

Revolutionizing Informed Consent Law and Practice: Empowering Patients with Certified Decision Aids

ICCH 2018 - International Conference
on Communication in Healthcare
Porto, Portugal • Sept. 4, 2018

Thaddeus Mason Pope, JD, PhD

ASSEMBLEIA DA REPÚBLICA

Lei n.º 31/2018

de 18 de julho

Direitos das pessoas em contexto de doença avançada
e em fim de vida

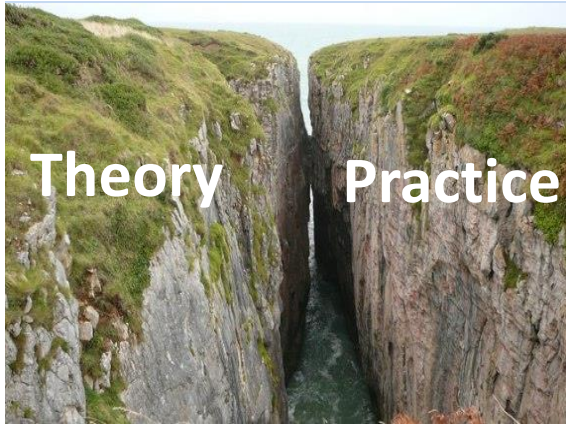


“matéria de
informação e
de tratamento”



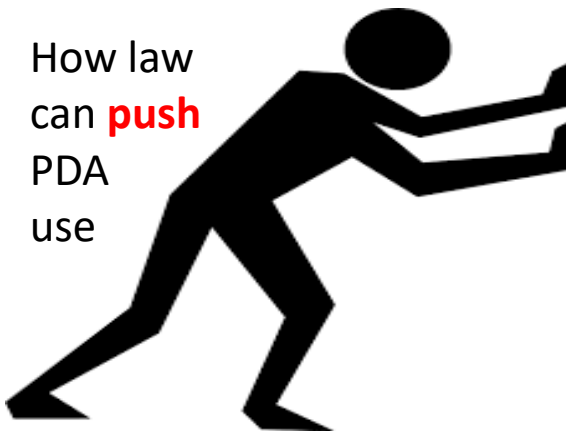
BUT

Declaring
legal rights is
not enough



Patient
decision
aids

PDA's



What are PDAs?

Evidence based educational tools

2

Before
encounter



During
encounter



Present options
clearly &
graphically

Do they
work?

Yes

Robust evidence
shows PDAs are
highly **effective**

> 130
RCTs

30,000 patients

50 conditions



Improved
knowledge

More accurate
expectations

Lower
decisional
conflict

(less uncertainty)

More value
congruent
choice

Great
evidence

What is
the
problem?

Too few clinicians use PDAs



National Strategies
for Implementing
Shared Decision Making

| BertelsmannStiftung

Australia	Norway
Canada	Taiwan
Denmark	UK
Germany	USA
Netherlands	

“**More work** has
been done on SDM
in **the US** than in
any other country.”

BUT

“**not** incorporated
into mainstream
care”

So:

Move PDAs
from research
to practice

From lab
to clinic

3 Legal
tools

Liability Tools



Safe harbor

legal immunity
for using PDA



Liability

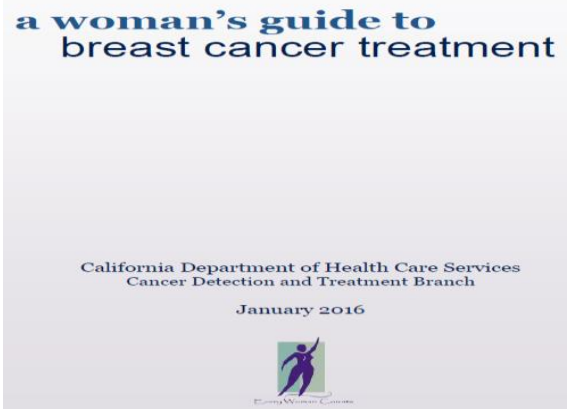
protection

for using PDA

Mandate Tools



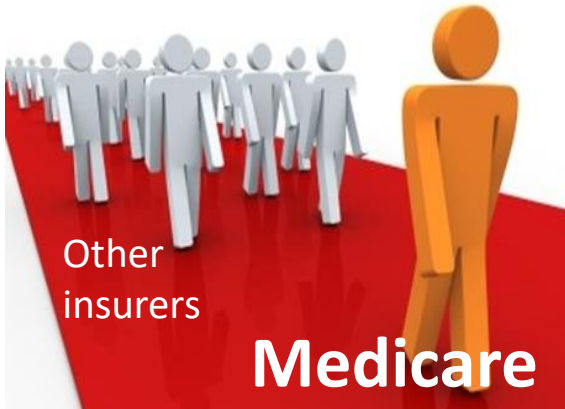
“Mandated
standardized
written
information”



