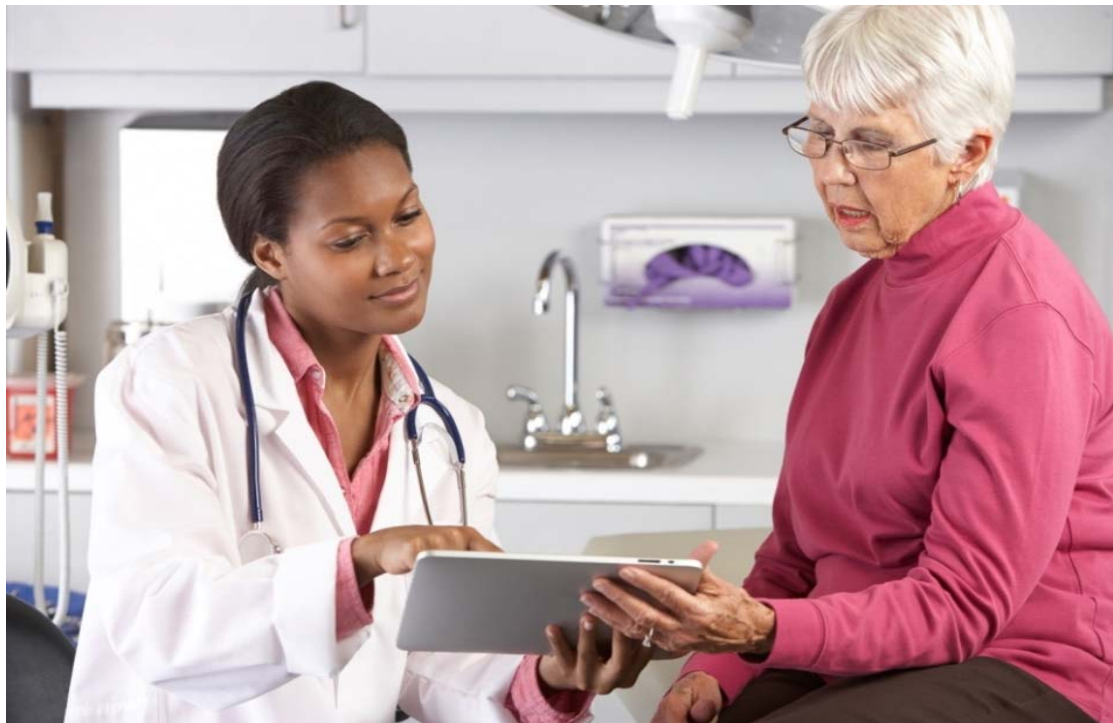

Informed Consent



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(2-18)

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Overview

- Capacity
- Surrogate Decision-makers
- Treatment without Consent
- Informed Consent
- Documenting Consent
- Advance Directives



Preliminaries

- Informed consent is generally governed by state law.

- Know your state law!

- Statutes and regulations
- Licensing standards
- Case law
- Community standard of care
- Accreditation standards



Preliminaries

- Written materials
 - Stanger, *Consent Forms v. Informed Consent*
 - CMS Conditions of Participation Interpretive Guidelines for Hospitals
 - Hospitals: 42 CFR 482.24(c)(4)(v) and 482.51(b)(2)
 - CAHs: 42 CFR 485.638(a)(4) and 485.639
 - Sample Informed Consent Policy
 - Check your state law and modify as appropriate!

Preliminaries

- Submit questions via chat feature or directly to kcstanger@hollandhart.com.
- The session will be recorded and available for download at <http://www.hhhealthlawblog.com/webinar-recordings-and-presentations>.

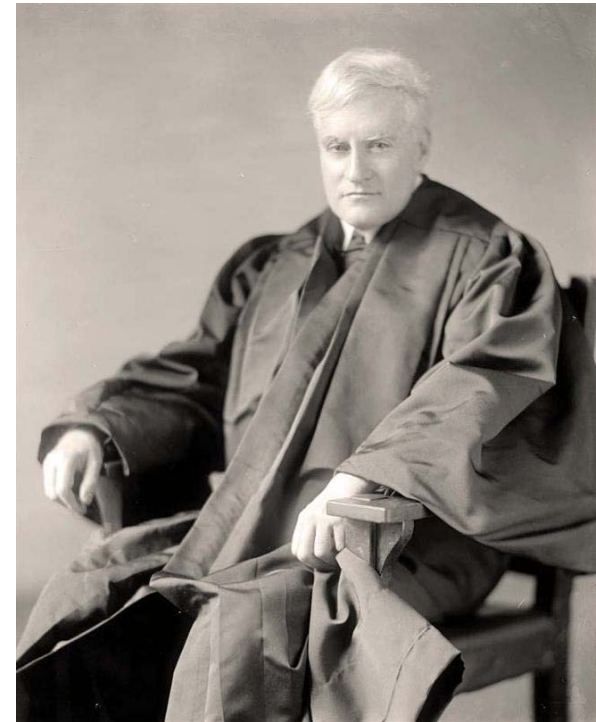
Informed Consent for Treatment



Consent: General Principles

“Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages.”

