

Informed Consent

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Disclosures

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

Vignette #1

- **Ms. A**, a 32-year-old woman, presents to the outpatient psychiatry clinic with symptoms of low mood, fatigue, and diminished interest in daily activities.
- Following a comprehensive evaluation, she is diagnosed with **Major Depressive Disorder**.
- The psychiatrist recommends initiating an SSRI to address her symptoms.

- The psychiatrist explains the **intended benefits** of the medication, including mood improvement and increased energy.
- **Potential side effects** such as gastrointestinal discomfort, sexual dysfunction, and risk of increased suicidal thoughts are reviewed.
- **Alternative options**, including psychotherapy, other pharmacologic treatments, or no medication, are discussed.

- Ms. A engages in the conversation, asks clarifying questions, and expresses understanding of the risks and benefits.
- She agrees to begin treatment with sertraline, and the discussion is documented in the clinical record.

Informed Consent

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

Elements of Informed Consent

- Informed
- Voluntary
- Competent



The Three Elements of Informed Consent: *Knowing*

- What Does *Knowing* Mean?
 - Materiality Standard: what a reasonable patient would need to know to make the decision, typically including:
 - Diagnosis
 - ⑩ Specifics of Treatment
 - Consequences with/without treatment
 - Alternative Treatment Modalities

The Three Elements of Informed Consent: *Knowing (continued)*

- Standards for Provision of Information
 - Professional standard
 - "Reasonable physician"
 - E.g., New York Public Health Laws, Section 2805
 - Materiality standard, e.g., Massachusetts
 - "Reasonable patient"
 - Best practice to consider particular patient

The Three Elements of Informed Consent: *Knowing (continued)*

- Generally Required Information:
 - 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 Tx**

Three Elements of Informed Consent: *Voluntary*

- What Does *Voluntary* Mean?

The treatment decision was made by the patient voluntarily without coercion

- No physician coercion
- No environmental coercion
- Family persuasion is not usually your problem, with caveats

Three Elements of Informed Consent: *Voluntary* (continued)

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

Three Elements of Informed Consent: *Intelligent*

What Does *Intelligent* Mean?

A decision must be made intelligently or competently:

- The ability to **express** a choice
- The ability to **understand** presented information
- The ability to **appreciate** the significance
- The ability to **reason logically** about rx options

Vignette #2

- Dr. B meets with Mr. C, a 45-year-old man diagnosed with schizophrenia, to discuss initiating a long-acting injectable antipsychotic.
- Prior to tx with oral medication, Mr. C had expressed delusions regarding an implanted microchip and was suspicious of providers.
- Since, he has been adherent with treatment with improvement of his paranoia and delusions.
- Now, Mr. C expresses concerns about potential side effects but engages thoughtfully in the conversation with good insight.

Competency

- 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:
 - Treators
 - 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 surrogate decision makers 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!