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Informed Consent

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Why is this Topic Important?

- Obligation to be Truthful
- Engenders Patient Trust
- Develops Patient Autonomy
- Integrity of the Profession

Informed consent

43

6/15/2015

What is “informed consent?”

- The process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention.
- The patient must be competent to make a voluntary decision about whether to undergo the procedure or intervention.
- Informed consent is both an ethical and legal obligation of medical practitioners in the US and originates from the patient's right to direct what happens to their body.
- Implicit in providing informed consent is an assessment of the patient's understanding, rendering an actual recommendation, and documentation of the process.

Origins

Medical

The year was 578. Justin II, the emperor of Byzantium, was in excruciating pain and begged court physicians to operate. They resisted treating him, though, fearing severe punishment if they failed, according to John of Ephesus, the ancient historian who recorded the saga in his Historia ecclesiastica. So what did they do? They asked that he hand them the scalpel they would be using for the surgery as a sign of his free and complete consent.

Legal

The concept of informed consent has a relatively short history, beginning with a series of 4 judicial decisions in the early 20th century that laid the foundation for the principle of patient autonomy:

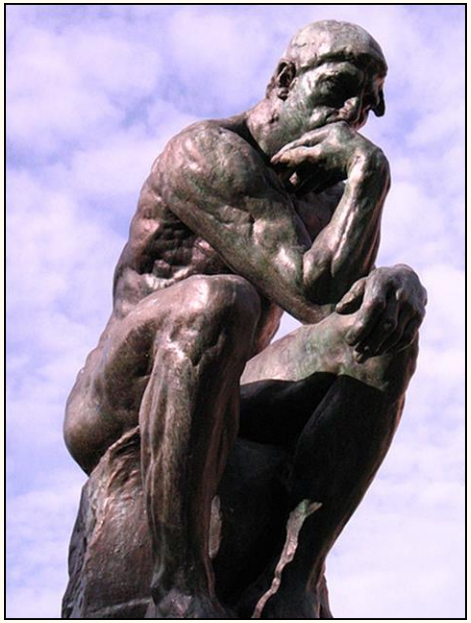
- Mohr v Williams
- Pratt v Davis
- Rolater v Strain and
- Schloendorff v Society of New York Hospital

These cases established and solidified the principle of patient autonomy that ultimately formed the basis of the requirement for informed consent in medicine and research

Origins of Informed Consent

Philosophical Perspective

- Beneficence
  - Obligation to maximize benefit
  - Obligation to minimize harm
- Non-maleficence
  - Doctrine of “primum non nocere”
  - No deliberate harm
- Justice
- Equals should be treated equally
- Autonomy (self governance)



Beneficence

- The Physician:
  - Must have the best interests of the patient in mind
  - Minimally influenced by other concerns
- The Patient:
  - Must trust that the physician their advocate/agent

Non-malificience

Primum non Nocere

- The Physician:
  - Must not intentionally harm or disadvantage a patient.
- The Patient:
  - Must trust that the physician will not willingly harm

