MEDICAL PRACTITIONERS INDEMNITY

JLT

SEPTEMBER 2016 | ISSUE 1

Risk Alert

Risk Management Advisory Notes

Informed Consent – A Risk Management View

Jardine Lloyd Thompson Sdn Bhd

Informed consent is an interactive process culminating in an agreement between a patient and a healthcare provider on a course of treatment. Signing a consent form is evidence that the process has occurred and suggests an agreement has been reached.

Informed consent is defined as "permission for something to happen or agreement to do something". Valid consent must be obtained before starting treatment or physical investigation, or providing personal care. Informed consent requires the patient to understand the diagnosis and uncertainties about it as well as the different treatment options (including doing nothing) and their advantages, disadvantages and achievable outcomes. Acquiescence where the person does not know what the intervention entails is not consent. The amount of information required to make consent informed may vary depending on the complexity and risks of treatment as well as the patient's wishes.

Valid consent must be:

- given voluntarily i.e. not under influence/duress
- by an appropriately informed person
- who has capacity to consent to the intervention in question

Consent can be given by;

- the patient if they have capacity
- someone with parental responsibility for a patient under the age of 18
- relative in the case of an adult, if the patient is incapable of giving consent
- By two psychiatrists, one of whom shall be the attending psychiatrist, if there is no guardian or relative of the patient available and the patient is incapable of giving consent

Lack of informed consent is an area that is often alleged in medical malpractice claims. Lack of informed consent occurs when a physician does not provide adequate information to the patient to make an informed decision. Touching a patient without valid consent may constitute the civil or criminal offence of battery; negligence; grounds for an internal complaint; or grounds for a complaint to the relevant professional/regulatory body. For a civil claim, the patient must demonstrate that if adequate information had been provided he or she would have made a different decision. A physician is obliged to disclose information to the patient and to warn the patient of

ELEMENTS OF INFORMED CONSENT

It is generally accepted that it is the physician's duty to obtain the informed consent from each patient for each treatment or procedure. To satisfy this duty the physician must disclose sufficient information in each of the following areas:

Physician to disclose information in the following areas:

- The patient's diagnosis,
- The patient's prognosis,
- The proposed treatment,
- The risks & benefits associated with the proposed treatment,
- Any alternative treatments,
- The risks and benefits of the alternatives, and
- The risks of forgoing treatment, should the patient refuse.

The responsibility for communicating the consent information should rest with the physician. Signing the consent form, or in other words validating or witnessing the consent, may rest with or be delegated to others, such as the hospital staff. Policies should be established for this practice.

Things to keep in mind:

- Only licensed professionals – nurses or physicians should obtain and witness the patient's signature.
- The conversation should be conducted in a private setting rather than in a waiting room and before the patient has received any sedation, preferably at any pre - assessment.
- The patient should be asked to state the procedure they are consenting to and asked if all of their questions have been answered to their satisfaction at the time the consent is obtained and again before the procedure is

material risks before taking consent. Additional information provided or material risks highlighted should be specifically noted and documented.

In addition to legal protection, physicians and hospitals should embrace the informed consent process as away to demonstrate concern for their patients. A well-performed consent process will make patients feel both informed and involved in their care and may be the best medicine in warding off a claim of medical malpractice. The purpose of this advisory is to take the mystery out of the informed consent process and to explain a health care provider's responsibility for validating consent and to provide suggestions for facilities to include in their policies and procedures.

Documentation of the Informed Consent Process

In informed consent litigation, usually the content of the documentation is what is at issue rather than the format of the documentation whether it is included as part of the medical record or as a separate consent form. There is debate regarding the way in which physicians should document what is disclosed and discussed with the patient. One viewpoint is that physicians should provide an exhaustive list of all the information that was disclosed and the risks and benefits that were discussed. Critics of this method suggest that if a patient suffers a complication that is not listed, the physician may be subject to a claim of lack of informed consent.

Although informed consent documentation is evaluated on a case-by-case basis, generally, the amount of documentation provided parallels the amount of protection gained. Therefore, physicians should consider including a list of information that was disclosed and discussed, along with a preliminary statement such as "including but not limited to." Also any patient education materials (such as brochures, print material, or videos that were watched) should be documented.

Minors and Consent

In the case of patients who are under the age of 18 (minors), the consent of at least one parent or someone with parental responsibility is required before any medical treatment.

Any consent given must be "in the best interest of the patient / minor". Medical practitioners are in the best position to determine if the decision made by parent(s) or legal guardian in relation to the treatment, is the most appropriate and fair to the minor under such circumstances.

References:
1. The Oxford Dictionary of new English, Oxford. Oxford University Press, 1998
2. GMC (1998) Seeking patients' consent: The ethical considerations, General Medical Council, London
3. Government response to Report on Mental Capacity Act, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/318730/cm8884-valuing-every-voice.pdf
4. Mental Health Act 2001
5. MMC Guideline – Consent for Treatment of Patients by Registered Medical Practitioners

Ratnawati Osman - Vice President, MPI
T: +603 2723 3210 | E: mpi@jltasia.com
mpi-jlt.com.my

Jardine Lloyd Thompson Sdn Bhd
Suite 10.2, 10th Floor, Faber Imperial Court,
21A Jalan Sultan Ismail, 50250 Kuala Lumpur, Malaysia
T: +60 3 2723 3388 | F: +60 3 2723 3399
jltasia.com

undertaken.
- If a patient expresses unanswered questions or concerns, they should not sign the form and the procedure should not go ahead until they have been answered by the physician.

SPECIAL SITUATIONS

Special situations that should also be disclosed to patients and also require their informed consent include:

- Students performing or participating in any procedure.
- The presence of equipment manufacturing representatives or other non-employees.
- The taking of photographs, videotaping or the production of slides.
- Procedures for the disposal of tissue or its use in grafts.
- Any procedure that is experimental, including clinical trials or institutional review board consents.
- The possibility of the need for and the administration of blood or blood products.

PATIENTS WHO LACK CAPACITY

Section 2 Mental Capacity Act 2005 provides:

"A person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain".

A person is unable to make a decision for himself if he is unable:
- to understand the information relevant to the decision
- to retain that information
- to use or weigh that information as part of the process of making the decision, or
- to communicate his decision (whether by talking, using sign language or any other means)

Any act or decision on behalf of a patient who lacks capacity must be in their best interests. For more information see the MMC Guideline – Consent for Treatment of Patients by Registered Medical Practitioners.

If the patient lacks capacity, from the guardian in the case of a minor or a relative in the case of an adult. If the guardian or relative is not available, two psychiatrists, one of whom shall be the attending psychiatrist.