

# Linking Payment to Patient Preference

Medicare Coverage Mandates for Shared Decision Making

1



@ThaddeusPope

16th Annual Beazley Symposium on Health Law & Policy • Nov. 11, 2022

2

nothing  
to disclose

3

1972

4



5



6



7



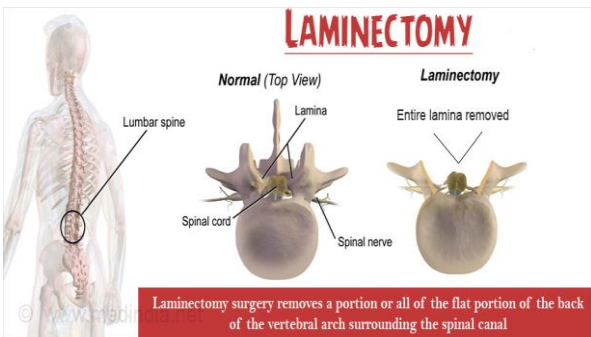
8

**Jerry W. CANTERBURY, Appellant,**  
**v.**  
**William Thornton SPENCE and the Wash-**  
**ington Hospital Center, a body cor-**  
**porate, Appellees.**  
**No. 22099.**  
**United States Court of Appeals,**  
**District of Columbia Circuit.**  
**Argued Dec. 18, 1969.**  
**Decided May 19, 1972.**  
**Rehearing Denied July 20, 1972.**

9

informed  
 consent

10



11



12

also

13



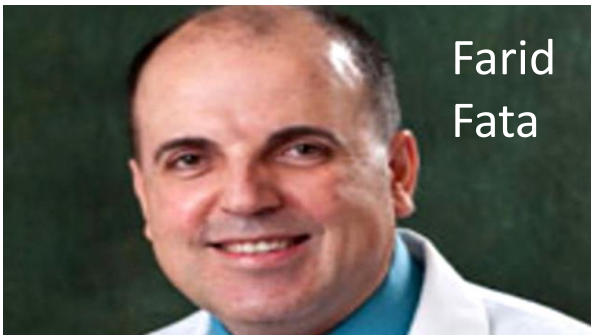
14



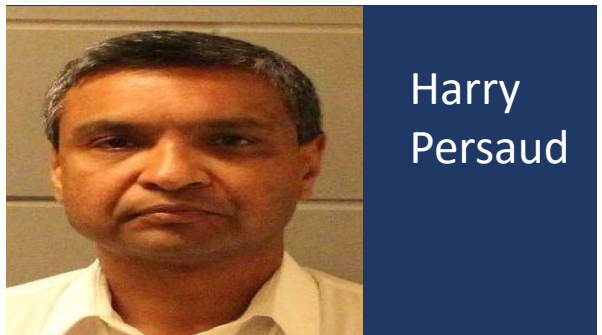
15

clinically  
indicated

16



17



18

but

19

while clinical  
indication is  
**necessary**

20

not  
**sufficient**

21

**clinically**  
indicated

22

also

23

**preference**  
indicated

24



25

want & value  
the treatment

26

why?

27

respects patient  
autonomy

28

avoids waste  
& saves \$\$

29

shared  
decision  
making

30

recognition  
endorsement

31



32



33



34

implementation  
adoption

35



36

shared  
decision  
making

37

seldom	stagnant
incomplete	elusive
infrequent	rare

38



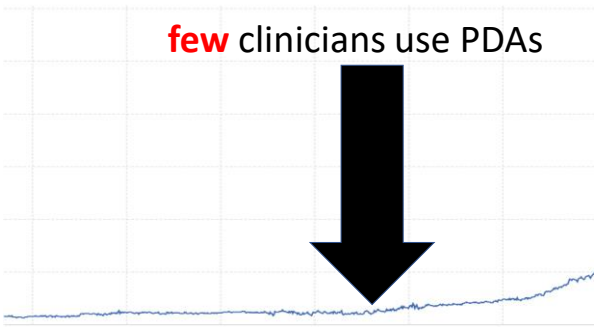
39

“significant and  
sustained adoption  
**problem**”

40

“**not** incorporated  
in mainstream care”

41



42

recognition  
endorsement

43



44



45



46

Roadmap

47



48



4

49

patient  
decision aids

50

3 Medicare  
mandates

51

how they  
**failed**

52

how to  
**fix** them

53

patient  
decision  
aids

54

what are  
PDAs?

