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INFORMED CONSENT
MARYLAND STATUTES AND CASELAW

Disclaimer: This information does not constitute legal advice, is general in nature, and because individual circumstances differ it should not be interpreted as legal advice. The speaker provides this information only for Continuing Medical Education purposes.

Objectives: Participants will understand (1) the general rules of "modern consent theory," (2) how Maryland's high court interprets "modern consent theory," and (3) special consent issues such as futility, surrogacy, and end-of-life consent.

I. GENERAL CONSIDERATIONS

A. General Consent - for standard/routine treatment or procedures without material risks

B. Specific Consent - for all other interventions

C. Exception: implied/emergency consent (Md. Code HG §5-607)

D. Right to Refuse
   1. General rule: The U.S. Supreme Court stated that patients have a "liberty interest" in refusing medical care. *Cruzan v. Director, Mo. Dept. of Health,* 497 U.S. 261 (1990).
   2. Maryland Statute: Md. Code HG §5-613(b). Specifies the right of competent patients to refuse medical care, or right of proper surrogate to refuse medical care.
   3. Exceptions
      a. Suicidal patient
      b. Incompetent patient
         (1) should perform mini-mental status examination
         (2) document "lack of capacity to understand"

E. Obtaining Consent After Providing Narcotic Analgesia
   1. Document mental status
   2. Depriving patient of pain relief until he signs consent form may constitute coercion. Am J Emerg Med 1999; 17:113-116

II. MODERN THEORY OF INFORMED CONSENT IN MARYLAND

A. *Sard v. Hardy,* 379 A.2d 1014 (Md. 1977). Dr. Hardy performed a BTL on Mrs. Sard during a caesarian section. Mrs. Sard subsequently became pregnant. She sued Dr. Hardy for negligent consent because he did not inform her of alternative procedures or the risk of failure. The Court held (1) physicians must disclose material risks, and (2) proximate causation is determined by an objective standard of what a reasonable prudent person in the plaintiff's position would have done if the material risks were properly disclosed. A subjective standard would allow the plaintiff to testify as to what they would have done if they received the proper information.

1. General duties regarding informed consent: (PAR)
   a. explain the **p**rocedure
   b. **a**lternatives
   c. material **r**isks
2. Definitions of "material risks"
   a. (incidence)(severity) = materiality
   b. A risk is material if a reasonable person would want to know about that risk prior to making an informed decision.

B. *Reed v. Campagnolo,* 630 A.2d 1145 (Md. 1993). The plaintiff sued her obstetrician when she gave birth to a baby with multiple birth defects. She made multiple allegations, including negligent consent. She claimed her obstetrician never gave her the option of an AFP test. She sued in federal court. The federal district court sent two certified questions to Maryland's highest court: (1) whether Maryland recognizes a cause of action for wrongful birth and (2) whether the continuation of pregnancy requires informed consent? The Court held that Maryland recognizes a cause of action for wrongful birth, but continuation of pregnancy does not require informed consent.

C. *Dingle v. Belin,* 749 A.2d 157 (Md. 2000). Dr. Dingle, an attending surgeon, obtained consent from Mrs. Belin to perform a laparoscopic cholecystectomy. A resident performed most of the procedure and cut the common bile duct. Mrs. Belin required corrective surgery at another hospital. She sued Dr. Dingle, alleging a breach of contract (misrepresentation). The trail court dismissed this claim. The Court of Appeal described a new additional duty to disclose who will perform the procedure, and held that the plaintiff successfully pled a breach of contract.

1. The breach of contract claim is an action for failure to adhere to a specific agreement.
2. The court remanded the case to the appellate court with instructions to dismiss the plaintiff's claim because she could not prevail on the facts. The signed consent form had no evidence of the allocation of functions

claimed by the plaintiff.

