05-11-16

# Medical Jurisprudence

Behavioral Sciences Term
St. Georges University
School of Medicine

Visiting Professor
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Thursday
July 28

**Segment**
**2 of 8**

# Informed Consent

# Objectives

At the conclusion of this unit, the medical student should be able to answer the following 10 questions

1. What is the **history** of informed consent?
2. What is medical **battery**?
3. What is the **difference** between battery and informed consent?

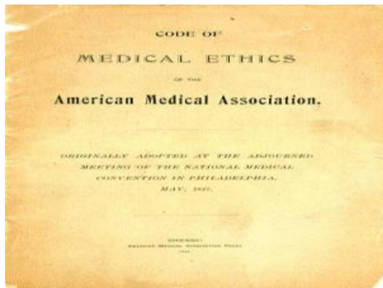
4. What are the **elements** of an informed consent cause of action?
5. What are the two U.S. **standards** for measuring a physician's duty of disclosure?

6. What are the 6 **exceptions** to this duty of disclosure?
7. What does the **causation** element require?
8. What is SDM and patient **decision aids**

9. What are statutory disclosure mandates?
10. What are patient **decision aids**?

# History

# 1847


CODE OF
MEDICAL ETHICS
OF THE
American Medical Association.

ORIGINALLY ADOPTED AT THE ADJOURNED
MEETING OF THE NATIONAL MEDICAL
CONVENTION IN PHILADELPHIA.
MAY,

Do **NOT** consider patient's "own crude opinions"

# 1905

# Battery

No consent **at all**

# 1914

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . . "

As of 100 years ago, law required physicians to get consent

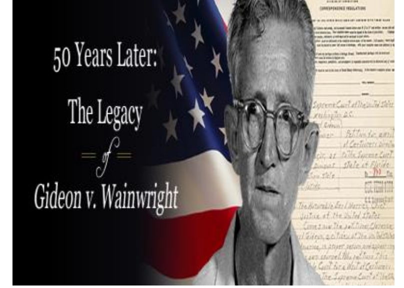
It did not yet require that the consent had to be informed

# 1957

Salgo v. Leland Stanford (Cal.)

# 1960

Natanson v. Kline (Kan.)



**1972**

Jerry Canterbury

That was just a **historical** sketch,
Now, let's look at this **doctrinally**

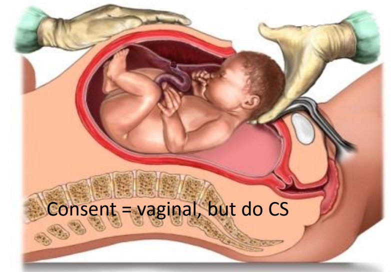
**Battery**

No consent
**at all**

# 4 variations

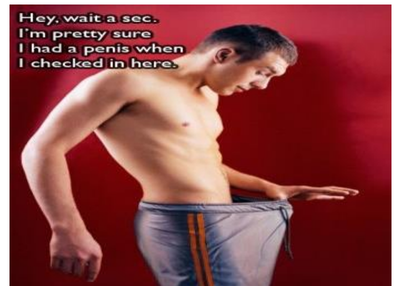
(1) No consent to **any** procedure

(2) Consent only to **different** procedure

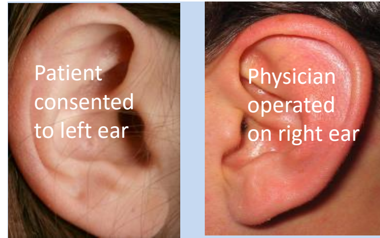



**Seaton v. Patterson**

**(Ky. App. 2012)**



(3) Same procedure, **different body part**



Mohr v. Williams (Minn. 1905)

(4) Same procedure, same part, **different doc**

**Comparing battery & informed consent**

Battery is far **simpler**

| | Informed Consent | Battery |
|---|---|---|
| Injury | X | |
| Duty | X | |
| Exceptions | X | |
| Conduct causation | X | |
| Experts re risks (or duty –IN,DE) | X | |
| Punitive damages | | X |

PTF **need not be injured** (can even be benefitted)

(harm is to **dignity**, not body)

Battery

PTF: "I did **not** consent to what doc did"

**Informed consent**

PTF: "I **did** consent . . . "

"**BUT** I would not have consented, **if** disclosure had been appropriate [non-negligent]"

**Comparing malpractice & informed consent**

"medical malpractice"

Breach of **any** duty owed as physician

Abandonment
Informed consent
Confidentiality
Deviation SOC

But deviation from SOC is also referred to "malpractice"

