Informed Consent

Ethics & Law: More than a Piece of Paper

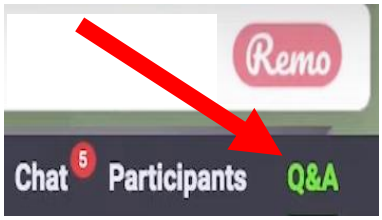
Thaddeus Mason Pope, JD, PhD, HEC-C
Vermont Ethics Network Fall Conference
November 9, 2020

1

Nothing

to disclose

2



3

Roadmap

4

4

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Legal primer

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Problems & failures

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Gap law & ethics

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PDAs

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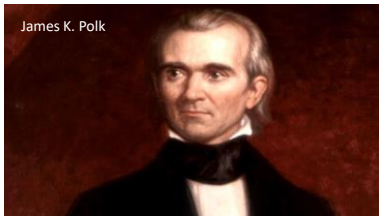
History of Informed Consent Law

10

1847

11



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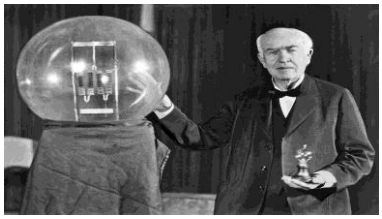

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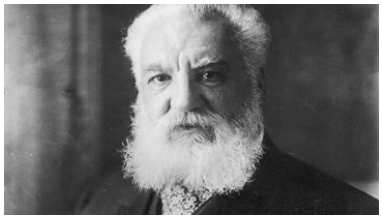

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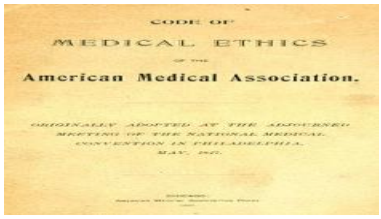

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Do **NOT** consider patient's "own crude opinions"

16

17

18

1905

19

20

21

22

Medical battery

23

Do **not** touch the patient without consent

24

4 forms

25

1

26

No consent **at all**

27

U.S. Immigration and Customs Enforcement

19 women allege medical abuse, including surgery without consent, while at ICE detention center in Georgia

Chicago Tribune

28

"Do **not** intubate"

$1,000,000

Alicea (Ga. 2017)

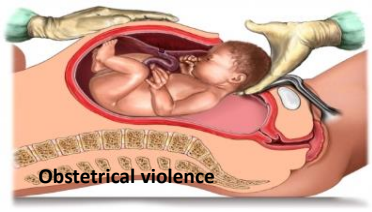
29

2

30

Consent to **different** procedure

31



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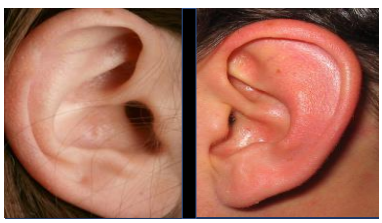
3

33

Same procedure different **body part**

34



35

4

36

Same procedure,
same part,
different doc

37

38

Battery

39

40

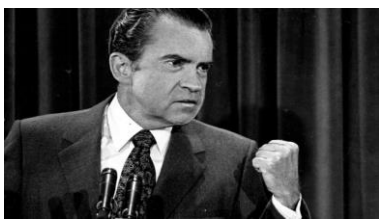
No consent
at all
for what done

41

42

1972

43



44

45

46

Informed Consent

47

No mismatch

48

Example

49

50

51

Got what I asked for

52

BUT

53

54

55

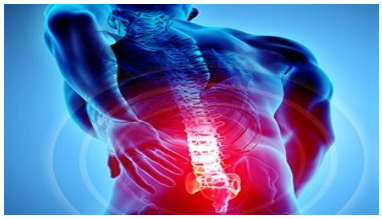
Starbucks had my **bare** consent but not my **informed** consent

56

In medical treatment context

57

58



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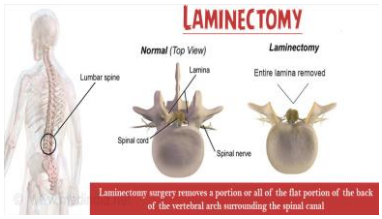


60

1% risk paralysis

61

MD did **not** disclose 1%

62

Jerry paralyzed

63

Jerry:

"I **did** consent"

64

No battery

65

BUT

66

"I would **not** have consented, **if** disclosure had been appropriate."

