Consent in Medical Practice 4
– Managing the Risk with Effective Communications and Documentation of the Process

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This is the fourth and final instalment of a series on informed consent. The first 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). The second instalment, titled "Consent in Medical Practice 2 – Disclosure of Medical Information and Communicating Risks", can be found in the July 2013 issue (http://goo.gl/9963UM). The third instalment, titled "Consent in Medical Practice 3 – Dealing with Persons Lacking Capacity", can be found in the August 2013 issue (http://goo.gl/xjh9th).*

Consent is the ethical and legal authority which has to be obtained before any medical intervention. A failure or refusal of informed consent is an absence or denial of such ethical and legal authority to proceed with medical care. Thus, doctors have a professional (ethical) and legal duty to provide sufficient information to patients when taking consent, in a way the latter can understand, to enable them to participate effectively in medical decisions about their care.

The professional and legal standards in the duty to inform (warn)

Informed consent is often considered the Achilles heel in medical risk management, in the defence of a charge of medical negligence for failure to inform or warn, and a charge of professional misconduct for the same failure. At the same time, consent taking is the same process in which doctors and patients develop a trusting therapeutic relationship. A resilient therapeutic doctor-patient relationship, which meets the expectations of all stakeholders, is the strongest strategy and defence against medical litigation and complaints of professional misconduct.

When there is a claim of malpractice in the duty to inform, the defendant doctor has to show that the standard of care has been upheld by showing documented evidence that the process of consent taking has met the professional standards of care. The legal standard of care in the duty to inform (or advise) in Singapore is the Bolam test supplemented by the Bolitho logic. This combination has sometimes been summed up in the local context as the Gunapathy test (James Khoo v Gunapathy [2002] 2 SLR 414). The professional standard of care in the case of professional misconduct cases heard in Singapore Medical Council (SMC) disciplinary tribunals for failure in consent taking has not been clearly defined, and appears to be a higher standard of documentation than that of the law courts' legal standards.

Effective patient-centred communication

Effective communication is the key to enabling patients to make informed decisions. The application of effective communication would help determine the amount of information required and the patients' preferences in shared decision making. In the process of medical decision making, patients have different approaches and preferences. These preferences could be generally divided into five groups, but they are by no means exclusive. Preferences may change, even in the same patient during different circumstances – for example, if it is an emergency as opposed to an elective procedure, or an acute illness as opposed to a chronic care or palliative care approach. The five possible groups of preferences are:

1. Benevolent paternalism

In the first group, a patient (like one who is hospitalised) would prefer a benevolent paternalistic approach, where the doctor processes the information and makes the decision. The doctor then informs the patient why this is the best approach for the latter. By displaying respect, empathy and sincerity, the doctor wins the trust of the patient and he consents. The doctor must display solidarity (support) and journey with the patient in the entire process of care.

2. Physician as the agent

In the second group, the patient would want to know more information and what to expect after the treatment or investigations. He would like his preferences to be taken into consideration, but will leave it to the doctor to process the information and make the final choice or decision. The patient expects the doctor to foresee (predict) difficulties and mitigate them.

3. Shared decision making

In the third group, a patient prefers more detailed information including risks, alternatives and uncertainties. He is actively involved in a shared decision-making process. His concerns (fears and worries) and expectations should be addressed. Both the patient and his doctor are equally involved in a therapeutic partnership in the decision-making process. The majority of patients prefer this approach.

4. Informed decision making

In this group, the doctor provides information and resources, and answers all aspects of the patient's questions. The patient processes the information and then engages the doctor in her experience and expertise. Finally, the patient makes his decision.

5. Independent client approach

In the final group, the patient finds his own resources and does his own research, even before he comes to the doctor for additional information. The independent client employs the doctor to do the task and to affirm his decision. The patient makes the decision by himself and the doctor is often delegated to the role of an expert technician.

Determining the preferred approach

The best way to determine the patient's preferred decision-making approach is to engage and ask him in an open dialogue of mutual respect and trust.

Challenges in consent taking

Like many other aspects of life, the practice of clinical Medicine is complex and filled with uncertainty. This uncertainty can trouble clinicians and patients. Taking informed consent is the art of communicating medical uncertainty by conveying caution, not fear; and promoting hopeful optimism, not unrealistic expectations. Clinicians must acknowledge the uncertainty in Medicine, and normalise and share it with their patients, which is the first step in establishing realistic expectations.

