

# Informed Consent

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Before surgery or any other diagnostic or therapeutic intervention, information is given, and patients have to give their informed consent. It is, however, not unequivocally clear what 'information' and 'informed consent' exactly means. Both concepts are not strictly defined and tend moreover to change over time and to vary from country to country. The conflicts between patients and doctors are frequently based upon a perceived lack of information. We believe that the modern web technology provides a unique opportunity to give adequate, updatable information, which is precisely the aim of this site.

## What is information ?

There is no doubt that patients should receive information. The content of the information which should be given is more controversial

1. **Any information carries a dilemma** . Complete, precise and detailed information is practically impossible, since it requires a medical back-ground to fully understand the subtle differences. Moreover this would require a prohibitively long time to give. Another difficulty is that some information is not always wise to give.
2. **Information should be given in an understandable language** : this is an additional difficulty. The medical language was developed to facilitate communication, between doctors. Without the medical language information becomes imprecise.
3. **No uniformity exists about which information should be given** : the median standard of care for a given country at a certain point in time, or the best care available at that moment. The prevailing medicolegal standard against which any problem is judged, is 'the median standard of care in that country at a given moment'. Therefore the median standard is what is generally given as information, and what is translated by professional bodies into '**Guidelines**'. This discrepancy between **median standard of care versus best care available** becomes especially difficult in periods of transition An example is e.g. when open surgery was and is being replaced progressively by laparoscopic surgery. Hysterectomies can be done by open surgery, as a laparoscopic assisted vaginal hysterectomy, or as a full laparoscopic hysterectomy. The choice and information will depend to a large extent upon the stage of transition of the individual surgeon from open surgery to laparoscopic surgery.
4. For **results, risks and complications**, the peer reviewed literature is the gold standard and this information should always be given. It should be understood, however, that the peer reviewed literature contains 2 types of information. First the complications reported by **centers of excellence** devoted to a specific pathology : these groups have more expertise but simultaneously treat more severe pathology. The former will decrease the complication rate, the latter will increase the complication rate. Secondly in the literature **overviews of countries** or other reviews are reported : these figures obviously are different from those reported by centers of excellence : they contain all surgeons, including those with little experience, and overall deal with less severe pathology

5. It is unclear **how detailed the list of complications** should be. It is practically impossible and also not desirable to list all the potential complications, even those with a very low risk. It is widely accepted that overall no information is given about complications with a frequency less than 1%.

6. **Individual information versus general information.** One may ask the question whether individualized information should/can be given for results and complications? Should the patient receive information about the individual gynecologist's results and complications? Should a patient know how experienced a surgeon is in a given operation?

7. **What is a complication?** A complication is poorly defined. To illustrate this, the following 2 examples are given. Complete excision of endometriosis infiltrating through the bowel wall, requires resection of part of the bowel wall: this is complete surgery, not a complication. The best definition of a complication I could find is '*a complication is something which was not necessary, or avoidable and which enhances the morbidity or mortality of the patient*'. With this definition, any surgery which can be done with equal results by laparoscopy, but is done by laparotomy has the complication of a laparotomy by definition.

## What is consent?

Informed consent can only be given after having been informed. Since information is not clearly defined, it is obvious that consent also is not clearly defined. This moreover varies from country to country, and over time.

For surgery there is the additional difficulty of **complications which can occur during surgery**, which are generally very rare but which necessitate immediate action, i.e. without the possibility of additional information and consent. This is often solved by asking permission to 'do whatever might be necessary'. This is difficult for the patient, whereas to give detailed and full information about all possibilities is practically impossible.

## The informed consent form.

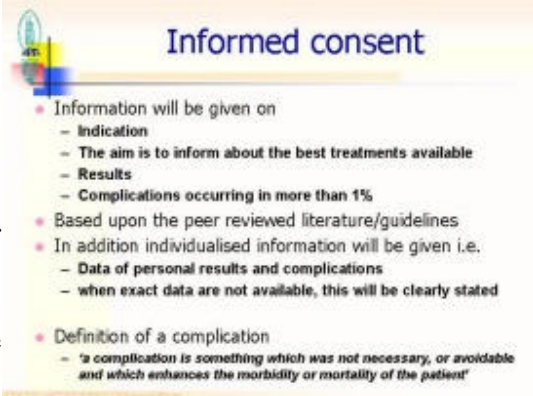
### *The patient will be informed about*

-**indication of proposed treatment**: i.e. why an intervention is proposed

-**alternative treatments**: we intentionally will try to give information about all treatments available also when we do not offer them ourselves, and not only about those which are considered 'standard of care'

-**results of treatment**: whenever possible, the patient will be informed about our personal results during a given period including the number of patients who have undergone a similar operation. Simultaneously the standard of care results will be given.

-**complications**: not only the 'reported incidences will be given, but also our personal complication rates during a given period, for that intervention.



**Informed consent**

- Information will be given on
  - Indication
  - The aim is to inform about the best treatments available
  - Results
  - Complications occurring in more than 1%
- Based upon the peer reviewed literature/guidelines
- In addition individualised information will be given i.e.
  - Data of personal results and complications
  - when exact data are not available, this will be clearly stated
- Definition of a complication
  - 'a complication is something which was not necessary, or avoidable and which enhances the morbidity or mortality of the patient'

Information will be given orally. Additionally more detailed information is given for some interventions using brochures etc when available. Given the complexity of the information, which moreover is prone to undergo changes over time the initiative to develop this web site was taken, in order to provide up to date and individualized information. Each page will have to possibility to be downloaded and printed, and will feature the name of the author and the date it was written.

***An informed consent form will have to be signed by the patients.***

On this form will be written

-**which information** was given

-**who gave** the information

-**for which operation**/intervention the patients gives consent

-**which intervention the patient does wants not to have** , e.g. removal of an ovary or a uterus.

-**who gave the consent** to do a specific intervention eg the parents for minors.

-eventual **additional consent** : eg **to store data** of the patient in a database for later scientific use, to store **blood, fluid or tissue samples** for later research use.