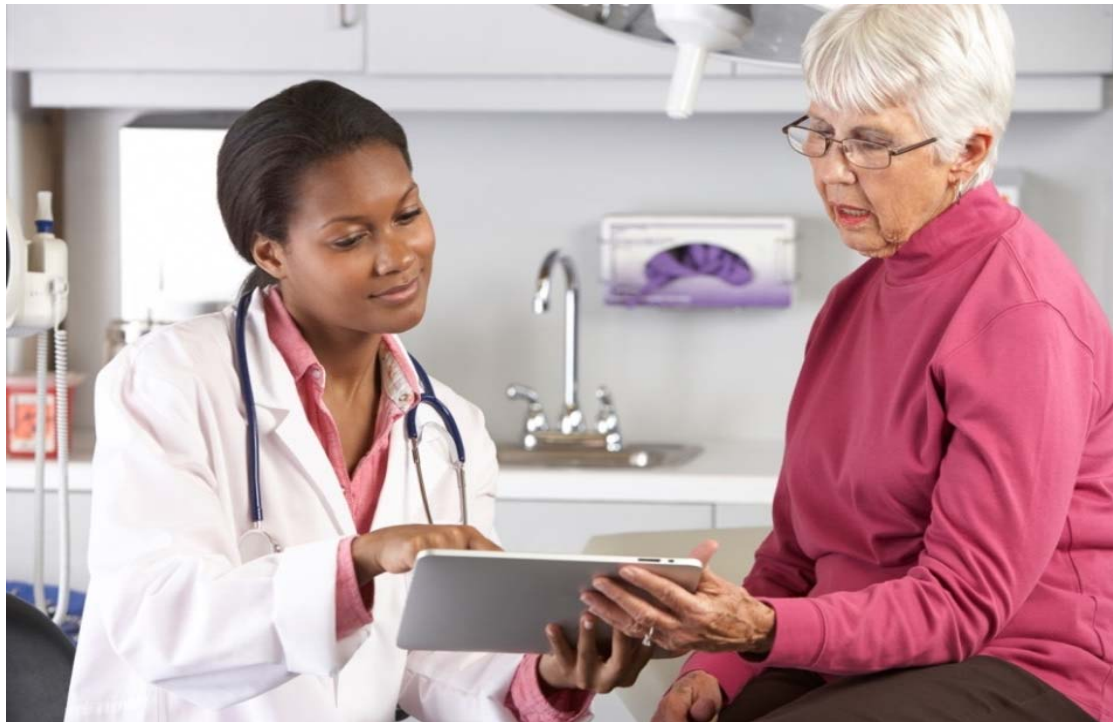


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# Informed Consent



Brad Cave

# Overview

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- Informed consent
- Capacity
- “Substitute” decisionmaker



