What is valid and informed consent?

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'Absent consent, surgery becomes stabbing, chemotherapy becomes poisoning, and urological examinations become sexual assaults.'

Consent benefits patients who get the information they want and need (and professionals who get protection from 'hindsight-regret')

Tús Áite do Shábháilteacht Othar
Patient Safety First

Quality and Patient Safety Directorate

National Consent Policy

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

- Consent is the giving of permission or agreement for an intervention following a **process of communication** about the proposed intervention.

- Consent must be obtained before starting treatment or investigation, or providing personal or social care for a patient or involving a patient in teaching and research.

- The need for consent, and the application of the general principles in this policy, extends to **all interventions** conducted by or on behalf of the HSE on patients in all locations.

What is valid and informed consent?

For consent to be valid, the person must:

1. Have received sufficient information in a **comprehensible** manner about the nature, purpose, benefits and risks of an intervention/service = INFORMED

For consent to be valid, the person must:

2. Not be acting under duress – person must understand they have a choice. (Not inconsistent with trying to persuade someone to make a particular choice).

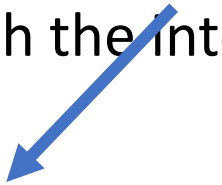
For consent to be valid, the person must:

3. Have capacity to make that particular decision (need to understand relevant information, retain it long enough to make a choice, use or weigh it in making the decision and to communicate decision by any means)

What information?

- Importance of **individual circumstances** – Discussions as much as possible tailored to individual needs and wishes, prior level of knowledge, preferred communication styles, factors such as occupations or lifestyles.

- The amount of information will **depend on urgency, complexity, nature and level of risk** associated with the intervention.



Information requirements higher for elective than for emergency treatment

- General rule: provide information that a **reasonable person** in patient's situation would expect to be told:
  - Side effects or complications of an intervention;
  - Likelihood that an intervention will achieve the desired aim;
  - The risks associated with taking no action or with taking an alternative approach.

- A risk is **material/significant** if a reasonable person in the patient's position, if warned, would attach significance to it. Such risks must be disclosed to the patient.
  - Common, even if minor, side effects should be disclosed as should
  - Rare but serious adverse outcomes such as death, permanent disability (such as paralysis or blindness), permanent disfigurement and chronic pain.

Geoghegan v. Harris

"The application of the reasonable patient test seems more logical….

As a general principle, the patient has the right to know and the practitioner a duty to advise of all material risks associated with a proposed form of treatment....

The reasonable man, entitled as he must be to full information of material risks, does not have impossible expectations nor does he seek to impose impossible standards."

Kearns J.

Putting risks in perspective

Table. Risk that an individual will die in any one year[30]

Term used	Quantitative Risk Range	Example	Measured Risk
High	Greater than 1/100		
Moderate	1/100 to 1/1,000	Smoking 10 cigarettes per day	1/200
		All natural causes, age 40 years	1/850
Low	1/1,000 to 1/10,000	Influenza	1/5,000
		Road accident	1/8,000-1/16,000
Very low	1/10,000 to 1/100,000	Accident at home	1/26,000
		Homicide	1/100,000
Minimal	1/100,000 to 1/1,000,000	Drowning in bath tub	1/800,000
Negligible	Less than 1/1,000,000	Wasp or bee sting	1/5,000,000
		Hit by lightning	1/10,000,000

Support people to make their own decisions

Presumption of capacity unless the contrary is shown.

Presumption of capacity is to consent and decision making what the presumption of innocence is to criminal law.

Making an "unwise" decision is not indicative of lacking capacity to make a decision

Professionals have a duty to maximise person's their ability to make their own decisions

- Especially important for those who may have difficulty making decisions (e.g. communication difficulties, intellectual disability or cognitive impairment).
- Right time and place
- Adequate time and support, including, if necessary, repeating information
- Use of simple, clear English and avoidance of medical terminology
- Professional interpreter if needed
- Supplement verbal information with information leaflets or visual aids
- Ask patient if bringing a relative or friend to consultations would help

Is it always necessary to seek consent?

