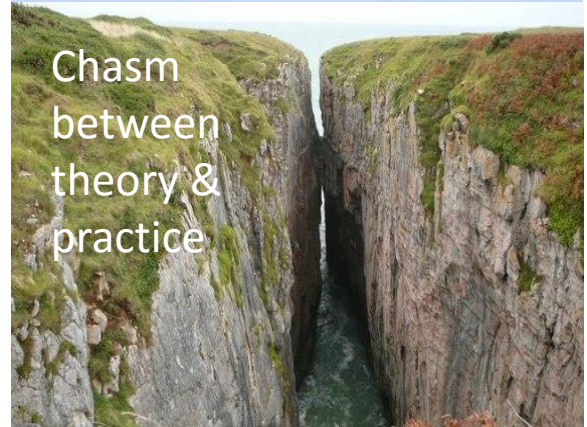


# Revolutionizing Informed Consent with Certified Patient Decision Aids

Institute of Medical Ethics  
June 18, 2016 (Edinburgh)

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

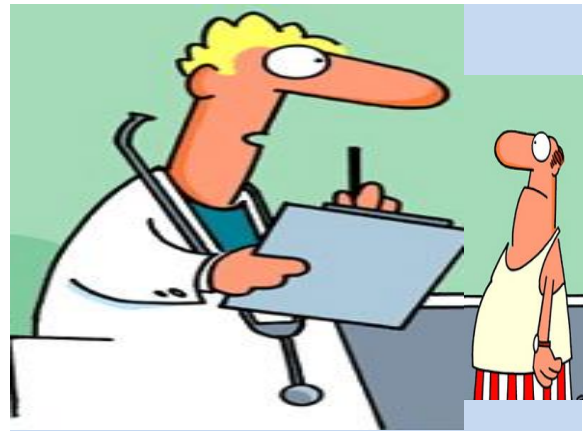


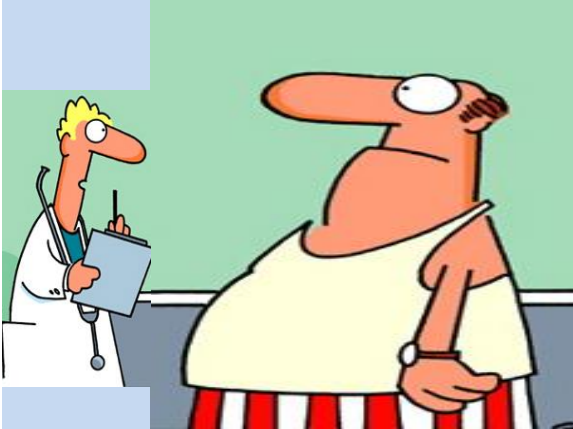
# Theory

Appellate opinions  
autonomy  
self-determination

# Practice

Not even close



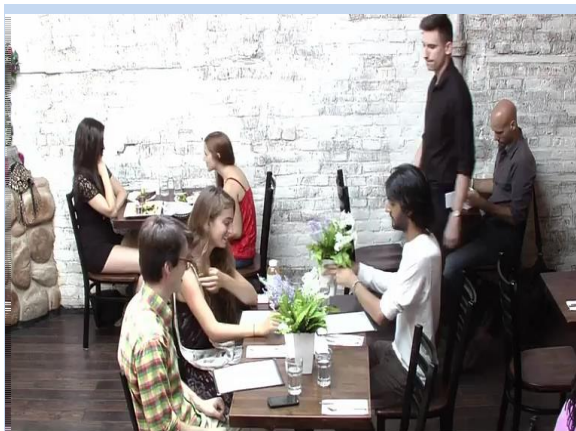


# Roadmap

# 5

- Failure of informed consent
- What are PDAs
- PDAs are effective
- Moving PDAs from lab to clinic
- Certification

