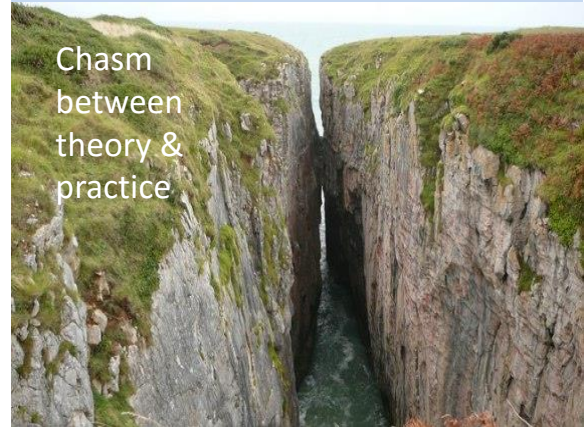


Revolutionizing Informed Consent with Certified Patient Decision Aids

ASLME HLP (Boston, MA)
Saturday, June 4, 2016

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



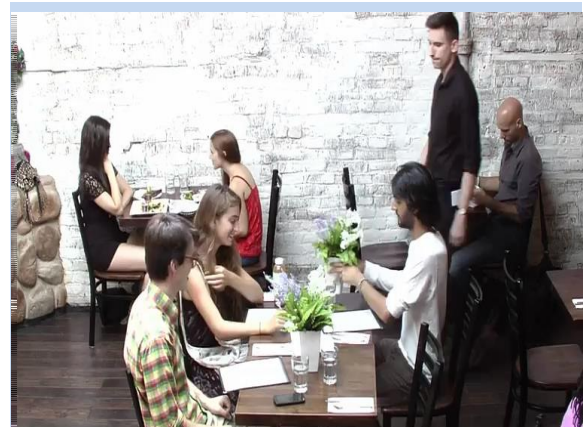
Theory

Appellate opinions
re autonomy &
self-determination

Practice

No

Not even close



Too much
Too fast
Too complex

Also in
medicine

Even if
accurate &
complete
(but often is not)

Roadmap

5

Failure of informed consent

What are PDAs

PDAs are effective

Moving PDAs from lab to clinic

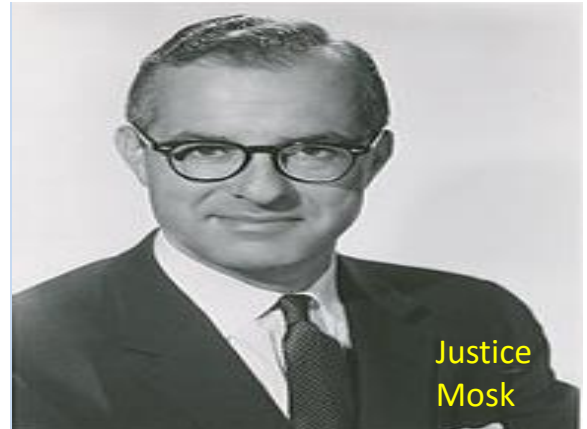
Certification

**Failure of
informed
consent law**

1972



Jerry
Canterbury



Justice
Mosk

“lengthy
polsyllabic
discourse”

2016



“lengthy
polsyllabic
discourse”

Still



Process
problem

Terrible
outcomes

Only **12 in 100**
understand
cardiac
catheterization

Only **5 in 100**
understand
cancer diagnosis

Only **3 in 100**
understand PCI

90%
fail rate



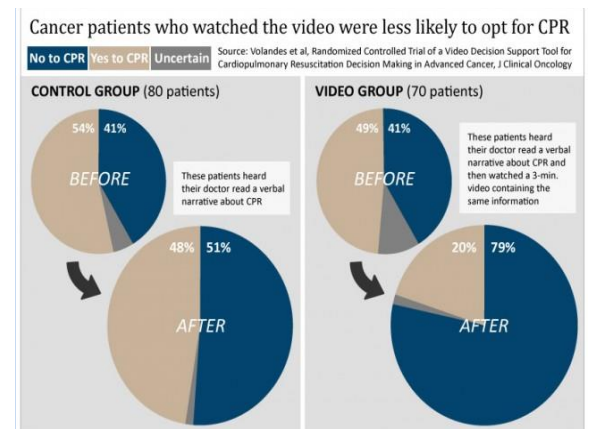
Fix

Patient decision aids

Evidence based
educational
tools



Accurate
Complete
Understandable



**PDA
work**

Robust evidence
shows PDAs are
highly **effective**

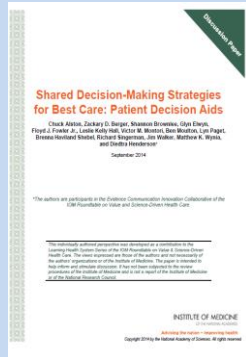
> 130 RCTs



BUT

Hardly any
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
Presented meaningfully
Free from bias / COI