67

"I would not have consented, **if** I knew the risks"

68

New theory: that docs have **duty** to disclose that

69

Jerry W. CANTERBURY, Appellant,
v.
William Thornton SPENCE and the Washington Hospital Center, a body corporate, 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.

70

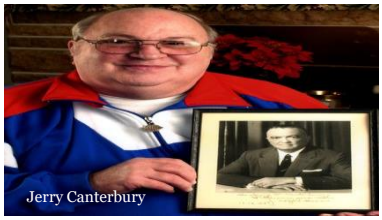
MD must obtain not just consent but **informed** consent

71

Obituary
05/2017

The New York Times

72



73

"**landmark** … ruling … **fundamentally transformed** how doctors deal with patients"

74

BUT

75

How informed does the patient need to be?

76

77

Jerry W. CANTERBURY, Appellant,
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William Thornton SPENCE and the Washington Hospital Center, a body corporate, Appellees.
No. 22099.
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78

Disclose all risks a **reasonable patient** would find important

79

Disclose what **patient** considering a laminectomy would **deem significant**

80

Patient focused

81

Majority rule in law & ethics

82

Law **different** in Vermont

83

Vermont Law

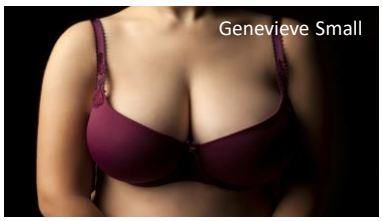
84

1975

85

Gifford Medical Center

86



87

Genevieve:
"I **did** consent"

88

BUT

89

"I would not have consented, **if** I knew the risks"

90

91

92

Agrees with

Canterbury

93

Disclose all risks a

reasonable patient

would find important

94

Patient

focused

95

BUT

96

1976

97

98

99

12 VSA 1909

100

"disclose … alternatives … and … reasonably foreseeable risks and benefits"

101

Which ones?

102

"as a **reasonable medical practitioner** … would have disclosed"

103

Different standard

104

Duty measured by professional **custom**

105

Physician focused

106

Duty to disclose what **reasonable physician** does

107

Less patient centered

108

109

"**not** as broad"

"**lessens** burden on physicians"

110

111

Rejected

physician standard

112

"Letting the medical profession set its **own** standards . . . by which the sufficiency of the information is measured is **unduly restrictive**"

113

114

Other informed consent laws

115

"Patients with a **terminal illness** have the right to be informed of all available options"

18 VSA 1871

116

"**Hospital patients** have a right to receive . . . Information necessary to give informed consent"

18 VSA 1852

117

We'll focus on 1976 statute

118

Patient → Physician

119

Does **not** matter

120

121

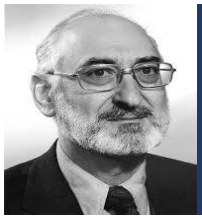
122

Problems

123

Quality

124



Avedis Donabedian

125

3 domains of quality

126

Structure
Process
Outcomes

127

Structure

128

What you "**have**"
Stuff
Resources

129

Facilities
Equipment
Staffing

130

Process

131

What you "**do**"
Actions

132

% preventive services
(e.g. mammograms, immunizations)

133

Outcomes

134

End results
Look at **patients**, not at HCP

135

What **happens** to patient after encounter

136

e.g.

HAI rate

Surgical mortality rate

137

Framework

Assessing healthcare quality

138

Apply this framework to informed consent

139

Structure

Process

Outcomes

140

Structure

141

Do you have necessary **resources** for communication?

142

143

2 examples

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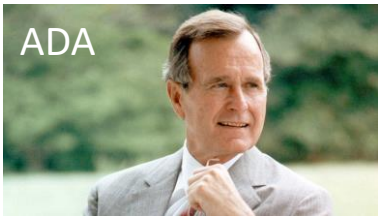
145

Disabling

25% 65-74

50% 75+

146



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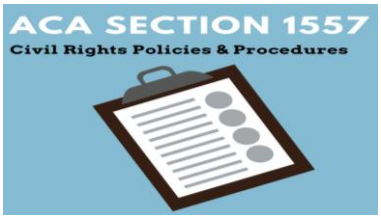


149

150

Widespread noncompliance

151

e.g.

rely on companion

152

University of Vermont Medical Center Voluntary Resolution Agreement with HHS Office for Civil Rights & U.S. Department of Justice (Dec. 2017)

153

154

155

1 in 13
LEP

156

157

158

159

Process

160

Are relevant risks, benefits, alternatives **disclosed**?

