GUIDELINE OF
THE MALAYSIAN MEDICAL COUNCIL
MMC GUIDELINE 002/2024

CONSENT FOR TREATMENT OF PATIENTS BY REGISTERED MEDICAL PRACTITIONERS

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Preamble

Every patient has the autonomy to decide whether or not to proceed with any proposed treatment. The necessity to obtain a patient's consent is a reflection of such autonomy, and is both an ethical and a legal requirement. It is an important concept within the medical profession as part of good medical practice, and forms an essential component of the doctor-patient relationship. Obtaining consent throughout the course of any treatment is an ongoing process and not an one-off event.

Generally, except in specific situations, no treatment may be given to a patient without prior consent. Failure to obtain valid consent, as described below, can result in disciplinary proceedings being instituted by the Malaysian Medical Council (MMC) against a Registered Medical Practitioner (RMP).

1 Definitions

1.1 Autonomy

is the right of persons with mental capacity to make decisions about their lives based on their own values and interests.

1.2 Consent

refers to the voluntary approval by a patient with mental capacity to treatment proposed by a RMP.

1.3 Material Risk

is a risk that (1) a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to in the circumstances of the particular case, or (2) a RMP is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to.

1.4 Medical emergency

is an injury or illness that is acute and poses an immediate risk to a person's life or long-term health.

1.5 Mental Capacity

refers to the patient's ability to make decisions about treatment based on the criteria set out in Paragraph 3.1.1 of this document.

1.6 Minor

is an individual who has not yet obtained the age of majority based on current legal provisions.

1.7 Supported decision-making

is a tool that allows patients to retain their decision-making capacity and make decisions about their own lives with the support of a team of people they choose. These supporters can consist of trusted friends, family members, or professionals.

1.8 Surrogate decision-maker

refers to a person who is entitled to provide consent for treatment for a patient who does not have mental capacity.

1.9 Therapeutic privilege

refers to withholding relevant information at that point in time from a patient if the RMP believes that non-disclosure will be in the best interests of the patient.

1.10 Treatment

refers to the provisions detailed in the MMC Code of Professional Conduct 2019 (Section 1.1), and includes (1) the assessment of the history, symptoms and signs of a patient's condition; (2) examination and where necessary, diagnostic investigations; (3) management of the patient; (4) action upon evidence suggesting the existence of a condition requiring urgent medical intervention; and (5) referring

the patient to appropriate professional colleagues where the circumstances so warrant.

2 Provisions

2.1 Criteria for validity

A valid consent can be obtained in various ways (e.g. implied, expressed verbally or non-verbally, written). Nevertheless, all the following criteria must be fulfilled for consent to be valid. The person giving consent must:

a) Possess the Mental Capacity to do so;

i. In regards to mental capacity, all the following criteria must be fulfilled for a person to be determined to possess mental capacity. The person must be able to:
   - receive the information provided;
   - understand and weigh the information;
   - make a decision based on the information;
   - communicate the decision.

ii. The determination of mental capacity is decision-specific and time-specific.

iii. All RMPs should be mindful of the mental capacity of the patient based on the criteria set out in Paragraph 3.1.1 before obtaining consent from the patient for the proposed treatment. Should there be doubt regarding the patient's mental capacity to provide consent, the RMP should refer the patient for a formal assessment of mental capacity to make that particular decision. This formal assessment can be performed by an RMP who has been suitably trained in mental capacity assessment.

iv. In cases where a patient's mental capacity appears to be impaired, RMPs should attempt to engage in supported decision-making in order to facilitate these patients in making autonomous decisions.

b) Be Informed;

i. The person giving consent must be provided with information specific to the proposed procedure/treatment.

ii. The information should include the following details, where relevant:
   - the patient's diagnosis and current condition
   - investigation and/or treatment options (including alternatives, if any),
   - benefits and risks of each option (including material risks, possible adverse effects or complications),
   - residual effects (if any),

- the likely result if treatment is not undertaken, and
- any other details to enable the person to make his own decision.

iii. The RMP must communicate these details to the person in a manner that is understandable.

iv. In the process of providing the person with information regarding material risks, a RMP may ethically withhold information by invoking therapeutic privilege. However, the reasons for doing so need to be documented in the patient's medical records.

v. RMPs are encouraged to use visual aids, charts, models or any other accessories or means available to explain the procedure especially in complicated procedures. Prepared materials such as brochures or information sheets may also be useful if given to the patient as a means of stimulating discussion and for guiding the RMP when informing the patient about a proposed treatment. However pre-prepared material should not be used as a substitute for informing or making sure that a patient understands the nature of, and risks involved in, the treatment. The RMP must ensure that any pre-prepared material given to the patient is current, accurate and relevant.

vi. RMPs may also provide additional information on risks and adverse effects of any procedure in a written explanatory document. This document may be appended to the consent form (refer to relevant provisions in the guideline on 'Medical Records and Medical Reports').

vii. The RMP should verify that the person has understood the information provided and allow the person an opportunity to seek further explanation and clarification.

viii. Where necessary, a translator should be engaged to facilitate communication with the person.

c) Provide the Consent Freely and Voluntarily;

i. Consent must be given freely and voluntarily. It must not be induced by fraud, deceit or coercion.

ii. A patient has the right to withdraw the consent that was given at any time prior to the treatment, without assigning any reasons to do so

2.2 Consent as a process

Obtaining consent is a process. Information regarding this process, including the people involved, information provided, questions asked, etc. must be documented in the patient's medical records as evidentiary proof that this process has taken place. Any additional information or explanatory notes

should also be documented in the patient's medical records. It is advisable to have a witness to attest to the process.

