Revolutionizing Informed Consent with Certified Patient Decision Aids
ASLME HLP (Boston, MA)
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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

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 polysyllabic discourse”

2016
“lengthy polysyllabic 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
PDAs 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. All anticoagulation in patients with NVAF must occur prior to LAAC; must be documented in the medical records; must include discussion of the benefits and harms, must

No criteria
No process
No entity
for certification

2006
Certification is underway

2016

Criteria

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
Safe harbor for using “certified” PDA

Presumption that duty fulfilled
Rebuttable only with clear & convincing evidence

State as purchaser
30% citizens
Medicaid - 1.8m
Employees - 350k

State as first mover

3

New standard of care

Looking ahead

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

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).


