Middlesex University

A Conceptual Model of Informed Consent for Web Based mHealth Services

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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

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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)

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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

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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 el, 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)

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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)

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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

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Informed consent in mHealth

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

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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
  - Opt-out and Opt-in with Granularity

(Illinois Government 2013)

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Challenges - mHealth and Informed Consent

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

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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

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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.

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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

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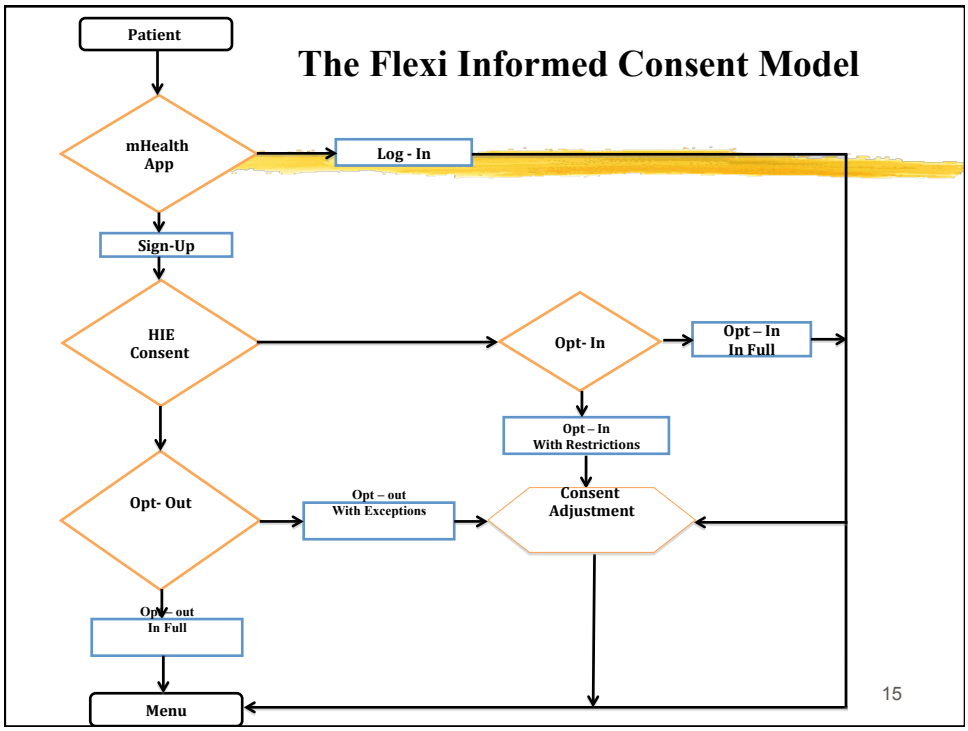
The Flexi Informed Consent Model
Patient
mHealth App
Log - In
Sign-Up
HIE Consent
Opt- In
Opt – In In Full
Opt – In With Restrictions
Opt- Out
Opt – out With Exceptions
Consent Adjustment
Opt – out In Full
Menu
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Sign or Create New Account In Phase
Back
mHealth app
Sign In
Email ID
Password
Login
Forgot your password?
powered by
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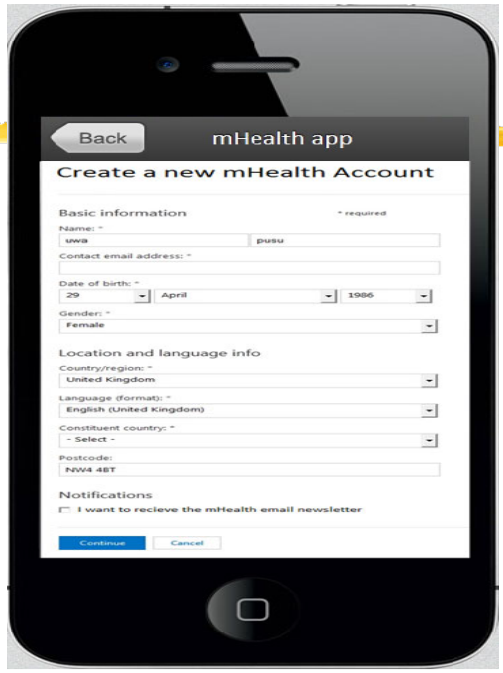
Sign or Create New Account In Phase



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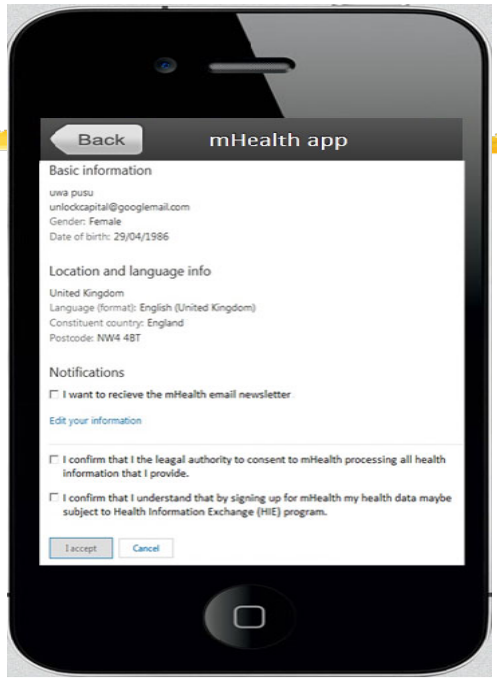
Confirmation/ Acceptance Phase



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Disclosure + Informed consent Phase

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Menu

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Review of Consent Phase

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Evaluation (component based)

- **Comprehension** – ability for patient to accurately interpret information disclosed.
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(Annas et el, 1977; Friedman et al, 2000)

- **Model Addresses existing problems!**

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