Informed Consent
Session Goals

• Identify the importance of informed consent

• Identify the challenges to effectively auditing and monitoring informed consent

• Applying the Auditing and Monitoring Framework to Medical Treatment Consent

• Audit steps to validate and improve compliance with Medical Treatment Consent requirements
Why Informed Consent?

• Obtain the Patient / Subject Permission for Treatment or Clinical Research
• Inform and Protect the Patient:
  – Avoid Unnecessary Patient / Subject Harm
• Protect the Hospital:
  – Protect the Hospital / Physician / Subject
  – Avoid Malpractice Lawsuits
  – Avoid Battery, False Imprisonment, Defamation Invasion of Privacy and other Charges
  – Avoid Negative Publicity
  – Avoid Payment Denials

Informed Consent Challenges: Definition

Consent: Merriam-Webster’s
  – to give assent or approval: **to agree**
  – to be in concord in opinion or sentiment
• Inform:
  – to **communicate knowledge**
  – to **impart information** or knowledge
• Is it so straightforward?
• A single definition of informed consent does not appear to exist.
Informed Consent Challenges: Definition

CMS April 2007 Revisions to the Hospital Interpretive Guidelines for Informed Consent:
• “The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.”

Informed Consent Challenges: Definition

Office for Human Research Protections in their FAQs regarding Informed Consent:
Q1: What is informed consent and when, why, and how must it be obtained?
– Response: 861 words.
– Never really provides an “Informed Consent is…” statement.
– Addresses things like process, documents, and legal requirements
Informed Consent Challenges: Definition

According to the American Medical Association:

• Informed consent … more than simply getting a patient to sign a written consent form.

  a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.

Informed Consent Challenges: Definition

According to FindLaw.com:

• Although the specific definition of informed consent may vary from state to state, it basically means that a physician (or other medical provider) must tell a patient all of the potential benefits, risks, and alternatives involved in any surgical procedure, medical procedure, or other course of treatment, and must obtain the patient's written consent to proceed.

• The concept is based on the principle that a physician has a duty to disclose information so the patient can make a reasonable decision regarding treatment.
Informed Consent
Challenges: Definition

According to The Burton Report:

• Informed consent represents the single most important issue in the delivery of health care.
• Informed consent exists only when there is full disclosure of known relevant information and known risks presented to the patient in a manner that they can understand.

Informed Consent
Challenges: Definition – Lay Terms

• Consent:
  – Consent means agreeing to something

• Treatment:
  – Clinician action intended to improve the patient’s health
  – It might be a test, an injection, medicine, an operation or something else.
Informed Consent
Challenges: Definition – Lay Terms

• General Rule:
  *The hospital may not permit any treatment, without risk of liability, unless the patient, or a person legally authorized to act on the patient’s behalf, has “consented” to treatment.*

• Patients Demonstrate Consent to Treatment by:
  – Completing an action to show agreement (i.e., show up/not leave).
  – Saying or stating that they agree.
  – Signing a form indicating agreement.

Informed Consent
Challenges: Definition – Lay Terms

“Consent” vs “Informed Consent”

• “Consent:”
  – Agreeing to receive treatment
  – All Treatments require patient “consent”
  – “Consent” alone is required for “simple and common” procedures/risks commonly understood

• “Informed Consent:”
  – Agreeing to receive a specific treatment that is not deemed “simple and common”
  – Also! Being informed of risks for declining a treatment.
  – Documented consent is typically required, including specificity regarding what is documented
Informed Consent Challenges: Definition – Lay Terms

- “Informed Consent” Key Components:
  (California Supreme Court Cobbs vs Grant)
  The patient must be informed of:
  - Nature of procedure
  - Risks, Complications and Expected Benefits or Effects of the Treatment
  - Any Alternatives and Related Risks
  - Potential Conflicts of Interest on the Part of the Physician

Informed Consent Challenges

- Consent / Informed Consent is typically NOT Required when...
  - The treatment is an emergency
  - It assumed that a reasonable person would want to be minimally stabilized in a life or death situation.
  - But...
    * Physician must initially determine patient competency
    * Only the emergency condition may be treated.
Informed Consent
Challenges: Communication

• Informed Consent = A Communication Process!
• When is a patient/subject sufficiently informed?
• When is information properly communicated?
• How much information must be communicated?
• How are language barriers (spoken and written) addressed?
• Can we communicate more than we know?
• Where does risk start and end?
  – For the Patient?
  – For the Physician?
  – For the Hospital?
• When are changes in knowledge communicated?