- Emergency situations
  - In an emergency life-threatening situation if person lacks capacity to consent or urgency imposes limitations on discussions, necessary treatment may be administered in the absence of expressed consent.
  - **Limited to situations where the treatment is immediately necessary to save the life or preserve the health of the patient.**
- Where the patient declines information
  - While should be respected if possible, some basic information need be provided about major interventions so consent can be obtained. If a person refuses to receive detailed information about their condition, this should be documented.
- If it might worry the person? NO
  - The fact that a person might be upset or refuse treatment as a result of receiving information is not a valid reason for withholding information that they need or are entitled to know.

Role of 'Next of Kin'? None

- HSE National Consent Policy (5.6.1)
  - *"…no other person can give or refuse consent on behalf of an adult who lacks capacity unless they have specific legal authority to do so."*
  - Include '*those who have a close, ongoing, personal relationship*' in discussions and decision-making – '*not to make the final decision*' but to provide greater insight into the views and preferences of the person.
- A false belief persists among staff and the public that consent should be sought from the 'next of kin' if a person can't consent
- 'Next of kin' used to imply that others close to the person (such as a cohabitee or close friend) have no say or insight into person's preferences or interests.
- Delays while frantic efforts are made to contact distant uninvolved relatives.
- *'I'm the next of kin'! 'No, I am'!*
  - I'm the eldest
  - I live with Mammy
  - Mammy is leaving me the house / farm
  - I love Mammy the most
  - Mammy loves me the most
  - I'm recorded in the chart as next of kin/ contact person

Scope of consent

Need clarity about what has is agreed especially if:

- Treatment provided in stages and changes might be needed
- Different professionals provide particular parts of a treatment, e.g. anaesthesia and surgery
- If additional problems might arise during an intervention when person may not be in a position to speak

Who should obtain consent?

- The person providing a particular health and social care service or intervention is ultimately responsible for ensuring that the person consents to what is proposed.

- Seeking consent may be delegated to another suitably trained and qualified professional with sufficient knowledge of the proposed intervention to be able to provide the information the person needs.

- Inappropriate delegation may mean that the “consent” obtained is not valid.

- If different aspects of care are to be provided by different professional disciplines, each should usually obtain consent for their particular intervention.

When should consent be obtained?

- Often a continuing, rather than once-off, process of keeping people up to date with their condition and proposed interventions.

- For major interventions, good practice where possible to seek consent well in advance – can take their time thinking over their decision, ask questions

- Seeking consent just before procedure is due to start or if person is sedated, in pain or anxious, creates doubt as to validity of the consent.

How should consent be documented?

- It is essential to document clearly the person's agreement to the intervention and the discussions that led up to that agreement particularly if:

  The intervention is invasive, complex or involves significant risks;

  There may be significant consequences for employment, or social or personal life;

- Agreement can be documented by a signature (or mark if unable to write) on a consent form or through documenting in their notes that they have given verbal consent.

- *While it is important to document consent adequately, the process and quality of communication are of equal importance.*

- **A signature on a form** is evidence that a process of communication has occurred and that a patient agrees to an intervention: it is, however, **not proof that an adequate process of communication has occurred or that the consent is valid.**

I got signed consent from my patient 6 weeks ago, but his operation was delayed. Has the consent 'expired'?

- Some services may opt for pragmatic reasons to set a maximum fixed time period for which consent remains valid in their particular service. However there is no legal authority to support the validity of any particular time period.

- In general, if there is a significant time-lapse between the initial giving of consent and actual date of an intervention, check if the patient can remember the treatment information and if they have any questions in relation to that information.

- If the patient isn't satisfied that he or she can remember the earlier information or if there is a change in their condition or in the information about the proposed intervention, a fresh consent following provision of appropriate information should be sought.