Chapter

4

The Law and Paediatric Anaesthesia

Consent, Refusal, Restraint and Research

Hugo Wellesley

Introduction

A nine-year-old boy is listed for circumcision. You preassess him on the paediatric day ward. He appears nervous but cooperative. He is tearful as you collect him from reception, but he walks to the anaesthetic room with his mother. He refuses to accept either inhalational induction or insertion of a cannula, or indeed to get on the trolley. His mother is insistent that you proceed. Would you continue, and if so, how?

This chapter aims to give you a legal and ethical framework on which to base your approach to such clinical problems. It relates to practice in the United Kingdom (UK). There are differences between the law in England and Wales and the law in either Scotland or Northern Ireland.

Consent

Self-Determination

Self-determination with respect to one's body is a fundamental human right. From the 1960s, the rights of those under 18 to self-determination have been progressively recognised and protected in law. Medical examinations, treatments and investigations all represent intrusion of bodily integrity and as such require consent from the child or their guardian. Only in limited circumstances can a doctor proceed without it. Consent may be expressed or implied, and it can be written, verbal or even non-verbal. For consent to be valid, the person giving consent must be capable of taking that particular decision, be acting voluntarily and be provided with enough information to make an informed decision.

Consent serves several purposes. It recognises the individual's rights of autonomy and self-determination. It demonstrates cooperation and belief in a treatment modality, which in itself is integral to the success of many treatments. It also offers some protection to the medical practitioner where disputes arise.

Battery

Failure to obtain consent can result in an action for battery (a criminal case) or a claim of negligence (a civil lawsuit). It can also result in disciplinary action for the professional concerned from their regulatory body. An action for battery arises where the defendant has been touched and for which there has been no consent, either expressed or implied. No actual physical harm need arise, and the intentions of the perpetrator are irrelevant. An action of battery can be pursued where a doctor has proceeded in the face of a refusal to a procedure or has undertaken an additional procedure unconnected to the one for which consent was obtained. In order to avoid an action of battery, a doctor needs only to explain the 'broad nature' of the procedure that is proposed – this is a much lower standard than that required to avoid a claim of negligence, as well as the standard required of doctors by the General Medical Council (GMC).

Negligence

In an action based on negligence, on the other hand, the plaintiff must prove causation. The plaintiff must show that the defendant proceeded without valid consent, and that this *caused* the injury for which they are seeking damages. The court must be satisfied that the patient would not have given their consent had they been properly informed of what was to be done. Where a patient has consented to a procedure but the doctor failed to mention a complication that the patient subsequently suffered, there is a basis for a claim in negligence. The negligence refers to the failure to inform rather than the way in which the procedure was performed.

Minors 16–18 Years

Anyone under the age of 18 is legally a minor; however, the rules regarding consent differ between those who are under 16 and those who are 16 or 17 years old. Sixteen- and 17-year-olds are presumed to be competent. This is referred to as the presumptive test of competence and is defined by the Family Law Reform Act 1969 in England and Wales or the Age of Legal Capacity (Scotland) Act 1991. For those who are felt might not be competent, the onus is on the treating doctor to demonstrate that they are not competent, for which there is a two-stage test, as laid out in the Mental Capacity Act 2005:

(1) Does the patient have a disturbance in the functioning of the mind or brain?
(2) Is the patient unable to understand the information relevant to the decision, retain that information and then use or weigh that information to make a decision at the particular time that it needs to be made?

The child must be provided with all the support they need to maximise their ability to fulfil the requirements of capacity; if it is decided that the child lacks capacity, then someone with parental responsibility can give consent for the child.

