Resolving Medical Futility Disputes

Thaddeus Mason Pope, J.D., Ph.D.

Fletcher Allen Health Care

May 10, 2013

1

2

"I'm afraid there's really very little I can do."

Non-beneficial

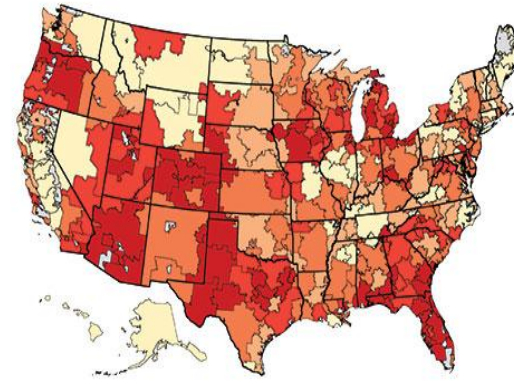
4

- 73yo male
- PVS
- COPD
- End-stage renal disease
- Hypertensive cardiovascular disease
- Stage 4 decubitus ulcers
- Osteo-myeletitus
- Diabetes
- Parchment-like skin

- "The only organ that's functioning really is his heart."
- "It all seems to be ineffective. It's not getting us anywhere."
- "We're allowing the man to lay in bed and really deteriorate."

Surrogate driven over-treatment

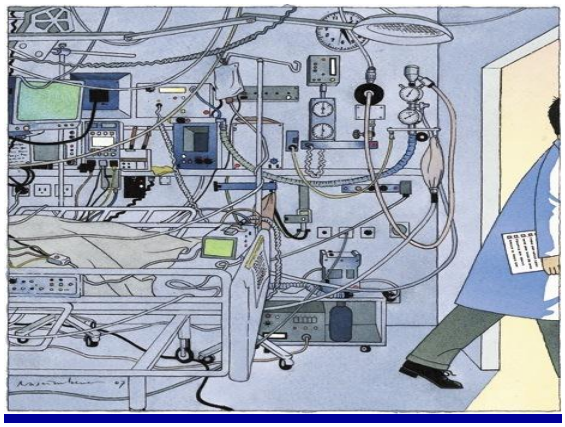
7



Clinician	Surrogate
CMO	LSMT

2 features

10



1. Causes
2. Prevention
3. Consensus

4. Intractable
5. ATS policy

Causes

16

Question and Responses[a]	Public, % (n=1006)	Professionals, % (n=774)
If doctors believe there is no hope of recovery, which would you prefer?		
Life-sustaining treatments should be stopped and should focus on comfort	72.8	92.6
All efforts should continue indefinitely	20.6	2.5

1. **Surrogate demand**
2. **Provider resist**

18

Surrogate demand

19

Cognitive

20

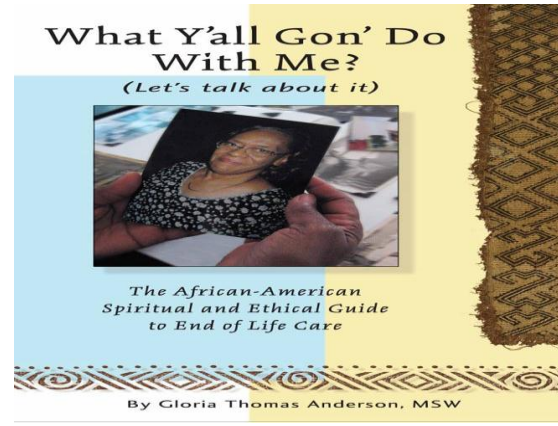
Iatrogenic

- Inadequate communication
- Uncoordinated, conflicting
- Undue pressure

22

Mistrust

23

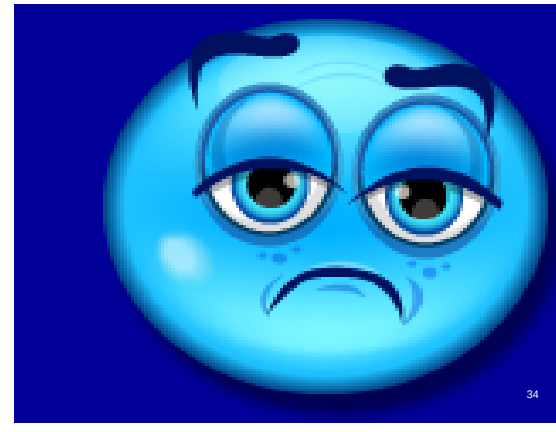


Emotional Barriers

28

Psychological Barriers

32



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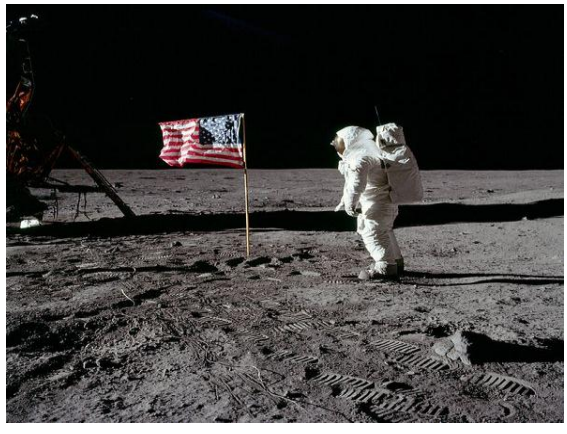
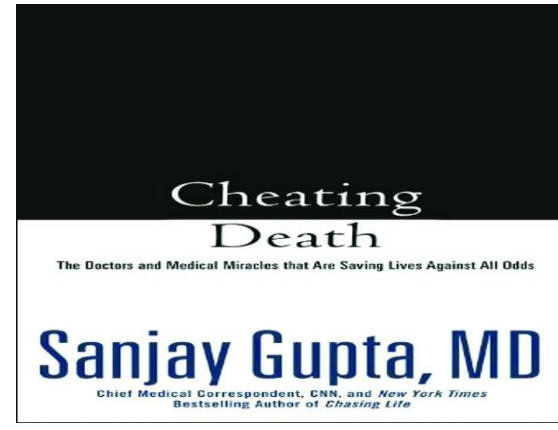
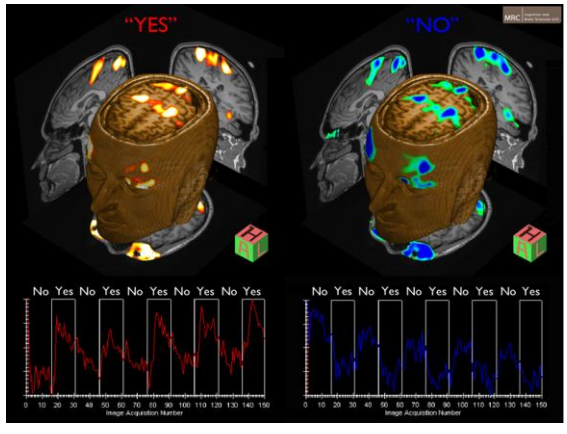



Never give in, never give in,
never, never, never, never, . . .


