
Consent Issues

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Definition of consent

- Consent is the process whereby a competent patient or parent/guardian signifies their **permission** to undergo a medical or surgical procedure.
- Consent must always be obtained **before** the event.
- Healthcare professional provides **sufficient information** in a way **a patient can understand**, to enable them ...to make informed decisions...including all significant or substantial risks.

Why is consent required?

Consent acts as protection for both health professionals and individuals so if any questions are asked in the future there is a record available to show what the individual agreed to on the day of consent.

What constitutes informed consent?

- **Informed or valid consent**

- must be freely and voluntarily given,
- the patient must have the capacity to give a valid consent,
- sufficient information clearly setting out the:
 - benefits
 - risks
 - alternative options.

Information for consent

- The person giving consent must receive sufficient information, in a way that they can understand, about the nature, purpose, benefits and risks of an intervention/service/research project as well as that of any available alternative treatment.
- They should also receive information on the consequences of refusing the treatment.
- Information to an individual should be tailored to:
 - Their needs, wishes, priorities.
 - Their level of knowledge and understanding of their condition, prognosis and treatment options.
 - Their ability to understand the information and language used:
 - Use simple, clear, concise, language avoiding jargon and medical terminology.
 - Use of interpreter service (not family or friends); lip reading/e-mail/texting/large print/audio. Translated information materials.
 - The nature of their condition.

Capacity for consent

- Every adult patient is presumed to have the capacity to make decisions about their own healthcare.
- People who are considered not to have the capacity to give their consent are still entitled to the same respect for their human dignity and personal integrity as any person with full capacity.
- Where capacity is “proved to be lacking” take reasonable steps to find out whether any other person has legal authority to make decisions on the patient’s behalf.

Voluntary consent

- For consent to be valid, care should be taken that people do not feel forced into making a particular decision. They must understand that they have a choice.
- Duress does not refer to:
 - the pressure that the illness itself can impose on the service user
 - strongly recommending a particular treatment or change in lifestyle activity
 - pointing out the likely consequences of choices the service user may make on their health/treatment options.

Context for consent to immunisation

- Immunisation is a preventive medical treatment.
- It is generally offered to well people.
- It is generally not an emergency intervention.
- We know a lot about vaccine preventable diseases.
- The safety of vaccines is more rigorously monitored than for other medicines.

Consent to immunisation

- What vaccines will be administered and against which disease they provide protection.
- What are the benefits and risks of immunisation and the risks of disease(s).
- What are the possible side effects of immunisation, when might they occur and how should they be treated?
- Alternatives to vaccination.

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How long does consent remain valid?

- There is no legally prescribed time.
- Consent is valid unless it is withdrawn.
- If the patient's condition has changed or if there is new information available on the intervention then fresh consent should be obtained.

How should consent be recorded?

- The consent form should be signed before the procedure/treatment begins.
- All discussions and decisions that have taken that led to agreement should be recorded.

Is verbal consent valid?

- Written consent provides a permanent record, but either written or verbal consent is required at the point where vaccination is about to take place, provided the individual's fitness and suitability has been established.
- In the schools immunisation programme, if the consent form returned is not clear a nurse or doctor may phone a parent/legal guardian to clarify consent. The consent or refusal of consent should be witnessed by two members of staff. If discussion about risk/benefit of immunisation is required the parent/legal guardian is invited to attend a clinic for further discussion.

What if the person's first language is not English?

- Use translated information leaflets www.immunisation.ie
- Use a translator (other than friend or family)

What happens if the person is illiterate?

- The person can be asked to make their mark on the consent form and have it witnessed by someone other than the healthcare professional seeking consent.
- If unable to make their mark this needs to be recorded in the medical notes and witnessed by someone other than the healthcare professional seeking consent.

What is the age of consent?

- The Non-Fatal Offences Against the Person Act, 1997, Section 23 permits a minor who has attained the age of 16 to consent to treatment.
- For children under 16 years consent is given by parents or legal guardians.

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Who can give consent for children?

