Informed Consent in the ASC
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Progressive Huddle
November 17, 2014

Emergence of Participatory Healthcare

- 1847: AMA Code of Medical Ethics for Patient Rights
- Prior to 1900s, physicians had unchallenged power regarding patient care:
  - Research
  - Legal testimony and patient injuries and deaths
  - Physician statements about patient injuries and deaths.
Emergence of Participatory Healthcare

- 1905 Court opinion
  - “rights as free citizens prohibited a physician or surgeon, however skillful or eminent...to violate without permission the bodily integrity of his patient...and (to operate) on him without his consent or knowledge.”

- 1914 Supreme Court decision.
  - Justice Benjamin Cardozo, “A surgeon who performs an operation without his patient’s consent commits an assault.”

- Late 1950s: Patients to be told benefits and risks
- 1960s: Social changes increased patient participation
- 1972: Physicians were required to specifically disclose the risks in a language the patient was able to understand

Informed Consents in ASCs

- State Licensure Regulations
- CMS Conditions for Coverage
- Accrediting Body Standards
- Risk Management
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416.41 Governing Body and Management

Make sure you have well documented the following in meeting minutes, policies, bylaws, etc. as appropriate to your facility:

1. The GB is responsible for establishing the ASC's policies, making sure they are implemented, and monitoring internal compliance, as well as monitoring those policies periodically and revising as appropriate.
   - QAPI program
   - Quality of healthcare services
   - Safety in the ASC environment
   - Development and maintenance of a disaster preparedness plan

2. All GB delegations must be documented, specifically authority for:
   - HR administration
   - Medical staff credentialing and privileging
   - Management of nursing services
   - Management of pharmacy services
   - Management of lab/path services
   - Management of physical plant
   - Management of infection control
   - Management of QAPI program

3. Make sure policy and procedure adoption is documented and P&P's are annually reviewed by the GB

4. Make sure QAPI oversight and accountability is clearly documented at the GB level, (i.e., in meeting minutes)

416.41 (a) Contracted Services

1. Contracted services must be monitored. Data about the quality of services delivered must be gathered and this assessment must be included in the QAPI program. You can access an audit tool for documenting contract oversight and evaluation.

2. Any contracted persons working in the facility, i.e., a 1099 administrator for instance, needs a complete file documenting qualifications, scope of services, job description, orientation, evaluation, etc.

§416.50 Condition for Coverage

Patient Rights

• Standard: Exercise of Rights and Respect for Property and Person.....The patient has the right to the following:
  - Be fully informed about a treatment or procedure and the expected outcome before it is performed

Informed Consent

• “Consent is a process, not a form” (Fay Rozovsky)
• Communication between a patient and healthcare provider
• Patients have responsibilities
• A signed consent records the conclusion of the process
Informed Consent Process

- Description of proposed surgery including anesthesia
- Who will conduct surgery and provide anesthesia
- Diagnosis
- Surgical procedure to be performed including benefits, risks and alternatives
- Time involved for procedure and recovery
  - Ride home with responsible adult
- Restrictions on resuming normal activities
- Requirements for follow up care

American College of Surgeons

- Instructions to patients: …but you should seek the answers to questions such as:
  - What are the indications that have led your doctor to the opinion that an operation is necessary?
  - What, if any, alternative treatments are available for your condition?
  - What will be the likely result if you don’t have the operation?
  - What are the basic procedures involved in the operation?
  - What are the risks?
  - How is the operation expected to improve your health or quality of life?
  - Is hospitalization necessary and, if so, how long can you expect to be hospitalized?
  - What can you expect during your recovery period?
  - When can you expect to resume normal activities?
  - Are there likely to be residual effects from the operation?

Physician, Facility, & Anesthesia

- What is the difference between a physician consent, facility consent and anesthesia consent?
- Must give consent prior to agreeing to surgery
  - GI
  - Vascular
  - Facility must ensure that the practitioner responsible for the care obtained consent
Physician, Facility, & Anesthesia

- Do you need separate consent forms for the procedure and anesthesia? (from a legal standpoint, not accreditation body requirement)
- Must give consent prior to agreeing to anesthesia administration
- Anesthesia consent process should contain:
  - Explanation of the anesthesia, benefits, risks, alternatives, blood and blood product information
  - Who can obtain anesthesia consent? CRNA? MDA?
  - Surgeon?
- If not the provider, it raises the risk that a non anesthesia provider is not equipped to obtain an informed consent

Physician, Facility, & Anesthesia

- AANA
  - Pre anesthesia evaluation imperative and time must be allowed to obtain anesthesia consent

Gail Van Norman, MD
Assistant Professor, Anesthesiology
Faculty Associate, Medical History and Ethics

- Article: Ethics in Medicine:
  https://depts.washington.edu/bioethx/topics/infc.html#ques8

- Is the surgical consent sufficient to cover anesthesia care?
  - Principles involving the informed consent process require that the best available information regarding procedures and risks be provided to patients. Just as anesthesiologists lack the expertise to discuss risks of surgery, surgeons lack expertise to discuss the nature and risks of anesthesia. While the surgical consent form does contain a phrase regarding consent for anesthesia care, the informed consent process requires that a separate discussion of anesthesia risks be carried out by the anesthesia provider.
Sample Verbiage

• Consent to Surgical or Diagnostic Procedure. I acknowledge that I have authorized and directed my physician (named above) and/or associates or assistants of his/her choice to perform the following operation and/or procedure on me ___________________________________________________________________.

