Surgical Consent Guidelines

This Surgical Consent Guidelines handout is based on the "FIGO Best Practice Guidance in Surgical Consent" and has been tailored to ensure comprehensive patient understanding and informed decision-making.

Elements of valid consent

Elements of valid consent include the following:

Capacity/competence
It must be demonstrated that the patient has the ability to understand the information provided, analyze/process that information, and make a decision that is in her best interest based on the provided information. Patients must have attained the legal age of competency and possess the mental capacity to give informed consent. In the case of a minor, or when it has been established that a patient does not possess the mental capacity to give informed consent due to a serious condition or if unconscious or comatose, consent can be given by a surrogate or substitute decision maker, usually a parent, spouse, or offspring.
The patient must have the capacity to make a healthcare decision. It is important to ensure that:
• They understand that they are ill and require treatment • They understand their treatment options and the general risks and benefits of each • They have the capacity to make sense of the information presented and can process it rationally to reach a decision that furthers their healthcare goals • They have the capacity to communicate their wishes.
Incapacitated patients do not lose their right of consent. Instead, it is transferred to an authorized surrogate decision maker to exercise on their behalf. Coercion can arise from individuals who may not be present in the room but who have a relationship of power over the patient. If we have reason to suspect this, we can ask a general question, such as “Do you feel safe and free to give consent? Are you feeling pressure from anyone to have this operation?”.
Disclosure
Patients should be provided with accurate, necessary, and relevant information to enable them to make an informed and autonomous decision, taking into account their concerns and wishes. Information should be provided in clear, unambiguous, and simple language that is easily understood by the patient. In case of language differences or barriers, a professional medical interpreter/translation service should be employed. Information provided should include the diagnosis, the name and description of the proposed procedure/intervention, the intended benefits of the procedure, the possible complications/risks, any extra procedures that may become necessary during the procedure, alternative treatments (including no treatment and non-operative care in case of consent for surgery)—including the benefits and risks of the alternatives, and the options and risks of anesthesia.

Even though it is often impracticable to discuss every potential risk or complication with the patient, the most likely and/or serious risks must be explained. Reasonable people need to know their choices and the general benefits and harms of each choice to make a rational healthcare decision. Physicians should communicate the risks of treatment to the extent that they are common or serious.

Risks should be expressed as percentages (e.g. 10%) or frequencies (e.g. 10 in every 100 people).

The latter, with a corresponding verbal descriptor, better conveys information on risk, such as “very common” corresponds to 1/1–1/10, and “very rare” is less than 1/10 000. The patient should be allowed to discuss the mode of anesthesia and its risks in detail with the anesthetist before the planned procedure.

Understanding

Comprehension of the information provided must be confirmed by asking the patient to recap or summarize what has been disclosed to her and allowing sufficient time to ask questions and clarify. After the patient recaps the disclosed information, any identified gaps in the patient's understanding must be addressed by repeating the misunderstood parts of the information.

Voluntariness

Patients should be allowed to use the information disclosed to intentionally and voluntarily make a decision without coercion or inducement. The consent process should not be a one-off event occurring immediately before the planned procedure.

It should ideally, except in emergencies, involve multiple sessions and encounters so that the patient has ample time to further discuss and reflect on the disclosed information before making a decision. Until the planned procedure has commenced, the patient reserves the right to withdraw her consent and this should be respected.

The patient must consent freely:

- Patients should not be coerced into accepting treatment by a physician.
- Making a strong treatment recommendation is persuasion, not coercion. Coercion is the use of threats that a reasonable person would not be expected to resist.

It is appropriate to document a refusal of surgery when that choice carries considerable risk.

Documentation

All of the above discussions should be fully documented in the patient's records. The patient's consent is completed by the patient signing a “consent form”, which is included in her medical records. This form is often standardized in a hospital or region, and it is usually generic and not specific to obstetrics and gynecology. Hence, it is necessary to augment it with any additional relevant information.

The consent form should be countersigned by the personnel administering and witnessing the consent process. If the patient has objected to the use of a particular instrument or any procedures aside from the one planned, this should be documented in the signed consent form.

Challenges and situations doctors should avoid when obtaining informed consent

Surgery produces anxiety in patients, and some display this stress more than others. Hearing their surgeon iterate a long list of things that can go wrong is frightening. Another challenge is the language barrier when a friend or family member translates the surgeon's explanations into brief sentences, with the patient receiving a fraction of the information provided. A hospital interpreter can be a valuable resource.

Informed consent requires surgeons to make reasonable attempts to answer the patient's questions. With all the information available on the Internet, patients may wish to engage in an intensive, detailed discussion, and the surgeon must be patient while facilitating their understanding of the wealth of data they have acquired.

Proper documentation is the only objective measurement of what information was communicated to the patient and provides legal protection for the surgeon.

The dialogue and documentation of informed consent for surgery have evolved from a brief chat and a quick signature into a major and sometimes complex component of surgical practice.

Additional notes

Topcu, E. G., McClenahan, P., Pule, K., Khattak, H., Karsli, S. E., Cukelj, M., ... & Fogarty, P. (2023). FIGO Best practice guidance in surgical consent. *International Journal of Gynecology & Obstetrics*, *163*(3), 795-812.