An Enterprise Risk Management Approach to Consent to Treatment

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AGENDA

• Discuss the historic risk management perspective on consent.
• Describe enterprise risk exposures involving flawed consent practices.
• Identify a framework for identifying consent ERM risk exposures.
• Examine how to transform consent to treatment into a powerful loss prevention and patient safety tool.
HISTORICAL RISK MANAGEMENT PERSPECTIVE ON INFORMED CONSENT

100 Years and Counting

• End Results
  Proprietary Hospital, 1911-1916, Beacon Hill, MA
“Each patient had an end-result card which included presenting symptoms, initial diagnosis prior to treatment, treatment given, in-hospital complications, discharge diagnosis, and the result a year later. These case reports were abstracted and published in the ‘Report of the Hospital’ and made available to prospective patients who might wish to know what the outcome of care had been.”


Consent in Perspective

**Individual Litigation**

- **Battery Theory**
  - Patient vs. Care Provider.

- **Negligence Theory**
  - Patient vs. Care Provider.

- **Negligence Theory**
  - Patient vs. Healthcare Institution.

- **Professional Licensure Action**
  - Going after the care provider’s license to practice.
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Historical Perspective

State legislation with specific consent requirements

- Basis for litigation
- Basis for professional discipline

Historical Risk Management Perspective on Informed Consent

- Liability Concerns
  - 42.2% of all physicians have been sued
  - 89.8% of those General Surgeons age 55 or older
  - 77.1% of those Ob/Gyn’s age 55 or older

History Lessons

Most of the consent cases decided in favor of the care provider

Lack of effective communication.

“Legislating” consent has not stopped litigation

Lack of effective change through individual case law decisions.

Emerging theories of litigation on consent.

ENTERPRISE-WIDE PERSPECTIVE ON INFORMED CONSENT
An ongoing business decision-making process instituted and supported by the healthcare organization’s board of directors, executive administration, and clinical leadership. It has as its goal to assist in the reduction of uncertainty and process variability, promote patient safety and to maximize asset preservation. ERM is about identifying, managing, controlling, and monitoring all risks to the healthcare organization.

Enterprise-Wide on Informed Consent Case Example

- T.C., a sixty-nine year old store owner underwent diagnostic tests that revealed she had a cancerous tumor in her left kidney. After discussing her treatment options, T.C. agreed to removal of the kidney. Dr. Rebert, the surgeon told T.C. that once the pathologist’s report was back they would discuss next steps.

- T.C. signed a consent form that described total removal of the left kidney.

The Case of T.C.

- T.C. completed a pre-op work-up with an anesthesia provider at the hospital. On the paperwork, the indication was a right nephrectomy.

- During the time out process, Dr. Rebert told the team, “Okay. So I am assuming you have done everything on the list. Let’s get started.”

- Surprised by the doctor’s attitude, no one picked up on the discrepancy. Dr. Rebert removed T.C.’s healthy right kidney.
The T.C. Case

- Dr. Rebert was shocked when he read the pathologist report. It was when he reviewed pre-op paperwork that he realized what had happened.

- Dr. Rebert apologized to T.C. and said that “Somehow there had been a mistake.”

- Because the patient had cancer, she was barred from being a kidney transplant recipient.

ERM Consent Risk Exposure

- Hospital Negligence Lawsuit
- National Coverage Determination
- Immediate Jeopardy
- Licensure Action
- Loss of Market Share
- Adverse Publicity
- Professional Disciplinary Action
- Negligent Consent Litigation
“This is the third time Dr. Rebert failed to follow the time out procedure. Enough is enough.”

What is it with him? Doesn’t he read the consent forms before starting a procedure?”

“He was warned after the FPPE.”

“Get the notice letter ready. I will talk with the Chairman of the Board. We have got to revoke his privileges.”

A wrong-site surgery event will reach a patient once per year in a 300-bed hospital.

Failure to verify consent forms was a major contributor to errors.

Enterprise-Wide Perspective
Informed Consent-Reimbursement

- National Coverage Determination
  - 140.6 Wrong Procedure
  - 140.7 Wrong Site
  - 140.8 Wrong Patient

CONSENT PROCESS AUDIT
Consent Process Audit - I

- Evaluate the current consent communication process.
- Is it consistent with policy, procedure, and applicable law?
- Is it patient-centered and family focused?
- Identify the areas for improvement.