161

No

162

Medscape

2020 survey
1400 physicians

163

Would you **withhold risks** from patient to encourage consent?

164

165

3 data points

166

1

167

Clarence Braddock

168

> 1000 physician–patient encounters

59 PCP

65 surgeons

169

170

>3500 clinical decisions made during these encounters

171

How **frequent** was discussion of risks and benefits?

172

9%

173

2

174

Michael Rothberg

175

audiotaped conversations between physicians and patients

176

angiography & possible PCI for stable coronary disease

177

3%

178

3

179

Alison Brenner

180

181

lung cancer screening

182

0%

183

Process perspective

184

Are relevant risks, benefits, alternatives **disclosed**?

185

Very often, **no**

186

Outcomes

187

Even if disclosed, did patient **understand**?

188

No

189

Most are seriously **misinformed**

190

Few examples (of many)

191

1

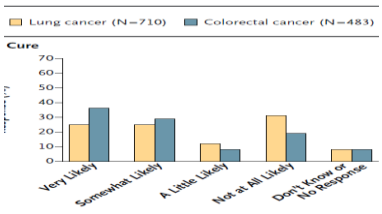
192

The NEW ENGLAND JOURNAL of MEDICINE

Patients' Expectations about Effects of Chemotherapy for Advanced Cancer

chemotherapy for **incurable** cancers – palliative only

193



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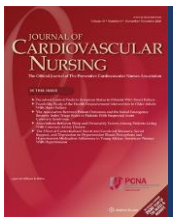


78% with ICD thought would forestall further deterioration

196

3

197

Only 14% undergoing vascular procedure could correctly recall essential information

198

4

199

150 patients undergoing elective surgery under general anesthesia

200

Informed 4 risks

- Death
- Pneumonia
- Heart attack
- Stroke

201

Day of surgery, **63%** could not recall **any** risks

202

5

203

Only **5 in 100** understand their cancer diagnosis

DOI: 10.1200/JCO.2015.63.6696 *Journal of Clinical Oncology* 34, no. 20 (July 2016) 2398-2403.

204

6

205

Only **12 in 100** understand their cardiac catheterization

206

7

207

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

208

> 90%

fail rate

209

Structure

Process

Outcomes

210

Diagnosis

211

Focus on **disclosure** not understanding

212

There is a legal **duty** to inform

213

214

215

BUT

216

Law focuses on **what** discussed, not **how**

217

What

218

Incomplete

Inaccurate

Outdated

219

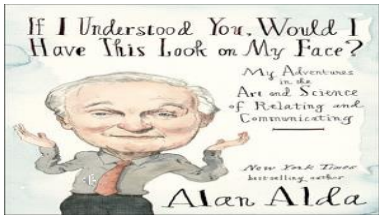
How

220

Not meaningfully conveyed

Not understood

221



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The role of informed consent in patient complaints: Reducing hidden health system costs and improving patient engagement through shared decision making

By Karen L. Posner, PhD, Julie Severson, PhD, JD, and Karen B. Domino, MD, MPH

JOURNAL OF HEALTHCARE RISK MANAGEMENT • VOLUME 35, NUMBER 2

223

224

"potential risk of harm . . . **included**"

225

BUT

226

"**not** clearly understood"

227

"Risk of **dental injury** . . . disclosed"

228

BUT

229

"not **appreciate** implications . . . appearance . . . (front teeth). . ."

230

"**Nerve injury** . . . disclosed"

231

BUT

232

"**not understand** . . . manifest as pain or weakness in an extremity"

233

Got disclosure

234

BUT

235

Too much
Too fast
Too complex

236

237

238

1972

239

240

241

"lengthy
polysyllabic
discourse"

242

2020

243

244

"lengthy polysyllabic discourse"

