PATIENT CONSENT TO TREATMENT: PATIENT'S RIGHTS, PATIENT REFUSAL, LEGAL ISSUES

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Introduction

The Miller-Keane Encyclopaedia and dictionary of medicine defines consent as an agreement made voluntarily by the patient before any procedure. This agreement is made in full knowledge of the procedure, and is based on the ability of the patient to reason (1). The ability to reason is dependent on two factors, capacity and competence (2, 3). According to the World Health Organisation mental capacity is the ability of a person to make decisions. Competence means the legal judgment of the individual's ability to make decisions. Competence is determined by judges as a legal outcome and capacity is a decision made by clinicians based on the mental status of the patient (2, 4, 5).

The principles of patient autonomy and privacy form the basis of an informed consent (1). Patient autonomy is the right of the patient to make decisions without any manipulation (7, 8). It includes the right to choose and free will of a patient (9). Other rights of patients include; the right to proper medical care, the right to be informed, the right to "privacy and confidentiality" and the right to "access of efficient complaint system" (10). If the patient is incompetent his rights are executed by the legal guardian his behalf (10). A balance should be maintained in respecting the patient's rights and protecting those who are incompetent (11). Therefore, it is crucial to assess whether the patient is competent or not (11).

Certain groups of patients have impaired ability to make decisions. These include those with Alzheimer's disease and other dementias (11, 12), stroke (11, 13), neurologic and infectious diseases, psychiatric conditions like schizophrenia, depression, bipolar disorders (6, 14, 15, 16), patients in the intensive care units (6, 17), and nursing homes (6, 18, 19), and intoxicated patients.

Physicians should be able to assess patient's competence (11). The mini-mental state examination (MMSE), is very fundamental in clinical assessment of mental capacity (11, 20),

and it is used to identify patients with cognitive dysfunction (11, 21, 22). It is a questionnaire that tests the patient's memory, arithmetic capabilities, orientation in place and time, language and ability to understand complex commands. Scores range from 0-30, lower scores (less than 19) indicate an impairment and are associated with incompetence (11, 21, 22). The MacArthur competence assessment tool for treatment can also be used, which is an interview that specifically includes information that relates to the patient's condition (11, 23).

The Law and medical ethics requires that consent be obtained before any treatment (11). This basic principle was first mentioned in the Nuremberg Code of 1947, which was initiated after World War II, in response to the cruel experiments performed by the German Nazi regime. It makes informed consent compulsory whenever humans are involved (24). In 1964, the world medical association adopted the declaration of Helsinki which places importance in obtaining a voluntary permission in medical research involving humans (25). Consent can be expressed or implied consent (26). A patient who goes for medical consultation in his own accord is considered to have consented to treatment. Implied consent is based on the patient's behaviour when visiting the doctor, this includes willingly following doctor's orders (26). Should an intimate examination like vaginal examination be required, an orally expressed consent may be needed. A written consent is required for invasive procedures (26).

Both the physician and the patient are involved in the decision making process (27, 28). "The physician gives information about the diagnosis, prognosis, treatment options, risks and benefits, medical opinion and treatment recommendation. The patient then to gives information about his values, preferences and health care goals" (27, 29, 30). Informed consent is a process that involves a two-way communication between the patient and the physician throughout the patient's care (27). The signing of a consent form serves as evidence that the patient has agreed to treatment (27).

A valid consent should meet these conditions: firstly, the patient giving permission for treatment must be competent (27). The ability to make informed decision is associated with maturity of the patient. Generally an 18 year old person has attained an age of maturity and has the capacity to give permission for treatment (26). Children are therefore not presumed to be competent, "instead a limited right to consent is provided by common law" (32, 34). The competence of a child is dependent on the stage of the child's intellectual development (32). Children must satisfy a test of capacity, they must show some level of competence. They should be able to retain information and clearly express their decisions (32, 35). Young people are generally able to make decisions and can consent to treatment (32, 33). When a competent child or young person rejects a proposed treatment, parental consent or legal intervention should be sought (32).

If a patient shows incompetence, regardless of their age, a legal guardian should be appointed to act on their behalf (27). Any consent received from an incompetent patient is considered to be invalid (11). Should a patient lose the ability to make decisions, the surrogate's authority becomes effective (27). Choosing a surrogate should be taken seriously since the surrogate has a greater role in decisions regarding the patient (27, 31). Sometimes the surrogate makes decisions that are not beneficial to the patient, either for personal gain or due to emotional reasons (27). Therefore, the surrogate's decision should always be assessed for reasons or motives influencing his decision (27). When a conflict regarding the patient's interests arises, the physician should ask for the ethics consultation which will provide an external view on the surrogate's decision (27).