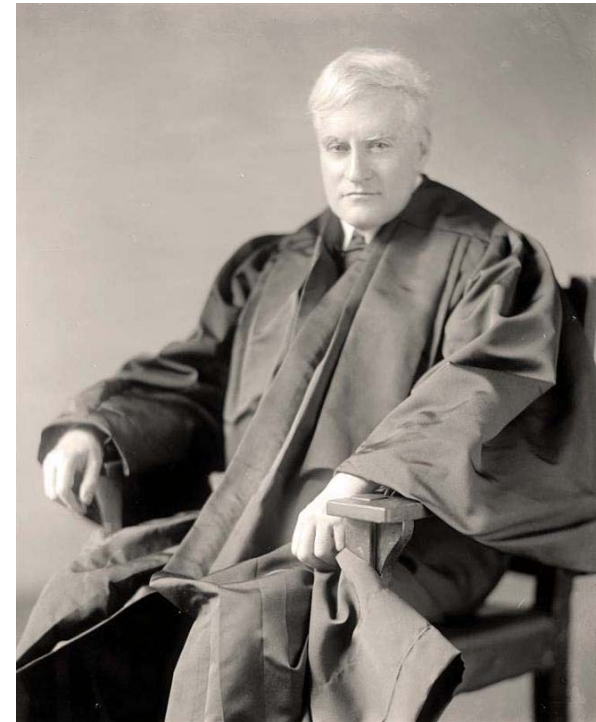
# Informed Consent for Treatment



# 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

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- Right to consent = Right to refuse consent.
- Must have valid consent for treatment.
- Consent must be voluntary.
- If patient lacks capacity to consent, law supplies various means of obtaining consent.
- In an emergency and no time to obtain consent, provide necessary care.
- Must provide sufficient information to ensure that the consent is informed.

# Informed Consent - Defined

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- **Wyoming Supreme Court:**
  - The physician is required to disclose only such risks that a reasonable practitioner of like training would have disclosed in the same or similar circumstances
  - Must disclose usual risks associated with the procedure or plan of care
  - Liability requires proof that a reasonable person in the plaintiff's circumstances would have declined the procedure that caused injury if adequately informed of risks

# Informed Consent

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- 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

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- 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.



# Responsibility for Obtaining Consent

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- 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

# 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

## Hospital Conditions of Participation

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- 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))

# 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**

# Scope and Duration

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- 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.*

# Lack of Informed Consent

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- 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

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- **Mental capacity:**
  - Able to understand significant benefits, risks and alternatives to proposed health care and communicate a health care decision (Wyo. Stat. 35-22-402(a)(iv))
  - Capacity for health care decisions is presumed until the “primary physician” certifies a lack of capacity
- **Age:**
  - Minors <18 usually lack capacity to consent to or refuse
  - Subject to exceptions

# Minors: Emancipation

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- Emancipated minor may usually consent to their own care.
- Common emancipating events
  - Court order
  - Marriage
  - Pregnancy (maybe)
  - In armed forces
  - Living on own and managing own affairs
  - Parents cannot be located and need for care is sufficiently urgent
- Must still satisfy the basic test, i.e., able to comprehend the relevant facts and make rationale decisions.

# Exceptions Allowing Minor to Consent

- Emergency medical exam and stabilizing treatment in hospital (HHS Interpretive Guidelines to 42 CFR 489.24; Wyo. Stat. 14-1-101(b)(iii))
- STD examination or treatment (Wyo. Stat. 35-4-131(a))
- Family planning and contraceptives through WYDOH (42 USC 300(a); 42 CFR 59.5(a) and 59.11; Wyo. Stat. 52-5-101(a))
- Abortion, by court order or imminent peril determined by physician (Wyo. Stat. 35-6-118)
- Sexual assault exam, if minor makes report and parents cannot be located, or parent is perpetrator (Wyo. Stat. 6-2-309(e))
- Tobacco cessation program (Wyo. Stat. 14-1-101(b)(vi))
- Reportable diseases (WYDOH Regs, Prev. Health Div., Ch. 11)

# Minors:

## Mature Minor Doctrine

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- Constitutional right of privacy may grant minor 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))
- Wyoming Supreme Court has not clearly decided whether this doctrine applies in Wyoming

# Minors:

## Mature Minor Doctrine

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- 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
    - WHRIA and HIPAA usually limits disclosures.

# Substitute Decision Makers



# Substitute Decision Makers

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- Wyoming law recognizes hierarchy of substitutes who have power to consent for patient without capacity:
  - Agent under a durable power of attorney (DPOA)
  - Guardian
  - Surrogates

# Substitute Decision Makers

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## Caution:

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



# 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)

# DPOAs/Advance Directives



# DPOAs and Advance Directives

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- Advance health care directive (AHCD) can include:
  - Individual instruction concerning a health care decision for the individual, and/or
  - Durable power of attorney (DPOA)
- DPOA appoints an agent to make health care decisions
- Presumed to have capacity to execute, unless certified to the contrary by primary physician