55

evidence based  
educational tools

56

2 types

57

**before**  
encounter

58



59

**during**  
encounter

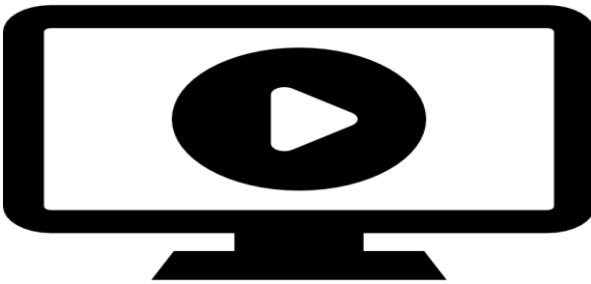
60



61

present options  
clearly &  
graphically

62



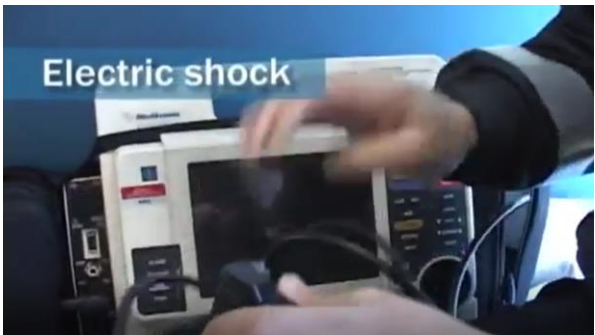
63



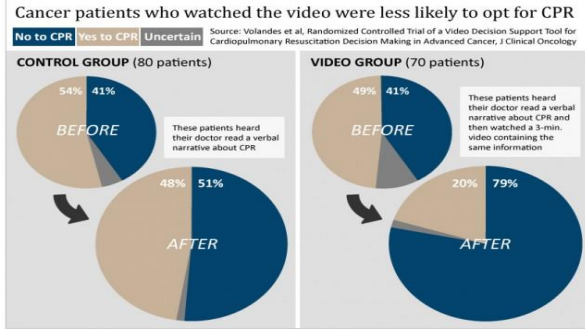
64



65



66



67

do they work?

68

yes

69

robust evidence shows PDAs are highly **effective**

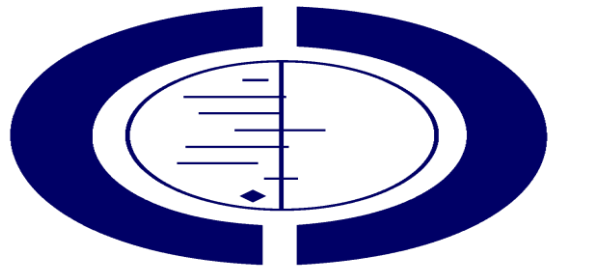
70

> 130 RCTs

71

30,000 patients  
50 conditions

72



THE COCHRANE  
COLLABORATION®

73

JOURNAL OF SURGICAL RESEARCH • MARCH 2019 (235) 350-366

## A Review of Decision Aids for Patients Considering More Than One Type of Invasive Treatment

Kathleen A. Leinweber, BS,<sup>a</sup> Jesse A. Columbo, MD, MS,<sup>a,b,c,d,e</sup>