Physician may have **performed** the right procedure perfectly

Might still have breached duty of informed consent

Problem is physician did not make appropriate **disclosures**

PATIENTS' PREFERENCES MATTER

Stop the silent misdiagnosis

Even without clinical diagnosis, can be preference misdiagnosis

The King's Fund

# Informed Consent
## (Elements)

| | |
|---|---|
| **Duty** | What to disclose |
| **Breach** | Did not disclose |
| **Injury** | Undisclosed risk happened |
| **Causation** | With disclosure, would have avoided injury |

# Duty

Core complaint:

Physician failed to disclose information

But legally actionable only if physician had a **duty** to disclose that information

2 main tests or measures of duty

# Types of information to disclose

# Risks

**Inherent risks** from proposed treatment

Probability

Severity

# Alternatives

Benefits & risks of each **alternative**

One alternative is doing nothing

# Who

**Who** will be providing treatment

Including: role of: residents, fellows, students, and others

# Physician experience

*"No, I haven't performed the procedure myself, but I've seen it done successfully on 'E.R.' and 'Chicago Hope.'"*

**Conflicts of interest**

Disclose intent in using patient for research and economic gain

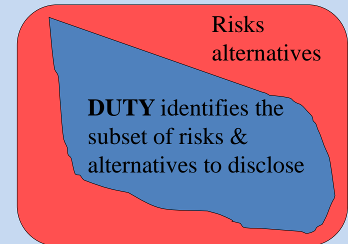
These are just **types** or categories of information

Doc does **not** have a duty to disclose all of this

**What** to disclose?

**Not** everything

Can't send patient to med school




**2** main ways to **measure** MD duty

Reasonable physician

20+ states

Reasonable patient

20+ states

Which standard applies depends on **which state** you are in

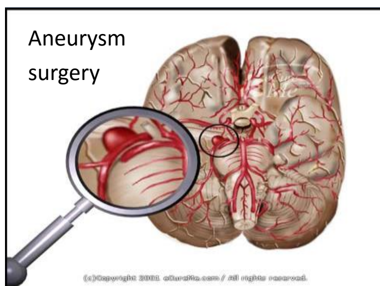
**Reasonable Patient Standard**

aka "material risk" standard

Duty measured by **patient** needs

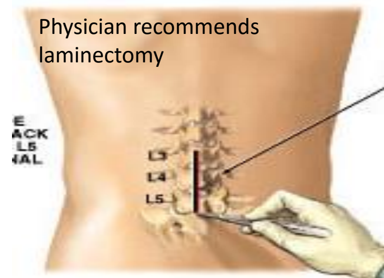
Duty to disclose what would a **reasonable patient** consider important / significant in making this treatment decision

**Johnson v. Kokemoor**




| Doc Said | Best in world | Literature | Limited experience |
|---|---|---|---|
| **2%** | **11%** | **15%** | **30%** |

**Canterbury v. Spence**




Right procedure

Performed competently

No malpractice

But inherent non-negligently caused risk

1% risk paralysis

Reasonable prudent patient would want to know that risk

Therefore, physician has duty to disclose it

Duty measured by what **hypothetical reasonable patient** would deem material, significant in making this treatment decision

# Reasonable Physician Standard

aka "professional standard"

aka "malpractice standard"

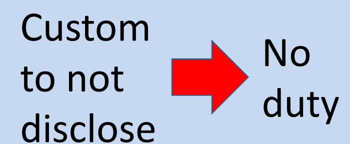
Duty is measured by professional **custom**

Duty to disclose what would the **reasonable physician** have disclosed under the circumstances

Risks, alternatives DEF has **duty** to disclose

Are those **reasonable physician** would disclose under circumstances

Custom to not disclose



No duty

How do we know what a reasonable physician would disclose

Expert witnesses

Almost always, PTF needs **expert witness** to establish the standard of care

No expert → no SOC

No SOC → no breach

No breach → no case

In any given state, duty is established in just **one** way

However duty is established, no duty if an exception applies

# Exceptions to duty

Even if *prima facie* duty under reasonable patient **or** reasonable physician standard, no duty if any 1 of **6 exceptions** applies

# 1

**Information already known**

- To this particular patient
- Or commonly known

# 2

**Emergency**

- Urgent immediate need
- Patient lacks capacity
- No opportunity for consent from surrogate
- No known objection

3

**Therapeutic privilege**

Disclosing risk information would make the patient so upset:

- **That** could not make a rational choice
- **That** would materially affect medical condition

