
HSE National Consent Policy 2013

Mary Dowling
Clinical Risk Manager
28/08/2014

HSE National Consent Policy 2013

- Applies to all interventions conducted by healthcare professionals on behalf of their employer on patients / service users
- Acute and PCCC settings

HSE National Consent Policy 2013

- Commissioned by HSE Quality & Patient Safety Directorate in 2012 (Dr Philip Crowley)
- Group chaired by Dr Deirdre Madden – reps from all areas of healthcare provision including patient reps
- Document legally proofed
- Launched in June 2013
- Each hospital to adapt policy to local setting
- National Standards Safer Better Healthcare 2012
Theme 1 Person Centred Care Standard 1.5 – Informed Consent

HSE National Consent Policy 2013

- **Part One** - General Principles
- **Part Two** - Children and Minors
- **Part Three** - Research
- **Part Four** – Do Not Attempt Resuscitation (DNAR)

Principle - Respect for Autonomy

- Autonomy is a fundamental principle in medical ethics which means that one's actions and decisions are one's own and should be respected
- Respecting the right to consent to or refuse medical treatment

Legal Perspective

- Consent justifies what would otherwise be an unlawful interference with the body i.e. trespass to the person
- “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained.”
- Schloendorff v Society of New York Hospitals 1914

Definitions

Informed Consent

- is the giving of permission or agreement for an intervention, receipt or use of service or participation in research following a **process of communication** in which the service user has received sufficient information to enable him/her to understand the nature, potential risks and benefits of the proposed intervention or service

What is informed consent?

- Legal and ethical obligation / principle
- HSE National Policy
- Informed exercise of choice
- Patient being able to understand and sufficiently retain the information they are given so as to enable them to analyse that information and use it to make a decision
- It is a continuous process not an once off event

General Principles

- **All patients** have the right to self determination – the right to control their own life and to decide what happens to their body.
- No other person can give consent on behalf of another person unless the patient is a **ward of court** or the person has been given enduring **power of attorney** which covers the decision in question.
- Consent must be obtained before starting treatment or investigation, or providing personal or social care to a patient.
- Requirement for and obtaining of consent is good practice – evidence of safe and effective care and is also recognised in Irish and International law.
- In some cases permission rather than consent may be required e.g. take blood, take B/P

Underpinning Principles

- Competence / capacity
- Disclosure of information
- Comprehension
- Voluntariness

Definition of Capacity

Capacity – ability to understand the nature and consequence of a decision to be made by a person in the context of available choices at the time the decision has to be made (allows for fluctuations in capacity)

Lack of Capacity – unable to understand information relevant to decision, retain that information, use or weigh that information as part of the process of making the decision or to communicate

Capacity to Consent

All adults are presumed to have capacity to consent or refuse treatment (Legal Principle)

- Efforts should be made to support the patient in making their own decision where possible
- The presumption of capacity should only be challenged if, having after been given all the appropriate help and support, the patient is obviously unable to understand and use the information to make and communicate a clear and consistent choice
- The test for capacity is a functional one i.e. it is to be judged in relation to the particular decision to be made at the time
- The more serious the decision, the greater the capacity required

Assessment of Capacity

- Does the patient understand in broad terms and believe the reason for and nature of the decision in question?
- Does the patient have sufficient understanding of the main benefits and risks and alternative options after these have been explained in a way and language appropriate to them?
- Does the patient understand the relevance of the decision and the choices open to them and can they retain this knowledge long enough to make and communicate a choice?

Fitzpatrick v K (2008) – 23 year old African woman in post partum haemorrhage refused a blood transfusion on religious grounds

- **Court** – “her capacity to refuse treatment was to be determined on the basis of whether her cognitive ability had been impaired to the extent that she did not understand the nature, purpose and effect of the treatment and consequences of rejecting it

If the patient lacks capacity?

- Is lack of capacity temporary or permanent?
- What is in the best clinical interest of the patient?
- Which option is least restrictive of the patients future choices?

