References

- Sources are indicated by [RefSource] where the complete citation will be at the end
- Inside citations will be From: CitationSource
Legal and Ethical points

This section is based on the chapter “Legal and Ethical Aspects”, by Benedict Stanberry, from the book “Introduction to Telemedicine” 2nd Ed, Edited by Richard Wootton, John Craig, Victor Patterson.

The contents of this section can not be considered legal advice and are provided as notes and points to research further.
As such, following the points provided will not guarantee compliance to any law in any state or country.
The author is therefore not responsible for any damages or liabilities incurred by following in any way the contents of the subsequent slides.

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Main points

• Health Information
• Responsibility, liability and good practice
• Guidelines, Protocols and best practice
• Cross border practice
• Supplying Telemedicine Services
• Standards and interoperability
• Medical devices liability and safety
• Intellectual Property Rights

Health Information

• Confidentiality (remember Hippocrates)
  • Issue: Digital format + access from different places
  • Patient consent for disclosure
  • Versus use in research
    • Anonymized information
• Consent for treatment
  • Informed decision
  • Assumed consent
• Take into account EU data protection directive [EUDP]
Responsibility, liability and good practice

• Malpractice is usually defined in comparison to standard and defined procedures
  • Not that many in Telemedicine

• Equity in health treatment may imply use of Telemedicine
  • Usually politically (government) and not legally mandatory

Guidelines, Protocols and best practice

• Use of standards:
  • ATA, IHC, Royal College of Radiologists, etc.

• However [CLLAW]
  • not necessarily “gold standard” for courts
  • Non-compliance does not imply negligence

• See EUReport and Diffen for Malpractice and negligence.
Cross-border practice – I

Which jurisdiction applies?

• *Forum non conveniens*
  • Courts refuse jurisdiction as a more appropriate forum exists;
  • Forum should be most convenient and fair to all parties

• Usually:
  • Geographical location of act
  • Registered office
  • Contract establishes applied jurisdiction
  • Place where tort/harm was committed

Cross-border practice – I

Which jurisdiction applies (cont.)

• Other options, place:
  • of residence/business of performer in contract;
  • where branch, agency is situated;
  • where contracted performance was done;
  • where contract was done;
  • where advert/invitation for contract was made;
Cross-border practice – II

Registration and supervision system of health professionals

- USA
  - Doctors are visiting the patients in Telemedicine consults
    - Need patient state’s certification

- EU
  - Same system applies for countries
  - Qualifications are recognized within the EU
    - But application for recognition is necessary

Cross-border practice – III

Registration and supervision system of health professionals – Issues:

- Lack of disciplinary and criminal charges “history” interchange between states
- Differences in duration and content of states qualifications
- Different legal obligations of continued medical study/development
- Language/cultural barriers
- Liability insurance (in most cases not applicable outside country of registration)
- Reimbursement of healthcare
Supplying Telemedicine Services

• EU’s Distance Selling directive (1997/7/EC)
  • Covers all forms of distance selling (including internet)

• Electronic Commerce (2000/31/EC)
  • Regulates services provided at a distance by electronic means
  • Regulates electronic contracts
    • States that the governing law will be from the supplier’s established country
    • The Roman Convention states that should be the consumer’s
  • 2000/31/EC provides directives for dispute resolution

• Electronic Signatures (1999/93/EC)
  • Defines electronic and advanced signatures
    • Electronic – attached to a electronic document providing identification
    • Advanced – using cryptographic functions to be able to act as a regular “pen-based” signature in legal terms.

Standards and Interoperability

• Lack of standards in Telemedicine

• A standard is not per se a “legal standard”
  • Complying to a standard may mean complying to a legal requirement;
  • A law will not (usually) regulate a specific standard to be used;
  • Standards tend to be used to define the legal requirements;

• EU Council decision obliges Institutions to promote and apply standards in public sectors in regards to information technology and telecommunication
Medical devices liability and safety

- In a telemedicine liable parties are suppliers, manufacturers, and maintainers responsible for:
  - Acquisition device (e.g.: dermatology scanning device);
  - Telecommunication system/devices;
  - Display devices

- Accrued by different jurisdictions.

Medical devices liability and safety

- Medical devices regulation by European Directive (93/42/EEC)

'In a medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;
Medical devices liability and safety

- Medical devices regulation by European Directive (93/42/EEC)
  - CE seal of approval mandatory
  - Certification by competent authority in each country
  - Manufacturers are obliged to report errors to the authority
    - Even if user error is only suspected
- Similar for the USA’s Food and Drug Administration

Medical devices liability and safety

Product Liability – Contractual liability

- EU directive for consumer contracts 93/13/EEC
- Suppliers can not set/omit reasonable guarantees
  - Even limitation clauses need to be “fair and reasonable”
- Usually in (Tele)Medicine supply, there is no direct contract with the provider
  - Either free or paid by a 3rd party insurance
Medical devices liability and safety

Product Liability – Tortious liability

- When harmed by a defective product;
- Supplier is negligent or did not act \( \Rightarrow \) harm;
- No contractual relationship required;
- Support also means providing information on new discoveries on new problems of the system

