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Avoiding Critical Flaws in the Consent Process

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Disclosure to Learners

No planner, reviewer, faculty, speaker, or staff for this activity has any relevant financial relationships with ineligible companies.

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Objectives / Outcomes

- Apply the key elements of consent when obtaining informed consent during patient interactions.
- Demonstrate the risks associated with failing to obtain proper informed consent.
- Utilize effective communication techniques (teach-back, open-ended questions, interpreters/translators, etc.) using common language to encourage patient engagement in the consent conversation.
- Demonstrate the ability to communicate effectively with patients who choose to refuse recommended treatments or procedures.
- Documentation of informed consent and informed refusal thoroughly, including the information provided, patient questions and their decision.

Outline

- Consent Process: Review, Essential Elements, & Recurring Themes
- Consent Process Framework
  - Recognizing & Overcoming Biases
  - Cultural Considerations & Health Literacy
  - Consent Discussion
  - Consent Documentation
- Case Studies
- Consent Process Round-up: Risk Reduction Strategies
- Consent Process Round-up: Key Points / Takeaway

Consent Process: Review

Consent is a legal, ethical process and fundamental patient right of self-determination

In medical care, a patient who is able to make decisions has the right to decide what happens to their body

Simple Consent	Informed Consent
• Injections • Blood draw(s) • Financial consents	A communication process where the healthcare provider educates a patient about the risks, benefits, and alternatives of a proposed treatment or procedure

Consent Process: Review

1

Discussion with the purpose of communication, education, and listening

2

Documentation of the discussion in the medical record

3

A consent form that captures the discussion and the patient's agreement

Consent Process: Essential Elements

California Supreme Court

1972

Cobbs vs. Grant

Established a legal foundation for informed consent

1. Decisional capacity allows a person to make decisions about their own healthcare *even if these decisions seem unwise*.
2. A person is to *be informed* about recommended care and treatment
3. A physician *cannot delegate the responsibility* to another person

The case also defined the four (4) elements of a proper informed consent discussion

1. Nature of the treatment
2. Specific risks to the patient
3. Expected benefits
4. Alternatives explained, including DOING NOTHING

Consent Process: Essential elements…

Disclosure

The process of providing the patient or participant with all relevant information regarding the procedure, treatment, or study.

This includes the purpose, risks, benefits, alternatives, and potential consequences of refusing treatment

Understanding

Ensuring that the person receiving the information fully understands it.

This means the information must be communicated clearly, and, in a manner, appropriate to the individual's language, education level, and cognitive ability

Capacity

The individual must have the mental capacity to make decisions.

Involves the ability to understand the information, appreciate the consequences, reason about treatment options, and communicate a decision

Voluntariness

The decision to consent or refuse must be made freely, without coercion, manipulation, or undue influence

Consent

After disclosure, understanding, and ensuring competence and voluntariness, the individual gives explicit permission (consent) or refuses the proposed intervention

Consent Process: Recurring Themes

- Insufficient provision of information
- Improper delegation to another healthcare provider
- Failure to obtain consent
- Misrepresentation and Fraud
- Decisional Capacity
- Duress or Coercion

Overall, the most common theme is *inadequate discussion*

Consent Process Framework: Recognizing Common Biases

Recognizing Our Biases Matters

*In healthcare, **nearly 83% of disparities** are thought to be **cognitive in origin**, affecting every stage of the diagnostic, treatment & prescribing process:*

- Biases can affect **patient safety**, **treatment equity**, and **care quality**
- Biases can lead to **over-** or **under-treatment**
- Biases contribute to **health disparities**

Consent Process Framework: Common Biases Affecting Our Decisions

Implicit Bias: *In healthcare, implicit bias refers to the unconscious attitudes and stereotypes that influence our understanding, actions, and decisions in patient care.*

Barriers in Overcoming Our Biases

- **Personal beliefs, attitudes, and knowledge gaps.**
- **External pressures such as patient expectations, time constraints, and systemic factors.**
- **Difficulty overcoming established habits despite new evidence or guidelines.**

Implicit bias barriers can be overcome by introspection

Consent Process Framework: Cultural Considerations & Health Literacy

Individual differences and cultural diversity in patient populations can impact both perceptions and expectations on both sides leading to disparities

