

SPECIAL ARTICLE

Consent for anaesthesia

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Summary

Current professional guidelines concerning information and consent for anaesthesia are a fair representation of English law. However, they reject the need for specific, written consent for anaesthesia, a position which is in accordance with other Western jurisdictions. This is understandable, as there would be a number of problems inherent in such an approach: the consent process would be unnecessarily labour and time intensive, the generic nature of the information to be disclosed would not allow for operator-dependent variables, and many of the disclosable risks continue to be of uncertain incidence. Moreover, written consent is not needed in order to defend cases of assault by anaesthetists. However, for the very reason that there are a large number of risks associated with anaesthesia (risks that are unknown to the majority of surgeons), together with the possibility of the courts moving towards a reasonable patient standard of information disclosure (as a result of the introduction of human rights legislation into English law), it is our view that the Association of Anaesthetists of Great Britain and Ireland should change their guidelines and advise anaesthetists to obtain separate, written affirmation from patients that certain risks and consequences of anaesthesia have been explained to them. In addition, a standardised consent form for anaesthesia may prove invaluable in retrospectively defending a claim of negligence founded around information disclosure, by recording exactly the risks and consequences of interventions discussed by the anaesthetist and the patient.

Keywords *Anaesthesia: standards. Informed consent: consent forms. Legislation: jurisprudence.*

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Anaesthetists are directly involved in the care of two-thirds of hospital inpatients, underpinning £10 billion of National Health Service income at a pay cost equivalent to 3% of this sum [1]. Contrary to lingering public perceptions [2], modern general anaesthesia is very safe, with an attributable mortality of less than 1 : 100 000 in the UK [3] (1 : 68 000 in Australia [4]). High-quality delivery of anaesthesia also reduces peri-operative morbidity [5]. As a result of these facts, anaesthesia has become a victim of its own success, with surgeons willing to perform increasingly complex surgery on sicker patients, in turn resulting in more technically challenging anaesthesia.

The varied and expanding role of the anaesthetist inevitably increases their amount of patient contact. Anaesthetists are often required to perform interventions

that are distinctly separate from treatment administered by other specialities, e.g. the provision of epidural pain relief during labour. In addition, the growing threat of litigation has stimulated a re-evaluation of traditional practices, litigation which has developed from the advance of medical consumerism, which places great emphasis on individual choice. These trends have led anaesthetists to reconsider their position with regard to separate consent for anaesthesia, resulting in the recent publication of practice guidelines by a Working Party of the Association of Anaesthetists of Great Britain and Ireland (see below).

Traditionally, consent for surgery was obtained by junior surgeons. The evolution of medical law made this arrangement untenable, because it was recognised both that junior surgeons invariably did not perform the surgery

for which they obtained consent, and possessed insufficient knowledge concerning the nature and risks of operations to relate to patients when eliciting their consent [6]. The nature and risks of anaesthesia were considered in generic terms as part of the general information given about the process of surgery, but this is also non-sensical for two reasons. Firstly, anaesthesia is associated with its own particular set of risks and consequences that are quite independent from those associated with surgery, e.g. allergic reactions to anaesthetic drugs. Second, the nature and purpose of anaesthesia are different from those of surgery, facilitating rather than delivering definitive medical treatment. Legally, confusion about whether separate consent is needed for anaesthesia, who should obtain it and what the level of information disclosure should be, could render both surgeons and anaesthetists liable in battery and negligence.

Therefore, the aim of this paper is to argue that anaesthetists should obtain separate, written consent for anaesthesia, even though this is at odds with current professional guidelines.

Ethical considerations

Western society is predominantly a consumer society, i.e. a society in which the user or buyer of services dictates the provision of those services. A myriad of contractual relationships exist between individuals, groups and states. Central to many such relationships is the notion of consent, a concept that reflects the respect given by Western societies towards the autonomy of their citizens. General consent may be implied by an individual's actions or by explicit statement. However, specific consent usually involves one individual allowing another individual to perform an act. In law, 'informed consent' is an instrument that engenders respect for autonomy [7]. The moral foundations of autonomy are manifested in the three components of legally valid informed consent, namely that the individual should be competent to decide, be given information on which to base that decision and be allowed to make the decision voluntarily. In the medical setting, informed consent allows an individual to define and protect his or her own interests and to control body privacy. For example, an anaesthetist may be liable in battery if he or she administers a general anaesthetic to a patient, i.e. touches a patient, without their consent. Retaining the capacity to make autonomous medical decisions has been shown both to improve patient satisfaction and medical outcomes [8].

However, there are a number of instances in which patients' decision-making capacity is compromised. Some, such as unconsciousness and dementia, are obvious. The majority of cases are less clear, and relate to

degrees of partial autonomy. Children, for example, are individuals in that they are capable of independent thought and deed, but may not be judged to possess a capacity for decision-making that is quantitatively or qualitatively similar to adults. A continuum may be envisaged along which mental, physical and moral development matures towards full autonomy (see Lords Fraser and Scarman in *Gillick* [9]), but this inevitably results in either a status approach to autonomy, i.e. children become autonomous above a certain age, or means that children may be considered autonomous in making some decisions and not others. Similarly, mental illness or retardation may transiently or permanently limit capacity, but again such limitations may be circumstantial – a person may be assessed as a chronic paranoid schizophrenic, but still retain the capacity to consent to, or refuse, limb amputation [10].

Three scenarios are of special interest to the practice of anaesthesia. Anaesthetic intervention is often required during pregnancy and labour. Anaesthetists provide pain relief in about a third of pregnancies [11]; labour can undoubtedly be very painful. Indeed, pain could be envisaged as being of such severity that it eroded personal autonomy to an extent that it invalidated any consent given by the labouring woman (see the discussion in *ReMB* [12]). The woman is in such agony that she will consent to any form of analgesia, without reflecting upon either the coercive nature of severe pain or the risks inherent in a definitive pain-relieving procedure (epidural). Second, patients who experience chronic pain, i.e. pain lasting for more than six months after injury, are often physically and psychologically dependent on anaesthetic intervention, particularly when they are referred to chronic pain outpatient clinics, which frequently provide their last hope of conventional pain relief. Third, patients may experience a diminution of their autonomy after the administration of certain drugs [13], notably sedatives and opioid analgesics – drugs that are frequently used as premedicants before surgery, and both of which erode the capacity for thought and decision-making.