Minors under 16 Years: Gillick Competence

Below the age of 16 years, a minor can give valid consent themselves if they demonstrate Gillick competence. This test of competence is derived from the case of *Gillick v West Norfolk & Wisbech AHA* (1985) and requires the child to be able to demonstrate competence (whereas it should be presumed for the 16- and 17-year-olds). The Gillick case set a precedent that permitted children of sufficient maturity to seek contraceptive advice without the knowledge of their parents but was subsequently applied more generally to allow children who fulfilled the criteria to consent to other forms of medical treatment. The age at which Gillick competence can be demonstrated will depend on the child and the complexity of the treatment or procedure. Where a Gillick-competent child requests non-disclosure to their parents, their confidentiality must be respected, although it is good practice to encourage children to involve their parents.

In order to demonstrate Gillick competence, the child should understand that there is a choice to be made and demonstrate a willingness to make it. The child should be able to understand the nature of the proposed treatment and the risks involved. They should appreciate what the effects of non-treatment might be. It is important that the child can retain the information long enough to come to a decision.

Assent to Treatment

The term 'assent' is sometimes used to describe an agreement by the child to participate with a degree of explanation and understanding appropriate to their age and development but falling short of fully valid consent. It is a term borrowed from the United States and does not have a legal basis in the United Kingdom but is nevertheless sometimes used to refer to a child's willingness to participate. It does not replace the need for full consent from someone who is able to give it.

Parental Responsibility

Where the child does not have the capacity to give consent, it must be sought from someone with parental responsibility (PR). In most situations, the law only requires consent from one person with PR; however, it is good practice to involve all relevant parties. One important exception is for circumcision, where consent from everyone with PR is required (usually this means both parents). As a rule, you should be very wary of proceeding with any treatment if you are aware that someone with PR actually objects.

The following people have parental responsibility:

- The child's mother
- The child's father, if married to the mother at the time of conception (for births registered in Scotland) or at the time of birth (in the rest of the United Kingdom)
- If unmarried at conception or birth, the child's father can obtain PR by one of the following means:
    - If the couple subsequently marry
    - By being recorded on the child's birth certificate: for all children in Northern Ireland, and for children registered after 1 December 2003 in England and Wales, or after 4 May 2006 in Scotland (this can be the date of the original registration or a subsequent re-registration). For children

born outside the United Kingdom, the rules of the country of residence apply.
    - By making a parental responsibility agreement with the mother (this must be registered with a court)
    - By court order
- Adoptive parents
- A court-appointed guardian
- A testamentary guardian (i.e. one appointed in a person's will) if no one with PR survives the testator
- A person awarded a residence order
- A local authority designated in a care order (except where the child is being 'accommodated' or in 'voluntary care' – see Section 20 of the Children Act)
- A person or authority holding an emergency protection order for that child

Since 2009, both parents, regardless of gender, can have their names on the birth certificate, giving them both parental rights. Parents do not lose PR if they divorce, even if a parent has no contact with the child. Grandparents, stepparents, and foster parents do not have parental responsibility unless it has been specifically arranged through a parental responsibility agreement (registered with the court) or a court order. For children born under surrogacy arrangements, the surrogate mother has PR (along with her husband, if she is married) until the intended parents either adopt the child or obtain a parental order from a court (under the Human Fertilisation and Embryology Act 1990).

Parents have parental responsibility in order to give them the legal power to make decisions to safeguard and promote their child's health, welfare and development. Parental rights only exist to enable them to fulfil their responsibilities. These rights can therefore be challenged if it is felt that the parents are not acting to promote their child's interests.

It may be that those with PR do not themselves have the capacity to consent on behalf of the child owing to mental illness or special needs, in which case legal advice should be sought.

Emergency Treatment

In the situation where no one is able to give valid consent, it is lawful to provide emergency treatment in the absence of consent on the basis that it is in the child's best interests. Assessment of best interests should be based on the physical, emotional, social, cultural and psychological needs of the individual. The views of and the effect on other family members may need to be considered. Evidence of the effectiveness of the proposed treatment, risks of treatment and of delaying or withholding treatment must be taken into account. Where possible, treatments that maximise the patient's future choices should be offered so the child can exercise their autonomy when they do attain competence. It is not necessarily the case that any treatment that prolongs life is in a child's best interests.

