Implementing SDM into Clinical Practice Law & Policy Update

> Thaddeus Mason Pope, JD, PhD, HEC-C ISDM • June 21, 2022



implementation

3







What is Ready for Prime Time #5 keynote

ZEITSCHRIFT FÜR EVIDENZ, FORTBILDUNG UND QUALITÄT IM GESUNDHEITSWESEN



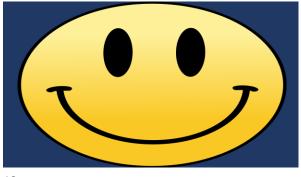
QUALITY IN HEALTH CARE

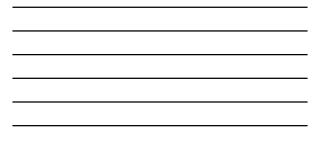
Recognition Endorsement













Implementation

Adoption





seldom	stagnant
incomplete	elusive
infrequent	rare

F			
L			



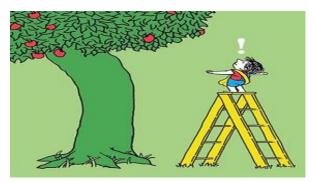
THE JOURNAL OF EVIDENCE AND QUALITY IN HEALTH CARE

"significant and sustained adoption problem"

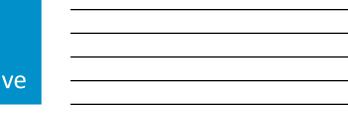
16

17

Recognition Endorsement









Roadmap



	3	
23		

Legal incentives push PDA uptake

Medicare mandates

25

26

Are those mandates working?

Legal tools to push SDM

Legal tools to promote PDA use

5

Liability tools







Safe harbor legal immunity for using PDA

31



32

Mandate tools

Not just incentive Legally required

Let's <u>Require</u> Patients to Review a High-quality Decision Aid Before Receiving Important Tests and Treatments

Floyd J. Fowler Jr, PhD,* Michael J. Barry, MD, MACP,† Karen R. Med Care 2021 Jan; 59(1): 1–5

Payment tools

34



38

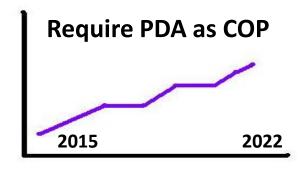
Most used incentive

Payment tools



50,000,000







Lung Cancer Screening with Low Dose CT







Before CT scan

49

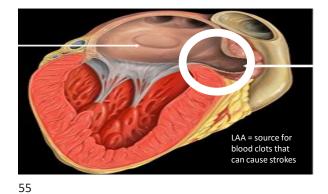
50

"must receive ... SDM visit"

"one or more decision aids"



Percutaneous Left Atrial Appendage Closure Therapy







6/19/2022



59

Before implantation

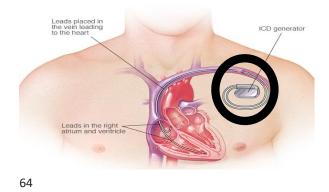
"formal SDM interaction"

"evidence-based decision tool"

61



Implantable Cardioverter Defibrillator



Before implantation

"formal SDM encounter must occur"

66

"evidence-based decision tool"

67



LDCT LAAC ICD

Assess

70



Journal of Cardiovascular Electrophysiology



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,

43% reported using PDA

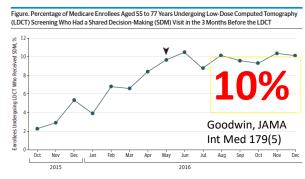


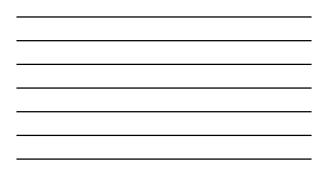




Renda Soylemez Wiener, MD, MPH^{1,2}, Elisa Koppelman, MSW, MPH^{1,3},

0% zero





82

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

J Am Coll Radiology 2022

Tina D. Tailor, MD^a,

00

83

42% SDM



Low quality

86

23% PDA

8% required

88

Upshot





Lack of compliance

Only 8% - 10% LDCT mandate



Lack of enforcement

95

LDCT & ICD without required SDM







No penalties

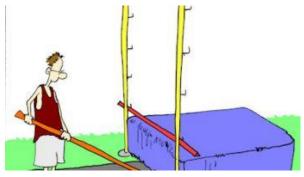
for violating SDM rules





LDCT

Centers for Medicare &
Medicaid Services (CMS)
Date: April 29, 2022









"drop the requirement for a SDM session"

107

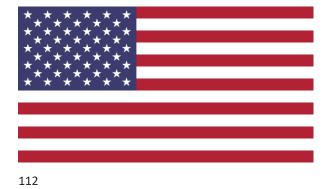
Conclusion





110

SDM/PDA also waiting to take off



Moved from guidelines to incentives



Must enforce the incentives

115



116

Thaddeus Mason Pope, JD, PhD, HEC-C

Mitchell Hamline School of Law 875 Summit Avenue Saint Paul, Minnesota 55105

- **T** 651-695-7661
- **C** 310-270-3618
- ${\bf E} \quad {\rm Thaddeus.Pope@mitchellhamline.edu} \\$
- ${\bm W} \hspace{0.1 cm} www.thaddeuspope.com$
- B medicalfutility.blogspot.com

References

118

Materials from this presentation are available

http://thaddeuspope.com

119

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

Informed Consent and the Oncologist: Legal Duties to Discuss Costs of Treatment, ASCO POST (Nov. 25, 2017).

121

Thaddeus Pope, Decision Aids Reflect Patients' Values and Preferences for Care: So Why Aren't More Oncologists Using Them? ASCO POST (May 10, 2018).

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

122

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). Emerging Legal Issues for Providers in the US, in SHARED DECISION MAKING IN HEALTHCARE: ACHIEVING EVIDENCE-BASED PATIENT CHOICE (Oxford University Press 2016) (with Benjamin Moulton).

Legal Briefing: Informed Consent in the Clinical Context, 25(2) JOURNAL OF CLINICAL ETHICS 152-174 (2014) (with Melinda Hexum).

Legal Briefing: Shared Decision Making and Patient Decision Aids, 24(1) JOURNAL OF CLINICAL ETHICS 70-80 (2013) (with Mindy Hexum).

124

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).

125

Thaddeus Pope, Legal Briefing: POLST (Physician Orders for Life-Sustaining Treatment), 23(4) J. CLINICAL ETHICS 353-376 (2012) (with Mindy Hexum).

Thaddeus Pope, Legal Briefing: Informed Consent, 21(1) J. <u>CLINICAL ETHICS</u> 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).

Thaddeus Mason Pope, JD, PhD, HEC-C

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
- ${\bm W} \hspace{0.1 cm} www.thaddeuspope.com$
- B medicalfutility.blogspot.com