

# Telemedicine Legal Workshop

Overview of the Legal Status  
in the EU Member States

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# Background

- European Study: Legally Interoperable eHealth
  - 27 country profiles on national legal rules which are most relevant for e-Health
  - Overall legal analysis and assessment report + set of recommendations



# Definition used in the Study

“exchange of medical information  
from one site to another  
via electronic communications  
with the purpose to improve patient’s health status”

# Some results

- Austria: “persönlich und unmittelbar” – remote medical treatment only admitted in cases of emergency/necessity (but ongoing discussion) – re-imbursement possible in certain cases
- Belgium: practice of medicine via Internet poses too many unsolved problems (Order of Physicians, 2000)

# Belgium: proposed legislation 2005

- Telemedicine: “transmission of personal health data between a patient and a health care professional , aiming at a total or partial provision of a diagnosis, a treatment or intervention with regard to the patient’s health”.
- Introduction of three novel concepts
  - Teleconsultation: consultation of one or more healthcare professionals by one healthcare professional who is locally present, about the case of a patient, the diagnosis and the treatment, by means of telecommunications
  - Telemonitoring: registering, transmitting, receiving and processing parameters concerning a patient, with or without the patient’s intervention, in order to permit one or more health care professionals on a distant location to follow up and evaluate the health status of the patient and to decide about a treatment within the boundaries of the transmitted parameters
  - Electronic Prescription

“An American physician who, on a non-occasional basis, wishes to be employed on board on a ship under Belgian flag, has to fulfill the conditions for exercising medicine in Belgium, e.g. the condition to be registered on the list of the Order of Physicians. “

(Belgium: Opinion of the Council of the Order – 2000)

- Generally speaking the provision, on a regular basis, of medical advice has to be considered as a form of exercising medicine if it 1) relates to a particular therapy , 2) aims at treating or preventing a particular disease, 3) is addressed to a particular individual or identifiable group of individuals, and 4) precises the way the therapy has to be applied.
- If a particular form of providing advice by a foreign physician fulfills these conditions and the advice is provided by a physician who has his medical residence in Belgium, the physician needs to comply with the conditions for exercising medicine in Belgium.

(Belgium: Opinion of the Council of the Order – 2000)

# Denmark

- The Danish National Board of Health has issued legal guidelines regarding liability and other legal matters in connection with physicians' use of telemedicine ("Vejledning nr. 9719 af 9. November 2005)
- The guidelines refer to rules and principles in the existing legislation which also apply in connection to telemedicine
- The guidelines conclude that the use of telemedicine does not affect the usual legal liability and other legal obligations of physicians
- There is no jurisprudence with regard to the liability of physicians using telemedicine.

# Estonia: role of the State

- The healthcare providers are required by law to provide data for the digital images project as well as the digital registration project.
- The Estonian Health Insurance Fund is allowed to conclude remuneration agreements only with healthcare providers who comply with requirements of the digital registration project.

# Finland

- The Executive Board of the Finnish Medical Association has approved ethical guidelines in telemedicine in 1997.
- The guidelines define the following domains: medical competence, patient - doctor relationship, physician's liability, quality, security and safety in telemedicine, handling of patient documents, and rules and practices for medical ethics, patient consent and confidentiality.

# France

- The Healthcare Insurance Act (13 August 2004) provides a legal basis for the practice of telemedicine.
- Article 32 defines telemedicine as the practice of medical acts on distance, under the control and responsibility of a physician, in direct contact with the patient, through communication means appropriate to the performance of the act.

# France: Legal provisions on telemedicine

- Article 32

La télémedecine permet, entre autres, d'effectuer des actes médicaux dans le strict respect des règles de déontologie mais à distance, sous le contrôle et la responsabilité d'un médecin en contact avec le patient par des moyens de communication appropriés à la réalisation de l'acte médical.