Informed Consent
Challenges: Communication

• What we don’t want is failure to communicate.
• Informing and obtaining consent is required of the physician, not the hospital.
• Common Communication Mechanisms:
  – Physician / Patient Discussion
  – Posted Signs & Pamphlets
  – Forms
  – Videos
• The hospital must verify that the physician properly documented informed consent.
Informed Consent
Challenges: Documentation

• All communication between the physician and the patient or research subject may not be documented.
• Physician progress notes represent only the physician’s indication of the communication that occurred.
• Forms are only as good as the forms and the individuals who complete them.
  – Forms document that “a” communication occurred, NOT that the right information was conveyed and understood.

Informed Consent
Challenges: Follow-Through

• Like all compliance matters, if it isn’t documented it didn’t happen.
• Do clinicians and staff know who is responsible for documenting consent?
• How do you ensure the physicians complete and accurately document?
• How then to document as hospital personnel?
• Who to hold accountable?
• Who and how to educate?
• How to ensure follow-through (monitor)?
Informed Consent
Summary of Challenges

• Not easily defined:
  – Consent: Patient consent is required for all treatments and...
  – Informed Consent: written “informed consent” is required for specific invasive procedures and other treatments not deemed “simple and common”

• Communication is easy to send but difficult to ensure it was received and understood

• Physician Documents / Hospital Ensures Documented

• As with all compliance tasks, follow-through “in the field” is often difficult

AHIA and HCCA Collaboration
Auditing and Monitoring

• AHIA - Association of Healthcare Internal Auditors
• HCCA - Health Care Compliance Association
• Boards of AHIA and HCCA met to develop guidance on compliance auditing and monitoring
• Created a Focus Group that:
  – Adopted the “Seven Component Framework” for auditing and monitoring
  – Issued a series of related articles in their respective journals demonstrating the application of the auditing and monitoring framework
AHIA / HCCA
“Seven Component Framework” for Compliance Auditing and Monitoring

- Perform a Risk Assessment & determine the level of risk
- Understand laws and regulations
- Obtain / establish Policies for specific issues and areas
- Educate on the policies and procedures and communicate awareness
- Monitor compliance with laws, regulations and policies
- Audit the highest risk areas
- Re-educate staff on regulations and issues identified through auditing and monitoring efforts

Informed Consent
Risk Assessment

You have risk in this area!

"Personally, I wouldn't have signed it."
Informed Consent
Risk Assessment

- Compare services provided to applicable laws, rules, regulations and policies.
- In which cases does “consent” alone work?
- In which cases can “general” consent forms (i.e., conditions of admission, etc.) suffice?
- When is “informed consent” required and are documentation practices in place?
- Are policies in place to address requirements?
- Have Med Staff Rules identified informed consents?

Informed Consent
Risk Assessment

- Consequences for non-compliance include:
  - Unexpected Patient Harm
  - Malpractice Claim
  - Battery
  - False Imprisonment
  - Defamation
  - Invasion of privacy
  - Negative Public Relations
  - Denial of reimbursement
Informed Consent Laws and Regulations

• No one organization (or regulation) explicitly defines all the specific requirements of informed consent.
• Some of the requirements came about through case law.
• Many States add additional requirements for specific procedures.
• Hospital and accreditation associations also recommend certain language for consent forms.

Key Laws, Regulations and Other Criteria:

• Human Subjects Research:
  – 45 CFR 46
  – 21 CFR 50 and 56

• Medical Treatment:
  – CMS Conditions of Participation / Hospital Interpretive Guidelines
  – State Specific Consent Requirements
  – The Joint Commission Hospital Standards
Informed Consent
Laws and Regulations

• Medical Treatment:
  – CMS Conditions of Participation / Hospital Interpretive Guidelines
• “The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.”
• For the most part, CMS defers to State Law

Informed Consent
Policies & Procedures

• This may not be your easiest policy and procedure review exercise.
• P&Ps Should Address Consent and Informed Consent Requirements
• Including Medical and Research Consents, we identified 113 separate policies that addressed some sort of consent requirement in our organization.
  – Excludes some department specific policies
Informed Consent Education

- Should be specific.
- Should include all applicable
  - Clinicians,
  - Physicians, and
  - Staff
    involved in the “process.”
- Should be repeated.
- Determine if ample and focused communication have occurred.

Auditing and Monitoring Preparation

- In Summary, from the framework:
  - Obtain, Review, Understand Laws and Regs
  - Obtain, Review, Understand P&Ps
  - Understand Extent of Education Conducted
  - Identify key risk areas:
    - No P&Ps
    - Little or no education
    - Known problems
    - Random selection
    - Responsibility Confusion
Informed Consent
Auditing & Monitoring

• Stratify audit work to facilitate your efforts:
  – Medical Treatment and Research Informed Consent have different requirements: audit separately.
  – For Medical Treatment Consent:
    • Auditing informed consent is somewhat limited since: you can cover what’s documented but can you actually determine that true consent occurred?