Making decisions if capacity is absent: p32

- No legislative guidance – however Irish case law, national and international guidance – in making decisions for those patients who lack capacity the healthcare professionals should determine what is in the patient's best interest by reference to their values and preferences if known.

What can you do?

- Support patients as much as possible in making their own decisions
- Consider any previous expressed preferences such as advance healthcare plan – **Campaign Think Ahead**
- **Clinical Team** makes decision in the best interests of patient by reference to their wishes and preferences if known. Consider the views of those close to the patient
- Some situations may require legal advice e.g. major surgery

Role of family / carers

- Family members do not have any legal right to give or withhold consent unless they have specific legal authority to do so
- No current legal provision for surrogate decision making other than the Wardship under the Lunacy Regulations (Ireland) Act 1871

Disclosure of Information

- Patient centred test of disclosure in keeping with respect for autonomy
- Information to be provided will depend on the urgency, complexity, nature and level of risks involved

What would a reasonable person need to know in order to make this decision?

Disclosure – who, what, where and why

- Legal obligation to warn of risks that might affect the judgement of a reasonable patient
- Protects healthcare professionals from subsequent litigation
- Responsibility of person providing treatment to discuss it with the patient
- **Delegation** – person suitable trained, has sufficient knowledge of the procedure and understands the risks involved
- Timing is important – treatment options must be discussed at a time and place when the patient is best able to understand and retain the information

Risks and side effects of an intervention:

General Rule: - is to provide information that a reasonable person in the patient's situation would expect to be told.

Such information includes the likelihood of

- Side effects or complications of an intervention
- Failure of an intervention to achieve the desired aim and
- The risks associated with taking no action or with taking an alternative approach

Discussion should include

- Diagnosis and prognosis
- Treatment options
- Reason and purpose of intervention
- Potential benefits and risks
- Alternatives
- Costs (if relevant)

If possible patients should be invited to take time to understand and ask questions

A risk maybe seen as material / significant if a reasonable person in the patient's position if warned of the risk would attach significance to it. Such risks must be disclosed to the patient.

- Therefore, common even if minor side effects should be disclosed as should rare but serious adverse outcomes.
- This includes death, permanent disability, permanent disfigurement and chronic pain.

When should consent be sought?

- Should not be an 'once off' / 'eleventh hour' event – continuous process
- Good practice to seek consent well in advance – no legal timeframe
- Check before procedure starts – patient has no concerns
- If significant time has lapsed – check with patient what they remember

Part Two – Children and Minors

- Policy advocates a ‘**centred child approach**’
– putting the interests of the child at the centre of all decisions
- Children have the right to be involved in decision making and to give their assent **UN Convention on the Rights of the Child**
- Information in child friendly language

Definitions

Minor – a person who is less than 18 years of age, who is not or has not been married

Legal Guardian – a person with formal rights and responsibilities in respect of someone who lacks legal capacity

Legal Guardianship – refers to the right of a parent to be involved in all major decisions affecting the welfare and upbringing of a child

Children and Minors

- Legal age of consent to medical, surgical or dental treatment is 16 years **Section 23 Non Fatal Offences Against the Person Act 1997**
- Cannot refuse unless 18
- Uncertainty regards children < 16 i.e. mature minor – exceptional circumstances only
- Mental Health same principles unless application of Mental Health Act 2001 if patient is < 18 parental consent is required
- FOI – parents may have legal right to records under age of 18 **unless evidence not in the minors best interest**
- Consent of one parent who is legal guardian is regarded as sufficient – maybe exceptions **for example** if the decision will have serious consequences for the child

Refusal of Treatment

- Refusal of treatment between guardians may require court intervention – recent case involving parents in a disagreement over vaccination

North Western Health Board v HW and CW 2001

- No hierarchy of rights between 2 parents the decision will be made by the court in the best interest of the child
 - State cannot intervene other than in exceptional circumstances
-

The State may only intervene to override any parental decision in exceptional instances. For example, in ***North Western Health Board v HW and CW*** the Supreme Court did not override the refusal of parents to consent to doctors carrying out the “heel prick” PKU blood test on their baby boy.

