



1

Decline & Fall of Informed Consent

Long Live Shared Decision Making with Certified Patient Decision Aids

2

Thaddeus Pope

3

I have **no** relevant financial relationships with any ineligible companies.

I will **not** discuss off label use or investigational use.

4



5



6



7



8

cannot trust PI with medical research
 → **external regulation**

9



10



11

research
 → treatment

12

moving to **same**
approach for
treatment

13

informed
consent

14

1972

15



16

but

17



18

roadmap

19



20

3 parts

21

design
flaws IC

22

failures
of IC

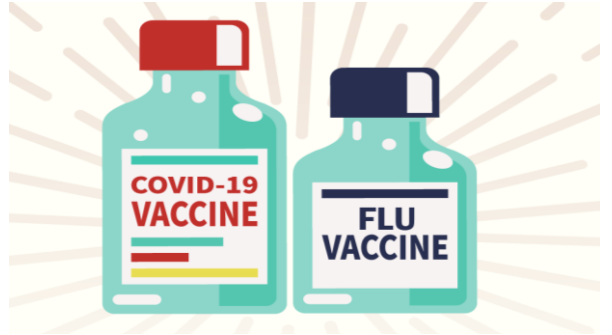
23

new
paradigm

24

design flaws

25



26

I certify that I am not the patient and at least 18 years of age. (b) the legal guardian of the patient, or if a person authorized to consent on behalf of the patient who is not otherwise competent or unable to consent for themselves. Further, I hereby give my consent to Walgreens or Duane Reade and the licensed healthcare professional administering the vaccine, as applicable (such as applicable Provider), to administer the vaccine(s) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccines. I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the EUA fact sheet on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised that the patient should return near the vaccination location for observation for approximately 15 minutes after administration. On behalf of the patient, the patient here and personal representatives, I hereby release and hold harmless each applicable Provider, its staff, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above. I acknowledge that: (a) I understand the purposes/benefits of the above vaccination request(s) (State Registry) and my state health information exchange (State HIE); and (b) the applicable Provider may disclose my vaccination history to the State HIE, to the State HIE, or through the State HIE to the State Registry, or any state or federal governmental agencies or activities (Government Agencies), such as state, county, or local Departments of Health or the Registry under State HIE for purposes of care coordination. I acknowledge that, depending upon my state law, I may permit, by using a state approved opt-out form or, as permitted by my state law, an opt-out form (Opt-Out Form) furnished by the applicable Provider (b) the disclosure of my vaccination information by the applicable Provider to the State HIE and/or State Registry or to the State HIE and/or State Registry from having my vaccination information with any of my other health care information required by state law, to be grouped into a common pool. The applicable Provider will, if my state permits, provide me with an Opt-Out Form. I understand that, depending on my state law, I may need to specifically consent, and in the event of a breach disclosed to the State Registry and/or State HIE, the applicable Provider may, if my state permits, provide me with an Opt-Out Form. I understand that my consent will serve in effect with whatever my permission to that I may withdraw my consent to information to or through the State HIE or to Government Agencies as required or permitted by law. I further authorize the applicable Provider to (a) release my medical or other information, including any communicable disease (including HIV), and requested health information to, through, the State HIE or Government Agencies to my healthcare professionals, Walgreens, Meditech, or other third party where necessary to facilitate care or prevent, (b) assist in claim or to file or to the above sharing amounts, except for those information that I have, by the requested form and services, as well as for any vaccine forms and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or that the applicable Provider incurs no other fee of service, upon receipt of such invoice. Walgreens or its affiliate may contact you, including by text and/or automated phone calls and texts, at any time using the contact information provided to me and regarding health and safety matters, such as vaccine reminders.

Patient Signature: *[Signature]* Date: *02/19, 2023*

*Healthcare providers can be an individual pharmacist or a registered nurse, licensed practical nurse, licensed vocational nurse, nurse practitioner, physician or physician assistant.

27

disclosure not understanding

28



29

3 analogies

30



31



32



33



34



35

MIRANDA WARNING

. YOU HAVE THE RIGHT TO REMAIN SILENT.
. ANYTHING YOU SAY CAN AND WILL BE USED AGAINST YOU IN
A COURT OF LAW.
YOU HAVE THE RIGHT TO TALK TO A LAWYER AND HAVE HIM PRESENT
WITH YOU WHILE YOU ARE BEING QUESTIONED.

36

“do you
understand each
of these rights?”

