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Consent

Introduction

Consent must be obtained before starting any treatment or physical investigation or before providing personal care for a patient. This includes the administration of all vaccines. The guidance in this chapter is based both on the current legal position and the standards expected of health professionals by their regulatory bodies. Further legal developments may occur after this guidance has been issued and health professionals should remember their duty to keep themselves informed of any such developments that may have a bearing on their area of practice.

There is no legal requirement for consent to immunisation to be in writing and a signature on a consent form is not conclusive proof that consent has been given, but serves to record the decision and the discussions that have taken place with the patient or the person giving consent on a child's behalf.

The giving and obtaining of consent is viewed as a process, not a one-off event. Consent obtained before the occasion upon which a child is brought for immunisation is only an agreement for the child to be included in the immunisation programme and does not mean that consent is in place for each future immunisation. Consent should still be sought on the occasion of each immunisation visit.

Consent must be given voluntarily and freely. The individual must be informed about the process, benefits and risks of immunisation and be able to communicate their decision. Information given should be relevant to the individual patient, properly explained and questions should be answered fully.

Consent remains valid unless the individual who gave it withdraws it. If there is new information between the time consent was given and when the immunisation is offered, it may be necessary to inform the patient and for them to re-confirm their consent. This includes new evidence of risk, new immunisations (e.g. pneumococcal vaccine) becoming available or where there is a significant change in the individual's condition, such as treatment for cancer.

Consent

Advice on consent which is specific to Wales, Scotland and Northern Ireland is available or in preparation. Please refer to the end of this chapter for further details.

What information should be provided?

Individuals, or those giving consent on their behalf, must be given enough information to enable them to make a decision before they can give consent. This should include information about the process, benefits and risks of the immunisation(s).

The four UK countries provide a wide range of information, including leaflets, posters, videos, information packs, factsheets, and websites to support all aspects of the immunisation programme. This information is based on the current scientific evidence and clinical advice and will have been tested on relevant population groups.

Written or verbal information should be available in a form that can be easily understood by the individual who will be giving the consent. Where English is not the first language, translations and properly recognised interpreters should be used.

Consent is valid if the individual, or person providing consent, is offered as much information as they reasonably need to make their decision, and in a form that they can understand. Case law on this area is evolving – more detail can be found at www.dh.gov.uk/consent

Health professionals should ensure that the individual (or those giving consent on their behalf) fully understands which immunisation(s) are to be administered; the disease(s) against which they will protect; the risks of not proceeding; the side effects that may occur and how these should be dealt with; and any follow-up action required.

In line with current data protection and Caldicott guidance, individuals should also be informed about how data on immunisation will be stored, who will be able to access that information and how that data may be used. It is important to emphasise that such information is used to monitor the safety and efficacy of the current vaccination programmes.

How should consent be sought?

The health professional providing the immunisation should ensure that consent is in place.

It is good practice to check that the person still consents to your providing each immunisation before it is given.

The Nursing and Midwifery Council's Code of Professional Conduct: standards for conduct, performance and ethics paragraph 1.3 (NMC, 2004: www.nmc-uk.org/aFrameDisplay.aspx?DocumentID=201) states that 'You are personally accountable for your practice. This means that you are answerable for your actions and omissions, regardless of advice or directions from another professional.' Giving an immunisation without consent could leave the health professional vulnerable to legal action and action by their regulatory body.

Who can give consent?

Adults

Adults are those aged 18 or over. An adult must consent to their own treatment. Under English law, no one is able to give consent on behalf of an adult unable to give consent for examination or treatment him or herself. The Mental Capacity Act 2005 is due to come into force in 2007 and sets out how treatment decisions should be made for people of 16 years of age or older who do not have the capacity to make such decisions (more information will be available at www.dh.gov.uk/consent).

If an adult has refused immunisation before losing the capacity to make a decision, this decision will be legally binding, provided that it remains valid and applicable to the circumstances. If an adult has not clearly refused the treatment before losing the capacity to make such a decision, you will be able to treat an adult who is unable to consent if the treatment would be in their best interests, e.g. in a nursing home situation where the risk of influenza could compromise the individual's health. This decision would be made by the patient's doctor in discussion with those close to the patient.

