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

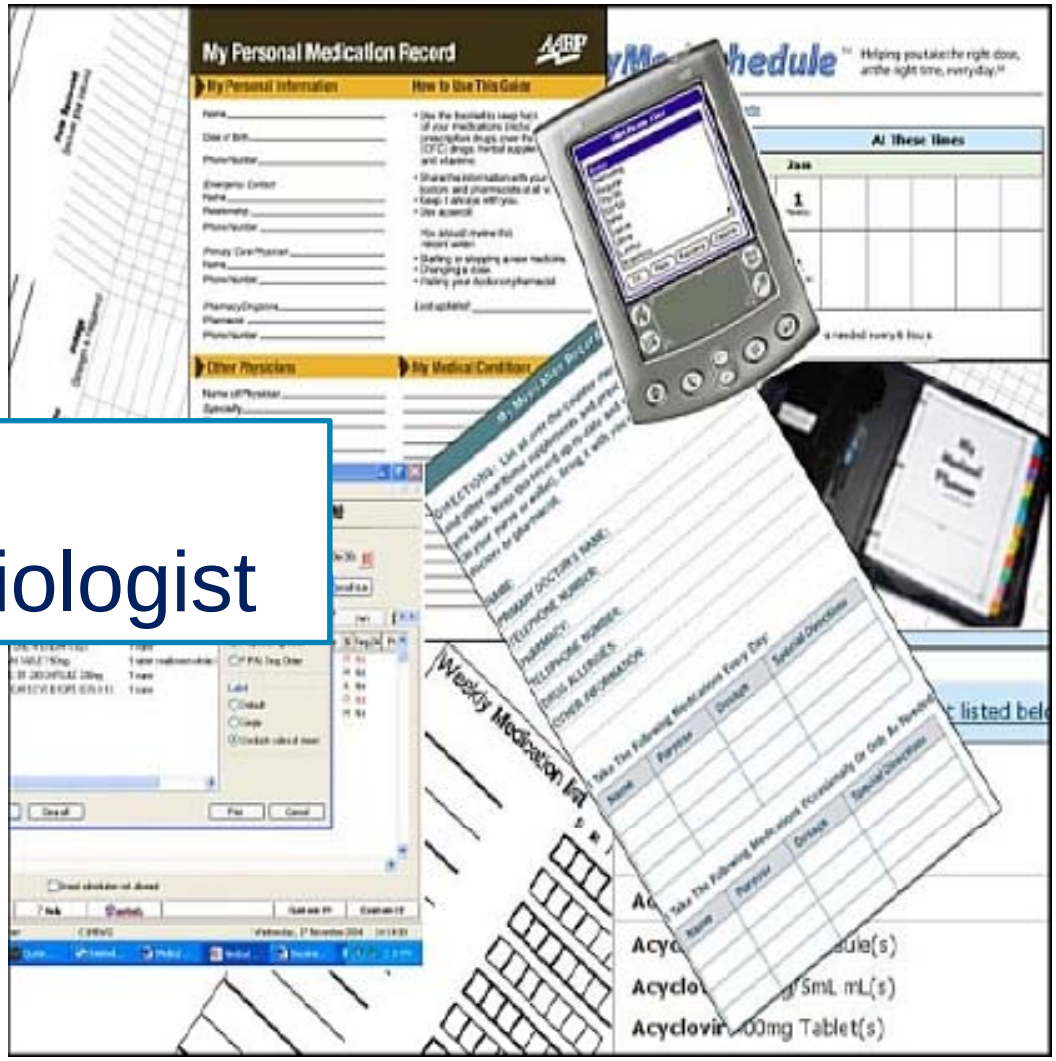
- Must be safe
- Must be accredited with CE mark
- Must be supplied with and used in accordance with manufacturer's instructions
- Manufacturer must foresee all reasonable uses
- Includes any software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes
- Generally 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
- Enure 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 rectifcation 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

Information Society Services II

Directive 2005/36 on Mutual Recognition of Professional qualifications

- applies to doctors, nurses, midwives, dentists pharmacists …

Directive 1997/7 on distance contracts

- right to restrict certain trade on basis of public safety

Directive 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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