Consent in Medical Practice 2

– Disclosure of Medical Information and Communicating Risks

By Dr T Thirumoorthy, Executive Director, SMA Centre for Medical Ethics & Professionalism

This is the second instalment of a series on informed consent. The previous instalment, titled "Consent in Medical Practice 1 – Understanding the Concepts behind the Practice", can be found in the June 2013 issue of SMA News *(http://goo.gl/gmbx2).*

Consent in medical practice is a shared decision making process by both the patient and clinician. The clinician provides medical information and the competent patient exercises his autonomy to accept the most appropriate choice from the various options discussed.

Informed consent, for the purpose of discussion, is divided into:

1. Capacity – the patient's capacity or competence in decision making;
2. Disclosure or information – the clinician provides the patient with medical information; and
3. Voluntariness – the patient makes the decision voluntarily, without coercion or constraints.

Ethical and legal basis of the duty to inform

The ethical duty to inform or advise is embedded in **the ethical principles of respect for patient autonomy and beneficence.** Often, patients do not have the relevant medical information and experience on their health and illness to make appropriate medical decisions. As such, they need to receive sufficient information from their doctors, in a manner that can be understood, so they can make an informed and reasonable choice.

In addition, the doctor owes a *legal duty of care to inform (or advise),* to provide her patient with important information on his health and illness that will help him better understand and make appropriate medical decisions for his present illness and future medical care. The legal term that describes a process by which a clinician provides information on a medical investigation or treatment to a patient is called **disclosure**.

A clinician should bear in mind that in giving information, her primary obligation is to always put the patient's best interest above hers. The communication is based on mutual respect, open clear communication (transparency) and trust. The perception of lack of sufficient information and expediency in disclosure leads to frustration, uncertainty, and erodes trust and confidence in the doctor-patient relationship.

Photo: iStockphoto

The nature and amount of information to share

Individuals need varying amount, frequency and emphasis (or focus) of information to make decisions. The circumstances and seriousness, or risk related to the decision to be made varies with each individual as well. The better the clinician knows the patient, the more effective the medical disclosure will be.

How much information to disclose depends on:

1. The patient's needs, preferences, expectations and concerns;
2. The patient's depth of knowledge of the procedure and treatment options;
3. The nature of the medical condition;
4. The complexity of the proposed treatment;
5. The risks involved in the procedure; and
6. The ease with which beneficence (good medical outcome) is achieved.

A clinician can have difficulty in accurately predicting her patient's preferences and thus, should not make assumptions about:

1. What information the patient should hear;
2. The significance of the questions asked by the patient;
3. The clinical risks and benefits that the patient considers significant; and
4. The patient's level of knowledge and understanding of medical issues (health literacy).

A clinician should not ignore nor override her patient's questions, however trivial they may appear. *All concerns need to be acknowledged, explored and addressed.* In doing so, the clinician would be in a better position to understand the patient's perspective. Clinicians tend to overestimate the depth of patients' understanding on medical issues, and can often underestimate some patients' ability or willingness to make medical decisions.

In medical decision making, a patient may need to know and understand the following:

1. The diagnosis, complications and prognosis of his condition;
2. The various treatment options available within and outside the present healthcare centre;
3. The proposed plan of the investigations and treatment based on the clinician's professional judgement;
4. The goals (aims) of therapy, the benefits and chance of successful outcome of the proposed action;
5. The risks and the likelihood of the risks materialising, consequent burden and known mitigating steps to minimise the risks. Discuss the serious risks, even those of low frequency, and all common risks of the proposed action, and also discuss all risks that may lead to permanent disability;
6. The risks and benefits of the other options;
7. The risks and benefits of no active treatment;
8. What to expect after the procedure, duration of disability, rehabilitation and when full recovery is to be expected, if it is possible;
9. What the areas of his life that may be significantly impacted by the procedure are; and
10. The estimated cost of the entire treatment, including potential complications.

Maximising patient autonomy

Medical decision making can be difficult when the patient is ill, anxious and in pain. It is important to enhance the patient's autonomy by removing obstacles. These may include treatment of pain, removal of sedating agents, avoiding medical jargon, using terms that a patient can understand, getting the help of interpreters, significant family members and other healthcare team members. Written information and audiovisual aids should be made available. Information disclosure may need the use of diagrams, videos, pictures and other aids. The patient may need time and opportunity to consult others before coming to a decision. The physician has a duty to inform and educate her patient on the risks and benefits of his medical decision in a language and manner that he can understand, so as to enable the patient to reach a maximally autonomous decision.

Legal standards in disclosure

The clinician must be aware of the legal responsibilities and standards in giving medical information in informed consent. For *valid consent,* the patient must be informed, in "broad terms", of the nature and purpose of the medical procedure. Valid consent provides a defense to the tort of battery.

To meet *the standard of disclosure in informed consent for a defense in medical negligence*, a more detailed discussion on risks, benefits, burden of consequences of the procedure and alternatives must be shown to have occurred. Failure to provide adequate information may give rise to a claim in medical negligence. The standard of disclosure in medical negligence varies with different jurisdictions.

