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Title of Talk: The Patient Consent Process
VMS Wednesday Webinar Series
The Patient Consent Process

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**Purpose Statement/Goal of This Activity:**
Define as well as differentiate between general and informed consent.

**Learning Objectives:**
- Physicians will identify the legal concepts behind consent requirements.
- Understand consent for the care of minors.
- Master Vermont’s informed consent requirements around opioid prescribing.

**Disclosures:**
- Is there anything to Disclose?    Yes ☐ No ☒
- Did this activity receive any commercial support?    Yes ☐ No ☒

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In support of improving patient care, this activity has been planned and implemented by the Robert Larner College of Medicine at the University of Vermont and the Vermont Medical Society. The University of Vermont is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

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The Patient Consent Process

Lou Anne McLeod, MHA, CPHRM, FASHRM, HACP
Senior Risk Manager
Objectives

• Understand the General Consent Process
• Review the elements of a General Consent
• Risk management recommendations for the informed consent process
• Consent and minors
• Opioid prescribing informed consent process
Disclosure as a Communication Tool

“Effective disclosure/communication begins with informed consent, which is basically a proactive form of disclosure of an unanticipated or undesired outcome.” (ASHRM)
Why Is Consent Necessary?

• In the US common law has long recognized that adults of sound mind can determine what happens to their bodies.
• This means: You can’t touch someone without their explicit permission
• If a patient hasn’t given consent to be touched, for example with a medical treatment, this could be considered as a cause of action against the health care provider for a battery.
What is a Battery?

- A battery is an intentional act that results in a harmful contact with another
- In healthcare this could mean that a provider performs a procedure without the patient’s consent
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General Consent Process

• Obtained upon admission or registration for diagnostic or treatment services
• Provides authorization for routine services only
• Does NOT provide authorization for complex diagnostics or therapeutic procedures
Liability Protection in the General Consent

- Claims for Battery [unauthorized touching]
- The General Consent Form should contain a statement that indicates the patient has been informed that additional consents must be obtained by the treating provider if the treatment/procedure is non-routine.
Capacity to Consent

• A person must have the capacity to consent to a treatment or procedure.
• Capacity to consent is defined by state and federal laws.
Capacity defined

- Implied Consent (Emergency consent)
- Adult – age 18 years or older
- Parent
- Legal Guardian
- Competency to Consent
  - LEP
  - Incompetent
  - Incapacitated
Emergency

• Treatment may be provided without consent in the case of emergency
• 18 V.S.A. 1852(4) and 12 V.S.A.1909(b)
Treatment Without Consent

- Risk too commonly known, or not substantial
- Patient assures would go ahead regardless of risks
- Patient states they don’t want to know
- Consent not reasonably possible
- Reasonably prudent person would consent
Treatment Without Consent

Informed consent discussions or exceptions to informed consent should be documented in medical record, including the reason for the exception.
Some minors may provide consent to all types of healthcare treatment

All minors may provide consent to some types of healthcare treatment
What HC treatments can minors always consent to?

Minors may request examination or treatment of emergency medical conditions according to CMS (EMTALA)
What HC treatments can minors always consent to?

- Laws vary between the states but generally all minors can consent to:
  - Blood donations at age 17
  - Sexual assault forensic exam
  - Treatment for sexually transmitted diseases
  - Treatment for abuse of drugs or alcohol
  - Psychological service around abuse of drugs and alcohol
  - Contraceptive services
Which minors can give consent to all treatment?

- 12 V.S.A. 7151
- Married or have been married
- Members of the US Armed Services
- Minors emancipated by the court, provider should ask for proof, i.e. court order
Emancipated Minor

- 16 years old
- Lives apart from parents for 3 months
- Managing their own finances
- Demonstrated ability for self-sufficiency
- HS diploma or is earning passing grades
- Not under custody of state
- Not under custody of Comm. Of Corrections
Divorced Parent

• If parents are divorced or separated, there is an assumption that both parents have equal rights regardless of who has physical custody.
Blood Draw for Law Enforcement

A healthcare provider may be liable if they fail to obtain consent for drawing blood from a conscious patient who refuses law enforcement request to a blood test.
Informed Consent

Informed consent is a process by which a patient is provided with information to make an informed, reasoned decision regarding their healthcare and any proposed treatment.
Current Vermont Informed Consent Laws

• Hospital Patient’s Bill of Rights 12 V.S.A. 1990, 12 V.S.A. 1853 (3) and (4).