Cheating
Death
The Doctors and Medical Miracles that Are Saving Lives Against All Odds
Sanjay Gupta, MD
Chief Medical Correspondent, CNN, and New York Times
Bestselling Author of Chasing Life


"YES"
"NO"
No Yes No Yes No Yes No Yes No Yes
No Yes No Yes No Yes No Yes No Yes


Ceci n'est pas une pipe.


autonomy

Religion

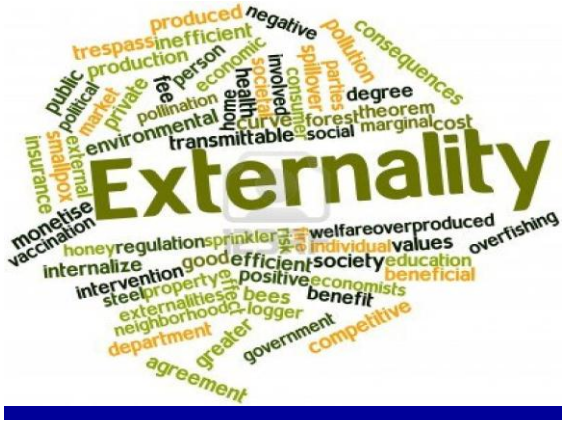
43

Question and Responses[a]	Public, % (n=1006)	Professionals, % (n=774)
If the doctors treating your family member said futility had been reached, would you believe that divine intervention by God could save your family member?		
Yes	57.4	19.5
No	35.5	61.1

"**religious grounds** were more likely to request continued life support in the face of a very poor prognosis"

Zier et al., 2009 *Chest* 136(1):110-117

46

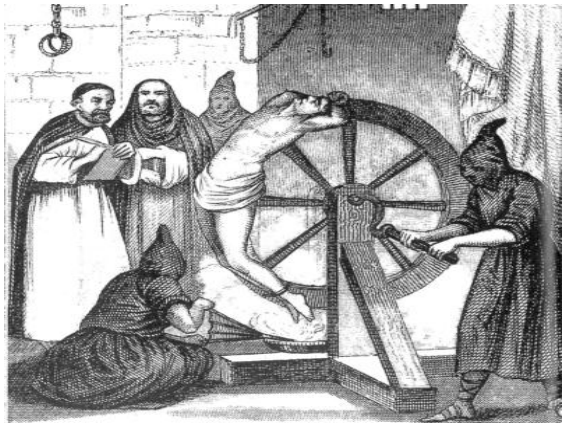


Clinicians resist

49

Avoid patient suffering

50



"This is the Massachusetts General Hospital, not Auschwitz."

"I do not see much difference between what we are doing . . . and . . . **atrocities** . . . in **Bosnia**."

53

Moral distress

54

Absenteeism

Retention

Quality

56

Integrity of profession

57

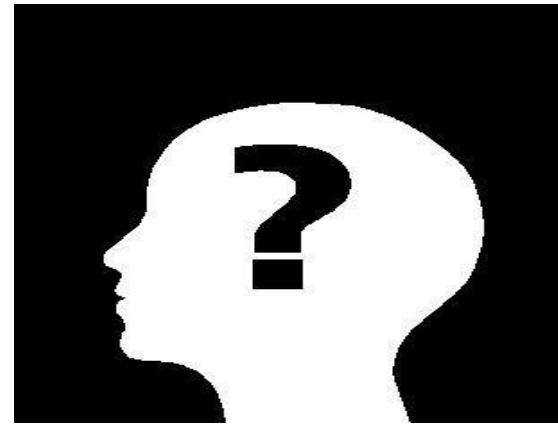
Stewardship

59

Limited ICU beds
ER boarding
Antibiotic resistance

Distrust surrogate

61



66% accurate

50% = pure chance

63

Prevention

64

71%: "More important to enhance the **quality** of life for seriously ill patients, even if it means a **shorter life.**"

National Journal (Mar. 2011)

66

Question and Responses[a]	Public, % (n=1006)	Professionals, % (n=774)
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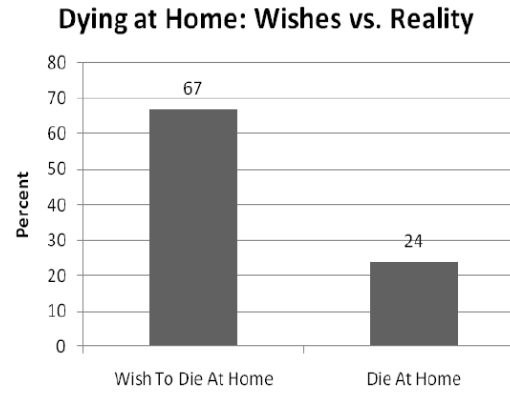
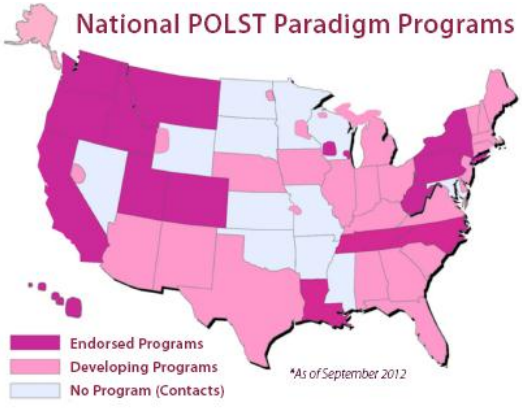




113TH CONGRESS
1ST SESSION

H. R. 1173

To amend the Social Security Act to provide for coverage of voluntary advance care planning consultation under Medicare and Medicaid, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 14, 2013

Mr. BLUMENAUER (for himself, Mr. HANNA, Mr. ROE of Tennessee, Mr. REED, Ms. SCHWARTZ, Mr. KIND, Mr. GEORGE MILLER of California, Mr. MCDERMOTT, Mr. BERA of California, Ms. SCHAKOWSKY, and Mrs. CAPPS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Social Security Act to provide for coverage of voluntary advance care planning consultation under Medicare and Medicaid, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

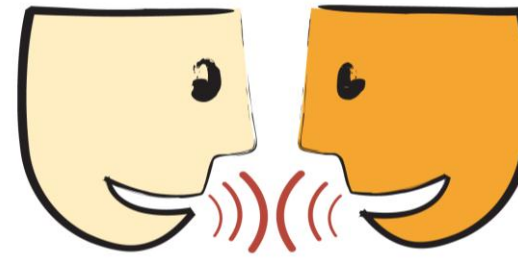
SECTION 1. SHORT TITLE; FINDINGS; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Personalize Your Care Act of 2013".