37

disclosure
not
understanding

38

3

39



40

disclosure
not
understanding

41

worse

42



43

less Pt centered

44

disclose even less

45

not what reasonable patient would want/need

46

what clinicians decide to disclose

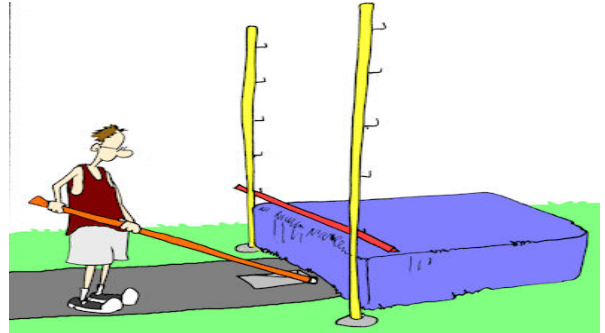
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48



49



50

some states
extra low

51

failures
informed consent

52

only duty
disclose RBA

53

2 failures

54

does **not**
happen

55

when happens
done **badly**

56

few
examples

57

1

58

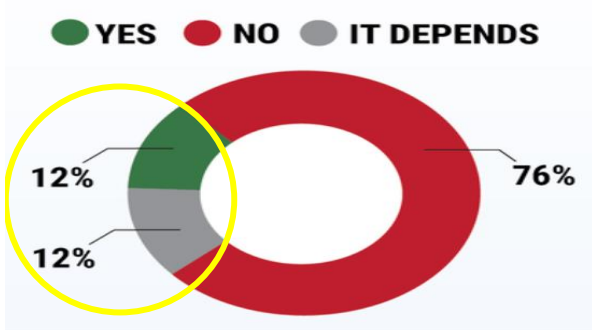
Medscape®

2020 survey
1400 physicians

59

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

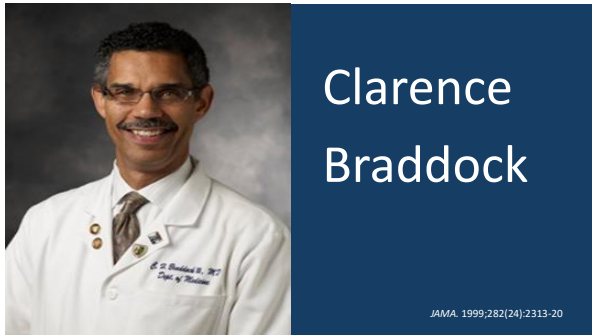
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61



62



63



64

how **frequent** was discussion of risks & benefits?

65



66

inadequate disclosure **91%**

67

3

68



Michael Rothberg

69



PCI for clogged coronary arteries

70

how **frequent** was discussion of risks & benefits?

71

3%

72

4

73



Alison Brenner

JAMA Intern Med. 2018; 178(10):1311-1316

74



LDCT for lung Ca screening

75

how **frequent** was discussion of risks & benefits?

76

0%

77



78

process
measure

79

worse

80

outcome
measure

81

even if disclosed,
did patient
understand?

82



NO!

83

most are
seriously
misinformed

84

few
examples

85

1

86

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

87



88

“potential risk
of harm . . .
included”

89

“**nerve injury**
. . . disclosed”

90

but

91

“not clearly
understood”

92

“not understand . .
. manifest as pain
or weakness
in an extremity”

93

2

94

The NEW ENGLAND JOURNAL of MEDICINE

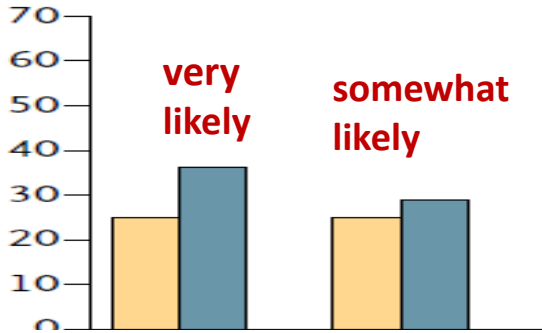
Patients' Expectations about Effects
of Chemotherapy for Advanced Cancer

chemotherapy for **incurable**
cancers – palliative only

95

no chance
chemotherapy
will cure them

96



97



98

JOURNAL OF CARDIOVASCULAR NURSING
The Official Journal of The Preventive Cardiovascular Nurses Association

