Opinion Medico-Legal

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Understanding informed consent

***Ms Suzanne Creed**, Clinical Risk Advisor at Medisec, explains what exactly is meant by informed consent*

Informed consent is a process of communication between a patient and their doctor, providing sufficient information for the patient to 'make a choice', about their proposed intervention, ie, a patient-centred approach.

Obtaining informed consent is a fundamental principle of medical law. Consent is an essential part of respect for patients' autonomy and self-determination. Consent is consistent with the principles of good practice in communication and decision-making, while aligning with national health and social care policy. A failure to obtain adequate informed consent could result in a complaint to the Medical Council, a clinical negligence claim, or even criminal proceedings for assault, trespass, or battery.

The HSE's national consent policy defines consent as "the giving of permission or agreement for an intervention, receipt or use of a service, or participation in research following a process of communication about the proposed intervention".

The Medical Council's *Guide to Professional Conduct and Ethics for Registered Medical Professionals* specifically references the need to obtain consent before any medical investigation, examination, or treatment. Treatment includes medicines. This Medical Council guidance is especially relevant when prescribing high-risk medication such as lithium, methotrexate and sodium valproate (Epilim). Patients should be informed of the risk-benefit profile of every medication. This consent process should be carefully documented in the clinical record, especially when prescribing high-risk medication. This should also include all recommended monitoring and blood tests.

What is informed consent?

There are three components to informed consent:

1. *Adequate information:* The patient must have sufficient information to 'make a choice', as without adequate information to make a decision any consent given would not be valid.
2. *Capacity:* The patient must have the capacity to understand and make the decision in question.
3. *Voluntary:* The patient must be able to give their consent freely and without coercion.

Adequate information

Informed consent is the process where sufficient information is provided to the patient about the nature, purpose, risks, benefits, and alternatives to a proposed treatment or intervention so that they can make an informed choice.

Patients should be given sufficient time, asked if they understand the information provided and whether or not they would like more information before making a decision. The patient should also be given time to ask any questions relating to the proposed treatment or intervention. Information provided should be in a format that the patient can understand. It is important to consider cultural factors, personal values, and beliefs that may affect the patient's decision-making process. Language or communication barriers may also impede the consent process. Information leaflets are a valuable adjunct when providing information to patients about proposed treatments or procedures. However, they should never be used as a replacement for adequate discussion between the doctor and patient. Discussions about a proposed intervention may take place on more than one occasion and often over several consultations, all forming part of the consent process.

All information provided, including discussions around the consent process should be clearly documented in the patients' medical records as evidence that these discussions took place. It is advisable to also retain a copy of any information leaflets given to the patient in the medical records.

Capacity

Every adult is presumed to have the capacity to make decisions about their own medical treatment. Under the Assisted Decision-Making (Capacity) Act 2015 (which is not yet fully commenced), a person lacks the capacity to make a decision if they are unable to:

- Understand the information relevant to the decision;
- Retain that information long enough to make a voluntary choice;
- Use or weigh that information as part of the process of making the decision; or
- Communicate his or her decision (whether by talking, writing, using sign language, assistive technology, or any other means).

There are instances where a person's capacity to provide consent can be affected by infirmity. In this regard, the Medical Council advises that a functional approach should be taken, when considering the capacity requirements. The criterion in assessing the relevant choice depends on the following:

- The patient's level of understanding and retention of the information they have been given;
- Their ability to apply the information to their own personal circumstances and come to a decision;
- Their ability to communicate their decision, with help or support where needed.

Family members, friends, carers or those close to patients cannot, without lawful authority give consent on behalf of patients. Where there is nobody with legal authority to make decisions on behalf of the patient, the Medical Council's ethical guide specifies that the doctor should decide what is in the patient's best interest and provide guidance on the factors that should be considered when making that assessment.

> *The informed consent process creates many challenges for doctors as they seek to ensure that patients understand the information they receive and are able to make informed decisions about their healthcare*

Voluntary

Consent must be voluntary and without coercion: Pressurising patients into consenting to treatment invalidates the consent. This applies to the patient's family and friends as well as clinicians who may try to exert their opinions on the patient openly or subtly.

Conversely, every adult with capacity is entitled to refuse medical treatment or withdraw consent and doctors must respect a patient's decision to refuse treatment or withdraw consent, even if they disagree with that decision. In these circumstances, a doctor should explain clearly to the patient the possible consequences of refusing treatment and, where possible, offer the patient a second medical opinion. It is very important to take detailed notes of any such discussions with a patient.

Verbal versus written consent

Patients can express their consent in a variety of ways; for example in writing, verbally face-to-face, and, in certain circumstances, by implication, for instance rolling up their sleeve when having their blood pressure recorded.

Consent can be verbal, but for interventions commonly associated with any significant risk – including surgical procedures – it is more commonly written. A common misperception is that a signed consent form demonstrates informed consent. By itself, a consent form does not verify that true informed consent was obtained; it merely documents that some discussion about the procedure or investigation took place. Consent forms are evidence of a process, but not the process itself.

With the exception of certain treatments under the Mental Health Act 2001, there is no legal requirement to obtain written patient consent. However, in certain circumstances, written consent forms are considered best practice to record the consenting process.

Healthcare facilities, including public and private hospitals, clinics, and GP surgeries should have policies in place outlining when written consent should be obtained. It is advisable to use a consent form in the following instances:

- There is significant or potential risks or side-effects associated with the proposed intervention;
- The patient's lifestyle, personal relationship, or employment could potentially be adversely affected by the outcome of the proposed intervention;
- Where the proposed intervention is focussed on enhancing appearance, eg, cosmetic surgery rather than providing clinical care;
- The proposed treatment or procedure being undertaken is part of a research study.

Consent and minors

Paragraph 18 of the Medical Council ethical guide states: "When treating children and young people, your primary duty is to act in their best interests. You should involve them as much as possible in discussions about their healthcare, give them information suitable for their age, listen to their views and treat them with respect."

Patients aged 16 years and over are entitled by law to give consent to surgical medical or dental treatment and patients aged 18 years and over can consent to psychiatric treatment. The law relating to a refusal of treatment by a patient between 16 and 18 years, which is against medical advice and parental wishes, is not certain and you should consider seeking legal advice if this situation arises.

If a patient aged under 16 years seeks to make a healthcare decision on their own behalf, they should be encouraged to involve their parents in the decision, bearing in mind the paramount responsibility to act in the patient's best interests, bearing in mind the specific guidance from the Medical Council ethical guide (Paragraphs 18.3-18.7).

In some cases, a patient under 16 may not wish to involve their parents and the ethical guide says that you can provide treatment in such cases provided you have considered the factors above. Medisec recommends that you note your decision-making process carefully in any such circumstances. Obtaining consent for minors aged 16-to-17 years, in particular when providing advice regarding contraception, often raises many ethical and legal issues for doctors. Medisec members may wish to contact us directly to seek advice with such issues.

Conclusion

The informed consent process creates many challenges for doctors as they seek to ensure that patients understand the information they receive and are able to make informed decisions about their healthcare.

Careful planning and development of consent protocols can help practitioners provide patients with appropriate information to facilitate a patient-centred approach, hold meaningful discussions with patients and potentially mitigate risks related to allegations of inadequate informed consent.

If you have any specific queries or concerns surrounding the issues raised in this publication, please do not hesitate to contact a member of the Medisec team.