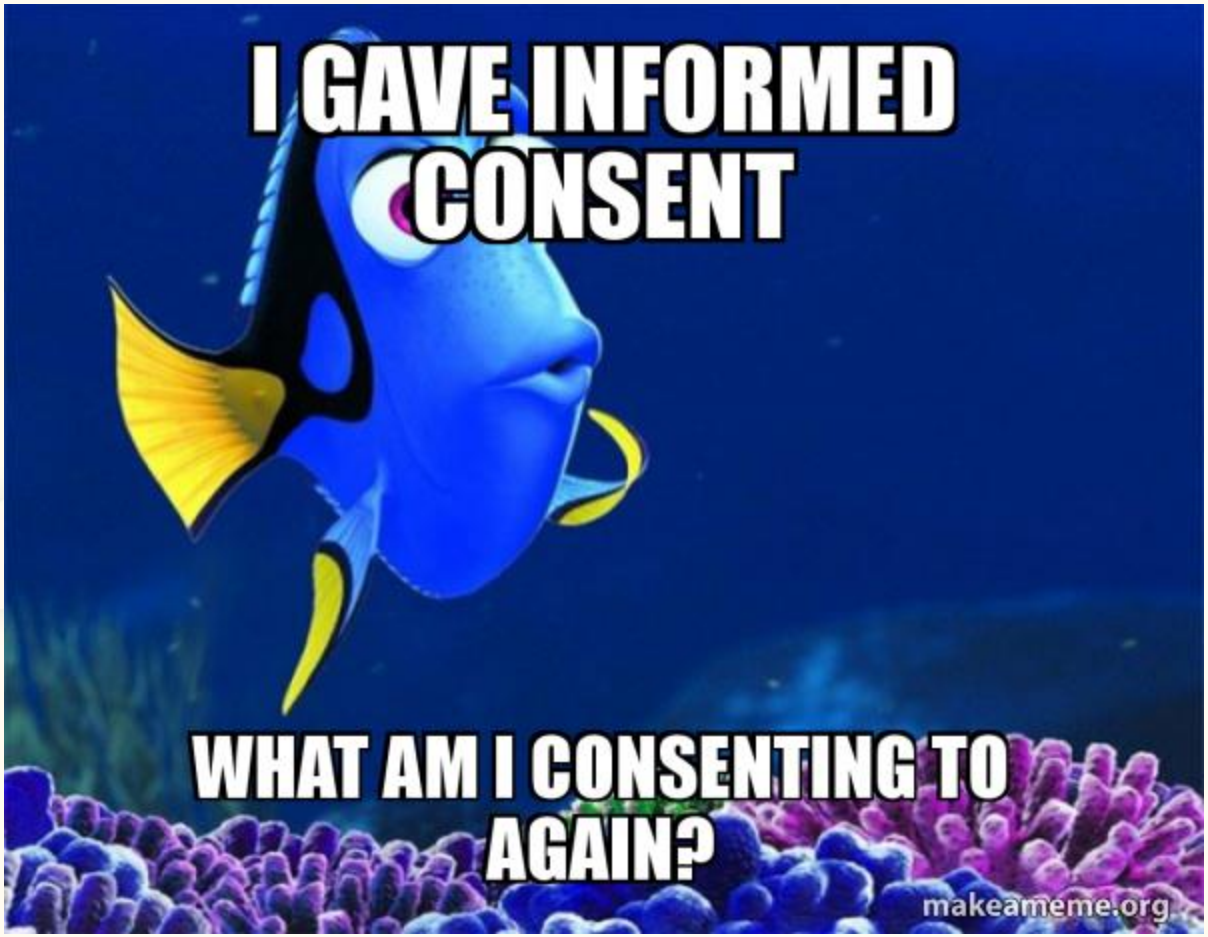
Justice

- Prohibition against denying benefit:
  - Capriciously
  - By selective criteria
- Obligation not to “selectively burden”

Autonomy

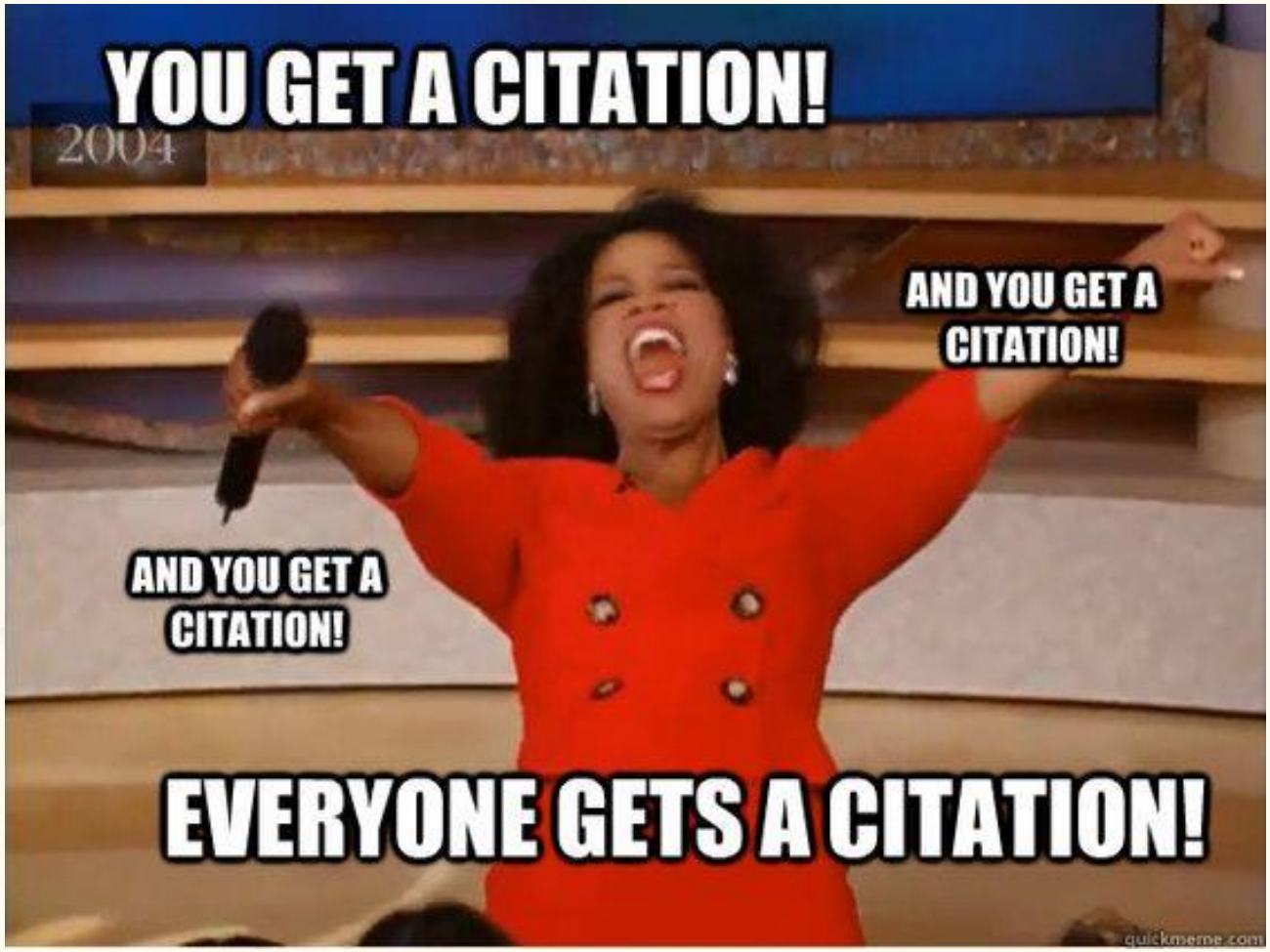
- Patient's self governance: "Being one's own person, without constraints either by another's action or by psychological or physical limitation."

