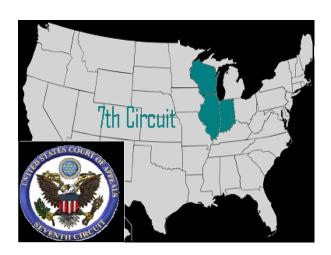
Unilateral Refusal of Treatment by Providers: Ethical & Legal Challenges

Thaddeus M. Pope, J.D., Ph.D.

Widener University Law School

Meriter Hospital Fall Ethics Conference November 5, 2010







March 2008 Volume 4 Number 7

EMTALA: Its Application to Newborn Infants by Thaddeus M. Pope, Widener University Law School, Wilmington, DE

Bridon Preston v. Meriter Hospital

Roadmap (part 1)

- Definition & orientation
- Causes
- Typical resolution pathway

Today

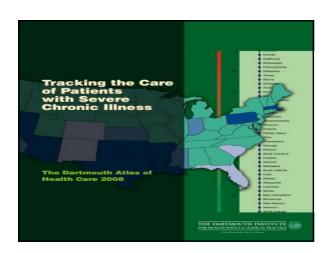
The Wisconsin Surgical Society
A Chapter of the American College of Surgeons

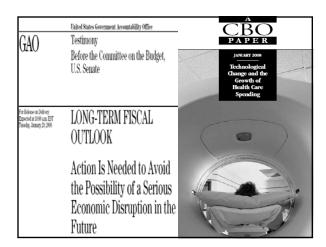
Past few weeks



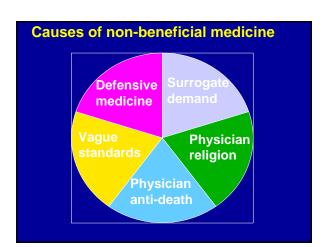


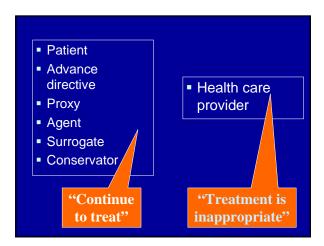
What is a medical futility dispute?

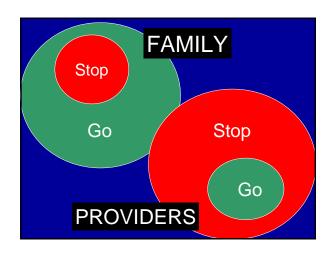


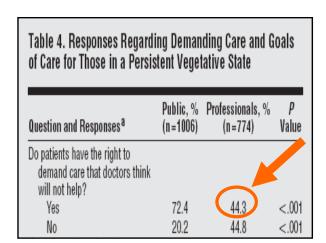












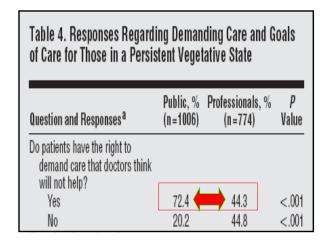
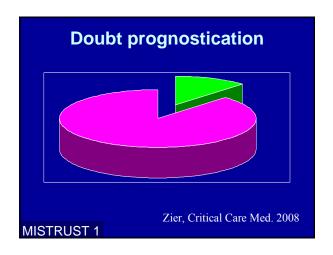


Table 3. Preferences for Goals of Care and Limited Resources				
Question and Responses ^a	Public, % (n=1006)	Professionals, % (n=774)		
If doctors believe there is no hope of recovery, which would you prefer?				
Life-sustaining treatments should be stopped and should focus on comfort	72.8	92.6		
All efforts should continue indefinitely	20.6	2.5		

Why do surrogates demand non-beneficial treatment?