A doctor can enable her patient to accept uncertainty by acknowledging and empathising with the emotional impact of the uncertainty of illness and clinical outcome. A clinician must recognise and acknowledge the cognitive and emotional difficulty her patient has in medical decision making, in the midst of illness, uncertainty and medical complexity. A clinician must be aware of her own emotional reactions and her patient's anxiety, as anxiety and strong emotions in both parties could result in poor decision making. Active listening, expressing empathy and appropriate reassurance are essential for a doctor to build trust and help a patient journey through illness.

The clinician needs to provide adequate and accurate information. There is no obligation to disclose every conceivable risk, which would cause information overload and frighten the patient. Information overload would inadvertently result in an unbalanced decision, often to the detriment of the patient's welfare.

The clinician must acknowledge her own discomfort with medical uncertainty, and recognise the difficulty in communicating complex medical concepts in simple language to the patient. She must be aware of her own emotional discomfort and how it may influence her conversations with the patient. Managing emotional reactions is pivotal in effective medical communication.

The clinician must show respect for the patient's wishes by providing him with space and time to elicit other issues, concerns and expectations. Managing unrealistic expectations early is a key stage in risk management in medical consent. The clinician should not dismiss the patient's questions as frivolous nor be cursory, or assume that he understood because he did not ask questions. It is the doctor's duty to inform.

Medical communication skills

A doctor can learn and practise communication skills that would enable her to communicate medical uncertainty and complexity in an effective manner. Effective interpersonal and communication skills involve appropriate introduction, active listening, empathising, and taking time and effort to explain.

Apply effective communication techniques like the Ask-Tell-Ask method to ensure the patient understands the information provided. Pause to appreciate his reactions, emotions and predicament by his words and body language, before proceeding.

Explore and encourage the expression of issues, concerns and expectations. Explore the patient's perspective before explaining. It is important to address all questions and concerns he raises in a clear and complete manner. Answer all questions honestly and in a manner relevant to his situation. Do not convey the message that the intervention is routine, simple and safe. All medical procedures carry risk and can go wrong. Where the information is incomplete or unavailable, the clinician should offer to find out or name other resources.

Always show respect, empathy and sincerity in communications with the patient in simple, clear language and answer questions in an effective manner. These skills can be mastered by training, repeated practice, feedback and reflection.

Documentation

There is native wisdom in medical malpractice literature which goes: "good clinical records is good defence, bad records is bad defence, no records is no defence".

As part of a good risk management strategy, the following aspects of the consent process are best documented in the form of contemporaneous case notes, in addition to the signed and dated consent form:

- Document any information given during the first consultation in the clinic for diagnosis and possible therapeutic options. This will help clarify when the consent process was started.
- Document when any written information, brochures, leaflets, or videos were provided. This is best done in advance of the intended treatment. Keep a copy of the information given so it is easily retrievable when needed.
- Document that the patient was given an opportunity to ask questions throughout the process. Ask and document if patient has any specific questions or concerns.
- Document that patient was encouraged to do his own research and revert with queries (in appropriate cases).
- Document, where appropriate, that the patient had been given information by other members of the medical team. Ask the patient what he already knows, or was told of the condition and its treatment before he came to see you, and document this. If the patient already has preexisting knowledge from other sources such as other doctors in the team, there is no need to repeat the advice in depth.
- Document, where practical, that the patient had sufficient time to consider (cooling off period) and sufficient time to confer (getting a second opinion) before signing the consent form.
- Get the consent form signed in the clinic, rather than on the day before the surgery, which signifies the patient has been given suitable time, space and privacy. There is evidence of lowered risk when informed consent is taken by the operative surgeon in the office or clinic, as compared to the hospital ward or day surgery holding area. Documentation in office or clinic notes, as opposed to only the consent form, lowers one's risk.[1]
- Ensure that the consent form is accurately and completely filled in, and that it is easily retrieved when requested. The consent form should include addendums for the particular procedure and risk acknowledgment documented and signed by the patient. It is good practice to give a copy of the consent form to the patient.

Conclusion

Taking consent is an essential requirement before any medical intervention, to ensure that doctors' medical practice is ethical and legal. Failure to do so runs the risk of professional malpractice. Consent taking is a process of relationship building, determining the patients' expectations, and meeting the professional and legal standards of care. Skills and good habits in communication and documentation are essential for a fulfilling practice and defence against medical malpractice. SMA

Reference

1. *Bhattacharyya T, Yeon H, Harris MB. The medical-legal aspects of informed consent in orthopaedic surgery. J Bone Joint Surg Am 2005; 87(11):2395-400.*