Another important argument concerns whether informed consent actually represents any sort of protection of individual autonomy. Several commentators, including Veatch [14], Jones [15] and O'Neill [16] have examined the shortcomings of informed consent, finding that it does not fulfil the purpose for which it was developed. Many conceptual problems with informed consent remain, including sexual, cultural and socio-economic differences in decision-making, and difficulties associated with assessing capacity and voluntariness. In addition, the patient may tell the doctor to do 'what they think is best', or implicitly entrust their welfare to the doctor by, for example, signing the consent form without

reading it (which occurred in 69% of 265 patients in one study [17]).

In practice, there remains a considerable gulf between the ethical necessity for consent and the practicalities of obtaining consent. Obtaining ‘real’ consent is time-consuming and impractical given the constraints of an overstretched National Health Service. Under-provision of hospital beds, for example, means that patients are rarely admitted to hospital until the day of their surgery, even in the case of major surgery. On admission, patients are subjected to a bewildering array of people and paperwork at a time when they are most anxious about their health and imminent surgery. ‘Active, reciprocal and fluid discussion’ about the proposed treatment, in the authors’ experience, is therefore rarely possible; it takes time to explain anaesthesia to patients, and time for them to reflect on this information and ask further questions, before giving valid consent – time which is just not available if surgical lists are to start on time and progress without interruption in order to be completed. There is a dichotomy therefore between what is ideal (i.e. ‘active, reciprocal and fluid discussion’) and what is possible (i.e. the anaesthetist briefly stating what (he or she intends to do, to the lower standard of legal acceptability). Consequently, society (and anaesthetists) must decide what is to be considered more important: ‘real’ consent that fulfils morally and legally acceptable criteria, or patient throughput, that fulfils legal criteria, but to an extent steamrolls patient autonomy in order to maximise service provision.

Problems with current practice guidelines

Anaesthetists, like all other doctors, are legally and ethically obliged to seek consent from a patient before medical intervention wherever possible. The legal obligations of anaesthetists concerning consent for anaesthesia have recently been thoroughly reviewed by the Association of Anaesthetists of Great Britain and Ireland (AAGBI) [18]. The AAGBI have stated that express consent should be obtained for any procedure that carries a material risk (at 2.2.2.1) (‘A risk is... material when a reasonable person in what the physician knows or should know to be the patient’s position would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy’ – Lord Scarman, in *Sidaway*, at 887 [19]). Although they saw no reason to sign a separate consent form [20], they indicated that an entry should be made in the clinical notes of the patient to record ‘the anaesthetic techniques ... which have been discussed and agreed by the patient, and ... the material risks which have been explained’ (an approach supported by the British Medical Association in their

‘Report of the Consent Working Party’ March, 2001 [21]).

However, we live in an increasingly rights-orientated and litigious society. Whilst at present a signed consent form is not a necessary piece of evidence in the defence of accusations of assault or negligence in England (see Popplewell J in *Taylor v Shropshire Health Authority* [22]), there is a genuine concern that ‘in the case of an action brought several years after the event, a judge may prefer a patient’s evidence to that of a practitioner if a signed consent form cannot be produced’ [23]. The Department of Health have previously suggested that written consent should be obtained for anaesthesia [24] (reiterated in the Poswillo report [25]), although this was not explicitly reconfirmed in the 2001 guidelines [26]. The General Medical Council have suggested that ‘if you are the doctor providing treatment ... you must give a clear explanation of the scope of consent being sought. This will apply particularly where: ... different doctors ... provide particular elements of an investigation or treatment (for example anaesthesia in surgery)’, that ‘if you are the doctor providing treatment ... it is your responsibility to discuss it with the patient and obtain consent’ and that ‘you should obtain written consent in cases where the treatment or procedure is complex, or involves significant risks and/or side-effects’ [27]. Written evidence of separate anaesthetic consent is strongly advised in other jurisdictions, including Australia and New Zealand [28], the United States [29] and Ontario [30]. In addition, several authors have suggested that separate, written anaesthetic consent should be obtained by anaesthetists before each medical intervention [31,32].

The advice given by the AAGBI (which effectively provides the practice guidelines for anaesthesia in the UK) is timely, comprehensive and commendable. However, the advice attracts three criticisms.

Firstly, the advice contradicts (or at least demands a lower standard compared to) that given by both the Department of Health and the General Medical Council concerning the obtaining and recording of consent. There is little in the AAGBI advice about the legal definitions of competence, save the interpretations provided by *ReC* and *Gillick*, and no mention of voluntariness. The guidance that a written record detailing pre-operative discussion and patient consent overlooks two problems, both of which are potentially subject to legal challenge, concerning the validity of the consent: that the records are made retrospectively, and that they are not countersigned by the patient.

Second, the guidelines fail to differentiate between primary and secondary procedures, i.e. procedures in which anaesthetic intervention *is* the treatment (e.g.

epidural analgesia during labour), and procedures in which anaesthesia *facilitates* the treatment (e.g. general anaesthesia for surgery). In the former, anaesthetists would appear to have a duty to obtain consent of a legal standard similar to that which a surgeon might obtain before an operation. In the latter, the AAGBI guidelines could be regarded as sufficient.

Finally, it should be noted that the requirement to obtain consent is imposed by law, not by professional guidelines [33]. As one observer has noted [34], ‘while there may be certain efficiencies associated with the use of clinical practice guidelines as the legal standard of care (relating to tort liability in medical malpractice), their use is deeply problematic’, because they provide a quasi-legal shield behind which the professions can protect themselves from negligence suits by claimants.

