Legal and Ethical issues in Telemedicine

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Adam’s Story

Adam has had some problems in the past with his cardiac and general health:

- He is overweight (BMI 29)
- He has mild hypertension (average BP 140/100)
- He has a recent history ventricular tachycardia
- He has been diagnosed as at risk of recurrent ventricular tachycardia
Adam’s Story

- After consultation with his cardiologist Adam has now entered a ‘Supported Heart Health Programme’ which has the following components:
  - Implanted cardioverter defibrillator with data report and remote reset functionality
  - Personal use sphygmomanometer with wireless data report functionality
  - Web based PHR which obtains heart rhythm and BP data from devices wirelessly
  - Automated physician alert tool in PHR activated when parameters are exceeded
  - Targeted dietary advice provided through the PHR webpage to the patient.
  - Integration of PHR data into EHR
## Legal Issues in Adam’s Programme

### Medical Devices
(Dir 90/385/EEC – Active implantable Medical Devices, amended by 2007/47/EC)
- Duties of a medical device manufacturer or vendor
- Duties of a device user (patient and professional)

### Data Protection and Privacy
(Dir 95/46/EC – Data Protection)
- Rights of a patient or consumer
- Duties of a data controller
- Duties of the device manufacturer

### Liability for Goods and Services
(Dir. 85/374/EC & Directive 1999/34/EC - Liability for Defective Products; Dir. 2001/95/EC - Product Safety; Dir. 1999/44/EC - Sale of Goods; Dir. 2000/31/EC – eCommerce)
- Duties of a manufacturer or vendor
- Rights of a purchaser
- Duties of an eServices supplier

- **Snapshot**
  - EU level law only
  - No general medical law
- **End-of-life issues**
Medical Devices Regulation

• An implanted medical device

• Software for data collection and sharing

• A consumer medical device
Medical Devices

Dir 90/385/EEC – Active implantable Medical Devices, amended by 2007/47/EC

- Must be safe
- Must be accredited with CE mark
- Must be supplied with and used in accordance with manufacturer’s instructions
- Manufacturer must foresee all reasonable uses
- Includes any software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes
- Generally manufacturer will be strictly liable for harm arising from product
Medical Devices - the doctors’ and hospitals’ duties

- Ensure that it is used within manufacturer’s guidelines
- Ensure that any software used with it is duly accredited as a part of the device or as an accessory
- Ensure the patient understands how to use the device - possible contributory liability of patient
Data Protection and Privacy

• on-line PHR
• shared with cardiologist
Data Protection and Privacy

Directive 95/46 on Data Protection

- **Objective:** to facilitate internal market through free movement of data, through harmonized rules, within a framework of respect for privacy and personal life (ECHR – art 8)
- Provide special protection for sensitive data, including medical data (art 8)
  - informed consent
  - for medical treatment
  - by a healthcare professional

Directive 2002/58 Electronic Communications

- Security of networks and services
- Confidentiality of communications
Data Protection - the doctors’ and hospitals’ duties

Doctor must:

- Ensure consent is informed, specific and freely given.
- Ensure patient knows who has access to what data and for what purpose.
- Ensure that nominative data is treated securely.
- Ensure that ‘technical’ data is treated securely or anonymised.
- Ensure that specific consent is obtained for any research.
Data Protection - the doctors’ and hospitals’ duties

Controller must:
- ensure secure storage, processing and transmission
- ensure that processors are fully under his control.
- provide access and rectification opportunity.
- notify supervisory authority
Telemedicine Services

- Remote Physician Alert
- Web based patient advice
Information Society Services

Directive 2000/31 on Information Society Services and Electronic Commerce

• Applies to some medical services
• Country of origin principle applies
• For regulated professions - detail of local accreditation, and local applicable rules
• Special rules on contract formation – right to rescind
• Telecoms service provider is a ‘mere conduit’, not liable for the information transmitted
Directed 2005/36 on Mutual Recognition of Professional qualifications
• applies to doctors, nurses, midwives, dentists pharmacists …

Directed 1997/7 on distance contracts
• right to restrict certain trade on basis of public safety

Directed 2001/83 on medicinal products for human use
• No direct to consumer advertising of POM
Telemedicine Service Providers’ Duties

Service provider must:

- Obtain informed consent of patient
- Ensure patient understands country of origin principle if applicable
- Ensure secure storage, processing and transmission
- Ensure medical staff are fully briefed
Telemedicine Service - doctors’ and hospitals’ Duties

Healthcare providers must:
- Obtained informed consent of patient
- Ensure patient understands limits of the services
- Ensure adequate coverage
- Ensure adequate training
- Ensure adequate insurance
End of Life Issues

- Advance Directives and Living Wills
- Patients’ Right to Decide
- Patients’ capacity to decide
- Ensuring patient understands what will happen
- Life sustaining or life enhancing
- Personnel to be involved
End of Life Issues II

• Terminally ill patients
  - Life sustaining or life enhancing
  - In patients’ best interests
  - Device specific
  - Doctrine of double effect

• Personnel involved
  - Technical or medical staff, remains medical responsibility
  - Guidelines needed (ACC/AHA/HRS 2009)
  - Training needed
Telemedicine - Public Trust is Key

"On the Internet, nobody knows you’re a dog."
Thank you

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