74

**6** big  
benefits

75

improved  
knowledge

76

**more** accurate  
expectations

77

**more** value  
congruent  
choice

78

**higher**  
patient  
satisfaction

79

**less**  
decisional  
conflict

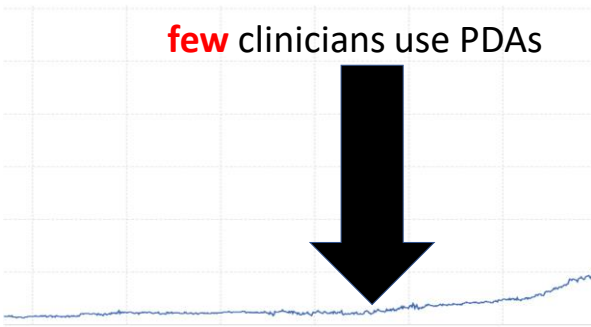
80

**less**  
patient  
anxiety

81

great  
evidence

82



83



84

**3 Medicare mandates**

85



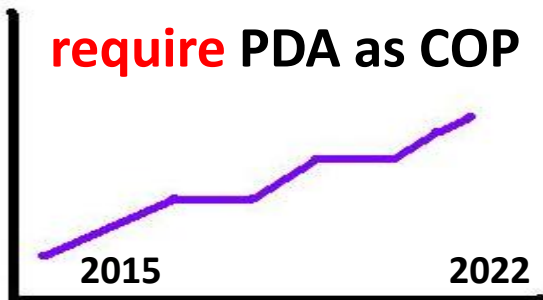
86

**50,000,000**

87



88



89

**no PDA → no pay**

90

**3** examples

91

**2015**

92



93

**NCD**

94

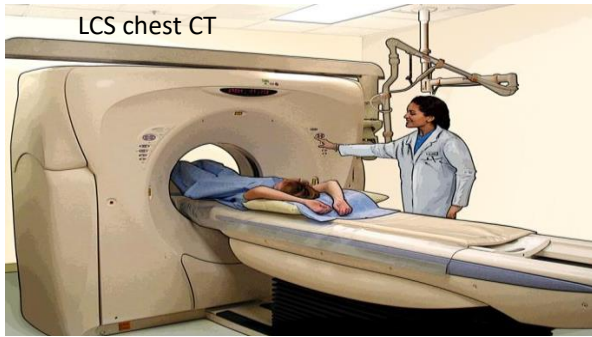
low dose CT  
lung cancer screening

95

**1<sup>st</sup> time**  
Medicare  
required PDA

96





97



98

**before**  
CT scan

99

**“must receive**  
... SDM visit”

100

**“one or more**  
**decision aids”**

101

102

coding  
& billing

103

G0296  
SDM  
G0297  
CT scan

104

why  
require PDA?

