

Implementing SDM into Clinical Practice: Law & Policy Update

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ISDM 2019 - Quebec City

1

I have **nothing**
to declare

2



3

Australia
Canada
Denmark
Germany
Netherlands
Norway
Taiwan
UK
USA

4

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

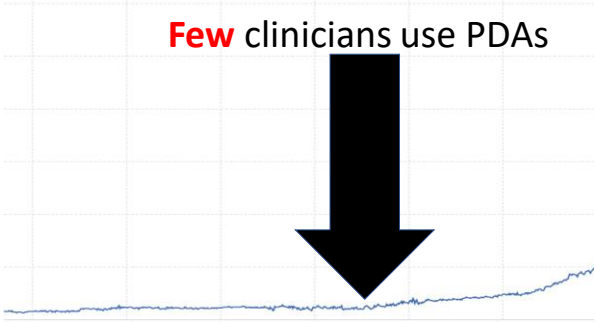
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BUT

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“**not** incorporated
in mainstream care”

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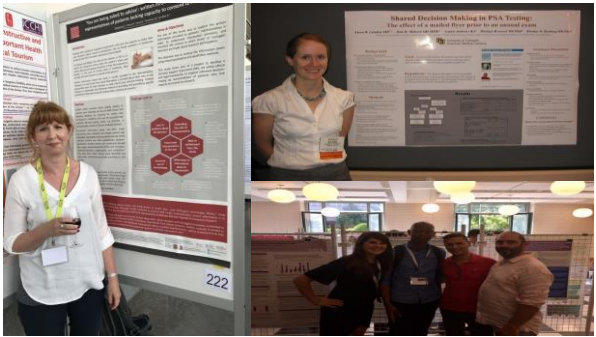
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BUT

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“comprehensive
strategy . . . to promote
wider uptake of SDM”

Coulter - World Psych 16:2 - June 2017

16



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18

Roadmap

19

4 parts

20

4

Legal **tools**
to promote
PDA use

21

1

22

Liability tools

23

2

24

Mandate
tools

25

3

26

Payment
tools

27

4

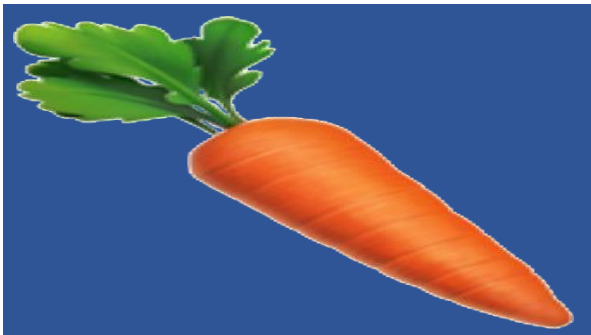
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Certification

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Liability
Tools

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Liability **protection**
for using PDA

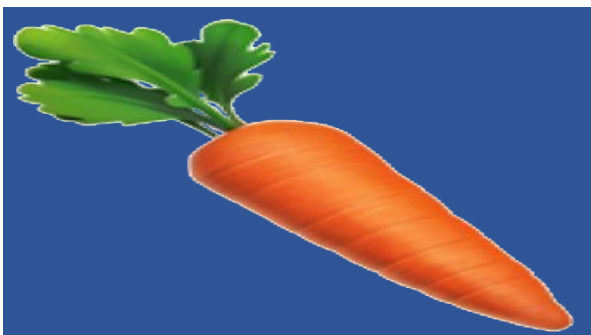
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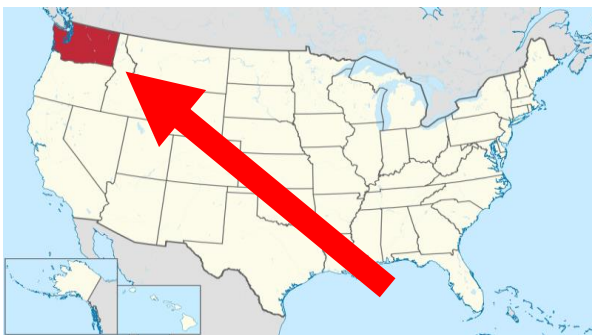
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Liability **risk**
for **not** using PDA

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Safe harbor

legal immunity
for using PDA

38

Mandate Tools

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Not just incentive
- a **requirement**

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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE



SDM in accreditation
measures starting 2019

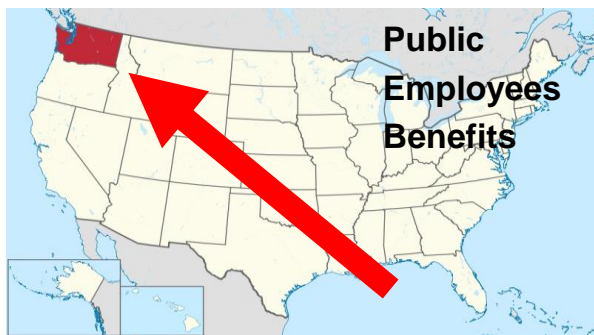
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SENATE, No. 3375

STATE OF NEW JERSEY

218th LEGISLATURE

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DOH develop SDM
 tool for **maternity
 care** hospitals

47



48

“Mandated
standardized
written
information”

49

a woman's guide to
breast cancer treatment

California Department of Health Care Services
Cancer Detection and Treatment Branch

January 2016

50

of careful testing in clinical trials before becoming standard treatment (also called standard of care).