Could use
PDAs instead
of MSWI

Not yet

Payment Tools



PDA use =
“condition
for payment”

No
PDA



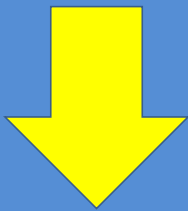
Logic

Medicare only pays

**“medically
necessary”**

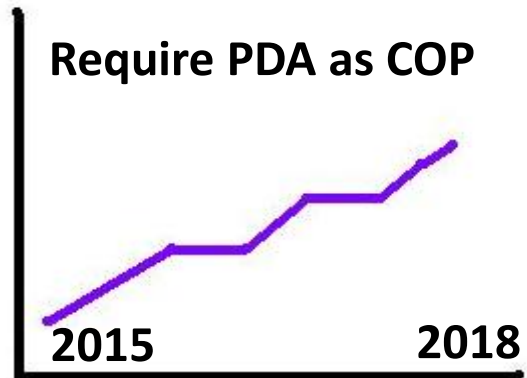
“Medically
necessity” **not**
purely clinical
determination

Unwanted



Not med. necc.

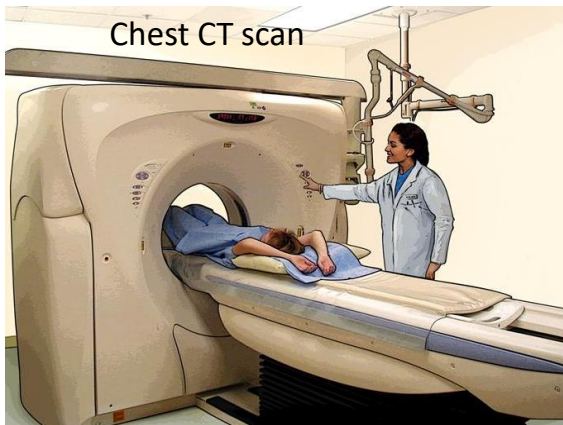
Require PDA as COP



3 examples

1

Screening for Lung Cancer with Low Dose Computed Tomography



Before
CT scan

“must receive
... SDM visit”

“include . . .
one or more
decision aids”



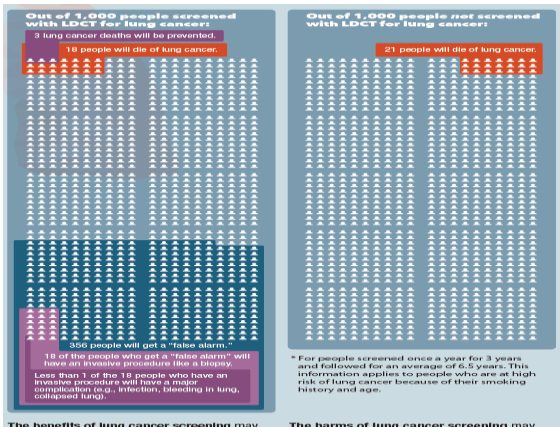
CENTERS FOR DISEASE CONTROL AND PREVENTION Memorial Sloan Kettering Cancer Center™



Is Lung Cancer Screening Right for Me?

A decision aid for people considering lung cancer screening with low-dose computed tomography

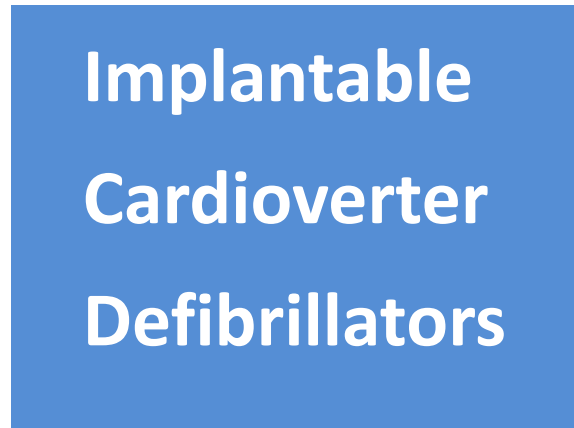
If you have smoked for many years, you may want to think about screening (testing) for lung cancer with low-dose computed tomography (LDCT). Before deciding, you should think about the

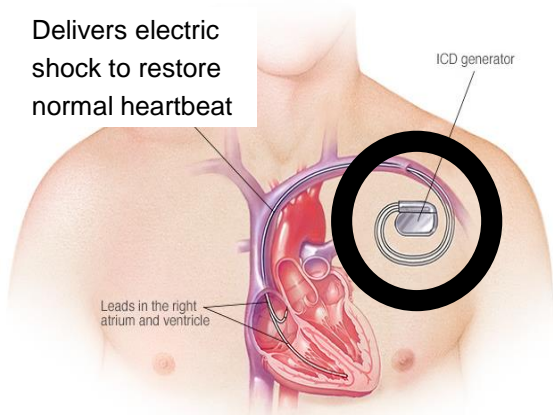


WHAT IS IMPORTANT TO YOU WHEN DECIDING ABOUT SCREENING FOR LUNG CANCER?