Assent

Consent

73



EOL disclosures (NY, CA, MI, VT)

ASCO® American Society of Clinical Oncology

Making a world of difference in cancer care

Limited effectiveness

Side effects

Options

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Choosing Wisely®

An initiative of the ABIM Foundation

IPDAS

International Patient Decision Aid Standards Collaboration

Informal Resolution

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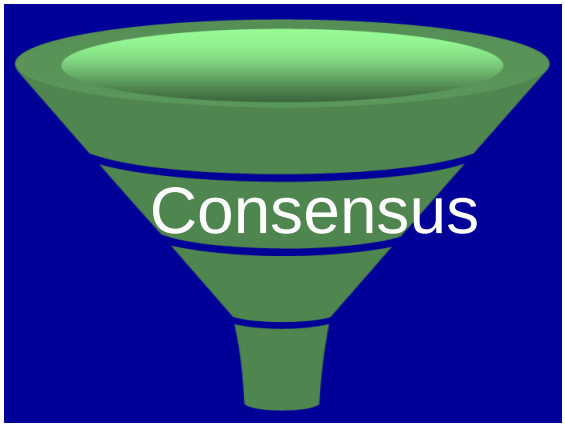


Consensus

Intractable

81

Prendergast (1998)

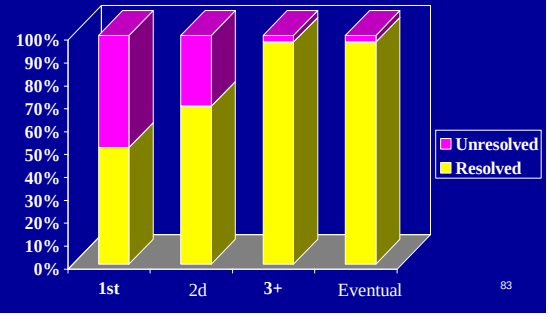
57% agree immediately

90% agree within 5 days

96% agree after more meetings

82

Garros et al. (2003)



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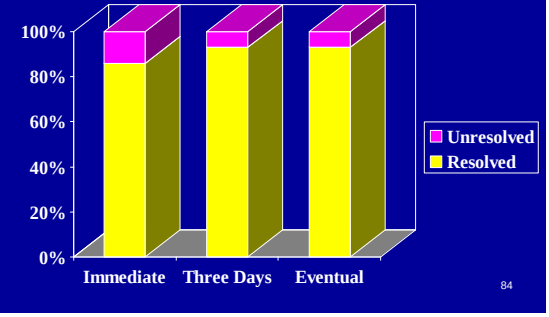
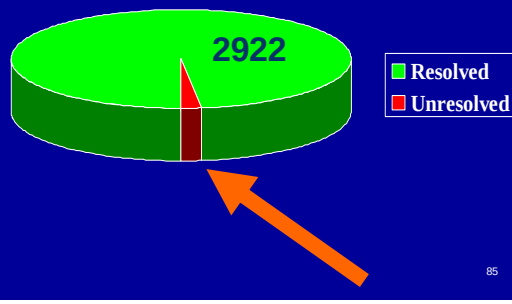
Fine & Mayo (2003)



84

Hooser (2006)



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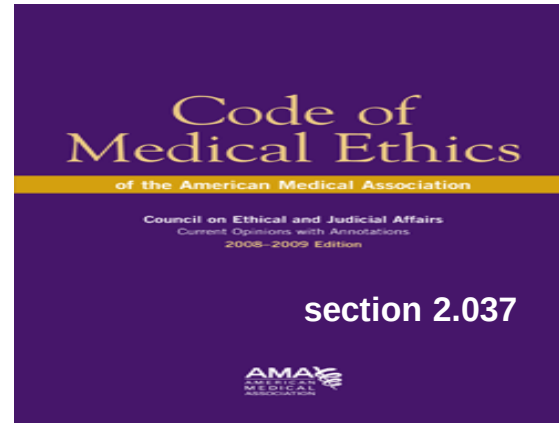

1. Earnest attempts . . .
   deliberate . . .
   negotiate . .
2. **Joint** decision-making
   . . . maximum extent . .

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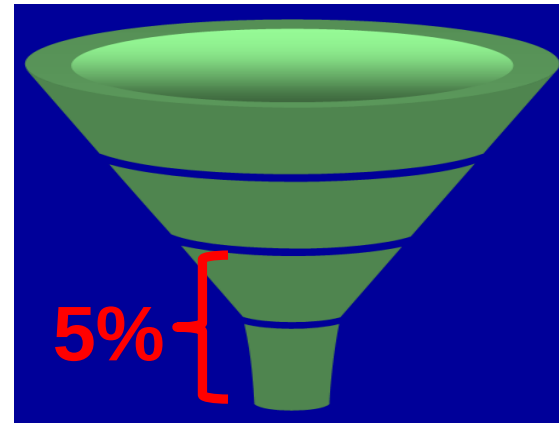
3. Attempts . . .
   negotiate . . .
   reach resolution . . .
4. Involvement . . .
   ethics committee . . .

88

95%

89



Transfer

91

Rare, but possible

92

Intractable Conflict

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1. Covert
2. Cave-in
3. New surrogate
4. Unilateral stop

Covert

95

Asch, Am J Resp Crit Care Med (1995)

PROPORTION OF PHYSICIANS (n = 726) WHO WITHHELD LIFE-SUSTAINING TREATMENT ON THE BASIS OF MEDICAL FUTILITY

Consent Status	n (%)
Without the written or oral consent of the patient or family	219 (25%)
Without the knowledge of the patient or family	120 (14%)
Despite the objections of the patient or family	28 (3%)

Cave-in

99

Perceptions of "futile care" among caregivers in intensive care units

Robert Sibbald MSc, James Downar MD, Laura Hawryluck MD MSc

CMAJ 2007;177(10):1201-8

"Why they follow the . . . SDMs instead of doing what they feel is appropriate, almost all cited a **lack of legal support.**"

100

"Remove the ___, and I will **sue you**."

101

Legal Risk

104

"It is **not** settled law that, in the event of disagreement . . . **the physician** has the final say."

Golubchuk v. Salvation Army Grace Gen. Hosp., 2008 MBQB 49 (Feb. 13, 2008).

