Informed consent: Principles & Relationships

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Disclaimer

I am responsible for the contents of this presentation. The views expressed should not be construed as representing those of the National Center for Ethics in Health Care, the Department of Veterans Affairs, or the US Department of Defense.
Charles wants to stop dialysis

• Charles is a 51 year African American man with schizophrenia with end stage renal disease
• He wants to stop dialysis
• His mother is his legal guardian
• He is on the waiting list for a transplant
• He is not psychotic and does not currently show delusional, or pathologically illogical thinking.
• He is aware that he will die without dialysis.
• He is especially bothered by receiving laxatives before dialysis and then having bathroom access limited.

Thanks to the nursing staff at Yale-New Haven Hospital, Psychiatric Service
Informed Consent

Respect for Autonomy

Relational Ethics
Objectives

Participants will be able to:

• Identify the rationales for respecting autonomy and the situations and how informed consent shows this respect.

• Identify the elements essential to informed consent.

• Identify conditions when respect for autonomy is not required.

• Identify the chief critiques of informed consent, especially in relation to nursing practice.

• Identify clinical
Outline

A. Respect for Autonomy

B. Informed consent as chief technique for respecting patient autonomy
   1. Decision-making capacity
   2. Information
   3. Consent
   4. Exceptions

C. Informed Consent and Clinical Relationships
   1. Critique of informed consent
   2. Shared decision-making v. Informed consent
   3. Risky behavior
   4. Ethical use of influence
   5. Responsibility, empathy, and informed consent
A. Respect for autonomy
What is Autonomy?

• Autonomy is a property intrinsic to the concept of personhood

• An autonomous act has these properties*:
  – Intentional - Free will, self-directed
  – With understanding - Role of information
  – Without coercion

*From: Beauchamp & Childress, 2001
Why Respect Autonomy?

- **Agency** - A self capable of deliberate (autonomous) action
  
  +

- **Respect for person** - Persons have ultimate value
  
  +

- **Moral equality** - Each person’s moral worth is synonymous
  
  equals →
• **Liberty** - The right to pursue one's own interests without interference.

• **Which in health care means:**

• **Respect for autonomy** - The duty of clinicians to respect and enhance patients’ autonomy over treatment decisions and health care goals.

• *Note: Respect for Autonomy is active requiring skill and effort by the clinician while liberty is a passive right.*
John Stuart Mill (1806-1873)

Each is the proper guardian of his own health, whether bodily or mental or spiritual.

*On Liberty.* 1859.
Four Senses of Autonomous Action*

- **Free Action** - Action is competent and not coerced
- **Authentic** - Action consistent with prior decisions
- **Effective Deliberation** - Considering options in light of one's values
- **Moral Reflection** - Consideration of basic values


Hierarchical in the moral weight given by an observer clinician
“That pill they advertise all the time on TV. I’m not sure what it is, but I want it!”
B. Informed consent is the chief technique for respecting patient autonomy.
“Every human being of adult years and sound mind has the right to determine what shall be done with his body, and a surgeon who performed an operation without his patient’s consent commits an assault for which he is liable for damages”

Schloendorff v NY Hosp, 211 N.Y. 125 at 129, (1914)
The voluntary consent of the human subject is absolutely essential.*

1945 - Dr. Karl Brandt, a Nazi who experimented on humans, stands trial in Nuremberg.

What is informed consent?

• An autonomous authorization by individuals for treatment.

• Adequate informed consent requires three elements*:
  1. **Decision-making capacity** – An essential precondition to giving a valid informed consent
  2. **Information** – That relevant information is given to and understood by the patient
  3. **Consent** – That the patient voluntarily agrees to the treatment

*From: Beauchamp & Childress, 2008
B.1. Decision making capacity
Elements of DMC

• Understanding
• Appreciation
• Reasoning
• Expressing a choice*

*Grisso & Appelbaum, 1998
Ten myths of decision-making capacity

1) DMC and legal competency are the same.
2) Lack of DMC can be presumed when patients go against medical advice.
3) There is no need to assess DMC unless patients go against medical advice.
4) DMC is an “all or nothing” phenomenon.
5) Cognitive impairment equals lack of decision-making capacity.
Ten myths of decision-making capacity

6) Lack of DMC is a permanent condition.

7) Patients who have not been given relevant and consistent information about their treatment lack DMC.

8) Patients with certain psychiatric disorders lack DMC.

9) Patients who are involuntarily committed lack DMC.

10) Only mental health experts can assess DMC.