# Failure of informed consent law



Too much  
Too fast  
Too complex

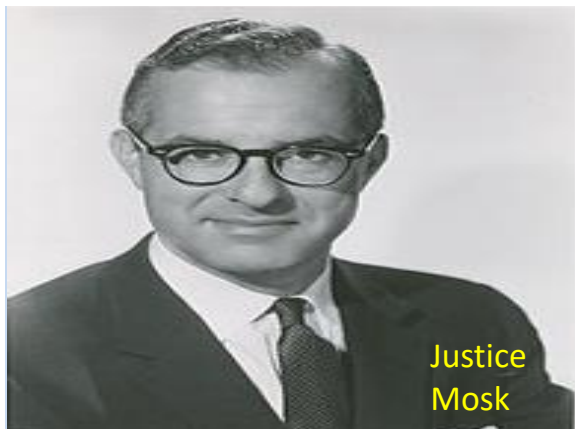
Also in  
medicine

Bad

**Even if**  
accurate &  
complete  
(but often is not)

1972





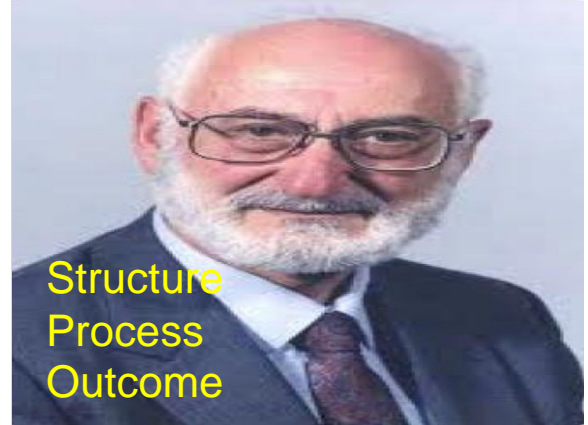
“lengthy  
polsyllabic  
discourse”

**2016**



“lengthy  
polsyllabic  
discourse”

**Still**



Process  
problem

Terrible  
outcomes

Just **3**  
examples  
(of many)

Only **12 in 100**  
understand  
cardiac  
catheterization

Only **5 in 100**  
understand  
cancer diagnosis

Only **3 in 100**  
understand PCI

>90%  
fail rate

Fix

**Patient  
decision  
aids**

Evidence based  
educational  
tools



Accurate  
Complete  
Understandable

**Breast cancer: surgical options**

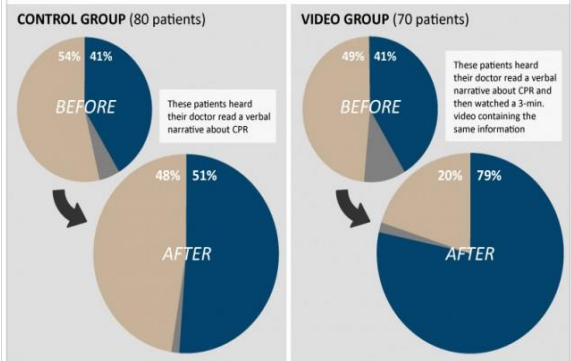


Use this **Option Grid™** decision aid to help you and your healthcare professional talk about how best to treat breast cancer.

Frequently Asked Questions ↓	Lumpectomy with radiotherapy	Mastectomy
<b>What is removed?</b>	The cancer lump is removed, with some surrounding tissue.	The whole breast is removed.
<b>Which surgery is best for long-term survival?</b>	Survival rates are the same for both options.	Survival rates are the same for both options.

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

No to CPR Yes to CPR Uncertain Source: Volandes et al, Randomized Controlled Trial of a Video Decision Support Tool for Cardiopulmonary Resuscitation Decision Making in Advanced Cancer, J Clinical Oncology



**PDA's  
work**

Robust evidence shows PDA's are highly **effective**



> 130  
RCTs



**BUT**

Very little  
clinical usage

“Promise  
remains  
elusive”



**Move PDAs  
from lab  
to clinic**



We must  
**incentivize**  
PDA use

Assure PDA  
**quality**

**Certification**

**Risks, benefits, options**

Complete

Accurate

Understandable

Free from bias / COI

**2010**





## Title III

Improving the  
Quality & Efficiency  
of Health Care



§ 3056

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

2016

**you can't finish  
what you never**

**started**

### 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** in 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

No PDA →  
no payment  
(or less payment)



