Background  Informed consent is frequently misunderstood as something that only applies to research trials or a form that a patient signs to indicate understanding and agreement when undergoing an invasive procedure. This Fast Fact reviews the legal basis for informed consent. Fast Fact #165 will discuss common myths about informed consent in the care of seriously ill and dying patients.

Definition  Informed consent is a process, not a signature, whereby a physician discloses key information to help patients make a choice among healthcare options. The informed consent process requires that three conditions be met: a) the patient is able to make a voluntary choice, b) the patient is informed (see below), and c) the patient has the capacity to make medical decisions.

Legal Standard  The legal standard of informed consent varies between states. Some use: what a reasonable patient would want to know; in other states the standard is, what a reasonable physician should provide. A failure to meet the legal standard may meet the threshold for liability.

Information  No matter which legal standard is operational, the consensus among national medical and ethical organizations is that following information should be provided to meet the spirit of the informed consent doctrine:

- The patient's diagnosis, if known;
- The nature, purpose, risks and benefits of a proposed treatment or procedure;
- The nature, purpose, risks and benefits of alternative treatments or procedures;
- The risks and benefits of not receiving or undergoing a treatment or procedure.

Emergency Exception to Informed Consent—physicians may proceed with treatment in emergency situations when all of the following criteria are met:

- Life threatening emergency and time is of the essence.
- Patient is not decisional and no legal surrogate decision maker is available.
- Reasonable person would consent to the emergency treatment.

Therapeutic Privilege  A long-standing legal principle is that physicians may withhold information if they believe the information would harm the patient. The use of this privilege should be restricted to rare instances when there is good evidence that providing information will upset a patient so he/she “could not rationally engage in a conversation about therapeutic options and consequences” (Meisel 1996). Physicians should not use the privilege out of concern that with information, the patient will refuse a recommended treatment, nor out of fear of provoking normal emotional reactions to bad news.

Summary  The purpose of the informed consent doctrine is to promote autonomy of the individual in medical decision making (Meisel 1996). However, the informed consent process is often viewed by physicians as being counter to an equally desirable social goal – a physician’s responsibility for a patient’s well-being and promotion of health. The point of balance between these two social goals is frequently misunderstood, and will be discussed in the next Fast Fact.

References

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