D. *McQuitty v. Spangler,* 976 A.2d 1020 (Md. 2009). The defendant obstetrician admitted Ms. McQuitty and kept her at bedrest when she developed a small abruption. She signed a consent for a caesarian section at a later date so her baby would have a greater chance of survival. She had a larger abruption on her 39th hospital day. Dr. Spangler then performed an emergency caesarian section. The baby was born with cerebral palsy. Ms. McQuitty lost her malpractice case, but also alleged Dr. Spangler failed to inform her of the risks and benefits of alternative treatments throughout her hospital stay. Dr. Spangler argued that a procedure must occur for a cause of action based on improper consent. The Court held for Ms. McQuitty.

1. The court expected Dr. Spangler to meet impossible standards, but . . .
2. The actual holding of the case creates no new law.

E. *Shannon v. Fusco,* 89 A.3d 1156 (Md. 2014). The defendant oncologist prescribed amifostine to prevent radiation damage to the patient's bladder. The patient developed Stevens-Johnson Syndrome. He died shortly thereafter from pneumonia. The plaintiffs used a pharmacologist as an expert witness and tried to use the package insert as evidence that amifostine should nat have been prescribed in this case. The court held . . .

1. A pharmacologist is not per se unqualified to testify as an expert witness in an informed consent case when a physician is a defendant.
2. This pharmacologist was properly excluded because he testifies as to negligence rather than limiting his testimony to the risks and benefits of amifostine.

F. Improper Consent

1. Legal actions formerly based on battery claims
2. Now in Maryland such actions based on negligence or breach of contract.

III. MINOR CONSENT

A. Treatment for Health Related Problems Md. Code HG §20-102

1. Minor who is <u>married</u> or is the <u>parent</u> of a child has the same capacity as an adult to consent to medical care.
2. <u>Emergency Treatment</u>: A minor has the same capacity as an adult to consent to medical care if, in the judgment of the attending physician, the life or health of the minor would be adversely affected by delay.
3. <u>Specific Treatment</u>: A minor has the same capacity as an adult to consent to treatment for or advice about:
   a. drug abuse (including psychologic treatment)
   b. alcoholism (including psychologic treatment)
   c. venereal disease

d. pregnancy
e. contraception other than sterilization
f. injuries from rape or other sexual offenses
g. obtaining evidence of an alleged rape or sexual offense
h. examination for admission to a detention center

4. Capacity to refuse treatment: Minors may not refuse treatment for drug abuse or alcoholism if a parent or guardian has provided consent.
5. Liability: Physicians who treat minors without parental consent have no liability based on an allegation that the minor lacked capacity to consent.
6. Disclosure: Physicians have complete discretion whether to disclose information to parents or guardians, except information regarding abortions.

B. Abortion Md. Code HG §20-103

1. A physician may not perform an abortion on an unmarried minor unless the physician first provides notice to a parent or guardian.
   a. Incomplete notice: The physician may perform an abortion without providing notice to a parent or guardian if (1) the minor does not live with a parent or guardian, or (2) a reasonable effort to provide notice is unsuccessful.
   b. Waiver of notice: The physician may perform an abortion without notice if, in the professional judgment of the physician,
      (1) notice may lead to physical or emotional abuse of the minor
      (2) the minor is mature and capable of giving informed consent
      (3) notification would not be in the best interest of the minor
2. Liability: The physician has no liability if following the requirements of this statute.

C. Other Statutes: Specific statutes allow minors to consent for blood donation (§20-101) and mental health problems (§20-104).

D. Caveats

1. The minor should be able to comprehend and make reasonable decisions (the "mature minor). The consent must be "informed."
2. Generally, attempt to contact a parent or guardian.
3. Don't delay in emergency situations.
4. The more elective the treatment, the more important it will be to contact a parent or guardian.

IV. SURROGATE DECISION-MAKING (Md. Code HG § 5-605)

A. Competent adults may provide their own consent..

B. The statute provides a clear ranking order of those who may provide consent for

an incompetent patient. The health care practitioner may proceed to the next class when no one from a higher-ranking class is reasonably available.

1. health care agent (as designated in advanced directive)
2. guardian
3. Spouse
4. adult child
5. parent
6. adult sibling
7. friend or other relative who meets the following criteria:
    a. competent
    b. presents an affidavit stating:
        (1) the person is a relative or close friend of the patient
        (2) facts demonstrating the person has maintained regular contact with the patient, sufficient to be familiar with the patient's activities, health, and personal beliefs.

