INFORMED CONSENT
ARE YOU DOING IT RIGHT?

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Objectives

In many situations, when medical care or treatment is provided, medical practitioners are required to obtain a patient’s "informed consent."

1. What does this term mean?
2. Why do we need informed consent?
3. Scope of the informed consent process
4. What can happen if proper informed consent is not given?
5. Some considerations for improving the process at your organization
What is informed consent?

“What a rote process by which practitioners obtain patient signatures on template forms or make notes in patient records.”

**WRONG ANSWER**

What is informed consent?

“The **process** of communication between patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention.”

American Medical Association, 1998

...*It’s more than a signature on a piece of paper!*

Further....failure to obtain informed consent renders any U.S. physician liable for negligence or battery and constitutes medical malpractice.
General Concepts

In most instances:
A physician (or other medical provider) must tell a patient all of the ...
  • potential benefits
  • potential risks
  • alternatives
... involved in any surgical procedure, medical procedure, or other course of treatment, and must obtain the patient’s written consent to proceed.

Why do we need informed consent?
The short answer:

- It’s the ethical thing to do
- It’s a safety and quality of care issue
- It’s an access/diversity issue
- And…it’s the law!
A bit of history

“Every human being of adult years and sound mind has a right to determine what shall be done with his own body....”

Schloendorff v. Society of New York Hospital, 105 N.E. 92 (N.Y. 1914)

Why do we need informed consent?

The slightly-longer answer:

✓ Greater patient safety and satisfaction
✓ Attainment of higher ethical standards and organizational morale
✓ Closer adherence to legal requirements and reduced risk of litigation
✓ Increased levels of institutional quality (e.g., compliance with accreditation standards)
✓ Potential time and money savings (or offsets) related to reduced litigation
Who is responsible for informed consent?

- The individual clinician has ultimate responsibility
- However, a team approach is required with contributions from:
  - entire clinical staff
    (physician, nurse, technicians, pharmacist)
  - administrative and clinical leadership
  - legal counsel

2016 Informed consent legal issue

- A case before the Supreme Court of Pennsylvania could have major implications for how physicians obtain informed consent prior to a surgery.
- At stake in *Shinal v. Toms*, is whether a patient’s informed consent to surgery can be predicated on information provided in part by a physician’s assistant, as opposed to just the physician.
- Both the Medical Care Availability and Reduction of Error Act (MCARE) and common law have made it the physician’s duty to see that the proper information is conveyed, but the question is whether delegating tasks to qualified professionals is also within the bounds of the law and common medical practice.
Role of the physician

Physicians themselves, rather than a representative, nurse, or other related health care professional, are the best choice to speak to the patient about informed consent.

The physician should cover:

• Patient’s diagnosis, if known
• Nature and purpose of the proposed treatment or procedure
• Benefits and risks of proposed treatment or procedure
• Alternatives to the proposed treatment or procedure
  • Regardless of their cost and regardless of whether they will likely be covered by insurance
  • Risks and benefits of any alternative treatments or procedures
    • Including risks and benefits of not receiving or undergoing any treatment or procedure

Role of others in the consent process

Generally, nurses and others are responsible for different aspects, depending on type of consent and the setting:

• Ensuring that the consent form is signed by the appropriate person; a witness that the patient has signed and dated the form
• Documenting in the chart that consent was obtained
• If the patient seems confused about the procedure or has additional questions, notifying the appropriate provider
• Providing an explanation of the nursing care that will take place before and after the procedure or treatment; what medications will be administered and any other aspect of nursing care
• Providing assistance and support to the patient and family or guardian while waiting for the procedure or treatment to begin
Role of the patient

• Although a physician is generally required to inform a patient about benefits, risks, and alternative treatments, patients must also play a part in the informed consent process

• Patients must listen to the physician and should ask questions of the physician if they do not understand, or if they would like more detailed information

When is informed consent required?

In most institutions, informed consent is required for:
- Surgery
- Anesthesia
- Other invasive or complex medical or radiologic procedures
- Anything further specified in the organization’s policies
State variation

Laws regarding exactly when and how formal informed consent must be provided vary by state.

Amount of information a healthcare provider is required to disclose to the patient varies:
- “Reasonable physician” Standard
- “Reasonable patient” Standard

When is informed consent required?
Legal parameters

Unfortunately there is no continually updated national list describing exactly when informed consent is required.