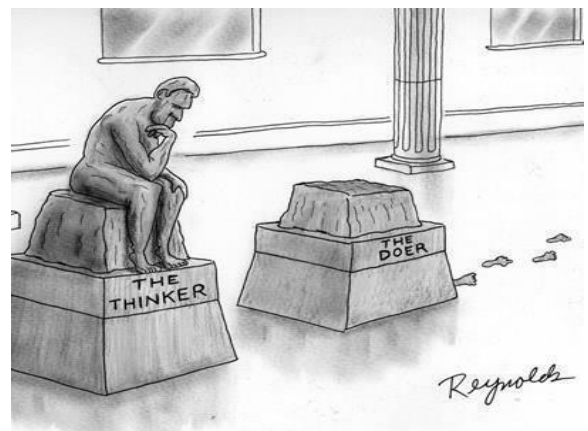
Certification assures PDA presents accurate, unbiased, up to date, understandable information + assistance in values/preferences clarification

2010

ACA 3056

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

2016



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 criteria
No process
No entity
for certification

2006



Certification
is underway

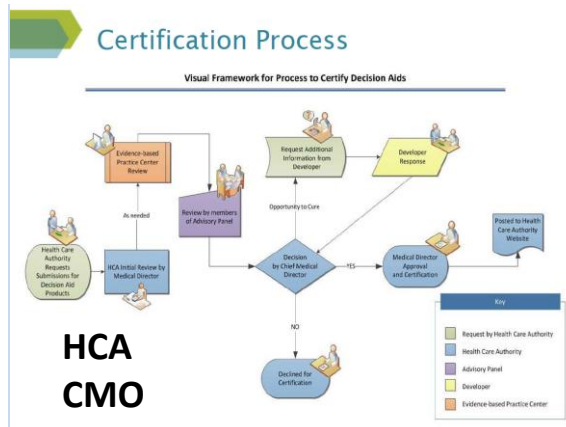
2016

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"> 1. Describe the health condition or problem 2. Explicitly state the decision under consideration 3. Identify the eligible or target audience 4. Describe the options available for the decision, including non-treatment 5. Describe the positive features of each option (benefits) 6. Describe the negative features of each option (harms, side effects, disadvantages) 7. 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 8. Make it possible to compare features of available options 9. Show positive and negative features of options with balanced detail 10. Provide information about the funding sources for development 11. Report whether authors or their affiliates stand to gain or lose by choices patients make using the PDA 12. Include authors/developers' credentials or qualifications 13. Provide date of most recent revision (or production) 	<ol style="list-style-type: none"> 14. Describe what the test is designed to measure 15. Describe next steps taken if test detects a condition/problem 16. Describe next steps if no condition/problem detected 17. Describe consequences of detection that would not have caused problems if the screen was not done 18. Include information about chances of true positive result 19. Include information about chances of false positive result 20. Include information about chances of true negative result 21. Include information about chances of false negative result <p>Does the Patient Decision Aid and/or the accompanying external documentation (including responses to the application for certification) adequately:</p> <ul style="list-style-type: none"> • Disclose and describe actual or potential financial or professional conflicts of interest? • Fully describe the efforts used to eliminate bias in the decision aid content and presentation? • Demonstrate developer entities and personnel are free from listed disqualifications in Attachment A2? • Demonstrate that the Patient Decision Aid has been developed and updated (if applicable) using high quality evidence in a systematic and unbiased fashion? • Demonstrate that the developer tested its decision aid with patients and incorporated these learnings into its tool?

Process



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

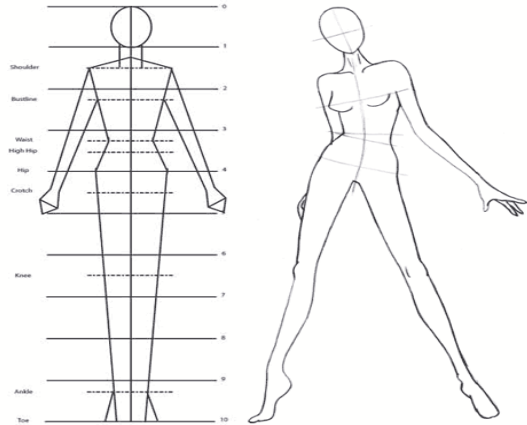
State as
first mover

3

New standard
of care

Looking
ahead





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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Revolutionizing Informed Consent with Certified Patient Decision Aids

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

Overview

Informed consent law has failed. But robust evidence shows patient decision aids (PDAs) significantly enhance patient knowledge and understanding. Certification encourages PDA use by endorsing PDAs that meet consensus based quality standards.

Informed Consent Failed

Only 3 in 100 understand their prognosis. Only 3 in 100 understand their percutaneous coronary intervention.

Patient Decision Aids

PDAs are evidence-based educational tools that facilitate shared decision making. PDAs include: written materials, decision grids, videos, and web-based or other electronic interactive programs.



PDAs Empower Patients

Over 230 RCTs show PDAs significantly enhance patient knowledge of treatment options, risks, and benefits. Cochrane and other meta-reviews confirm these benefits.



Move PDAs from Lab to Clinic

The research is done. But implementation is sparse and incomplete. "The promise... remains elusive." By assuring the quality of PDAs, certification improves and incentivizes shared decision making.

PDA Certification Is Coming

In April 2016, Washington State launched a PDA certification process (starting with maternity health). Washington further incentivizes clinicians by linking PDA use both to payment and to liability protection. Washington State's leadership provides a model that other jurisdictions can adopt. USGOV is moving to activate the (still dormant) certification mandate in the 2010 Affordable Care Act.

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