NEW DEVELOPMENTS IN INFORMED CONSENT

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Shared Decision Making
the Essence of Informed Consent (IC)

- Ethical vs. legal approach to IC
- Louisiana law gives physicians the presumption of having obtained informed consent provided statutory requirements are followed
- Presumption may be lost if
  - Current lists of material risks are not maintained
  - Physician fails to communicate risks/benefits/alternatives
- Modern era of patient centered medicine
  - Shared decision making
    - Contemplates MD/patient discussion re specific complications due to patient’s co-morbid condition or cultural issues
Informed Consent Fundamentals

- Informed Consent Discussion
  - Consent obtained by the MD who is performing procedure
  - Best for MD to sign at same time as patient
  - Describe procedure and purpose
  - State alternatives, including doing nothing
  - Explain risks & benefits
  - Elicit patient’s questions/concerns
  - MD answers all questions
  - Document this discussion

Informed Consent 2013

- Informed consent may be either expressed or implied
- To grant informed consent the patient must
  - Possess reasonably complete information about proposed treatment
  - Informed about the risks, benefits, and acceptable alternative methods of treatment
  - Consequences of not consenting
- Without this information the patient’s consent is not informed

Informed Consent Case Law

- Case law demonstrates the trend of courts moving away from doctor centered healthcare toward patient centered healthcare especially as it relates to communicating risks, benefits and alternatives
- “The courts are interested in increasing communication between physicians and their patients and in emphasizing the competent individual’s freedom of choice.” (Showalter, 2007)

Keys to Patient Centered Medicine

- Communication and education
- Shared decision making
  - Discussion of risks especially important if the occurrence of a specific risk would be particularly detrimental to a patient
  - Example: Professional singer contemplating consent to anterior cervical fusion
    - Should the risk of vocal cord paralysis occur it would destroy his/her career
Informed Consent Case Study

• **Internal Medicine Physician**
  • Failure to inform
    • Risks associated with medicine, i.e. significant side effects
      • Drug involved in class action claim
    • Internal Medicine physician settles case
  • **Take away**
    • Patients have legal right to know about material risks involved in their medical care
    • Especially important for GP, FP, and Internal Medicine physicians
      • Relative to informed refusal
        • More to follow

Informed Consent Case Study

• **Surgeon**
  • Failure to inform patient regarding alternative procedure
    • Patient later claimed he would not have consented to extensive procedure had he known about the more conservative alternative
      • *Bang v. Miller Hospital*
        • Transurethral resection vs. more conservative interventions with lower probability of successful medical outcome but lower risk potential
  • **Take away**
    • Patients have legal right to know about risks, benefits
    • As well as risks and benefits of any alternatives to proposed procedure
      • This includes the alternative of doing nothing
• The Etiology of Informed Consent in Medicine
  • Ethics/social philosophy
  • Legal doctrine
  • Regulatory rules/guidelines
  • Hospital bylaws, etc

• Ethics/social philosophy
  • 19th Century John Stuart Mill
  • That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right. Over himself, over his own body and mind, the individual is sovereign.”

Sources of Informed Consent Theory

• Legal doctrine—Case Law
  • Justice Cardozo, 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.”

• Common Law
  • Recognizes the innate right of self-determination
  • Louisiana civil law accepts this common law principle

Who determines “material risk”?  

• Reasonable Doctor Rule
  • Two 1960 cases established reasonable doctor rule
    • Physician must disclose those risks that a reasonable doctor would disclose under the circumstances.
      • Requires expert testimony at trial to establish what should have been disclosed
      • Non medical jury then decides
  • In Mitchell Missouri Supreme Court held
    • Patient should have been informed
      • Convulsions associated with electroshock
Who determines “material risk”?

