



# Patient Safety and Healthcare: Nosocomial Infections

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#### Patient safety and law?



Does the law hinder patient safety?

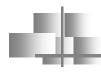
Does defensive medicine offer legal certainty?

- 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



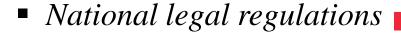






#### Patient Safety and the Law

- 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.





 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  $\rightarrow$  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 dutybound (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

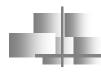
■ The *VerbandsverantwortungsG* = regulates the liability of an association (e.g. hospital operator) for criminal offences committed by its decision-makers and employees (e.g. doctors)

#### 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

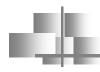
 For each hospital, a professional for hygienic issues must be appointed.

#### 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 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