--Justice Cardozo, *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914)



Consent: General Principles

- Right to consent = Right to refuse consent.
- Must have valid consent for treatment.
- If patient lacks capacity to consent/refuse, need:
 - **Advance directive**
 - **Consent from authorized surrogate**
 - **Statute or law authorizing treatment without consent**
- In an emergency and no time to obtain consent, provide necessary care.
- Must provide sufficient information to ensure that the consent is informed.

Consent Requirements

- Found in:

- Common law

- Cases

- Statutes

- Licensing regulations

*Know your
state law!*

- Medicare/Medicaid conditions of participation

- Facility standards

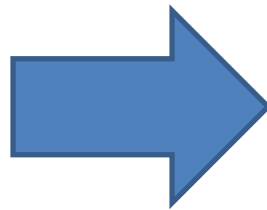
- Patient rights

- Accreditation standards

Consent: Liability

Failure to Obtain Consent =

- Malpractice
- Battery
- False imprisonment
- Tort of lack of informed consent
- Other?



Penalties

- Criminal fines
- Prison
- Civil damages
- Adverse licensure action

Informed consent is a defense!

Lack of Informed Consent

- Treat patient who lacks capacity to consent to their own care (e.g., patient medicated, intoxicated, underage, etc.).
- Ignore patient's prior wishes or decisions (e.g., provides care contrary to advance directive).
- Continue treatment even though patient has objected or withdraws consent.
- Provides treatment that exceeds scope of consent.
- Fails to inform patient of sufficient info reasonably necessary to enable patient to make an informed decision.
- Fails to effectively communicate with patient so as to convey or receive informed consent (e.g., limited English proficiency, disability, etc.).

Capacity/Competency



Capacity/Competency

- General Rule: Patient must have sufficient capacity/competency to provide effective consent.
 - Mental capacity:
 - Able to comprehend the relevant facts and make rationale decisions.
 - Depends on individual and circumstances.
 - Age:
 - Unemancipated minors usually lack capacity to consent to or refuse their own care.
 - Subject to exceptions.
- May be defined by statute, regulation or cases.

Capacity: Adults

Standard

- **Does patient understand the circumstances and consequences of their decision?**
- Courts generally presume adult is competent to make their own decisions unless proof of alternative.
- Document close cases.

Factors

- Intelligence
- Maturity
- Consciousness
- Emotional status
- Impairment from injury, drugs, alcohol, etc.
- Other

Capacity: Minors

Standard

- Unemancipated minor (under age 18) usually lacks competency to consent to their own care.

Exceptions

- Emancipation
- Law or regulation grants authority to minor
- “Mature minor” doctrine

Minors: Emancipation

- Emancipated minor may usually consent to their own care.
 - Common emancipating events
 - Court declares the minor to be emancipated
 - Marriage
 - Pregnancy (maybe)
 - In armed forces
 - Living on own and self-sufficient; rejected parent child relationship
 - Others?
 - Must still satisfy the basic test, i.e., able to comprehend the relevant facts and make rationale decisions.
- **Know your state law!**

Minors:

Common Laws Allowing Minor to Consent

- Laws may allow minors above a certain age to consent to some types of care, e.g.,
 - Emergency medical exam and stabilizing treatment in hospital. (HHS Interpretive Guidelines to 42 CFR 489.24)
 - Family planning services funded by Title X of the Public Health Services Act. (42 USC 300(a); 42 CFR 59.5(a) and 59.11)
 - Contraceptives
 - Communicable diseases
 - Mental health
 - Substance abuse
 - Others
- **Know your state law.**

Minors:

Mature Minor Doctrine

- In some states, minors with sufficient maturity may consent to their own care.
 - Constitutional right of privacy may grant individual with sufficient capacity the fundamental right to make decisions about themselves and their offspring, especially in matters of reproductive rights. (*See, e.g., Carey v. Population Services Int'l* (S.Ct. 1977))
- **But be careful before issue is decided in your state...**

Minors:

Mature Minor Doctrine

- Risks of allowing minor to consent to their own care absent express statute or case:
 - May expose practitioner to lawsuit if parents or others challenge consent.
 - No payment.
 - Litigation costs.
 - Potential damages.
 - May limit ability to obtain payment.
 - Minor may not have assets.
 - No agreement by parents to pay.
 - May limit ability to disclose info to parents.
 - HIPAA usually limits disclosures.