Immunisation of younger children

For young children not competent to give or withhold consent, such consent can be given by a person with parental responsibility, provided that person is capable of consenting to the immunisation in question and is able to communicate their decision. Where this person brings the child in response to an invitation for immunisation and, following an appropriate consultation, presents the child for that immunisation, these actions may be considered evidence of consent.

Who has parental responsibility?

The Children Act 1989 sets out who has parental responsibility for a child. Mothers automatically have parental responsibility for their children. A father also has parental responsibility if he was married to the mother when the child was born, or if he subsequently married her. An unmarried father may also acquire parental responsibility by:

- Parental Responsibility Order granted by the court
- Residence Order granted by the court. This will give the person with the residence order parental responsibility as well as those of the child's parents which have parental responsibility. More than one person can have parental responsibility in more than just this case. For example, two parents or the local authority and a parent where there is a care order.
- Parental Responsibility Agreement. This must be signed by both parents, their signatures witnessed by an Officer of the Court who is authorised to administer oaths, or a Magistrate or justices' clerk, or assistant to a justices' clerk, and the form sent to the Principal Registry of the Family Division (High Court) for registration after which it becomes effective.

Since 1 December 2003, an unmarried father who is the natural father of the child can also acquire parental responsibility if he is named as the father on the child's birth certificate. Unmarried fathers who are already on the child's birth certificate before 1 December 2003 will not automatically acquire parental responsibility, and would only acquire it by either later marrying the child's mother or signing a Parental Responsibility Agreement with the mother or getting a court order.

A step parent may acquire parental responsibility of a child where s/he is married to, or a civil partner of, the child's parent who has parental responsibility and either (i) there is a parental responsibility agreement to this effect or (ii) the court grants a parental responsibility order (see Section 4A of the Children Act 1989).

Routine immunisation in schools

Where immunisations are routinely offered in the school setting,* the situation differs depending on the age and competence of the individual child or young person. Information leaflets should be available for the child's own use and to share with their parents prior to the date that the immunisation is scheduled.

Young people aged 16 and 17 are presumed, in law, to be able to consent to their own medical treatment. Younger children who understand fully what is involved in the proposed procedure (referred to as 'Gillick competent') can also give consent, although ideally their parents will be involved.

If a person aged 16 or 17 or a Gillick-competent child consents to treatment, a parent cannot override that consent.

If the health professional giving the immunisation felt a child was not Gillick competent then the consent of someone with parental responsibility would be sought.

If a person aged 16 or 17 or a Gillick-competent child refuses treatment that refusal should be accepted. It is unlikely that a person with parental responsibility could overrule such a refusal. It is possible that the court might overrule a young person's refusal if an application to court is made under section 8 of the Children Act 1989 or the inherent jurisdiction of the High Court.

There is no requirement for consent to be in writing.

* Where a mass immunisation campaign is to be carried out in schools such as the MenC campaign 1999/2000, different guidance regarding information and consent would apply

Other issues

Although the consent of one person with parental responsibility for a child is usually sufficient (see Section 2(7) of the Children Act 1989), if one parent agrees to immunisation but the other disagrees, the immunisation should not be carried out unless both parents can agree to immunisation or there is a specific court approval that the immunisation is in the best interests of the child.

The person with parental responsibility does not necessarily need to be present at the time the immunisation is given. Although a person may not abdicate or transfer parental responsibility, they may arrange for some or all of it to be met by one or more persons acting on their behalf (Section 2(9) of the Children Act 1989).

There is no requirement for such arrangements to be made in writing. Children may be brought for immunisation by a person without parental responsibility, for example, a grandparent or childminder. Where a child is brought for immunisation by some one who does not have parental responsibility the health professional would need to be satisfied that:

- the person with parental responsibility has consented in advance to the immunisation (i.e. they received all the relevant information in advance and arranged for the other person to bring the child to the appointment) or
- the person with parental responsibility has arranged for this other person to provide the necessary consent (i.e. they asked the other person to take the child to the appointment, to consider any further information given by the health professional, and then to agree to immunisation if appropriate).

If there is any evidence that the person with parental responsibility:

- may not have agreed to the immunisation (e.g. the notes indicate that the parent(s) may have negative views on immunisation), or
- may not have agreed that the person bringing the child could give the necessary consent (e.g. suggestion of disagreements between the parents on medical matters) then the person with parental responsibility should be contacted for their consent. If there is disagreement between the people with parental responsibility for the child, then immunisation should not be carried out until their dispute is resolved.

