

ROME



EUROPEAN TELEMEDICINE CONFERENCE

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TELEMEDICINE LEGAL CHALLENGES

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Introduction

- I. Key legal issues of telemedicine.
- II. Other relevant legal aspects.
- III. How can information be collected on legal aspects?
- IV. Practical experiences.
- V. Conclusion.

Key Legal Issues of Telemedicine

- **Licensing / Registration of healthcare professionals.**
- **Liability issues and product safety.**
- **Healthcare professional liability.**
- **Information governance.**

Licensing / Registration of Healthcare Professionals

Questions to be answered:

- Are healthcare professionals accredited to deliver services at distance?
- Is their accreditation valid at their registration location?
- Is their accreditation valid at the point of delivery?

Liability Issues and Product Safety

Questions to be answered:

- Where the systems or devices used in the application subject to rules of certification (e.g. Medical Device Directive, CE Certification)?
- If yes, were all devices or systems intended for use in the application certified or did substitutions have to be made?

Healthcare Professional Liability

Questions to be answered:

- Does the accreditation regulation of each actor of the system envisage liability problems?
- Is professional liability insured?
- Who is responsible for what in the system (think about every event)?
- Is there any element of patient liability involved?

Information Governance (1)

Issues linked to patient identifiable information access and transfer are:

- Data processing.
- Access rights of healthcare professionals.
- Responsibilities of data controllers and processors.
- Free flows of personal (medical) data within telemedicine applications.

Information Governance (2)

Patients' Rights

The rights of the patients are:

- Right to be informed.
- Right to access their data.
- Right to rectify their data.
- Right to object the processing.

Other Relevant Legal Aspects

Reimbursement

Confidentiality and Security

- High standards appropriate to the data type

Liability

- Service supply
- Integrity of the data

Intellectual Property Rights

- Data ownership
- Re-use of clinical data

Collection of Information on Legal Aspects

- Laws and regulations.
- Studies (doctrine).
- Case Law.
- Referral to judicial and ethics committees.

Practical Experiences (1)

Drafting and Filing a Legal Analysis Table

Legal Issue	Legislation	Applicability / Amendment
Clinician Accreditation	E.g.: Professional Registration	Needed new rules for remote clinician ID management
Device Certification	E.g.: Medical Devices Directive, Medical Devices Law	
Professional Liability Patient Responsibility	E.g.: Medical professional insurance law	
Information Governance	E.g.: Data Protection Directive, Data Protection Law	

Practical Experiences (2)

Drafting and Filing a Legal Analysis Table

Legal Issue	How was the issue addressed?	Date	Evidence
Clinician Accreditation	New System of clinician ID created	May 2014	Required close cooperation with local ethics and professional registration committees
Device Certification	E.g.: Medical Devices Directive, Medical Devices Law		
Professional Liability Patient Responsibility	E.g.: Medical professional insurance law		
Information Governance	E.g.: Data Protection Directive, Data Protection Law		

Conclusion

- Recommendations to those planning an assessment of an existing telemedicine application / service.
- Recommendations to those planning the creation of a new telemedicine application / service.

THANK YOU FOR YOUR ATTENTION

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