105



106

doubt

107

accurate  
unbiased  
balanced

from the  
clinician

108



109

**your** discussion  
with patient is  
**not** good enough

110

patient must  
**also** be informed  
with PDA

111

PDA makes  
**difference**

112

with PDA  
**40%** decline  
LDCT

113



114

false +  
incidental findings  
overdiagnosis  
radiation

Shared Decision-Making and Use of Low-Dose CT Screening for Lung Cancer

115

that's

LDCT

116

2016

117



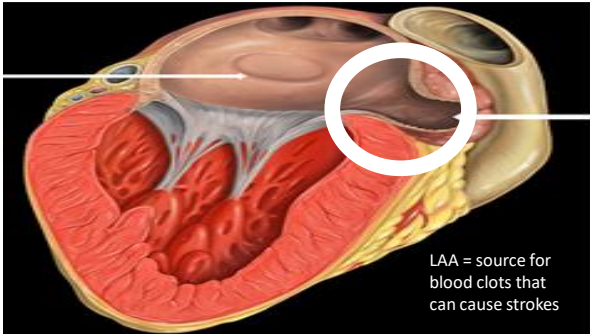
118

NCD

119

percutaneous left  
atrial appendage  
closure therapy

120



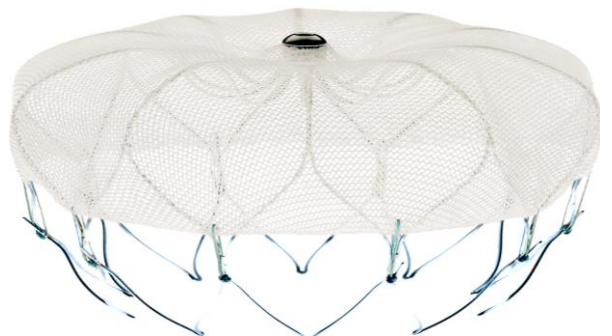
121



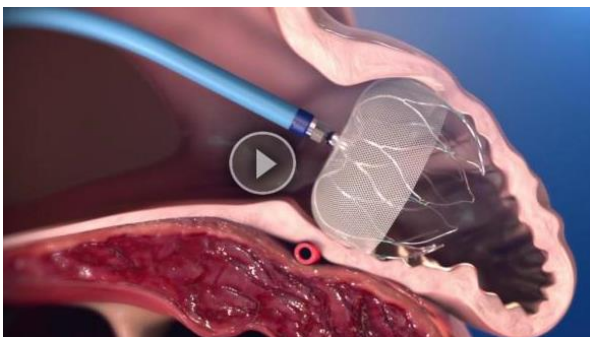
122



123



124



125



126

“formal **SDM**  
interaction”

127

“evidence-based  
**decision tool**”

128



129

require PDA  
as with LDCT

130

**non**-interventional  
clinician

131

that's

**LAAC**

132

2018

133



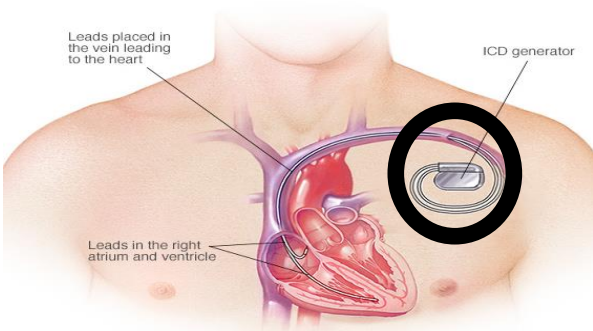
134

NCD

135

implantable  
cardioverter  
defibrillator

136



137

before  
implantation

138

“formal SDM  
encounter  
**must occur**”

139

“evidence-based  
**decision tool**”

140

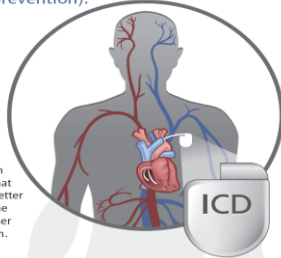
A decision aid for  
**Implantable Cardioverter-Defibrillators (ICD)**  
For patients with heart failure considering an ICD who are at risk  
for sudden cardiac death (primary prevention).

**What is an ICD?**

An ICD is a small device that is placed under the skin of the chest. Wires (called “leads”) connect the ICD to the heart. An ICD is designed to prevent an at-risk person from dying suddenly from a dangerous heart rhythm. When it senses a dangerous heart rhythm, an ICD gives the heart an electrical shock. It does this in order to get the heart to beat normally.

**Is an ICD right for me?**

Your doctor has suggested that you might benefit from having an ICD. This is a big decision. Understanding what to expect after getting an ICD might help you to feel better about your decision. The ICD may not be right for some people. Although this may be hard to think about, other patients like you have wanted to know this information.



141

that’s

**ICD**

142

**3** SDM/PDA  
mandates

143

LDCT  
LAAC  
ICD

144

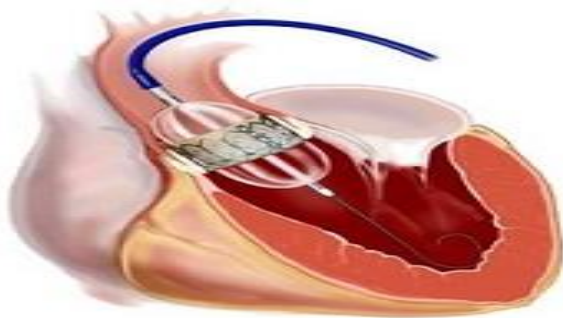


**more**  
to come

145

transcatheter  
aortic valve  
replacement

146



147



148

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

149

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

150

but

151

“not a fully developed tool available”

