Ethics: Bioethics (Fall 2014)

Laura Guidry-Grimes

Challenges of Informed Consent

Requirements and Aims of Informed Consent

- Crucial aspect of respecting autonomy of patients and research subjects
  - But respecting autonomy involves more than offering informed consent form!

- "requires much more than avoiding deception and coercion. It requires an attempt to instill relevant understanding and to avoid many forms of manipulation" (Beauchamp & Childress 118)
  - What's an example of unintentional manipulation that could be foreseeable in a clinical or research context?

Meanings of 'Informed Consent'

- **Autonomous authorization**
  - More than mere assent
  - Does not have to be perfect to have moral force
- **Legally and institutionally valid consent**
  - Based on social rules, avoiding legal liability
  - "Blunt" determination – not as fine-grained or individualized
- Can autonomously authorize without being able to give valid consent and *vice versa*

Limits of Informed Consent (?)

- Cannot always tailor to informational and autonomy needs of particular patient/subject
- Limitations in information processing, understanding, reflective and true beliefs
- Therapeutic privilege
  - Controversial, can be narrowly or broadly interpreted
- Research study designs
  - General vs. specific consent
  - Single- and double-blind studies, placebo control group

Forms of Influence & Obligations

- **Coercion**
  - "one person intentionally uses a credible and severe threat of harm or force to control another" (B&C 133)
  - Credible threat + subject responds as if threatened
- **Persuasion**
  - Remonstration, appeal to reason
- **Manipulation**
  - "swaying people to do what the manipulator wants by means other than coercion or persuasion" (B&C 134)
  - Problem of informational manipulation
- Problems of inducement in medical research, attempts to convince patients to agree with physician in medical care, paternalistic policy measures

Surrogate Decision-Making Standards

- **Substituted Judgment**
  - Formerly capacitated patients with eligible surrogate who has sufficient knowledge of what the patient would want in these circumstances
- **Pure/Precedent Autonomy**
  - Formerly capacitated patients: "whether or not a formal advance directive exists, caretakers should accept prior autonomous judgments" (B&C 137)
- **Best Interests**
  - Never capacitated or insufficiently known wishes: Choose option with the highest net benefit and lowest net harms/risks for this particular individual
- **What do you foresee as difficulties with implementing each of these standards?**

Discussion Groups

- Problem-solve the following scenarios with the aims of **securing informed consent/refusal** and **establishing a trusting physician/researcher-patient/subject relationship.**
  - **Idiosyncratic religious belief**
    - e.g., refusing treatment based on religious conviction that others in that religious community do not share
  - **False belief / therapeutic misconception**
    - e.g., case on pg. 131 of B&C
  - **Over-optimism**
    - e.g., conviction in a miracle, hopefulness that does not match the odds
  - **Inconsistent beliefs**
    - e.g., patient claims to value living but refuses life-saving procedure

Questions? Comments?