Surrogate Decision Makers



Surrogate Decision Makers

- If patient lacks capacity, may need to obtain consent from authorized surrogate decision maker, e.g.,
 - Guardian
 - Holder of durable power of attorney
 - Spouse
 - Adult children
 - Parent
 - Other appropriate family member
 - Other person?

➤ **Know your state law.**

Surrogate Decision Makers

Caution:

- Surrogate usually lacks authority to trump prior expressed wishes of competent patient.
 - Express instructions
 - Advanced directive
- Some surrogates may have more authority than others.
 - For example, legal guardian > parent
- Surrogate must have sufficient capacity to make their own healthcare decisions.

Care Without Consent



Care Without Consent

- In emergency situation, provider is usually authorized to provide emergency care if there is no time to obtain informed consent.
 - Should be consistent with any known wishes of patient.
 - Seek consent from patient and/or authorized surrogate as soon as possible.
 - Limit to scope of emergency.
- Document:
 - Emergent condition
 - Efforts to obtain appropriate consent

Care Without Consent

Some statutes allow treatment without consent.

- “Mental hold” statutes.
 - **Make sure you satisfy criteria**
- Treatment of infant or minor brought for shelter care.
- Certain tests and treatments for newborns, including germicide and PKU tests.
 - **Parents may refuse based on religion.**
- Limited testing or treatment ordered by law enforcement, such as blood test for DUI or testing of prisoners for communicable diseases.
 - **Undermined by recent court cases and media coverage.**

➤ **Know your state law!**

Form of Consent



Form of Consent

- In general, consent may be:
 - Implied
 - Oral
 - Written

The more significant the treatment, the greater the need to document informed consent.
- Other laws, payor terms, or accreditation standards may require documented consent, e.g.,
 - Telemedicine
 - Certain types of procedures
 - Hospital Conditions of Participation
 - Joint Commission RC.02.01.01
 - Others

Form of Consent: Suggestions



Invasiveness and Risks

- **Specific consent: significant treatment**
 - Communication about specific treatment.
 - Pre-published forms may help provide info and document consent, but beware undue reliance.
 - Medical record notes confirming that elements of consent satisfied, e.g., patient competency, discussion, understanding, questions/answers.
- **General consent: upon registration**
 - Covers basic treatment activities, e.g., physical exams, basic medications, diagnostic tests, labs and pathology, photos, etc.
- **Implied consent**

Informed Consent



Informed Consent

Informed Consent = Communication

- Practitioner communicates info relevant to treatment
- Patient understands the material facts, e.g., benefits, risks, and likely consequence of the proposed treatment and alternatives.
- Patient makes informed decision to consent or refuse treatment.

Consent form = Documentation

- Supplements oral or other info given by the practitioner.
- Documents that the communication process took place, e.g., that practitioner communicated relevant info, patient understood info, and patient made voluntary, informed decision.

Informed Consent

- Beware situations where consent may not be informed.
 - Provider fails to provide sufficient relevant information to enable informed decision.
 - Patient lacks sufficient education, intelligence or maturity to understand relevant considerations.
 - Patient does not speak the same language or suffers from disability.
 - Patient is medicated, distracted, stressed, etc.

Informed Consent

- Ensure that patient understands.
 - Evaluate whether patient is in a condition so as to be able to process relevant info.
 - Speak at the patient’s level of understanding.
 - Beware language barriers.
 - Discrimination statutes may require interpreters, translators, or communication aids.
 - Supplement oral communications with written or visual material and documentation.
 - Give the patient an opportunity to ask questions and receive answers.

Informed Consent

- Informed consent typically requires disclosure of:
 - Nature of proposed treatment.
 - Potential benefits, risks or side effects, including problems that might occur during recuperation.
 - Likelihood of achieving goals.
 - Reasonable alternatives.
 - Relevant risks, benefits and side effects of alternatives, including consequences of not receiving care.
 - Persons who will perform significant aspects of treatment.
- *What information would you want to make informed decision?*

Informed Consent

Hospital Conditions of Participation

- Name and signature of patient or legal representative.
- Name of the provider.
- Name of treatment or procedures.
- Name of all practitioners performing the procedure and individual significant tasks if more than one practitioner.
- Risks and benefits.
- Alternative procedures and treatments and their risks .
- Date and time consent is obtained.
- Statement confirming procedure was explained to patient.
- Signature of person witnessing the consent.
- Name and signature of person who explained the procedure to the patient or guardian.

(See CMS SOM to 42 CFR 482.24(c)(2)(v))

Informed Consent: Therapeutic Privilege

- In some states, provider may refuse to disclose certain information to patient if non-disclosure is determined to be in the patient's best interests.
- HIPAA allows provider to refuse to disclose info to patient to avoid substantial risk of harm. (45 CFR 164.524)
- Use cautiously!
 - May not apply in your state.
 - Contrary to general presumption that patient is entitled to make informed decision.
 - If invoke, document basis.