152

**TREATMENT OPTIONS**

<p><b>TAVR</b> Transcatheter Aortic Valve Replacement transcatheter procedure</p> <p><b>WHAT:</b> TAVR is a procedure where a new valve is placed in the heart through a small tube (called a “catheter”) typically in the leg.</p> <p><b>HOW:</b> This procedure involves a small incision where a catheter is inserted to access the heart to replace the valve.</p>	<p><b>SAVR</b> Surgical Aortic Valve Replacement open-heart surgery</p> <p><b>WHAT:</b> SAVR is open-heart surgery where a new valve is placed in the heart directly, replacing the old valve.</p> <p><b>HOW:</b> This surgery usually involves an incision along the breastbone to access the heart to replace the valve.</p>
--	--

153

more

154



Jun 06, 2022

**The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality**

By: Michelle Schreiber, M.D.; Adam C. Richards, MA; Jean Moody-Williams, RN, MPP; Lee A. Fleisher, M.D.

155

goal 4 (of 8)

156

foster  
engagement  
with PDAs

157

more

158



159

3 Medicare  
mandates

160

LDCT<sup>2015</sup>  
LAAC<sup>2016</sup>  
ICD<sup>2018</sup>

161

How are the  
mandates  
working

162



163



164



165



ORIGINAL ARTICLE

Physicians' perceptions of shared decision-making for implantable cardioverter-defibrillators: Results of a physician survey

Fatima Ali-Ahmed MD ✉ Daniel Matlock MD, Emily P. Zeitler MD, MHS,

166



167



168

probably  
**higher**

self-reported

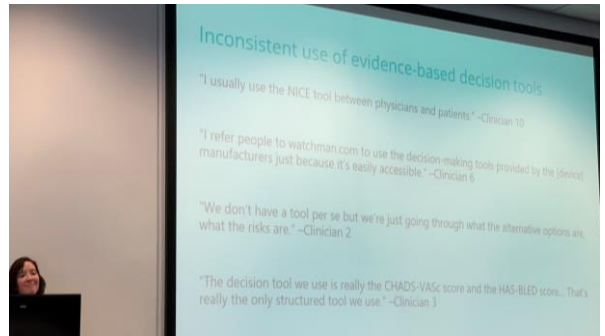
169

LAAC

170

**not** yet  
published

171



172

LDCT

173

started

2015

174

**3** phases of published studies

175

2018

176

JAMA Internal Medicine | Original Investigation | LESS IS MORE

**1** Evaluating Shared Decision Making for Lung Cancer Screening

Alison T. Brenner, PhD, MPH; Teri L. Malo, PhD, MPH; Marjorie Margolis, MSPH; Jennifer Eston Lafata, PhD;

---

**2** Patient and Clinician Perspectives on Shared Decision-making in Early Adopting Lung Cancer Screening Programs: a Qualitative Study

Renda Soylemez Wiener, MD, MPH<sup>1,2</sup>, Elisa Kappelman, MSW, MPH<sup>1,3</sup>,

177

0% zero

178

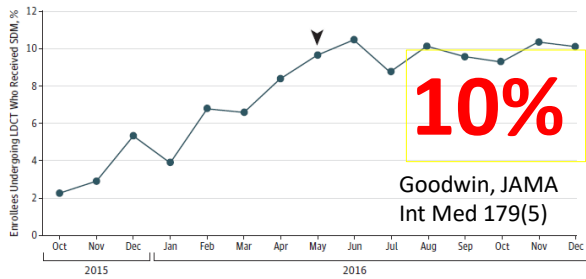
**not one** clinician used PDA as required by NCD

179

2019

180

Figure. Percentage of Medicare Enrollees Aged 55 to 77 Years Undergoing Low-Dose Computed Tomography (LDCT) Screening Who Had a Shared Decision-Making (SDM) Visit in the 3 Months Before the LDCT



181

90%  
noncompliance

182

2022

183

Prospective Multisite Cohort Study to Evaluate Shared Decision-Making Utilization Among Individuals Screened for Lung Cancer