Civil liability

- Battery
- Medical malpractice
- Informed consent
- State HCDA
- EMTALA

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Licensure discipline

Criminal liability

e.g. homicide

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Providers have **won almost every single** damages case for unilateral w/h, w/d

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Providers typically lose only **IIED** claims

- Secretive
- Insensitive
- Outrageous

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Risk > 0

110

Liability averse

Litigation averse

111

Process

=

punishment

112

Even prevailing parties pay **transaction costs**

- Time
- Emotional energy
- Reputation

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Easier to cave-in

- Patient will die soon
- Provider will round off
- Nurses bear brunt

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Defensive Medicine

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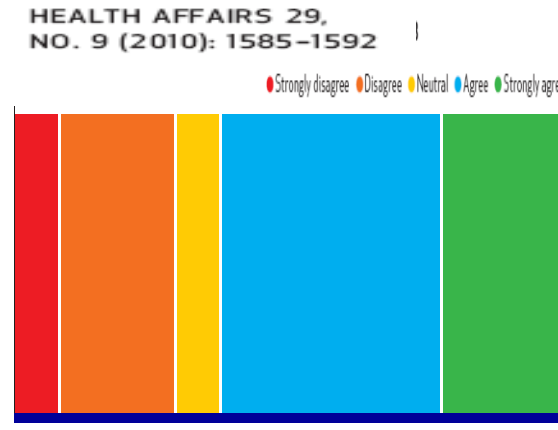

J Am Geriatr Soc 58:533–538, 2010.

Factor	Extremely or Very Important	Most Important of All Factors Listed
Patient's prognosis	98.5	12.0
What was best for the patient overall	98.1	33.2
Respecting the patient as a person	96.6	5.4
Patient's pain and suffering	94.6	12.5
What the patient would have wanted you to do	81.8	29.4
Providing the standard of care	81.5	2.2
Respecting the wishes of the family or surrogate(s)	80.9	3.3
Following the law	68.6	1.1
The burden on the family	44.8	0
Religious beliefs of the patient	35.3	0
Religious beliefs of the family or surrogate(s)	28.6	0
Cost to society of caring for the patient	14.2	0
Physician's religious beliefs	10.7	0
Concerns about paying for medical care	9.3	0
Concern that the surrogate(s) might sue	8.4	1.1

Get a new Surrogate

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Substituted judgment

Best interests

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18 Vt. Stat. § 9711(d)

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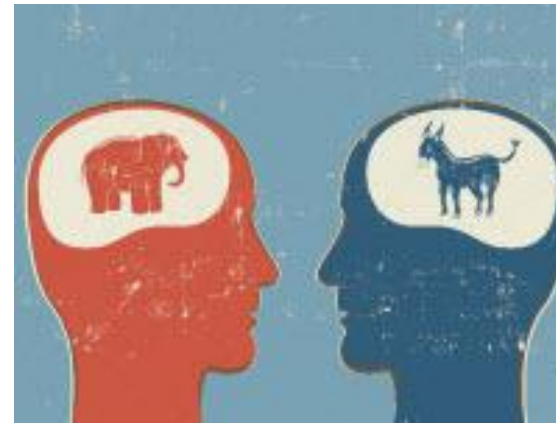

~ 60%

accuracy

More aggressive treatment

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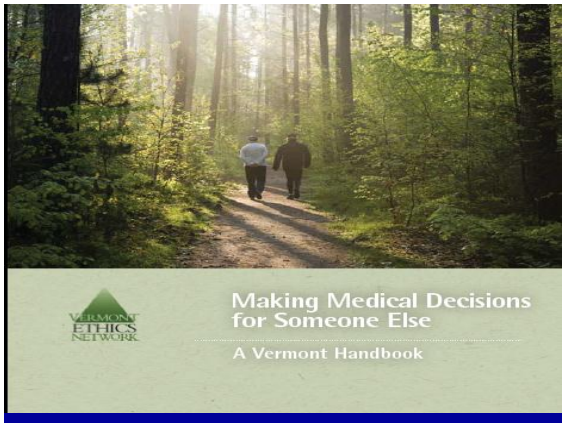
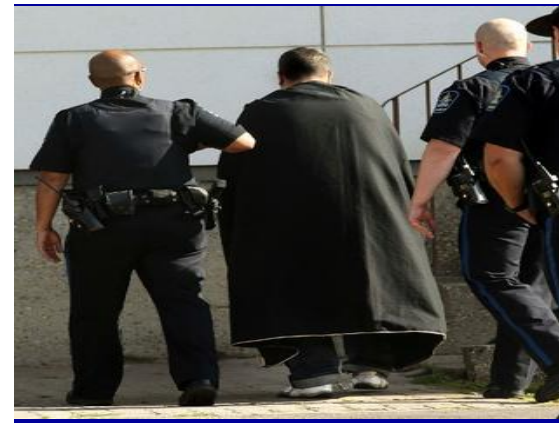
Improve Surrogate Accuracy



18 Vt. Stat. §§
9707(b)(1)
9711(d)(4)

129



Surrogate	Advance directive
GO	STOP

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Surrogate	Best interests
GO	STOP

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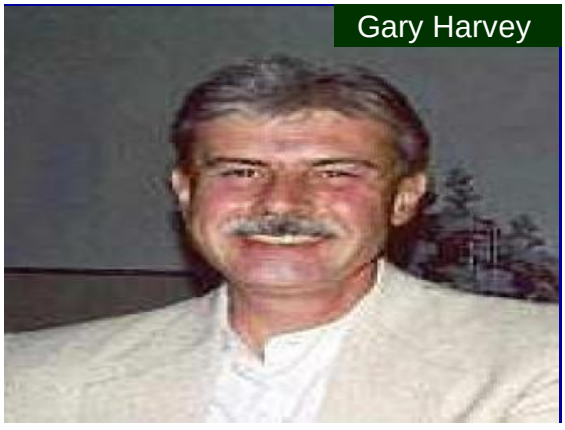

"failed to follow medical advice"

"failed to use good judgment"

Your own personal issues are "impacting your decisions"

"Refocus your assessment"

AMA Code Ethics 2.20

Though the surrogate's decision . . . should **almost always** be accepted . . . situations . . . may require . . . institutional or judicial review . . .