IN THIS ISSUE

- Perceived Clinical Practice Discretion Status in Patients With Heart Failure
- Secondary Effects of the Health Implementation Intervention on Child Abuse and Neglect
- The Association Between Patient Outcomes and the Social Emergency Center's Readiness
- Community-Based Interventions for Patients With Uncontrolled Atrial Fibrillation
- Assessment of Knowledge and Personality Factors Among Patients Living With Coronary Artery Disease
- The Effect of an Evidence-Based Risk and Care Model on Social Support and Depression in Postoperative Coronary Artery Disease
- The Effect of an Evidence-Based Risk and Care Model on Social Support and Depression in Postoperative Coronary Artery Disease

PCNA

78% with ICD thought would forestall further deterioration

99

similar findings **across** clinical settings

100



disturbing

101



102

RBA **not** disclosed

103



104

new
paradigm

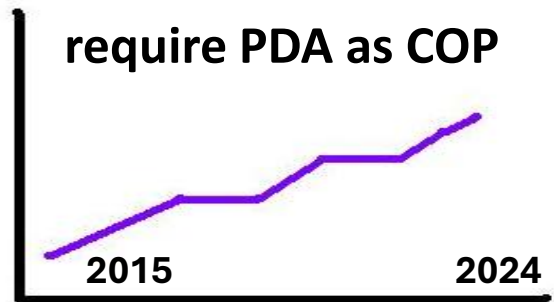
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mandated
SDM w/ PDA

106



107



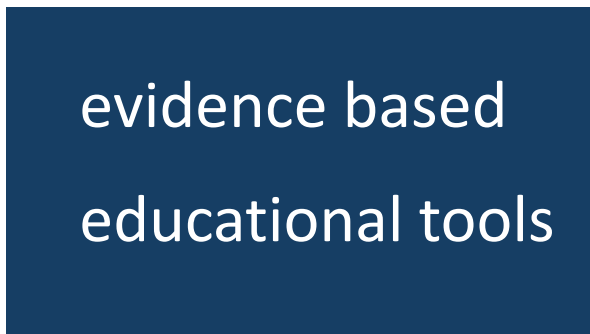
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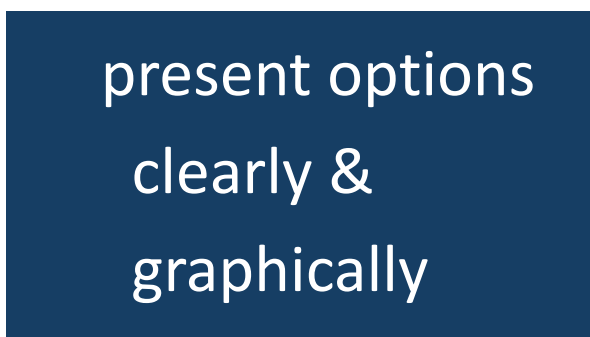
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111



112



113



114

SO ...

115

Screening for Lung
Cancer with Low
Dose Computed
Tomography

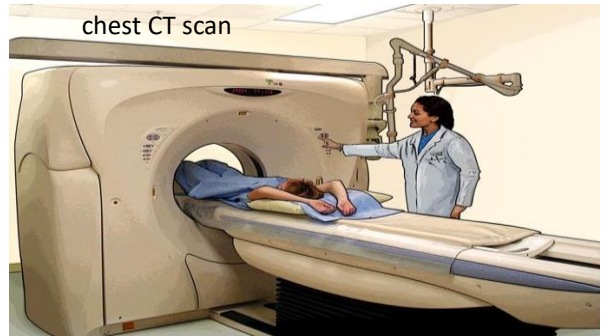
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30 pack year smoking history



117

chest CT scan



118

before
CT scan

119

“**must receive**
... SDM visit”

120

“include ...
one or more
decision aids”

121

why
require PDA?

122

doubt

123

accurate
unbiased
balanced

from the
clinician

124



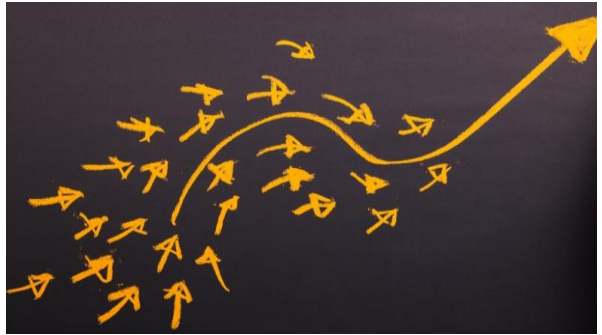
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your discussion
with patient is
not good enough