Application of current English case law to anaesthetic practice

Consent

Although not normally subject to statutory provision, the medical inviolability of bodily integrity has been stated in a number of important cases (*ReMB* [12], *St Georges NHS Trust v S* [35], *ReT* [36]). For example, in *Airedale NHS Trust v Bland*, Lord Browne-Wilkinson states: ‘Any treatment given by a doctor to a patient which is invasive ... is unlawful unless done with the consent of the patient: it constitutes the crime of battery and the tort of trespass to the person.’ [37]. In addition, respect for autonomy extends to patient refusals of treatment [12,36,37].

Consent may be expressed or implied, the form in which it is given having no bearing on its validity. Consent might be implied, for example, when the patient holds out their arm to the anaesthetist for an injection [38], rather than giving a verbal agreement, or does not push an oxygen mask away from their face before the induction of anaesthesia. It is questionable whether the inclusion of ‘catch-all’ clauses on consent forms validate implied consent [39]. Expressed consent may take the form of a verbal assent or written agreement, although a signed consent form merely acts as documentary evidence, rather than the legal affirmation of valid consent.

Consent may be withdrawn at any point. Withdrawal of consent renders subsequent treatment unlawful [40].

Consent is legally valid if it is given voluntarily by an appropriately informed person, who has the requisite capacity to exercise an informed choice. Three elements of legally valid consent are recognised, and concern the *voluntariness* and *capacity* of the patient when making a decision, and the suitability of the *information* provided to the patient.

Voluntariness

The issue of volition is interesting for anaesthetists. As Professor Aitkenhead has observed, ‘while (patients) are prepared to accept that surgery may not be entirely successful ... they anticipate perfection from the anaesthetist’ [41]. Patients consent to have surgery, but it is often the anaesthetic that frightens them [42] – ‘I hope I wake up’ or ‘I hope I wake up, except during the operation’. However, in many instances the patients do not have a choice, anaesthesia being a condition precedent to surgery. As such, the voluntariness of their consent for anaesthesia is called into question. One might argue that the fear of the anaesthetic more correctly erodes their capacity for consent, rather than their voluntariness. However, it is not a lack of capacity that might invalidate consent in this situation, as much as the compulsory necessity for anaesthesia. This argument has not formed the basis for any legal challenge thus far, and the implications of such an argument would be untenable, because the problem is insoluble – in the vast majority of cases, surgery requires some form of anaesthesia delivered by an anaesthetist.

Capacity

In the conclusion of her judgement in *ReMB* [12], Dame Elizabeth Butler-Sloss stated (at 436): ‘Every person is presumed to have the capacity to consent to or refuse medical treatment unless and until that presumption is rebutted’, and (at 437) that a person lacks capacity if some impairment or disturbance of mental function renders the person unable to make a decision whether to consent to, or refuse, treatment. That inability to make a decision will occur when: (a) the patient is unable to comprehend and retain the information which is material to the decision, especially as to the likely consequences of having, or not having, the treatment in question; (b) the patient is unable to use the information and weigh it in the balance as part of the process of arriving at the decision.

This statement was a redefinition of an earlier decision by Thorpe J in *ReC* [10], but notably omits that judge’s decision that a competent patient should *believe* the information presented to him, in addition to taking in and retaining the information, and weighing that information by balancing risks and benefits. Nevertheless, the spirit of the Court of Appeal’s decision in *ReMB* is approving of the three stage test of competency described in *ReC*.

Valid consent therefore requires that the anaesthetist make a judgement of a patient’s capacity to make an informed choice concerning anaesthetic intervention. Situations involving children, emergencies, ‘mental patients’ and pregnancy are discussed in more detail below. The effects of disease, premedication and pain on capacity have already been alluded to.

Several other issues need to be emphasised. Firstly, the decision made by the patient does not have to be sensible, rational or well-considered [35], although consent/refusal made on the basis of an irrational belief that is contrary to the evidence and not widely held by society might indicate that the patient is suffering from mental illness. Where a patient's competence is in doubt, declaratory relief should be sought from the courts [12,35]. Second, the more serious the decision to be made, the proportionately greater the level of capacity is required [36]. Third, contemporaneous competent refusals of treatment carry the same legal force as a competently given consent [36]. Finally, no other person (including the courts or those with legal powers of attorney) may consent to medical treatment for an incapacitated (or other) adult; doctors have a legal duty however, to treat incompetent patients in accordance with the concept of best interests, which necessitates wider assessment of the patient's welfare than what the benefits of medical treatment might be [43].

Information

There is considerable debate amongst lawyers and anaesthetists as to the quantity or quality of information that should be provided to patients in order to validate their consent. Whilst there is general recognition that patients are entitled to be told about their anaesthetic, particularly in terms of its nature and purpose, there is less certainty about the limits on the extent of risk disclosure. This is not rampant paternalism in action; there is a very real concern that alarming patients about their anaesthetic (a number of the risks of anaesthesia being potentially and rapidly fatal) may make the course of anaesthesia more hazardous, by eliciting an adrenergic 'stress response', the physiological effects of which may be complicated by anaesthetic drugs (although one study found that the provision of detailed information about the risks and complications of general anaesthesia did not increase patients' level of anxiety [44]). Moreover, another study found that it was the most anxious patients pre-operatively who requested more detailed information from their anaesthetist [45]).

A number of clinical studies have been performed in order to assess what patients would like to know about their anaesthetic [46–54]. The results of these studies did not reveal a simple answer. Many patients prefer to be given simple descriptions of procedures and explanation about the main risks and benefits, although a significant number would like to receive full information about procedures and risks. The use of an anaesthesia information sheet given to the patient before surgery may increase knowledge and decrease anxiety [55].

