Solving Persistent Problems of Informed Consent Law with Federally Certified Patient Decision Aids

ASLME Health Law Professors Conference
Atlanta, Georgia (June 10, 2017)

Thaddeus Mason Pope, JD, PhD
Mitchell Hamline School of Law

Jerry Canterbury
NYT 05/2017

"comforted to know that his lawsuit and suffering had **not** been in vain"

Much **smaller** impact than anticipated

Roadmap

4 parts

UMT
Failure IC law
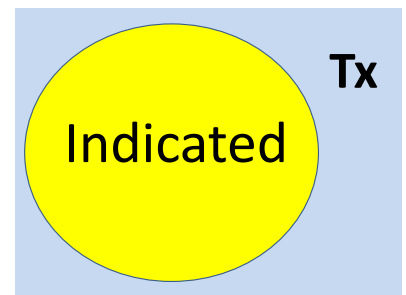PDA solution
Implementing

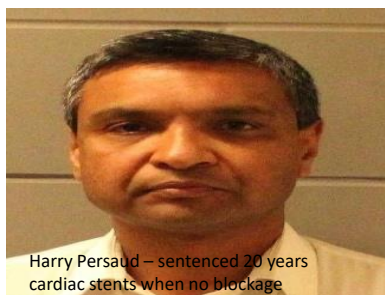**1**

Unwanted medical treatment

Patient did **not** want it
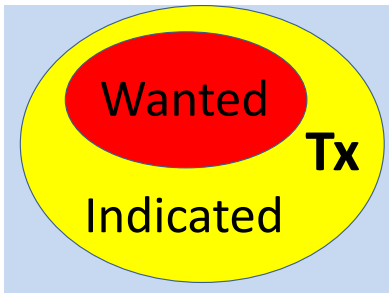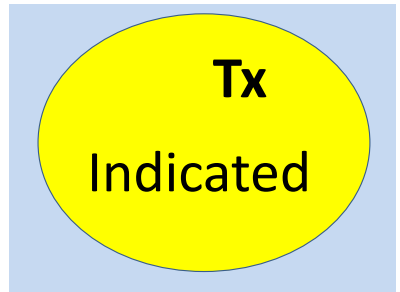
But **got** it anyway

3 **types** UMT

Type **1** UMT

Not medically indicated

Breast surgeon Ian Paterson jailed 15 years for needless operations

BREAKING NEWS
CANCER DOCTOR FARID FATA SENTENCED TO 45 YEARS IN PRISON

Harry Persaud – sentenced 20 years cardiac stents when no blockage

Tx

Indicated

No patient would want this

Type **2** UMT

Tx Indicated

Wanted **Tx** Indicated

Reasonable patient **might** want this

But . . .

this patient does not

2 examples
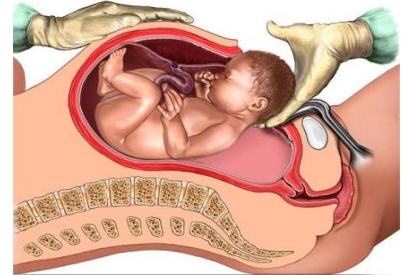
THE JOURNAL OF CLINICAL ETHICS

Example 1: advance directives

Doctors Hospital Augusta *v.* Alicea (Ga. 2016)

Example 2: forced cesareans

Crisp, clear, concrete UMT

Patient: "No. I do **not** want X."

Clinician: Does X

Explicit refusals only small fraction of UMT

Type **3** UMT

Most **common** UMT

No rejection

No refusal

Actual consent

uninformed

Ordered   Received

Did not know = 75g sugar
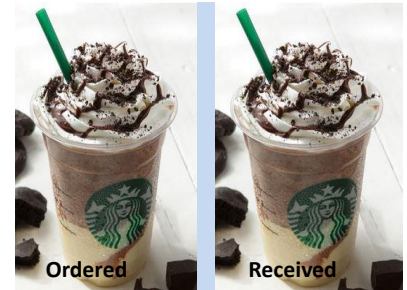
I would not have consented, **if** knew risks, benefits, alternatives

