A fundamental problem of consent

John Mitchell

A consultant anaesthetist gave a diclofenac suppository for postoperative pain to a patient having four teeth extracted under general anaesthesia in the dental surgery. He did not seek the patient's specific consent preoperatively for use of the suppository but told her afterwards what he had done. Charged before the professional conduct committee of the General Medical Council with failure to obtain informed consent and assault, the anaesthetist was found guilty of serious professional misconduct and admonished. This decision has far reaching implications and has caused great concern.

Consent and a patient's right to self determination are at the root of many important problems in medical ethics. In recent years consent, or the lack of it, has also become an increasingly common issue in medical negligence litigation. By contrast, the failure by a doctor to obtain consent to bona fide treatment has rarely if ever been the sole foundation for a finding of serious professional misconduct. I report a case recently brought before the professional conduct committee of the General Medical Council in which such a decision was reached.

Basis of charge

The facts of the case were simple. A 22 year old woman attended her local dental surgery for extraction of two wisdom teeth (lower eights) and two other teeth (lower fours). She knew that she was to have a general anaesthetic and gave her consent both verbally and by implication. She signed a form which stated: "I would like the dentist named overleaf to examine me under the NHS and to give me every necessary care and treatment which I am willing to undergo within NHS arrangements." Not unusually, there was no consent form specifically for the anaesthetic. Though the Poswillo report recommended that a national general anaesthetic consent form should be devised for general dental practitioners,¹ none has been produced.

The extractions were carried out safely and successfully. The anaesthetic was given by the respondent, a consultant anaesthetist of 10 years' standing, who was highly experienced in giving dental anaesthetics both in hospital and in dental surgeries. During the procedure, and while the patient was still unconscious, the anaesthetist loosened (but did not remove) the patient's clothing and inserted a diclofenac suppository for pain relief in the immediate postoperative period. The suppository was inserted in the presence of the dentist and two women dental surgery assistants. Pain relief had not been discussed with the patient beforehand, and in particular she had not been asked specifically whether she agreed to the insertion of a suppository. In accordance with the anaesthetist's usual practice, however, after treatment had been completed he told the patient and her husband about the suppository while she was in the recovery room.

Unfortunately, the anaesthetist had inadvertently inserted the suppository into the patient's vagina. The resulting symptoms led the patient to suspect that she might have been sexually assaulted and she reported the matter to the police. In the light of statements and forensic evidence, however, they rapidly concluded

that there was no question whatever of any sexual assault.

Nevertheless, a report was sent to the GMC and charges formulated against the anaesthetist, of which the following were found proved:

1. Prior to administering the general anaesthetic and when it was so required, you
(a) did not explain to the patient what form the general anaesthetic would take or ensure that this was explained to her;
(b) did not ensure that the patient was told that a [diclofenac] suppository would or might be inserted into her as a form of pain relief;
(c) did not obtain from the patient valid informed consent to the insertion into her of a [diclofenac] suppository;
2. (a) Whilst the patient was under the general anaesthetic you inserted a [diclofenac] suppository into her vagina;
(b) in carrying out this procedure you inserted the said substance without [the patient's] prior valid informed consent and thus assaulted her.

There was no dispute about the relevant facts. The issue was whether a specific separate consent from the patient was required for the insertion of a suppository in these circumstances.

Expert evidence

The anaesthetist maintained that analgesia in the immediate postoperative period was part of his responsibility. As such, the use of a suppository in these circumstances was part and parcel of the general anaesthetic and was covered by the consent for this. As recommended by the Poswillo report,¹ he had simply tried to maintain the same standard of anaesthesia, including pain relief, in the dental surgery as in hospital.

On the respondent's behalf evidence was called from several senior anaesthetists. None had actually given a suppository in the dental surgery. All, however, confirmed that the practice in many hospitals, both in the respondent's own area and nationally, was not to obtain specific consent in advance for the use of diclofenac suppositories, whether these were given in day case units or to inpatients. In this respect suppositories were no different from any other form of postoperative pain relief, including intramuscular injections. These might be given in the buttock and therefore might also entail disturbing or removing clothing on the lower part of the body. In some hospitals the patients were told afterwards that a suppository had been inserted.