Cultural Competence Gaps

- **Assumptions & Stereotyping**
- **Lack of Training**
- **Inadequate Communication Tools**

Cultural Expectations & Family Roles

- **Communication Styles**
- **Health Beliefs & Practices**
- **Trust & Historical Context**
- **Family Roles**

Literacy & Health Literacy

- **U.S. adults *(21%)* have below basic literacy skills** (ECRI, ASHRM).
- Nearly **90%** of adults struggle with health literacy, affecting understanding of medical instructions and adherence

Use of Professional Interpreters

- ***For patients with limited English proficiency***
- **Avoid family interpreters to maintain confidentiality and accuracy.**

Consent Process Framework: Discussion

- **Explain** diagnosis and nature of treatment
- **Review** proposed procedure
- **Share** expected benefits
- **Outline** material risks and complications
- **Discuss** reasonable alternatives
- **Discuss** risks of declining treatment or doing nothing
- **Encourage** questions
- **Confirm** understanding

Consent Process Framework: Discussion: DON'TS

- Don't **ONLY** use **medical jargon** or **technical language**
- Don't **delegate discussion** to staff
- Don't **rush** the discussion
- Don't **fail** to **discuss alternatives**
- Don't **assess understanding** by **ONLY asking** "Any questions?"
- Don't **discourage** questions
- Don't **fail to answer** questions
- Don't **guarantee outcomes or downplay risks**; i.e. *"You'll be back to playing soccer in no time!"*

Consent Process Framework: Discussion - DO'S

- **Use plain** language
- **Use** language **interpreter services** as appropriate
- **Include the patient**
- **Use educational aids** when helpful
- **Encourage questions** and **answer them** to the **best of your ability**
- Use **teach-back method** with patient / families to **repeat key information**
- **Meet anxiety** with **compassion**
- **Take your time**

Consent Process Framework: The Teach-Back Method

Teach-Back is NOT a memory test	Ask patients to explain in their own words – if they just repeat what you said, they may not truly understand
Use the "Show-Me" method	This helps spot mistakes - even if the patient can explain the instructions correctly
Clarify & Re-Check	Ask them to teach you back again - keep repeating until they explain correctly - in their own words
Chunk & Check	Break information into small parts - have the patient explain each part - then move on.

Consent Process Framework: The Teach-Back Method

Practice & Plan: Ask yourself, *"How will I ask open-ended questions…?"*

- You are **checking to see** how **well you explained** something, not testing the patient.
- Maintain a **warm** and **positive** tone… **smile** as you speak.
- **Reinforce** that **it's okay** to ask questions and admit confusion…

In the end:

- It's not what you say, **it's what they hear**
- It's not what you show, **it's what they see**
- It's not what you mean, **it's what they understand**

Consent Process Framework: Informed Refusal

- When it comes to informed refusal, the following three (3) steps should be taken:
  - Confirm the patient understands the risks of refusing recommended treatment or a delay of treatment
  - Document the informed consent discussion
  - Document that the patient specific objections were addressed
- Specify the patient's reasons for refusing treatment, investigate these reasons and document
- Understand and document the refusal

Consent Process Framework: Informed Refusal

California Civil Jury Instruction
534. Informed Refusal

- [A/An] [insert type of medical practitioner] **must explain the risks of refusing a procedure in language that the patient can understand** and give the patient as much information as [he/she/nonbinary pronoun] needs to make an informed decision, including any risk that **a reasonable person would consider important in deciding not to have** [a/an] [insert medical procedure].
- The patient **must be told** about **any risk of death or serious injury or significant potential complications that may occur if the procedure is refused**. [A/An] [insert type of medical practitioner] is not required to explain minor risks that are not likely to occur.