People who join clinical trials have a chance to benefit from new treatments before they are widely available. They are also helping others by participating in medical research. There are some risks involved with any treatments that are still being tested.

Choosing to receive treatment through a clinical trial is an option for some women with breast cancer. Each study has rules for who may enroll, based on such factors as age, cancer stage and type, and prior treatments. Once enrolled, patients are monitored during and after treatment. They may leave a trial at any time and for any reason.

If you are interested in learning about clinical trials for women with breast cancer, the National Institutes of Health offers a searchable database at <http://nct.cancer.gov>. The American Cancer Society and the National Cancer Institute can also answer your general questions about clinical trials (for contact information, see pages 3 and 4).

COMPLEMENTARY THERAPY

Complementary therapy includes a broad range of products and practices that are not currently considered part of standard medical care. Most have not been tested in clinical trials and have not been scientifically proven to be effective for treating cancer. However, certain complementary therapies may be used along with standard treatments to help manage symptoms and side effects. Acupuncture for pain, ginger for nausea, and yoga or meditation to reduce stress are a few examples.

Because some complementary therapies have proved useful to cancer patients, several leading medical centers have begun programs that combine standard treatments with certain complementary therapies (called integrative treatment, or integrated treatment programs). At the same time, some major insurance companies have started to cover a few of the more widely accepted methods. Still, most complementary therapies are not covered by insurance.

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Replace MSWI
with PDAs

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Liability tools
Mandate tools

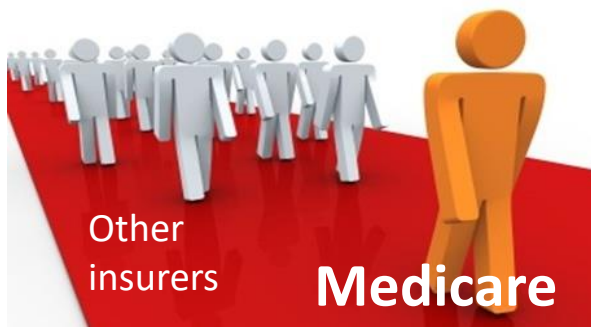
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Payment
Tools

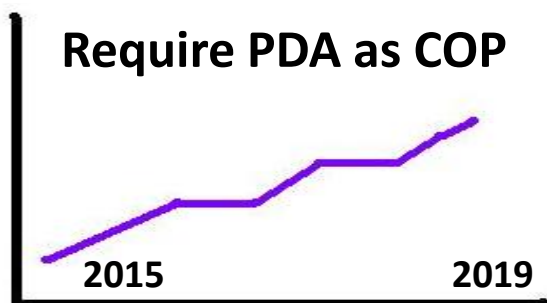
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1st time

Medicare
required SDM

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Screening for Lung
Cancer with Low
Dose Computed
Tomography

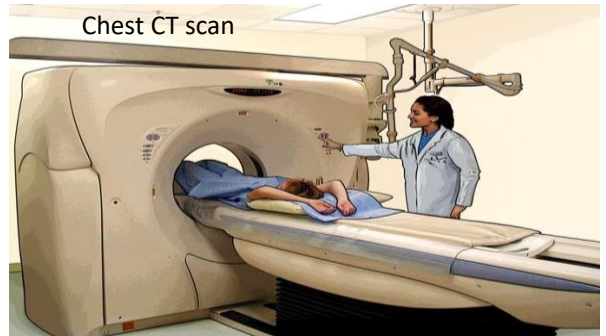
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30 pack year smoking history



63

Chest CT scan



64

Before
CT scan

65

“must receive
... SDM visit”

66

“include . . .
one or more
decision aids”

67

Coding
& billing

68

G0296
SDM
G0297
CT scan

69

Why
require PDA?