The GMC called evidence from other anaesthetists to say that in their hospitals specific consent was always taken for the use of diclofenac suppositories—certainly in day case units and sometimes from inpatients as well. In this context the GMC's experts drew a distinction between suppositories and intramuscular injections and, in particular, drew a distinction between a general dental surgery and a hospital. They said that the expectations and perceptions of a patient who arrived fully clothed in a general dental surgery were completely different from those of a patient who attended even a day case unit. This was despite evidence that the trend in day case units is to make

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them less like a traditional hospital and more “user friendly” and further evidence that in many day case units patients retain at least some of their own clothing. This might include in particular, their lower undergarments, the very presence of which might emphasise that they did not anticipate treatment to the lower part of their body, any more than would a patient in a general dental surgery.

Law of consent

The committee was referred to the case of *Davis v Barking, Havering, and Brentwood Health Authority*, which concerned a caudal block induced by injection during an operation.² In that case, following earlier cases including *Chatterton v Gerson*³ and *Sidaway v Governors of Bethlem Royal Hospital*,⁴ Mr Justice McCullough came down firmly against the idea of separate, “sectionalised” consent for separate parts of the same general anaesthetic. He commented that a “sectionalised approach” to consent would encourage the “deplorable” prospect of actions being brought in trespass rather than in negligence. He went on to say:

The extent of the particularity required, whether by way of detail or by way of explanation of risk, must be for the clinical judgment of the doctor, and in the event of a dispute about either the court will apply the *Bolam* test. Each case must depend on its own facts. Whether a particular aspect of what is proposed is a matter of detail or is in reality a matter sufficiently separate to call for separate mention is a question of fact and degree.

The *Bolam* test (*Bolam v Friern Hospital Management Committee*)⁵ is the proposition that a doctor is not negligent if he or she acts in accordance with a practice accepted at the time by a responsible body of medical opinion, even though other doctors may adopt a different practice. Though under criticism as providing doctors with a more favourable test for negligent conduct than other professions enjoy, *Bolam* is still essentially good law as far as medical negligence is concerned. However, the professional conduct committee’s legal assessor ruled that, though *Davis*, following *Bolam*, was a useful source of general principle, the committee should be cautious about following it blindly. Different considerations applied in a civil court and an allegation of serious professional misconduct involved different procedures and objectives. The committee should apply its own expert knowledge and experience to the whole of the evidence and consider whether in the light of circumstances at the time and generally accepted practice the patient should have been given a preoperative explanation which included specific mention of a diclofenac suppository. Put another way, was the use of a diclofenac suppository such a departure from what the patient might have expected that it should have been explained to her in advance?

Though the legal assessor advised the committee to take into account generally accepted practice, apparently this was not to be regarded as conclusive. If that is right, the rather surprising conclusion is that, unlike in a civil case, in the context of serious professional misconduct a doctor cannot safely assume that he or she will have a good defence merely because he or she follows a practice accepted by a responsible body of other medical practitioners. This would be a substantial extension of the principle⁶ that it is always open to the committee to decide on the evidence that, as a matter of fact, what a doctor did was not actually in accordance with accepted practice.

Against this background the professional conduct committee concluded that no valid consent had been given by the patient to the use of a diclofenac suppository.

Insufficient explanation

The committee also found that the anaesthetist had not provided a sufficient explanation to the patient about “what form the general anaesthetic would take.” In the context of the case this was a fairly small matter but the finding of the committee in this respect may have far reaching implications.

The anaesthetist had told the committee that his practice was simply to explain to a patient that he was the “sleep doctor” and that he was going to put a needle in her arm and that she would go off to sleep. He would also tell her that she was going to be “on television” as the pulse oximeter probe was put on her finger.

The practice of other consultant anaesthetists called both by the GMC and on behalf of the respondent varied in what they told the patient about the form of the anaesthetic. All considered that it was important to explain to the patient that the anaesthetist would remain with her during the anaesthetic and that she would be monitored. Only a few said they would go so far as to explain intubation and other details. All agreed that it was important not to frighten the patient. This was represented on behalf of the council as paternalistic. It was the patient’s right to be frightened and, if the patient so chose, to walk out and not have the operation at all.

