

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ



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Legal and ethical aspects of e-health

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What do we mean by e-Health?

- ◆ “the use, in the health sector, of digital data-transmitted, stored and retrieved electronically-for clinical, educational and administrative purposes, both at the local site and at a distance”.
- ◆ Health informatics;
- ◆ Medical informatics;
- ◆ Telemedicine..., tele-**any**;
- ◆ Tele-health.



What is Tele-health?

- ◆ Tele-health is the use of information and communication technology (ICT) to deliver health services, expertise and information over distance. It includes Internet or web-based “e-health” and video-based applications, and can be delivered “real-time” or through “store-and-forward” mode. Telehealth is unique in having the capability to cross-geographical, temporal, political, social and cultural barriers within the health sector.



Key challenges in e-health

- ◆ Lack of financial support and sustainability;
- ◆ Poor quality of technology and infrastructure;
- ◆ Lack of technically competent staff at all levels;
- ◆ Lack of awareness, access and attitudinal problems among users;
- ◆ **Legal and policy issues.**



Legal and policy issues resulted in:

- ◆ Lack of a clear policy direction towards ICT;
- ◆ Lack of political commitment;
- ◆ Ambiguous legal framework;
- ◆ Poor data management;
- ◆ Lack of data security policies or procedures.



Paper-based health information vs. e-health



What is different about e-health?

- ◆ Personal data has become more available and accessible to more healthcare professionals;
- ◆ Machine-readable data can be more easily manipulated, new data can be generated based on existing data and in multiple format;
- ◆ Globalization of access to data and information as geographic boundaries are coming down allowing for more trans-border data flow;



What is different about e-health?

- ◆ Technological convergence has made it possible to bring information and telecommunication technologies together, more systems are interoperable with more ability to read different types of data across systems. Multiple input, multiple access, multiple locations even outside the institution or the country;



What is different about e-health?

- ◆ Multimedia presentation and storage of data as voice, images, text, video or a combination of these have made data more readable and understandable by both specialists and the public;
- ◆ International standards applied across borders, languages, systems, cultures, etc.



Legislation can help health IT

- ◆ The American Clinical Laboratory Association told a congressional committee that H.R. 4157, the Health Information Technology Promotion Act, would help advance the adoption of health information technology throughout the health care system. (March 20, 2006). <http://www.govtech.com/gt/98833?topic=117677>



Electronic Records, Health IT Legislation Unlikely Until at Least 2008, Aides Say

- ◆ Congressional action on health information technology legislation, including provisions to promote the implementation of electronic medical records, likely will not occur until 2008 at the earliest, because lawmakers will be focused on other health care issues.

<http://subscript.bna.com/SAMPLES/prs.nsf/3a3dab06017d449c85256b57005cd381/a1272ca7b0b0262f852572ab008055d4?OpenDocument>



Areas of legal and regulatory concern in e-health

- ◆ **Access.** The conditions (technical and legal) that control access to health data;
- ◆ **Tracking.** The possibility and need to keep track of who has accessed which data elements, when, what for;
- ◆ **Interoperability.** The assurance to exchange data between similar and /or heterogeneous systems without corruption or deletion of any parts of it;



Areas of legal and regulatory concern in e-health

- ◆ **Common data set.** The assurance that an agreed upon set of data elements is used to exchange data between systems and institutions;
- ◆ **Information integrity.** The assurance that electronic transmission, storage and retrieval system is adequate to protect against data corruption, alteration and deletion, intentionally or unintentionally;
- ◆ **Privacy.** The assurance that sensitive and private data is fully protected and only used upon proper authorization;



Areas of legal and regulatory concern in e-health

- ◆ **Confidentiality.** The need to safeguard the confidential nature of health data and ensure that its communication between patients and providers;
- ◆ **Security.** The assurance that the electronic system provides protection against unauthorized intruders;
- ◆ **Storage and retrieval.** The assurance that the system stores data in a form capable of timely retrieval without impairing its integrity;



Areas of legal and regulatory concern in e-health

- ◆ **Sender verification and encryption.** The ability of the receiver of data to verify the authenticity of the sender;
- ◆ **Data replication.** The ability to reuse and replicate data between systems without losing any of its content or quality;
- ◆ **Dispute resolution.** In case of a legal these are alternatives to resolve disputes from the transmission, corruption, deletion, improper disclosure, alteration, and retention of data;



Areas of legal and regulatory concern in e-health

- ◆ **Scalability.** The ability to expand the system into a greater scope of capability without its total replacement and ability to add features without full reconstruction;
- ◆ **Sanction and penalty enforcement.** The authority of an institution or organization to enforce penalties or sanctions imposed as a result of a dispute stemming from improper data handling, protection, security infringement,



Data Security

- ◆ Data security exists when data are protected from accidental or intentional disclosure to unauthorized persons and from unauthorized or accidental alteration.



Data security

- ◆ **Authenticity:** to know and vet the identity of the specific sender of a message or initiator of a transaction, and the identity of its intended receiver;
- ◆ **Integrity:** to be totally sure that the contents of the message or transaction have not been changed;
- ◆ **Confidentiality:** to ascertain that nobody, other than the sender and the intended recipient, has the ability to view, copy or otherwise know the contents of the message or transaction;



Data security

- ◆ **Privacy:** to ensure that personal health information is not used or disclosed inappropriately leaving the individual vulnerable to unwanted exposure, stigma and discrimination;
- ◆ **Non-repudiation:** to maintain an unequivocal record of a message or a transaction such that neither its initiator nor its recipient is able to later deny the message exchange or the transaction.



Privacy protection models

- ◆ Comprehensive legislative regulation.
 - ◆ Adopted in Europe, Australia, New Zealand and Canada;
 - ◆ A comprehensive data protection law is enforced by a public official (Commissioner, registrar, etc);
 - ◆ Monitors and investigates breaches of the law and ensures compliance;
 - ◆ Responsible for education, international liaison and coordination.



Privacy protection models

- ◆ Sectoral regulation.
 - ◆ Adopted in USA;
 - ◆ Limited to specific sectors such as financial records, police files, etc
 - ◆ It maybe used to compliment some comprehensive laws;
 - ◆ Does not keep up with new developments.



Privacy protection models

- ◆ Self-regulation.
 - ◆ Adopted in USA, Singapore, Japan, Australia;
 - ◆ Self established code of practice;
 - ◆ Usually lack adequacy and enforcement (could be selective);
 - ◆ They provide weak protection.



Privacy protection models

- ◆ User-driven.
 - ◆ Adopted by technology companies and individuals to protect data;
 - ◆ Technology rather than law is used to protect;
 - ◆ Trustworthiness of systems is doubtful unless supported by legal framework.



Ethical aspects of e-health

Ten

Things to Know about Evaluating Medical Resources on the Web



1. Who runs the Web site?
2. Who pays for the Web site?
3. What is the purpose of the Web site?
4. What is the original source of the information on the Web site?
5. How is the information on the Web site documented?
6. How current is the information on the Web site?



7. How current is the information on the Web site?
8. How does the Web site choose links to other sites?
9. What information about users does the Web site collect, and why?
10. How does the Web site manage interactions with users?



Thank you

