Three Legal Tools to Promote SDM and PDA in USA

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Very little use of PDAs in USA

“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
Roadmap

3 parts

1. Problem
   PDA: high value
   Little use
   Existing law inadequate

2. New law
   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

The Cochrane Collaboration

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

“Promise remains elusive”

Little use in USA

Few clinicians use PDAs
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Incomplete  Inaccurate  Outdated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

PDA as shield

Safe harbor for using PDA

Use PDA \(\rightarrow\) presumption that fulfilled informed consent duty

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

PDA as sword
Could use PDAs instead of “forms”

Payment tools

No PDA

No use form → presumption that violated duty

Agency in charge is CMS

56,000,000

PDA use = condition for payment
Shared decision making, including the use of one or more decision aids, to include benefits, harms, follow-up testing, diagnosis, false positive rate, and total radiation exposure.

Proposed Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAS-04480N)

A formal shared decision-making interaction between the patient and provider using an evidence-based decision aid to anticoagulation in patients with AF must occur prior to LAA C. must be documented in the medical record, must include a discussion of the benefits and harms, must

<10 procedures

Mandates

Could use PDAs instead of “booklets”

Few tools deployed

Obstacle
<table>
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<tr>
<th>PDAs widely varying quality</th>
<th>Cannot attach legal consequences</th>
<th>Assure PDA quality</th>
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Certification

- Accurate
- Complete
- Understandable

No bias

No COI

2010

§ 3056

Contract with an entity to “synthesize evidence” and establish “consensus based standards”
2017
No criteria
No process
No entity
BUT
No criteria
No process
No entity
for certification

2016
In use

In use
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

National Standards for the Certification of Patient Decision Aids
References


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