**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 refers 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 about their proposed intervention 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 patient’s 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 Assist-