Getting Informed About Informed Consent

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Shannon has more than 20 years of experience in patient safety and risk management. Her background includes clinical experience in labor and delivery as well as outpatient women’s services. For the last 12 years, her focus has been quality, risk management, and patient safety.

Shannon’s experiences as the risk manager for a community hospital in Florida and as a patient safety consultant have made her adept at developing loss prevention strategies, devising performance improvement activities, and leading quality initiatives. These opportunities have offered Shannon valuable insight into the challenges of providing quality care in the current healthcare landscape and have provided her with extensive experience conducting site surveys, leading root cause analysis teams, and providing consultative risk management guidance.

Shannon earned a bachelor of science degree in nursing from Jacksonville University and a master’s degree in healthcare administration from Ohio University. She is a member of the American Society of Healthcare Risk Managers and is a Certified Professional in Healthcare Risk Management.
At the conclusion of this program, participants should be able to:

- Articulate key elements of a thorough informed consent process
- Know the value of and difference between a consent form and an informed consent discussion
- Discuss the benefits of a separate anesthesia consent form
- Understand the risks of a poor informed consent process

Informed consent - the Impetus
• Consumer focus
• Regulatory
  • CMS
  • Florida
  • FDA

• Accreditation
  • TJC
  • DNV
  • HFAP

• Case Law / Liability

• Engaged and informed patients

**Consents Continue to Pose Problems**

• Late identification of deteriorating vitals signs and delayed resuscitation efforts

• Inconsistent documentation of the dose of Propofol administered to Ms. Rivers

• **Failure to obtain Ms. Rivers’ informed consent for all procedures performed.** While Ms. Rivers went to the clinic for an endoscopy but also received a laryngoscopy, for which there was no documentation of consent.

• Allowing an unprivileged provider to administer care to Ms. Rivers

• Neither Ms. Rivers nor the clinic authorized the use of the phone or the photo (HIPAA).

• Failure to record Ms. Rivers’ weight prior to sedation
Florida Law

- A general understanding of the procedure;
- Medically acceptable alternative procedures or treatments;
- Risks and hazards inherent in the proposed treatment or procedures, which are recognized among other physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, or dentists in the same or similar community who perform similar treatments or procedures;
- In accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community as that of the person treating, examining, or operating on the patient for whom the consent is obtained;
- Consent is considered valid when evidenced in writing, signed by the patient or another authorized person and meets the requirements as noted above.
Non-delegable physician duty.
Florida law is devoid of any mention that someone other than designated individuals may be designated to obtain consent.

Florida Statute, §458.331(1)(w), states that delegating professional tasks to an individual who the professional “…knows or has reason to know that such person is not qualified by training, experience, or licensure to perform…” is grounds for disciplinary action by the state board.

Code 15

Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent

Florida Internal Risk Management Program, §395.0197
CMS

• Information must be specific to the patient
  – *The right to make informed decisions means that the patient or patient’s representative is given the information needed in order to make “informed” decisions regarding his/her care.* Interpretive Guidelines §482.13(b)(2)

• Consent must be executed by the patients in writing
  – *Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.* Interpretive Guidelines §482.24(c)(4)(v)

CMS

• Policy
• Form
• Process
• Survey
CMS - POLICY

- Who may obtain consent
- Which procedures
- Circumstances for no consent (emergent circumstances)
- Patient's representative may provide consent
- Content of the form and instructions for completing it
- The process used to obtain informed consent, including documentation
- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery
- Processes when consent is obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient's medical record
- Any state-specific requirements

Interpretive Guidelines §482.51(b)(2) – Surgical Services

CMS - The Form

- Name of the hospital
- Name of the specific procedure(s) or type of medical treatment
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative
- Date/time consent obtained.
- Names and the specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon or other physician.

42CFR482.51(b)(2)
CMS Form cont.

- Name of the practitioner who conducted the informed consent discussion
- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form
- Indication or listing of the material risks of the procedure or treatment that were discussed
- Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible Practitioner
- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

CMS Process and Survey

Process
- Detailed
- The Medical staff has specified which procedures and treatments require written patient consent.
- Role of a resident

Survey
- Review of policies, procedures, forms, and medical records
- Post surgical patient interviews

PA Supreme Court Narrows Informed Consent Requirement

Wednesday, July 5, 2017

“Informed consent requires direct communication between physician and patient, and contemplates a back-and-forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent. The duty to obtain the patient’s informed consent belongs solely to the physician.”

In Focus Blog — Published on: July 17, 2018

Integrating Person-Centered Care and Evidence-Based Research at Hospitals Caring for Vulnerable Populations
Laura Josct

A new road map highlights how to overcome barriers to integrating person-centered care and evidence-based research at hospitals caring for vulnerable populations.

Doctors interrupt after 11 seconds: How to get the most out of your visit
The doctor-patient conversation is an important diagnostic tool, but many physicians are rushing it, a new study confirms.