18 Vt. Stat. § 9714(a)

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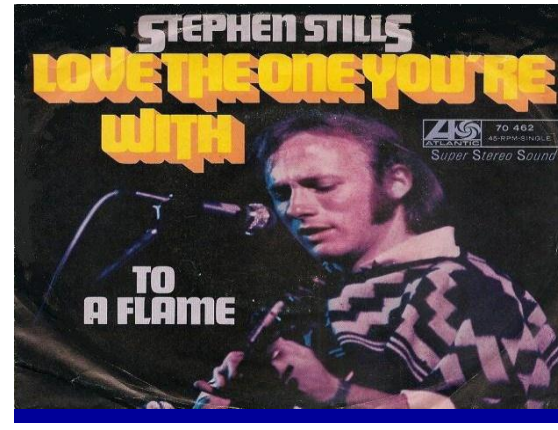
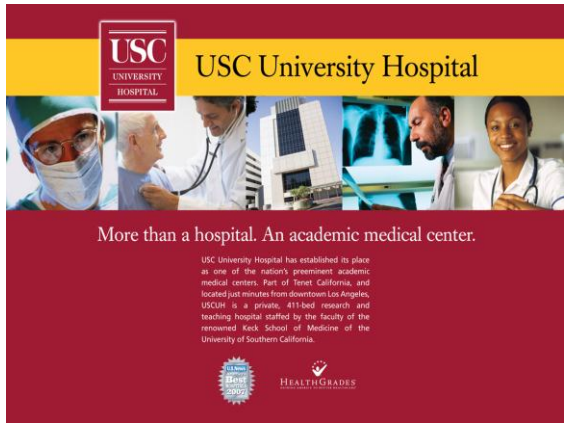




Plascentia McDonald, 74yo

Advance directive:

1. Bobby is agent
2. Cynthia is alternate
3. "Do No prolong life if incurable condition"

Aug. 14

Surgery
- thoracoabdominal aneurysm

Post-op infections

Aug. 30

Sepsis, non-cognitive

Continued LSMT

3 additional surgeries

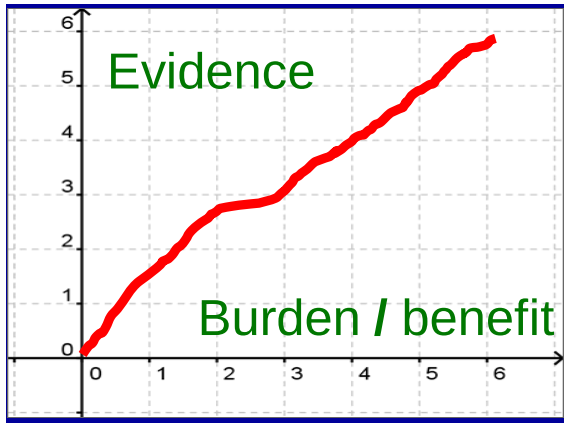
Disagrees w/ brother

USC: Probate Code 4740 immunizes providers who "in good faith comply with a health care decision made by one whom they believe authorized."

Court: "Compliance with agent's decision . . . **at odds** with the patient's own . . . AHCD . . . **not** qualify as in good faith."

Agent **not** authorized to depart from AD

USC should have known that



BUT

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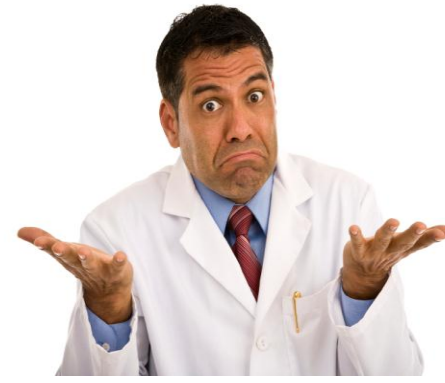
1

Providers cannot show deviation



2

Surrogates get benefit of doubt

3

Surrogates are faithful

Consent and Capacity Board

Ontario

163

Table 3. Preferences for Goals of Care and Limited Resources

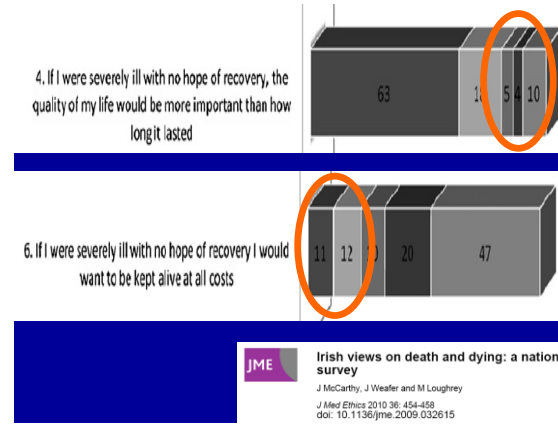
Question and Responses[a]	Public, % (n=1006)	Professionals, % (n=774)
If doctors believe there is no hope of recovery, which would you prefer?		
Life-sustaining treatments should be stopped and should focus on comfort	72.8	92.6
All efforts should continue indefinitely	20.6	2.5

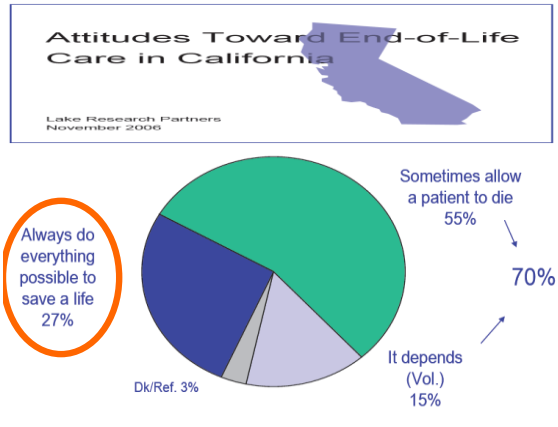
20%: "More important to prolong life."

National Journal (Mar. 2011)
Archives Surgery (Aug. 2008)

TREND: DO EVERYTHING TO SAVE LIFE, OR SOMETIMES LET PATIENT DIE?

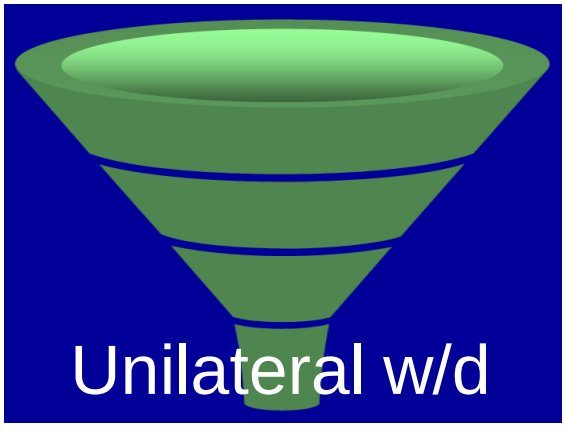
	May 1990			November 2005		
	Do everything to save life	Sometimes let a patient die	It depends / DK / Ref	Do everything to save life	Sometimes let a patient die	DK / Ref
	%	%	%	%	%	%
	15	73	12=100	22	70	8=100





Stop without consent

171



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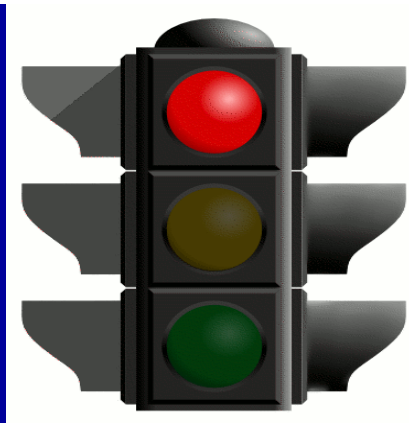

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"If surrogate directs [LST] . . . provider that does not wish to provide . . . **shall nonetheless comply** . . . ."