No criteria  
No process  
No entity

for certification

**2006**



Certification  
is underway

2016

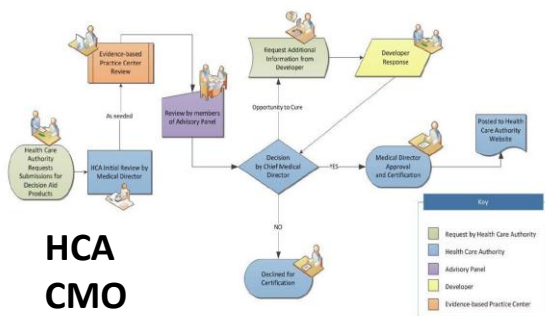
Criteria

Final Set of Certification Criteria	
Does the patient decision aid adequately:	Additional Criteria for Screening and/Testing, if applicable:
<ol style="list-style-type: none"> <li>Describe the health condition or problem</li> <li>Explicitly state the decision under consideration</li> <li>Identify the eligible or target audience</li> <li>Describe the options available for the decision, including non-treatment</li> <li>Describe the positive features of each option (benefits)</li> <li>Describe the negative features of each option (harms, side effects, disadvantages)</li> <li>Help patients clarify their values for outcomes of options by a) asking patients to consider or rate which positive and negative features matter most to them AND/OR b) describing each option to help patients imagine the physical, social (e.g. impact on personal, family, or work life), and/or psychological effects</li> <li>Make it possible to compare features of available options</li> <li>Show positive and negative features of options with balanced detail</li> <li>Provide information about the funding sources for development</li> <li>Report whether authors or their affiliates stand to gain or lose by choices patients make using the PDA</li> <li>Include authors/developers' credentials or qualifications</li> <li>Provide date of most recent revision (or production)</li> </ol>	<ol style="list-style-type: none"> <li>Describe what the test is designed to measure</li> <li>Describe next steps taken if test detects a condition/problem</li> <li>Describe next steps if no condition/problem detected</li> <li>Describe consequences of detection that would not have caused problems if the screen was not done</li> <li>Include information about chances of true positive result</li> <li>Include information about chances of false positive result</li> <li>Include information about chances of true negative result</li> <li>Include information about chances of false negative result</li> </ol> <p><b>Does the Patient Decision Aid and/or the accompanying external documentation (including responses to the application for certification) adequately:</b></p> <ul style="list-style-type: none"> <li>Disclose and describe actual or potential financial or professional conflicts of interest?</li> <li>Fully describe the efforts used to eliminate bias in the decision aid content and presentation?</li> <li>Demonstrate developer entities and personnel are free from listed disqualifications in Attachment A?</li> <li>Demonstrate that the Patient Decision Aid has been developed and updated (if applicable) using high quality evidence in a systematic and unbiased fashion?</li> <li>Demonstrate that the developer tested its decision aid with patients and incorporated these learnings into its tool?</li> </ul>

Process

## Certification Process

Visual Framework for Process to Certify Decision Aids



# In use

## Labor & Delivery

Especially C-section  
vaginal delivery

## Submission period

April 12, 2016

May 27, 2016

## Next priority areas:

Joint replacement and  
spine care (2017)

Cardiac care and end of  
life care (2018)

# Going **beyond** certification

# Incentives



# 1

**Safe harbor**  
for using  
“certified” PDA

**Presumption** that duty  
fulfilled

Rebuttable only with  
clear & convincing  
evidence

# 2

State as  
purchaser

30% citizens

Medicaid - 1.8m

Employees - 350k

PDA use  
required in  
contracts

State as  
first mover

3

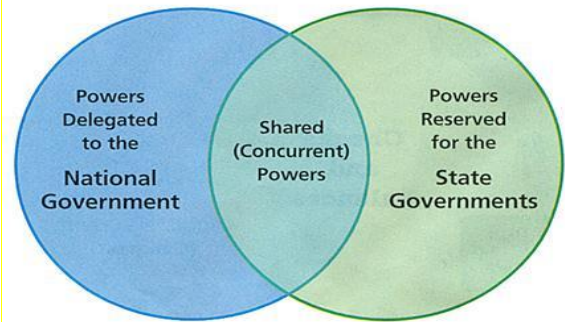
New standard  
of care

(evolution of  
common law duty)



# Looking ahead

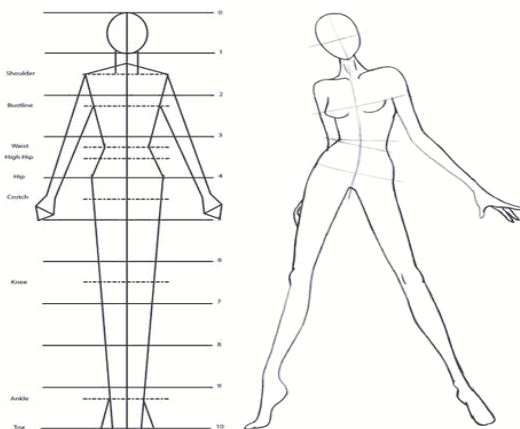
## Federalism



The overlapping spheres of power bind the American people together.



“A single courageous state may . . . serve as a laboratory; and try novel social . . . experiments . . .”





NQF sets standards.

NQF-endorsed measures are the gold standard for healthcare measurement in the United States.

#### Project meetings:

- June 22-23, 2016 In-Person Meeting
  - » Review pre-meeting draft materials:
  - » Environmental scan
  - » Business model
  - » White paper
- August Post In-Person Meeting Webinar

#### Final Report:

- December 2016

White paper on  
national standards

Business model for  
PDA certification

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**Selected  
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