A person giving consent on behalf of a child may change his or her mind and withdraw consent at any time. Where consent is either refused or withdrawn, this decision should be documented.

It is the duty of each healthcare professional to communicate effectively and share such knowledge and information with other members of the primary healthcare team.

Recording consent

Those who are capable of giving consent may do so in writing, orally or by co-operation. Completion of a consent form is not a legal requirement. A signature on a consent form does not itself prove that the consent is valid but it does serve to record the decision that was reached, and the discussions that have taken place. The Bristol Royal Infirmary Inquiry Final Report (2001) (www.bristol-inquiry.org.uk/final%5Freport/report/sec2chap23%5F15.htm) reported that ‘too great a regard is paid to the symbolic act of signing a piece of paper rather than to the real task ... which involves explaining what is to take place.’

It is important to ensure that the healthcare record for each child – Personal Child Health Record (PCHR) and GP record (either paper or computer) is an accurate account of care planning and delivery. It is good practice for proper records of any discussions to be recorded in the PCHR and completed with the involvement of the parent or guardian.

Professional liability

Doctors and other health professionals involved in the administration of immunisation are usually not negligent if acting within their competencies and within practice that conforms to that of a responsible body of medical opinion held by practitioners skilled in the field in question (see, for example, *Sidaway v Board of Governors Bethlem Royal Hospital* (1985) AC 871; *Bolam v Friern Hospital Management Committee* (1957) 2 All ER 118). However, the courts are willing to be critical of a ‘responsible body’ of medical opinion and will be the final arbiters of what constitutes responsible practice.

This summary cannot cover all situations. For more detail, consult www.dh.gov.uk/consent

Scotland

There are some important differences between England and Scotland, particularly when dealing with mental health, children or adults with incapacity. The Adults with Incapacity (Scotland) Act 2000 was introduced in stages, with Part 5, Medical Treatment and Research, coming into effect in July 2002. The Mental Health (Care and Treatment) (Scotland) Act 2003 came into effect in stages from March 2004 and is now largely in force, replacing the Mental Health (Scotland) Act 1984. Both Acts provide for delivering healthcare to people who lack the ability to make treatment decisions for themselves. Full details should be provided by the health professionals involved; however, further information is available from local health councils. The Age of Legal Capacity (Scotland) Act 1991 outlines that someone has the capacity to make decisions around consent from the age of 16. However, even under the age of 16, a young person can have the legal capacity to make a consent decision on a healthcare intervention, provided that they are capable of understanding its nature and possible consequences; this is a matter of clinical judgement.

Wales

The Welsh Assembly Government is working jointly with the Department of Health in developing updated guidance on patient consent to examination and treatment. It is expected that the new guidance will be published in both England and Wales around April 2007, to coincide with the Coming Into Force date of the Mental Capacity Act. Health professionals providing immunisation and vaccination services in Wales should refer to the guidance once published. In Wales, further information can be obtained at: www.wales.nhs.uk/sites3/page.cfm?orgid=465&pid=11930

Northern Ireland

Information regarding consent for immunisation can be found at: www.dhsspsni.gov.uk/publichealth-immuno-guidance.pdf

Guidance on consent

Guidance for patients

The following information is available from the NHS Response Line (08701 555 455) and at: www.dh.gov.uk/consent

Consent: what you have a right to expect: a guide for adults

Consent: what you have a right to expect: a guide for children and young people

Consent: what you have a right to expect: a guide for people with learning disabilities

Consent: what you have a right to expect: a guide for parents

Consent: what you have a right to expect: a guide for relatives and carers

Reference guide to consent for examination or treatment

Guidance for clinicians

HSC 2001/023: Good practice in consent: achieving the NHS Plan commitment to patient-centred consent practice.

References

Department of Health (2001) *Seeking consent: working with children*. London: Department of Health. www.dh.gov.uk/assetRoot/04/06/72/04/04067204.pdf

Scottish Executive (2006) *A good practice guide on consent for health professionals in the NHS Scotland*. www.show.scot.nhs.uk/publicationsindex.htm