Patient Safety and Healthcare: Nosocomial Infections

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Patient safety

- Competent patients
- Medication safety
- Documentation
- Culture of safety

Patient safety

- Reporting and learning systems
- Indicators
- Informing
- Quality assurance

Complaints management
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**
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)
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
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.
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.
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 nor 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