The Core Concepts of Consent in Medical Practice

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Everything in the doctor-patient relationship is consensual. The consent process starts the moment a patient seeks medical advice and continues throughout the relationship as a communication and educational process or dialogue. As such, a good understanding of the core concepts, the elements and acquiring proficiency in the process of consent-taking is essential for every clinician.

The basics of consent

Consent in medical practice is the voluntary authorisation by a competent patient for a medical intervention. **Informed consent** is voluntary authorisation by a competent patient based on the knowledge necessary to make an appropriate choice. Informed consent implies that the patient is informed of the various medically feasible options and is given the choice of choosing the one that best fits his/her needs and preferences.

Consent is a legal requirement before any medical intervention takes place. The legal basis for consent lies in the legal principle that every patient of adult years and sound mind has a legal and ethical right to determine what shall be done with his/her own body. Proceeding with surgery or an invasive medical intervention without consent, or that exceeds the scope of the consent given could amount to **battery or assault**. This could attract a criminal prosecution. When death occurs in the absence of valid consent, it could amount to homicide and a charge of **serious or criminal negligence.**

Failure to get valid, informed, or adequate consent breaches the professional or legal standard of care in medical advice and could attract medical litigation based on negligence in the duty to advise.

Professional ethics require doctors to get consent before medical interventions. If there is intentional departure from professional standards, coercion or misrepresentation in the consent process, this could amount to **professional misconduct**. Failure to get valid or informed consent could be considered an abuse of privileges of a registered medical practitioner, and thus could attract a disciplinary inquiry.

Consent in professional ethics is supported by **the principles of respect for patient autonomy and medical beneficence**. Consent is necessary to uphold **respect for the patient's wishes** and right to choose the medical interventions according to his/her values and preferences. It is only when doctors know their patients' wishes that they can deliver beneficial treatment. Patients are given the autonomy to refuse any medical treatment, even that of beneficial therapy, the refusal of which may lead to deterioration of health to the extent of death itself. In upholding **medical beneficence**, doctors must ascertain that the refusal of beneficial therapy by a patient is an informed and autonomous decision.

Elements of consent

The three main elements of consent are **capacity, disclosure** and **voluntariness**.

All adults are presumed to have capacity to consent to medical therapy unless proven otherwise. The threshold to capacity in medical practice is kept low so that everyone can participate in medical decision-making as regards their own health. When a patient is temporarily impeded or under reversible factors that could impede capacity to consent, it is the doctor's duty to enhance the capacity by removing these impeding factors. These could include withdrawal of sedating medications, reversal of metabolic causes of drowsiness and pain relief.

Disclosure is the information that the treating clinicians should provide before the medical intervention or procedure. This involves the **medical indications** and **nature of the procedure**, **the benefits** and expected outcomes, and **the risks** and how they

could be mitigated. There should be clear explanation on **the alternatives** including the choice of not proceeding with the interventions. Patients should be given sufficient information on the medical condition, the goals of therapy and options for treatment (including non-treatment) so that they are able to participate meaningfully in making decisions about their treatment.

The extent of disclosure will depend on the context and the needs of the patient. It is not necessary to disclose every conceivable risk as this may inappropriately or disproportionately affect the patients' decision-making. **Information dumping** does not support good medical decision-making. The common and important risks are to be explained as well as the ways of mitigating them when they arise. The patient is also to be informed on what to expect immediately after the procedure, so that he/she is forewarned.

The patient should be given **an opportunity to ask questions**, and raise concerns, issues and expectations that are **material or important to his/her particular needs** and situation. Doctors should address and take cognisance of the material risk raised by the patient. **The professional standard** of information disclosure is what a reasonable patient in that situation would need, along with addressing the material risks raised by him/her, so as to enable effective participation in the medical decision-making.

Consent is a voluntary process and the patient should not be subjected to any form of coercion or be rushed into making a decision. Sometimes pressure may be put on the patient by family members, employers, insurance companies, healthcare professionals or others to undergo or refuse particular tests, or to accept a particular treatment. It is important to ensure that patients have been given sufficient time and privacy to consider the options, and the opportunity to confer with others to reach their own decision.

Therapeutic privilege is an accepted legal and ethical concept where physicians may withhold information from the patient, if providing such information would lead to serious harm or significantly undermine the patient's ability to make medical decisions. Serious harm does not mean the patient would become upset, sad or decide to refuse treatment. Doctors should not withhold information just based on their concerns that the patient would refuse beneficial recommended treatment.

When patients indicate a **waiver of information** and insist that they do not want to know details about their condition and treatment, the doctor should explore and validate that they are in possession of the necessary information. It is necessary to explain the importance of knowing the options and what the treatment they may receive will involve. Patients have a right but not necessarily a duty to know.