Decision-making capacity is a continuum

**Capacity for decision-making**

- Early Alzheimer's, Residual phase Schizophrenia
- Substance dependant, Severe Personality Disorder
- Late adolescent, Impulsive personality
- Mature independent adult
- Professor of Moral Philosophy

**Lacks capacity**

No communication, No decision, or Nonsense
- Coma, Florid psychosis
- Delusional, Severe Alzheimer's
- Moderate Alzheimer's, Severe or psychotic Depression

Manifestly poor decisions without giving rationale
- Decision articulated but without any reflection
- Decision deliberated on socially accepted grounds

High level reflection

Graphic inspired by Chen et al, 2002, categorization by Miller, 1982
• Mental state is altered in mental disorder, by definition, and so capacity is always at issue.

• Psychiatric patients routinely have their capacity doubted unlike most medical patients.

• Geriatric-Psych patients are under double suspicion!
Aspects of “mental” influencing capacity that can be affected by psychiatric disorder

• Thought
• Mood
• Self (personality)
• Experience
• Relational functioning
• Behavior

“Mental” is a difficult category
Capable of “legally effective consent”

Incompetent

- No communication, No decision, or Nonsense
  - Manifestly poor decisions without rationale
  - Decision articulated without reflection
  - Decision deliberated within social norms
  - High level reflection

- Coma
  - Severe Alzheimer's
  - Severe psychosis
  - Delusional
  - Moderate Alzheimer's
  - Severe depression
  - Early Alzheimer's
  - Residual phase schizophrenia

- Moral philosopher
  - Mature adult
  - Impulsive personality
  - Substance dependence
  - Severe personality disorder

- Severe depression
- Early Alzheimer's
- Residual phase schizophrenia
Mental disorder & capacity - Some evidence

- Patients with mania scored lower but improved with simple interventions (Misra et al., 2008)*
- Vast majority understood information deemed relevant by the APA to consent to psychiatric admission (Appelbaum et al., 1998)**
- Little impairment in depressed outpatients (Appelbaum et al., 1999)*
- 76% patients with depression with and @50% with schizophrenia had capacity (Grisso, et al. 1995)**
- Inpatients with Anorexia had capacity similar to community samples (Tan, et al., 2003)**

*Research informed consent
**Treatment informed consent
Percent psychiatric and medical inpatients with decision-making capacity,
Psychiatric patients N=112; Medical patients N=231


*Includes patients who were severely cognitively impaired, unconscious, or unable to express a choice.
Percent psychiatric inpatients with decision-making capacity, N=338

Percent with decision-making capacity for research informed consent: Alzheimer's patients (N=37) and matched comparison group (N=15)

Percent of Alzheimer’s patients meeting criteria for decision-making capacity for research informed consent by each element needed for capacity, N=37

Mental disorder & capacity: Trends in the evidence

• Lack of capacity associated with severe symptoms
• Capacity can be improved with simple interventions

Chen, Miller & Rosenstein (2002) conclude, “Neither mental status examinations nor medical diagnostic categories in themselves yield sufficient indicators of capacity or incapacity to make treatment decisions… lack of decision-making capacity cannot be reliably inferred solely from diagnostic categories”
B.2. Information
Information:
Disclosure → Understanding → Appreciation

• What the patient understands or appreciates is more important than what is said.
  – Does the patient - “Get it.”

• Some barriers to understanding
  – Technical jargon and idiosyncratic usage.
  – Information overload
  – Patient’s situation, ex., sick, sleep-deprivation, etc.
  – Patient denial
  – Provider’s belief that, “If they really understood they would agree.”
Typical list of content to be disclosed

• Goal of the treatment
• What will happen and what is expected of them
• Treatment benefits
• Adverse effects
• Risks
• Alternative interventions including no treatment
  – Anticipated consequences of no treatment
Conditions of consent

• Coercion is inappropriate
  – Defined as a “controlling influence”

• BUT - it is appropriate to give the patient your recommendation
Ethical tension in “consent”

- Clinician recommendations influence patients
  - But too much influence is coercive
- How much and what types of influence are ethically justified? Required? Forbidden?
Flawed Consent

- Blanket consent
- Implied consent
- Retroactive consent
  - Research
- Gurney consent
B-4 Exceptions
When consent from the patient may not be required

- When overriding autonomy is justified
  - Someone else must consent
  - Protections
    - Assent
    - Substitute decision maker
    - Legal oversight
    - Criteria
    - Clinical oversight

- Protections vary by rationale for overriding autonomy and substitute decision maker
Potential exceptions to informed consent - 1

• Lacks DMC
  – Consent is not valid
  – Consent by surrogate
    • Substituted judgment
    • Best interests

