Three Legal Tools to Promote SDM and PDA in USA

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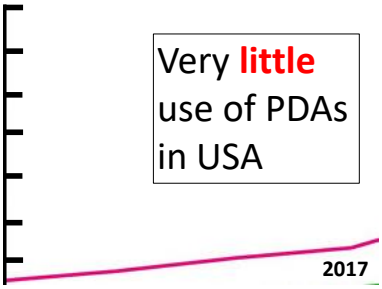
Thaddeus Mason Pope, JD, PhD
Mitchell Hamline School of Law



"**comprehensive** strategy is required to promote wider uptake of SDM"

Coulter - World Psychiatry 16:2 - June 2017

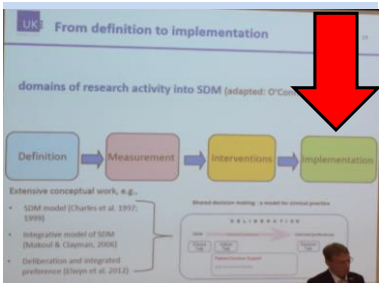
Research evidence showing that it can be effective in a specific clinical or local context

Medical leadership willing to encourage it

Demand for SDM from patient leaders and organizations

Training for clinical staff in SDM and risk communication skills, plus support and supervision for practising and maintaining these competencies;

Validated outcome measures to monitor the extent to which patients feel informed and involved in decisions about their care, plus feedback to enable clinicians to monitor progress.



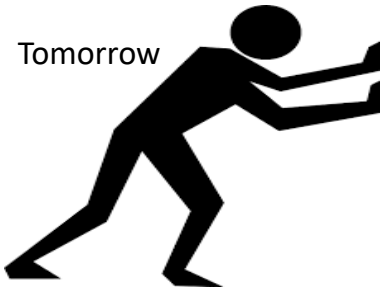
Institutional support for developing and updating patient decision aids

Availability of patient decision aids

Integration of patient decision aids into electronic medical record systems

Incentives for clinicians to change their practice – ethical, financial or professional

Certification scheme to assure the quality of patient decision aids



Roadmap

3 parts

1.
Problem

PDA: high value

Little use

Existing law inadequate

2.
New law

3 types

Liability tools

Payment tools

Mandates

BUT

Cannot deploy these tools until . . .

3. Certification

PDA value

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

Little use in USA

"Promise remains elusive"

Move PDAs from research to practice

From lab to clinic

BUT

Current law inadequate

Patients seriously **misinformed**

Only **5 in 100** understand cancer diagnosis

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

>90% **fail** rate

Wrong info

Incomplete

Inaccurate

Outdated

Worse

Not meaningfully conveyed

Not understood

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

Current law:

little incentive to use PDA

We need <u>new</u> legal tools

3

Liability tools

Payment tools

Mandates

Liability tools

PDA as shield

Safe harbor for using PDA

Use PDA → presumption that fulfilled informed consent duty

Strong presumption

Rebuttable only with clear & convincing evidence (80%) not just preponderance (50%)

PDA as sword

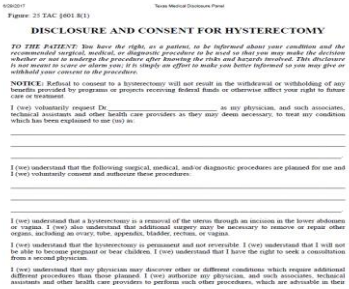


Figure: 25 TAC §601.8(1)

DISCLOSURE AND CONSENT FOR HYSTERECTOMY

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

NOTICE: Refusal to consent to a hysterectomy will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving federal funds or otherwise affect your right to future care or treatment.

I (we) voluntarily request Dr. _____ as my physician, and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me (us) as:

_____

_____

_____.

I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent and authorize these procedures:

_____

_____

_____.

I (we) understand that a hysterectomy is a removal of the uterus through an incision in the lower abdomen or vagina. I (we) also understand that additional surgery may be necessary to remove or repair other organs, including an ovary, tube, appendix, bladder, rectum, or vagina.

I (we) understand that the hysterectomy is permanent and not reversible. I (we) understand that I will not be able to become pregnant or bear children. I (we) understand that I have the right to seek a consultation from a second physician.

