Solving Persistent Problems of Informed Consent Law with Federally Certified Patient Decision Aids

ASLME Health Law Professors Conference
Atlanta, Georgia (June 10, 2017)

Thaddeus Mason Pope, JD, PhD
Mitchell Hamline School of Law

“comforted to know that his lawsuit and suffering had not been in vain”

Jerry Canterbury
NYT 05/2017

Much **smaller** impact than anticipated

Roadmap

4 parts

1

UMT Failure IC law PDA solution Implementing

Unwanted medical treatment
Patient did not want it. But got it anyway. 3 types UMT.

Type 1 UMT: Not medically indicated.

Breast surgeon Ian Paterson jailed 15 years for needless operations.

Harry Persaud – sentenced 29 years cardiac stents when no blockage.

Indicated Tx.
No patient would want this

Type 2

UMT

Tx

Indicated

Wanted

Tx

Indicated

Reasonable patient might want this

But . . .

this patient does not

2 examples

Example 1: advance directives
Example 2: forced cesareans

Crisp, clear, concrete UMT

Patient: “No. I do not want X.”

Clinician: Does X

Explicit refusals only small fraction of UMT

Type 3 UMT

Most common UMT

No rejection

No refusal
Actual consent  
uninformed

I would not have consented, if knew risks, benefits, alternatives

Did not know = 75g sugar

Failure of informed consent

There is a legal duty to inform
Thank you, Jerry.

But patients are seriously **misinformed**

Only 5 in 100 understand cancer diagnosis

Only **10 in 100** can answer basic questions about their spine surgery

>90% fail rate

What

Incomplete
Inaccurate
Outdated
How

Not meaningfully conveyed
Not understood

Informed consent law was not even designed to deal with this

Vast numbers of uninformed patients

Deluge of UMT
Solution PDAs

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

Evidence based educational tools
Informed patients request less aggressive treatment.

PDAs reduce UMT.

“Paradigmatic change in healthcare delivery”

More graphic
More user friendly
More accessible
More useable

Great evidence

But little clinical usage

“Promise remains elusive”
Move PDAs from research to practice

Using law to promote PDAs

<table>
<thead>
<tr>
<th>Liability incentives</th>
<th>Carrots</th>
<th>Sticks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhanced malpractice protection for using SDM</td>
<td>Expanded malpractice exposure for failing to use SDM</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Payment incentives</th>
<th>Carrots</th>
<th>Sticks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Shared Saving Program reimbursement for ACOs using SDM</td>
<td>Medicare and Washington state requirements to use SDM</td>
<td></td>
</tr>
</tbody>
</table>

No PDA

Widely varying quality

Should not attach legal consequences

Assure PDA quality
Certification

Accurate
Complete
Understandable

No bias
No COI

§

Agency in charge is CMS

- JCE from March 2013

Labor & Delivery (2016)

- 3 prenatal testing
- 2 birth options (VBAC, big baby)

Joint Replacement & Spine Care (2017)
End of life (2018)

WA is paving the way

Certify PDAs
Use PDAs
Less UMT

Thaddeus Mason Pope, JD, PhD
Director, Health Law Institute
Mitchell Hamline School of Law
875 Summit Avenue
Saint Paul, Minnesota 55105
T 651-695-7661
C 310-270-3618
E Thaddeus.Pope@mitchellhamline.edu
W www.thaddeus pope.com
B medicalfutility.blogspot.com