sup>20</sup> a scream of 'stop, I can't take any more' during a sigmoidoscopy, was held to be a withdrawal of consent by the patient and therefore the doctor was held liable in battery. Both these cases are Canadian, and there is no relevant English case law. The right to withdraw consent is not absolute where it would be either life threatening to do so or would pose immediate and serious problems to the health of the patient.

## How much information needs to be disclosed?

Sufficient information must be given to the patient in broad terms of the nature and purpose of the procedure that is being proposed (**Box 2**). The doctor also has a duty to discuss all alternative treatments and the risks and adverse effects that might be expected. The standard required has been that of the Bolam principle, i.e. 'a reasonably competent medical practitioner professing to have those same skills'. Even if there were a contrary body of opinion, albeit a minority, that would have done otherwise, then the defence would still stand. Clearly, this test has an element of

**Box 2****The level of information needed for the patient to be fully informed in broad terms**

- the nature of the intended intervention
- the purpose of the treatment
- the known risks and benefits of the treatment (including the percentage risk if known)
- the known risk of not carrying out the procedure (including the percentage risk if known)
- the known risks and benefits of alternative intervention (including the percentage risks if known)

subjectivity and reflects a philosophy of paternalism. In a Canadian study by Zupancic *et al.*,<sup>21</sup> patients were asked to complete a questionnaire assessing recall of management after counselling for impending preterm delivery. The study showed that 27% of women would have preferred to be advised by the doctor rather than having to decide for themselves.

Disclosure of risks was tested in the landmark case of *Sidaway v Bethlem Royal Hospital Governors*.<sup>22</sup> The claimant underwent a neck operation to relieve pain. She claimed that she had not been warned of the 1–2% risk of spinal cord damage, which she unfortunately suffered. The case of *Sidaway* suggests ‘material risks must be disclosed’

**Box 3****Reasons for application for court orders in ‘best interests’ scenarios**

- Proposed withdrawal of artificial nutrition and hydration (ANH) from a patient in a permanent vegetative state.
- Other cases where withdrawal of ANH is proposed where there may be:
  - doubt or disagreement as to the patient’s capacity
  - disagreement between health professionals
  - evidence that if competent the patient would have wanted treatment to continue
  - where there is disagreement of the close family or similarly interested persons with the assessment of best interests by the healthcare professionals.
- Proposed sterilisation of an incompetent patient.
- Proposed termination of pregnancy:
  - where there is dispute over capacity
  - where there is a realistic prospect that the patient will regain capacity within a short period
  - where there is disagreement between healthcare professionals as to best interests
  - where the Abortion Act 1967 procedures have not been properly followed
  - where family members or similarly interested persons (including the father of the fetus) oppose the termination or express views inconsistent with it, or where there are other exceptional circumstances
- Where the proposed treatment may involve force to restrain the patient, where the patient may resist it, where it carries significant risk or where it will have serious irrevocable effects.

subject to ‘therapeutic privilege’. Thus, if a patient asks certain questions, the doctor must answer in a ‘full and truthful manner’. This is not governed by the Bolam principle. Even if no other doctor who had been asked a specific question would impart the whole truth, this will not provide a defence for the doctor. The doctor must also communicate those risks which are so ‘obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it’ regardless of responsible medical opinion.<sup>22</sup> Failure to do so will not be saved by Bolam. ‘Therapeutic privilege’ allows the doctor to withhold information if he considers it is in the patient’s best interests (Box 3). The case of *Sidaway* rejected the concept of ‘informed consent’ and the ‘prudent patient test’ and confirmed Bolam. However, the decision in *Bolitho v City and Hackney Health Authority*<sup>23</sup> has marked the beginning of the undermining of Bolam, by adopting the view that the content of the duty to inform is a matter for the court to determine and not a reasonable body of professionals, as in Bolam. This was highlighted in *Pearce v United Bristol Healthcare Trust*<sup>24</sup> in which the Claimant suffered a stillbirth after seeking advice from the consultant, who advised waiting for spontaneous labour rather than induction of labour or elective caesarean section. Mrs Pearce argued that had she been told of the increased risks of stillbirth beyond 42 weeks she would have opted for an earlier delivery. She lost her appeal because the risk of stillbirth was estimated to be 1–2 in 1000, and in their opinion the experts did not think that this was a significant risk. In addition, the court took the view that, even if she had been advised of this risk, she would have opted to wait. The judges did rule that ‘significant risks’, i.e. risks that can affect the judgement of a reasonable patient, should be explained to the patient.