• Medical Malpractice: A Lack of Informed Consent
  – Failure to provide alternative, foreseeable risks and benefits
  – Failure to provide reasonable answers to specific questions about risks and benefits
AMA

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

- Diagnosis
- Proposed treatment or procedure
- Risk and benefits
- Alternatives
- Risk and benefits of alternatives
- Risk and benefits of no treatment or procedure
Federal Regulations
Conditions of Participation
For Hospitals

Addresses informed consent in:

- Surgery
- Medical Records
- Patient Rights
Objectives of the Informed Consent Process

• Support the patient’s legal and ethical right to direct what happens to their body.
• Supports the physician’s ethical duty to involve the patient in their health care.
• Provides the patient an opportunity to be an informed participant in the healthcare decision making process.
• Minimizes professional liability exposure.
The Elements of Informed Consent

Components to document:

- Proposed treatment
- Risks and Benefits
- Potential complications
- Alternatives
- Risks of no treatment
How Much Information is Enough?

Information should include:

- Medically significant risk
- Probable duration of incapacity
- Medically significant alternatives
Written Informed Consent?

• No specific requirement that informed consent be in writing, however the passage of time, makes documentation of consent important.

• In hospitals, CMS and accreditation agencies require a properly executed form to be included in the patient’s medical record.
Consent Process

• The patient has the opportunity to ask questions.
• He/She understands the discussion and demonstrates understanding.
• “Teach-Back” is a valuable tool to assess understanding.
• Patient then consents.
• Document of discussion and patient understanding.
Preparing for the Informed Consent Discussion

• Determine the patient’s capacity to engage in a meaningful discussion regarding their healthcare and proposed treatment.
• Ascertain the patient’s general health literacy.
• Provide patient specific education and information to improve their health literacy.
Even those who appear to understand may not truly be informed

- Signature may not be enough

- Studies show there is a gap in understanding

- Communicate clearly to allow patients to make informed decisions about their care.

  - 18-45% of patients unable to recall major risk of surgery or what procedures they agreed to
  - 44% don’t know the exact nature of their operation
  - 60-69% of patients do not read
  - Roughly 60% don’t understand the information in the informed consent despite signing them.
Well, yes, I suppose I could explain the test results in “plain English” - but then you’d know how sick you are.”
How is Health Literacy Measured?

The Health Literacy of America’s Adults
Results From the 2003 National Assessment of Adult Literacy
Health Literacy by Age

Figure 2-7. Percentage of adults in each health literacy level, by age: 2003

NOTE: Detail may not sum to totals because of rounding. Adults are defined as people 16 years of age and older living in households or prisons. Adults who could not be interviewed because of language spoken or cognitive or mental disabilities (3 percent in 2003) are excluded from this figure. SOURCE: U.S. Department of Education, Institute of Education Sciences, National Center for Education Statistics, 2003 National Assessment of Adult Literacy.
Best Practice: NQF 2010
Safe Practice 5 - Informed Consent

Patient explains in their own words

..the diagnosis or health problem requiring care, nature of that treatment, name and nature of the treatment, service, or procedure, including what receiving it will entail; and the primary risk, benefits, and alternatives

“Teach-Back” Concept
“Teach-Back”

The “teach-back” technique is an effective method for ensuring that patients understand what you have told them.

AMA Health Literacy and Patient Safety
Who’s Responsible

• The Physician – responsibility can’t be wholly delegated.