Product Liability – Tortious liability – Example

- For services: extended to any part in the service chain.
- Examples in a video consult:
  - Manufacturer of video conference system;
  - Software producer of the system;
  - Reseller of the system
  - Supplier or manufacturer of any middleware
  - Telecom network provider
  - Telecom equipment provider
  - Health care service provider that uses the system
  - Company that repairs, maintains, inspects the system
  - ...
Medical devices liability and safety

Product Liability – European Directive on liability for defective products

- 85/374/EEC
- Responsibility of producer;
- Producer: manufacturer of the finished product, part of, raw material, puts name/trademark on, sells the;
- If a producer cannot be found the service provider will be responsible;
- Service provider must
  - Keep records of product suppliers
  - Have insurance, indemnities against liability and insolvency

Medical devices liability and safety

Product Liability – European Directive on liability for defective products – II

- Consumer has to prove:
  - Defect of product
  - Harm done by product
  - Causality of defect to harm
  - No need to prove negligence
- Harm is death, personal injury, property damage or loss
Does your medical App need approval?

- See infographic from Anton Ekker and Barbara Rest, Nictz
- There is a "EC Commission Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps"

Intellectual Property Rights (IPR)

- “Knowledge or expertise that is capable of being owned”
  - Processes, ideas
- Protects the owner for exploitation and gaining benefits from.
## IPR – For telemedicine

<table>
<thead>
<tr>
<th>Type</th>
<th>Applies to</th>
<th>Directive</th>
<th>Protection Time</th>
</tr>
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<tbody>
<tr>
<td>Copyright law</td>
<td>Programs and databases; Protects the work against copying;</td>
<td>• Berne convention 2001/21/EC • Legal protection of computer programs 91/250/EEC • Protection of databases 1996/9/EC</td>
<td>Lifetime of author plus 70 years</td>
</tr>
<tr>
<td>Patents</td>
<td>Protection of technologies that demonstrated novelty, inventiveness and industrial application</td>
<td>European Patent Convention</td>
<td>4 years; may be renewed up to 20 years</td>
</tr>
<tr>
<td>Trademark</td>
<td>Words, designs, letters or numerals</td>
<td>89/104/EC</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Design rights</td>
<td>Original design (outward shape and appearance)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered design</td>
<td>Shape and appearance; Additional to copyright and design rights.</td>
<td>98/71/EC</td>
<td>25 years</td>
</tr>
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</table>

(2) By the end of 2011, Member States should have assessed and adapted their national regulations enabling wider access to telemedicine services. Issues such as accreditation, liability, reimbursement, privacy and data protection should be addressed.

• [EHREU10]
From EU Study

“Study on the Legal Framework for Interoperable eHealth in Europe” [LEXEUST]

- Main conclusions on the differences between EU countries on:
  - Legal qualification of healthcare professional;
  - Cross-border exchange of super visionary bodies information (banned professional in one country);
  - Liability regimes;
  - Duty of confidentiality;
  - Often enforced by criminal sanctions
  - Patients’ rights
  - ePrescription
  - Some opinions to apply consumer protection law for the “healthcare consumer”

Conclusions From [LEXEUST]

- “Telemedicine is probably not an adequate legal concept because it covers a much too heterogeneous field.”
  - Suggestion is to define regulations for specific processes (ex.: e-mail communication between physician and patient)

- Reimbursement policies similar
  - Ex.: Specify particular telemonitoring applications.

- ePrescription and EHR were also studied
  - More recent study on “EHR interaction with the provision of cross-border eHealth services”
More recent research...

• “In the framework of European law telemedicine is, simultaneously, a health service and an information service, therefore, both regulations apply. In what concerns healthcare and the practice of medicine there are no uniform regulations at the European level. […] many issues still lack uniform regulation, mainly the domain of medical liability and of medical leges artis. […] the European Union does not have, until now, a common set of norms regarding tort and criminal liability, much less specific legal norms on medical liability. […]

From [T-LegalFrame]

“Telemedicine: The legal framework (or the lack of it) in Europe”

• The paper discusses:
  • The legal framework for telemedicine within the European legal order
  • Patient’s rights in cross-border telemedicine
  • Licensing and qualifications
  • Protection of personal data in telemedicine

• “So, whenever telemedicine operates beyond national borders the regime of this Directive [2011/24/EU] will apply. On the contrary, whenever telemedicine operates within national boundaries the Directive is not applicable, since the competence to regulate healthcare delivery rests mainly with national states.”
End of Telemedicine Legal

References - Legal

- [EHREU10] “On telemedicine for the benefit of patients, healthcare systems and society” EU ICT for Health
- [EUDP] Data Protection in the EU
- [T-LegalFrame] Vera Lúcia Raposo, “Telemedicine: The legal framework (or the lack of it) in Europe”, GMS Health Technol Assess. 2016; 1
- “The applicability of existing Community legal framework to telemedicine services”, A Staff Working paper, European Commission (document currently not found)
- Euro-Lex, EU laws access
- EU data protection
Acronyms – Legal

- ATA – American Telemedicine Association
- EU – European Union
- FDA – Food and Drug Administration
- IHC – Internet Healthcare Coalition
- IPR – Intellectual Property Rights
- US – United States of America