2

Failure of informed consent

There is a legal **duty** to inform

Thank you, Jerry

But patients are seriously **misinformed**

Only **5 in 100** understand cancer diagnosis

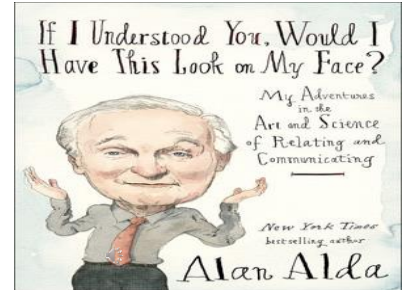Only **10 in 100** can answer basic questions about **their** spine surgery

THE JOURNAL OF LAW, MEDICINE & ETHICS

Under Attack: Reconceptualizing Informed Consent

>90% **fail** rate

What

Incomplete

Inaccurate

Outdated

How

Not meaningfully conveyed

Not understood

If I Understood You, Would I Have This Look on My Face? My Adventures in the Art and Science of Relating and Communicating — New York Times bestselling author Alan Alda

Informed consent law was not even **designed** to deal with this

ONE WAY

PD PHOENIX ARIZ 1963 446540
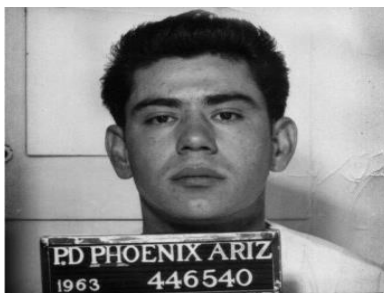
Vast numbers of uninformed patients

Deluge of UMT

3

Solution PDAs

Evidence based educational tools

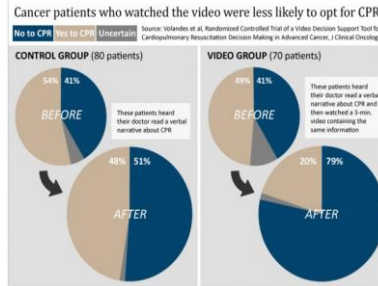Robust evidence shows PDAs are highly effective

> 130 RCTs

> 30,000 patients
> 50 conditions

THE COCHRANE COLLABORATION®

Improve knowledge
Feel better informed
Clearer about values
More accurate expectations
Value congruent choice

UMT

Informed patients request **less** aggressive treatment

Cancer patients who watched the video were less likely to opt for CPR

PDAs **reduce** UMT

"paradigmatic change in healthcare delivery"

On January 24th, Apple Computer will introduce Macintosh. And you'll see why 1984 won't be like "1984"

More graphic
More user friendly
More accessible
More useable

Great evidence

But **little** clinical usage

"Promise remains elusive"

Move PDAs from research to practice

4

Using law to promote PDAs

	Carrots	**Sticks**
Liability incentives	Enhanced malpractice protection for using SDM	Expanded malpractice exposure for failing to use SDM
Payment incentives	Medicare Shared Saving Program reimbursement for ACOs using SDM	Medicare and Washington state requirements to use SDM

No PDA

Proposed Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N)

Shared decision making, including the use of one or more decision aids, to include benefits, harms, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure;

Proposed Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N)

A formal shared decision-making interaction between the patient and provider using an evidence-based decision tool on anticoagulation in patients with NVAF must occur prior to LAAC, must be documented in the medical records, must include a discussion of the benefits and harms, must

Widely **varying** quality

Should not attach legal consequences

Assure PDA **quality**

Certification

Accurate

Complete

Understandable
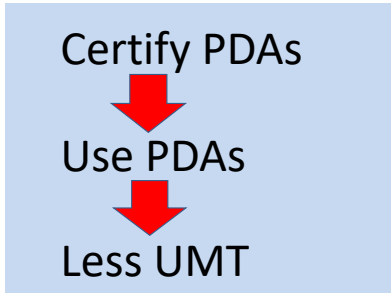
No bias

No COI

§ 3056

Labor &
Delivery
(2016)

3 prenatal testing

2 birth options
(VBAC, big baby)

Joint
Replacement
& Spine Care
(2017)

End of life (2018)

WA is paving the way

NATIONAL QUALITY FORUM

National Standards for the Certification of Patient Decision Aids

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Certify PDAs

Use PDAs

Less UMT

Thaddeus Mason Pope, JD, PhD
Director, Health Law Institute
Mitchell Hamline School of Law
875 Summit Avenue
Saint Paul, Minnesota 55105
T 651-695-7661
C 310-270-3618
E Thaddeus.Pope@mitchellhamline.edu
W www.thaddeuspope.com
B medicalfutility.blogspot.com