Concerns exist in the area of poor communication and negligent failure to inform. In *Carver v Hammersmith and Queen Charlotte’s SHA*,<sup>25</sup> the issue involved the negligent failure of the doctor to provide adequate information about the Bart’s test, which led the patient to misunderstand the results and her subsequent decision. She claimed damages for the wrongful birth of a baby with trisomy 21. The Claimant was adamant that she did not want a handicapped child, since her occupation involved working with them. When she became pregnant she requested an amniocentesis but was refused one under the hospital policy; she was offered a Bart’s test instead. She mistakenly believed that this test would determine whether or not she would have a child affected by trisomy 21. Although her risk was screen negative she had a child affected by trisomy 21 and claimed that, had she known this, she would have requested a termination. The

Claimant won because it was held that the doctor breached his duty by not advising the patient correctly.

## Informed consent

Recent case law has brought English law one step closer to the doctrine of informed consent. As the law currently stands, consent to treatment is invalidated if the patient is given inadequate information concerning the proposed treatment. When this happens the patient is entitled to claim damages for battery, even though he or she has signed the consent form. In the case of *Chester v Afshar*,<sup>26</sup> the Law Lords effectively discarded the principles of causation where a doctor failed to obtain a patient's fully informed consent. The Claimant consulted a neurosurgeon complaining of back pain and opted for elective spinal surgery, following which she developed paralysis. Although disputed, it was found that the surgeon had failed in his duty to warn her of the 1–2% risk of paralysis. It was also accepted that it was good medical practice to warn patients of these risks. The Claimant stated that, had she been so advised, she would have delayed the operation until at least the following week in order to obtain a second opinion and admitted she would have eventually had the surgery. Unfortunately, she developed cauda equina syndrome, despite the fact that the surgery had been performed skilfully and without negligence. On traditional principles, having established a failure to warn, the next step would be to convince the court that the Claimant would not have undergone surgery had she been aware of the risk. Thus, causation would be proved and the Claimant would win. However, the judges found in the Claimant's favour by taking the view that the test of causation had been satisfied on public policy grounds. Public policy is that the patient's autonomy and dignity should be respected to allow her to make an informed decision. Lord Steyn argued that 'but for the surgeon's negligent failure to warn the Claimant of the small risk of serious injury the actual injury would not have occurred when it did and the chance of it occurring on a subsequent occasion was very small.'

What are the implications of this case? Doctors will now have to take extreme care in documenting what they say to patients. It is even more important that doctors take extreme care in ensuring that patients are fully informed and that they understand the information and are given sufficient time to digest it. Nothing has changed with regard to the doctor's duty to inform. The effect of the judgement made by the House of Lords is to broaden the category of patients who could successfully claim if not adequately informed. They would be able to claim even if the patient could not say that, given the same inherent

### Box 4

#### Good practice points

- Always ask the patient if she has fully understood the information and whether she would like any more before she makes a decision.
- Always answer all questions as fully and honestly as possible.
- Ensure that the patient has had enough time to fully digest and think about the information prior to signing the consent form.
- Always make contemporaneous notes: write down a list of all the known risks and complications that you told the patient about or else state that the patient information leaflet has been read and understood by the patient.
- Remember that no one can consent on behalf of a competent patient.

risks, they would not have had the same treatment. The only patient who would now fail the issue of causation would be one who would have agreed to the procedure at the same time in the hands of the same surgeon. There is now, however, a remedy to patients for injury sustained from a risk of which they were not warned and which materialises. This case will not necessarily open the floodgates for further litigation because the situation still remains that claimants still have to prove that had they received the warning they would have acted differently.

## Conclusion

In the light of the *Chester v Afshar*<sup>26</sup> case, we now have the doctrine of informed consent in UK law. Doctors are now advised to take particular precautions when dealing with issues of duty to warn. More attention to warning patients of all material risks is needed. A 'material' risk is one in which if, in the circumstances of the particular case, 'a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it'.<sup>22</sup> The percentage likelihood of the risk should be given wherever possible. The doctor must also ensure that the patient understands the risk and has had time to digest it and think about it.

Detailed notes must be kept of the actual advice given to patients. In a study<sup>27</sup> of women who had consented during labour to epidural analgesia, 33% could not recall any discussion of risks when interviewed 48 hours past delivery. However, women who attended antenatal classes had better recall of specific risks. Thus, retention of information in labour was poor. A checklist and patient information leaflets are valuable, ensuring the quality and consistency of information given. Once this information has been given the patient should sign it to confirm that it has been given and understood.

Like it or not, the move from the paternalistic Bolam principle towards a more objective standard of disclosure, in the form of the doctrine of informed consent, is now upon us. It is important that doctors demand the resources and time necessary to implement these changes if we are to improve the already strained doctor–patient relationship (**Box 4**).

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