In order to defend an action in battery (defined as the intentional touching, however slight, of another's person), a doctor must be able to sustain a defence by providing sufficient evidence that he or she supplied the patient with adequate information about the nature and purpose of the procedure. In order to pursue an action in negligence, the plaintiff must prove, among other things, both that the doctor failed to disclose information about the risks and consequences of the procedure, and that but for the negligent failure to advise, the patient would have declined treatment [39]. The legal position with regard to information disclosure in the UK has moved from the 'reasonable doctor' standard of *Bolam* (i.e. the doctor only need disclose that which a responsible body of medical practitioners might disclose, the standard of care being that of the ordinary skilled man exercising and professing to have that special skill) [56] towards the 'reasonable patient' standard suggested by Lord Scarman in *Sidaway* [19], such that a doctor has a duty to warn a patient about a material risk if 'the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk' (our emphasis), unless 'he takes the view that a warning would be detrimental to his patient's health.'. This approach was confirmed in *Pearce* [57] (a case that considered *Sidaway* in light of *Bolitho* [58]), in which it was judged that there was a duty to disclose information that the patient would consider significant, the standard of the information being decided by the court rather than the doctors. Furthermore, decisions to withhold information by doctors would only be sanctioned by the court if they were rational, responsible and responsive; anaesthetists will no longer be able unilaterally to make the decision that disclosure 'would be detrimental to a patient's health' in order to avoid discussion about the risks of anaesthesia. As Kennedy and Grubb point out, this is likely to lead to an increase in the practice of defensive medicine, with a move towards the 'full disclosure' model favoured in some US states [59].

The main problem that arises with all the above case law concerns the definition of 'significant risk'. The law equates significant material risk with a degree of risk to which a patient would attach relevance. However, different patients on different occasions will interpret risk differently. The interpretation of material risk will always be inconsistent. The problem for doctors in general is that scientific risk equates to a numerical value, but the courts have been reluctant thus far to define what such an incidence might be in terms of 'significant' risk. Anaesthesia is by nature a practical specialty, every procedure performed carrying a range of risks, which may be minor or major in consequence, common or rare in incidence, causal or incidental to the harm sustained (if any),

convenient or inconvenient in timing, expected or unexpected, relative or absolute, operator-dependent or any combination of the above. In addition, there are significant difficulties in communicating risk, caused by patient perceptions, anaesthetist perceptions and the doctor–patient interaction, and complicated by the range of communication methods (numerical – percent/incidence/logarithmic/degree scale, verbal or descriptive) [60,61].

Professional bodies have attempted to address the obscurity of the legal definition of significant risk by publishing guidelines detailing what doctors should disclose to their patients [18,27]. However, these tend merely to restate the legal position, whilst providing examples of the type of risks and consequences that might be disclosed; the onus is still very much on the doctor to pitch the level of disclosure according to the rather abstract concept of ‘what a reasonable patient would consider significant’. The only way to overcome this problem would be to disclose fully all risks and consequences. However, several authors, in concert with professional organisations, have concluded that full disclosure is likely to bewilder and alarm the majority of patients, and could lead to situations in which patients consent to one treatment, for example, to blood transfusion, but refuse an ancillary procedure, such as intravenous access [62,63].

It is as yet unclear whether anaesthetists in the UK have a duty to disclose information beyond that required to inform the patient about the risks and consequences of a procedure. However, a number of situations might be envisaged in which information about factors other than procedural risks might be considered significant by the patient, such that they would not have consented to treatment had they known of them. Is there then a duty to inform a patient of risks that are not inherent to the procedure? No case law exists as such in the UK. However, commenting on the US case of *Faya and Rossi v Almaraz* [64] (see also the case of *KAC v Benson* [65]), Kennedy and Grubb suggest that ‘an English court is likely to take a similar view even applying the *Bolam* test and require very compelling reasons indeed to licence non-disclosure’ [66], although the courts may recognise problems concerning the remoteness of the damage. Moreover, the court in *Behringer Estate v Princeton Medical Centre* [67] ruled that a hospital had the right and the duty to inform patients that the plaintiff plastic surgeon was infected with HIV, even though the surgeon contested that the risk of transmission was negligible. Doctors with other blood borne viruses, particularly hepatitis B and C, may become subject to similar decisions [68], as may doctors dependent on alcohol or drugs, e.g. the Louisiana case of *Hidding v Williams* [69], although it is unclear how

persuasive this decision would be as a precedent in English common law, given that Louisiana law is based on a civilian tradition with French origins [70].

Traditionally, medical procedures have often been carried out by persons other than those to whom patients have given their consent, which could be interpreted as exposing patients to additional, and potentially avoidable, risk. Two situations might arise: either a more senior anaesthetist allows a junior to perform the procedure, or any grade of anaesthetist allows a non-anaesthetist to perform a procedure, e.g. training paramedics to intubate the tracheas of anaesthetised patients. It is accepted that liability is incurred if there is fraudulent misrepresentation of a second actor’s identity, e.g. a medical student introduced as an anaesthetist [71]. However, the validity of allowing trainees to perform specific anaesthetic procedures is yet to be challenged (although in *Wilsher, Glidewell LJ*, at 774, indicated that if a junior doctor is inexperienced in carrying out a procedure, then he must do so under the supervision of a more senior doctor; the latter would be liable in negligence if he failed to supervise the former adequately [72]). Professional guidelines AAGBI (Association of Anaesthetists of Great Britain and Ireland [18], paragraph 2.11, and Department of Health [73]) recommend that no non-anaesthetic staff should perform a procedure unless the patient has specifically consented to them doing so.

In future, there may be a duty to disclose alternatives to the proposed treatment, e.g. the Canadian case of *Haughian v Paine* [74], or to advise the patient about non-treatment, e.g. the Californian case of *Truman v Thomas* [75], or the consequences of non-treatment, e.g. *Pearce* [57]). The AAGBI recommends that anaesthetists should *consider* disclosing (rather than actually disclosing) ‘the estimated risks of alternative techniques’ and ‘the estimated added risks for the individual patient, e.g. as a result of concurrent disease’ (paragraphs 3.1.3.3 and 3.1.3.4 [18]).