—F.S. 766.103: Florida Medical Consent Law (standard)
“The action of the physician...advanced registered nurse practitioner, or physician assistant in obtaining the consent of the patient or another person authorized to give consent for the patient was 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.”
Common controversies

Indications for informed consent

• Invasive vs. non-invasive procedures: At what point does a procedure become invasive?
  – PICC lines, midlines, Foley catheters, NG tubes, surgery, clinical research
• When is consent implied?
  – Common interactions or therapies
    Blood draw, vaccination, peripheral IVs (gray area)

Specific v. general consent forms

Situations in which informed consent may not be necessary

Situations that do not involve medical procedures or treatment

Emergency situations
Scope of the informed consent process

Thoroughness and complexity of the process depends on the type of procedure or treatment involved:
- Minor vs. complex procedures
- Degree/level of risk

Tailor the process to each patient and his or her specific condition or situation, but...

Always include documentation of the informed consent process in the patient record, regardless of the complexity of the procedure.

Key elements of an effective consent process

An understandable, two-way communication regarding the following information:
- Indications for test or treatment
- Explanation of RECOMMENDED test(s) or treatment
- Description of probable benefit(s) and probable risk(s) of recommended test or treatment
- Description of alternate tests or treatment, including associated probable benefits and probable risks
- Description of probable consequences of declining either recommended or alternate test(s) or treatment

Test or treatment
Basic elements of an informed consent document

Basic elements of an informed consent document include:
• Patient name;
• Procedure name (both in medical and layperson’s terms);
• Description of the procedure;
• Risks and benefits of the proposed treatment or procedure;
• Treatment and alternatives, including doing nothing;
• Patient signature memorializing understanding and providing consent; and
• Witness signature

Informed consent documentation

Consideration of the following guidance on content, text, fonts, and layout as part of the informed consent process can improve patient understanding and compliance with care.

Additionally, repeating and reinforcing the information provided to patients by providing a copy of the consent form and additional educational materials can improve a patient’s retention and understanding.
Informed consent documentation

Content

• Limit content to what patients really need to know. Put the most important information first, and avoid information overload.
• Present information in a logical order, group related information together, and use descriptive headings and subheadings to help patients navigate the content.
• Use short paragraphs and focus on one topic per paragraph.
• Use words that are well known to individuals without medical training. For example, use “high blood pressure” instead of “hypertension,” or use “tooth decay” instead of “caries.”
• Use examples and visual aids (e.g., illustrations or tables) to make complex material easier to understand.
• Ensure that content is appropriate for the age and culture of the target audience.

Informed consent documentation

Fonts

• Use large font (minimum 12 point) in a familiar typeface (e.g., Arial, Times New Roman, or Tahoma).
• Although you may want to differentiate font style for headings and body text, avoid using multiple font styles on a page or throughout a document.
• Ensure consistency in appearance throughout printed and online materials (e.g., consistent font sizes, colors, spacing, etc.).
• Use uppercase and lowercase text. ALL UPPERCASE TEXT is more difficult to read.
Informed consent documentation

Layout

• Use white space effectively, and consider opening up line spacing or space between paragraphs to lighten the page.
• Use right justification instead of full justification.
• Use headings and subheadings to separate blocks of text.
• Use bulleted lists to focus on specific material, highlight information in a visually clear way, or clarify the chronological order of steps in a process.
• Keep the design of any graphics or illustrations as simple as possible.

Informed consent documentation

Text

• Write at or below a sixth-grade level. Several readability formulas (e.g., Fry, SMOG, and Flesch-Kincaid) can help determine how difficult a piece of writing is to read.
• Use one- or two-syllable words when possible. For example, use “blood clot” instead of “embolism.”
• Eliminate jargon and technical terms.
• Use the same term consistently to identify a specific thought or object.
• Favor active voice over passive voice. For example, use “report new or worsening symptoms to your doctor” instead of “new or worsening symptoms should be reported to your doctor.”
• Avoid wordy phrases. For example, use “because” instead of “due to the fact that.”
Legal and professional considerations in providing informed consent

• Ensure that informed consent processes and forms incorporate any specific requirements of states and their professional licensing boards