- Reasonable Patient Rule
- Courts began rejecting the reasonable doctor rule in the 1970s in favor of the reasonable patient rule
  - *Wilkinson v. Versey* 1972 RI Supreme Court held
    - The patient was entitled to know all "material" (important) information, regardless of how much other physicians usually tell their patients.
    - What the patient needs to know to make an intelligent choice is a question for laypeople (the jury) to decide.
    - Expert testimony no longer required

How Much Disclosure?

- How much do I tell the patient?
  - Is the patient likely to be unaware of a known hazard or risk?
  - Would a reasonable and prudent patient be likely to withhold consent if aware of the risk?
  - Is there any acceptable justification for failing to disclose?
  - Is the risk or hazard, however remote, material to the patient’s decision? (Showalter)
- Lay jury decides if the MD fully informed patient
  - Rationale for Louisiana’s Medical Disclosure law
  - Rationale for shared decision making
Informed Refusal

- Informed Refusal—GP/FM—Case history
- *Truman v. Thomas 1980*
  - Young female being treated by general practitioner six years
  - Patient refused Pap test
  - Physician did not specifically advise patient re risk of failing to have Pap test
  - Specialist eventually diagnosed cervical cancer
  - California Supreme Court held that the physician had a duty to disclose all relevant and material information, including the risks of refusing recommended care
- RM Hint: Document & have patient sign

Medical Literacy

- Patient signed a general consent form stating that she was consenting to a bilateral salpingo-oophorectomy.
- Question
  - How many lay people know that this means the patient would not be able to have children subsequent to the procedure?
Medical Literacy

- A study of 5 informed consent forms
  - Four were written on the level of a scientific journal
  - One was written on the level of specialized academic magazine
  - On a readability scale: 0 to 10 with 0 being most difficult
  - Score = 1.5
- Informed consent requires more than a mere signature on a consent form
  - Signature should document shared decision

*Brenner, Beyond Informed Consent: Educating the Patient, 2009*

Same Outcome, 2 different opinions

- Orthopedist—medical perspective
  - Successful surgical procedure
  - Uncomplicated post op period
  - Discharged to home
- Patient—psycho-social perspective
  - Terrible outcome
  - “I can no longer bike with my friends.”
Be Realistic

- Be realistic about recovery time and post op activity
  - A magazine editor underwent valve replacement
  - Pre-op surgeon said he would “stretch sternum” to get to heart, scar would be “a few inches long,”
  - OK’d patient’s plan to go to Spain in three weeks
  - “I never guessed that the stretching would be done with a saw, that the scar would measure ten inches and that Spain would be out of the question.” NY Times, 8/8/2010

From Reasonable Physician to Reasonable Patient

- Courts now favor reasonable patient rule re disclosing risks/benefits
- Louisiana’s Disclosure Panel lists consist of risks established primarily by physicians
  - Reasonable doctor vs. reasonable patient
  - Disclose risks that would be material to a reasonable patient—Hondroulis, LA Supreme Court
- Rationale for making IC process a shared decision making process
Shared decision making

- Three elements of shared decision making
  1. The medical evidence
  2. The clinician’s expertise
  3. The patient’s goals and concerns
- Patients want
  1. To know their options, the risks of each option, and to discuss the option of doing nothing
  2. Their care coordinated—“Who is in charge of my care?”
  3. To be more engaged with their MD—communication
  4. Shared decision making

*IOM Evidence Communication Innovation Collaborative, 2012*

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Shared decision making

- Shared decision making helps avoid unrealistic expectations
  - Recent study of patients after IC process
  - Elective diagnostic cardiac catheterization with possible percutaneous coronary intervention
  - 88% had mistaken beliefs about the benefits of the procedure
- Informed Consent is more than getting a form signed
  - It is a process in which the physician and patient share information, goals, concerns and make decisions

*Schenker, Meisel, Informed Consent in Clinical Care, JAMA 2011*
Risk Management Recommendations

RM Hints for better patient understanding

1. Use “teach-back” technique
   • VA study demonstrated significant improvement of patient’s comprehension with teach-back technique
   • Only increase MD/patient contact time by 4 minutes