245

Still

246

247

Stalled 50 years

248

Vast numbers of **uninformed** patients

249

250

Unwanted treatment

251

Worse

252

Informed consent was not even **designed** to deal with this

253

254

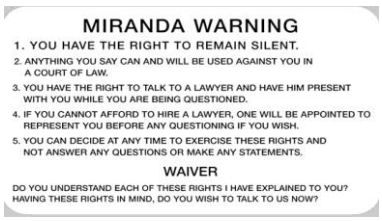
5 metaphors analogies

255

256

257

258


MIRANDA WARNING

1. YOU HAVE THE RIGHT TO REMAIN SILENT.
2. ANYTHING YOU SAY CAN AND WILL BE USED AGAINST YOU IN A COURT OF LAW.
3. YOU HAVE THE RIGHT TO TALK TO A LAWYER AND HAVE HIM PRESENT WITH YOU WHILE YOU ARE BEING QUESTIONED.
4. IF YOU CANNOT AFFORD TO HIRE A LAWYER, ONE WILL BE APPOINTED TO REPRESENT YOU BEFORE ANY QUESTIONING IF YOU WISH.
5. YOU CAN DECIDE AT ANY TIME TO EXERCISE THESE RIGHTS AND NOT ANSWER ANY QUESTIONS OR MAKE ANY STATEMENTS.

WAIVER

DO YOU UNDERSTAND EACH OF THESE RIGHTS I HAVE EXPLAINED TO YOU? HAVING THESE RIGHTS IN MIND, DO YOU WISH TO TALK TO US NOW?

259

260

Informed consent not done **with** patients

261

It is done **to** patients

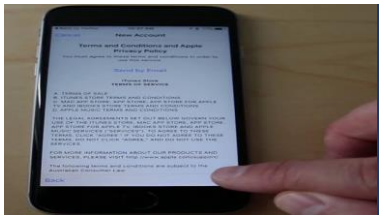
262

"Consent the patient!"

263

264

265



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267

Summing up

informed consent doctrine

268

Ethically, disclosure was thought a **means** to the goal of understanding

269

Today, disclosure **is** the goal

270

271

12 VSA 1909

272

Not only **what**

but also **how**

273

"in a **manner** permitting the patient to make a knowledgeable evaluation"

274

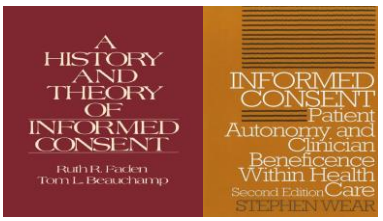
Enforced?

275

Gap

276

277



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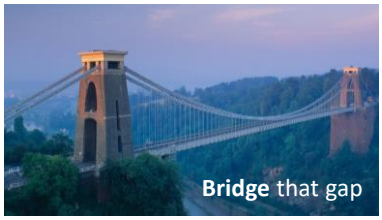

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How can we do better?

281

Decision Aids

282

What are PDAs?

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Evidence based educational tools

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Before encounter

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During encounter

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Present options clearly & graphically

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Examples

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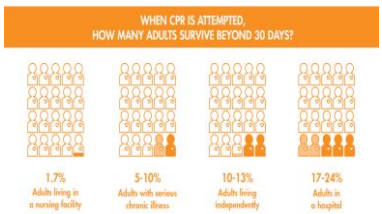

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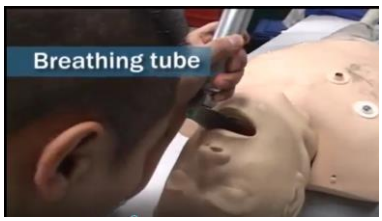

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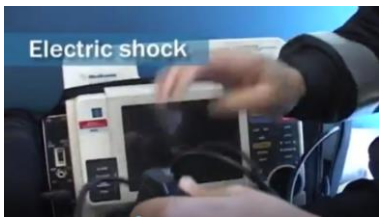

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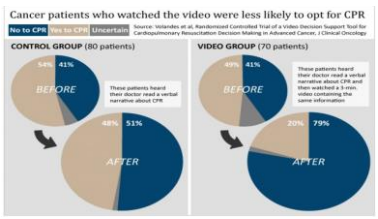


297

Do they work?

298

Yes

299

Robust evidence shows PDAs are highly **effective**

300

>130 RCTs

301

30,000 patients

50 conditions

302

THE COCHRANE COLLABORATION®

303

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,[a] Jesse A. Columbo, MD, MS,[a,b,c,d,e]

304

6 big benefits

305

Improved knowledge

306

More accurate expectations

more accurate perception of risks

307

More value congruent choice

308

Higher patient satisfaction

309

Less decisional conflict

310

Less patient anxiety

311

Great evidence

312

What's the problem?

