Health Law: Quality & Liability
Prof. Thaddeus Pope

Patient Decision Aids

Evidence based educational tools
Clearer idea of what ordering
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
Lower decisional conflict

(state of uncertainty about course of action)

UMT

Informed patients request less aggressive treatment
PDAs reduce UMT

“paradigmatic change in healthcare delivery”
More graphic
More user friendly
More accessible
More useable

PDAs underused
Great evidence

But little clinical usage

“Promise remains elusive”
Few clinicians use PDAs.

Move PDAs from research to practice.

From lab to clinic.
Promoting PDAs

Current law: little incentive to use PDA

How law can push PDA use
“comprehensive strategy is required to promote wider uptake of SDM”

Coulter - World Psychiatry 16:2 - June 2017

Liability tools
Payment tools
Mandates

law

39
Liability tools

PDA as shield
Safe harbor for using PDA

Use PDA →
presumption that fulfilled informed consent duty
Rebuttable only with **clear & convincing** evidence

PDA as sword
No form ➔

presumption that violated duty

Could use PDAs instead of “forms”
**Carrots** | **Sticks**
---|---
Enhanced malpractice protection for using SDM | Expanded malpractice exposure for failing to use SDM

**Payment tools**

**No PDA**
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, 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 or anticoagulation in patients with NVAF must occur prior to LAA, must be documented in the medical records, must include a discussion of the benefits and harms, must
30% citizens
Medicaid - 1.8m
Employees - 350k

2,200,000
~10 procedures

State as purchaser

State as first mover
New standard of care

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

Obstacle
PDAs widely vary quality

Cannot attach legal consequences
No bias

No COI

Assist to clarify values & preferences

2010
Contract with an entity to “synthesize evidence” and establish “consensus based standards”

Certify PDAs
Use PDAs
Less UMT

2017
No criteria
No process
No entity

BUT

for certification
Final Set of Certification Criteria

<table>
<thead>
<tr>
<th>Does the patient decision aid adequately:</th>
<th>Additional Criteria for Screening and/Testing, if applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Describe the health condition or problem</td>
<td>14. Describe what the test is designed to measure</td>
</tr>
<tr>
<td>2. Explicitly state the decision under consideration</td>
<td>15. Describe next steps taken if test detects a condition/problem</td>
</tr>
<tr>
<td>3. Identify the eligible or target audience</td>
<td>16. Describe next steps if no condition/problem detected</td>
</tr>
<tr>
<td>4. Describe the options available for the decision, including non-treatment</td>
<td>17. Describe consequences of detection that would not have caused problems if the screen was not done</td>
</tr>
<tr>
<td>5. Describe the positive features of each option (benefits)</td>
<td>18. Include information about chances of false positive result</td>
</tr>
<tr>
<td>6. Describe the negative features of each option (hazards, side effects, disadvantages)</td>
<td>19. Include information about chances of false positive result</td>
</tr>
<tr>
<td>7. Help patients clarify their values for outcomes of options by, e.g., asking patients to consider or rate which positive and negative features matter most to them</td>
<td>20. Include information about chances of true negative result</td>
</tr>
<tr>
<td>8. Help patients imagine the physical, social (e.g., impact on personal, family or work life), and/or psychological effects of options</td>
<td>21. Include information about chances of false negative result</td>
</tr>
<tr>
<td>9. Show positive and negative features of options with balanced scale</td>
<td>22. Does the Patient Decision Aid and/or the accompanying external documentation (including responses to the application for certification) adequately:</td>
</tr>
<tr>
<td>10. Provide information about the funding sources for development</td>
<td>• Disclose and describe actual or potential financial or professional conflicts of interest</td>
</tr>
<tr>
<td>11. Report whether authors or their affiliated stand to gain or lose by decisions patients make using the PDA</td>
<td>• Fully describe the efforts used to eliminate bias in the decision aid content and presentation</td>
</tr>
<tr>
<td>12. Include authors/developers’ credentials or qualifications</td>
<td>• Demonstrate developer entities and personnel are free from actual or perceived financial biases</td>
</tr>
<tr>
<td>13. Provide date of most recent revision (or production)</td>
<td>• Demonstrate that the Patient Decision Aid has been developed and updated (if applicable) using high-quality evidence in a systematic and unbiased fashion</td>
</tr>
</tbody>
</table>

Certification Process

[Diagram showing the process of certifying decision aids]

HCA
CMO
In use

2016

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

2017

Joint replacement & spine
2018

End of life

Washington State paving the way