A paper by Kellerman and Ackerman suggested that patients should provide informed consent before inter-hospital transfer [76]. Their argument concerned the practice of ‘patient dumping’ in the US, where uninsured patients are transferred out of hospitals unwilling to pay for their care. This practice is not applicable in the UK, but their arguments are of interest to the practice of anaesthesia in the UK, because anaesthetists are responsible for the transfer of acutely sick patients between hospitals, either to enable specialist treatment or (more commonly) because there is a shortage of intensive care beds. Inter-hospital transfer is a procedure that incurs additional risk to the patient and to the anaesthetist (hospital insurance cover may not extend to employees

operating outside the hospital premises). Kellerman and Ackerman argue that these risks should be disclosed and the patients' consent obtained before transfer in order to protect patient welfare, to make doctors accountable and to challenge decisions based on financial considerations. This would not delay emergency transfers, which would be necessitated in the patients' best interests. However, consent may be practically difficult to obtain in sedated or anaesthetised patients.

The arguments against the disclosure of non-inherent risks concern the retrospective nature of their assessment and their potential magnitude. A vast number of factors that are independent of procedural risk could be considered significant by the patient, imposing a duty for the anaesthetist to disclose them. Furthermore, the anaesthetist might only discover what those factors were after the court had retrospectively decided their significance.

A final dilemma concerning the disclosure of information relates to *who* should disclose information about the nature and risks of anaesthesia. A number of studies have shown that surgeons are inadequately knowledgeable about the risks of anaesthesia and rarely provide information beyond the type of anaesthetic techniques available, e.g. general or regional [77–79], and that anaesthetists are poor at recording discussions about consent [80]. However, it seems logical that the anaesthetist, with their expertise of anaesthetic risk, should be the practitioners responsible for obtaining consent.

Battery

Valid consent provides a defence which makes the action of touching lawful. Touching a patient without their consent may incur liability in both the crime and tort of battery (Sections 18, 20 and 47 Offences Against the Person Act, 1861) [81], and the tort of negligence [82]. In practice, actions are usually brought under tort (a tort is a civil wrong for which the remedy is a common law action resulting in the recovery of damages), because the criminal law requires the prosecution to prove beyond reasonable doubt that either the doctor had touched the patient with reckless intent (or that any consent given was vitiated by fraud), resulting in a battery, or that gross negligence had occurred. In addition, criminal actions are less amenable to financial restitution for the patient. It should be noted, however, that anaesthetists have been convicted of manslaughter by causing death through gross negligence (*R v Adomako* [1995] 1 AC 171; HL) [83,84]. The number of doctors standing trial for manslaughter has risen markedly since the 1990s: four doctors were charged with manslaughter in the 1970s and 1980s, whereas 17 were charged in the 1990s, and four have already been charged between 2000 and 2003.

Actions in the tort of battery are unusual in the UK. Courts have been reluctant to pursue such actions, because they are seen as inappropriate in circumstances where doctors are acting in good faith and in their patients' best interests [19,39,85]. However, this reluctance may be subject to future challenges under legislation introduced by the Human Rights Act, 1998, particularly with reference to Articles 3 (Prohibition of torture) and 8 (Right to private and family life) [86]. To prove a battery in tort, the patient has to prove that the doctor touched him without consent [87]; there is no requirement to prove that any physical harm ensued. An action in battery might arise in one of three situations: firstly, that the touching occurred contrary to the patient's expressed prohibitions (e.g. *Allan v Mount Sinai Hospital*, where an anaesthetist was held liable in battery for inserting a needle into a claimant's left arm, despite the patient's directions that he would have 'nothing but trouble there' [88]); secondly, that the touching occurred without the doctor obtaining consent, even though the outcome was beneficial (e.g. *Devi v West Midlands RHA* [89]), or that non-consensual touching occurred, but with a harmful result.

Two other cases with relevance to anaesthesia should be noted. In *Davis v Barking* [90], the court rejected a claim in battery against an anaesthetist who had administered a general anaesthetic and a caudal nerve block to a patient undergoing a gynaecological procedure, because it was decided that the patient had been informed in sufficient detail about the anaesthetic, even if 'sectionalised' consent for the caudal block had not been obtained.

In a separate judgement by the Professional Conduct Committee of the General Medical Council (GMC), an anaesthetist was charged with failure to obtain informed consent, and was found guilty of serious professional misconduct (although this judgement may have overstepped the boundaries of the GMC's jurisdiction [91]). The anaesthetist, a respected and competent individual, had administered an analgesic rectal suppository to an anaesthetised 22-year-old-female, who was undergoing dental surgery. In the event, he had actually administered the suppository vaginally, which led the woman to suspect that she had been sexually assaulted. The patient had signed a consent form before surgery stating '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'. However, no separate anaesthetic consent was obtained; the anaesthetist had not obtained the patient's consent for suppositories, in accordance with his usual practice, because he considered postoperative analgesia part and parcel of the general anaesthetic to which the patient had given consent. The decision of the GMC has

several implications. Firstly, that informed consent to a procedure obtained by a surgeon does not necessarily include valid consent to the treatments administered by an anaesthetist; the patient consented to ‘every necessary care and treatment which I am willing to undergo within NHS arrangements’, which is what she received, but the anaesthetist was still found guilty of failing to obtain adequate consent. Second, the GMC appears to oppose the dictum in *Chatterton v Gerson* [39] by indicating that considerably more information about the nature and purpose of anaesthesia is required than is commonly accepted in order to validate consent – it is insufficient to inform the patient in broad terms that a needle would be placed in her arm and that she would go off to sleep. Finally, the GMC appears to reject the court’s decision in *Davis v Barking*, and imply that sectionalised consent is required, at least in cases in which there may be some touching of the rectogenital area, e.g. injections into the buttocks, or other ‘private’ regions, e.g. attachment of electrocardiograph electrodes to the chest.