Beauchamp, T. L., & Childress, J. F. (1983). Principles of biomedical ethics (2nd ed.) New York: Oxford University Press


I GAVE INFORMED CONSENT
WHAT AM I CONSENTING TO AGAIN?
makeameme.org

The Joint Commission

- The Joint Commission requires documentation of all the elements of informed consent "in a form, progress notes or elsewhere in the record."
- The following are the required elements for documentation of the informed consent discussion:
  - (1) the nature of the procedure,
  - (2) the risks and benefits and the procedure,
  - (3) reasonable alternatives,
  - (4) risks and benefits of alternatives, and
  - (5) assessment of the patient's understanding of elements 1 through 4.


YOU GET A CITATION!
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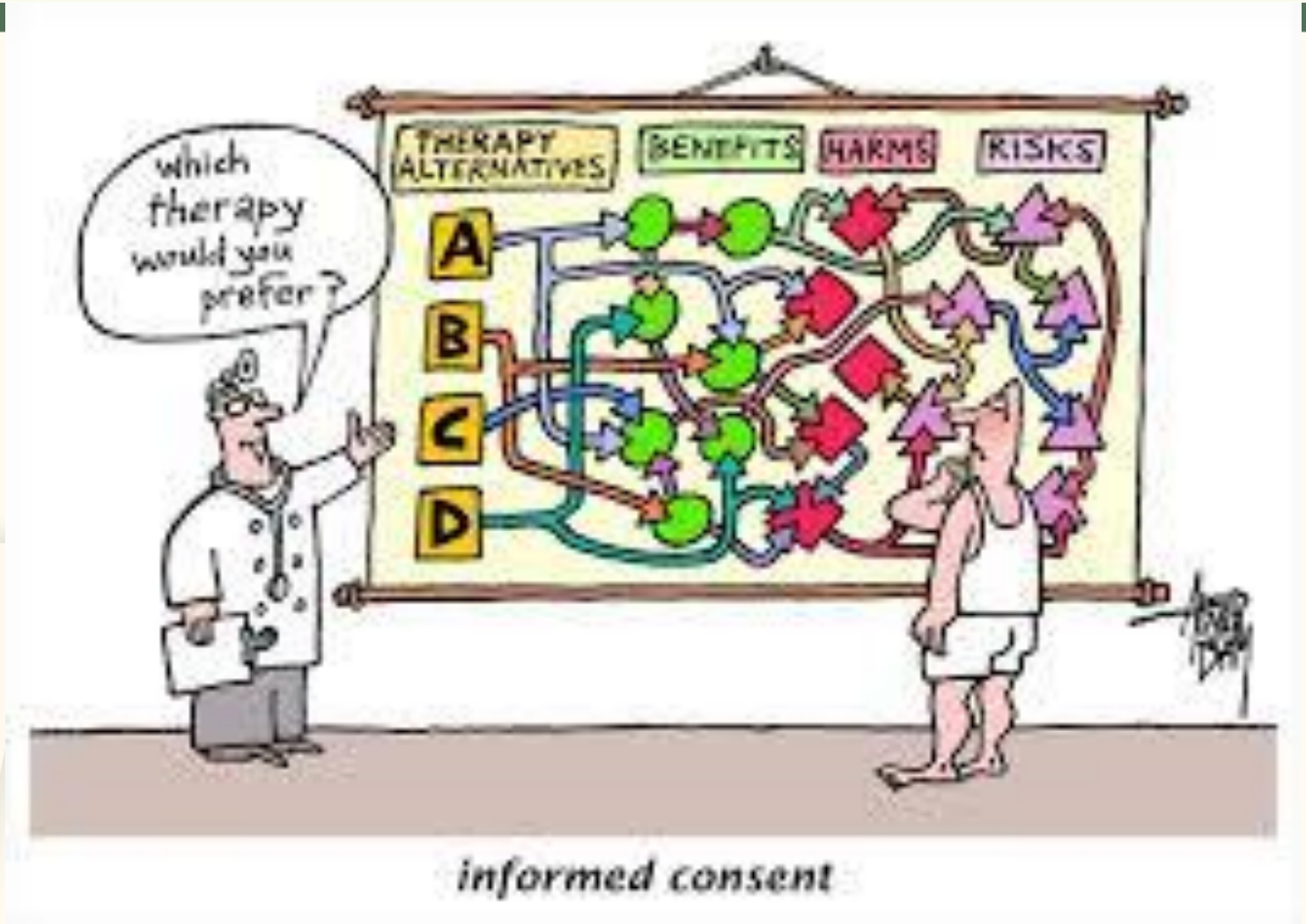
AND YOU GET A CITATION!
AND YOU GET A CITATION!
EVERYONE GETS A CITATION!
quickmeme.com