Voluntary Consent

- Consent must be voluntary.
 - Not coerced or obtained through intimidation.
 - Not given under duress, if possible.
 - Not obtained by fraud.

Scope and Duration

- Consent is generally limited to specific procedure or course of treatment for which consent was given and any incidental, included procedures.
- Consent generally does not extend to procedures outside scope of original consent.
- New consent should be obtained if change in circumstances, e.g.,
 - change that impacts risk.
 - change in method or treatment.
 - change in providers.
 - significant lapse in time.

Scope and Duration

- If possible, obtain consent sufficiently in advance to give patient time to consider and decide on alternatives.
 - Depends on circumstances.
 - But not so far in advance that circumstances might change.
 - Obtain or reaffirm consent if too much time has passed or circumstances have changed.
- *Beware “old” consents because circumstances may have changed.*

Responsibility for Obtaining Consent

- As a general rule, the practitioner who is ordering the care is ultimately responsible for ensuring that effective consent is obtained.
 - They have requisite knowledge to provide info necessary to obtain consent.
 - They can answer questions.
 - They are liable if they provide care without consent.
 - Tort (e.g., malpractice, battery, etc.)
 - Licensing standards
 - Statutory requirements

Refusal of Treatment



Refusal of Treatment: Patient

- Right to consent = Right to refuse consent.
- Competent patient generally has the right to refuse treatment.

Refusal of Treatment: “Against Medical Advice”

- Provide sufficient info to allow patient to make informed refusal.
- Document in chart:
 - Patient’s competency.
 - Explanation of risks and benefits.
 - Practitioner’s attempt to obtain patient’s informed consent.
 - Patient’s signature confirming voluntary decision.
 - Witnesses.
- Attempt to obtain patient’s signed refusal.
- Some statutes may require certain documentation for refusal, e.g., EMTALA, 42 CFR 489.24(d)(3), (5)

Refusal of Treatment: Surrogates

- Authorized surrogate generally has the right to refuse treatment for patient.
 - If authorized surrogates disagree re care:
 - Non-emergency: require them to work it out before you provide care.
 - Emergency: provide care based on consent from surrogate who approves necessary care.
 - If authorized surrogate refuses necessary care:
 - Confirm their authority to do so.
 - Report abuse or neglect to proper agency.
 - Seek court authority to provide care.
- **Know your state law!**

Refusal of Treatment: Surrogates

- Most states generally allow parents or guardians to decline treatment based on religious beliefs.
 - But state may still intervene to require care.
 - “The right to practice religion freely does not include the right to expose the community or the child to ... ill-health or death... Parents may be free to become martyrs themselves. But it does not follow they are free ... to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.” (*Prince v. Massachusetts*, 328 U.S. 158 (1944))
- **Make sure you have authority from state before intervening.**

Refusal of Treatment: Surrogates

- Common statutes that limit surrogates' refusal to consent to care.
 - Child abuse or neglect
 - Adult abuse or neglect
 - Protections for developmentally disabled
 - “Baby Doe” regs

Refusal of Care v. Euthanasia

Refusal of Care

- Refusing necessary care; allowing death by natural means.
- Generally allowed.

Euthanasia, Suicide, or Assisted Suicide

- Affirmatively taking steps to cause death.
- Illegal in most states.

Advance Directives



Advance Directives

- **Competent adult may express their directives through:**
 - **Direct instructions by competent patient.**
 - **Be sure to document same.**
 - **Advance directives executed in case the patient becomes incompetent or unable to communicate.**
 - **Living will**
 - **Durable power of attorney for healthcare**
 - **Physician orders for scope of treatment (“POST”)**
 - **Do not resuscitate order**
 - **Mental health directives**
 - **Other**
- **Know your state law.**

Advance Directives

Cautions:

- Understand requirements under state law.
 - **Technical compliance required?**
- Revocation requirements.
 - **Legal requirements**
- Suspension under certain circumstances.
 - **Surgery/anesthesia?**
- Obligation to seek or verify advance directives.

Patient Self-Determination Act

- Hospitals, nursing facilities, HHAs, FQHCs, RHCs, hospices, and personal care nursing supervisors must:
 - Provide written info to patients regarding right to make decisions concerning their care and execute advance directives.
 - Document in prominent place in medical record whether patient has executed advance directive.
 - Not condition care or discriminate based on advance directive.
 - Ensure compliance with state law regarding advance directive.
 - Educate staff and community regarding advance directives.

(42 USC 1395cc(f); 42 CFR 489.102)

Questions or More Information?



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