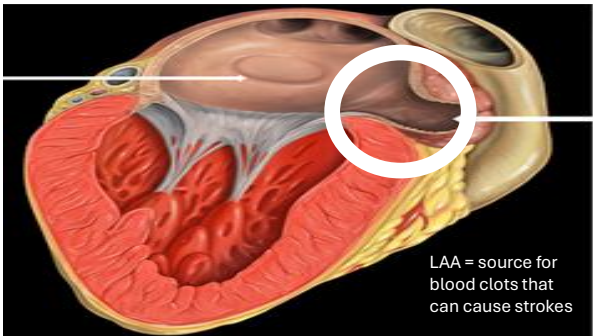
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patient must **also** get informed with PDA

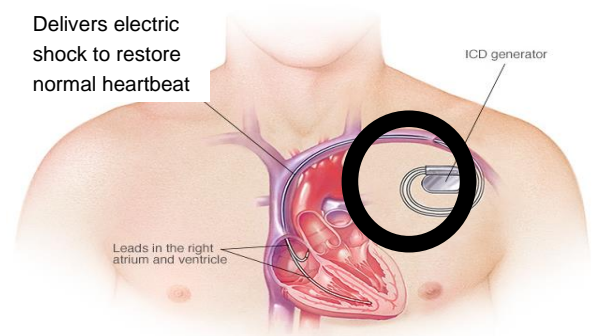
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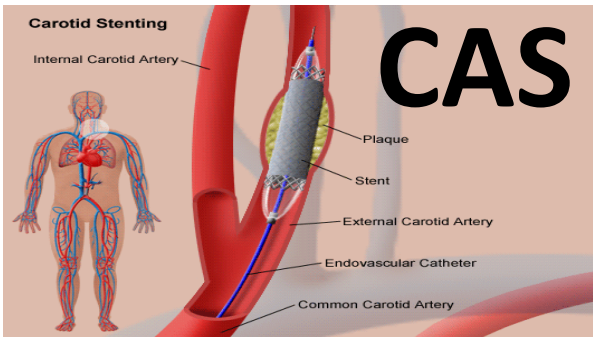
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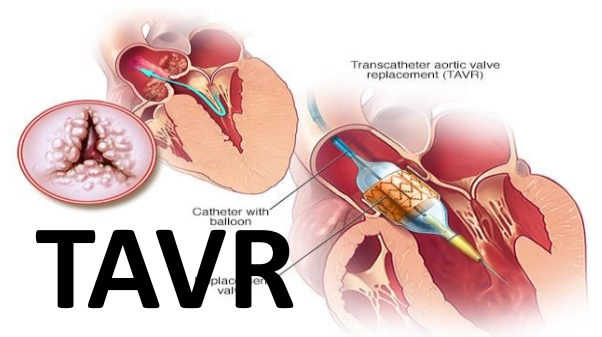
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130



131



132

“formal **SDM**
interaction”

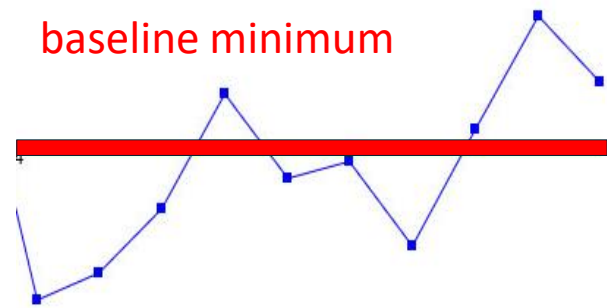
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“evidence-based
decision tool”

134



135



136

old

137



138

new

139



140



141

FDA Strengthens Safety Requirements and Updates Study Results for Breast Implants

Agency adds restrictions and approves new labeling for all approved breast implants



142

SENATE, No. 3375

STATE OF NEW JERSEY

218th LEGISLATURE

143

conclusion

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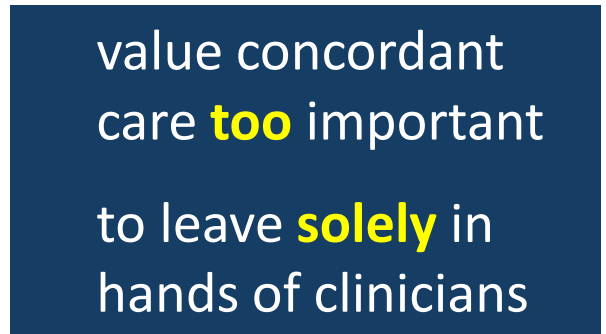
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147



148



149



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