There are many things to think about when deciding whether lung cancer screening is right for you. Below is a list of questions that may help you decide.

	Favors Screening		Favors No Screening	
	Very Important	Not Important	Not Concerned	Very Concerned
How important is:				
Finding lung cancer early when it may be more easily treated?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How concerned are you about:				
Having a false alarm?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having other tests if you have a positive screening test?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being exposed to radiation from lung cancer screening?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being treated for lung cancer that never would have harmed you?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being harmed by the treatments you receive for lung cancer?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>





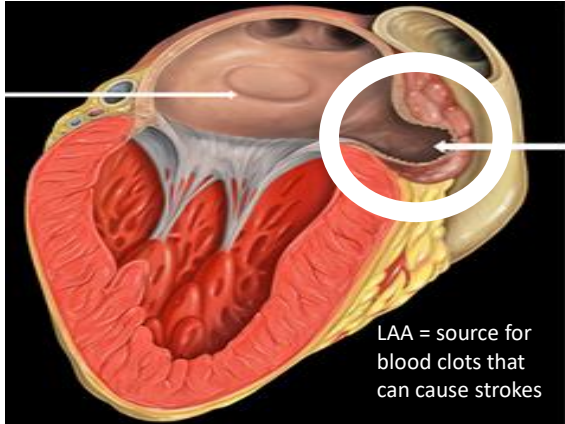
Before
implantation

“formal SDM encounter **must occur**”

“evidence-based **decision tool**”

3

Percutaneous Left Atrial Appendage Closure Therapy



Warfarin NA (Coumadin)

Thin blood with anticoagulant medication

2mg 90 Tablets

Mfg. By: Bristol-Myers Squibb Company
Garden City, NY

Repackaged by Aphena Pharma
Cookeville, TN 38506

Batch:
Exp:
Lot:

RX Only

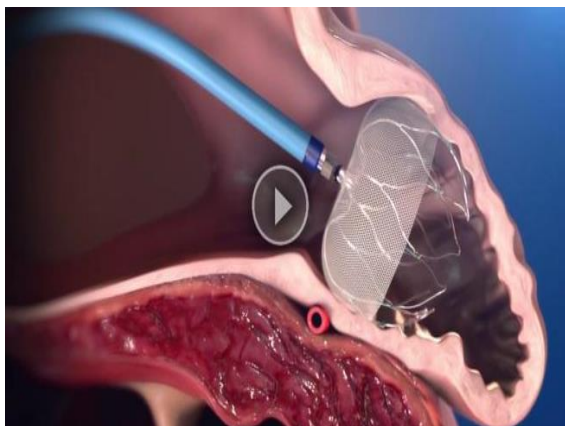
Warfarin NA (Coumadin) 2mg 90 Tablets

Boston Scientific
Advancing science for life®

PROFESSIONALS PATIENTS PRODUCTS ABOUT

THERE'S AN ALTERNATIVE TO WARFARIN

FOR PEOPLE WHO NEED ONE, IT'S CALLED WATCHMAN™.



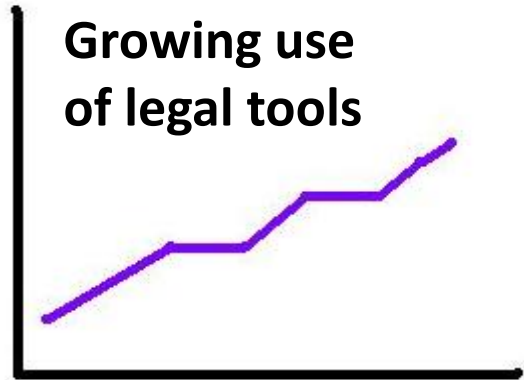
**Before
implantation**

“formal SDM
interaction”

evidence-based
decision tool”

Recap

**Growing use
of legal tools**



Rare

Type of Legal Tool	Number in Force
Payment	3
Liability	1
Mandate	0



PDA's widely
varying
quality

Cannot
attach legal
consequences

Assure PDA
quality

Certification

Accurate
Up to date
No bias, COI
Understandable



No **national** certification entity

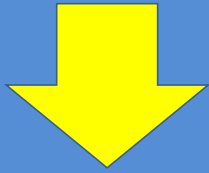
Need one

Conclusion

Certify PDAs
↓
More legal tools

More legal tools
↓
More PDA use

More PDA use



Better quality

References

Thaddeus Pope, *Decision Aids Reflect Patients' Values and Preferences for Care: So Why Aren't More Oncologists Using Them?* ASCO POST (May 10, 2018).

Thaddeus Pope, *From Informed Consent to Shared Decision Making: Improving Patient Safety and Reducing Medical Liability Risk with Patient Decision Aids* (workshopped at Harvard Law, Nov. 2017).

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

116