Basic Issues in Research Ethics

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Principles of Medical Ethics

- **Beneficence**
  - Do no harm
  - Secure well-being

- **Justice**
  - Fair distribution of benefits & burdens

- **Respect for Persons**
  - Autonomy (self-rule) - individuals should be treated as autonomous agents
  - Persons with diminished autonomy are entitled to protection
Research Ethics

- In Medicine and Behavioral Sciences, research ethics are built on, but are not the same as, clinical ethics.
- Goals of Research and Treatment are related but not the same.
- Research Integrity issues apply.
Beneficence in Research

- Risk/benefits for the subject
  - Risks should only exceed benefits when essential to design (and then minimally)
  - In clinical research, risks should be only minor increase over usual treatment
  - All risks should be minimized

- Collective benefits can count if the subject’s risk/benefit ratio is acceptable
Justice in Research

- An equal distribution of benefits and burdens of research

- What is equal?
  - Each person an equal share
  - Each person according to need

- Inclusion of everyone relevant to the study
  - Not just middle-aged white men
Respect for Persons in Research

- Informed Consent
  - Disclosure
  - Competence Assessment
    - Surrogate Decision-making
  - Minimizing Coercion and Pressures

- Informed Consent is intended to promote mutual decision making and discussion
Dimensions of Informed Consent: Disclosure (in federal regs)

- The nature and purpose of the study
- The reasonably foreseeable risks
- The foreseeable benefits
- Appropriate alternatives
- Confidentiality
- Description of available compensation
- Identified contacts when questions arise
- Voluntariness
Dimensions of IC: Competence

- Legal term and presumption
- Ability to perform a specific task
- Clinical approximations
  - decision-making capacity
  - functional competence
  - psychological competence
Competence: conceptual foundation

- Not a fixed attribute or dichotomy - will depend on the particular decision and its potential benefits
- A set of assessments from clinical data that are as mutable as its elements
- A factual basis for legal determination that corresponds to a clinical state
Standards for Competence Assessment

- Communicating a choice
- Understanding relevant information
- Reasoning (rational manipulation)
- Appreciating situation and its consequences

Appelbaum & Roth 1982, Grisso 1986, Appelbaum & Grisso 1988
Testing: Applying the Standards

- Evidencing a choice
- Understanding
  - Ability to understand
  - Actual understanding
- Reasoning
  - Vignettes, conversation
  - Logical progression
- Appreciating
  - Personalization, realistic valuation
Testing: Applying the Standards (cont.)

- The sliding scale
- More rigorous standards/stricter tests as risk-benefit ratio increases
- Critique: parentalistic variation of standard
- MA standard: “rational manipulation”
Testing Research Decision-making: Questions (MacArthur model)

- **Evidencing a choice:** “Based on what I have told you so far….”

- **Understanding:** “Participants in this study will do the following things…” (includes voluntariness, primary intent of research, r/b, research methods) “Please tell me your understanding in your own words.”

- **Reasoning:** “You think you would choose to be in the study. What makes this the best choice? How would you figure out what is best for you?”

Appelbaum & Grisso, 2001
Testing Research Decision-making: More questions

➢ Appreciation:

- “Do you believe people are asked to be in a study only to find out which medication is best for them?”

- “Do you believe if you were in this study you would get the medication your doctor thinks is best for you?”

- “Let’s pretend you agree to be in the study, then you change your mind. You don’t want to be in it anymore. What do you think will happen to you?”
Surrogate Decision-makers

- **When?**
  - Incapacity
  - Future/potential incapacity (dual consent models)
  - Children (assent v. consent)

- **Standards**
  - Substituted judgment
  - “Best interests”

- **Problems**
  - Surrogates do not follow their principals’ wishes
  - Surrogates and principals disagree
  - Surrogates not familiar with principals’ values
  - Surrogates may not be competent themselves
Therapeutic Misconception

- In clinical trials and other intervention research
- Confusing participation in research with receiving ordinary treatment
  - Overestimating personal benefit
  - Expecting treatment to be individualized
  - Misunderstanding the purpose of the research as treatment
Voluntariness

- No pressures (coercion)
  - Threats
  - Force
  - Unduly forceful persuasion

- Restrict reimbursements so they don’t cause subject to underestimate risks

- What is a threat?
- What is coercion?
Coercion, cases

- **Newgate Prison, 1722**
  - Smallpox vaccine or death: welcome offer or coercion?

- **Kaimowitz v. DMH, 1973**
  - “The inherently coercive atmosphere to which the involuntarily detained mental patient is subjected has bearing on the voluntariness of his consent… They are not able to voluntarily give informed consent because of the inherent inequality of their position.”

- **National Commission, 1976**
  - Although prisoners may not regard consent as coercive, research must be prohibited because adequate monitoring of consent is impossible.
What is Coercion? Some definitions

- Whether ordinary person finds an offer irresistible (Beauchamp & Faden)
- Whether offer is inherently unfair and “moral baseline” is illegitimate (Appelbaum)
- Whether there is a threat of severe negative sanction (Gert, Nozick)
- Can excessive compensation be coercive?
Coercion: MacArthur research

- Correlates of perceived coercion
  - Being included in decision-making
  - Nature of others’ intentions
  - Absence of deceit
  - Receiving respect
  - More relevant than threats, physical force, legal status

- What is ethical determinant: Individual perception or social value?
Voluntariness, a model

- Developmental
- Illness-related
- Psychological, cultural, religious
- External features/pressures

- Goal: coherence with one’s history, circumstances, values

Roberts LW, 2002
Voluntariness (cont.)

- Authenticity of choice based in:
  - Circumstances
  - History
  - Clarity
  - Intentionality
  - Coherence with values

- Which elements affect decision to participate?

- Which elements affect the experience of participation?
Research Integrity

- Obligations to subjects
  - We do not just owe our subjects good behavior
  - If the research was not done right, why did we put subjects through it?
- Obligation to funders & scientific community
- Obligations to future patients
- Obligation to community that privileges our activities
  - Permission to conduct research requires trust
Three Types of Research Misconduct

- Fabrication: making up data or results and recording or reporting them
- Falsification: manipulating materials, equipment or processes in order to represent data inaccurately
- Plagiarism: taking others’ work without appropriate credit

- Does not include honest error