Consent Process Framework: Documentation Components

Consent Form

- The signed legal document which authorizes the procedure
- Confirms patient agreement
- Usually standardized by the hospital

Consent Verification

- Confirmation of consent immediately before procedure
- Confirms correct patient / procedure / site / existing signed consent

Consent Note

- Reflects *personalized discussion* of the material risks, alternatives, questions asked and answered, and patient understanding

Consent Process Framework: Documentation Components

FORM

A signed form

DOES NOT

PROVE

consent

occurred

VERIFICATION

A completed verification

DOES NOT

REPLACE

the

consent discussion

NOTE

The consent note should capture the thoroughness of the discussion

~and~

is often the most important consent evidence in litigation

Consent Process Framework: The Consent Note - Why It Matters

When a complication, unanticipated outcome, and/or adverse event takes place, plaintiffs often claim:

- "No one **told us** this could happen."
- "We were **rushed** in making the decision."
- "We **would not have** proceeded **had we known the risks**."

A detailed consent note can strengthen the defense of a claim by demonstrating:

- Risks **were** discussed
- Patient **was encouraged** to participate **and** asked questions
- Questions and concerns were **specifically addressed**

The Consent Note: – DON'TS

- Don't **use generic language or generic templates**
- Don't **OMIT discussion** of **serious risks**
- Don't **FAIL** to include **"specific"** patient/family questions
- Don't **DOCUMENT ONLY AFTER** the procedure, treatment, and/or a complication has occurred…
  - *Creates credibility issues for the physician*
  - *Undermines purpose of informed consent*

The Consent Note: - DO'S

- Be **specific**
- Use **clear** language
- **Complete your note BEFORE the procedure or initiating treatment**
- Detail **risks specific** to the patient based on **their individual clinical history**
- Include '**specific quotes'** from patient's questions, concerns, and understanding…
  - *Demonstrates patient engagement; supports evidence of personalized discussion and informed decision*
  - *Strengthens physician credibility, professionalism, and may be perceived as more authentic evidence of the interaction*

Consent Note: Documentation - A Defensible Structure

- **Discussion** of diagnosis
- **Explanation** of proposed procedure
- **Discussion** of material risks
- **Review** of alternatives and the **risks** of doing nothing
- **Questions** from patient/family etc., in “quotes”
- **Statements or concerns** raised by patient, etc., in “quotes”
- **Confirmation** of patient understanding

Consent Note: Documentation – Weak Note Example

"Discussed appendectomy with patient's parents. Reviewed risks including bleeding and death, benefits, and alternatives including non-operative management. Parents agreed to proceed with surgery. Consent obtained."

The weak example note includes:

- NO diagnosis discussion
- NO description of procedure
- FEW and generic material risks
- NO **explanation of alternative management**
- NO patient/family questions or indication of patient/family understanding

Consent Note: Documentation – Stronger Note Example

"Met with the patient and patient's parents to discuss the diagnosis of acute appendicitis and recommended treatment of laparoscopic appendectomy. Explained the nature of the procedure to patient. Discussed that the appendix is inflamed and that surgery is recommended to remove it to prevent worsening infection or rupture. Provided details of the procedure including that it involved removal of the appendix using small incisions and a camera. Explained that in some cases conversion to an open procedure may be necessary depending on findings during the operation. Discussed expected benefits of surgery, including treatment of infection and prevention of rupture or worsening infection. *Reviewed material risks, including bleeding, infection, injury to the bowel or nearby organs, anesthesia complications, postoperative abscess, and the possibility of conversion to open surgery*. Discussed alternatives, including treatment with antibiotics alone and observation. Explained that non-operative management may carry risks of recurrence or worsening infection and may still require surgery. Parents asked questions regarding recovery time, pain control, and when the patient could return to school. The patient asked about whether the procedure would hurt and when he would be able to get back to "skateboarding and riding bikes." These questions were addressed. The patient's father stated, "we understand the options and risks and want to move forward with surgery." The patient indicated understanding of the plan and stated "Okay, you need to take my appendix out." All questions were addressed. Parents demonstrated appreciation of proposed procedure, risks, benefits, and alternatives and agreed to proceed with surgery. Patient indicated age-appropriate understanding and assent to the plan."