• National professional associations, e.g., AMA, AOA, ADA, etc. may also provide recommendations related to the informed consent process

Legal issues concerning ability to consent

Legal and mental capacity (ability)

• Patient is presumed to have requisite legal capacity to make decisions or a court appointed or healthcare proxy has the authority to do so

• Patient is presumed to have mental capacity to make a decision regarding a test or treatment

However, in a legal context, facts can rebut (claim and/or prove) that this presumption is false
Obtaining consent from incompetent individuals and minors

In most cases, a mentally disabled person has an appointed guardian authorized to make medical decisions and provide informed consent for that individual

• Providers: make certain consent is obtained from the correct person

In most situations, parents can give informed consent for treatment for their minor children

• Note: Some states allow those under 18 to play a more active role in their medical care and treatment, including the process of informed consent

Consent to treat foster children

• Foster parent(s) often have documentation from the court giving them permission to make decisions on behalf of the child for routine health care

• Birth parents do maintain parental rights with most foster care situations, so questions arise as to whether the parent maintains a right to request the child’s medical record when the child is under the care of a foster parent

• Consider contacting your state or local foster care agency, and/or a local attorney
Elderly patients

Elderly patients may present non-routine consent issues
• Powers of attorney (POA), guardianships, mental competence, etc.
• From whom do you need to obtain consent for an elderly patient’s care?

Powers of attorney:
• Limited, general, durable, and healthcare are the most common
• In a POA document, a “principal” names an attorney-in-fact (“agent”) to act on his or her behalf
• The POA usually outlines the breadth of the agent’s decision-making authority

Elderly patients

Suggestions:
• Establish consent when the patient is still of sound mind.
• Ask elderly patients if they have executed any type of POA, living will, or other document outlining who has decision-making authority in the event they are unable to make decisions
• Request a copy of documentation outlining decision-making authority for your patients
• Maintain this documentation in the medical record
• Consider reviewing this with the patient periodically to ensure it is still current
Flawed assumptions about consent communications

• “My patient can understand this stuff.”
• “He is okay. He does not need an interpreter.”
• “Look, this is one smart guy. He can digest all this data in one, fifteen-minute session.”
• “I never have any problems with my patients. They always listen to what I tell them.”
• “You have got to be joking! My patient influenced by the Internet, family or friends? No way!”

What patients want to know from the consent process

• Will I have a lot of pain?
• Will I be left disfigured or impaired?
• Will I need to go to a rehab facility for follow-up treatment?
• Will I need to take medication?
• Will I be left impotent from the prostate surgery?
• When I have the mastectomy can I have concurrent reconstructive surgery?
What the patient is saying

• Never mind about “the reasonable person.”
• Never mind what the statistics say about one type of treatment or another.
• “Focus on ME! Tell me what the proposed or alternative test or treatment means to me.”
• “What are MY probable benefits and probable risks?”
• “Level with me. Is there anything else I should consider? Tell me.”

Patient comprehension

Language/communication barrier:
• Approximately 21 million people in the U.S. speak English “less than very well.” (2007 Joint Commission study)

Low health literacy:
• Same study found many participants did not know the meaning of commonly used terms, such as ‘polyp,’ ‘tumor,’ lesion,’ or ‘blood in the stool.’ None of the participants knew what the colon or bowel was nor where it was located.
• 75% of people with chronic physical or mental illness have limited health literacy skills
• 44% of patients who signed an informed consent form did not know the exact nature of the operation to be performed
Patient comprehension

Provider factors:

• Lack of time for upfront patient education
• Overly complex or overly broad written materials
• Lack of clarity when involving interpreters
• Wrong assumptions about patient comprehension

“"It is likely the almost everyone has been, at some time, put off by densely worded forms, and confused by complex medical regimens, conflicting health care advice, poorly worded instructions, and medical speak that few on the receiving side of health care can understand.”

