



## When is Informed Consent Truly Informed?

Jeannie Huang, MD MPH

Associate Professor

University of California, San Diego

Rady Children's Hospital



---

---

---

---

---

---

---

---

## Faculty Disclosures

- None

---

---

---

---

---

---

---

---

## Objectives

- Definition of Informed Consent
- Ethical Principles
- Issues with Assent
- Research to date
- Methods for Improvement

---

---

---

---

---

---

---

---

## Definition

*American Medical Association:*  
Informed Consent =  
Process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention

<http://www.ama-assn.org>

---

---

---

---

---

---

---

---

## Definition

*American Cancer Society*  
Informed consent is a process where:

- The patient is told about the risks/benefits
- The patient is told about the R/B other options
- The patient has the chance to ask questions and get answers
- The patient has time if needed to discuss the plan with family/advisors
- The patient shares his/her decision with the medical team

ACS, 2014, [www.acs.org](http://www.acs.org)

---

---

---

---

---

---

---

---

## Legal Requirement

- Statutes and case law in all 50 states
- 1<sup>st</sup> case defining informed consent appeared in the late 1950's
- Earlier consent cases based in the tort of battery

---

---

---

---

---

---

---

---

## Health Care Decision Making Cases

- Schloendorff, 1914
- Salgo, 1957
- Canterbury, 1972
- Candura, 1978

---

---

---

---

---

---

---

---

### Schloendorff v. 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 an assault, for which he is liable in damages.”*

- Justice Benjamin Cardozo

---

---

---

---

---

---

---

---

### Salgo v. Stanford University 1957

- Term “informed consent” first used
- Court ruled that sufficient disclosure of possible risks and complications was necessary for patients to make autonomous decisions
- Court also noted that when discussing risk, the physician must disclose fully the facts necessary to an informed consent

---

---

---

---

---

---

---

---

### Canterbury v. Spence 1972

- Established an objective standard for the scope of disclosure in informed consent called the “prudent patient test”
- Risk was defined as what “a reasonable person...in the patient’s position, would be likely to attach significance to the risk in deciding whether or not to forgo the proposed therapy”

---

---

---

---

---

---

---

---

### Canterbury v. Spence 1972

- Disclosure should cover “the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated”

---

---

---

---

---

---

---

---

### Lane v. Candura 1978

- Competence defined as the capacity to make one’s own health care decisions, even if such decision was irrational to others

---

---

---

---

---

---

---

---

## Informed Consent Principles

- Grounded in the philosophical principle of autonomy, or the ability of adults to “self-rule” and to accept or decline any medical intervention

---

---

---

---

---

---

---

---

## Elements of Informed Consent

- Disclosure
- Understanding
- Voluntariness
- Competence
- Consent

Beauchamp and Childress, 1994

---

---

---

---

---

---

---

---

## Disclosure

- Disclosure of information to patients is a necessary component of consent
- Three standards
  - Professional practice standard
  - Hypothetical reasonable person standard
  - Subjective standard

---

---

---

---

---

---

---

---

## Disclosure

- Professional practice standard
  - Emphasizes patients' best medical interest
- Hypothetical reasonable person standard
  - Takes into consideration patient's need for information v. physician's opinion of the patient's needs
- Subjective standard
  - Disclosure of relevant information should be tailored to person based on individual needs

---

---

---

---

---

---

---

---

## Understanding

- Physicians need to provide an atmosphere that encourages patients to ask questions and to clarify ambiguities
  - Provision of translators/interpreters
  - Provision of hearing or seeing assistive devices
  - Optimize communication between physician and patient

---

---

---

---

---

---

---

---

## Voluntariness

- Voluntary participation in treatment is essential to concept of autonomy and self-determination
- Physicians may have influence on a patient's final decision but they may not be coercive

---

---

---

---

---

---

---

---

## Competence

- Competency - individuals having sufficient ability or possessing the requisite natural or legal qualifications to engage in a given endeavor
- To be determined incompetent, the individual is judged to be unable to make prudent decisions in his or her best interest
- Judgments can be task - specific in regards to competence hearings

---

---

---

---

---

---

---

---

## Lack of Competence

- Making health care decisions for those who lack competence is done by the legal standards of :
  - Best interest (promoting what is good for the patient)
  - Substituted judgment (based on proxy's knowledge of what patient's wishes would have been)
  - Reasonable judgment

---

---

---

---

---

---

---

---

## Provision of Consent

- No legal requirement for signature
- Must be documented in medical record
- Timing of discussion also not a requirement

---

---

---

---

---

---

---

---

## The Issue of Assent

- Assent is the obtaining of approval for participation from a minor
- Increasingly advocated/accepted to obtain assent prior to performance of procedures
- Considerations as prepare for transition

---

---

---

---

---

---

---

---

## Assent

- Encourages shared decision-making and active participation of the minor
- Supports ethical standard of respect for all persons
- Alleviate feelings of powerlessness

---

---

---

---

---

---

---

---

## Assent

- Should include the following elements
  - Helping the patient become aware of the nature of his or her condition.
  - Telling the patient what he or she can expect with tests and treatment(s).
  - Assess the patient's understanding of and response to the situation and whether there is coercion
  - Soliciting an expression of the patient's willingness to accept the proposed care.