C. Standards for Surrogates Md. Code HG §5-605(c). Basically states that surrogates should consider all relevant factors, act reasonably, and in accordance with the patient's known wishes.

D. Dispute Among Surrogates
1. Attending physician shall refer the case to the institution's patient care advisory committee, and may act in accordance with the committee's recommendation, or
2. transfer the patient (if the physician does not want to comply with the committee's recommendation).

V. CONSENT AT THE END OF LIFE (Md. Code HG §§5-601 et seq.)

A. Advance Directive
1. General Rule: Any competent individual may execute an advance directive regarding (1) provision of health care, and (2) withholding or withdrawal of health care.
2. Written instrument: dated, signed, and subscribed by two witnesses
3. Oral directive: has the same effect if made in the presence of the attending physician and one witness, and if then documented in the patient's medical records.
4. Directive only effective when the patient lacks capacity. This must be documented by the patient's attending physician and one other physician; or by only one physician when the patient is unconscious.
5. When properly notified, the physician has the responsibility to make the advance directive a part of the patient's medical record.
6. Revocation: A competent individual may revoke an advance directive at any time, either in writing or orally.

7. Certification of incapacity: by attending physician and one other physician. If unconscious, only one physician required.
8. Terminal or irreversible condition: Life-sustaining treatment may not be withheld based on an advance directive (where no agent has been appointed) or the authorization of a surrogate, unless (1) the patient's attending physician and one other physician certify that the patient has a terminal or irreversible condition, or (2) two physicians, one of whom is a neurologist, neurosurgeon, or one with special expertise in cognitive functioning, certifies that the patient is in a persistent vegetative state.
9. Liability: Health care providers who in good faith follow appropriate advance directives are not subject to criminal prosecution or civil liability. Md. Code HG § 5-609

B. Maryland Medical Orders for Life-Sustaining Treatment (2011)
1. The form is valid in "all health care facilities and programs" throughout Maryland. "Programs" presumably includes EMS systems.
2. Physicians or nurse practitioners may complete the forms.
3. A copy of the original form must be given to the patient or "authorized decision maker" within 48 hours if a patient is discharged or transferred.
4. Practitioners must "certify" they completed the form "as a result of a discussion with and the informed consent of" the patient, the appropriate surrogate, or the decisions are consistent with an advance directive.
5. Section 1 must be completed (CPR or no CPR with or without orior intubation).
6. Sections 2-9 are optional..

C. Medical Futility Md. Code HG §5-611
1. Nothing requires a physician to provide unethical or ineffective treatment.
2. A patient's attending physician may withdraw or withhold medically ineffective life-sustaining treatment. A second physician must also certify the futility of such treatment, and inform the family or surrogate of the decision. When in the emergency department, and only one physician is available, the certification of the second physician is not required.
3. Mercy Killing: The statute does not permit any affirmative or deliberate act to end a life. The statute only relates to the natural process of dying. Health care providers shall make every effort to provide patients with food and water by mouth.

D. Court Orders Md. Code HG §5-612
1. A health care provider who disagrees with a directive, shall
   a. petition a patient care advisory committee, or
   b. file a petition in court seeking an order to allow treatment
2. The patient or surrogate may likewise seek a court order.

E. Penalties Md. Code HG §5-610

1. willful defacement of a declaration
2. forgery of a declaration
3. misrepresentation/falsification of the wishes of the patient

F. Duty of Physicians (summary)
1. Document the presence of a terminal and irreversible condition
2. If unable to comply with an appropriately completed declaration, transfer the patient to the care of another physician.
3. What happens to physicians who ignore a declaration and treat a patient? Not directly addressed by the legislation, but probably has liability for treating the patient without consent.

