

# anticoagulation

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## Enabling anticoagulated patients for a better compliance and medication adherence

### Doctor's responsibility to inform and instruct anticoagulated patients

presented by Alexander P.F. Ehlers, Lawyer, MD, Munich, Germany:

#### Overview Anticoagulation

About 6% of all over 60 years old patients are taking anticoagulants.

Main legal challenges:

- ❑ Medical malpractice if anticoagulants are given too late/ not prescribed in spite of risk factors.
- ❑ Influence of anticoagulation on accidents and damages.
- ❑ Choice of individual therapy and preparation.



A.P.F. Ehlers, Lawyer, MD

### Legal situation of medical treatment

- ❑ According to German law, every medical treatment is a personal injury according to §§ 223 ff of the German Penal Code (STGB), § 823 of the German Civil Code (BGB).
- ❑ However, if the patient has declared consent, the doctor is **justified**.
- ❑ Required: **informed consent**.
- ❑ The lack of informed consent injures the right of **self-determination** of the patient (Art. 1 II, 2 I of the Constitution).
- ❑ The doctor has to respect the health status of the patient as well as his autonomy.  
→ „**salus et voluntas aegroti suprema lex**“  
Informed consent is also professional duty according to § 8 of the rules of professional practice and out of the treatment contract.

### „Law on patient rights“

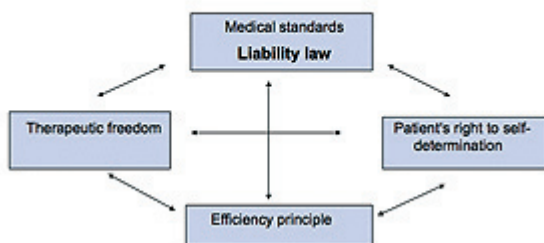
- ❑ Judicially defined principles regarding the requirements of the **informed consent codified**.
- ❑ § 630c,e BGB: Explanation of all facts that are important for the medical treatment, especially:
  - diagnosis;
  - predictable health development;
  - therapy and medical treatment options;
  - alternative therapy options;
  - pharmaceuticals' side effects.
- **No obligation to inform and explain ordinary risk!**

❑ § 630d BGB: Doctor is required to have patients' informed consent before any medical action is taking place.

(Right: Ludovic Drouet, MD, Paris, and Alexander P.F. Ehlers, Lawyer, MD, in discussion)



### Doctors' challenges



### Medical malpractice

The German Medical Service of the Health Funds (MDK) defines the medical malpractice basically broader than civil courts.

According to that, a case of medical malpractice encompasses:

- ❑ the omission of the required medical treatment;
- ❑ a medically not necessary intervention or
- ❑ a treatment that does not fulfill current standards.

### Anticoagulated patients and informed consent

- ❑ Extend of the patient's education depends on how dangerous pharmaceuticals can be.
  - The more risks are related to a drug, the more details must be discussed with the patient.
- ❑ Explanation about side effects of the respective preparation and required patient's behaviour.
- ❑ Doctor depends on **communicated symptoms**. However: If patient seems to have losses in sensory perception, the doctor needs to foresee special risks.
- ❑ Clear documentation of medical treatment!

### Doctor's liability

Consequences of a lack of patient's education:

- ❑ If the medical malpractice or lack of education are proven to be causal of the damage, the doctor is liable and needs to pay compensation.
- ❑ Criminal prosecution with respect to negligent physical injury or homicide.
- ❑ Crucial: Documentation of informed consent.

### Cases of medical malpractice associated with anticoagulants

Higher Regional Court of Hamm (Germany), Decision of 32.20.3007 (3 U 47/07) and Decision of 12.08.2013 (3U 122/12)

- ❑ Accumulation of risk factors indicate the need for anticoagulation.
- ❑ If the patient already had a myocardial infarction, the doctor is liable due to medical malpractice if no prescription of anticoagulation.
- ❑ Only in case patients had lone atrial fibrillation and no other risk factors, doctors can prescribe ASS.
- ❑ If stroke occurs anyway, doctor is *not* liable if the stroke had occurred also under anticoagulant therapy.
- ❑ Medical malpractice, if a radiologist does not involve a neurologist in case of a suspected stroke.

### Cases of medical malpractice associated with anticoagulants

Higher Social Court of Schleswig-Holstein, Germany, Decision of 18.01.2007 /L1 U 48/06)

- ❑ Anticoagulation in connection with a stem cell donation can lead to increased tendency to bleed. This can cause a subdural haematoma.

If this leads to a brain damage, the accident insurance of the clinic needs to cover the damage.

- ❑ Any pre-existing disease is irrelevant in that case.

### Choice of anticoagulation

**Efficiency principle, §§2, 12 SGB V: The most effective preparation for the individual patient to the lowest costs has to be prescribed.**

Guidelines of the Drug Commission of the German Medical Association:

- ❑ Standard Therapy: Vitamin-K antagonists
- ❑ New preparations:
  - Doctors need to justify the need because of 20x higher costs,
  - doctors need to explain possible adverse events in advance (no antagonism in case of an acute bleeding, lower possibility of lysis treatment in case of a stroke).

### Take home messages

- ❑ Detailed patient's education and documentation of the medical treatment as well as the informed consent.
- ❑ Analyze patient's risk factors carefully.
- ❑ Chose preparation individually.

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Following the lecture of Alexander Ehlers a round of talks took place. „**Five minute medicine: What can be done to improve the anticoagulation therapy?**“ Moderator Alexander P.F. Ehlers, Lawyer, MD, (right) discussed with (from left to right) Ron van't Land, MD, The Netherlands; Benjamin Dieplinger, MD, Austria; Hannelore Rott, MD, Germany; Gentian Denas, MD, Italy; Preben Mandrup Johansen, Denmark and Ludovic Drouet, MD, France. ●



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