Principles of Informed Consent

- Informed consent is a dialogue, including:
  - An assessment of patient competence to decide
  - Disclosure of relevant information
  - An assessment patients' comprehension
  - Affirmatively obtain consent from patient or surrogate
- Informed consent occurs before a patient or surrogate signs anything
- Informed consent is *not a signature on a document*.



informed consent

Practical Informed Consent

Disclosure

- The “reasonable person” standard
  - What a “reasonable person” would want/need to know
- The nature of the procedure and indications
- Expected benefits, advantages
- Possible risks, disadvantages (cannot be exhaustive)
- Uncertainties inherent in the intervention
- Reasonable alternatives, including observation

Practical Informed Consent

Documentation

- Rationale: Why the treatment is proposed
- Benefits: The advantages of the treatment
- Risks and Complications: Potentially adverse effects
  - If everything goes right
  - If something goes wrong
- Alternatives: What else can be done
  - (e.g. observation)

Adequacy of Informed Consent

- The required standard for informed consent is determined by the state.
- The three acceptable legal approaches to adequate informed consent are:
  - (1) Subjective standard: What would this patient need to know and understand to make an informed decision?
  - (2) Reasonable patient standard: What would the average patient need to know to be an informed participant in the decision?
  - (3) Reasonable physician standard: What would a typical physician say about this procedure?
- Many states use the "reasonable patient standard" because it focuses on what a typical patient would need to know to understand the decision at hand. However, it is the sole obligation of the provider to determine which approach is appropriate for a given situation.
- Indiana uses the “reasonable patient standard”

Practical Informed Consent

Special Situations

- Clinical research
  - Patients have right to know they are subjects
  - Includes retrospective reviews
- Use of off-label drugs/devices
- Surgical co-management
  - Patients have a right to know, and affirmatively consent to treatment by other providers
- Misleading advertising:
  - Subtle coercion may invalidate informed consent

"The single biggest problem in communication is the illusion that it has taken place."

George Bernard Shaw

Indiana Informed Consent Laws

- In Indiana, the requirement to obtain informed consent is imposed by statute.
- Indiana Code Sec. 34-18-13-3 requires Indiana physicians to obtain their patient's "informed consent" before any "treatment, procedure test, or examination" is performed by the physician.
- Under the statute, in order to obtain informed consent, the doctor must provide medical disclosure and advise the patient of:
  - The general nature of the patient's condition
  - The proposed treatment, procedure, examination or test
  - The expected outcome of the treatment, procedure, examination or test
  - The material risks of the treatment, procedure, examination or test
  - The reasonable alternatives to the treatment, procedure, examination or test
- If a physician or other health care provider fails to obtain his patient's informed consent to a procedure, the physician may be liable for any harm that results to the patient.

Indiana Informed Consent Laws

Rebuttable Presumption

- If a patient's written consent is:
  - (1) signed by the patient or the patient's authorized representative;
  - (2) witnessed by an individual at least eighteen (18) years of age; and
  - (3) explained, orally or in the written consent, to the patient or the patient's authorized representative before a treatment, procedure, examination, or test is undertaken;
- a rebuttable presumption is created that the consent is an informed consent.

IN Code § 34-18-12-2 (2022)

Thank You!

QUESTIONS??