- The **parent(s)** of the child can give consent for vaccination on their child's behalf.
- The Irish Constitution protects the rights of parents to make decisions for their children through the rights given to the family by **Articles 41 and 42** of the Constitution, as seen in a case about PKU test in 2001.*
- Under The Guardianship of Infants Act, 1964, the **mother** is given automatic parental responsibility for the child.
- The **father** is also given parental responsibility **if he is married** to the mother at the time of the child's birth or **if they marry after the birth** of the child or if **both adults adopt the child together**.
- However, if a child is **born outside marriage** the **mother** is given automatic responsibility for all decisions relating to the child.
- An **unmarried father** can apply to the **District Court** for **guardianship** of his child and he can then give consent for vaccination. This was recently confirmed by a Supreme Court decision in 2013.**

*Supreme Court Decision 08/11/2001 available at <http://www.courts.ie/Judgments.nsf/0/3788B4111F65A01480256CCC00587FDF>

**Supreme Court Decision 19/12/2013 available at <http://www.courts.ie/Judgments.nsf/0/449D9F5652D2B4C280257C660054C5C4>

What about adopted children?

- Adoptive parents are the legal guardians of the child and either parent can give consent.

What about separated/divorced parents?

- Where the parents of a child are legally separated, **either parent** can give consent to medical treatment **except** in a situation where a Court, in determining the conditions attached to the legal separation, conferred **sole custody on one parent** and gave directions or imposed conditions in relation to medical treatment. In such a situation the rights of the parent having legal custody would prevail.

What happens in surrogacy?

- Under Irish law the birth mother is automatically the child's legal guardian and parents must seek a court order to effectively become legal guardians to the child the same as adoptive parents.
- The genetic father can apply for a declaration of parentage to be made to the Circuit Court under Part VI of the Status of Children Act 1987.

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What about children in care?

- Where a child is under the **statutory care of the HSE**, the child will be subject to an Order by the Court under Section 18 of the Child Care Act, 1991:
 - In this situation the **HSE will have the necessary authority** to give **consent** to any medical procedure.
 - The **child's social worker** is usually the appropriate person to give such consent.
 - The child's **parent of guardian may still have a legal entitlement to give consent** where they are contactable and co-operative with medical personnel but the child's interests are, as always, the paramount consideration.
- The Child Care (Amendment) Act, 2007 inserted a new Section (43A) into the Child Care Act 1991. This provides that a **foster parent** who has been taking care of a child for **not less than five years** may **apply to the Court for an order** giving them more control and authority over the child, including authority to **consent to any necessary medical treatment**. The making of such an order must:
 - have the consent of the HSE,
 - be done in the child's best interests
 - where appropriate, the child's own wishes must be taken into account.
 - The Court Order, if granted, has the effect of giving the foster parents the same power and control over the child as if the foster parents were the child's own natural parents.

Data protection

Under Data Protection rules you must ...

1. Obtain and process the information fairly
2. Keep it only for one or more specified and lawful purposes
3. Process it only in ways compatible with the purposes for which it was given to you initially
4. Keep it safe and secure
5. Keep it accurate and up-to-date
6. Ensure that it is adequate, relevant and not excessive
7. Retain it no longer than is necessary for the specified purpose or purposes
8. Give a copy of his/her personal data to any individual, on request.

These provisions are binding on every data controller. Any failure to observe them would be a breach of the Act.

Resources

- National Immunisation Office (2008). A Practical Guide to Immunisation Chapter 6 Legal aspects of immunisation. Available at http://www.immunisation.ie/en/Downloads/PDFFile_15165_en.pdf
- Health Service Executive (2013). National Consent Policy. Available at http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/consenttrainerresource/trainerfiles/NationalConsentPolicyM2014.pdf
- Data Protection Commissioner (Ireland) www.dataprotection.ie/viewdoc.asp?DocID=4
- Medical Council (2009). Guide to Professional Conduct & Ethics for Registered Medical Practitioners, 7th Edition.

THANK YOU!