Informed Consent: The Role Of the Medical Practice Staff

March 2009
Today’s moderator

Theresa N. Essick, RN, CPHRM
Clinical Risk Management Leader

- Ms. Essick has 30 years of experience in the healthcare industry and has a broad understanding of the unique obstacles that providers must address on a daily basis. During her years as a consultant, Theresa became an expert in implementation of electronic records in physicians’ offices and industrial health issues, including workers’ compensation and wellness program development.

- Ms. Essick has held a registered nurse license in North Carolina and Georgia during the course of her career. She is a member of the American Society for Healthcare Risk Management, the North Carolina Society for Healthcare Risk Management and earned her designation as a Certified Professional in Healthcare Risk Management.
Do you know…

- How to access the PowerPoint presentation being used today?
- How can you use this program for future staff education?
- Are you aware of all the risk resources available to you as a MedPro insured?
Today’s speaker

- As Clinical Risk Management Education Leader, Ms. Roman oversees risk management and quality improvement education for 70,000 physicians and dentists. She has authored over 500 risk management articles, including a chapter on benchmarking published in the Handbook of the American Society for Healthcare Risk Management. Ms. Roman is a nationally-respected speaker on quality improvement and risk. She is editor of Protector, the nation’s oldest risk management newsletter for the health care professions. She also writes/edits risk management content for the company’s award-winning Website: www.medpro.com.

- Ms. Roman holds a bachelor’s degree in journalism and a master’s degree in healthcare risk management. She serves on the American Dental Association’s ad hoc insurance advisory committee and is a past president and current provider of risk management content for the Indiana Society of Healthcare Risk Management. Ms. Roman is a member of the American Medical Writers Association and a member of the American Society for Healthcare Risk Management.
Today’s speaker

Timothy J. Kelly, MS, MBA
Vice President, Dialog Medical

- Mr. Kelly has spent 25 years in the medical device and medical software industries specializing in the areas of patient safety, shared decision-making research, patient monitoring and device-related infections. In addition to his marketing responsibilities, he serves as Dialog Medical’s research liaison in support of studies and investigations including a recently-completed randomized, multi-center study evaluating the impact of “repeat-back” during the informed consent process.

- Mr. Kelly holds master’s degrees in biomedical engineering and in business administration. He has authored numerous articles and papers including an essay on the Joint Commission’s revisions to the Universal Protocol published earlier this year in Hospitals & Health Networks. He holds two U.S. patents.
Program Objectives

- Explain regulatory and ethical foundations of informed consent.
- List the elements of informed consent.
- Differentiate between the physician’s role and the staff’s role in the informed consent process.
- Participate in the development of policies and procedures that support this essential patient safety function.
Ethical Considerations

- Results of an 800-person survey on informed medical decisions.
- Over eighty percent said informed decisions are important because:
  - Better decisions would result.
  - It would give them peace of mind to know they understood their options.
  - It would enable them to have more say in their medical care.

Does Better Informed Consent Enhance Patient Safety?

- Analyzed the factors that contributed to all reported instances of wrong-site/wrong-procedure surgery in the state of Pennsylvania during a 30-month period.

- The two common means for successfully avoiding wrong-site surgery:
  - Intervention by patients and their families.
  - Verification of the consent form.

Regulatory Aspects of Informed Consent

- Revised Universal Protocol – effective January 1, 2009:
  - An “[a]ccurately completed, and signed, procedure consent form” must now be available in the pre-procedure area.
  - The time-out must now address “[a]n accurate procedure consent form.”

Financial Impact of Inadequate Informed Consent

- $150,000 indemnity payment for failure to disclose a non-surgical alternative treatment – Pennsylvania/urology procedure.
- $547,000 indemnity payment for a missing consent form/failure to obtain consent – Maryland/laparoscopic gynecology surgery.
- $1.8 million indemnity payment for failing to disclose/document relevant risks – New Jersey/spinal surgery.
Foundations of Present-Day Informed Consent
Legal Origins of Informed Consent

- Consent was a physician courtesy:
  - 1700s and 1800s.

- Protection against battery:
  - Justice Brown, Appellate Court of Illinois, 1905.¹

- Affirmative duty of disclosure:
  - Courts of California, North Carolina, and Minnesota.²

¹Pratt v. Davis, 118 Ill. App. 161, 1905 WL 1717 (Ill. App. 1 Dist.)
Informed Consent Today

- Spelled out in statutes and case law in ALL 50 states.
Accreditation/Compliance

- CMS Interpretive Guidelines for Informed Consent [§482.51(b)(2)] (revised 4/13/07)

- Applicable for Medicare/Medicaid patients.

- Hospitals are now responsible for ensuring that physicians performing procedures obtain consent in a manner that is consistent with the hospital’s informed consent policy.
Accreditation/Compliance

- Accreditation Standards:
  - Specify that an institution (Hospital, Office-Based Surgery Practice, etc.) must have a policy for informed consent – which procedures, process, how documented, exceptions, surrogates, etc.
  - Specify the exact elements that must be part of the informed consent discussion.

Joint Commission Standard RI.01.03.01 (revised extensively in 2009)
Elements of Informed Consent
How Are We Doing?

- A review of 540 written consent forms, from 157 hospitals, found the necessary elements of informed consent (purpose, risks, benefits, and alternatives) were present in only 26 percent of the documents.

How Are We Doing?

