

anticoagulation

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International Self-Monitoring Association of oral anticoagulated Patients (ISMAAP)

9th International Patient/Physician Conference on Oral Anticoagulation Therapy, Berlin, Oct 9th-12th, 2014

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“

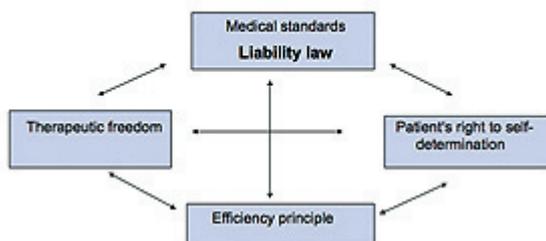
- ❑ Judicially defined principles regarding the requirements of the **informed consent codified**.
- ❑ § 630c,e BGB: Explanation of all facts that are important for the medical treatment, especially:
 - diagnosis;
 - predictable health development;
 - therapy and medical treatment options;
 - alternative 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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