Telemedicine, the Law and the Economics: A View from Both Sides of the Atlantic
International Society for Telemedicine & e-Health’s Med-e-Tel 2014 Conference

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• $11 billion integrated global health enterprise
• 60,000 employees
• U.S. News & World Report Ranked #10 nationally and #1 in Pennsylvania & Pittsburgh, PA
• Comprised of 22 Hospitals
• 400 clinic/office locations
• 2.3 million UPMC Health Plan members
• 4,500 licensed beds
• 3,500 employed physicians
How to Access UPMC Experts

Physicians and patients, regardless of location, have multiple ways to connect with experts at UPMC

**Advanced Clinical Care**
- Italy: transplant, oncology, radiotherapy
- Ireland: cancer, orthopedics, other surgical specialties
- United States: comprehensive adult and pediatric programs

**Telemedicine**
- Teleconsulting
- Telemonitoring
- Telementoring
- Second opinions
Access to UPMC: Advanced Clinical Care

Through destination medical facilities in three countries, patients from around the world can receive world-class health care

- **Italy**
  - ISMETT, Palermo: among the best international survival rates for liver transplantation
  - UPMC San Pietro, Rome: region’s first stereotactic radiosurgery center

- **Ireland**
  - UPMC Whitfield Cancer Centre, Waterford: radiation therapy
  - UPMC Beacon, Dublin: full-service, 140 bed facility
Access to UPMC: Advanced Clinical Care, continued

- Pittsburgh, Pennsylvania
  - UPMC Presbyterian Shadyside: transplant, neurology, surgery
  - Magee-Womens Hospital of UPMC: women’s health/child birth
  - Hillman Cancer Center: oncology
  - Children’s Hospital of Pittsburgh of UPMC: pediatrics
Telemedicine at UPMC

- Telepathology
- Teledermatology
- Teleconsults
- Telewound care
- TeleICU
- Teleophthalmology
- Telecardiology
- Pre-/Post-surgical care
- Telepsychiatry
- Telestroke (21 Hospitals)
- Teleradiology
- TeleMFM (Maternal Fetal Medicine)
- TeleEndocrine
- TeleTrauma
- TelePediatrics
- eVisits

16 Service Lines
21 Facilities

International Locations
- Colombia
- China
- Italy
- Ireland
On December 17, 2010, U.S. Department of Health and Human Services signed a Memorandum of Understanding with the European Commission in which both parties agreed to cooperate on topics directly pertaining to the use and advancement of eHealth/health IT in pursuit of improved health and health care delivery, as well as economic growth and innovation.
Current State of Telemedicine Law

- Advances in medicine and medical technology related to telemedicine remain far ahead of the legal precedents and standards for this area of healthcare law in both the US and the EU.
US and EU Major Telemedicine Legal and Economic Issues:

- Physician Licensure
- Online Medicine/Prescribing
- mHealth-Mobile Medical Devices and Medical Apps
- Patient Privacy and Medical Records
- Effective Economic Models: Telemedicine Expansion
US & EU Definitions of “Telemedicine” and “Telehealth”

- US Centers for Medicare and Medicaid Definitions: “Telemedicine” encompasses the overall delivery of healthcare to the patient through the practice of patient assessment, diagnosis, treatment, consultation, transfer and interpretation of medical data, and patient education, all via a telemedicine link.

- European Commission Definition COM(2008)689: “Telemedicine” is defined as “the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of “patients.”
The U.S. Supreme Court has held that “states have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests, they have broad power to establish standards for licensing practitioners and regulating the practice.”

50 different states = 50 different state boards of medicine.

Currently, there is no national license to practice medicine.

Several bills have been introduced in the US House of Representatives and US Senate to permit some type of national license, but none have been enacted to date.

If a health professional located in one state treats, diagnoses, or otherwise directs medical care to a patient located in another state, the health professional likely is practicing medicine in that state and needs a medical license from that state.
• Currently, there is no International or EU license to practice medicine.
• Each Member State has its own medical licensing registration.
  – Example: Physician has a medical license issued from Italy. To obtain a medical license from France, the Physician will still need to go through the process of applying for a medical license from France’s licensing body.
In 2011, Directive 2011/24/EU expanded the authority of health professionals licensed in one Member State to practice medicine via telemedicine in other Member States without the need to obtain a medical license in other Member States.

