



When is Informed Consent Truly Informed?

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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

Legal Requirement

- Statutes and case law in all 50 states
- 1st 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 alternatives during IC	66.7%
3. Average compliance % with patient discussion regarding benefits during IC	98.0%
4. Average compliance % with patient discussion regarding risks during IC	97.8%
5. Average compliance % with patient discussion regarding risk management during IC	84.7%
6. Average performance % of obtaining pediatric assent during IC	77.8%
7. Average compliance % with informing patients regarding trainee involvement	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, 8th 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

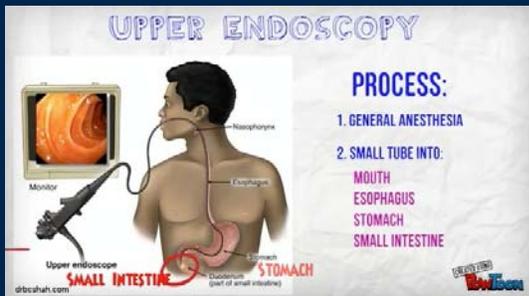


Video Enhanced IC

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

Yeh et al, unpublished

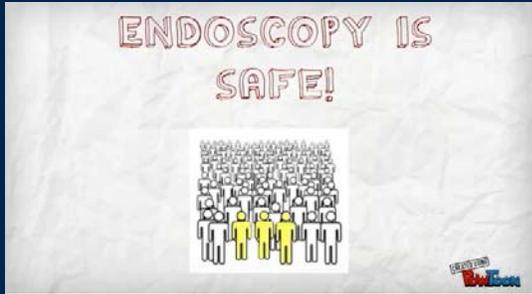
Video



Video



Video



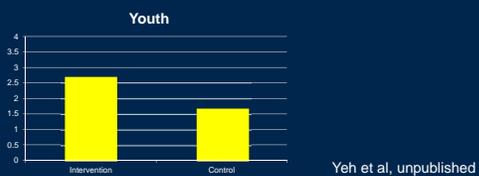
Results

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



Results

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



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