CAUTION: Not to be used when you think the patient is making a "stupid" choice

4

**Waiver**

Patient does not want to know (defers to physician)

5

**Public Health**

Must treat to protect the community (e.g. infectious disease)

6

**CBO clause**

Clinicians can sometimes avoid duty for moral/religious reasons

e.g.
Catholic ED after sexual assault

# Breach

If

1. Duty under the applicable standard
2. No exception applies

Then failure to disclose = breach

DEF **actually failed** to disclose what she had a duty to disclose

Contemporaneous record usually sufficient to prove disclosure made

But patients tape (BMJ)

# Injury

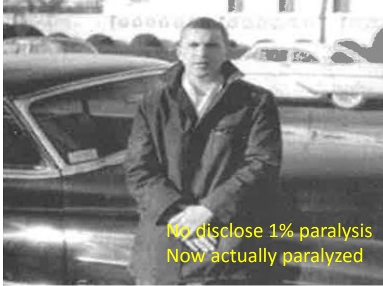
PTF must **actually be injured** from undisclosed risk

(no dignitary tort)

No injury →
No informed consent claim

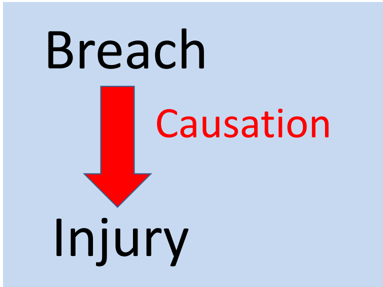
Not sufficient:

"I **could** have been . . . ."




# Causation

Trickiest of the 4 informed consent elements




Plaintiff must establish

**Without** DEF breach (i.e. lack of disclosure), PTF probably would not be injured

This is a hypothetical question

**3** sub-elements

**1**

**PTF** would have chosen differently

Had disclosure been made, **this patient** (PTF) would **not** have consented

e.g. Jerry Canterbury would not have gotten laminectomy (if knew 1%)

**2**

**Reasonable patient** would have chosen differently

Had disclosure been made, a **reasonable person** in the patient's circumstances would **not** have consented

e.g. person in Canterbury's situation would not have had laminectomy (if knew)

Disclosure → no consent

No consent → no procedure

But would a different choice have avoided injury

# 3

No procedure
→ no injury

The materialized risk must have been caused (etiologically) by the intervention

# Recap

If knew 1% risk, would JC & RPt have decided against procedure?

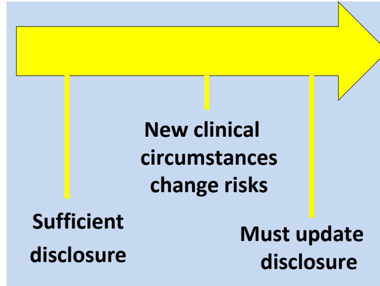
If yes, he would not have had procedure (else a battery)