Cerner Unveils Patient-Centered Tool to Support Value-Based Care
The EHR vendor will partner with health plan Lumeris to create a tool to improve patient-centered care and provider experience in value-based care models.
## Informed Consent “fails”

### Patient

58-year-old diagnosed with sub clavicular mass.

### Summary

Mass was first analyzed with FNA, but unable to obtain adequate specimen. Eventually the patient undergoes a surgical removal of mass located at common junction of cervical nerve root and posterior cord brachial plexus.

### Outcome

Partial dissection of nerve. Patient unable to move arm post-operatively. Patient alleges he asked the surgeon pre-operatively that if the mass involved any nerves, to end the procedure.
Patient comprehension

“Even after signing a consent form, many patients do not fully understand the nature, risks, benefits, and alternatives of their treatments.”

Salome Chitavi, PhD, Project Director
Division of Healthcare Quality Evaluation
The Joint Commission

Poor Consent Form Execution

- Missing
- Lacking specificity
- Missing information
- Illegible writing
- Abbreviations
- Version control
- Provider-to-provider variation
Informed Consent: The Malpractice Experience

**Informed consent: Allegation categories**

- Surgical Treatment: 42%
- Treatment-Related: 36%
- Communication: 3%
- Anesthesia-Related Treatment: 2%

Informed consent: Associated risk factors

- A recognized procedural complication is not unexpected, but combined with inadequate consent, a claim often results.
- Failure to document relevant details of the informed consent discussion is frequently problematic.
- Failure to select the most appropriate treatment for a patient’s condition is often seen in these claims.
- Failure to adequately assess the patient — pretreatment & posttreatment — is often linked to deficiencies in the consent process.
- Patient noncompliance and dissatisfaction with care contribute to claim allegations.

What is Informed Consent?
“It was case law that introduced the concept of informed consent to medicine in the twentieth century using the language of ‘self-determination.’ Shortly thereafter informed consent was transformed into a social context beyond the law from a malpractice issue to a moral duty incumbent on physicians.”


“According to the American Medical Association, ‘Informed consent is a basic policy in both ethics and law that physicians must honor . . .’ The process involves multiple elements, including disclosure, comprehension, voluntary choice, and authorization.”

Discussion of the risks, benefits, alternatives/options, as well as the risks of withholding treatment.

An opportunity for the patient to ask questions and receive answers to his/her satisfaction.

Documentation in the patient’s health record of all of the above details.
Responsibility for consent

Provider
- Generally, this is a nondelegable duty.
- Individual performing the procedure has the obligation to conduct the consent discussion.

Staff
- Staff may reinforce the information shared by the provider.
- Staff may provide supplemental educational information, resources, etc.

Considerations in consent

<table>
<thead>
<tr>
<th>Adequate information</th>
<th>Voluntary decision</th>
<th>Capacity to decide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>Understand right to choose</td>
<td>Able to communicate clearly?</td>
</tr>
<tr>
<td>Risks and benefits</td>
<td>Influences on ability to choose (illness?)</td>
<td>Understand the information given?</td>
</tr>
<tr>
<td>Implications for future choices</td>
<td>Emotional or mental issues</td>
<td>Able to reason using the information?</td>
</tr>
<tr>
<td></td>
<td>Religious or cultural influences</td>
<td>Appreciate implications of the decision?</td>
</tr>
<tr>
<td></td>
<td>Situational influences</td>
<td></td>
</tr>
</tbody>
</table>
Let’s Talk About Capacity!

- Competency is a global assessment and legal determination made by a judge in court.

- Capacity is a functional assessment and a clinical determination about a specific decision that can be made by any clinician familiar with a patient’s case.

Capacity Continued...

- Medical capacity can be determined by the use of the four-point test, which asks whether:

  1. The patient understands the nature of the intervention.
  2. The patient understands the consequences of the decision (especially refusal of treatment).
  3. The patient is able to communicate his/her wishes.
  4. Those wishes are compatible with the patient’s known values.
**Health Care Surrogate**

- Health Care Surrogate/alternate decision maker Florida statute 765.101: witnessed written document or oral statements in which instructions are given by principal expressing their desires concerning any aspect of the principal's health care or health information, including but not limited to: designating a health care surrogate, a living will, or an anatomical gift...
- If capacity is questioned it should be evaluated by another physician. If incapacity is determined, the healthcare surrogate should be contacted to make decisions for the patient

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**No Health Care Surrogate...**

- 765.401. The Proxy.
- (1) If an incapacitated patient has not executed an advance directive or designated a surrogate to execute an advanced directive (or surrogate is no longer available to make healthcare decisions), health-care decisions may be made in the following order of priority:
  - Judicially appointed guardian
  - Patient's spouse
  - Patient's parent
  - Adult sibling. If more than one, a majority of adult siblings available for consultation.
  - Adult relative who has exhibited special care/concern for patient and who has maintained regular contact with patient.
  - Close friend
  - Clinical social worker selected by provider's bioethics committee.
Consent is not required in medical emergencies

- Criteria for a medical emergency:
  - Patient is incapacitated and “unable to reach an informed choice”
  - Incapacitation may be due to:
    - Injury or sudden illness
    - Alcohol or drug intoxication
    - Shock or trauma
    - Underlying mental or physical disease or handicap barring a reasoned choice
  - Patient must have life-threatening disease or injury requiring immediate treatment

Is consent always necessary?