70

Doubt

71

Accurate
Unbiased
Balanced

from the
clinician

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73

Your discussion
with patient is
not good enough

74

Patient must
also get informed
with PDA

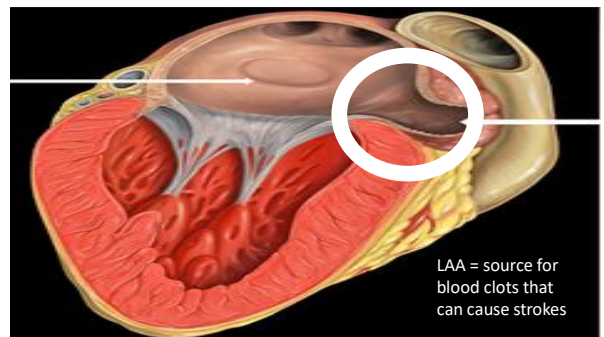
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2016

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Percutaneous Left
Atrial Appendage
Closure Therapy

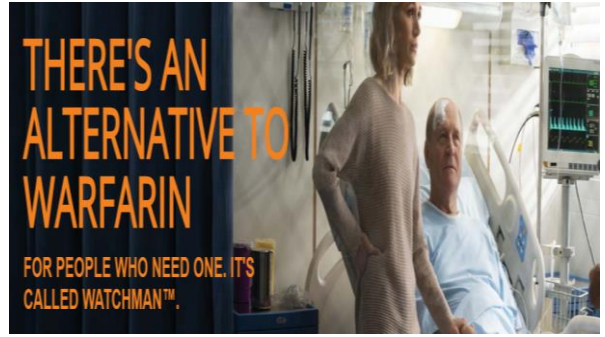
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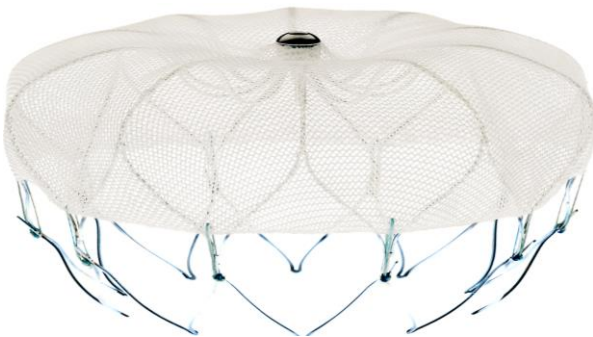
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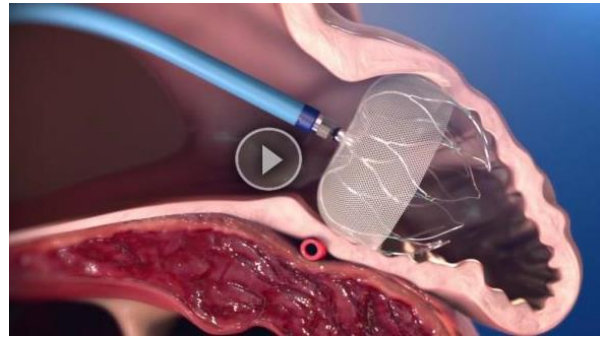
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Before
implantation

83

“formal **SDM**
interaction”

84

evidence-based
decision tool”

85

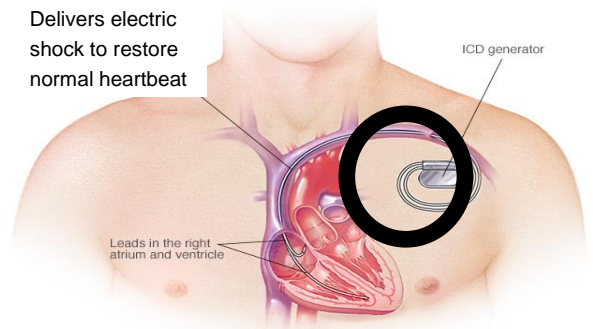
2018

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**Implantable
Cardioverter
Defibrillator**

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Delivers electric
shock to restore
normal heartbeat



88

Before
implantation

89

“formal SDM
encounter
must occur”

90

“evidence-based
decision tool”

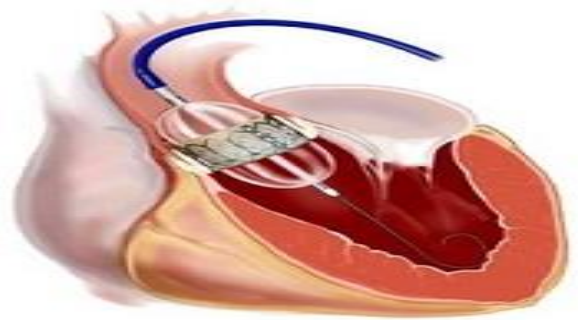
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2019

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Transcatheter
Aortic Valve
Replacement

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“CMS recognizes
the **importance**
of SDM.”