2. Timing matters
   • IC process often occurs after the decision to perform procedure has already been made
   • Patient has little time to consider risks/benefits/alternatives

3. Technology helpful but not substitute for physician

Hondroulis vs. Schuhmacher 1989

• Results of Court Decision
  • “It is obvious that a risk must have been understandably communicated before the element of awareness can be established.”
  • “Awareness requires that specific risks have been communicated in fact.”
  • Rejection of “reasonable physician” rule to determine what risks should be disclosed
  • Adoption of “reasonable patient” rule
## Hondroulis vs. Schuhmacher 1989

- Results of Court Decision
- Major confusion/concern among physicians
  - How much information should I disclose?
  - How do I determine if the risk is material?
  - How do I determine if the language I used to describe the risks was appropriate for a specific patient?
  - How do I document all of the above?
- Answers to be provided by lay jury!

## Enter the La. Medical Disclosure Panel, 1991

- Correcting *Hondroulis*
- Amended La. R.S. 40:1299.40
  - Added subsection E relating to use of Louisiana Medical Disclosure Panel lists
  - “Shall create a rebuttable presumption that the requirements …have been complied with and this presumption shall be included in the charge to the jury”
  - “The failure to disclose the risks…rebuttable presumption of a negligent failure …”
Enter the La. Medical Disclosure Panel, 1991

- Correcting *Hondroulis*
- Net effect
  - Use of list of risks identified by La. Medical Disclosure Panel gives presumption of IC
    - Objective standard
    - But—must add specific risks arising due to patient’s condition
    - Physician doing procedure must provide information
    - Risk/benefit of alternatives discussed
    - Provide patient with opportunity to ask questions
- Shared decision making opportunity
  - Enhance MD/patient rapport

What happened?

- Act 815 (2008 Regular Session)
- Included in the “housekeeping” changes
  - Abolished the Louisiana Medical Disclosure Panel (MDP)
  - Transferred the responsibility of updating and maintaining the medical disclosure lists to the Secretary of the Department of Health and Hospitals
- Why?
  - The MDP last met in 1999—Inactive!
House Bill No. 866

- House Bill No. 866 of the 2012 Regular Legislative Session was introduced
- Revised the Medical Disclosure Panel removing the duty to promulgate list of risks from the DHH and returning it to the newly constituted Disclosure Panel
- Allowed meetings via electronic means

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Louisiana Law

- “The physician…who will actually perform the contemplated medical or surgical procedure shall:
  1. Disclose the risks and benefits in the form and to the degree required by the panel,
  2. Disclose additional risks, if any, particular to a patient because of a complicating medical condition, either told to the physician or other health care provider by the patient or his representative in a medical history of the patient or reasonably discoverable by such physician or other health care provider.
  3. Disclose reasonable therapeutic alternatives and risks associated with such alternatives.”
Louisiana Law

• Section E of the Uniform Consent Law
  • Presumes shared decision making process took place
    • Patient and physician discussed rationale for procedure
    • Physician provided patient with medical advice which included physician’s opinion as to the better alternative from the medical perspective
    • Physician implicitly acknowledges patient’s cultural values and goals in making his/her informed decision regarding recommended medical/surgical intervention
  • Signed IC Form
    • Documentation that shared decision making was completed

Louisiana Disclosure Panel

• Keeping our IC statute—your part
• Review identified risks in your specialty
  • Are they current?
  • Should new procedures be added?
  • Consider instituting a specialty society IC committee and reviewing identified risks at the annual meeting
• Send results/recommendations to Secretary DHH and to members of the Disclosure Panel
• Make IC a shared decision making process
Summary

- Informed consent is more than obtaining the patient’s signature on the consent form
- To be legally binding the consent must have been obtained from an informed patient
- Shared decision making is the key to obtaining legally effective informed consent regardless of what consent form is used
- The material risks list must be reviewed & updated
- Current lists and shared decision making are primary keys to maintaining constitutionally valid IC statute