It is not clear from the committee’s decision how far it took account of the fact that—perhaps uniquely in the context of anaesthetics—the reason for not frightening a patient before a medical procedure is not merely humane. It is also scientific, as it is more difficult and dangerous to anaesthetise an apprehensive patient who has raised catecholamine concentrations. It is not the apprehensive patient who exercises the right to walk out who is the problem for the anaesthetist, it is the apprehensive patient who stays behind and submits to operation. It was pointed out that the problem of frightened patients is particularly relevant in the case of day patients who do not receive any premedication.

The finding that the respondent did not explain to the patient what form the general anaesthetic would take may well have been inextricably linked to the committee’s unwillingness to accept that consent for the general anaesthetic included consent for the diclofenac suppository. Nevertheless, in the light of the evidence—and as the GMC’s professional conduct committee still does not give reasons for its decisions—it would not be safe to assume that an explanation confined to telling the patient that he or she is going to have an injection and go to sleep will be regarded as sufficient by any future committee.

Assault upon the patient

The argument on behalf of the GMC that there is a distinction between the dental surgery and even a day case unit in hospital such that the use of a diclofenac suppository must be specifically mentioned to a dental surgery patient in advance is clearly tenable, even if the demarcation between dental surgeries and other milieus may not always be clear cut. Notwithstanding the dangers of “sectionalised consent” highlighted in the *Davis* case,² one might therefore not quarrel with the committee’s conclusion that in the particular circumstances of this dental surgery case no valid consent had been obtained for the use of a diclofenac suppository.

More worryingly, however, the committee went on to find that in inserting a suppository the respondent had assaulted the patient. Law reports are full of a frightening array of offensive weapons with which assaults have been committed, including baseball bats, rice flails, broken beer glasses, knives, and, during the Falklands war, a tin of Argentine corned beef.

Bona fide treatment—but has the patient given consent to all aspects?

However, this is no doubt the first time that anybody has been assaulted with a suppository.

It was agreed that as a matter of law⁷ if a doctor genuinely believed that a patient had consented to treatment, then carrying out that treatment would not constitute an assault, however unreasonable the doctor's belief might be objectively. In this case the respondent's evidence was that he had always assumed that the use of a suppository was part of the general anaesthetic and was covered by the consent for the anaesthetic. Furthermore, he had inserted a suppository on many occasions in the past without any patient who had been told about it afterwards objecting or complaining. Evidence from other anaesthetists confirmed that objections to the use of a suppository were extremely rare. Several said that before this case it had never occurred to them to seek a separate consent for the use of a suppository. Nevertheless, the committee found that an assault had been committed.

In reaching this decision the committee no doubt took into account a document which the respondent had drafted some months before the incident which was intended to convey information to a patient in advance about the use of suppositories. This draft document was part of a general review of anaesthetic procedures in the dental surgery, but unfortunately it was never finalised and put into use. The draft document had exposed some potential difficulties of its own and, as the respondent's practice with regard to suppositories had continued uneventfully for years, there did not seem any urgency about changing the procedures. Presumably, however, the committee must have concluded that, as the respondent had given some thought to the question of telling patients about the use of suppositories in advance, he could not have believed unreservedly that he had obtained consent under the umbrella of the general anaesthetic.

There is venerable legal authority for the proposition that changing procedures in the light of an accident is not evidence of negligence before the accident.⁸ Nevertheless, it seems that the danger period for doctors is between first contemplating changes to procedures and putting those changes into effect. The lesson may be that any proposed changes to procedure should be considered, decided on, and implemented as quickly as possible. In more complicated circumstances this may be difficult and result in changes being implemented which have not been fully thought through and which may cause more problems than they solve.

Serious professional misconduct

Undoubtedly the most worrying feature of this case for doctors is that on these facts and findings the respondent was found guilty of serious professional misconduct. Diclofenac suppositories were unanimously agreed to be safe and effective for postoperative pain relief after dental extractions. Many witnesses considered them to be ideal and to retain advantages over even the newest injectable non-steroidal anti-inflammatory drugs. One of the GMC's own experts described the idea of using diclofenac suppositories for pain relief in the dental surgery as "admirable." It is fair to say that the respondent's practice of using these suppositories without specifically mentioning them to the patient beforehand was also variously described as unwise, naive, and even unreasonable. Nevertheless, in the respondent's favour was not only the fact that the treatment was safe and effective but also the evidence on all sides that it had doubtless been given with the best interests of the patient in mind. The only error related to the failure to obtain specific consent in advance.