• Risks and Alternatives. My physician or his/her designee has explained to me the nature of the operation or procedure, the expected benefits or effect and the associated risks of such operation or procedure, and the risks of not performing the proposed operation or procedure. I certify that, based upon the information provided by my physician or his/her designee, I have a general understanding of the operation or procedure to be performed on me and that no warranty or guarantee has been made as to the result or cure.

• Consent to Administration of Anesthetics. I acknowledge that I have authorized and directed _______________________________________________ to administer anesthetics to me in connection with the operation or diagnostic procedure described above. The physician has explained to me the nature of these anesthetics, the way they will be given to me, their usual effects, and the hazards and risks in connection with their use.

Informed Consent Forms

• Long form: Lists the benefits, risks, alternatives
• Short forms: General with a statement that the patient is agreeing they have been given information about the procedure, benefits, risks and alternatives

Available on eSupport

• Operations_Sample Forms_Conents
Physician, Facility, & Anesthesia

- Facility consent is only to ensure the patient gave an informed consent to the provider(s).
- Do you need a copy of the physician’s consent form?
  - No
- Does the surgeon need to sign your facility consent form?
  - No

Issues to consider for facility consent process

- If witness is utilized, they are only ensuring the patient is signing.
- Facility consent discussion should be in a private location and before the patient has received any sedation.
- Ask patient to state the procedure to you.
- Ask patient if they have any questions.
- If a patient expresses unanswered questions or concerns, he or she should not sign the form until the physician has addressed all concerns.

Surgical Procedure

- Does the procedure have to be spelled out completely?
  - Yes, procedure should be worded in medical jargon.
  - No acronyms or abbreviations should be used.
  - Verbal description should be given in a manner the patient can understand.
Consent Witness

- Do you have to have a witness to a consent?
  - No
- Who can witness a facility consent?
  - Staff

Available on eSupport

- Compliance Policy and Procedure
  Update Administration Informed Consent Policy

Guardianship

- Who can sign a consent form for the patient and in what circumstances?
  - Minors
    - Parents or guardian parent
    - Legal Guardians
    - Know your state laws: “Mature Minor” or “Emancipated Minor”
    - May be procedure specific
  - Patients deemed incompetent
    - Legal Guardian previously chosen by patient
    - Medical Power of Attorney
    - Legal procedure to assign court appointed guardian
    - States addressing issues of growing elderly population
      - WV: MD or NP can select health care surrogate
      - NC: “Two Physician Rule”
Consent Time Limit

- Is there a time limit on consents?
  - No (other than reproductive permits)
  - Should be based on changes in patient history which would alter the risks, benefits and alternatives
  - Should have a policy indicating a time limit if you allow facility consent forms signed prior to date of service

HIV Testing

- Do you need a separate consent for HIV testing?
  - Old law: required a separate consent
  - 2006: CDC recommended routine HIV testing focused on adults, adolescents and pregnant women. Anyone between 13 and 64 years.
- Issues:
  - Who does counseling? Who discusses HIV testing benefits or positive test results?

HIV Testing

- HRET (The Health Research Education Trust) recommends including consent for HIV testing as part of consent form rather than a separate form.
- NCCC provides tool for state laws: http://nccc.ucsf.edu/clinical-resources/hiv-aids-resources/state-hiv-testing-laws/
Reproductive Consents

- Sterilization procedures
  - Failed sterilization
  - Complications
  - Spousal consent
    - Not required
    - Consent time limits
- Abortions
  - Parental consent of minors
  - Waiting period
  - Spouse/father notification

Consent Additions

- ASC items that require informed consent and should be disclosed to patients include:
  - Students
  - Outside representatives or other non-employees
  - Photographs, videotaping or the production of slides
  - Tissue disposal
  - Research
  - Use of blood or blood products

Lack of Informed Consent

- Assault and battery
  - Assault: placing someone in fear of being touched
  - Battery: Touching of another without express consent
- Negligence theory of consent
  - Proof of fraud, misrepresentation, or breach of contract with the informed consent process
Can you say the following?

- You’ll feel like your old self after surgery?
- "reassuring statement" vs. guarantee
- You must have _____ procedure.
  - Coercion (legal) and manipulation (ethical)

Patient Responsibilities

- Inform staff of all medical conditions
- Provide accurate information
- Ask questions about procedure
- Follow directions
  - Responsible adult for a ride home
  - Keep follow up appointments

Withdrawal of Consent/Refusal of Treatment

- Leaving AMA
  - Develop a policy on AMA
  - Have a form for the patient to sign
  - Document conversations leading up to the withdrawal of consent
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- Compliance Policy and Procedure Update_Nursing_Release against Medical Advice policy and form

Remember.....

- Consider the informed consent a process
- Encourage patients to ask questions
- Provide appropriate interpretation services, as needed
- Ensure patients can legally give consent
- If the patient has procedural questions, stop the process and notify the surgeon

Resources

Still not on Progressive eSupport?

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- Email us at [info@pss4asc.com](mailto:info@pss4asc.com)
- Or call us! (855) 777-4272

Mark your calendars!

Join us next time for:
**Life Safety Code**

January 12, 2014
11AM PT/2PM ET

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WEL Designs