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Discrimination in Denial of Life Preserving Treatment Act

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"Health care . . . **may not be** . . . **denied** if . . . directed by . . . surrogate"

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H.B. 1403 (2013)

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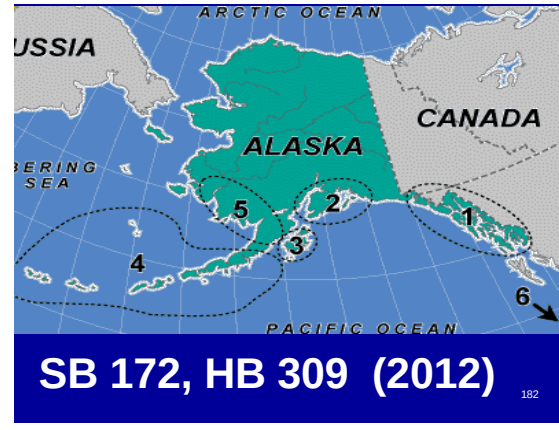
OKLAHOMA


ARCTIC OCEAN
USSIA
CANADA
ALASKA
BERING SEA
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2
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6
PACIFIC OCEAN
SB 172, HB 309 (2012)
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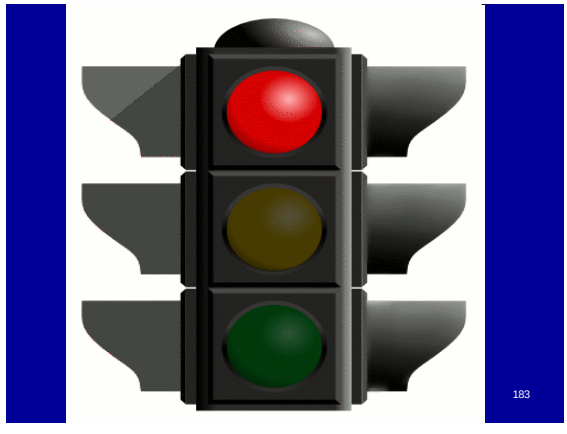
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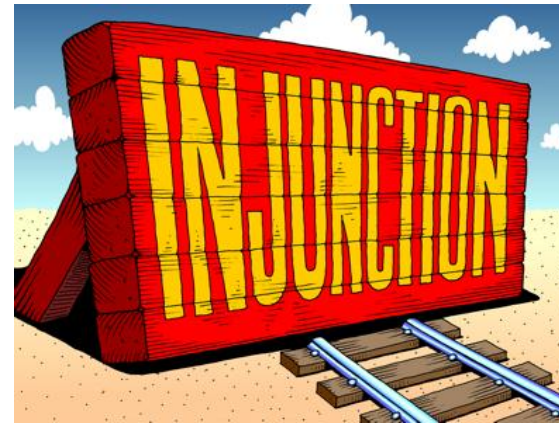
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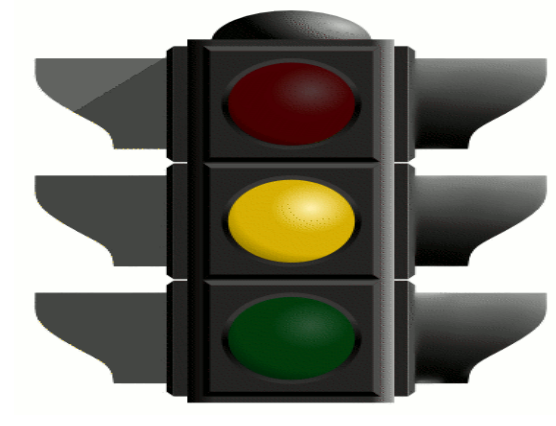
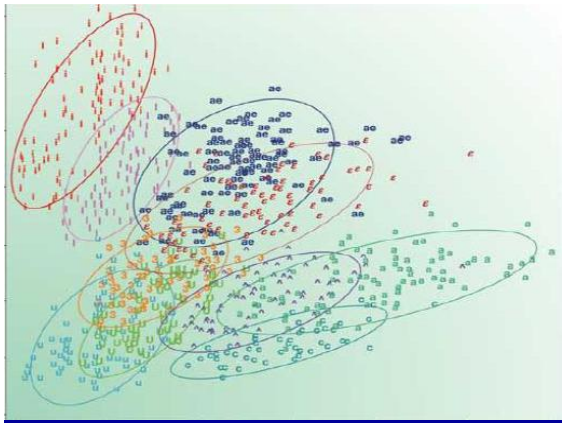


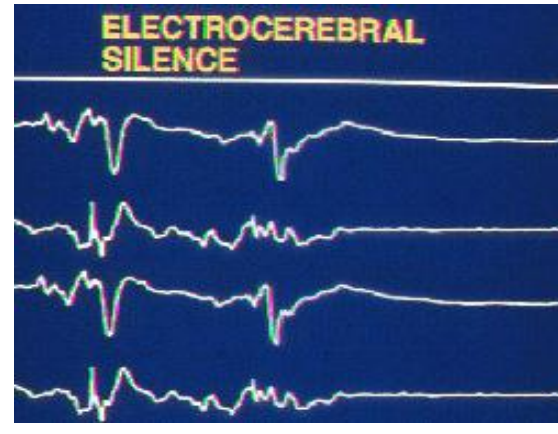
"generally accepted health care standards"

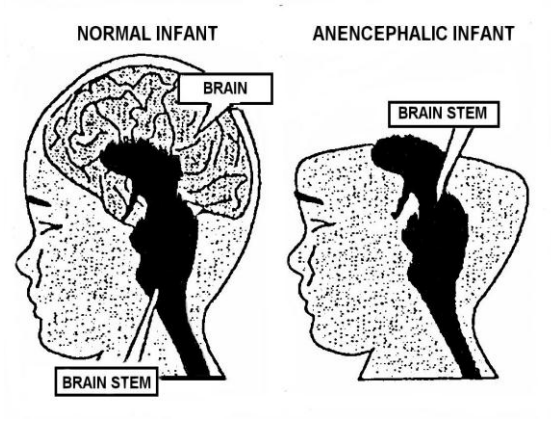


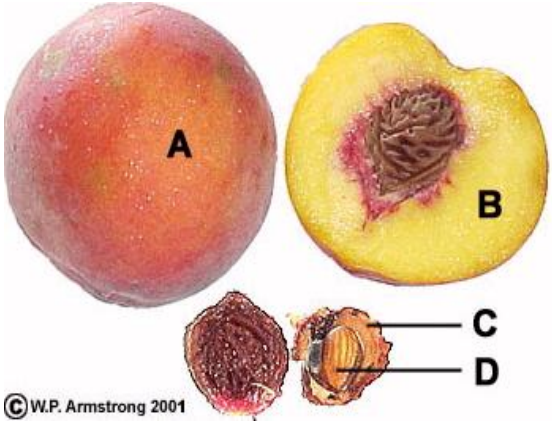
0% → 13%

Lantos, Am J Med 1989

Extrapolate: populations to individuals







"The essence of futility is overwhelming improbability in the face of possibility"