Refusal of Treatment

Although it might seem logical that someone who is competent to consent to treatment should also be competent to refuse treatment, this will not always be the case. Treatment is only proposed where it is felt to be in a child's best interest, so refusal of that treatment will usually be considered to be against their best interests. A refusal therefore requires a greater level of understanding, and there remain circumstances in which a decision by a competent minor can be overridden if it is in their best interests.

A court clearly can do this. There are also judgements that state that parents can do this; however, these predate the introduction of the Human Rights Act 1998, and there is a risk that accepting the consent of a parent in the face of a competent child's refusal could be found to have breached the child's rights. It has therefore been recommended by the Department of Health that 'it would be prudent to obtain a court declaration or decision if faced with a competent child or young person who is refusing treatment, to determine if it is lawful to treat the child'. The Mental Capacity Act 2005 Code of Practice also recommends a similar approach in the case of a disagreement between a 16- or 17-year-old with capacity who is refusing treatment to which a parent wants to consent.

It could be argued that children require a greater level of understanding than is asked of adults. The case of *Re E* in 1990 demonstrates this point. The patient was 15 years old and a Jehovah's Witness, as were his parents. He was suffering from leukaemia. The case arose when he and his parents refused a treatment regimen that offered a high chance of cure but involved blood

transfusions, in favour of a less successful treatment avoiding the use of blood products. Although impressed with his level of understanding and conviction to his faith, the judge declared that he did not adequately appreciate the pain and distress that would arise nor the effect on his family. Moreover, he felt the details were too distressing to even contemplate telling the boy. The court was unwilling to arm him with the information to allow him to make an informed choice. The ruling resulted in the boy receiving blood transfusions as part of his treatment. He continued to voice his objection until he reached adulthood, when he refused further blood transfusions and died.

Advance Directives, Living Wills

Although advanced care planning is encouraged for children with life-limiting illnesses, advance directives and living wills are not legally binding.

Obtaining Consent

The responsibility for seeking a patient's consent lies with the doctor undertaking the procedure. This task can be delegated to someone else provided that individual is suitably trained and qualified and has sufficient knowledge of the proposed procedure.

Legal and Professional Standards

The most pertinent legal case in this area is *Montgomery vs Lanarkshire Health Board* [2015] UKSC 11. This involved a woman (Mrs Montgomery) who had gestational diabetes and her son who had a very difficult vaginal delivery complicated by shoulder dystocia, which resulted in his developing a brachial plexus injury and severe cerebral palsy. The Supreme Court found that she had not been adequately informed of the risks of a vaginal delivery and had not been offered a caesarean section as an alternative. The court stated that a doctor should warn of all 'material risks'. It went on to define these as the risks to which a 'reasonable person in the patient's position would be likely to attach significance' and also the risks to which the 'doctor is or should reasonably be aware that the particular patient would attach significance'.

The GMC publishes guidance on consent which all doctors are professionally bound to follow. These are also cited in legal judgements and used to assess doctors' actions, so in effect they also become legally binding. Interestingly, the GMC intervened in the *Montgomery* case on behalf of Mrs Montgomery.

These guidelines were updated in 2020 and apply to consent for treating children as well as adults. They should be read in conjunction with the GMC's *0–18 Years: Guidance for All Doctors*. They emphasise the importance of a 'meaningful dialogue' with patients rather than just giving them lists of benefits and risks. The guidance states that the following information should be shared with patients:

- Recognised risks of harm that you believe anyone in the patient's position would want to know
- The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring
- Risks of harm and potential benefits that the patient would consider significant for any reason
- Any risk of serious harm, however unlikely it is to occur
- Expected harms, including common side effects, and what to do if they occur

There is therefore a high degree of agreement between the legal standard as described in *Montgomery* and the GMC's standards.

Documentation of Consent

There is no legal requirement for a signed consent form except for living organ donation and fertility treatment. A signed consent form serves as a record that a discussion took place, but it is not proof of valid consent. Where a competent child has given consent, their signature alone is sufficient. When obtaining consent for anaesthesia, this can be verbal, but you should always carefully document the consent and the discussions that have informed it.