VI. OTHER CONSENT ISSUES

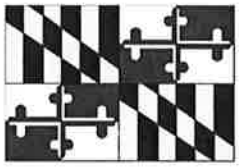
A. Refusal of Medical Care for Religious Reasons
1. Adults may refuse life-saving interventions for themselves, for religious reasons, if not suicidal.
2. Adults may NOT refuse life-saving interventions for their children for religious reasons.

B. Blood Alcohol Testing Md. Code HG §20-110
1. Healthcare providers are not civilly liable for taking blood samples from an individual without consent if requested by a police officer or a sheriff's office.
2. However, one who negligently obtains a blood sample causing injury to the patient may have liability for negligence.

C. Good Samaritan Act Md. Code CJP §5-603
1. Physician has no legal duty to render assistance at the scene of an emergency (i.e.: outside of a health care institution).
2. Physicians have no civil liability for ordinary negligence, only for gross negligence, or reckless/intentional behavior. The treatment must be gratuitous, and provided at the scene of an emergency or in transit to a medical facility.

INFORMED CONSENT

MARYLAND STATUTES AND CASE LAW



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OBJECTIVES

Participants Will Understand . . .

- general rules
- Maryland case law
- minor, surrogate, end of life

TAKE HOME POINTS!

1. the right to refuse
2. material risks
3. who can serve as surrogate
4. when an advance directive is effective

CONSENT

General Considerations

- general consent
- specific consent
- exception

CONSENT

Right to Refuse

- general rule (Cruzan)
- Md. Code HG§5-613(b)
- exceptions
  - suicidal
  - incompetent

CONSENT

What to disclose

- procedure
- alternatives
- risks

MARYLAND CASELAW

Sard v. Hardy, 379 A.2d 1014 (Md. 1977)

Holdings:

- material risks
- objective standard

MARYLAND CASELAW

Reed v. Campagnolo, 630 A.2d 1145 (Md. 1993)

Two certified questions:

- wrongful birth
- continuation of pregnancy

MARYLAND CASELAW

Dingle v. Belin, 749 A.2d 157 (Md. 2000)

- who will perform
- breach of contract

MARYLAND CASELAW

McQuitty v. Spangler, 976 A.2d 1020 (Md. 2009)

- battery/procedure
  - not required to state COA
- MD witheld information
- reversed trial court

MARYLAND CASELAW

Shannon v. Fusco, 89 A.3d 1156 (Md. 2014)

- non-MD may be exp W
- must limit testimony

MINOR CONSENT

When Minors May Consent for Medical Care

- married or parent
- emergency
- specific conditions

MINOR CONSENT
Other Considerations

- capacity to refuse
- liability
- disclosure

MINOR CONSENT
Abortion

- notice
- parent unavailable
- waiver of notice
- liability

MINOR CONSENT
Caveats

- capacity
- contact parent
- don't delay
- elective rx

CONSENT
Surrogate Decision-Making

- general rule
- ranking order

CONSENT
Dispute Among Surrogates

- pt care advisory comm.
- transfer
- (court order)

END OF LIFE
Md. Code HG §§5-601 et seq.

- Cruzan 497 US 261 (1990)
- general rule
- written or oral

END OF LIFE

Md. Code HG §§5-601 et seq.

- when effective
- medical record
- revocation

END OF LIFE

Md. Code HG §§5-601 et seq.

- certify incapacity
- term/irrev, or veg.state
- liability

MOLST (2011)

- valid throughout state
- MD, NP or PA
  - must complete § 1
- requires patient consent
- copy to pt within 48 hours

FUTILITY

Md. Code HG §5-611

- ineffective treatment
- attending MD + MD
- inform family
- mercy killing

END OF LIFE

Petitioning a Court: Md. Code HG §5-612

- MD disagrees with adv. directive
  - pt. care advisory committee
  - seek court order
- pt/surrogate has same rights

DUTIES

Summary

- document
- follow directives
- transfer
- appeal

TAKE HOME POINTS!

1. the right to refuse
2. material risks
3. who can serve as surrogate
4. when an advance directive is effective

QUESTIONS?

COMMON QUESTIONS

- serum alcohol levels
- consent after opiates
- transfusions
- Good Samaritan Act