“What Did the Doctor Say? Improving Health Literacy to Protect Patient Safety”
The Joint Commission, 2007 www.jointcommission.org

Patient comprehension

When determining how to effectively support patient comprehension, practitioners should consider:

• The patient’s current understanding of his or her condition and the proposed treatment plan;
• The patient’s overall capacity to understand;
• Cultural considerations that may affect the patient’s decision-making; and
• Any language barriers that may impede the consent process
Potential consequences of informed consent process deficiencies

- Violation of professional and ethical obligation to clinicians to communicate clearly
- Increased chance of a patient safety incident or medical error
- Increased chance of malpractice cases

Common consent related issues

- Failure to re-consent when new information becomes available
  - 65% of identified adverse incidents have been found to have communication failures as the underlying root cause
- Patient did not sign/date the form
- Consent documents are either incomplete or missing
- Use of wrong form
Suggestions for improving the informed consent process

Engage the patient in a dialogue about the nature and scope of the procedure
Two best practice examples:
   “Teach-back”
   “Show-me”

Designed to replace the common practice of simply asking a patient, “Do you understand what I have told you?”

Suggestions for improving the informed consent process

linguistics

Improve written consent forms and related written educational materials
   Readability (6th grade level)
   Layout/design
   Language

• Improve your capacity to provide informed consent to patients with limited English proficiency (LEP)

• Train interpreters to sight-translate consent forms for patients with LEP
  • Assess whether interpreters have the ability to sight-translate consent forms and translate informed consent discussions effectively
  • Assure the quality of translated consent forms
Suggestions for improving the informed consent process

In summary:
✓ Create the time for it
✓ Simplify your language
✓ Allow time for questions
✓ Make sure the patient understands
✓ Plan for language assistance in advance of appointment

Risk Management Considerations

• Improve understanding of informed consent and the related responsibilities and liabilities to health care organizations
  • Train support staff, nursing, physicians, administrators, interpreters, etc.

• Keep track of incidents related to informed consent process
  • Use quality improvement processes to monitor incidents related to informed consent
  • Develop targeted remediation to identified problems
Selected Medicare Standards

An individual clinical record is maintained for each person receiving care. [416.47(b)] Every record must be accurate, legible, and promptly completed. Each record includes at least the following:

Documentation of properly executed informed patient consent. [416.47(b)(7)]

10.I.I
The patient provides informed consent for the proposed procedure to be performed. [416.50(e)(1)(iii)]

1. There is documentation that the necessity or appropriateness of the proposed procedure or surgery, as well as alternative treatment techniques, have been discussed with the patient. [416.47(b)(7)]

Selected AAAHC Standards

Chapter 9 – Anesthesia Care Services

The informed consent of the patient or, if applicable, of the patient’s representative, is obtained before the procedure is performed. One consent form may be used to satisfy the requirements of this Standard and Standard 10.I.H.

Chapter 10 – Surgical and Related Services

10.I.H
Informed consent for the proposed procedure is obtained.

1. There is documentation that the necessity or appropriateness of the proposed procedure or surgery, as well as alternative treatment techniques, have been discussed with the patient.

2. The organization obtains written informed consent from the patient or the patient’s representative before the procedure or surgery is performed.

10.III.E.4 (same in Medicare Handbook)
The organization has written policies addressing: The requirement that signed consent forms are obtained prior to treatment.
Selected AAAHC Standards

Chapter 14 – Dental Services

14.I.H
The informed consent of the patient is obtained and incorporated into the dental record prior to the procedure(s).

Chapter 17 – Behavioral Health Services

17.J
A written and signed informed consent of the client is present in the clinical record at the start of treatment.
1. The informed consent is inclusive of the type and scope of treatment provided, treatment expectations and parameters, potential risks and protections related to treatment.
2. Instances of limited confidentiality are clearly articulated, reviewed with the client, and acknowledged by signature.
3. Client/patient consent is obtained for the coordination of care with family members and/or significant others who play a role in the plan of care or treatment of the client.

Selected AAAHC Standards

Chapter 19 – Research Activities

19.E.
Provisions are made to ensure that the rights and welfare of all research subjects are protected and that informed consent of each subject is obtained in the language or manner primarily used by him or her.

Chapter 24 – Radiation Oncology Treatment Services

24.G.6
The radiation oncology service has policies addressing the quality of care, including but not limited to policies for:
Obtaining signed informed consent prior to treatment.
Concluding comments

• The informed consent process creates many challenges, but these are outweighed by the opportunities for minimizing risk and enhancing patient care
• Documentation of informed consent may reduce the risk of claims and suits related to allegations of “lack of informed consent”
• The process facilitates increased patient participation and involvement in their medical care

Thank you!

Questions?
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