The legal standards can be classified as follows:

1. **The professional standard** – what a respectable, responsible and reasonable body of professionals would do in a similar situation (Bolam and Bolitho tests);
2. **The reasonable (*objective*) patient standard** – what a reasonable patient in this situation would need to make an informed choice. The court will decide that the disclosure of a particular risk was so obviously necessary for a patient to make an informed choice that no reasonably prudent medical professional would fail to make it; and
3. **The particular (*subjective*) patient standard** – a reasonable person in the patient's position, if warned of the risk, would likely attach significance to it or if the clinician is or should be reasonably aware that the particular patient, if warned of the risk, would be likely to attach significance to it. All material risks are to be disclosed. What is considered as material risk will be decided by the patient or based on the clinician's knowledge of the particular patient.

In Singapore today, the professional standard based on the Bolam and Bolitho tests is accepted as the legal standard of disclosure or advice in consent. The duty of the doctor in assessment (diagnosis), treatment and disclosure of information are considered a composite duty and thus, should be judged by the same standard. Legal jurisdictions outside Singapore have applied different standards to the duty to advise or inform for that of other duties of the doctor.

The legal standards would also take into consideration whether the patient was given sufficient time and privacy to ask questions and consider the facts. A "cooling-off period" for the patient to discuss with his significant others, and even get a second opinion in elective surgery, counts as meeting the standards of a reasonable and responsible professional.

Withholding information in informed consent

Withholding information in informed consent should only be done to prevent serious harm to the patient. This is termed **therapeutic privilege**. Therapeutic privilege is an ethical and legal doctrine where the physician may withhold disclosure of information, especially regarding medical risks, if such a disclosure will be detrimental to the patient's care and interest. Serious harm as a result of the disclosure includes psychological distress to the extent that the patient is unable to participate rationally and effectively in decision making – it is not just being sad or anxious, or the decision to refuse treatment.

Withholding information may be justified in other situations, but only when clearly substantiated, as in the following situations:

1. In the case of an emergency requiring a life-saving procedure, where the delay caused by seeking valid consent may harm the patient.
2. The clinician could waiver when the patient requests not to receive information. Basic information on what is to happen must still be provided to reach the standard of valid consent in cases of waiver.
3. It is not the family's prerogative to withhold information. The clinician should take cognisance of the family members' request but arrive at her own judgement after examining the facts of the case and decide whether to withhold information.
4. The clinician is dealing with an incompetent patient or one who lacks capacity.

When withholding information in any medical decision making or in taking consent, it is vital to document this appropriately in the medical records. Record the request and reasons to waive information in the case notes and better still, after discussing with a senior colleague. The notes must be able to explain and justify the decision made.

Who is qualified to take consent

It is traditional and appropriate for *the clinician who is directly treating the patient to seek the patient's consent and document it accurately.* If it is not practical to do so in entirety, this responsibility can be shared with or *delegated to healthcare professionals in the caring team* who are suitably qualified and trained, and has sufficient knowledge of the medical condition, proposed benefits and risks of the procedure. Wherever such delegation occurs, the treating or primary doctor must validate that the consent process is appropriate. Inappropriate delegation can result in not meeting the standards. In today's multidisciplinary team that is based on collaborative practice of Medicine, it is professionally acceptable for consent taking to be a team-based effort.

The clinician who is involved in giving medical information for medical decision making must reflect on her own competence in this area by:

1. Being suitably trained and qualified;
2. Ensuring sufficient knowledge and experience on the procedure;
3. Being up to date on the various treatment options and the risks;
4. Recognising potential areas of conflict (financial or research) of interest;
5. Giving balanced and unbiased information; and
6. Having effective communication skills and understanding the patient's perspective.

Obtaining informed consent is not a single isolated event that will occur just before the procedure. It is best if it is a continuous dialogue which is based on scientific facts, and understanding of the patient's preferences and concerns. Getting the patient to acknowledge the risk before the medical procedure is an important risk management strategy. It does not turn consent taking into a numeracy game of statistics and listing of risks, but about the patient's concerns being explored and explained. Consent taking is not meant to be a legal impediment to achieving the goals of medical care, but an enhancement tool for building trust to achieve good clinical outcomes.

Giving medical information to patients is a core skill of all clinicians. It has to be carefully acquired, practiced and continuously developed so as to meet both ethical and legal standards, and be effective in serving our patients' best interest. The process, timing, content and mode of delivery of the disclosure are all key factors in promoting mutual trust and confidence in the doctor-patient relationship. Consent taking is both an art of interpersonal skills and communication (conversation), with the exercise of sound clinical and ethical reasoning and judgement. SMA

Dr Thirumoorthy is Executive Director of the SMA Centre for Medical Ethics & Professionalism. In addition to being a practicing dermatologist with an interest in medical Dermatology, he serves as teaching faculty in the Practice Course of Duke-NUS Graduate Medical School.