I (we) understand that my physician may discover other or different conditions which require additional different procedures than those planned. I (we) authorize my physician, and such associates, technical assistants and other health care providers to perform such other procedures, which are advisable in their

No use form→

presumption that **violated** duty

Could use PDAs instead of “forms”

Payment tools

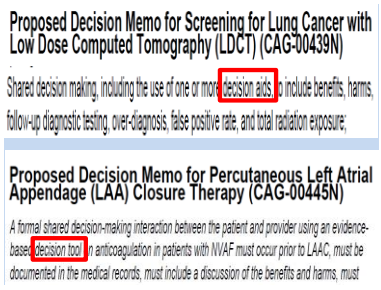
No PDA

CMS

CENTERS FOR MEDICARE & MEDICAID SERVICES

56,000,000

PDA use = condition for payment

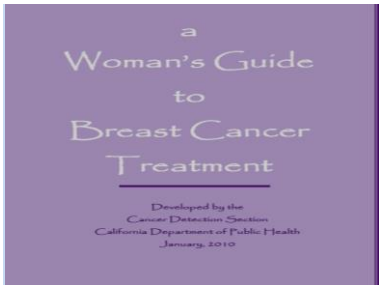


Washington State Health Care Authority

2,200,000

<10 procedures

Mandates



Could use PDAs instead of "booklets"

<u>Few</u> tools deployed

PDAs widely **varying** quality

Cannot attach legal consequences

Assure PDA **quality**

Certification

Accurate

Complete

Understandable

No bias

No COI

2010

Contract with an entity to "synthesize evidence" and establish "consensus based standards"

2017

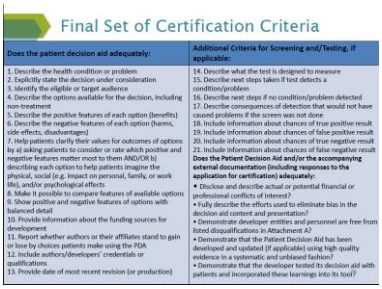
No criteria

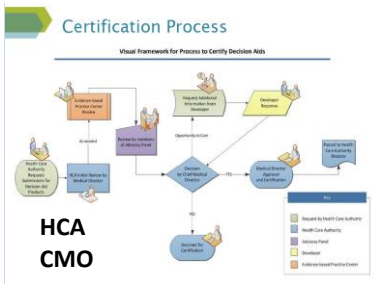
No process

No entity

for certification

BUT





In use

2016

3 prenatal testing

2 birth options
(VBAC, big baby)

2017

Joint replacement & spine

2018

Conclusion

NATIONAL QUALITY FORUM

National Standards for the Certification of Patient Decision Aids

Certify PDAs

↓

More legal tools

↓

More PDA use

References

Thaddeus Pope, *Certified Patient Decision Aids: Solving Persistent Problems with Informed Consent Law*, 45(1) JOURNAL OF LAW, MEDICINE & ETHICS 12-40 (2017).

Thaddeus Pope, *Revolutionizing Informed Consent: Empowering Patients with Certified Decision Aids,* 10 THE PATIENT - PATIENT CENTERED OUTCOMES RESEARCH (2017) (with Daniel S. Lessler).

Thaddeus Pope, *Emerging Legal Issues for Providers in the US, in* SHARED DECISION MAKING IN HEALTHCARE: ACHIEVING EVIDENCE-BASED PATIENT CHOICE (Oxford University Press 2016) (with Benjamin Moulton).

Thaddeus Pope, *Legal Briefing: Informed Consent in the Clinical Context,* 25(2) JOURNAL OF CLINICAL ETHICS 152-174 (2014) (with Melinda Hexum).

Thaddeus Pope, *Legal Briefing: Shared Decision Making and Patient Decision Aids*, 24(1) JOURNAL OF CLINICAL ETHICS 70-80 (2013) (with Mindy Hexum).

Thaddeus Pope, *Clinicians May Not Administer Life-Sustaining Treatment without Consent: Civil, Criminal, and Disciplinary Sanctions,* 9 JOURNAL OF HEALTH & BIOMEDICAL LAW 213-296 (2013).

Thaddeus Pope, *Patient Rights, in* OXFORD TEXTBOOK OF CRITICAL CARE (Webb, Angus, Finfer, Gattioni & Singer eds., Oxford University Press forthcoming 2015) (with Douglas B. White).

Thaddeus Pope, *Legal Briefing: The New Patient Self Determination Act,* 24(2) JOURNAL OF CLINICAL ETHICS 156-167 (2013).

Thaddeus Pope, *Legal Briefing: POLST (Physician Orders for Life-Sustaining Treatment),* 23(4) J. CLINICAL ETHICS 353-376 (2012) (with Mindy Hexum).

Thaddeus Pope, *Legal Briefing: Informed Consent,* 21(1) J. CLINICAL ETHICS 72-82 (2010).

Thaddeus Pope, *The Maladaptation of Miranda to Advance Directives: A Critique of the Implementation of the Patient Self Determination Act*, 9 HEALTH MATRIX 139-202 (1999).

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

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