AAP Committee on Bioethics, 1995

---

---

---

---

---

---

---

---



## Refusal to Assent

- A patient's reluctance or refusal to assent should also carry considerable weight when the proposed intervention is not essential to his or her welfare and/or can be deferred without substantial risk

AAP Committee on Bioethics, 1995

---

---

---

---

---

---

---

---

## Legal Emancipation

- Emancipated if
  - Self supporting
  - Married
  - Pregnant or a parent
  - In the military
  - Declared emancipated by the court
- Many states give decisional authority (without need for parental involvement) to minors if seeking treatment for STDs, pregnancy, drug/alcohol abuse

---

---

---

---

---

---

---

---

## Ability to Provide Consent

- Weithorn and Campbell
- Evaluated decisional capacity (competency to make informed treatment decisions) 96 subjects – 24 at each of 4 age levels
  - 9 y
  - 14 y
  - 18 y
  - 21 y

Weithorn & Campbell, 1982

---

---

---

---

---

---

---

---

## Ability to Provide Consent

- Overall 14 year olds did not differ from adults
- 9 year olds less competent than adults in their ability to reason about and understand treatment information
- 9 year olds did NOT differ from adults in their expression of reasonable preferences re: treatment

Weithorn & Campbell, 1982

---

---

---

---

---

---

---

---

## Ability to Provide Consent

- Conclusions
  - “Findings do not support denial of right of self-determination to adolescents in healthcare situations on the basis of a presumption of incapacity”
  - Children as young as 9 y can participate meaningfully in personal health-care decision making

Weithorn & Campbell, 1982

---

---

---

---

---

---

---

---

## Are Youth Interested in Information?

- Fortier et al
- 43 children aged 7-17 y completed a 40-item assessment of desired surgical information
- Most children had a desire for information about their surgery
  - information about pain and anesthesia
  - procedural information
  - potential complications

Fortier et al. 2009

---

---

---

---

---

---

---

---

## Are Youth Interested in Information

- 56.6% What will I eat after the operation?
- 54% When will I get to go home?
- 51.8% Will the doctor tell me about the operation and what it will be like when I go home?
- 51.8% What am I allowed to eat before and after the operation
- 47.8% How long will I be asleep for?

Fortier et al. 2009

---

---

---

---

---

---

---

---

## Youth and Informed Consent

- 88 youth
- Most youth (88%) reported having the IC process occur in front of them
- Less (84%) reported participation in the IC process

Jubbal et al. JPGN 2015

---

---

---

---

---

---

---

---

## Youth and Informed Consent

- 77% youth reported a desire to participate in the IC process for pediatric endoscopy
- Of these, 77% believed they should receive all the information regarding the procedure to make their decision

Jubbal et al. JPGN 2015

---

---

---

---

---

---

---

---

## Research to Date

- Few studies in the literature
- Inadequate sharing of information between patients and providers
- Suboptimal patient understanding of shared information as required for informed consent

---

---

---

---

---

---

---

---

## Adult IC Comprehension Screening Colonoscopy

- A telephone survey of 98 patients scheduled for a screening colonoscopy
- Assessed knowledge of procedural benefits, risks, and alternatives
- ~91% described the purpose of screening colonoscopy
- 48% could name one risk
- 24.5% could name one approved alternative test

Schwartz, 2013

---

---

---

---

---

---

---

---

## Youth & Parental IC Comprehension Pediatric Endoscopy

- We performed an oral survey in 88 youth undergoing endoscopy and their parents following the IC process
- Demonstrated poor comprehension of key IC elements

Jubbal et al, JPGN 2015

---

---

---

---

---

---

---

---

## Youth & Parental IC Comprehension Pediatric Endoscopy

- Suboptimal youth understanding was demonstrated
  - nature of the procedure 25%
  - related risks 17%
  - alternatives 14% to the procedure
- Youth overall understanding of IC varied by age

Jubbal et al, JPGN 2015

---

---

---

---

---

---

---

---

---

---

## Youth & Parental IC Comprehension Pediatric Endoscopy

- Suboptimal parental understanding was demonstrated
  - alternatives 14% to the procedure
- Parental global understanding of IC varied by physician

Jubbal et al, JPGN 2015

---

---

---

---

---

---

---

---

---

---

## Informed Consent MOC – Data Entry 1

1. Average compliance % with IC performance in the patient's desired language	99.8%
2. Average compliance % with patient's discussion regarding <b>alternatives</b> during IC	66.7%
3. Average compliance % with patient discussion regarding <b>benefits</b> during IC	98.0%
4. Average compliance % with patient discussion regarding <b>risks</b> during IC	97.8%
5. Average compliance % with patient discussion regarding <b>risk management</b> during IC	84.7%
6. Average performance % of obtaining pediatric <b>assent</b> during IC	77.8%
7. Average compliance % with informing patients regarding <b>trainee involvement</b>	46.5%