Secondly, the patient should have received all the necessary information (27). Such information should include the nature of the patient's condition, the type and purpose of treatment, the risks and benefits, treatment options and the option to refuse proposed

treatment. This information should be shared with the patient unconditionally (11). The information should be in a language that the patient understands (26).

Thirdly, the patient should freely make a decision, without manipulation (27). The patients should not be forced to agree to treatment, but should decide on their own to accept or reject treatment. The right to refuse is an essential part of an informed consent. Without this right, consent holds no meaning (27). When a patient refuses treatment that would otherwise be beneficial to him, the physician can persuade the patient into accepting treatment (27). Some patients may refuse treatment for religious reasons (36). For example, Jehovah's Witness follower may refuse a blood transfusion that would otherwise save his life, because it is against his believe (36). This causes conflict between the patient's right to make an informed refusal and the physician's obligation to protect life (36). Therefore, when confronted with such a situation both the patient and the physician should come to a decision, with a witness present. It is important to write in the patient's record all information shared with the patient when making consent (27).

Patients have the right to choose and physicians should respect that. Article 8 of The Human Rights Act 1998, "Right to respect for private and family life", states "there shall be no interference by a public authority with the exercise of this right, except such as in accordance with the law and is necessary, for the prevention of disorder or crime, for the protection of health or morals or for the protection of the rights and freedom of others" (32). Informed consent acknowledges the patient's autonomy and recognizes that patients have the right to choose according to their preferences and standard of good life (27).

In emergency cases, threats to public health or danger to self or others, informed consent can be exempted (27). In such cases consent is presumed, and emergency intervention can be given. All physicians are authorized by the emergency treatment doctrine to give an

emergency treatment when necessary (27). The physician is bound by the Hippocratic Oath to protect the human life, and has to provide emergency interventions without waiting for an informed consent (26). “No law or state action can intervene to avoid or delay the discharge of the paramount obligation cast upon members of the medical profession. The obligation of a doctor is total, absolute, and paramount” in this case (26).

If a physician gives treatment without any informed consent, they will be legally responsible under both the “criminal and tort law” (26). Tort is a personal harm, usually due to wrong conduct in which the accuser can sue the accused for compensation. The patient may sue the physician for trespass of person or negligence under tort. If a force is used against the patient without proper reasons, the physician may be held responsible under the tort law (26). In the criminal law, the patient may sue the physician for assault or battery. Battery is an act that harms the patient deliberately or due to negligence (26). The outcome in tort is compensation, while in the criminal law the accused faces imprisonment (26).

Discussion

The concept of informed consent has long been in practice. Informed consent is birthed from the concept of human rights and patients' rights. Patient's right to make decision is the most fundamental aspect in planning and giving of treatment. Two components are essential in making an informed decision; these include mental capacity and competence. The ability to reason is often associated with age. Eighteen year old patients are believed to have reached an age of maturity where they can make their own decisions (26). However, not all 18 year olds are mature enough; an input of parental or legal authority may be needed when obtaining consent.

Patients may show incompetence. Therefore physicians should be able to assess the competence of their patients. Several tests are available for this; most commonly used being the mini-mental state examination (11, 20) and the MacArthur competence assessment tool for treatment (11, 23). For young people and children, when necessary a legal guardian should be appointed or the court may decide on their behalf regarding any treatments (32-35). Regardless of their age, patients who show incompetence should have a legal guardian appointed for them.

Informed consent is a process not an event where the patient signs consent form (27). It is a bidirectional information sharing and communication between a physician and a patient. Patients may change their mind even though they have signed the consent form (27), so it is necessary to confirm again with patient before the procedure. Good and clear communication between the physician and the patient forms the basis for a good consent (27). Language plays an important role in this communication (36). If the patient and the physician do not understand each other's language a translator should be sought to translate for the parties involved.

Without an informed consent the physician is at a risk of facing claims or law suits (11,). The physician can be charged under the tort law for trespass of person or for negligence, for which compensation may be required (26). They may also be charged for assault and battery under the criminal law, for which the physician faces imprisonment (26). When the patient is not able to give consent, a legal guardian or a witness should be sought for legal purposes. The physician is authorized by the emergency treatment doctrine to provide common emergency treatment based on presumed consent (27). In these cases, the physician's obligation to protect life under the Hippocratic Oath is enforced, and therefore the physician is legally safe (26).

Conclusion

An informed consent forms a vital part in any medical setting, whether for diagnosis, treatment or research. It is not just a signature on the consent form but a process that involves a two-way communication between the physician and the patient. Consent should be obtained from a competent patient, when necessary a legal guardian should be appointed. A witness may be needed in some cases. It is also important to write information regarding the consent into the patient's record.

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