MALAYSIAN MEDICAL COUNCIL
FREQUENTLY ASKED QUESTIONS (FAQs)

CONSENT FOR TREATMENT OF PATIENTS BY REGISTERED MEDICAL PRACTITIONERS

These FAQs are intended to provide guidance to Registered Medical Practitioners (RMPs) on common questions raised about this matter. RMPs should adhere to the principles laid out in the Guideline as well as to provisions pertaining to consent that are included in all other MMC guidelines. This list of FAQs are not exhaustive. RMPs are advised to refer any queries or seek clarification via the contact details provided on the MMC website.

1. What is 'informed consent'?

Informed consent is providing information on the risks and benefits of the proposed treatment including the consequences of not proceeding with the treatment. A RMP has a duty to warn a patient of material risks inherent in the proposed treatment: a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or if the RMP is or should be reasonably aware that the particular patient, if warned of the risk, would be likely to attach significance to it. The patient should also be informed of alternative treatment options available.

A RMP has both an ethical as well as a legal obligation to obtain informed consent before treatment. A RMP should seek legal advice if concerned about any legal liability.

2. How should consent be obtained in a medical emergency?

In a medical emergency where the patient retains the mental capacity to decide, the patient must personally consent to the proposed treatment. In the event that the patient is unable to provide valid consent, a RMP should attempt to identify and contact the patient's surrogate decision-maker (Section 3.8) where time permits. If the surrogate decision-maker is not contactable or available during the critical period to provide consent, or if no decision-maker can be identified, then the RMP can proceed to make decisions that are in the best interests of the patient (Section 3.8.3), subject to the determination that there are no unequivocal written direction by the patient refusing the proposed treatment.

In such circumstances, where practicable, a consensus of the attending RMP who is managing the patient, and a second RMP needs to be obtained that the proposed treatment is required to mitigate the immediate risk to the person's life or long term health. Both RMPs should co-sign a statement on the consent form stating that the decision was made in the best interest of the patient and that delay will endanger the life of the patient. Attempts to identify and efforts to contact a suitable surrogate decision-maker must also be documented in the patient's medical records.

3. Is consent obtained from one parent sufficient to provide treatment to a minor?

In general, consent of either parent to his/her child's medical treatment is usually sufficient because each parent has full responsibility for each of his/her children

under 18 years of age, and this parental responsibility is not affected by changes to spousal relationships (e.g. if parents are separated). Exceptions to this are when there is a court order to the contrary, or when there appears to be a dispute among the parents.

The best way of handling the latter situation is by counselling the parents and reaching consensus of what is in the child's best interests or seeking an ethics consult where available. If there is any doubt as to who may provide consent, legal advice should be obtained.

4. Can consent be obtained for the treatment of minors who present with an accompanying adult who is not their parent?

If it is a medical emergency, refer to FAQ 2

If it is a non-emergency, the attending RMP should attempt to ascertain the accompanying adult's relationship to the patient, and the adult's authority to provide the required consent for the proposed treatment as a surrogate decision-maker.

A blanket consent form signed by parents allowing any third party to authorize treatment for their children on their behalf cannot be considered valid consent for treatment.

Reference should also be made to Section 3.6 and 3.7 of the Guideline.

5. How should consent be obtained for patients with mental disorders?

Patients suffering from mental disorders who have mental capacity should provide consent for any treatment.

Section 77 of the Mental Health Act 2001 stipulates how consent should be obtained from mentally disordered patients who do not have mental capacity and are required to undergo surgery, electroconvulsive therapy or be recruited into clinical trials.

6. How should a RMP assess what is in "the best interests of the patient"?

An assessment of best interests will include what is clinically indicated in a particular case. A RMP should also consider:

- the views of the patient, so far as they can express them, including any previously expressed preferences
- the cultural, religious or other beliefs and values of the patient
- the views of others involved in providing care to the patient

This list is not exhaustive. The weight attached to each point will depend on the circumstances and any other relevant information. A RMP should not make unjustified assumptions about a patient's best interests based on irrelevant or discriminatory factors, such as their behaviour, appearance or disability.

7. Who can be a witness when a RMP is taking consent, and what is the role of the witness?

A witness should be another healthcare professional (e.g. RMP, nurse, allied health professional, etc.) who is preferably not directly involved in the management of the patient, nor related to the patient or the RMP. The role of the witness is to attest to the process during the taking of the consent. A RMP should bear in mind that the witness should be capable and available to attest to the consent process should the need arise.