Negligence

In order to bring a successful action in negligence, the patient must prove that the doctor owed him a duty (e.g. agreed to take on the patient’s care), that the duty of care was breached (e.g. failed to deliver the correct form of treatment), and that the breach of duty caused harm to the patient. Negligence actions are preferred by the courts in the United Kingdom when pursuing a cause of action, both because medical intent is not an issue, and because defendants are liable to pay financial damages to compensate for the actual damage caused by negligence. Consent in the context of negligence differs to that required in the tort of battery. In battery, it is sufficient in broad terms to inform the patient of the nature and purpose of the procedure intended (though see *supra*). Negligence, however, may involve a significant discussion of the risks and consequences of treatment. Furthermore, a successful action in negligence requires that the patient prove that the breach of the duty to inform caused damage. The relationship between patients, doctors and the law on consent in negligence has been examined in the ‘Information’ section above.

The vast majority of consent-related actions brought against anaesthetists lie in the tort of negligence (although these are still rare: only 1% of cases brought against anaesthetists in the US involve consent [92]), but this causes a significant dilemma for contemporary anaesthetic practice. Between 1970 and 1982, 750 cases of anaesthetic-related death or cerebral damage were reported to the Medical Defence Union; 270 cases (36%) were due to misadventure, 480 (64%) were due to error. One thousand, five hundred and one cases of untoward

anaesthetic-related events, i.e. not death or cerebral damage, were recorded, 52% of which were related to dental damage, the remainder including damage to peripheral nerves, awareness under anaesthesia [93], lung damage and body surface trauma. The causes of anaesthesia-related mortality and morbidity observed are therefore numerous, often difficult to predict and in many instances related to human error. As the current AAGBI guidelines point out: ‘it is necessary only to demonstrate that the warnings which were given (to the patient) did not conform to an acceptable standard and that if the warning had been given, the patient would not have consented to undergo the procedure’. This produces two problems. Firstly, a number of anaesthetic mishaps happen unexpectedly; they are a potential hazard of anaesthesia or indeed of any drug administration, e.g. allergic reactions, and are often significant and life-threatening, but are invariably very rare reactions. However, they are risks to which patients are likely to attach significance (being potentially fatal), and therefore anaesthetists have a duty to inform patients of them. The anaesthetist’s legal liability to inform, then, can only be served by full disclosure. Second, the majority of mishaps are caused by anaesthetists’ errors. Is it then incumbent on the anaesthetist to inform the patient of this – that during the course of the anaesthetic it is possible that the anaesthetist may inadvertently cause permanent paralysis to the patient, fail to recognise a disconnected breathing tube or knock a number of the patient’s teeth out? In short, should the anaesthetist inform the patient that there is a risk of a mishap occurring due to an anaesthetic mistake? This is surely not the intention of the judgement in *Pearce*, and would necessitate a very high standard of disclosure to avoid an action in negligence, but would be likely to lead to a great deal of anxiety amongst patients. Again, there is an issue concerning the legally undefined meaning of ‘standard’, when applied to the quantity and quality of information revealed – indeed, it has been suggested that no defined disclosure technique can guarantee legal protection [94]. In practice, until recently, the courts have been reluctant to accept the arguments of claimants that had they been warned of the risks beforehand they would not have undertaken treatment (e.g. *Smith v Barking*). This position may change in light of the recently decided case of *Chester v Afshar*, in which the Court of Appeal held that ‘where, as a result of a doctor’s failure properly to advise a patient about the risk involved in a surgical procedure, the patient had an operation which she would not have otherwise have had at that time, and the risk materialised and caused her injury, the causal connection between the negligence and the damage was not broken merely because the patient had been unable to show that she would never, at any time in

the future, have had an operation of that kind, carrying the same or similar risks' [95].

Special circumstances

The analysis of case law and professional guidelines provided thus far has dealt with consent issues concerning competent adult patients. However, anaesthetists are likely to encounter a number of patients whose capacity and volition are affected either by their age or their medical condition. The following 'special circumstances' address the application of English common law to such patients.

Children

Under subsections (1) – (3) of Section 8 the Family Law Reform Act, 1969, 16 and 17 years-old children are rebuttably presumed to be competent to give consent for any surgical, medical or dental treatment that would otherwise constitute a trespass against them [96]. Therefore, 16 and 17 years-olds are presumed competent to consent unless it can be shown that they are incompetent, such that they fail the two stage test of competence stated in *ReMB* (the patient is competent if they can take in and retain information, use it and weigh it in the balance). However, it should be noted that both Section 8(1) of the Family Law Reform Act, 1969 (which states 'the consent of a minor who has attained the age of 16 years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian'), and *ReW* discuss consent to treatment. Refusals of treatment by competent 16 and 17 years-olds are likely to be overruled by the court (Balcombe LJ in *ReW* [40], at 86).

Children under the age of 16 are rebuttably presumed to be incompetent to consent to treatment (this is not the case in Scotland, where under Section 2(4) of the Age of Legal Capacity (Scotland) Act 1991, a 'person under the age of 16 years shall have legal capacity to consent on his own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment'). However, a *Gillick* competent child can consent to treatment (after *Gillick v West Norfolk and Wisbech Area Health Authority* [9]), their competence being a question of fact, such that the child should understand the nature and implications of the proposed treatment. *Gillick* competent under 16 s should be encouraged to inform their parents about treatment, but

a refusal to do so forbids the doctor from disclosure to the parents. When the consequences of a decision puts the child's life at risk, a very high level of understanding may be required by the court (e.g. *ReL* [97]) – the courts have proved very adverse to any child refusing potentially life-saving medical treatment, overruling their refusals even if they are legally competent (e.g. *ReM* [98]). However, English law has yet to consider a case in light of either the United Nations Convention on the Rights of the Child (which states that the child's views should 'be given weight in accordance with the age and maturity of the child' (Article 12(1)), or the Human Rights Act, 1998 (specifically Articles 3 and 8).