Should there be a change in the nature, clinical course and presentation of the illness for which the consent had initially been obtained, these need to be discussed with the patient, and consent will need to be re-obtained.

2.3 Exceptions to obtaining prior consent

Exceptions to the duty of obtaining consent prior to treatment may include the following situations:

a) a medical emergency
b) treatment required by law

The exception to consent in a medical emergency should be used sparingly as it undermines the patient's right to autonomy. Any non-consensual treatment should be limited to the procedures that are required to address the immediate necessity.

2.4 Consent involving Minors

Younger children are generally considered not to be competent to provide consent. However, whether a minor has the mental capacity to provide a valid consent to medical treatment depends on whether he or she has sufficient maturity and intelligence to understand the nature and implications of the proposed treatment. This can be decided on a case-by-case basis by the RMP treating the patient who is a minor.

RMPs should as far as possible respect the decisions of mature minors, while at the same time being mindful of provisions in the law that require parental consent.

2.5 Consent involving Adult Patients without Mental Capacity

Impairments to reasoning and judgment due to medical conditions may make it impossible for someone to provide informed consent. These impairments may be permanent or transient. In such cases, a surrogate decision-maker should be identified by the RMP treating the patient.

If there is a person with legal authority to make decisions for the patient as the patient's surrogate decision-maker, consent should be sought from this person.

In the absence of a person with legal authority, RMPs should consider the following:

a) Whether the patient had identified or nominated any person as a surrogate decision-maker,
b) Whether an appropriate surrogate decision-maker who knows the values and preferences of the patient can be identified

In the absence of a suitable surrogate decision-maker, RMPs can proceed to make decisions that are in the best interests of the patient. However, steps must first be taken to attempt to identify a suitable surrogate decision-maker, and these efforts must be documented in the patient's medical records.

All treatment decisions made for a patient without mental capacity should be made in the best interests of that particular patient.

2.6 Advance Decisions

A RMP should refrain from providing treatment where there is an unequivocal written directive by the patient that such treatment is not to be provided in the circumstances which now apply to the patient.

If a patient has made advance decisions, or expressed his/her wishes when he/she had mental capacity, the RMP should consider:

a) whether these are sufficiently clear and specific to apply to the clinical circumstances which have now arisen,
b) whether the decision remains current,
c) whether there is any reason to doubt the patient's capacity at the time that the decision was made, and
d) whether there was any undue pressure on the patient to make the decision

If there are doubts regarding the validity of an advance decision, especially in a medical emergency, the RMP should proceed in the patient's best interests, while attempting to determining the validity of the advance decision. Such decisions should be clearly documented in the patient's medical records.

2.7 Refusal of Treatment

Generally, any patient who possesses mental capacity can refuse consent for any treatment without assigning any reasons to the decision.

The refusal of treatment by a patient, and where possible the specific details of the refusal that have been discussed, should be recorded by the RMP in the patient's medical record, or by way or signing a refusal of treatment form.

If the surrogate decision-maker of an incapacitated patient refuses to consent for any treatment for the patient, and the decision is deemed to not be in the best interest of the patient, a RMP should seek an ethical consult, and/or legal support, which may include a court decision.

2.8 Practical Aspects of Obtaining Consent

Ultimately, it is the RMP who is providing the treatment who is responsible to ensure that prior valid consent was obtained from the patient. Where possible, the prior consent should be obtained personally by the RMP providing the treatment.

All RMPs who undertake the task of obtaining consent for treatment need to ensure that they possess the necessary competence, communication skills, experience and knowledge in order to perform the consent taking process.

Consent obtained from patients are only applicable for the specific purposes for which they were obtained. If additional purposes are proposed, additional consent should be obtained. These may include the following situations:

a) photographs and audio-visual recordings taken during treatment,
b) releasing of patient data to a third party, or
c) keeping organs or tissues removed at surgery for purposes other than treatment (e.g. teaching, research, etc.)

Consent for sterilisation procedures in a woman or man should be given by the patient concerned. Similarly, hysterectomy and orchidectomy must also involve consent by the patient. While discussions between spouses should be encouraged, this does not and should not deny the rights of the patient concerned in making the final decision and giving consent.

If a RMP plans to use and rely on an artificial intelligence (AI) tool and/or technology in the treatment of the patient, the RMP is required to inform the required relevant information regarding this to the patient before the treatment, and to inform the patient that the RMP remains responsible and accountable for the patient's clinical outcomes.

While a patient might consent to a procedure after being informed in broad terms of the nature of the procedure, this consent will not amount to an exercise of choice unless it is made on the basis of relevant information and advice. Hence, a "blanket" or universal consent for treatment obtained on admission of a patient, either as an out-patient or in-patient is not considered to be valid.

2.9 Consent for Procedures in Other Guidelines and Laws

Consent related other aspects of the provision of healthcare may be covered in other MMC Guidelines, and it is the duty of the RMP to refer to these when a relevant situation arises.

RMPs should also be cognisant of the relevant laws pertaining to consent for treatment.

3 Note

1. The following are the members of the drafting committee for updating this guideline:
    - Dato' Dr. N.K.S. Tharmaseelan
    - Assoc. Prof. Dr. Sharon Kaur A/P Gurmukh Singh
    - Assoc. Prof. Dr. Mark Tan Kiak Min.

2. This updated guideline was endorsed by the Ethics Committee 21st October 2024, and endorsed by the Malaysian Medical Council on 18th February 2025.

3. This guideline was first published 21st June 2016, with subsequently revisions on 19 September 2017.

4. This guideline is scheduled for review two years after endorsement. Any changes to the law before the review is completed may render parts of this guideline obsolete.