8. Must a RMP providing the treatment personally obtain the consent of the patient?

Prior consent *should* be obtained personally by the RMP providing the treatment. In the event of the RMP obtaining or signing the consent form, and the RMP providing the treatment, being two different RMPs, the final responsibility will still rest on the RMP who provides the treatment. See Section 3.16 of the Guidelines.

9. Can a medical practitioner who is provisionally registered obtain consent for treatment from patients?

Section 3.17 of the guideline requires that all RMPs, regardless of type of registration, who undertake the task of obtaining consent for treatment from patients to possess the necessary competence, communication skills, experience and knowledge in order to perform the consent taking process.

In essence, it is the RMP who is providing the treatment who is responsible to ensure that prior valid consent was obtained from the patient, and where possible, the prior consent should be obtained personally by the RMP providing the treatment. The treating RMP who delegates another RMP to perform this task, be it due to practical necessity, or as part of training, must be willing to take full responsibility for their actions.

10. What is the duration of validity of a consent obtained from a patient prior to the proposed treatment?

In general, a consent obtained remains valid as long as the patient’s condition remains the same. If there should be a change in the nature, clinical course and presentation of the illness, these need to be discussed with the patient, and consent will need to be re-obtained.

In instances where the procedure consented for is delayed, postponed, or if the patient is discharged home in the interim, consent needs to be re-obtained as the patient's condition may have changed during this period..

In the case where, due to a practice of convenience, consent is obtained from the patient in the out-patient clinic by the RMP prior to scheduling the treatment, the consent of the patient for the proposed treatment and the details on the consent form must be re-confirmed with patient on admission.

11. Does consent need to be re-obtained at each instance for conditions requiring periodic treatment?

A good standard of care requires that consent for treatment needs to be contemporaneous. In addition, accurate and specific information of the current condition should be provided to the patient in order to make a decision.

In some instances, consent may be obtained from patients for the provision of treatment based on a series of predetermined episodes. Examples of these include a chemotherapy or radiotherapy regimen, or a course of psychotherapy. The specific details of such treatment plans (e.g. the duration, interval period, total number of episodes, etc.) must be informed to the patient prior to the consent being obtained for the whole series of treatment. The consent will be considered valid as long as the patient's condition and the risks of the treatment remain the same. For such purposes, the patient's clinical condition should be evaluated prior to each episode of the proposed treatment. Consistent with the provisions in Section 3.3 of the guideline, 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.

Similarly, in instances where patients present for periodic treatment of a chronic condition, such as regular haemodialysis, repeated de-sloughing of a wound, or periodic blood transfusion, consent should be re-obtained prior to each treatment as the condition of the patient, and consequently the associated risks, may have changed since the last treatment being provided.

12. For patients undergoing a treatment considered to be of high-risk, is a patient's next-of-kin also required to sign the consent form?

There is no distinction legally between a 'normal' consent and a 'high-risk' consent, nor are there any additional ethical or legal requirements for another individual to sign the consent form for a treatment that is considered as 'high-risk'.

If a treatment is considered to be of high-risk, the patient should be encouraged to discuss the treatment option(s) with any individuals (including family members, close friends, etc.) that the patient wishes in order to support the patient's decision-making process prior to making a decision on the proposed treatment.

It is good practice to document these conversations and explanation of risks in the patient's medical records.

However, requiring another individual to provide consent after the patient who possesses mental capacity to do so has provided his/her own consent a violates the respect for a patient's autonomy.

13. What information should be informed to patients by a RMP who proposes to utilise artificial intelligence (AI) tools and/or technology in the proposed treatment of the patient?

A RMP should inform patients of the following details prior to obtaining consent:

a) How the AI tools and/or technology are being used in their clinical care.
b) The basis of the results or recommendation generated by AI.
c) Any known risks associated with the use of the AI tool and/or technology.
d) Safeguards that are in place to prevent errors and/or data breaches.
e) Any conflicts of interest the RMP has or may have in relation to the AI tool and/or technology used.
f) That the RMP remains responsible and accountable for the patient's clinical outcomes.

In addition, the patient retains the right to know when an AI tool and/or technology has failed and/or has led to an adverse outcome.