Directive 2011/24/EU requires that cross-border healthcare is to be provided in accordance with the legislation of the Member State of treatment (Article 4(1) of the Directive).

In the case of **telemedicine** the Member State of treatment is defined as the Service provider’s (i.e. the physician’s) Member State of establishment (article 4(1)(A) of the Directive).

eCommerce Directive (Directive 2000/31/EC) also supports the principal that the Physician is free to provide services in other Member States so long as the Physician complies with his or her Member State of establishment’s legislation regarding holding a valid medical license.
Establishing the Physician-Patient Relationship-US/EU

- Online web-portals designed to diagnose and treat patients without an initial in-person medical examination

- Satisfying the minimum standards of care and establishing a bona-fide physician-patient relationship (varies per state law)

- Prescribing non-controlled substances

- Patient abandonment issues
• In the US, the Food and Drug Administration (FDA) regulates all medical devices, including mobile medical data systems (e.g., telemedicine cart).
• FDA also regulates mobile medical applications (app from your I-Phone® that diagnoses medical conditions).
  – New FDA Guidance on Mobile Medical Apps (2013)
• In the EU, no central integrated governing body like FDA.
• Software itself, if intended by the manufacturer to be used for one or more medical purposes, is also regulated as a medical device. 2007/47/EC
• January 2012, new EC Guidance Document on Stand Alone Software Used in Healthcare
• 26 September 2012, EC proposed new regulations on medical devices
• Health Insurance Portability and Accountability Act (1996) (federal law applies to all 50 states)
• HIPAA Privacy Rule (2000)
• HITECH Act (2009)

• Significant restrictions and safeguards for the protection and security of patients’ “protected health information.”
• Individual states may have stricter privacy laws than what is required by HIPAA.
• HIPAA and individual state privacy laws can be significant challenges; electronic health records and portability of such records to be transmitted in seconds to cross-border add complexity.
Patient Privacy And Medical Records-EU

• Data Protection Directive 95/46/EC – special rules apply to:
  – "the processing of personal data … concerning health or sex life" (Art 8(1))

• Sensitive data can only be processed when it is necessary to protect the vital interests of the individual – usually interpreted to mean the provision of healthcare.

• Sensitive personal data may not be transferred outside the European Union unless:
  – transferred to an ‘adequate protection jurisdiction’
  – transferred pursuant to the EU Standard Contractual Clauses
  – Individual’s freely given and explicit consent has been obtained
  – transfer is necessary to protect the vital interests of the individual (exception)

• All Privacy Principles apply
Patient Privacy And Medical Records-EU

• January 2012-European Commission proposed a reform of the EU’s data protection rules

• Reform includes a Draft Proposed Data Protection Regulation setting up a general EU framework for data protection, including patient-protected data

• Draft Data Protection Regulation will update the data protection principles enshrined in the 1995 Data Protection Directive (Directive 95/46/EC) with new rules with respect to the processing of personal data and on the free movement of such data

• March 12, 2014-European Parliament voted overwhelmingly in favour of implementing the draft Data Protection Regulation

• In order to become law in the EU, the draft Data Protection Regulation must now be negotiated and adopted by the Council of Ministers

• Goals for Reform: strengthen privacy rights and boost Europe’s digital economy
Draft Data Protection Regulations and Examples of Effect on Patient Privacy and Medical Records:

– Article 4 – definition of ‘data concerning health’ means any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual;
– Article 81 obliges Member States, further to the conditions for special categories of data, to ensure specific safeguards for processing for health purposes.