• Dangerous with mental disorder
  – Legal/procedural protections
  – Limited, e.g. consent needed for medication even after civil commitment
Potential exceptions to informed consent - 2

• Emergency
  – Assessed by clinician
  – Criteria based

• Public health e.g. mandatory vaccine
  – Large social benefit to personal cost
  – Governing body

• Therapeutic privilege – Not telling dx
  – Least protections
C. Informed consent & Clinical relationships
Critique of informed consent - 1

• Acts of care v. Treatments/procedures
  – IC designed for discreet acts

• Decision-making capacity
  – In Western culture: Rationality=Personhood
  – Judgment and skill

• The influence paradox
  – There cannot be “influenceless” decisions

• Necessary judgment about information disclosed
Historical definitions of personhood emphasize rationality.

Aristotle (350 BCE)

“...since mind more than anything else is man.”
Critique of informed consent - 2

• Shifting responsibility
  – Caring v. reduction of liability/responsibility

• Isolates the individual from context
  – Atomistic individualism
  – No necessary role for family or other

• Emphasis on information to refuse tx not information patient wants to know

• Focus on physical benefit/risk in disclosure
Hypothetical social network of home care patient

Wife & CAREGIVER

Son

Sister

Daughter

Co-worker prior to illness

Housebound Neighbor

Visiting Nurse

Primary Care Physician

Psychiatrist

Therapist
Again, we see instances in which European conceptions of morality have been seen as timelessly and universally valid, and used to denigrate other cultures and groups.

From: *New Literary History*, 2001, pg. 885
Shared Decision-Making
Shared Decision-Making in VHA

“The process of collaboration between the clinician and patient in making health care decisions, to which the clinician contributes his or her knowledge and compassion, and the patient his or her values, preferences, and goals for care.”
Information needed to consider refusing treatment

v.

Information one wants to live life and plan for the future
Assessment of risk
Assessing risk of health behaviors

**Patient factors decreasing perception of risk**
- Sense of control over unhealthy behavior
- Familiarity with unhealthy behavior
- Active involvement
- Discounting the future
- Visceral factors
  - Healthy behavior unpleasant
  - Unhealthy behavior has increased desirability (addiction)

**Clinician factors increasing perception of risk**
- No control over patient behavior
- More familiar with negative consequences
- Not involved
- Future not considered
- No visceral reaction to patient behavior
Ethical use of influence in clinical relationships
Influence

• “the power to have an effect on people”

• Distinctions
  – Wanted v. Unwanted influence
  – Internal or External influence
Influence is intrinsic to the meaning of treatment
Responsibility, empathy, and informed consent
## Autonomy and Responsibility

<table>
<thead>
<tr>
<th>Criteria for:</th>
<th>Autonomy</th>
<th>Informed Consent</th>
<th>Responsibility</th>
<th>Criminal Responsibility</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autonomy</td>
<td>Competent and gives authorization</td>
<td>Causality</td>
<td>Did the person perform the act? <em>Actus Reus</em> (Bad Action)</td>
<td></td>
<td>Criteria of autonomy and criminal responsibility bear on teleologic cause, i.e., intention - Why an act was done?</td>
</tr>
<tr>
<td>Intentional (Competence)</td>
<td>Competent and gives authorization</td>
<td>Foresight</td>
<td><em>Mens rea</em> (Bad intent)</td>
<td></td>
<td>More knowledge confers greater the responsibility. However, as the severity of consequences increases we tend to imbue more responsibility with at lessor levels of understanding.</td>
</tr>
<tr>
<td>With Understanding</td>
<td>Clinician gives proper disclosure</td>
<td>Appreciation of wrongfulness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without coercion</td>
<td>Without coercion</td>
<td>Control</td>
<td>Irresistible impulse Act a product of mental disorder Under Duress?</td>
<td></td>
<td>The less influence the more autonomous the decision. (That decisions can not be entirely without influence is a critique autonomy; to decide is to sort among influences.)</td>
</tr>
</tbody>
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Responsibility

• Closely tied to autonomy
  – One is only responsible for autonomous acts

• IC shifts responsibility onto patients
  – Risk is a strategy for redistributing responsibility (Douglas, 1990)

• People tie positive regard to responsibility
  – “He brought it on himself.”
Allow patients to feel ambivalent about treatment

• Providers are often invested in having patients give their treatment unqualified endorsement

• Interaction must go beyond convincing patients to accept the recommended treatment

• Working through treatment goals is part of treatment
“And remember when you’re out there trying to heal the sick, you must always first forgive them.”

From *Open the door, Homer* by Bob Dylan
The End