Revolutionizing Informed Consent Law and Practice: Empowering Patients with Certified Decision Aids

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“matéria de informação e de tratamento”

BUT

Declaring legal rights is not enough
How law can push PDA use

Theory

Practice

Patient decision aids

Bridge that gap

PDAs
What are PDAs?

Evidence based educational tools

2

Before encounter

During encounter
Present options clearly & graphically

Do they work?
Yes

Robust evidence shows PDAs are highly effective

> 130 RCTs
30,000 patients
50 conditions

Improved knowledge

More accurate expectations

Lower decisional conflict
(less uncertainty)

More value congruent choice
Great evidence

What is the problem?

Too few clinicians use PDAs

Australia
Canada
Denmark
Germany
Netherlands

Norway
Taiwan
UK
USA

“More work has been done on SDM in the US than in any other country.”
BUT

“not incorporated into mainstream care”

So:

Move PDAs from research to practice

From lab to clinic

3 Legal tools
Liability Tools

Safe harbor
legal immunity
for using PDA

Liability protection
for using PDA
Mandate

Tools

“Mandated standardized written information”

Could use PDAs instead of MSWI

Not yet
Payment Tools

Agency in charge is CMS

Other insurers

Medicare

PDA use = "condition for payment"

No PDA

Logic
Medicare only pays "medically necessary" "Medically necessity" not purely clinical determination

Unwanted

Not med. necc.

3 examples

Require PDA as COP

2015 2018

1
Screening for Lung Cancer with Low Dose Computed Tomography

30 pack year smoking history

Chest CT scan

Before
CT scan

“must receive
. . . SDM visit”

“include . . .
one or more
decision aids”
Implantable Cardioverter Defibrillators

Is Lung Cancer Screening Right for Me?
A decision aid for people considering lung cancer screening with low-dose computed tomography
If you have smoked for many years, you may want to think about screening (testing) for lung cancer with low-dose computed tomography (CT). Before deciding, you should think about this...

WHAT IS IMPORTANT TO YOU WHEN DECIDING ABOUT SCREENING FOR LUNG CANCER?
There are many things to think about when deciding whether lung cancer screening is right for you. Below is a list of questions that may help you decide.

<table>
<thead>
<tr>
<th></th>
<th>Favors Screening</th>
<th>Favors No Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>How important is:</strong></td>
<td>Very Important</td>
<td>Not Important</td>
</tr>
<tr>
<td>Finding lung cancer only when it may be easily treated?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>How concerned are you about:</strong></td>
<td>Not Concerned</td>
<td>Very Concerned</td>
</tr>
<tr>
<td>Having a false alarm?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Having other tests if you have a positive screening test?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Being exposed to radiation from lung cancer screening?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Being treated for lung cancer that never would have killed you?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Being burdened by the treatments you receive for lung cancer?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Delivers electric shock to restore normal heartbeat

Before implantation

“formal SDM encounter must occur”

“evidence-based decision tool”

Percutaneous Left Atrial Appendage Closure Therapy
LAA = source for blood clots that can cause strokes

Before implantation
“formal SDM interaction”

evidence-based decision tool”

Recap

Growing use of legal tools

<table>
<thead>
<tr>
<th>Type of Legal Tool</th>
<th>Number in Force</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment</td>
<td>3</td>
</tr>
<tr>
<td>Liability</td>
<td>1</td>
</tr>
<tr>
<td>Mandate</td>
<td>0</td>
</tr>
</tbody>
</table>
PDAs widely varying quality

Cannot attach legal consequences

Assure PDA quality

Certification

Accurate
Up to date
No bias, COI
Understandable
Need one
certification entity

Certify PDAs
More legal tools

More legal tools
More PDA use

Conclusion
More PDA use

Better quality

References


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