Consent Note: Documentation – Stronger Note Example

The stronger note example includes:

- Diagnosis ***discussion***, recommendation, and description of procedure
- Specific material risks to the procedure noted, alternatives and their inherent risks, including doing nothing and the risks of doing nothing noted
- Questions from both the parents (and the patient minor) with direct "quotes" included in the documentation
- Consent obtained (*including age-appropriate explanation and patient assent*) and clearly documented

Case Study 1

Patient	Recommendations / Intervention	Complications	Outcome	Consent Flaws
73-year-old male referred to vascular surgeon for exertional leg pain, (L > R) **MHx:** Smoking, HTN hyperlipidemia, CAD (no chest pain reported) **Phy Exam:** Absent right femoral pulse, diminished left femoral pulse, no foot pulses, pink skin without tissue loss **Studies**: Arteriogram showed severe bilateral aortoiliac occlusive disease, worse on right, with "coral reef-like" calcifications and right common iliac artery occlusion	Surgeon **recommended** EITHER extra-anatomic bypass or an aortobifemoral bypass Patient **chose** aortobifemoral bypass	During surgery, severe aortic calcification prevented clamping; Balloon catheter ruptured causing hemorrhage and cardiac arrest Attempts to control bleeding and place graft failed due to aortic tearing; Patient arrested again and died from acute abdominal hemorrhage	Autopsy revealed significant coronary artery stenosis contributing to outcome	**No discussion of less invasive alternatives or treatments** **Lacked discussion of surgery risks related to coronary artery disease.** **No preoperative cardiac clearance obtained**

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Case Study 2

Patient

57-year-old male presents w/throat pain

Studies

CT scan: bilateral cervical lymphadenopathy (right > left)

Pathology: Fine needle aspiration (FNA) of right cervical node:

negative for epithelial / granulomatous cells;

low-grade lymphoid neoplasm not excluded

Recommendations / Intervention

Recommendation:

Excision biopsy with fresh tissue for flow cytometry

Intervention:

One month later - Tonsillectomy and excision biopsy performed without complications

Discharged same day

One-month follow-up scheduled

Complications

Two weeks p/o: Resumed work; after two days, fatigue, malaise, choking sensation

Several days later: Coughing up blood, then coughing up excessive blood

Taken to local ED: Choking, gagging, unable to speak,

Cardiac arrest

Difficult intubation due to large blood clot

CPR and airway established; taken to surgery for atrial bleed repair from left tonsillar fossa (site of tonsillectomy)

Outcome

Prolonged coma due to anoxic encephalopathy from cardiac arrest and delayed intubation

Ventilator dependent

Discharged to skilled nursing facility for ongoing care

Consent Flaws

None

Case Study 2

A robust informed consent AND solid office procedures allowed doctor to prevail

- **Postoperative Consult**:
  - Patient was told to call or go to ED if there was a certain amount of bleeding, which patient did not.
- **Documented Calls**:
  - The spouse claimed that they reported bleeding, but a review of documented calls revealed no such thing; and, in fact, the wife reported the patient was 'doing well'.
- **Legal Assertions**:
  - The plaintiff attempted to assert lack of informed consent; however, consent was clearly documented.
  - Failing that tact, the focus shifted to the bleeding problem.

Round-up: Risk Reduction Strategies

Obtain Consent in Advance: For any **planned procedures**, **don't wait** to obtain consent on the day of the procedure.

Teach-Back Method: Use simple easy-to-understand language when having the consent discussion. ***Reconfirm understanding*** early and often.

Document: The consent conversation thoroughly, be sure to include ***all required elements*** and the potential risks **specific to the procedure** being performed.

Ensure: A copy of the signed consent form is placed in the patient's medical record and, if necessary, a copy in the hospital record as well.

Round-up: Key Points to Remember

- Provide enough information so the patient can make an educated decision
- Provide the information in the language the patient understands
- Evaluate the patient's understanding through Teach-Back Methods
- Identify benefits, risks and alternative treatment plan(s)
- Obtain the patient's signature, *if possible*
- Document your discussion

Round-Up: Key Takeaways

- A signed consent form **alone is insufficient evidence** that a **proper informed consent discussion** occurred
- Informed Consent is a **thoughtful discussion** that helps patients **understand their care** and **make informed decisions**
- **Time spent now** to conduct and document **a thorough consent discussion** prevent the risk of a claim and serve as a lifeline if a medical malpractice claim is filed in the future

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Thank You

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