If JC did not have the procedure, would he be paralyzed

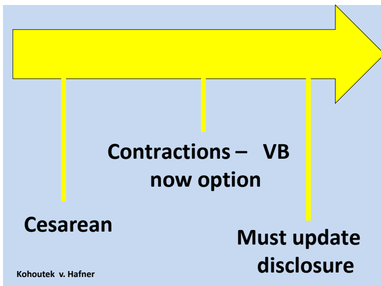
**Diachronic Aspect to Duty**

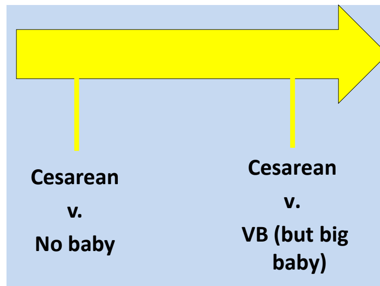
Not a one-time

**ongoing** duty



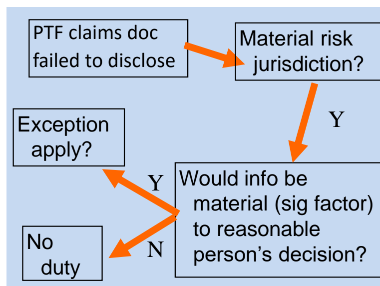

Disclose the new alterative / option

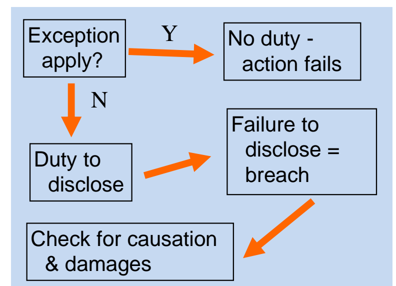


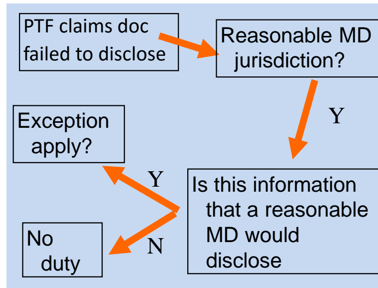

**Only the duty element varies from state to state**

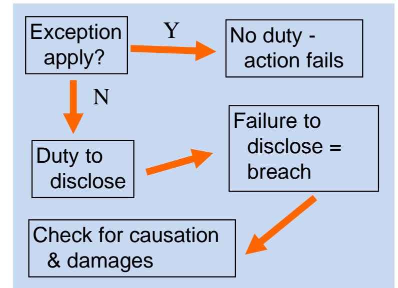
Reasonable patient states: duty disclose new information **IF** reasonable patient would find material



Reasonable physician states: duty disclose new information **IF** professional custom to disclose that



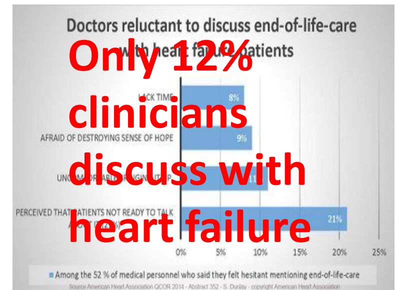

# Big problems

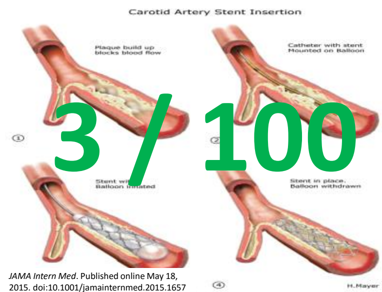
Health Care Costs in the Last Week of Life

*Associations With End-of-Life Conversations*

**Only 31% with advanced cancer had EOL discussions**

*Arch Intern Med. 2009;169(5):480-488*




*JAMA Intern Med*. Published online May 18, 2015. doi:10.1001/jamainternmed.2015.1657

# Statutory Mandates

CALIFORNIA REPUBLIC

Right to Know End-of-Life Options Act
Cal. H&S Code 442.5

"When . . . provider diagnoses . . . terminal illness, . . . comprehensive **information and counseling** regarding legal end-of-life options"

**Prognosis** with or without disease-targeted treatment

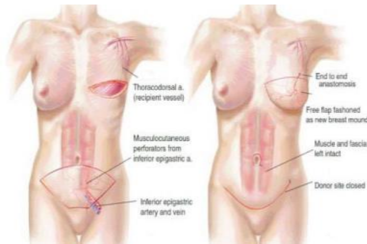
Right to accept **disease-targeted treatment**, with or without palliative care

Right to refuse or withdraw from **life-sustaining treatment**

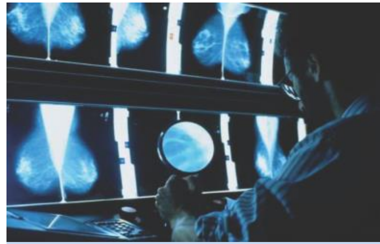
Right to have comprehensive **pain** and symptom management

Meaning and availability of **hospice** care

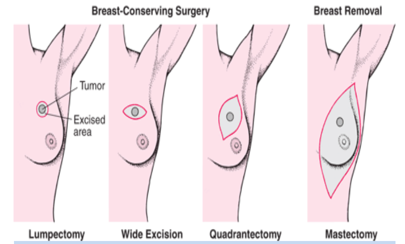
Right to give individual health care **instruction** (POLST; AD)




Breast reconstruction coverage



Breast density




Breast cancer (1979-1986)

STATEMENT OF PRINCIPLES ON THE ROLE OF GOVERNMENTS IN REGULATING THE PATIENT-PHYSICIAN RELATIONSHIP

A Statement of Principles of the American College of Physicians
July 2012

Continuing Medical Education **Credits**

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CME

# 1972

"lengthy polsyllabic discourse"

*Cobbs v. Grant* (Cal. 1972)

# 2016

"lengthy polsyllabic discourse"

Too much
Too fast
Too complex

Accurate
Complete
Understandable

Robust evidence shows PtDAs are highly effective

# BUT

Hardly any clinical usage

ACA
3506

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