The question of who takes written consent for radiological investigations under general anaesthesia has been the subject of debate. It has been argued that the risk associated with anaesthesia is greater than the risk of the investigation; however, the risk of anaesthesia can only be taken into context when one understands how the information the scan provides will help the child, what the

alternatives to having that investigation are and the implications of not having the scan. These can only be imparted by the clinician or team requesting the test.

Court Orders

If agreement between a child, their parents and the medical team cannot be reached within a reasonable time period, then it may be necessary to ask the court to intervene. This typically happens in cases involving withdrawal of life-sustaining treatment. Second opinions should be sought in situations involving serious disagreement, and increasingly there is a move to try formal mediation before referral to the court. The courts have the power to consent to treatment on behalf of a minor when they consider that treatment to be in the child's best interests. However, no child, parent or court has the power to force a doctor to perform a procedure that the doctor does not feel is clinically justified.

Cases can also be referred to the court when parents disagree amongst themselves about what to do, particularly for certain procedures such as organ donation, sterilisation or circumcision.

Restraint

The Department of Health defines restraint as 'the positive application of force with the intention of overpowering the child'. Restraint implies a restriction of liberty or freedom of movement, and so constitutes a breach of an individual's autonomy. Restraint also breaches the Human Rights Act Articles 3, 5 and 9 and therefore needs to be justified. Justification for restraint in limited circumstances can be argued on the principles of beneficence and non-maleficence, but it needs to be in the overall best interests of the child.

Restraint in Anaesthesia Practice

It is common for a child to demonstrate varying degrees of resistance to aspects of medical management. The causes may be many and include a wariness of strangers, unfamiliar settings, anxiety, frustration, phobia or a genuine refusal. Management in the setting of surgery and anaesthesia is made more difficult because the anaesthetist will often not have a pre-existing relationship with the child, preoperative fasting results in distress to the child and the process can involve separation from their parents. Decisions as to whether to proceed often have to be made in a very narrow time frame. It is important to try to interpret the child's behaviour in light of their developmental age. In addition to the views of the child, consideration must also be given to the urgency of the procedure, the presence of valid consent from someone with parental responsibility and the consequences of not proceeding or delaying treatment. Proceeding with treatment against the child's wishes may be legal but may require either physical and/or pharmacological restraint and may have unwanted psychological sequelae, even if it is done as considerately as possible. This risk must be taken into account when assessing whether or not the procedure is still in the child's best interests.

Using restraint or force to impose a treatment on an unwilling patient is in practice very difficult and fortunately rarely necessary. With sufficient time and explanation, most children will accept and cooperate with treatment. Most of the medical literature regarding restraint appears in relation to psychiatry and some articles relating to dentistry for those with special needs.

The Royal College of Nursing has guidance on the appropriate use of restraint. This guidance uses the term 'clinical holding', which is defined as the use of limited force to hold a child still to enable a health care procedure. According to these guidelines, it should be clear who is deciding what is in the child's best interests, and there should be an effective mechanism for staff who disagree to be heard. Where clinical holding might be required, staff should:

- Carefully consider whether the procedure is really necessary and explore alternatives to holding
- Anticipate and prevent the need for holding by giving the child information, encouragement, distraction, analgesia and, if necessary, sedation
- Obtain the child's express agreement in all but the very youngest children and, for any procedure which is not a true emergency, seek parental consent
- Pause prior to a procedure to discuss with the child and their parents what will happen and what people's roles will be
- Ensure that any holding that is used is the least restrictive option required and is used for the minimum amount of time

- Ensure parental presence and involvement if they wish to be present and involved
- Explain parents' roles in supporting their child and provide support for them during and after the procedure
- Comfort the child where it hasn't been possible to obtain their agreement, and explain clearly why it was necessary to hold them still
- Ensure clear documentation afterwards

The degree of force used should not be excessive and should be in proportion to the perceived benefit. Inappropriate use of restraint may result in criminal charges, action in civil law or prosecution under health and safety legislation.