There can never be an exhaustive list of conduct by a doctor which will be regarded as serious professional

misconduct by the GMC. Equally, it cannot come as a surprise that in certain circumstances a lack of consent to treatment might amount to serious professional misconduct. What is more surprising is that the manner of giving treatment which is otherwise safe and effective—and, indeed, "admirable"—may still be regarded as serious professional misconduct. Though in this case no actual penalty was imposed on the respondent, this finding in these well intentioned circumstances may still be particularly disturbing for doctors. The conduct of the respondent was said by several senior colleagues to mirror their own practice and, in their belief, the practice of the majority of anaesthetists throughout Britain. The evidence was that before this case there had never been any guidance from any source with respect to obtaining consent for the use of a suppository. The issue had not been discussed in any research paper on suppositories, and there had been no guidance whatever on the subject from any of the royal colleges or, indeed, from the GMC itself. As one witness said, before this case it was a non-issue.

In criminal law the creation of a new offence with retrospective effect is exceedingly rare and condemned by all concerned with civil liberties. At the GMC the criminal standard of proof applies, and perhaps the criminal law presumption against retrospective effect should also be applied in appropriate cases. Such cases might include those in which the respondent's conduct has accorded with a practice previously accepted as proper by a responsible body of medical opinion but which is subsequently found wanting. Notwithstanding any naivety or error on his part, the respondent in this case might be entitled to feel very unlucky, in that when the music stopped the serious professional misconduct spotlight was on him. The dentist concerned—who had never even touched the diclofenac suppository—might feel even more aggrieved that the General Dental Council had found him guilty of assault and serious professional misconduct on the same facts.

Reaction and discussion

Not surprisingly, the fallout from this case has already been considerable among anaesthetists. Many, including those in the respondent's own hospital, changed their practice overnight and now seek specific preoperative consent to the use of a diclofenac suppository. Others stopped using diclofenac suppositories completely and changed to other agents which may or may not in the long term prove to be an adequate substitute. Abandoning the suppository completely may perhaps be an overreaction, though it was arguably prudent before the extent and limit of the GMC's findings were made known. On the face of it the committee's decision with regard to the need for specific consent is now confined to the use of diclofenac suppositories in the general dental surgery. But, as the evidence with regard to modern day care units showed, the distinction is not necessarily clear and conclusive and doctors will be forgiven for continuing to take a cautious view. If this results in increasingly lengthy preoperative discussions it will compound the problems already faced by anaesthetists in day care units.

The implications of this case may go beyond just the use of diclofenac suppositories. The question of intramuscular injections into the buttock was raised more than once at the hearing. Doctors can hardly be confident that an aggrieved day case patient may not in the future complain about receiving such an injection without specifically being told about it in advance. What, too, of the application of electrocardiogram leads to the chest of an anaesthetised woman patient, an example specifically raised in the *Davis* case:

If it is necessary to attach the patient to an electro-

Home of the GMC. Decision by the professional conduct committee has far reaching implications for all branches of medicine

cardiogram during surgery under general anaesthetic, ought not consent for that to be specifically sought lest, for example, the woman whose foot is to be operated upon may not have appreciated that while unconscious ECG leads would be attached to her chest thus exposing her breasts?²

What, too, of the general practitioner who has to deal with fully clothed patients in the community. Rectal diazepam given to a convulsing patient may well be covered by the exception for urgent cases in which specific consent need not necessarily be taken in advance. But what of the female patient, vomiting and confused as a result of raised intracranial pressure, to whom the male general practitioner wishes to give an antiemetic suppository in her home when there is doubt whether she is alert enough to consent and there is no chaperon present?

