

Informed Consent in Urology



What's new ?

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3 aspects of informed consent

1. provide adequate information
2. obtain the informed consent to treat
3. protect yourselves from complaint



Framing the questions

1. informed consent: legal reality or illusion ?
2. what did the Law of 22 August 2002 regarding the rights of patient's add ?
3. the decision of the Court de Cassation 2009
4. what does all of this have to do with urology ?

1. Informed Consent: illusion or legal reality?

- illusion ?
- legal reality ?

1. Informed Consent: illusion or legal reality?

■ illusion ?

– twenty year old study N. Engl. J. Med.

- oral and written information on therapy, risks and alternatives
- 81,5 % knew the diagnosis after 24 hours
- 60% understood the purpose of the operation after 24 hours
- 55% knew just one risk after 24 hours
- 27% could give a possible alternative treatment

– therefore: low quality improvement in doctor-patient relationship

■ legal reality ?

1. Informed Consent: illusion or legal reality?

- illusion ?

- legal reality ?

- case law of the nineties: reversal of the burden of proof
- the Law of 2002 regarding the rights of the patient
- the decision of the Court de Cassation of 2009

2. What did the Law of 2002 regarding the rights of patient's add ?

- codification of existing rights
- no obligations for patients
- no penalties
- art. 8: informed consent

2. What did the Law of 2002 regarding the rights of patient's add ?

Right to informed consent

The information shall concern:

- the purpose
- the nature
- the degree of urgency
- the duration
- the frequency
- the relevant contraindications
- adverse reactions
- the **risks of intervention**
- the aftercare
- (unconventional character)
- consequences in case of withheld
- the possible alternatives
- the financial consequences

3. Court of Cassation 26 June 2009

Court of Appeal in Antwerp

“The patient needs not to be informed about the complication, because of its extremely rare nature.”

Court of Cassation

“The **rare nature** of the risk is in itself an **insufficient** reason for a physician to be exempted from disclosure to his patient”

3. Court of Cassation 26 June 2009

- The Court of Cassation does **not** put forward that rare risks **always** need to be disclosed.
- It is **only** stated that the **rare nature** of the risk cannot be a **sufficient** criterion for the Court of Appeal to exempt a physician from his duty to inform.
- The Court of Cassation did however not pronounce its opinion about which criterion applies instead.

4. what does all of this have to do with urology?

- “patients want little information about therapeutic risks¹”
- “patients should be asked how much information they want and then given it accordingly”
- “why striving for high standards of consent in acute conditions²”
- “patients may feel unable to understand the information they require to give proper consent”

1. Beresford M. et al., Risks of elective cardiac surgery: what do patients want to know? *Heart* 2001; 86: 626-631
2. Ågård A. et al., Patients experiences of intervention trials on the treatment of acute myocardial infarction, is it in time to adjust the informed consent procedure to the patients capacity? *Heart* 2001; 86: 632-637



4. what does all of this have to do with urology?

These arguments are flawed on empirical grounds

- **poor communication leads to poor understanding**
- **if patients want their urologist to make the final decision, it does not mean they do not want to be involved in it**



4. what does all of this have to do with urology?

Legal pitfalls for urologists

1. Individualising the risk

- clinical setting (emergency care vs. elective)
- patient clinical characteristics
- institutional (and operator) variables

2. Communicating the information

- language (no high-tec or latin)
- risk presented in the form of probabilities
- risk presented as “low” or “high risk”
- time (second opinion)

3. Consent should be part of communication

- patients do not want written consent only³



Framing the questions

1. informed consent: legal reality as well as psychological illusion
2. what did the Law of 22 August 2002 regarding the rights of patient's add ?
codification of already existing rights
3. the decision of the Court of Cassation in 2009: it's not because the risk is rare that you are exempt of informing the patient

Why a written informed consent?

remember the 3 aspects of informed consent

1. provide adequate **information**
2. obtain the informed **consent to treat**
3. **protect** yourselves from complaint

Why a written informed consent?

- 1. **Standardized** identical information for all urologists. No promo-flyers/ no veiled use of language.
- 2. The **authority** of information given by a professional organisation (BAU) is much higher than individualized information.
- 3. **No false expectations.** Patients will be less inclined to look for (foreign/dated/wrong) information on the internet.

- 4. **Rare risks** can easily be incorporated. Orally this information would be too time consuming.
- 5. Medical information, but also proof of a **financial agreement**.
- 6. **Materialized proof** of consent in case of incident



Thank you

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