- A review of 89 written consent forms for radical prostatectomy:
  - The potential need for blood transfusion was disclosed on 88.8 percent of the consent forms.
  - HOWEVER, proper consent for blood products was ONLY obtained in 25.8 percent of the cases.
  - 92.1 percent of patients ultimately received a transfusion.

How Are We Doing?

- **Note:**
  - Limited descriptions.
  - Illegible handwriting.
  - Use of unacceptable abbreviations.
Elements of a Well-Designed Informed Consent Process

- **Description** of procedure.
- **Indications** for the proposed treatment.
- **Risks and benefits**.
- **Alternatives**, including risks and benefits.
- **Consequences** of refusing treatment.
- **Who will conduct the procedure/administer anesthesia?**
Roles in the Informed Consent Process
Physician’s Role in Informed Consent

“

It is a process of communication between a patient and physician that results...

“In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient...

Staff’s Role in Informed Consent

- Identify patient concerns and ensure that they are addressed by the physician.

- Document and report:
  - Any/all questions, concerns, or requests for updates.
  - Any/all signs of non-compliance.
  - Any/all indications of dissatisfaction.

- Keep patients informed about the current status of their treatment plans.
Staff’s Role in Informed Consent

- Assist with supplying patient education provided that:
  - Staff training has taken place and has been documented.
  - Education does not involve any component of patient decision-making – that educational discussion is the sole duty of the physician.
Cases in which staff members contributed to informed consent error

- Staff failed to initiate process that would obtain informed consent for pediatric orthopedic surgery. Child sustained nerve damage. Permanent limp. Lawsuit against surgeon was settled before trial.

- Ophthalmologist promised patient self-adjusting lens. Written in consent. Staff discovered that lens was not available in the patient’s size; substituted non-regulating lens, without telling surgeon. Patient sued. Settled before trial.
Cases in which staff members contributed to informed consent error

- Informed consent was in patient’s record but it was a consent for a completely different procedure. Patient had a complication that had not been listed on the incorrect form. Patient given full refund.

- Informed consent was in patient’s chart but had never been signed. Staffer forged patient’s signature. Patient already had a copy of form. Doctor was sued.
Surgeon operates on wrong knee at Miriam Hospital

A doctor at the Miriam Hospital yesterday operated on the wrong knee of a patient undergoing elective surgery, despite the hospital’s increased focus on preventing such wrong-site surgeries.

The surgical team had apparently followed the key safety protocols, including marking the correct knee and pausing to verify the site before operating — but somehow still made the error, according to Dr. Kathleen C. Hittner, hospital president and chief executive officer.

The mistake was first noticed by the patient when she regained consciousness. The hospital then performed the surgery on the correct knee, and the patient is doing well, Hittner said. The patient was scheduled to go home yesterday.
Policies and Procedures That Support an Effective Informed Consent Process
Where To Obtain Consent and How To Document the Process

- Obtain consent in the office vs. in the preoperative holding area.
  - $65,600 reduction in legal expenses.
  - $257,000 reduction in indemnity payments.

- Document the informed consent discussion in a supplemental note.
  - $102,000 reduction in legal expenses.
  - $352,000 reduction in indemnity payments.

Effective Informed Consent Is Crucial When Outcomes Are Not Optimal

“There are two things that you never want to hear from a patient:”

- “Had I known this would occur I would not have chosen to do this.”
- “I wish that I had known about ‘plan B.’”

James Gottesman, MD, practicing urologist (Seattle, WA), founder of Dialog Medical, and a Medical Protective Insured for 14 years.
Enterprise Risk Management

- We need to remind ourselves that the dollars represent loss/injury in patients’ lives.

- Lost dollars are lost to the healthcare system: research, charity care, education for healthcare professionals, prevention of disease, etc.
Evaluate Standardized or Automated Solutions

- Companies offer software tools that produce detailed, procedure-specific consent forms.

Review Your Current Informed Consent Process

- Procedures:
  - Do you have them, are you following them?
  - What are your resources?

- Audit your forms – on a regular basis!
  - Review for completeness.
  - Check consistency provider-to-provider.
  - Confirm signatures and dates.

- Evaluate your workflow.
  - Where are you obtaining consent?

- Are there supplemental notes in the chart?
What Can You Accomplish Immediately?

- Typical procedure involving laterality.
What Can You Accomplish Immediately?

- Add two “blanks” to your consent form.
I understand that this consent and release should be read before signing, and I have read and understand this document.

Timothy J. Kelly

Signature of Patient

Please Print Full Name of Patient

1/2/06 4:50am

Date

1/28

Time 8:41

A.M. P.M.

Witness:

Procedure: Internal fixation with 3 or 4 screws of femoral neck fracture (preference is for 3 screws)

Location: Right Hip
Suggested Resources

- CMS Interpretive Guidelines for Informed Consent

- Health and Ethics Policies of the AMA House of Delegates
Suggested Resources

- Consent to Treatment: A Practical Guide (4th Ed.) by Fay Rozovsky, JD, MPH
  - [Link](http://www.aspenpublishers.com/Product.asp?catalog_name=Aspen&product_id=0735562040&cookie%5Ftest=1)
  - [Link](https://www.ecri.org/Documents/Sample_HRC_Informed_Consent_Report.pdf)
What questions do you have?

Thank You!
Please take time to answer the polling questions.

THANK YOU for your participation and look for our next Webinar in July 2009.