Most doctors accept the occupational hazard of being sued for medical negligence and, by and large, the defensive medicine which is practised in response is proportionate to the perceived danger. By contrast, no doctor will wish to risk a finding of serious professional misconduct and the possible end of his or her career. Hence the degree of defensive medicine practised in response to decisions of the professional conduct committee is bound to be much more extreme. The

decision in this case may reassure patients that the professional conduct committee is fiercely protective of their dignity. There must, however, be a balance, and the patient's right to the most effective treatment reasonably available may be affected by overemphasis on other rights.

Given the concern of many consultant anaesthetists about this case, the problems which it has thrown up deserve further consideration by both the GMC and the royal colleges. Doctors and patients will surely welcome any further guidance and reassurance which can be given.

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1 Poswillo DE, Hopwood WA, Robson JS, Russell DI, Ryder W, Zideman DA. *General anaesthesia, sedation and resuscitation in dentistry*. London: Department of Health, 1990.

2 *Davis v Barking, Havering and Brentwood Health Authority* [1993] 4 Med LR 85.

3 *Chatterton v Gerson* [1981] QB 432; [1980] 3 WLR 1003.

4 *Sidaway v Governors of Bethlem Royal Hospital* [1985] 1 AC 871.

5 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

6 *Hucks v Cole* [1968] in [1993] Med LR 393.

7 *R v Glanville Williams (G)* 78 CR App Reports 276; *R v Beckford* [1988] AC 130 (PC).

8 *Hart v The Lancashire and Yorkshire Railway Company* [1869] LTR 262.

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Commentary

The legal position

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The case presented by John Mitchell raises several important legal issues.¹ By far the most important in the context of the law on consent to medical treatment is the role of the medical profession in setting the parameters of consent. In the tort of negligence the *Bolam* test provides that a doctor who conforms with a practice accepted as proper by a responsible body of professional opinion is not negligent, allowing always for the possibility that there may be more than one responsible body of professional opinion.² In general terms it is possible to say that it is the profession which effectively sets the standard of competence required by law.

The law on consent to treatment should be distinguished, however, from the law of negligence. Any treatment that entails the physical touching of a competent adult patient without consent constitutes the tort of battery. Consent provides a defence which makes the touching lawful. With consent involving a competent adult the simple question from the lawyer's perspective is, did the patient in fact consent to the procedure? It is important to note that the question is not, did a responsible body of professional opinion consider that consent could be dispensed with? The requirement to obtain consent is imposed by law, not by the practices of the profession. The fact that the treatment may be safe and effective and given with the best interests of the patient in mind is irrelevant to the question of whether in fact the patient consented.

Though in the context of the criminal law it may be true to say that a doctor's genuine belief that a patient was consenting would give the doctor a defence, however unreasonable the doctor's belief might be on objective criteria, it is doubtful whether the same rule applies in the civil law. Moreover, even when applying a subjective test, if the belief were wholly unreasonable

this would raise serious doubts whether the doctor could genuinely have held the belief.

In any event, in the case presented by Mitchell, it is questionable whether the fact that the anaesthetist had always assumed that the use of the suppository was covered by the consent for the general anaesthetic would fall under the principle that the doctor genuinely believed that the patient was consenting. This was not a case where there was an apparent consent to procedure A but subsequently it turned out that the patient had not, in fact, consented to A. It was a case where there was consent to procedure A but the doctor performed procedure B as well. There was never any apparent consent to B. The crucial issue was whether procedure B could be regarded as part and parcel of A and therefore was within the actual consent given by the patient to A. This was not a matter on which the doctor's beliefs, however genuine, could be determinative.

It is clearly possible for a patient's consent to be very specific in its ambit. For example, the patient could consent to an injection in her right arm but specifically refuse consent to an injection in her left arm.³ When the patient gives no specific instructions the rule applied in English law is that once the patient is informed in broad terms of the nature of the intended procedure and gives consent the consent is valid.⁴ Unfortunately, this leaves considerable room for disagreement about what falls within "the nature of the procedure" and what constitutes information "in broad terms." Ultimately, this is treated as a question of fact in any given case.

In the case of *Davis v Barking, Havering, and Brentwood Health Authority* it was held that a patient who had signed a general consent form authorising marsupialisation of a cyst and the use of a general