Research in Children

Society as a whole benefits from quality research. However, the extent to which individuals should be subjected to risks for the good of others, especially where those individuals lack the ability to consent, is a difficult ethical dilemma. The Nuremberg Code of 1947 suggests that those who cannot express their views should be excluded from research. There is a strong argument, however, that excluding children from research is unjust because it breaches their right to the best attainable health care. Therapeutic research can be in a child's best interests, but non-therapeutic research is harder to justify. However, if the purpose of research is ultimately to improve diagnosis and treatment of patients, then not to allow children to participate in research is to deny the paediatric population advances in clinical management.

Professional Guidance for Research Involving Children

The Royal College of Paediatrics and Child Health (RCPCH) has guidance for research involving children. It recognises that many diseases are unique to children, and that response to treatment differs from that in adults, making research involving children vital. Children should, therefore, 'be offered the opportunity to participate in research, and have their care *assured by research*'. It also states that research that is of 'no benefit to that child (non-therapeutic research) is not necessarily either unethical or illegal'.

All trials must be approved by a research ethics committee, and studies involving particularly vulnerable groups (such as children with life-threatening illnesses) should be reviewed by a research ethics committee with appropriate knowledge and experience. As always, voluntary informed consent is essential, and it must be emphasised to the patient and family that they are free to withdraw at any time without care being affected. When consent has been obtained from the parents, the agreement of school-age children should also be requested by researchers. A parent cannot override a Gillick-competent child's refusal to consent for non-therapeutic research.

Levels of Risk

It is generally accepted that a lower degree of risk is acceptable for children subjected to research compared with adults. There is little consensus, however, as to how to define acceptable risk.

Minimal risk describes procedures such as non-invasive urine sampling or using blood or tissue taken as part of management of a clinical condition.

Low risk describes procedures that cause brief pain, emotional distress or small bruises such as blood sampling. Low-risk procedures are unlikely to be considered acceptable if there is no benefit to the child. However, if the child shows altruism and on careful explanation is willing to accept this discomfort, then it may be reasonable to proceed.

High-risk invasive procedures may only be justifiable for research when the procedure is part of diagnosis or treatment intended to benefit the child subject.

Clinical Scenario

Returning to the opening clinical example of the nine-year-old boy listed for circumcision, one approach would be to remove the child from the stressful environment or alternatively remove all the unnecessary staff from the room so it appears less threatening. Ascertain whether the child is anxious about a particular aspect of the procedure, such as insertion of the cannula, or fundamentally does not want the operation. It can be very helpful to involve the surgeon who may already have a rapport with the child from a previous clinic appointment. It is also an opportunity to establish with the child how strong the indication for surgery is. It may be that his symptoms have subsided and that he is rightfully questioning the need for surgery. If he is fearful of a particular element of the

procedure but in agreement with the need for surgery, returning to the ward for an anxiolytic premedication might be an acceptable way to proceed. An alternative to this would be to postpone surgery to allow a play therapist or clinical psychologist to work with the child. This would have the advantage of hopefully arming the child with coping strategies to deal with similar stressful situations in the future. If the child consistently disagrees with there being a need for surgery, then restraint, whether it be chemical or physical, is inappropriate and the child should be reviewed in clinic.

Key Points

- A child below the age of 16 can give consent if they demonstrate Gillick competence.
- Once a child is 16, they should be presumed to be competent to consent to medical treatment.
- Discussions with patients and families should include those risks and benefits that anyone in their position would want to know and also those risks and benefits you are able to ascertain that they would consider significant for any reason.
- The use of restraint should be avoided if possible and, where it is used, needs to be justified and in the child's best interests.
- Research involving children is vital but poses unique ethical challenges. Given the right conditions, both therapeutic and non-therapeutic research can be ethical and legal.

Further Reading

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