- Article 33

Les schémas régionaux d'organisation sanitaire intègrent la télémedecine. Chaque schéma définit les modes opérationnels pour répondre aux exigences de la santé publique et de l'accès aux soins.

# France: CNOM guidelines on telemedicine

- Only the health condition of the patient could justify the use of telemedicine in specific circumstances (emergency, insufficient number of physicians in a defined area, etc.).
- The technical and communication means, the competence and qualification of “tele-experts” should meet quality requirements, independently of the problems that could stem from health economics.
- The patient should freely consent to the use of telemedicine. The information should be simple, concise and accurate. Consent should be obtained in written. By the same token, inadequate telemedicine tools cannot be imposed to the physician. It goes without saying that these requirements should be relaxed in emergency situations.
- Professional secrecy. The anonymity of the patient, the confidentiality of the personal medical records and the related communication, the staff’s professional secrecy, the tracking of the medical acts performed should be ensured. The means to ensure professional secrecy should be clearly described in the contract governing the provision of telemedicine tools.
- Liability. Patients are responsible for the information provided. The physician is fully liable for the use he makes of this information. The telemedicine contract should identify clearly the identity of the patient, the “tele-experts” and the physician in contact with the patient.
- The physician practicing telemedicine on a usual basis should be bound by a contract compliant with the aforementioned criteria. The contract should include the usual functioning mode of telemedicine, the material used, modalities of information to the patient; and identify the physician consulted, the physician carrying out the act, as well as the means implemented to ensure professional secrecy. The contract should moreover be submitted to the Provincial Council of the Order of Physicians for opinion.

# Germany

- One major legal obstacle to practice (a certain manner of) telemedicine derives from the professional code of conduct.
- The code requires that physicians should not diagnose and start therapy if they have not examined the patient personally. A physician who violates the code of conduct does not practise in line with the professional standard. Therefore, liability issues may arise.
- Of course, this is no obstacle for telemedicine applications which solely support the treatment.

# Germany

- Another obstacle is the observance of personal data protection law.
- Data protection rules expressly refer to access and process of health related data as they are supposed to be accessible by means of the electronic health card.
- The problems of data protection law are closely connected to the health personnel's observance of medical secrecy. This issue is supposed to be solved by issuing the Health Professional Card

# Lithuania

- The Minister of Health of the Republic of Lithuania adopted decision on Telephone Consultation by Health Care Providers (No. V-230, 14 April 2004). It regulates procedure and payment for telephone consultation services provided by physicians.
- Earlier telephone consultations were not regulated, although, it was a common practice to make a call directly to a physician for a long time. It must be pointed out that telephone consultations (Phone number 8 655 65 555) under the regulation adopted in 2004 are not so popular in the society because the patients are charged for them and the State Patients' Fund does not cover these expenses.

# Scotland

- In May 2008, the Health Services Ombudsman reported an incident with a patient who had telephoned with symptoms consistent with his having suffered a stroke (which was indeed the case) and was wrongly diagnosed as suffering a less serious condition and instructed to drive himself to a local emergency care centre rather than ensuring that an ambulance
- In legal terms, however, the fact that advice was dispensed by telephone rather than in face to face consultation would not per se impact upon the existence or extent of potential liability

# Slovak Republic

There are no specific provisions in Slovakia with regard to telemedicine.

On the other hand, there doesn't seem to be major legal obstacles to practice telemedicine in Slovakia. There may appear only practical problems to exercise telemedicine in its purest form, whereby patients are really receiving treatment from a distance.

The scarce legal literature about telemedicine in Slovakia refers mainly to the application of personal data protection law and shared medical secret and to the regulatory framework for information society services (transposition of the e-commerce directive).

In order to have a treatment reimbursed by the health insurance funds the physical presence of the physician seems to be required.

