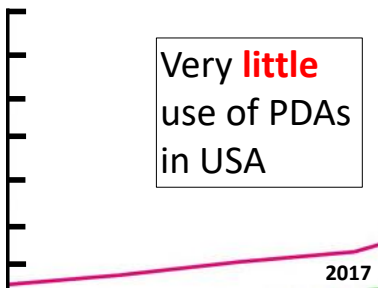


Three Legal Tools to Promote SDM and PDA in USA

9th International Shared Decision Making Conference • Lyon, France (July 5, 2017)

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



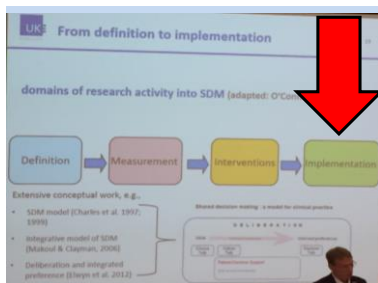
“comprehensive strategy is required to promote wider uptake of SDM”

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.

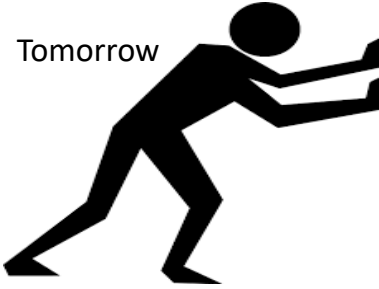


Institutional support for developing and updating patient decision aids
Availability of patient decision aids
Integration of patient decision aids into electronic medical record systems
Incentives for clinicians to change their practice – ethical, financial or professional
Certification scheme to assure the quality of patient decision aids

How **law** pushing today



Tomorrow



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



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

Little use in USA



Few clinicians use PDAs

“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
new
legal tools**

3

Liability tools
Payment tools
Mandates

Liability tools

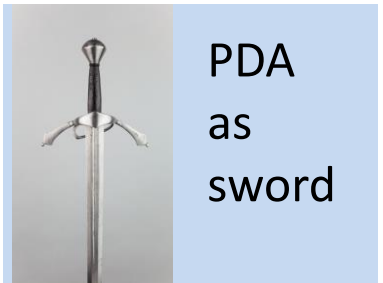


Safe harbor
for using PDA

Use PDA →
presumption that
fulfilled informed
consent duty

Strong presumption

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





©2007 Texas Medical Devices Panel
 Figure 23 TAC (001-913)

DISCLOSURE AND CONSENT FOR HYSTERECTOMY

FOR THE PATIENT: You have the right as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedures to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and benefits involved. This procedure is not meant to cure or alter 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 these

No use form →
 presumption that
violated duty

Could use PDAs instead of "forms"

Payment tools

No PDA



56,000,000

PDA use = condition for payment

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**; 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



2,200,000

<10
procedures

Mandates

a
Woman's Guide
to
Breast Cancer
Treatment

Developed by the
Cancer Detection Section
California Department of Public Health
January, 2010

Could use
PDAs instead
of "booklets"

**Few tools
deployed**



PDA's 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

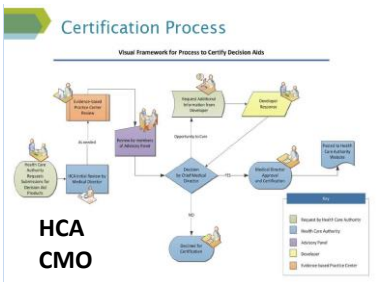
No criteria
No process
No entity
for certification

BUT



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 asking patients to consider or rate which positive and negative features matter most to them AND/OR by 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 relevant 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 not 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 false positive result 19. Include information about chances of false negative result 20. Include information about chances of false 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 biased disqualifications in Attachment A? • 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 their learnings into its fact?



In use

2016



3 prenatal testing
2 birth options
(VBAC, big baby)

2017



Joint replacement & spine

2018



End of life

Conclusion

Washington State paving the way



Certify PDAs



More legal tools



More PDA use

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