Failure to obtain consent — potential consequences

- Potential allegation of battery (criminal offense)
- Unexpected outcome — patient unprepared for results
- Civil liability
  May be in violation of (a) state statutes/regulations, (b) organizational policies and procedures, or (c) governing professional bodies’ ethics (AMA, ADA, etc.)
What medical situations should involve consent?

- Surgery
- Anesthesia
- Medications
- Noninvasive treatments
- Treatment of chronic conditions
- Human subjects research
- Vaccines

A Separate Anesthesia Consent?

- Delivery of safe anesthesia care is a challenging process, and we should engage our patients as partners in their care to ensure the best outcome. An informed consent empowers the patient to have a greater involvement in his or her own health-care decisions and improves satisfaction. It is not acceptable that a surgical team member obtains consent for anesthesia. Anesthesiologists need to do this to ensure that the patient is fully informed of the process, risks, benefits, and alternatives.
In most states, minors can consent to:

- Contraceptive services
- Sexually transmitted infections services
- Prenatal care
- Adoption
- Medical care for a child
- Confidentiality of health record for these services


Risk strategies
Personalized Content: Procedure and Patient

“There is an important ethical mandate, beyond the legal mandate, of informing patients about their risk and to engage them in choosing therapy aligned with their own personal goals and values.”

Dr. John Spertus
Mid-American Heart Institute,
Co-Developer of PRISM

“Patients cannot make an informed decision about their own risks or benefits with any given therapy based solely on population-wide data. They need estimates based on their own unique characteristics.”

Reed Miller
Customized Informed Consent Improves Communication
(Medscape, November 15, 2011)

E-Consent

• Improves legibility, consistency and understanding

• Supplement or replace paper-based informed consent processes

• The responsibility remains with the physician

• Allow patients the time to ask questions

• Interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narration can assist the patient in understanding the material.

• Improved versioning and documentation
Allow time between the informed consent discussion and the proposed procedure for:

- Comprehending
- Seeking answers to questions
- Researching proposed procedure using:
  - Websites
  - Practice handouts
  - CDs, DVDs, etc.

Document the informed consent discussion

The quality, not the quantity, of the documentation is important

- Entry should be objective, factual, and concise

Record essential elements: RBAC

- Risks
- Benefits
- Alternatives
- Consequences of doing nothing

Document patient’s understanding

Note questions that the patient asked

- How were these questions answered?
- Was the patient satisfied with the responses?

Other considerations

- Mention educational pieces given to patient to reinforce consent process
- Note patient refusal of proposed treatment and reasons given
Recommendations

- Establish policies and procedures for obtaining informed consent outside your walls.
- Ensure that you have a policy and process to document consent for multiple procedures or concurrent procedures.
- Policies and procedures should require the identification and role of residents or vendors.
- Ensure that you obtain and document consent for foreseeable or “possible” procedures that may be performed based on intraoperative findings.

Next Steps

- Conduct an informed consent audit by randomly sampling charts of procedures that required informed consent.
- Consider implementation of “teach back” methodology.
- Ensure compliance with state laws and federal regulations.
- Know how to respond to informed refusal (revocation/withdrawal).
- Evaluate computer-assisted informed consent tools to enhance, improve, and standardize the informed consent process.
- Explore innovative resources to better educate patients in the decision making process.
RESOURCES

- A Practical Guide to Informed Consent (Temple University Health System)
- AMA Code of Medical Ethics, Chapter 2: Opinions on Consent, Communication & Decision Making (American Medical Association)
- An Overview of Minors’ Consent Law (Guttmacher Institute)
- Clear Communication (National Institutes of Health, U.S. Department of Health and Human Services)
- Consent in Adolescent Health Care (UpToDate)
- Culture, Language and Health Literacy (Health Resources and Services Administration, U.S. Department of Health and Human Services)
- Health Literacy (Centers for Disease Control and Prevention)
- Health Literacy Online (Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services)

RESOURCES CONT.

- Health Literacy Resources for Healthcare Professionals (University of Maryland, School of Public Health, Horowitz Center for Health Literacy)
- Informed Consent for Anesthesia Care (American Association of Nurse Anesthetists)
- Informed Consent: More Than Getting A Signature (The Joint Commission)
- The Legal Authority of Mature Minors to Consent to General Medical Treatment (Pediatrics, Volume 131, Issue 4)
- Minor’s Rights Versus Parental Rights: Review of Legal Issues in Adolescent Health Care (Medscape)
- Toolkit for Making Written Material Clear and Effective (Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services)
Comments and questions?