Proxy consent may be provided for incompetent children by parents, temporary carers, local authorities or the courts, provided the consent is given in the best interests of the patient, which are not necessarily the medical best interests. Parents, or those with parental responsibility according to the Children Act 1989, e.g. legal guardians nominated by the parents, unmarried fathers who have entered and registered a parental rights agreement, are the most obvious repositories of proxy decision-making power, though they themselves must be competent to make the decision and it must be made in the child's best interests. The child's best interests are determined by the court, who may take into account the wishes of the child (*ReP* [99]), or parent(s) (*ReT* [36]).

Each parent has the right to consent (Section 2(7) of the Children Act, 1989, Article 8 of the Human Rights Act, 1998), though when a major decision has to be made there may be a duty incumbent on the consenting parent to inform the other parent (*ReG* [100]). If there is disagreement between the parents, the courts may limit the power of one parent to refuse treatment that is in the best interests of the child (*ReJ* [101]). If both parents refuse, an application may be made to the court to overrule the parents.

Temporary carers include teachers and doctors. Anyone aged over 16 who has responsibility for a child under 16 has a duty to obtain essential medical assistance for the child (Section 1 Children and Young Persons Act, 1933). Likewise, anyone who does not have parental responsibility but has care of a child may do all that is reasonable to secure the welfare of the child (Section 3(5) Children Act 1989). Although it is usually not lawful to do so, doctors may treat children without any proxy consent if: it is impossible/impractical to seek consent from a parent or the court, or if the parents refuse and the treatment is vital and there is no time to seek the court's assent (*Gillick* [9]). A local authority which has care of a child has parental responsibility (Section 33(3)(a) Children Act, 1989) and can therefore make treatment decisions. The

courts may provide proxy consent in one of three ways: by making the child a ward of court, by employing its inherent jurisdiction, or by making a specific issue or a prohibited steps order.

The process of surgery and anaesthesia are stressful for children and parents, particularly if the treatment proposed is major and the child is uncooperative. Several strategies are available to anaesthetists confronted with anxious parents or children. Paediatric anaesthesia information leaflets decrease anxiety in parents of children requiring surgery, although verbal communication of the nature and risks of anaesthesia are still of primary importance. Stokes and Drake-Lee reported two cases of children (12 and 13 years old) refusing anaesthesia, who had their operations cancelled despite the parents consenting to surgery [102]. The doctors emphasised that they had informed the parents of the risks of not operating, and were understandably reluctant to use reasonable force in order to anaesthetise the children. This is a sensible approach, and may protect the anaesthetist from future liability under the Human Rights Act, 1998. However, reasonable force may have to be used in some cases. Reasonable force may require authorisation by the Court, under Article 5 (Right to Liberty and Security) of the Human Rights Act, 1998 (e.g. *Herczegfalvy v Austria* [103]).

Occasionally, parents may consent to surgery, but not to aspects of the anaesthetic. In some instances, this disagreement can be resolved either by further communication with the parents, or by respecting their refusal, e.g. parents who refuse a regional anaesthetic technique in addition to general anaesthesia. In other instances, application may need to be made to the courts for a decision, e.g. refusal by the parents to allow their child a blood transfusion.

Pregnancy

Anaesthetic intervention may be required throughout pregnancy, e.g. general anaesthesia for appendectomy. Perinatal intervention often occurs at short notice, and may be the only medical intervention, other than the actual delivery, that the patient requires. Patients are often distressed and in pain, and may have been given opiate or inhalational analgesics before the anaesthetist is consulted about pain relief. A number of legal issues arise, and have worried and confused anaesthetists [104]. Firstly, pregnant women are no less autonomous than non-pregnant women. Pain and distress do not necessarily make a labouring woman incompetent. However, a number of decisions [105–107] in the late 1990s held that labouring women were incapable of making decisions whilst in labour, which allowed the courts to authorise Caesarean sections in the best interests of the

mother. This alarmed a number of agencies, who saw that health authorities and trusts were beginning to rely on the coercive threat of court intervention in order to achieve a successful delivery, despite legal assurance that competent women are allowed to refuse treatment even if this harms their foetus. Fears were calmed by the learned conclusions of Dame Elizabeth Butler-Sloss in *ReMB*: ‘the “temporary factors” mentioned by Lord Donaldson MR in *ReT* (confusion, shock, fatigue, pain or drugs) may completely erode capacity but those concerned must be satisfied that such factors are operating to such a degree that the ability to decide is absent’ [12].

Second, the AAGBI recommends that a birth plan that contains references to analgesic and anaesthetic techniques should be treated as an advanced directive. The legal validity of anticipatory decisions was confirmed recently in *ReAK* [108]. Such decisions are valid if at the time they were made the patient was informed, competent and made the decision voluntarily, and the decision was intended to apply in the circumstances arising. The problem that anaesthetists face is that the advice of various pregnancy support groups often fails to inform women of just how painful the process of giving birth can be. There is also a question of ‘peer pressure’ when refusing any medical intervention in ‘a natural process’. The situation then arises of a woman who, having made a valid anticipatory refusal of epidural pain relief, demands epidural analgesia during labour, which leaves the anaesthetist in a quandary whether to respect the anticipatory refusal, or accede to the current request and hope that there are no legal repercussions based on the woman’s state of mind during labour. This dilemma may be partly resolved by the anaesthetist themselves discussing perinatal pain relief and the interventional possibilities during operative delivery some time before labour. However, this occurs rarely, due to the pressure of clinical workload (only 36% of anaesthetic departments in one Canadian study taught pain relief methods during prenatal classes [109]). Nevertheless, a number of studies have suggested that pregnant women value comprehensive disclosure of all the risks associated with epidural/spinal anaesthesia in labour [110–112]. The AAGBI does not suggest that consent should be obtained in writing, although there is some debate over whether consent should be obtained in writing, bearing in mind the poor recall of facts reported after delivery in labouring women [113].