# Greece

- The draft law for the establishment and operation of the primary health care includes telemedicine in the primary healthcare. More specifically it describes the provision of medical consultancy and services from a distance and via the use of advanced technologies and infrastructures, especially via a special telemedicine system and an open communication line. However this provision has already been heavily criticised

# Poland

- Art. 42 Act of 5 December 1996 on Professions of Physician and Dentist provides explicitly that the doctor announces the state of health of a given person after examining him/her personally, unless separate legislation provides otherwise.
- No such a provision regarding telemedicine exists, which excludes setting diagnosis remotely, implicitly assuming that proper assessment requires physical contact with the patient, in order to receive the information which otherwise might be missing.
- Except for this only aspect of setting the (final) diagnosis, there is no other regulatory framework allowing or precluding telemedicine.
- It is assumed, without an explicit legal provisions in this matter, that the profession of a physician is to be exercised with due diligence, using appropriate means, current medical knowledge and professional ethics. If, therefore, a given telemedicine practice complies with the standards, it fits into both the obligations of medical professionals and rights of patients.

# The Netherlands

- Guideline (2007) on online doctor-patient contact
  - Applicable to 3 kinds of contacts
    - advise (specifically addressed to the patient)
    - start of new pharmacotherapy
    - renewal of pre-existing prescriptions (repeat prescribing)
  - Only allowed if embedded in pre-existing doctor-patient relationship
  - Cross-border contacts not recommended (lack of supervision)
  - Online exchange of medical data between professionals: same conditions as paper files
  - ...

# UK

- Although not specifically related to telemedicine the issue has been raised in other contexts whether a doctor is obliged to physically attend a patient. There does not appear to be any general legal principle requiring this.
- NHS Direct makes heavy use of the telephone and nurse advisers for consulting and advising patients.
- In legal terms, however, the fact that advice was dispensed by telephone rather than in face to face consultation would not per se give rise to potential liability unless in all the circumstances of that particular case, the giving of telephone advice alone was unreasonable and not supported by a reasonable body of medical opinion.

# Some conclusions

- Regulatory issues mainly focus on telemedicine as “remote medical treatment”
- General tone: reluctance (for ex: only in the framework of an existing doctor-patient relationship)
- Scarce specific legislation on telemedicine (exception: France)
- General principles in professional codes of conduct (Denmark, Finland, Netherlands, France)
- (Rare) jurisprudence mainly related to liability in case of medical advice by telephone
- Re-imburement by public health insurance on a case-by-case basis (ex. Teledermatology in the Netherlands)
- Electronic commerce legislation only marginally relevant (though extensively commented in legal literature)

# Teleconsultation (Romania)

- Medic4you
- messages
- your account
- Info 311
- calling options
- international services
- mobile banking
- data services
- PrePay recharge
- special services offered by Romtelecom
- client services
- PrePay services
- costumized dialing



powered by 

Health and prevention

## Medic4you

### What is telemedicine

Telemedicine uses the latest telecommunication systems and biometric technologies to provide medical services and to transmit medical information remotely.

Operational centres provide such services to their customers through operators. In addition, medical services are provided by qualified physicians trained by health service organisations, who have also received instruction regarding telemedicine services from the Medic4all group.

#### Why Medic4you

- We believe that good health is the fundamental value for quality of life, which is why we're making available medical services based on the latest technologies and solutions
- Our platform provides medical services anywhere and anytime you need them
- We are at your side all the time, from the first medical tests added to your Personal medical file, tracking your medical history in order to prevent disease, and during treatment
- Our services are aimed at permanently tracking your health status, prevention and remote medical support

#### Medic4you service plan

You can set up the service for an existing Orange phone number or you have to sign up for an Orange service plan, if you are not a customer. Monthly charges varies according to the minimum service agreement period, and you'll get a special price for the Wrist Clinic™ device.