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“strongly **encourage** standardized decision aids & tools that meet NQF standards”

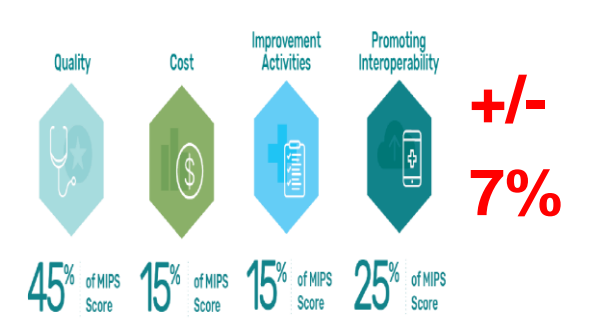
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BUT

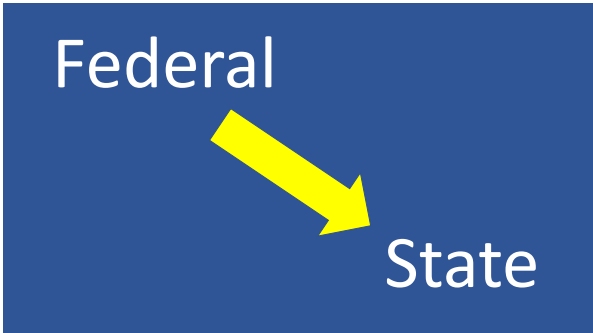
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“**not** a fully developed tool **available.**”

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SENATE, No. 1891

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED FEBRUARY 15, 2018

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Medicaid cover
advance care
planning

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“ACP shall consist
... **decision aids**”

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Recap

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Link PDA use to
Liability
Mandates
Payment

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SPEED LIMIT



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Type of Legal Tool	Number in Force
Payment	4
Liability	1
Mandate	2

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PDAs widely
varying quality

112

LDCT

113



CENTERS FOR DISEASE CONTROL AND PREVENTION Memorial Sloan Kettering Cancer Center

114

“gratuitously
inaccurate”

115

“miserable
failure”

116

“not ready for
prime time”

117

Ought not
attach legal
consequences

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Assure PDA
quality

119

Certification

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Accurate
Up to date
No bias + No COI
Understandable

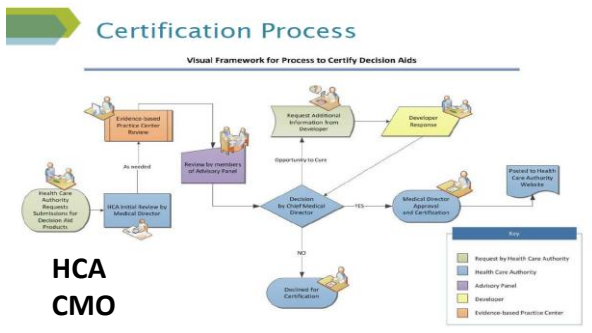
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Final Set of Certification Criteria	
Does the patient decision aid adequately:	Additional Criteria for Screening and/Testing, if applicable:
<ol style="list-style-type: none"> 1. Describe the health condition or problem 2. Explicitly state the decision under consideration 3. Identify the eligible or target audience 4. Describe the options available for the decision, including non-treatment 5. Describe the positive features of each option (benefits) 6. Describe the negative features of each option (harms, side effects, disadvantages) 7. Help patients clarify their values for outcomes of options by a) asking patients to consider or rate which positive and negative features matter most to them AND/OR b) describing each option to help patients imagine the physical, social (e.g. impact on personal, family, or work life), and/or psychological effects 8. Make it possible to compare features of available options 9. Show positive and negative features of options with balanced detail 10. Provide information about the funding sources for development 11. Report whether authors or their affiliates stand to gain or lose by choices patients make using the PDA 12. Include authors/developers' credentials or qualifications 13. Provide date of most recent revision (or production) 	<ol style="list-style-type: none"> 14. Describe what the test is designed to measure 15. Describe next steps taken if test detects a condition/problem 16. Describe next steps if no condition/problem detected 17. Describe consequences of detection that would not have caused problems if the screen was not done 18. Include information about chances of true positive result 19. Include information about chances of false positive result 20. Include information about chances of true negative result 21. Include information about chances of false negative result <p>Does the Patient Decision Aid and/or the accompanying external documentation (including responses to the application for certification) adequately:</p> <ul style="list-style-type: none"> • Disclose and describe actual or potential financial or professional conflicts of interest? • Fully describe the efforts used to eliminate bias in the decision aid content and presentation? • Demonstrate developer entities and personnel are free from listed disqualifications in Attachment A? • Demonstrate that the Patient Decision Aid has been developed and updated (if applicable) using high quality evidence in a systematic and unbiased fashion? • Demonstrate that the developer tested its decision aid with patients and incorporated these learnings into its tool?

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In use

125



126



Spine & joint replacement

7

127



Cardiac care

3

128



End of life

24

129

BUT

130

No **national** certification

131

Not yet

132

Conclusion

133

Certify PDAs



More legal tools

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More legal tools



More PDA use

135

More PDA use



Better quality

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