MASSACHUSETTS GENERAL HOSPITAL
PSYCHIATRY ACADEMY

# Informed Consent

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# Disclosures

Neither I nor my spouse/partner has a relevant financial relationship with a commercial interest to disclose.

# Informed Consent

- A **PROCESS** by which one individual agrees to allow another to intrude upon his bodily integrity or other rights where the agreeing party is competent to consent and does so voluntarily and with a reasonable degree of knowledge.

# Elements of Informed Consent

- Informed
- Voluntary
- Competent

# Standards for Provision of Information

- Professional standard
  - "Reasonable physician"
    - E.g., New York Public Health Laws, Section 2805-d
- Materiality standard, e.g., Massachusetts
  - "Reasonable patient"
  - This patient


SIDE
EFFECTS

# Off-Label Use of Medications

- FDA Approval
  - Approval given to marketing information based on research-proven efficacy and safety
  - Not intended to interfere with doctor/patient decisions regarding specific medication
- Physician may prescribe any FDA-approved medication for any purpose, using his/her professional judgment
  - Lack of FDA approval not a material risk
  - Malpractice claims due to negligent professional judgment
  - Protection: documented studies of safe use in the manner chosen and in similar practice

# Information: General Requirements

- Nature of condition
- Nature & probability of material risks of Treatments
  - E.g., black box warnings, type II diabetes
- Reasonably expected benefits & side effects
- Inability to predict results
- Potential irreversibility of the procedure
- Likely results, risks, and benefits of **no and alternative Txs**

# Voluntary

- Free of coercion from the clinician
  - Overt
  - Subtle
- Family pressure or encouragement is acceptable from a legal standpoint
  - Treatment adherence issues
  - Assent vs. consent

# Competency

- Basic issue
- Incompetence defined: Incompetence constitutes a status of the individual that is defined by *functional* deficits (due to mental illness, mental retardation, or other mental conditions) judged to be sufficiently great that the person *currently* cannot meet the *demands* of a specific decision-making situation, weighed in light of its potential *consequences.* (Grisso, Appelbaum, 1998.)

# Competency

- Assessment (Appelbaum, 2007)
  - Express a preference
  - Factual understanding
  - Appreciation of seriousness of condition and consequences of accepting or refusing
  - Able to manipulate information in a rational fashion

# Assessment of Capacity to Consent to Treatment

- Expresses a preference
  - Muteness regarding the treatment decision raises a presumption of incapacity
  - Why mute?
  - Cross cultural issues and the Western concept of autonomy and informed consent
    - Similar principles
    - Different approaches and attitudes, e.g. authority
  - Shifting decisions raise presumption of incapacity

# Assessment of Capacity to Consent to Treatment

- Factual understanding
  - Just the basics
  - Affected by clinical conditions: level of alertness, CNS processes, other conditions such as severe pain and mental illness, mental retardation, information processing disorders
  - But also: language, education, cultural, and interpersonal issues

# Assessment of Capacity to Consent to Treatment

- Appreciation of the seriousness of the condition and consequences of accepting or refusing treatment
  - Understanding beyond basic facts
  - Ability to weigh relevant factors against each other
  - May be affected by: pain, CNS processes, mental illness, intellectual disability, information processing disorders, personality disorders
    - And also: language, education, cultural, and interpersonal issues

# Assessment of Capacity to Consent to Treatment

- Able to manipulate the information in a rational fashion
  - Rationality does not equate with what the treatment team wants
  - The Jehovah's Witness example

# How Much Capacity is Enough?

- The sliding scale model (Roth 1977; President's Commission 1982) for level of capacity

Risk/Benefit Ratio of Treatment

| Pt's Decision | Favorable | Unfavorable or ? |
|---|---|---|
| Consent | Low test for capacity | High test for capacity |
| Refusal | High test for capacity | Low test for capacity |

# Common Approaches to Capacity

- Capacity rarely questioned if the decision is in the patient's best interests as viewed by:
  - Treaters
  - Family
  - Others
- Treatment refusal is the most common reason for questioning capacity

# Common Approaches to Capacity

- Avoiding court/litigation at all costs
- Preference for battery/malpractice suit over allowing a patient to go untreated

# Exceptions to Informed Consent

- Emergency
  - Must assess capacity to consent first
  - Emergency exception does not override treatment refusal by patient capable of giving consent
  - If patient's consent cannot be obtained, emergency physician should seek the consent of family member if time and circumstances permit

# Exceptions to Informed Consent

- Incompetence
  - Must assess and document
  - Seek alternative decision maker
- Therapeutic privilege
  - Established in NY by Pub Health §.2805-d
  - "the practitioner, after considering all of the attendant facts and circumstances, used reasonable discretion as to the manner and extent to which such alternatives or risks were disclosed to the patient because he reasonably believed that the manner and extent of such disclosure could reasonably be expected to adversely and substantially affect the patient's condition."

# Thank you!