Explanatory notes:

“The processing of personal data concerning health … deserves higher protection [and] may often be justified by a number of legitimate reasons for the benefit of individuals and society as a whole, in particular in the context of ensuring continuity of cross-border healthcare. Therefore this Regulation should provide for harmonised conditions for the processing of personal data concerning health…”
• Master the legal issues
• Learn and fully understand the clinical disciplines involved = engage physician and hospital clinical leadership
• Work directly with the applicable Chief Quality Officer
• Work directly with the Information Technology Department= master the technology and IT architecture involved with the project
• After commencement, follow-up with the clinical, quality and IT personnel to ensure results are achieved
Recommendations—Telemedicine Legal

- Standardized national and international telemedicine licenses.

- Uniform national and international regulations for medical record and patient health information use and storage, in order to ensure protection of patient privacy but permit the secure transmission of patient data cross-border.

- Uniform standards for mHealth technology, including medical devices and mobile medical apps.

- Development of broader models for telemedicine service reimbursement by the US and EU.
Total health expenditure as a share of GDP, 2011, OECD countries
Factors exerting upward pressure on health spending will continue to drive health spending higher in the future:
- technological change,
- population, expectations,
- increased incomes and
- population ageing (so-called longevity risk*)

*As populations age in the decades ahead, aging individuals will consume a growing share of resources, straining public and private balance sheets. The financial implications of people living longer than expected are very large. If average life spans by 2050 were to increase 3 years more than now expected, the already vast cost of aging would increase by 50 percent.

Source: THE FINANCIAL IMPACT OF LONGEVITY RISK, Global Financial Stability Report, IFM, April 2012
The need for economic evaluation of Telemedicine to support its wider use

Decision-makers need strong evidence in order to expand the development of telemedicine

Economic evaluation of telemedicine is required to provide decision-makers with appropriate information on costs and benefits

Health Care system policies may be considering broad deployment of telemedicine

Funding agencies may require evaluations to justify expenditures
• There is a need to consider who benefits, who the decision makers are, and what policies are involved

• Whether an outcome is a benefit may depend on the perspective of patients, health professionals, and other stakeholders like payers/insurers, employers or taxpayers.

• Outcomes included as economic benefits from the perspective of a particular group of stakeholders could actually become economic costs or irrelevant when viewed from another perspective
UPMC Teleconsult Center Patient Benefits:

• Access to specialists
• Reduced travel time and cost
• Bringing timely treatments closer to home
• Improved quality of care
• Physician access to medical history
• Improved Care Coordination
75 patients (liver transplants) were included in the study starting from July 2011 until February 2013.

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• The average postoperative hospital stay of these patients was 19.8 days, significantly shorter than the one of ISMETT patients (control group) between 2009 and 2011, equal to 25.4 days.
• No urgent readmissions were observed (there were 4 in the control group).
• In terms of economic benefits, the reduction in the length of stay (average 6 days / patient) reduced ISMETT hospitalization costs by 360,000 euro, ten times the cost of the “home monitoring” (37,800 euro for 60 patients followed for a period of three months).
The highlighted cost reduction arises from decreasing costs of technology and the increasing number of patient visits for which this technology is used.

Telemedicine may be cost competitive with in-person consults when telemedicine consultations exceed 200 annually.

Fixed costs are expected to decline as cheaper equipment becomes available. Consequently, this will strengthen the economic case for telemedicine.

Efficacy to better serve patients in medically underserved areas.
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<td><strong>When study outcomes are measured as health maintenance or wellness, potential savings from telemedicine appear to be much greater</strong></td>
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<td>It may be especially cost effective for high-risk and chronically ill patients</td>
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<td><strong>Home monitoring can help optimizing the investments made in hospitals (fixed costs)</strong></td>
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<td>A better distribution of the healthcare from the hospitals towards the territory helps optimizing the use of hospital resources</td>
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<td><strong>Telemedicine can guarantee a wider access to healthcare</strong></td>
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<td>It is possible to prevent/predict patients’ health conditions before they get serious</td>
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<td>More medical care may not be as cost-effective as maintaining or improving health</td>
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<td>Activities that prevent illness are often far more cost-effective than medical care treatments</td>
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<td><strong>Spillover effects</strong></td>
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<td>Research studies should not be focused on the single project only, but should be developed under a systemic approach, observing outcomes at macro level</td>
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<td>Positive externalities affect a number of sector and individuals not directly involved in the health care process</td>
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