• Participation of staff important – not a substitute for personal communication with the responsible physician

• Signature on form is not enough. Document the process, the conversation, and include all informed consent elements.
Shared Decision Making

- Relationship: patient and physician
- Communication
  - Willingness
  - Sharing
  - Conveying
  - Exchanging
  - Clarifying
  - Understanding
  - Responsibility
Skills for Eliciting Informed Consent

• Empathetic Listening

• Disclosing and Explaining

• Framing
The Right of Refusal

“Implicit in and intrinsic to the concept of consent for treatment is the option of refusal” 14th Amendment US Constitution

Who can refuse:

- Competent adults.
- Authorized surrogates.
- Parents.
Medical Decision-Making

Assess decision-making capacity:

- Does the patient understand all the information?
- Does the patient appreciate how the information applies?
- Can the patient evaluate the information? Risks? Benefits?
- Can the patient make a rationale, consistent choice?
- Can the patient communicate their understanding?

* Evaluate the medical record for evidence of capacity
Potential Liability Claims

Allegations in professional liability claims:

- Failure to properly inform.
- Failure to properly care for and treat.
- Failure to properly evaluate and diagnose.
- Failure to properly order diagnostic studies.
Informed Refusal

- An education process.
  - Provides the patient a full understanding of all facts.
- A patient assessment process.
  - Provides an opportunity for evaluation of the patient’s level of understanding.
- A communication process.
  - Provides both the patient and the practice an opportunity to explore the reasons for refusal.
Documentation of the Refusal Discussion

Include the following notation:

- Information provided to the patient regarding their diagnosis.
- The proposed treatment plan.
- Reasons for the proposed treatment plan.
- Outline of the possible risks and consequences of not following the proposed treatment plan.
- Complete an informed refusal form.
Provision of Ongoing Patient Care

The obligation to provide care in the patient’s best interest:
- Maintaining long-term patient relationships.
- Document the patient’s refusal for proposed treatment.
- Build a case for treatment over time.
- Document review of the recommended treatment at subsequent appointments and leave the door open for a change of plan.
- Document ongoing refusal.
Death by Drugs: Opiates Claimed a Record Number of Vermonter in 2016

By MARK DAVIS  @DAVIS7D
New Focus and Guidelines

• A failure to be familiar with and follow these rules can lead to actions by the Board of Medicine, malpractice suits and criminal convictions.
Must Provide Education and Informed Consent

• Cannot be delegated
  – In-person discussion
  – Risks, potential side effects, alternatives
  – Safe Storage and disposal

• Education sheet created by Dept. of Health
Your provider is prescribing an opioid drug to treat pain. Anyone can get addicted to these powerful drugs.

Ask yourself: Do I really need this?
Talk with your doctor about risks, side effects and other ways to treat your pain.
If you decide to take this drug, here’s what you need to know:

Using this drug may cause addiction.

- Opioid addiction is a lifelong problem. It can start with just one prescription.
- Children and youth have a higher risk of future addiction if they take opioids when they are young.
Prescribed Opioid Informed Consent

Your provider has prescribed opioids to treat your pain. It is important for you to understand the risks associated with this medication. While opioids can be effective at treating acute (sudden or short-term) pain, using them even for a short time can increase your chances for addiction in the future, especially if taken early in life. Many patients find that there are other methods, such as ibuprofen and acetaminophen, as well as physical therapy, massage or acupuncture, to treat their pain and that they do not need opioid medications. Talk to your provider about other options for pain relief.
Talk to Your Patients

• Discuss with your patients:
  – Risks of taking prescription opioids
  – Screening tools to assess risk
  – Non-opioid treatment options

• Use teach-back to verify understanding
Storage and Disposal

• Make sure your patients are aware of the risk of unsecured locations
• Grandparents’ medicine cabinets
• Options for unused medications
Vermont Drug Disposal

Vermont Department of Health: Safety Store and throw away unused or expired medicine. It prevents misuse.
Drug Disposal

• Assist your patients in properly disposing of their unused medication by being aware of drop-off sites in your community
Risk Management Recommendations: Informed Consent

1. Policies and procedures
2. Comprehension
3. Elements
4. Documentation
5. Refusal
6. Opioid Prescribing
Questions?

This presentation is not intended to replace specific legal advice from an attorney. It is an educational program expressing views and opinions using generally acceptable risk management methodology.
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