



MEDIZINISCHE
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Patient Safety and Healthcare: Nosocomial Infections

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Patient safety and law?

- Does the law hinder patient safety?
- Does defensive medicine offer legal certainty?
- Legal aspects of quality assurance
 - The term “quality assurance” first appears in medical law texts in the mid-1980s.
- Securing patient safety

NI and Patient Safety

- **Consequences of NI:**
 - Human suffering and higher mortality risk
 - Expenses for the economy
 - Costs and image damage for the affected hospital as well as serious legal consequences for the patient and his employees

- 20 – 30% of Nosocomial Infections could be avoided with appropriate hygienic measures and control mechanisms.

Nosocomial Infections ↔ Patient Safety



Patient Safety and the Law

- The connection between law and Patient Safety becomes apparent in the multitude of legal regulations on medical and health law.
 - *International legal regulations*
 - Binding regulations
 - Non-binding resolutions (soft law)
 - e.g recommendations provided by organizations such as the WHO.
- *National legal regulations*
 - Multidisciplinary approach: Regulations in all fields of law (criminal law, civil law, public law,...)

Physician-Patient Relationship

Rights and Duties on both sides:

- Patients
 - Patient Right to free choice
 - information obligation
 - duty to collaborate
- Doctors
 - appropriate treatment
 - documentation
 - confidentiality



Hygiene as legal obligation

- A *lege artis* treatment of the patient (including the application of all necessary hygienic measures) is a legal requirement according to multiple regulations.
 - Treatment contract
 - KAKuG (provisions governing hospitals in general)
 - Laws governing the medical professions
 - Gesundheitsqualitätsgesetz (provisions governing health and quality)

NI and hospital liability

- Patients no longer accept hospital infections as an accidental side effect of a hospital stay → liability claims will become more likely in the future.
- **Fundamental question:** *“Have all medical and hygienic standards been met and could the Nosocomial Infection have been prevented?”*
 - Infections can also occur despite compliance with all medical and hygienic standards → no liability.
 - If due diligence is not met → liability can be considered.

NI – coincidence or liability issue?

- The nosocomial infection can only be basis for liability claims if a negligence has occurred.
 - Have the recognized rules of medical science been followed?
 - Comparison with the diligent, insightful and duty-bound (average) health professional.
 - Division of labor: The principle of trust limits the obligation to monitor other people (unless they visibly behave contrary to diligence).

Liability of the Individual

Who can be affected by liability claims?

- ***Individual physicians*** and other healthcare professionals who are involved in the treatment
- ***Nurses*** if they do not meet the required quality and hygiene criteria or if they do not remedy defects immediately and report them to the legal entity.
- ***Employees*** and management of the legal entities (hospitals)

→ The spectrum of those potentially affected by the liability issue is very broad

Liability of the Hospital Operator

- Hospital operators have to create an **organized structure** where *state of the art* treatment can be provided.
- **Hospital hygiene:** legal requirements, Austrian standards, guidelines, scientific requirements, etc. play an important role.
- If a NI occurs: hospital carrier can be held accountable if a lack of organization is causal for the infection
 - *Example:* information from employees about possible hygiene deficiencies were ignored.

Responsibility of legal Entities - VbVG

- The *VerbandsverantwortungsG* = regulates the liability of an association (e.g. hospital operator) for criminal offences committed by its decision-makers and employees (e.g. doctors)

- **Requirements**
 - offence was committed for the benefit of the association, or to fulfill an obligation of the association (§ 3 Abs 1 VbVG)
 - Offence was committed due to an organizational fault of the association.

Medical hygiene officer

- For each hospital, a professional for hygienic issues must be appointed.
- **Duties:**
 - hygiene plan including measures for monitoring nosocomial infections
 - Professional is involved in the purchase of relevant equipment
 - Gives advise on hygienic measures
- Failure to comply → can lead to claims for damages



Burden of Proof

- **General Rules** → The applicant has to prove that the violation was caused by the accused.
- However: *hygiene regulations are protective regulations* → shift of the burden of proof (hospital is assumed to have acted unlawful).
- The patient only has to prove damage and the causation.
- The hospital owner must prove that the behavior was neither illegal nor culpable.

Compliance with orders

- Doctors or nurses profession are not released from their professional duties by unlawful instructions.
- Doubts must be communicated to the superior in certain cases the instruction may not be obeyed.
- *Example: A nurse informs the surgeon, that the surgical instruments are not stored in a sterile manner and the doctor insists that they should still be used → order may not be followed. The incidence has to be reported.*

Practical Tips

For Medical Professionals

- Knowledge of/
compliance with hygiene
regulations and guidelines
- Drawing attention to
possible risk factors and
informing of the
responsible body

For Hospitals

- Hygienic training
- Implementation of a
control system
- Drafting guidelines for
employees

Thank you for your attention

