Quality Assurance Committee
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Guide to the informed consent discussion

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Preamble:

Informing our patients about diseases, diagnostic and therapeutic interventions, and particularly upcoming surgical procedures, is an integral part of the work of a medical professional. The western understanding of self-determination and our patients' right of autonomy require a comprehensive, understandable and relevant informed consent process for patients. Apart from the ethical aspects, there are legal reasons for the consent process. From the legal standpoint, the patient informed consent procedure is an obligation of the doctor to enable the patient to provide her consent. If the information provided is inadequate, the patient's consent is no longer effective and, in our view, loses its justification. Once the patient has given us her consent, we doctors are exempt from any criminal allegation of bodily injury and civil liability provided the treatment is carried out carefully.

The briefing provided by the doctor is intended to enable the patient to weigh up the advantages and disadvantages of the planned procedure and then make her decision as part of a shared decision-making process. A comprehensive and patient-oriented informed consent discussion should help the patient reach her decision for or against the procedure. Exercising her right of self-determination lies at the heart of this process.

The informed consent discussion should usually take place in the context of a consultation. In special situations such as pandemics, for example, the discussion can be conducted in the form of a video conference if the patient has given her explicit consent.

In emergency situations the discussion may be shortened in order to avoid exposing the patient to unnecessary health risks as a result of any delay in the treatment.

Preparing for the discussion:

The following points should be clarified before the informed consent discussion:

Language problems: A check should be made before the discussion to ensure that the patient understands our language or can bring with her someone who is sufficiently fluent in the language.

Conducting the discussion with minors: The key factor is not whether the patient is an adult or child, but rather her ability to make a sound judgment concerning the upcoming matter / treatment. It is part of the doctor's job to decide, at his/her own discretion, whether a patient has decision-making capacity or not. The decision should be documented in writing. This is mandatory before performing sterilizations. This also applies to assisted reproductive techniques and in research.

As with adult patients, the informed consent discussion with a minor must be carefully documented, especially the decision as to why the patient was considered to have decision-making capacity. (https://www.samw.ch/de/Publikationen/Leitfaden-fuer-die-Praxis.html "Rechtliche Grundlagen im medizinischen Alltag".
https://www.samw.ch/en/Publications/Medical-ethical-Guidelines.html "Assessment of capacity in medical practice", Form for evaluating and documenting the decision-making capacity)

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Timing of the informed consent discussion: The cantonal legislation must be observed (e.g. in the canton of Zurich: informed consent discussion must take place at least 3 days before major procedures). Depending on the situation, it is essential, before any planned hospitalization / operation, for the patient to attend an outpatient appointment for the preliminary discussion. She must be given sufficient time to reflect and decide whether to undergo the procedure or not. The informed consent discussion should take place some days before the operation (does not apply to emergency or urgent procedures).

Aids: Various aids should be used to better visualize the content of the discussion, e.g. pictures, videos, sketches, information brochures, books, etc.

We would strongly recommend that the informed consent discussion is documented by the doctor in informed consent protocols developed by gynécologie suisse / SGGG. If no informed consent protocols are available, the discussion should be documented in sufficient detail in the patient's medical history.

Course of the discussion:

Illness / Complaint:
Recapitulate the investigation steps that ultimately led to the diagnosis and to the treatment that is now proposed. Any uncertainties and the patient's questions should be clarified.

Measures and alternatives:
State the procedure and refer to alternatives such as conservative treatments, other surgical approaches and methods or drug treatments.

Indication / Procedure and possible extension:
Explain why this specific procedure is preferred. The benefit and the advantages, as well as any disadvantages, of the planned procedure should be outlined again. This particularly applies to procedures with serious and /or lasting consequences (e.g. mutilating procedures). The *urgency* in respect of the timing and nature of the procedure (outpatient/inpatient; minimally invasive/open) must also be discussed.

The *technical sequence* should be explained with the aid of sketches, using the above-mentioned aids, in simple and understandable language.

Extensions of the procedure may be required as a result of complications or the disease itself. Accordingly, the scope of the extension must be discussed beforehand, referring explicitly to the option of a *one-stage or two-stage process*. Exceptions are life-threatening situations such as emergency procedures.
For procedures that are not primarily indicated medically (desired procedures), the complications, any disadvantages and potential risks of the procedure should be highlighted in particular. It must also be explained to the patient that the procedure is not, or is only weakly, indicated from the medical standpoint, and this should accordingly be carefully documented.

Accompanying measures:
Positioning on the operation table, venous accesses, antibiotic cover, thromboprophylaxis, catheter, perioperative tocolysis, ICU monitoring, stay in the recovery room, bowel preparation, etc. must be mentioned.

Risks / Consequences / Disadvantages and chances of success:

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The briefing provided by the doctor about the risks, consequences, advantages and disadvantages of the procedure should enable the patient to weigh up the advantages and disadvantages of the planned procedure so that she can then make her decision. The most common general risks such as thromboses, bleeding, infections and the procedure-specific risks listed in the protocol must be mentioned. These include a possible increased blood loss and the need for transfusion. The probability of the need for receiving allogeneic blood and the possibility of autologous blood donation should be mentioned. Any risks with the potential to affect the patient's lifestyle should be mentioned. If at all possible from the medical standpoint, the likelihood of occurrence should be mentioned. Risks queried by the patient must be discussed.
The chances of success of a treatment should be disclosed to the patient in relation to her individual situation.

After the procedure:
The anticipated postoperative course should be discussed, particularly any restrictions (catheter, diet, infusion, mobilization, etc.). The duration of the hospital stay and unfitness for work should also be discussed so that the patient can plan accordingly.

Information on the initial period after discharge from hospital is useful and helpful and will also facilitate the patient's planning. Particular mention should be made of any follow-up treatment, any required physical resting or convalescent stay, independence at home, need for external help. The patient's social environment should be included in the discussion.
Targeted advice should also be given on activities of daily living (e.g. sport, body care, leisure activities, resumption of sex, etc.).

Anesthesia:
State the possible types of anesthesia for the planned procedure and consistently refer to the anesthetist, who will have to conduct his/her own comprehensive informed consent discussion about the anesthetic procedure.

Costs:
The costs payable by the health insurance funds and the general coverage of costs should be clarified and documented. For supplementary insurance policies, the rate class for the fee should be established.

At the end of the discussion, the doctor should point out that the patient will, in any case, be given the opportunity before the operation to clarify any unresolved questions or uncertainties. The treatment-specific/operation-specific informed consent form will be completed before the operation, signed by both sides and a copy given to the patient.

Make time at the end for questions and mention the possibility of taking more time to think about the situation.

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