Consent Process Audit - II

- Evaluate care provider consent process.
- Evaluate when consent documentation is completed.
- Determine who is managing the consent process.
- Determine if there is a process for managing exceptional situations.
- Determine if there is a process for handling patients undergoing ongoing or repetitive procedures.
STRATEGIES FOR IMPROVEMENT

• Prior to beginning the informed consent process, conduct a Time Out.

• Best if supported by policy with a written procedure.

Strategies for Improvement – Consent Time Out

- Auditory analysis
- Vision assessment
- Speech analysis
- Physical assessment
  - Sign documents?
- Cognitive analysis
  - Medications?
  - Extra time required?
- Language needs
- Cultural Concerns
- Health literacy
- Family participation
- Functional learning

Strategies for Improvement – NQF Safe Practice 5

- Ask each patient or legal surrogate to “teach back,” in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.
Strategies for Improvement – NQF Safe Practice 5

- The latest evidence – a randomized controlled trial of “teach back” (“repeat back”)
  - 575 patients
  - 7 sites


Strategies for Improvement – NQF Safe Practice 5

- Two arms:
  - An automated informed consent software application that produces detailed, procedure-specific consent forms.
  - The same system with a series of six repeat-back (teach-back) prompts based on NQF-recommended language and a mechanism for documenting the patient’s response.
Strategies for Improvement – NQF Safe Practice 5

• Results:

  • Significantly higher patient comprehension in the group exposed to repeat-back.

  • The repeat-back process took only 2.6 additional minutes on average.

Strategies for Improvement – WHO Surgical Safety Checklist

**Surgical Safety Checklist (First Edition)**

- Before induction of anesthesia
- Before skin incision
- Before patient leaves operating room

**Sign In**
- Operative or procedure team members have introduced themselves by name and role
- Surgical anesthesia, professional, and patient are concurred on date, site, and procedure
- Authorized official events
- All members of the operative or procedure team, using their full names, are concurred on date, site, and procedure
- All surgical/procedural equipment has been gathered within the last 12 hours
- Actual, intended, and expected access and closure plans

**Time Out**
- The name of the procedure recorded
- That instrument, sponge, and needle counts are correct and set
- Any required emergency equipment to be assessed
- Any unexpected personnel, equipment or orders for the success of the procedure

**Sign Out**
- The patient and family are informed of the planned care

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The American College of Surgeons’ recommended consent template:

- Sign In
- Time Out
- Sign Out
Opportunity to bring the patient’s understanding of his or her treatment or procedure into the Time Out.
Enterprise Consent

Consent is a TWO-WAY communications process

Enterprise Consent Lessons

- Patient Engagement.
- Medical History.
- Discussion of recommended and alternate care: medical, surgical, or watchful waiting.
- Set expectations of care.
- Teach back.

Document the consent process in a substantive manner to avoid a host of enterprise risk exposures.
Enterprise-Wide on Informed Consent Case Example

- A 65-year old woman was evaluated for pain and stiffness in the ring finger of the left hand.
- Dexamethasone was injected locally.
- Eight weeks later there was no improvement and informed consent was obtained for a release of trigger-finger procedure.


The Case of the Trigger Finger Release

- One hour before the procedure Dr. Ring, the surgeon, translated the preoperative preparation for the patient because no Spanish-speaking interpreter was available. Dr. Ring confirmed the persistent trigger-finger of the left ring finger with the patient.
- Dr. Ring then left to perform an extremely challenging carpal-tunnel release procedure on a different patient. That patient was very agitated both before and after the procedure. Dr. Ring told himself that the next operation would be “the best carpal-tunnel release that I have ever performed.”
The Case of the Trigger Finger Release

- Delays by other surgeons caused a change in the operating room and in the operating room staff, including the nurse who had performed the preoperative assessment on the patient scheduled for the trigger-finger release procedure.
- When Dr. Ring arrived at the OR, the patient was already prepped. Dr. Ring spoke briefly with the patient in Spanish – that conversation was believed by the OR staff to be a time-out.
- No formal time-out took place.

The Case of the Trigger Finger Release

- Dr. Ring performed an uneventful carpal-tunnel release on the patient.
- 15 minutes later, when dictating the report of the procedure, Dr. Ring realized the error.
- Dr. Ring immediately apologized to the patient and offered to perform the correct procedure.
- The staff was reassembled and the trigger-finger release procedure was performed without complication.
A Final Lesson Learned From the Trigger Finger Case

Consent is a communications process that when completed properly and documented effectively can help avoid needless medical malpractice litigation while enhancing patient safety.