Tina D. Taylor, MD<sup>a</sup>, *J Am Coll Radiology* 2022

184

23%  
used PDA

185

but

186

**low** quality

187

**8%**

included  
required  
elements

188

recap

189

**1**

190

**lack** of  
compliance

191

**only** 8% - 10%  
LDCT mandate

192



2

193

**lack** of  
enforcement

194

LDCT, ICD, LAAC  
**without**  
required PDA

195

NCD

196

but

197

**no** penalties

198

mandates  
**not** working

199

worse

200



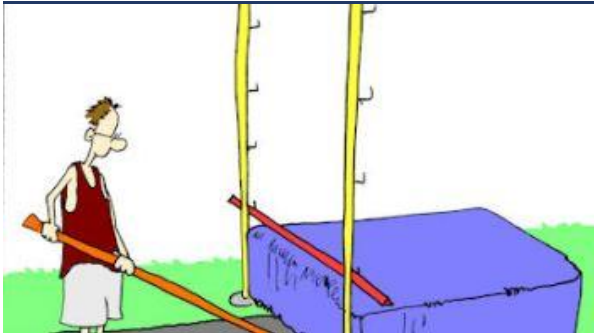
201

LDCT

202

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11388	Date: April 29, 2022

203



204



The Society of Thoracic Surgeons

ACR  
AMERICAN COLLEGE OF RADIOLOGY

“**drop** the requirement for a SDM session”

205



206

**innovative payment model**  
that can reduce waste & low-value care

207

better informed patients **forgo** expensive therapies

208

**premature** to weaken or eliminate PDA mandates

209

**enforce PDA mandates**

210

**VERY**  
SERIOUS

211

**NCD**

212



213

**ICD**

214



215

**\$250,000,000**

216

no ICD if **recent**  
heart attack  
heart bypass  
angioplasty

217

**waiting** gives heart  
chance to improve  
function, so ICD may  
be **unnecessary**

218

violate that NCD  
requirement →  
\$250,000,000

219

violate **this** NCD  
requirement →  
penalties

220

failing to use PDA  
**also** results in  
unnecessary ICDs

221

**Conclusion**

222

shared  
decision  
making

223

**moved** from  
guidelines to  
incentives

224

now

225

must **enforce**  
the incentives

226



227



228



229

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W www.thaddeuspope.com

B medicalfutility.blogspot.com

230

230

## References

231

231

Materials from this  
presentation are  
available

<http://thaddeuspope.com>

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*Patient Decision Aids Improve Patient Safety And Reduce Medical Liability Risk*, 74(1) MAINE LAW REVIEW 73-100 (2022).

*Informed Consent Requires Understanding: Complete Disclosure Is Not Enough*, 19(5) AMERICAN JOURNAL OF BIOETHICS 27-28 (2019).

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*Providing Cancer Treatment Without Patient Consent*, ASCO POST (Feb. 25, 2018).

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*Certified Patient Decision Aids: Solving Persistent Problems with Informed Consent Law*, 45(1) JOURNAL OF LAW, MEDICINE & ETHICS 12-40 (2017).

*Revolutionizing Informed Consent: Empowering Patients with Certified Decision Aids*, 10 THE PATIENT - PATIENT CENTERED OUTCOMES RESEARCH (2017) (with Daniel S. Lessler).

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*Clinicians May Not Administer Life-Sustaining Treatment without Consent: Civil, Criminal, and Disciplinary Sanctions*, 9 JOURNAL OF HEALTH & BIOMEDICAL LAW 213-296 (2013).

*Patient Rights*, in OXFORD TEXTBOOK OF CRITICAL CARE (Webb, Angus, Finfer, Gattioni & Singer eds., Oxford University Press forthcoming 2015) (with Douglas White).

*Legal Briefing: The New Patient Self Determination Act*, 24(2) JOURNAL OF CLINICAL ETHICS 156-167 (2013).

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Thaddeus Pope, *Legal Briefing: Informed Consent*, 21(1) J. CLINICAL ETHICS 72-82 (2010).

Thaddeus Pope, *The Maladaptation of Miranda to Advance Directives: A Critique of the Implementation of the Patient Self Determination Act*, 9 HEALTH MATRIX 139-202 (1999).

239

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240