313

314

Australia
Canada
Denmark
Germany
Netherlands
Norway
Taiwan
UK
USA

315

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

316

BUT

317

"**not** incorporated in mainstream care"

318

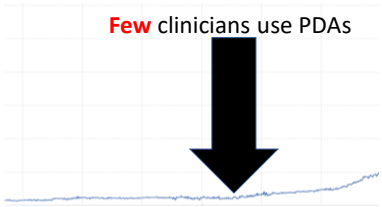
319

320

321

322

323



324

BUT

325

326

PDA Uptake

327

How **law** is pushing change

328

"**comprehensive** strategy . . . to promote wider uptake of SDM"

Coulter - *World Psych* 16:2 - June 2017

329

330

4 Legal **tools** to promote PDA use

331

Liability tools

332

Mandate tools

333

Payment tools

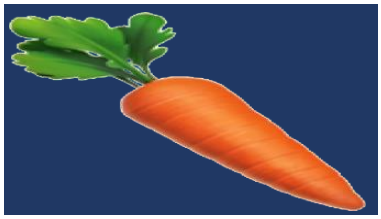
334

Certification

335

Liability Tools

336



337

Liability **protection** for using PDA

338

339

340

Safe harbor legal immunity for using PDA

341

342

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

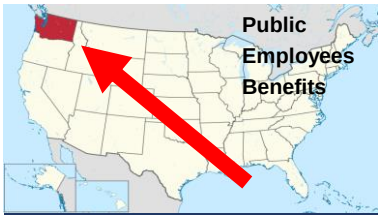
343

Mandate Tools

344

Not just incentive - a **requirement**

345



346

SENATE, No. 3375

STATE OF NEW JERSEY

218th LEGISLATURE

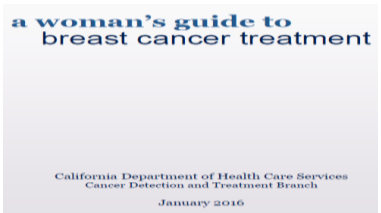
347

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

348

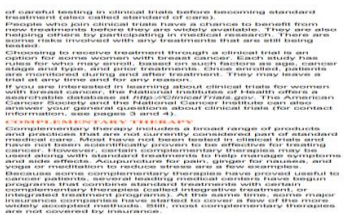
"Mandated standardized written information"

349


a woman's guide to breast cancer treatment

California Department of Health Care Services
Cancer Detection and Treatment Branch
January 2016

350


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 risks and 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 type, and how far the cancer has spread. People in trials 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 website for finding trials. 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. Many of these therapies, such as herbal remedies, 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 for fatigue are a few examples of these therapies.
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 integrative medicine). Some health plans and major insurance companies have started to cover a few of the more widely accepted methods. Still, most complementary therapies are not covered by insurance.

351

Replace MSWI with PDAs

352

VERMONT
GREEN MOUNTAIN CARE BOARD

353

rules & standards to regulate Accountable Care Organizations (ACOs)

354

"**must use decision support tools** … that enable Enrollees to assess the merits of various treatment options and their relative risks and benefits in the context of their own values and convictions"

355

Liability tools

Mandate tools

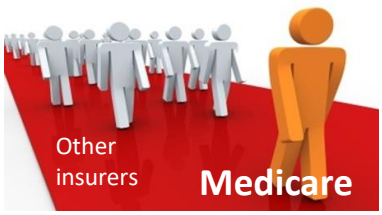
356

Payment Tools

357

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

358



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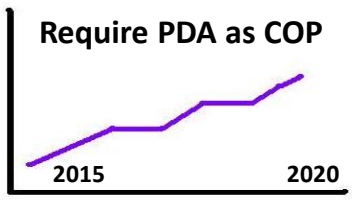


360

No PDA

361

5 examples

362

2015

363

1st time

Medicare required SDM

364

Screening for Lung Cancer with Low Dose Computed Tomography

365

366

367

Before

CT scan

368

"**must receive**

. . . SDM visit"

369

"include . . .
one or more
decision aids"

370

Coding
& billing

371

G0296 SDM
G0297 CT scan

372

Why
require PDA?