# DPOA Creation and Effect

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- DPOA must be notarized or signed by at least two witnesses present when DPOA signed and who sign under penalty of perjury
- Authority under DPOA arises when primary physician determines patient lacks capacity, and ceases when primary physician determines capacity has been recovered
  - Primary health care provider can make decision if primary physician unavailable

# DPOA Creation and Effect

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- Agent's decisions governed by:
  - Individual instructions (including as stated in AHCD or POLST)
  - Other patient wishes to extent known
  - Agent's determination of patient's best interests, considering patient's personal values to extent known
- Agent's decisions take precedence over guardian's decisions, absent contrary court order
  - With court order, guardian can execute DPOA, AHCDs and individual instructions for patient/ward

# Psychiatric Advance Directives

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- Permits advance consent or refusal for psychiatric restabilization:
  - Measures to restore mental functions or support mental health including medications by mouth or injection, physical restraint, seclusion or crisis counseling
- Must inform psych patients of option, and HCP must assist in preparing the directive
- Become effective when patient lacks capacity
- Valid for two years, with option to extend for two more

# HCP Duty to Comply

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- HCP must chart any knowledge about AHCD or revocation or designation or disqualification of surrogate, and shall request copy of any documentation
- HCP must record and communicate to patient and APs all determinations about capacity or any condition that affects an instruction or authority of agent, guardian or surrogate

# HCP Duty to Comply

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- HCP or institution providing care shall:
  - Comply with individual instruction of patient and reasonable interpretation of that instruction made by authorized person (AP)
  - Comply with health care decision made by AP as if decision made by patient while having capacity
- If patient can comprehend, HCP shall promptly communicate decision and who made it



# HCP Duty to Comply

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- May decline if instruction/decision requires medically ineffective care or contrary to generally accepted and applicable standards
- HCP may decline for reasons of conscience
- Institution may decline when contrary to written policy if policy communicated upon receipt of AHCD that conflicts with policy

# HCP Duty to Comply

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- If HCP or institution declines to follow individual instruction or AP decision, must:
  - Promptly inform the patient, if possible and any APs
  - Provide continuing care, including life sustaining care, until transfer can occur
  - Make all reasonable efforts to assist in transfer to willing HCP or institution, unless AP or patient refuses assistance

# Revocation

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- DPOA revoked by:
  - An individual with capacity can revoke a DPOA only by a signed writing
  - Divorce or legal separation revokes a designation of spouse as agent unless DPOA specifies otherwise
  - Legal guardian can revoke with court order

# Revocation

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- AHCD revoked by:
  - Patient with capacity can revoke all or part of AHCD in any manner that communicates intention to revoke
    - Revocation should be documented and signed, dated by patient or witness as soon as possible
  - A later AHCD revokes earlier AHCD to extent of any conflict between the two
  - Guardian can revoke/adopt new AHCD with court order
- Duty of all to notify institution of fact of revocation

# Surrogates

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- Surrogate can make decision for adult or emancipated minor who lacks capacity if:
  - No valid AHCD
  - No agent or guardian appointed or “reasonably available”
- Adult/emancipated minor can designate or disqualify a person as surrogate by personally informing primary health care provider
  - Capacity to designate is presumed

# Surrogates

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- If no surrogate designated, or designated surrogate not reasonably available, following order applies:
  - Spouse, unless separated
  - Adult child
  - Parent
  - Grandparent
  - Adult sibling
  - Adult grandchild
  - Adult who has exhibited special care and concern for patient and is familiar with personal values and available

# Surrogates

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- HCP can require individual to provide declaration under penalty of perjury of facts to establish authority to act as surrogate
- Surrogate must promptly communicate assumption of authority to members of patient's family who can be readily contacted
- If conflict within surrogate class and disagreement on a health care decision, primary HCP shall follow majority decision

# Surrogates

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- Surrogate bound by patient's individual instruction, other wishes, patient's best interests considering:
  - Patient's personal, philosophical, religious and ethical values to the extent known to surrogate, and
  - Reliable oral or written statements made by patient to family members, friends, HCPs or religious leaders





Questions?