When patients request for **delegation of the decisions** on their behalf to the clinician or nominate a relative or third party to make decisions for them, it is still necessary to explore the reasons for the delegation and explain the importance of knowing for themselves what is likely to occur during the treatment and the options available. Although it is acceptable for the patient to seek the advice of others, the legal position is that no other persons may make decisions on behalf of a competent adult.

Involving the patient in medical decisions

It is difficult for physicians to predict patients' preferences and their tolerance of medical risk without deriving the necessary information from them. This is best done through the form of dialogue in a **shared medical decision-making process.**

The commonly preferred process of consent taking is often termed **shared decision-making**. Here, the doctor explores the patient's values, preferences, issues, concerns and expectations. The clinician shares his knowledge, experience and recommendations on the diagnosis, prognosis and therapy of the patient's medical condition. **Shared decision-making is an interactive, communicative and educational process** of information sharing and building trust and mutual respect.

Patients may vary in their preferred **mode or style of decision-making** in a spectrum, from benevolent paternalism mode on one end (where the doctor processes the information and shares his decision for the patient to agree), to that of independent client mode (where information processing and decision-making is done almost entirely by the patient) on the other end. Most patients prefer a shared medical decision-making process by way of dialogue between them and the doctor. Good professional practice requires doctors to know the mode of decision-making and engage the patient accordingly while fulfilling their legal and ethical obligations.

It is **the doctor's responsibility to initiate the discussion in consent** and not depend only on the patient to ask questions. The lack of knowledge and experience often impedes patients in asking the relevant questions. However, when patients ask questions, doctors must make an effort to explain in a way that the patient can understand, even if the doctors feel the question is irrelevant or unimportant.

Shared decision-making involves providing appropriate, relevant and adequate information in a manner that enables patients to participate meaningfully in medical decision-making. **Shared decision-making is a collaborative process of building an effective therapeutic doctor-patient relationship that promotes trust and confidence.**

In the process of information sharing and shared decision-making, the doctor should deliberately determine whether the patient is able to **understand, retain, weigh the facts, and make and communicate a decision**. Failure in any one of these components would suggest a state of diminished capacity.

In making a medical decision on behalf of **persons with diminished or lacking capacity**, the proper principle is to apply **the best interest principle**. To arrive at the best interest of the patient, the discussion would involve persons who have legal authority to act on behalf of the patient, consider the patient's previously stated preferences, involve relevant healthcare professionals and significant other persons who are aware of the patient's medical, psychological, social, cultural and other relevant factors.

In the case of **minors**, medical decision-making is done by doctors, parents and legal guardians applying **the best interest principle**. Doctors, parents and guardians have the responsibility to make decisions that always **uphold the best interest of the**

minor. Doctors should engage minors with information on their medical condition and the proposed treatment in a manner that they can understand. Where it is appropriate, based on their mental maturity and decisional capacity, their assent to medical treatment should be sought.

Adolescents, children and minors are at various stages of mental and emotional maturity and to a large extent financially dependent on their parents. As many things in their lives are not within their control, they are often not fully autonomous individuals for medical decision-making. Minors need to be **protected from decisions that could lead to harm to them.**

In **situations of emergency** or when delay of treatment could lead to serious deterioration of health, permanent impairment or even death, the doctor is to **act on the principle of medical necessity and treat the patient without the formal consent process.**

Documenting consent

Authorisation by a consent form shows that the patient was informed of the various medically feasible options, given the choice of choosing the one that best fits his/her needs and preferences, and has exercised his/her decision. **Explicit written consent** by way of an accurately filled **consent form** is necessary for letting the others in the healthcare team know the scope of the nature of the medical intervention. A properly filled consent form provides support for legal defence against claims of negligence in duty to advise.

Documentation of the consent process in a contemporaneous manner in the clinical case notes or medical records is an **important risk management strategy** in defending legal claims. Patients' **requests for waiver** of information must be appropriately documented, including the reasons for the request. In addition, documentation of risk acknowledgement by the patient and **reasons for the preferred choice for the medical intervention** are key to good practice and risk management.

Conclusion

Doctors have an **ethical and legal responsibility** to their patients to share information on their illness and treatment, and in meeting the **professional and legal standards** of care in medical advice by way of the consent-taking process. In addition, good professional practice involves building an **effective therapeutic doctor-patient relationship and promoting trust and confidence** by a **shared decision-making** strategy in consent taking and duty to advise. ◆

This paper was prepared as reading materials for the SMA CMEP Course for Advanced Specialist Training and Advanced Trainees by Dr T Thirumoorthy in October 2021.