373

Doubt

374

Accurate
Unbiased
Balanced from the clinician

375

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

376

Your discussion
with patient is
not good enough

377

Patient must
also get informed
with PDA

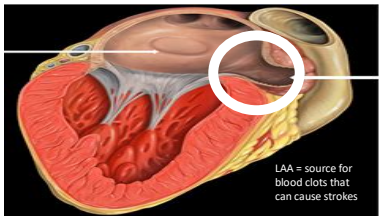
378

2016

379

Percutaneous Left Atrial Appendage Closure Therapy

380



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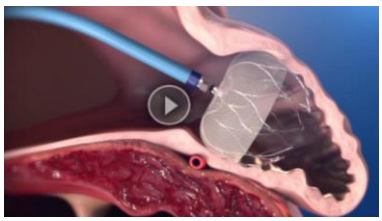


385

Before implantation

386

"formal **SDM** interaction"

387

evidence-based

decision tool”

388

2018

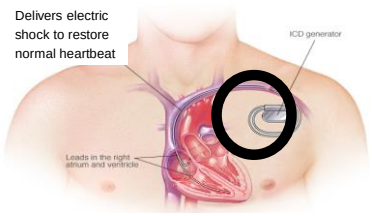
389

Implantable

Cardioverter

Defibrillator

390



391

Before

implantation

392

“formal SDM encounter

must occur”

393

“evidence-based

decision tool”

394

2019

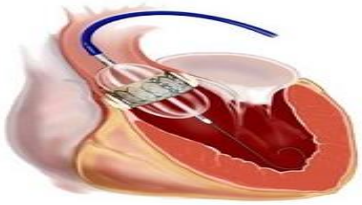
395

Transcatheter

Aortic Valve

Replacement

396



397

June 2019

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

398

"CMS recognizes the **importance** of SDM."

399

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

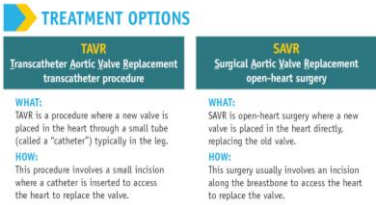
400

BUT

401

"**not** a fully developed tool **available**."

402



403

2019

404

405

Federal → State

406

407

408

SENATE, No. 1891

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED FEBRUARY 15, 2018

409

Medicaid cover advance care planning

410

"ACP shall consist . . . **decision aids**"

411

Recap

412

Link PDA use to
Liability
Mandates
Payment

413

414

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

415

416

PDAs widely **varying** quality

417

LDCT

418

NIH NATIONAL CANCER INSTITUTE
UNIVERSITY OF MICHIGAN
CDC CENTERS FOR DISEASE CONTROL AND PREVENTION
Memorial Sloan Kettering Cancer Center

419

"gratuitously inaccurate"

420

"miserable failure"

421

"not ready for prime time"

422

Ought not attach legal consequences

423

Assure PDA **quality**

424

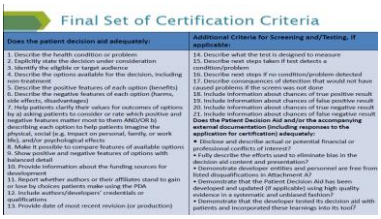
Certification

425

Accurate
Up to date
No bias + No COI
Understandable

426

427



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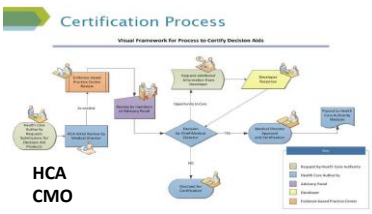


429

In use

430

431

Spine & joint replacement
7

432

Cardiac care

3

433

End of life

24

434

BUT

435

No **national** certification

436

Not yet

437

Conclusion

438

Certify PDAs

↓

More legal tools

439

More legal tools

↓

More PDA use

440

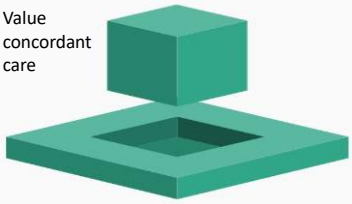
More PDA use

↓

Better quality

441

Value concordant care



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References

444

Materials from this presentation are available

http://thaddeuspope.com

445

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).

446

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

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

447

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

Thaddeus Pope, *From Informed Consent to Shared Decision Making: Improving Patient Safety and Reducing Medical Liability Risk with Patient Decision Aids* (under submission).

448

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).

449

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).

450

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).

451

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. 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).

452

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