#### Wrist Clinic



|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
|  | 1-year service plan | 2-year service plan | 3-year service plan |
|--|---------------------|---------------------|---------------------|

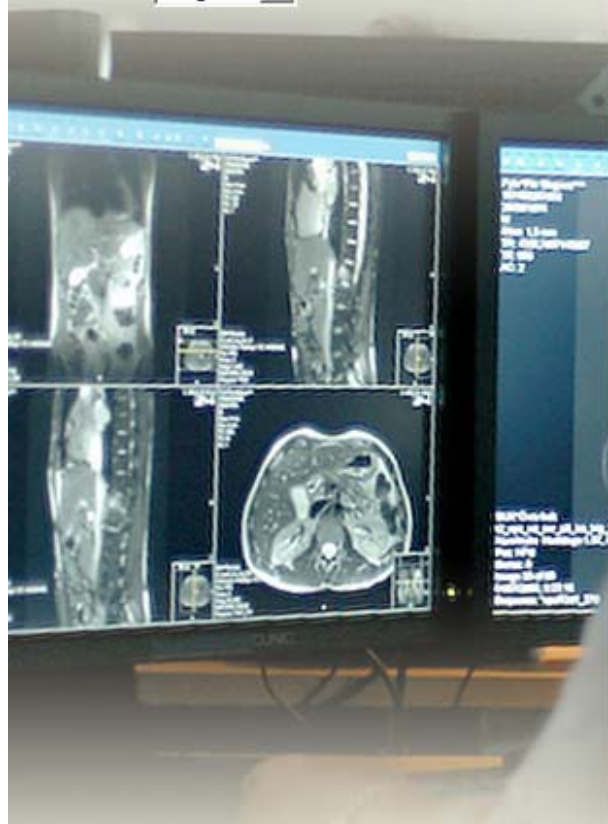
# More problematic: cross-border telemedicine

- Rule of origin?
- Registration
- Supervision
- Liability
- Data Protection
- Patient Rights

# Example: Barcelona Telemedicine Clinic

Home  
Our Company  
Our Services  
Our Clients  
Quality & Security  
Press  
Careers  
Contact  
Client login

English ▾



**TELEMEDICINECLINIC™**  
Distributing Diagnostic Competence

## Europe's Leading Sub-Specialty Radiology Centre

Telemedicine Clinic is a sub-specialist radiology centre that provides day and night reporting services and support to more than 100 public service hospitals and local health authorities in Europe.

We have 70+ accredited sub-specialist radiologists who focus on specific diagnostic areas that include Neuro, Body, Musculoskeletal, PET-CT, Mammography Screening and Nuclear Medicine.

Our structured focus gives us the added edge to guarantee delivery of high quality readings in a timely manner.

## News and Updates

E-poster on Double Reporting of Brain MR wins an Award at the UKRC.

Geared up to reach NHS' new diagnostic

## A Trusted Diagnostic Partner to Hospitals

Barnsley Hospital (UK) meets Diagnostic Targets and gains Foundation Status.

[Read more](#)

Karolinska University Hospital (Sweden) reduces waiting times for CT and MRI thorax cases

[Read more](#)

Lund University Hospital (Sweden) reduces waiting times for complex oncology cases.

[Read more](#)

TMC supports over 60 NHS hospitals with MRI reporting.

[Read more](#)

Akademiska Hospital (Sweden) receives emergency assistance in reporting for Neuro cases.

[Read more](#)



# How do they solve it in practice?

- Radiologists are registered/accredited in every Member-State where hospitals are using the service (= back office)
- Contract between BTC and hospitals deals extensively with liability and other issues (SLAs)
- Hospitals use BTC service on a selective basis (not every image is systematically sent to Barcelona/Sydney)

# Discussion

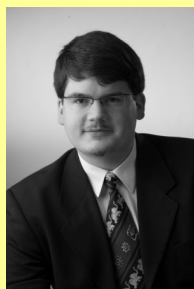
- Do we need particular rules:
  - on telemedicine?
  - on cross-border telemedicine?
- Legal rules or professional codes of conduct?
- Example: mutual recognition of accreditation?
- Health insurance: how to solve “the chicken and the egg” problem?

# Principal contacts



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