A Conceptual Model of Informed Consent for Web Based mHealth Services

Summary

- Consent
- Informed consent
- mHealth
- mHealth and Patient Health Information (PHI)
- Informed Consent models
- Challenges
- A new Informed Consent model
  - Requirements, design principles
  - Flexi Informed Consent model
Consent

- A fundamental principle in medical practice.
- Consent = giving permission to carry out an activity.
- To be effective consent needs to be informed
  - Adequate + necessary information needed
    (Anna et al, 1977, RCN, 2013)

Informed Consent

- The means by which an individual authorises intervention in his own care.
  - 1957 – landmark case, Salgo v Leland Stanford Jr
- A fundamental tenet in health care
  - Both a legal and ethical regulator
  - Protects individual autonomy in medical decisions
  - Protects privacy + unwanted intrusions
  - Encourages rational decision making
  - Effective participation of individual
Informed Consent – Conceptual components

- **Comprehension** – ability for patient to accurately interpret information disclosed.
- **Voluntariness** – to ensure patient not coerced or forced to participate.
- **Competence** – mental, emotional and physical activity needed.
- **Agreement** – patient giving a clear and open to accept or decline to take part in activity.
- **Disclosure** – provision of all necessary information needed for decision making.

(Annas et al, 1977; Friedman et al, 2000)

Informed Consent (IC) challenges

- Application on IC in healthcare system continues to face challenges
  - Use of ICT in health care
  - E.g. mHealth & health information exchange (HIE)

- mHealth poses new challenges to IC
  - Difficult to establish tradeoff between patient health information control and participation in HIE

Mantovani and Quinn (2013)
mHealth

“The practice of medicine and public health supported by mobile devices”

- Establishes treatment relationship between patient and doctor, not reliant on proximity of geographic location.
  (Mantovani & Quinn, 2013)

- Supports patient’s self-management, self-care, remote monitoring & consultation etc
  (Bardram et al, 2007)

mHealth and Patient Health Information (PHI)

- PHI collected using mHealth devices
- Uploaded to patients online healthcare account,
- Stored on web-based EHR or PHR
- Web-based EHR or PHR made available to healthcare provider via mHealth applications.
- Huge challenge – finding ways to address role of consent for patients in Health information exchange
Informed consent in mHealth

Informed Consent = How the patient wants to share health information while using mHealth applications

Informed Consent models

Traditional models (Lidz et al 1988)
- The Event Model
- The Process Model

mHealth - models of Informed Consent
- No Consent Model
- Opt-out and Opt-in in Full Model
Challenges - mHealth and Informed Consent

- Not devoid of manipulation
- Mandate on full information disclosure
- Comprehension
- Limits informed consent to act
- Ease of consent withdrawal

Research methods/tools

- Comparison of current information consent models
- UML – used to show a visual diagrammatic description of current informed consent models
- Data flow diagrams – show slow of information in systems
- Prototype mobile application (infinite monkey)
- Scenario-based comparative evaluation
New Informed Consent Model requirements

- Provide avenue for easy consent withdrawal mHealth
- Provide an avenue for consent modification
- Proactively encourage comprehension of disclosed information amongst mHealth users.

An Informed consent model - design principles

- Full Disclosure
- Take out technical jargon
- Put users in control of their consent decisions
- Present ease of consent withdrawal
The Flexi Informed Consent Model

Log-In

mHealth App

Sign-Up

HIE Consent

Opt-In

Opt - In

In Full

Opt-Out

With Restrictions

Opt - out

With Exceptions

Consent Adjustment

Patient

Sign or Create New Account In Phase
Sign or Create New Account
In Phase

Confirmation/ Acceptance Phase
Disclosure + Informed consent Phase

Menu
Review of Consent Phase

Evaluation (component based)

- **Comprehension** – ability for patient to accurately interpret information disclosed.
- **Voluntariness** – to ensure patient not coerced or forced to participate.
- **Competence** – mental, emotional and physical activity needed.
- **Agreement** – patient giving a clear and open to accept or decline to take part in activity.
- **Disclosure** – provision of all necessary information needed for decision making.

(Annas et al, 1977; Friedman et al, 2000)

- **Model Addresses existing problems!**
Bibliography
