Revolutionizing Informed Consent with Certified Patient Decision Aids

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Chasm between theory & practice

Theory
Appellate opinions
autonomy
self-determination

Practice
Not even close
Roadmap

5

Failure of informed consent
What are PDAs
PDAs are effective
Moving PDAs from lab to clinic
Certification

Failure of informed consent law
Too much
Too fast
Too complex

Also in medicine

Bad

1972

Even if accurate & complete (but often is not)

Jerry Canterbury
“lengthy polysyllabic discourse”

2016

“lengthy polysyllabic discourse”

Still
Process problem

Terrible outcomes

Just 3 examples
(of many)

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
Breast cancer: surgical options

Use this Option Grid™ decision aid to help you and your healthcare professional talk about how best to treat breast cancer.

<table>
<thead>
<tr>
<th>Frequently Asked Questions</th>
<th>Lumpectomy with radiotherapy</th>
<th>Mastectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is removed?</td>
<td>The cancer lump is removed, with some surrounding tissue.</td>
<td>The whole breast is removed.</td>
</tr>
<tr>
<td>Which surgery is best for long-term survival?</td>
<td>Survival rates are the same for both options.</td>
<td>Survival rates are the same for both options.</td>
</tr>
</tbody>
</table>

Accurate  Complete  Understandable

PDAs work

Robust evidence shows PDAs are highly effective
> 130 RCTs

BUT

Very little 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
- Understandable
- Free from bias / COI

2010
Title III
Improving the Quality & Efficiency of Health Care

§ 3056

Contract with an entity to “synthesize evidence” and establish “consensus based standards”
No PDA ➞

no payment
(or less payment)

No criteria
No process
No entity

for certification

2006
Certification is underway

2016

Criteria

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 true positive result</td>
</tr>
<tr>
<td>6. Describe the negative features of each option (harms, 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 asking patients to consider or rate which positive and negative features matter most to them and/or (OR) describing each option to help patients imagine the physical, social (e.g. impact on personal, family, or work life), and/or psychological effects</td>
<td>20. Include information about chances of true negative result</td>
</tr>
<tr>
<td>8. Make it possible to compare features of available 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 detail</td>
<td>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 affiliates stand to gain or lose by choices 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 that the developer tested its decision aid with patients and incorporated these learnings into its tool</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>
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

2. Presumption that duty fulfilled
   Rebuttable only with clear & convincing evidence

3.
State as purchaser

30% citizens
Medicaid - 1.8m
Employees - 350k

PDA use required in contracts

State as first mover

New standard of care
(evolution of common law duty)
Looking ahead

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

Federalism

Powers Delegated to the National Government

Shared (Concurrent) Powers

Powers Reserved for the State Governments

The overlapping spheres of power bind the American people together.
NQF sets standards. NQF-endorsed measures are the gold standard for healthcare measurement in the United States.

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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Selected References


