Informed Consent, overview

- Legal and ethical doctrine
- Collaboration with patient
  - Intended to promote mutual decision-making/discussion
- Support for self-rule (autonomy)
  - But persons with diminished autonomy are entitled to protection
- Cardinal feature: minimizing coercion
  - Exceptions under incapacity, emergency, waiver, privilege (greater harm than good)
- Our context this morning: focus on disclosure
  - How much information is necessary, appropriate?
IC Definition

- Process, not event
- Disclosure of information
  - Nature of procedure/Rx
  - Significant/material risks/benefits (+probability)
  - Alternatives (incl. no Rx)
  - Nature/purpose/limits of consent
- Understanding
- Voluntariness (present in acute context, new dx, change in condition?)
- Threshold elements+info+consent
- Time for questions, reflection, 2d opinion
Voluntariness

- Absence of pressures (coercion)
  - Threats
  - Force
  - Unduly forceful persuasion

- Supports authentic, stable choice

- 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.
Coercion, 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)
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

- Consent process should address these

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

- 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, esp. when choice is restricted or threatened, affect patient’s decision? The experience of decision-making?

- Can there be voluntariness when circumstances are not of patient’s choosing?
Informed Consent under Stress: Our Obligations

- Minimizing effect of circumstances
  - Respect
  - Disclosure
  - Transparency
  - Balance (individual, family, team, community)

- Offering information so it can be heard

- Maintaining protections
  - Sensitivity to circumstances
  - Familiarity with theoretical/cultural perspectives
  - Applying habits/skills of the ethical practitioner
Decision-making capacity

- Bulwark of Informed Consent
- Determines how pts are handling info
- Information disclosure, understanding, voluntariness require capacity
- Review of exceptions to IC underscores importance of competence
  - incompetence
  - emergency
  - waiver
  - therapeutic privilege
Ethical/Legal Standards

- 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

- Requirement of jurisdiction
- MA standard: “rational manipulation”
Testing at the Bedside: Basic Questions

- Competent for what?
- What information received?
- By whom?
- Under what conditions?
- Using what language?
Testing at the Bedside: Constructing an Interview

- Mental status examination (MSE)
  - attention
  - concentration
  - orientation
  - memory
  - thought process/content
  - mood/affective state

- Mini-Mental State Examination (MMSE)

- History: place/meaning of intervention
Testing at the Bedside: Pitfalls

- Diagnostic impressions: factors confounding diagnosis
- Miscommunication/misunderstanding
- Same-faith/same-race informants
- Exhaustion
- Education
- “Pseudoempathy:” abandoning patients to their choices
Testing at the Bedside: The Framework

- **Evidencing a choice:** “Have you decided...?” “Can you tell me...?”

- **Understanding:** “In your own words, please tell me the nature of your condition, the recommended treatment/test, the possible r/b, alternatives...”

- **Reasoning:** “Please tell me how you reached the decision to...” “What were the important factors; how balanced?”

Testing at the Bedside: The Framework (cont.)

Appreciating:

- “Please explain to me what you really believe is wrong with your health now?”
- “Do you believe you need treatment?”
- “What is the treatment likely to do for you?”
- “Why do you think your doctor recommended (specific Rx) for you?”
- “What effects on your own life?”
Documentation

- Findings and recommendations
- Detail conditions distorting thought process
- Describe patient’s view of illness, treatment, outcome
- Avoid global/extreme positions
- Concede islands of functioning
- Anticipate future interactions
Disputes and Appeal

- Have disputee present
- Re-conduct disputed element of exam
- Obtain second opinion
  - psychiatrist, forensic psych, ethics committee, court/guardianship

Alternatives
- limited/temporary guardians
- Ulysses contract
Data on Disclosure

- Pts want more
- Prefer risks over benefits
- Information heard best
  - over time
  - part by part
  - with someone else present
  - jargon-free
- Many physicians do not believe pts can give IC
- Pts’ retrospective view does not favor the intervention
- Disclosure of errors results in better relationships, less liability
Withholding information without knowledge or consent is unacceptable

But need not be communicated immediately or all at once; is pt capable of receiving? Tailor information to needs, expectations, preferences.

May delay only if early communication is “clearly contraindicated”

Monitor and offer complete disclosure when pt is able to decide whether or not to receive it; with a definite plan so delay is not permanent.

Consultation with family, colleagues, ethics committee may help in assessing the balance of benefits and harms associated with delayed disclosure.