---

---

---

---

---

---

---

---

---

---

## How to Improve?

- Aids
  - Visual
  - Written information
  - Literacy
- Teach-back and Teach-to-Goal
- Technology

---

---

---

---

---

---

---

---

## Optimizing the Consent Message

- 640 parents of children undergoing surgery randomized to receive information in consent documents with various edits to improve understanding
- Consent documents with high processability, 8<sup>th</sup> grade reading level and graphics resulted in greater understanding

Tait, 2013

---

---

---

---

---

---

---

---

## Optimizing the Consent Message

- 121 consecutive trauma patients randomized to receive structured verbal information +/- written information at time of surgical consent
- Recall of risks discussed was significantly improved in those receiving written information (p=0.0014)
- 90% of patients preferred both written and verbal information v. verbal alone

Smith, 2012

---

---

---

---

---

---

---

---

## Optimizing the Consent Message

- Systematic review of studies to improve IC comprehension in low literacy subjects
- Studies w human-human interactions with subjects achieved the highest level of comprehension

Tamariz, 2012

---

---

---

---

---

---

---

---

## Teach Back Method

- Participants are asked to recall or explain in their own words what has been discussed
- Techniques recommended to enhance communication and confirm understanding, particularly among persons with limited literacy skills

---

---

---

---

---

---

---

---

## Technology

- Increasing use of media with ubiquity of mobile devices
- Particular opportunity with youth with great uptake of technology

---

---

---

---

---

---

---

---

## Video Enhanced IC

- 77 pairs of children undergoing endoscopy and their parents recruited RCT
- Intervention: video + IC process
- Control: IC process alone

Yeh et al, unpublished

---

---

---

---

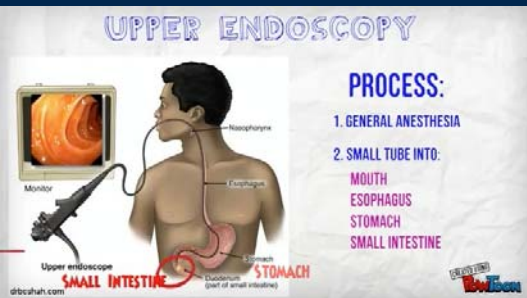
---

---

---

---

## Video



---

---

---

---

---

---

---

---

## Video



---

---

---

---

---

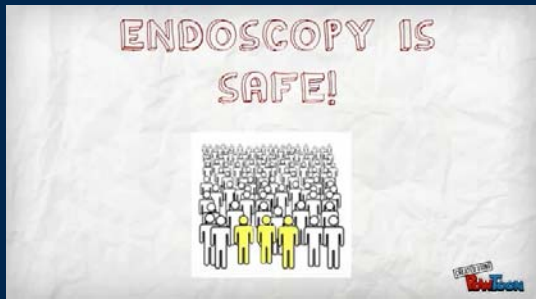
---

---

---



## Video



---

---

---

---

---

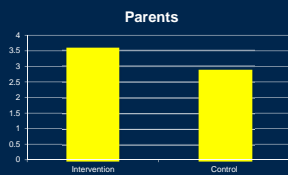
---

---

---

## Results

- Intervention parents demonstrated higher IC comprehension scores (Range 0-4) v. control
  - PARENTS: 3.6 (0.7) v. 2.9 (0.9),  $p < 0.0001$



Yeh et al, unpublished

---

---

---

---

---

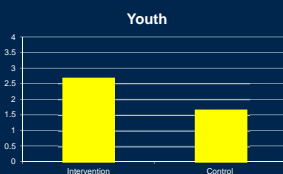
---

---

---

## Results

- Intervention youth demonstrated higher comprehension scores v. controls
  - YOUTH 2.7 (1.1) v. 1.7 (1.1),  $p < 0.0001$



Yeh et al, unpublished

---

---

---

---

---

---

---

---

## Results

- Intervention Parents : higher comprehension scores v. control
  - Risks and alternatives to the procedure
- Intervention Youth : higher comprehension scores v. control
  - Nature and risks of the procedure

Yeh et al, unpublished

---

---

---

---

---

---

---

---

## The next steps

- Opportunities for improvement exist
- MOC activity focused on informed consent



### MODULE: Informed Consent

This module will provide the registrant with **25 points** towards MOC Part IV (a minimum of 40 points is required to meet requirements during a given cycle). **Always check your specific MOC requirements on your ABP profile** in order to be familiar with your specific situation.

**TIME REQUIREMENT:** Minimum of 4 months to complete.

**READ AND FOLLOW ALL DIRECTIONS BELOW TO RECEIVE CREDIT.**

---

---

---

---

---

---

---

---

## Summary

- Informed Consent is a necessary part and requirement of procedural practice
- Variation in informed consent practices exists
- Consider performance of evidence based methods to improve understanding

---

---

---

---

---

---

---

---