Optimizing Informed Consent in Clinical & Research Settings

Helen Sharp, Ph.D. CCC-SLP
Director and Professor
School of Communication Sciences and Disorders
Pacific University
Forest Grove, OR

Disclosures

- ✓ Full time employee of Pacific University Oregon

Ethics

- Why focus on Informed Consent?

Ethics

- ✓ ASHA added informed consent to the Code of Ethics in 2016
- ✓ Central to every clinical interaction
  - Builds trust
  - Allows for patient autonomy
  - Guides decisions when patients refuse
  - Identifies patients who lack capacity to give consent

A Model for Clinical Decision-Making

Clinical Indications	Patient Preferences
External Quality of Life Judgments	Contextual Features

Jonsen, Siegler, & Winslade

What is Informed Consent?

- Serves as the bridge between the clinician and the patient

Examples of When Informed Consent Should Be Obtained…

Where does the concept of consent come from?

Justice Cardozo – Opinion Schloendorff v. Society of New York Hospital 1914

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits and assault, for which he is liable in damages, except in cases of emergency, where the patient is unconscious, and where it is necessary to operate before consent can be obtained.

Cardozo (1914) to ASHA Code (2016)

- 1938 - mid 1940s: Human experiments conducted by Nazi physicians and nurses
- 1956-1970: Willowbrook State School, NY: Deliberate hepatitis infection given to children in residence
- 1932-1972: US Public Health Service: "Tuskegee Study of Untreated Syphilis in the Negro Male"

Cardozo (1914) to ASHA Code (2016)

Outcomes

- International Codes: Nuremberg Code; Declaration of Helsinki
- Institutional Research Boards (IRB)
- 1981 American Medical Association added informed consent to its Code of Ethics
- Increased focus on patient rights, particularly the right to self determination (autonomy) through 20th century
  - Oregon Code. §127.507 "Capable adults may make their own health care decisions."

Types of Consent

- Full
- Verbal
- Minimal / Assent*

When do we use each type?

*American Academy of Pediatrics, 1995

Informed Consent as a Process

Voluntary, informed permission - requires that the patient

- ✓ Is given clear and adequate information about
  - Diagnosis and prognosis
  - Treatment options
  - Risk and benefits of each option
- ✓ Has the cognitive capacity to make a rational choice
- ✓ Is able to decide freely and without coercion (voluntary)
- ✓ Agrees to proceed

Berg, 2001; Bernat, 2001

A signed consent form ≠ informed consent

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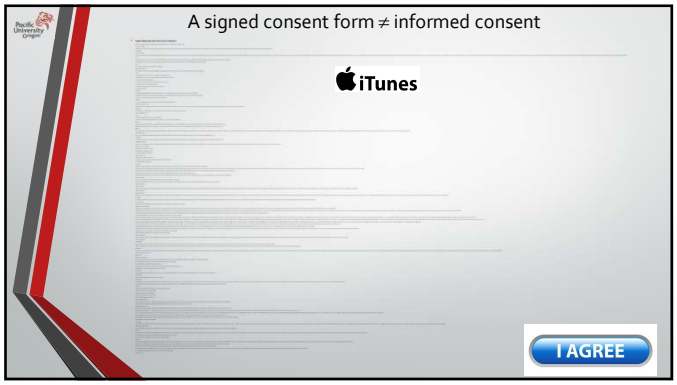

How Do We Resolve the Problems Observed?

Barriers to Achieving Informed Consent

- Jargon
- Communication and Cognitive Disorders
- Language Barriers
- Reliance on Consent Forms

Green & Mackenzie, 2007; Lidz et al, 1983; Penn et al, 2009; Schenker et al, 2007; Triebel et al, 2014

Capacity to Consent

Individual giving consent must:

- ✓ Understand the information given
- ✓ Be able to weigh risks and benefits for each option
- ✓ Make a rational decision
- ✓ Express a choice

Appelbaum & Grisso, 1988; Lo, 1990

Competence v. Capacity

Competence is a legal term

- Assumed at 18 years of age
- Can only be reversed by a judge
- Often interpreted as all or none

Capacity is a clinical term

- Evaluated for *every* decision, never assumed
- Fluctuates (e.g., meds, time of day, situational)
- Task specific
- Sliding scale

Appelbaum & Grisso, 1988; Lo, 1990

Competence v. Capacity

DMC (clinical)	Competent (legal) +	Competent (legal) -
+	++ Most adults	- + e.g., adolescent ≥ 14 y.o
-	+ - Adult lacks DMC (e.g., sedated)	-- Adult with guardian and significant cognitive impairment

Role of the Speech-Language Pathologist in Determination of Decision Making Capacity (DMC)

Informed Refusal

If we accept a patient's (or participant's) right to give consent, we must also accept that the right to refuse is embedded as an option

Case Example: Mr. D

- 57 year old male sustains cerebellar CVA
- Swallow eval in acute care
- Modified diet: soft foods, thick liquids, no straws.
- Transferred to rehabilitation service at a county longterm care facility 5 days post-stroke
- Observed cough during & after meals
- Bedside & modified barium swallow repeated
- Aspiration on all consistencies, cough inconsistent

Recommendation:

NG tube with intervention, goal to restore oral intake

What are some reasons a person might refuse…?

- Clinical evaluation
- Clinical intervention
- Participation in research

What Should You Do When a Patient Refuses?

What Should You Do When a Patient Refuses?

Evaluate DMC

- ✓ Revisit information given – was it clear? Were options presented?
- ✓ Revisit comprehension of information
- ✓ Determine patient goals
- ✓ What are the reasons for the refusal? Is it rational?

What Should You Do When a Patient Refuses?

If the patient has DMC

- ✓ Re-evaluate your own goals and list of options
- ✓ Draw up a new plan of care *with* the patient
- ✓ Include plan for negative outcomes (advance planning)

If the patient lacks DMC

- ✓ Identify surrogate or proxy
- ✓ Evaluate the need for cooperation
- ✓ Plan for reassessment of DMC

Review the case. Could a surprise refusal have been prevented?

Mr. D Revisited

Against Medical Advice Forms

What if the Patient Lacks DMC?

Identify the appropriate surrogate decision-maker

Determine whether the patient has executed a Power of Attorney for Health Care

Surrogate Selection in the Absence of Guidance

- Legal Guardian
- Spouse or domestic partner*
- Adult child
- Parent
- Adult sibling
- Adult grandchild*
- Close friend
- Guardian of the estate

*varies by state (e.g., Maryland (2013) § 5-605; Illinois Public Act (1991) § 92-0364

Let's Apply It

- ❑ Consent forms
- ❑ Interpreters
- ❑ "Routine" assessments – oral exam; bedside swallow
- ❑ Assumptions about DMC
- ❑ Non-compliance (~~non-compliance~~)
- ❑ Research – therapeutic misconception (Lidz et al, 2004)

Obtain Consent for EVERY Interaction?

Best practice

- ✓ Consider consent a process and not an event
- ✓ Conduct the process of consent at every step of every clinical pathway
- ✓ Evaluate DMC as part of the consent process
- ✓ Use "teach back"
- ✓ Modify communication where appropriate
- ✓ Use professional interpreters
- ✓ Document!
- ✓ Separate clinical work from research to minimize therapeutic misconception
  - Engage someone other than the clinician in research enrollment

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