• From your risk assessment, management input, industry or state focus, select specific areas or types of consents:
  – We ultimately used the California Healthcare Association published lists

Informed Consent
Auditing & Monitoring

• Tone at the Top Considerations:
  – Is there a management line of authority / accountability for informed consent?
  – Who will ultimately address identified improvement opportunities?
    • Compliance, Nursing, Risk Management, etc.
    • Are specific informed consents addressed in Medical Staff Bylaws?
  – Who is responsible for periodic review and notification whenever new informed consents are required/changed and to ensure existing informed consent document is relevant?
Verify that hospital policies address:

- Patient’s right to make informed decisions and articulates how the hospital assures patients’ ability to exercise this right.
- Delegation of the patient’s rights to a representative / file a grievance.
- Patient’s right to have information on medical status, diagnosis and prognosis
  - articulates the hospital’s process for assuring that patients have this information.
- Patient involvement in planning and treatment.

Verify that hospital policies address:

- Handling of patient requests for treatment and the circumstances under which a patient request for treatment can be denied.
- Circumstances when a treatment is deemed an emergency and not require an informed consent form.
Informed Consent
Auditing

Verify that hospital policies address:

• Advance Directives.
• Personal Privacy.
• Record Confidentiality.
• Freedom from physical or mental abuse, and restraints.

Informed Consent
Auditing

• Verify that the hospital has assured that the medical staff has specified which procedures are considered “complex” and thus, require a properly executed informed consent form. (CMS)
• Test that the hospital’s standard informed consent form is consistent with the hospital’s policies and the requirements of State law. (CMS)
Informed Consent Auditing

You might considering starting with the easy stuff – “Consent”:

- Standard Consents / Conditions of Admission
- Required signage
- Standard Forms:
  - “An important message from Medicare”
  - “Patient self-determination act”
  - “Notice of privacy practices”

Once understood, move to “informed consents”

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Informed Consent Auditing

Identify Required Locations and Walk Around looking for posting of required signs:

- Newborn safe surrender site
- Location of free anonymous HIV test
  Be Informed (breast cancer screening or biopsy site)
- ChargeMaster availability
  (Emergency dept, billing office, admissions office)
- Charity care and discount payment policy
  (Emergency dept, billing office, admissions office)
- EMTALA sign (in Emergency Department)
- Availability of Interpreter services
Informed Consent Auditing

Identify Required Locations and Walk Around looking for posting of required signs:
- Mental health patient complaint procedure / rights poster  
  (Required languages in all applicable public areas)
- Obstetrical care notice (in obstetrical admitting areas)
- Be Informed  
  (Outpatient prostate cancer screening or treatment site)
- Patient Complaints
- Patients rights (in California posting a sign is required)
- Proposition 65 notice  
  (Clean drinking water & cancer causing agents)
- Smoking/No Smoking

Informed Consent Auditing

Verify Compliance w/Hospital P&Ps and Medical Staff Rules:
- From a population of admissions,
  - Identify the types of procedures requiring "Informed consents"
  - Identify the applicable clinical areas
  - Identify the types of procedures for which additional information must be provided to the patient
  - Identify the types of patient who cannot consent for themselves
  - Identify the type of patient who may refuse treatment.
  - Select a sample of patients from all of the above areas, verify complete and accurate documentation is in the medical record.
Informed Consent
Auditing

Verify that completed informed consent forms:

• Contain the information for each of the elements required of a properly executed informed consent, specific to each treatment (and any additional elements required by State law or hospital policy).
• Are Dated prior to the procedure or treatment that requires informed consent.
• Includes the actual side being operated on if a patient has 2 of the same organ.
• The operation being consented to agrees with the procedure written in the operative report.
• Is signed by the appropriate signers per policy, law, and the patient’s advance directive.

Informed Consent
Auditing

• Verify that patient chart includes documentation that the appropriate required information has been provided to the patient.
• This is basically all the hospital can really do since physicians must communicate and obtain informed consent.
• The hospital must ensure it is documented before the treatment occurs.
Informed Consent
Auditing – Improvement Opportunities

• Enhance education
• Monitor medical records:
  – Add specific verifications to periodic nurse and medical records staff monitoring rounds
• Forms that do not address consent requirements (some requirements are very specific).
• P&P Clarification
• Improve signage / signage inventory
• Form signed but check boxes not checked