Even though the Supreme Court noted that most parents would be happy to have the test carried out and the medical view was that the test be done, it decided that any overriding of parental decision-making would only be suitable if the refusal threatened the child's life or immediate health.

O'S & anor – v- Doyle & ors 2013 SC

Whether 5 year old boy should receive 4:1 & MMR booster injections. Mother opposed vaccinations. Father applied to District Court for vaccinations to be carried out. Unmarried parents lived together for 2 years after birth of son – Father granted guardian of the child in 2009 – mother consented. Later order granted joint custody to the father.

2012 – District Court – booster injections proceed

High Court – Judicial review – District Court had not erred in judgement – principle of best interest of the child - appealed to the Supreme Court

Supreme Court

- Rights of family recognised under Constitution
- The concept of Guardianship – custody and guardianship must not be confused
- The welfare of the child
- The extent of the natural father's rights
- Health Act 1953

APPEAL WAS DISMISSED

- Mother did not present medical or scientific evidence for refusal – legal principles

This policy acknowledges that in health and social care practice it is usual to involve parent(s)/legal guardian(s) and seek their consent when providing a service or treatment to a minor under 16. However, the minor may seek to make a decision on their own without parental involvement or consent. In such circumstances it is best practice to encourage and advise the minor to communicate with and involve their parent(s) or legal guardian(s). It is only in exceptional circumstances that, having regard to the need to take account of an objective assessment of both the rights and the best interests of the person under 16, health and social care interventions would be provided for those under 16 without the knowledge or consent of parent(s) or legal guardian(s).

Circumstances defined in the policy

Other Sections

- Refusal of care by parents page 56
- The minor parent
- Children in the care of HSE
- Mental Health Services
- Sexual health services – it is criminal offence to engage in sexual act with a child under 17- creates difficulties with contraceptive advice

Is Consent always necessary?

- Consent applies to all decisions about care, from minor treatments to major interventions
- Amount of information given maybe abbreviated in some situations – emergency treatment
- Where patient declines information – this should be respected and documented but some basic information about major interventions should be given so that consent may be obtained
- The fact that a patient may become upset about hearing information is not a valid reason to withhold information that they may need to know

Refusal of Treatment

- An adult with capacity is entitled to make a voluntary and informed decision to refuse treatment
- The decision must be respected even where the decision may have serious or fatal consequences
- The discussion and decision should be accurately documented
- If there any doubts about patient's capacity guidance within the document should be followed
- Making an unwise decision is not indicative of being unable to make a decision

Documentation of Consent

- Document the consent process – intervention is invasive, complex or involves significant risks or consequences for the patient
- If given verbally should be documented in the healthcare record

Consent Forms

- Over reliance on forms
- A negligence action may still be taken alleging lack of consent even if a consent form has been completed – may alleged he / she was not given relevant information and an opportunity to ask questions

Good Communication

- Discussion may take place over a period of time
- **NB** – 40% of Irish people have either inadequate or problematic health literacy i.e. the capacity to process and understand basic health information needed to make appropriate health decisions (2012 EU Health Literacy Survey)

Communication

7'C's

- Clear
- Concise
- Concrete
- Correct
- Coherent
- Complete
- Courteous

How to aid understanding?

- Simple, clear language – translate medical terminology into plain English – **NALA**
- Use visual aids – videos, diagrams
- Consider different formats for patients with hearing and visual impairments
- Material in other languages
- Interpreter services
- Avoid yes or no answers – tell me what you understand, what would your concerns be now?

Our responsibility as healthcare professionals

- Provide safe and effective care
- Minimise harm
- Have meaningful dialogue with patients
- Keep up date with standards

Resources

<http://www.hse.ie/go/consent>

Thank You