Bernat 2008

Safe Harbor®

Safe harbor attributes

- Clear
- Precise
- Concrete
- Certain

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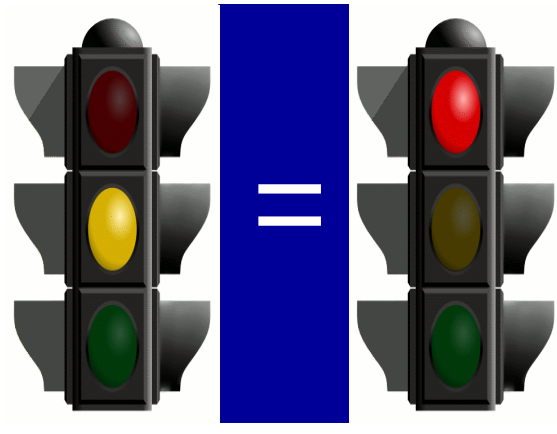


Not just ambiguity

Providers continue to create the "wrong" standard of care

Dan Merenstein
291 *JAMA* 15 (1994)

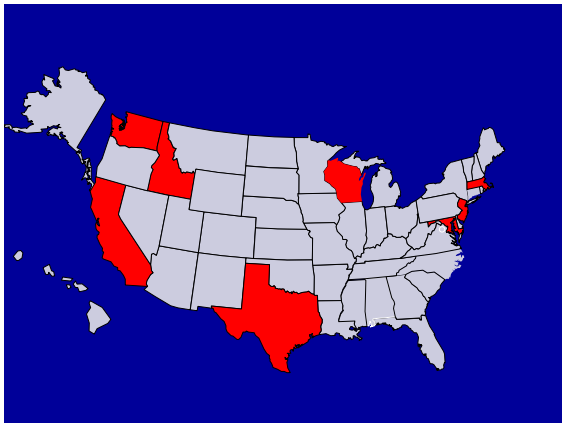
M.D. may stop LSMT

for **any reason**

- with immunity
- if your HEC agrees

Tex. H&S 166.046

1. 48hr notice
2. HEC meeting
3. Written decision
4. 10 days to transfer
5. Unilateral WH/WD



Resolution 505-08 TITLE: LEGAL SUPPORT FOR NONBENEFICIAL TREATMENT DECISIONS

Author: H Hugh Vincent, MD;
William Andereck, MD

Introduced by: District 8 Delegation

Endorsed by: District 8 Delegation

CA

E

Reference Committee

October 4-6, 2008

WASHINGTON STATE MEDICAL ASSOCIATION
HOUSE OF DELEGATES

WA

Resolution: C-5
(A-09)

Subject: Legal Protection for Physicians When Treatment is Considered Futile

Introduced by: King County Medical Society Delegation

Referred to: Reference Committee C

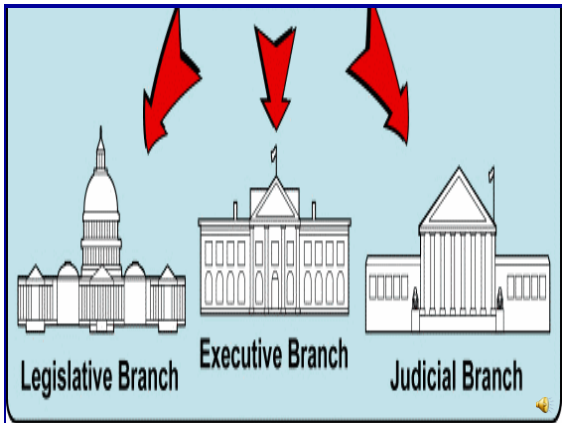
RESOLUTION 1 - 2004
(read about the *action* taken on this resolution)

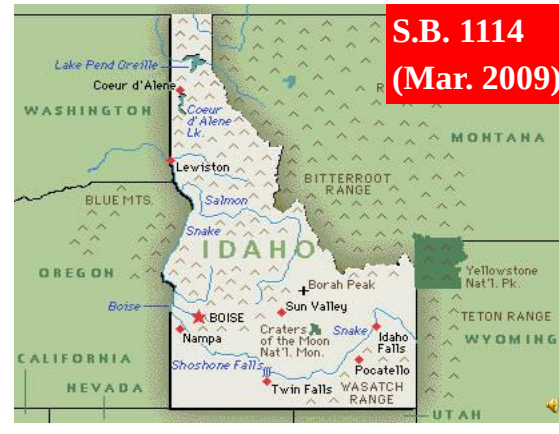
WI

Subject: Futility of Care

Introduced by: Michael Katzoff, MD and the Medical Society of Milwaukee County

RESOLVED, That the Wisconsin Medical Society, concurrent with a recommendation of the American Medical Association, Medical Futility in End-of-Life Care policy E-2.037, supports the passage of state legislation which establishes a legally sanctioned extra-judicial process for resolving disputes regarding futile care, modeled after the Texas Advanced Directives Act of 1999.





No substantive criteria

↓

Pure procedure

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If process is all you have, it must have **integrity and fairness**

1-5 members	48%
5-10 members	34%

Mostly physicians, administrators, nurses

No community member requirement, like IRB

< 10% TX HECs have community member

Notice
Opportunity to present
Opportunity to confront
Assistance of counsel
Independent decision-maker
Statement of decision
Judicial review

Tex. S.B. 303

224

Neutral independent decision maker

Appellate review

225

226

Treat 'til transfer

228

Want to refuse

↓

Try to transfer

No transfer

↓

Must comply

18 Vt. Stat.
§ 9707(b)(3)

231

Miss. Code § 41-107-3

232

L.B. 564 (2013)

41

Mich. S.B. 136 (2013)

42

KENTUCKY

H.B. 279 (2013) (over veto)

40

OKLAHOMA

Okla. H.B. 2460 (2012)

236

237

18 Vt. Stat. § 9708(d)(3)

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HIPAA PERMITS DISCLOSURE OF COLST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY

DNR/COLST
CLINICIAN ORDERS
for DNR/CPR and OTHER LIFE SUSTAINING TREATMENT

Patient Last Name
Patient First/Middle Initial
Date of Birth

FIRST follow these orders, **THEN** contact **Clinician.**

(If patient/resident has no pulse and/or no respirations)

A

DO NOT RESUSCITATE (DNR)

☐ **DNR/Do Not Attempt Resuscitation (Allow Natural Death)**

CARDIOPULMONARY RESUSCITATION (CPR)

☐ **CPR/Attempt Resuscitation**

For patient who is breathing and/or has a pulse, GO TO SECTION B – G, PAGE 2 FOR OTHER INSTRUCTIONS. CLINICIANS MUST COMPLETE SECTIONS A-1 THROUGH A-5

A-1 Basis for DNR Order
Informed Consent - Complete Section A-2
Futility - Complete Section A-3

A-2 Informed Consent
Informed Consent for this DO NOT RESUSCITATE (DNR) Order has been obtained from:

Name of Person Giving Informed Consent (Can be Patient)

Relationship to Patient (Write "self" if Patient)

A-3 Futility (required if no consent)

☐ I have determined that resuscitation would not prevent the imminent death of this patient should the patient experience cardiopulmonary arrest. Another clinician has also so determined:

MM 2 2012

Page 1 of 2

Maryland Medical Orders for Life-Sustaining Treatment (MOLST)

Patient's Last Name, First, Middle Initial

Date of Birth

☐ Male ☐ Female

This form includes medical orders for Emergency Medical Services (EMS) and other medical personnel regarding cardiopulmonary resuscitation and other life-sustaining treatment options for a specific patient. It is valid in all health care facilities and programs throughout Maryland. This order form shall be kept with other active medical orders in the patient's medical record. The physician or nurse practitioner must accurately and legibly complete the form and then sign and date it. The physician or nurse practitioner shall select only 1 choice in Section 1 and only 1 choice in any of the other Sections that apply to this patient. If any of Sections 2-9 do not apply, leave them blank. A copy or the original of every completed MOLST form must be given to the patient or authorized decision maker within 48 hours of completion of the form or sooner if the patient is discharged or transferred.

CERTIFICATION FOR THE BASIS OF THESE ORDERS: Mark any and all that apply.

I hereby certify that these orders are entered as a result of a discussion with and the informed consent of:

_____ the patient; or
_____ the patient's health care agent as named in the patient's advance directive; or
_____ the patient's guardian of the person as per the authority granted by a court order; or
_____ the patient's surrogate as per the authority granted by the Heath Care Decisions Act; or
_____ if the patient is a minor, the patient's legal guardian or another legally authorized adult.

Or, I hereby certify that these orders are based on:

_____ instructions in the patient's advance directive; or
_____ other legal authority in accordance with all provisions of the Health Care Decisions Act. All supporting documentation must be contained in the patient's medical records.

New Policy

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ATS 1991

AMA 1999

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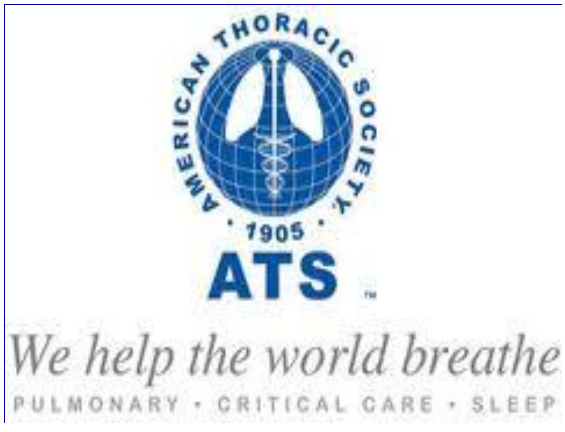

1. Futile
2. Inappropriate
3. Provisionally inappropriate

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Futile treatment	Interventions that cannot accomplish the intended physiological goals

1. A surrogate requests antibiotics as treatment for an acute MI in a critically ill patient.
2. A clinician refuses to provide CPR in a patient with rigor mortis.

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Inappropriate Treatment	Treatments which may accomplish an effect desired by the patient, but for which there are widely accepted rules that prohibit their use

2. A surrogate requests that clinicians circumvent the lung organ allocation policy to help a critically ill patient get faster access to an organ for transplantation.
3. A patient requests a prescription for a lethal dose of barbiturates (in states where PAS is illegal).

Provisionally Inappropriate Treatment	Treatments that have at least some chance of accomplishing the effect sought by the patient or surrogate and are not prohibited by an existing rule, but medical professionals believe that competing ethical considerations justify treatment refusal.

1. A surrogate requests ongoing mechanical ventilation for a patient with widely metastatic cancer and refractory multi-organ failure with progressive extremity necrosis from high-dose vasopressors.
2. A surrogate requests initiation of dialysis for a patient in a persistent vegetative state

Figure 1- Recommended approach to the management of disputed requests in ICUs

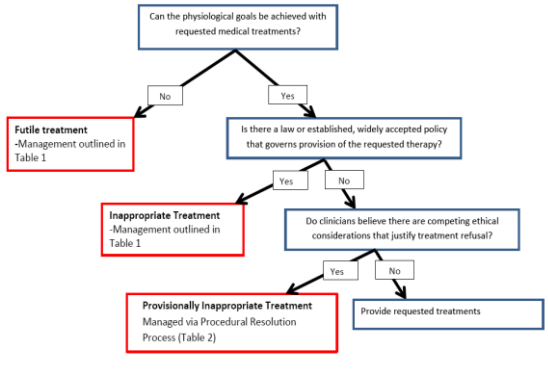

Table 2- Model policy highlighting procedural steps for resolution of conflict regarding life-sustaining treatments

1)	Prior to initiation of and throughout the formal dispute resolution procedure, clinicians should enlist expert consultation to aid in achieving a negotiated agreement.
2)	Surrogate(s) should be given clear notification in writing regarding the initiation of the formal conflict resolution procedure and the steps and timeline to be expected in this process.
3)	Clinicians should obtain a second and independent medical opinion to verify the diagnosis and prognosis.
4)	There should be case review by an interdisciplinary institutional committee.
5)	If the committee agrees with the clinicians, then clinicians should offer the option to seek a willing provider at another institution and should facilitate this process.
6)	If the committee agrees with the clinicians and no willing provider can be found, surrogate(s) should be informed of their right to seek appeal to an independent body.
7a)	If no willing provider can be found and the surrogate does not seek independent appeal or the appeal affirms the clinicians' position, clinicians may withhold or withdraw the contested treatments, and should provide high quality palliative care.
7b)	If the committee agrees with the patient or surrogate's request for life prolonging treatment, clinicians should provide these treatments or transfer the patient to a willing provider.

Time pressured decisions

- Consensus among clinicians present
- Case review to extent possible

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