Mental illness

Mental illness may impair a patient’s capacity to provide valid consent or refusal for an anaesthetic intervention. However, a person receiving treatment for mental illness

should not be assumed to be incapable of providing valid consent for treatment (*ReC* [10,114]). In English law, it is clear that no one may consent to medical treatment on behalf of a mentally incompetent adult [*ReT* [36] (next of kin), *TvT* [115] (guardians appointed under s.58 of the Mental Health Act, 1983), and *ReF* [43] (revocation of courts' *parens patriae* jurisdiction by s.1 MHA, 1959).

Part IV of the Mental Health Act, 1983, deals with issues of consent and non-consensual treatment for those with a defined mental illness (amongst many other things). Section 63 states that 'the consent of a patient shall not be required for any medical treatment given to him *for the mental disorder from which he is suffering*', i.e. consent is still required for treatment that is not aimed at curing his mental condition. Even then, the patient's consent is still required for psychosurgery (requires consent and a second opinion, Section 57) and electroconvulsive therapy (ECT – requires consent or a second opinion, Section 58). The Mental Health Act, 1983, has recently been extensively reviewed in the White Paper *Reforming the Mental Health Act*, chapter 5 of which deals with criteria for compulsory care and treatment, and chapter 9 of which deals with treatment [116]. Psychosurgery still requires patient consent and a second opinion. Treatment proposed under Section 58 of the 1983 Act (including ECT) will be subject to special safeguards: the consent of the patient is required, or, in the case of the incapacitated, the authorisation of a mental health tribunal (rather than a second medical opinion) will be required. ECT may not be used under Section 62, which continues to authorise treatment without consent if necessary to save the patients life, prevent a serious deterioration of health, alleviate serious suffering or prevent the patient harming himself or others (this section is of importance to anaesthetists who may be asked to sedate violent patients brought to an Accident and Emergency Department subject under a Section 136 order).

Emergencies

Emergency medical treatment – when the patient is incompetent, and has not advanced a living will – excludes the requirement for informed consent. There may even be duty to provide medical treatment [43], provided the treatment is both necessary and cannot be reasonably delayed. This holds for adults, children and the otherwise incompetent.

Comparative legislation

The English common law with respect to consent for anaesthesia is unclear, unsatisfactory and at odds with other jurisdictions.

Internationally, courts have recognised that written consent forms are neither necessary nor sufficient evidence that valid consent has been obtained [117], rather that they provide documentary confirmation that a process of consent has taken place. Nevertheless, in many US states the consent form is treated as presumptively valid consent to treatment, with the burden on the patient to rebut the presumption (e.g. Fla. Stat. Ann 766.103 (4)). In one survey, 79% of patients (55% of doctors) thought that the primary purpose of consent forms was to protect physicians from lawsuits, 86% (62%) that written consent established valid consent and 65% (64%) that written consent was helpful to the doctor-patient communication [118]. The American Medical Association stress that 'to protect yourself in litigation ... it is important that the communication (about consent) itself be documented' [29]. In Ontario, the Health Care Consent Act, 1996, states that patients' wishes may be expressed in any form, written or otherwise, although the College of Physicians and Surgeons of Ontario strongly advise physicians to obtain express written consent [119]. The Canadian Anaesthesiologists Society do not explicitly advise that consent to anaesthesia should be documented, but state that the pre-operative evaluation, which includes the consent process, should be documented. However, they advise that informed consent for obstetric regional anaesthesia should be documented in the medical record [120]. The Australian Law Reform Commission emphasises that signature on a consent form may be substantial evidence that the patient consented, but it is not conclusive [121]. Professor Skene suggests that 'good note keeping is still a doctor's best defence' against disputes about what information was provided [122]. The Australia and New Zealand College of Anaesthetists advises anaesthetists to record a written summary of the pre-operative assessment, including those risks and potential complications discussed with the patient [25].

The information that should be disclosed in order to validate consent, however, varies significantly between jurisdictions [123,124]. Traditionally, English courts have adopted a doctor-based standard of disclosure, such that medical opinion is determinative in deciding what the patient should be told. However, *Pearce* has suggested that English courts are moving towards the 'reasonable patient' standard advocated in Canada (*Reibl v Hughes* [125]), Australia (*Rogers v Whittaker* [126]), New Zealand [127] and Germany [128], such that 'a reasonable patient in the patient's position would be likely to attach significance' to a risk if they were informed (other English cases include *Smith v Tinbridge Wells HA* [129], *Newell and Newell v Goldenberg* [130], and *Lybert v Warrington HA* [131]).

Since *Canterbury v Spence* [132], the majority of US States have also adopted the reasonable patient standard. However, there appears to be an expanding number of obligations with regard to information disclosure in the US [133], including information about the physician's physical condition (see above), financial responsibilities and research interests [134], any alternative therapies available [135] and the consequences of non-therapy [136].

Conclusions

Professional guidelines concerning issues of consent in anaesthesia are a fair representation of current English law. They emphasise that consent is a fluid, two way process of discussion, and provide useful advice to anaesthetists about who may provide legitimate consent and what information should be disclosed in order to obtain valid consent, whilst rejecting the need for specific written consent for anaesthesia. Indeed separate, written, informed consent for anaesthesia is not a legal requirement in any Western jurisdiction. This is understandable, as there would be a number of problems inherent in such an approach: too much information would need to be disclosed, the consent form would have to be too detailed, full disclosure would take up too much time, the information disclosed would be generic (i.e. would not allow for operator-dependent variables), and many of the risks are of uncertain incidence. Moreover, we would suggest that written consent is not needed in order to defend cases of assault by anaesthetists. However, for the very reason that there are a large number of risks associated with anaesthesia (risks which are unknown to the majority of surgeons), together with the possibility of the courts moving towards a reasonable patient standard of information disclosure (as a result of the introduction of human rights legislation into English law), it is our view that the AAGBI should change their guidelines and advise anaesthetists to obtain separate written affirmation from patients that certain risks and consequences of anaesthesia have been explained to them. In addition, a standardised consent form for anaesthesia may prove invaluable in retrospectively defending a claim of negligence founded around information disclosure, by recording exactly the risks and consequences of interventions discussed by the anaesthetist and the patient.

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