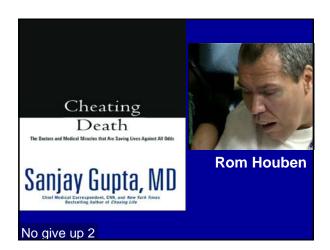














Externalization

- Costs
- Guilt





Question and Responses ^a	Public, % (n=1006)	Professionals, % (n=774)	<i>P</i> Value
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	<.001
100 N	35.5	61.1	<.001

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

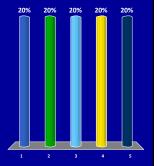
Zier et al., 2009 Chest 136(1):110-117

Religion 3

Why do providers resists surrogate requests?

Why do YOU resist surrogate demand for non-beneficial treatment

- 1. Professional integrity
- 2. Patient suffering
- 3. Stewardship/ resources
- 4. Distrust surrogate
- 5. Avoid staff moral distress



Avoid patient suffering

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

"abomination,"
"immoral,"
"tantamount
to torture"





	4.00		_		
Cate	gory: futile care				
1,	Follow the family's wishes for the patient's care when I do not agree with them but do so because hospital administration fears a lawsuit	41 (93)	29 (66)		
2.	Follow the family's wishes to continue life support even though it is not in the best interest of the patient	42 (95)	39 (89)		
3.	Carry out a physician's order for unnecessary tests and treatment	43 (98)	32 (73)		
5.	Initiate extensive life-saving actions when I think it only prolongs death	44 (100)	38 (86)		
12.	Carry out the physician's orders for necessary tests and treatments for terminally ill patients	43 (97)	30 (68)		
19.	Prepare an elderly man for surgery to have a gastrostomy tube put in, who is severely demented and a "No Code"	42 (95)	18 (41)		
2400			\sim		
ORIG	INAL ARTICLE	cterturatets.com/	mornale/score		
Pe	e relationship between moral distres rception of futile care in the critical	s and care u	nit"		
Melinda J. Mobley *, Mchamed Y. Rady ***, Joseph L. Verheijde*, Bhavesh Patel *, Joel S. Larson *					





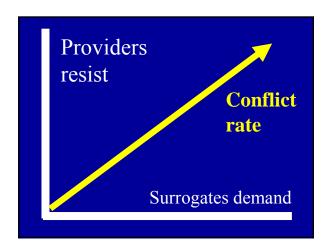
Table 2. Predictive Accuracy of Surrogates Versus a Preliminary Population-Based Treatment Indicator				
	Accuracy	(95% CI)		
Overall ^a				
Surrogates	78.4%	(73, 84)		
Treatment indicator	78.5%	(72, 85)		

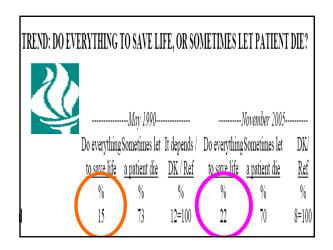


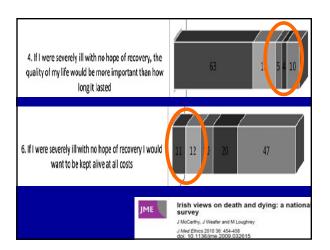
Growth in rate of conflict

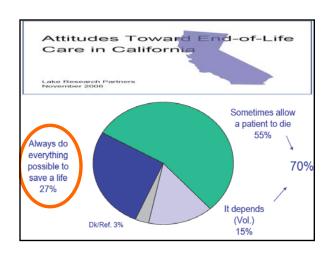
Population or percent,						
sex, and age	2000	2010	2020	2030	2040	2050
PERCENT OF TOTAL						
TOTAL						
TOTAL	100.0	100.0	100.0	100.0	100.0	100.0
0-4	6.8	6.9	6.8	6.7	6.7	6.7
5-19	21.7	20.0	19.6	19.5	19.2	19.3
20-44	36.9	33.8	32.3	31.6	31.0	31.2
45-64	22.1	26.2	24.9	22.6	22.6	22.2
65-84	10.9	11.0	14.1	17.0	16.5	15.7
85 +	1.5	2.0	2.2	2.6	3.9	5.0

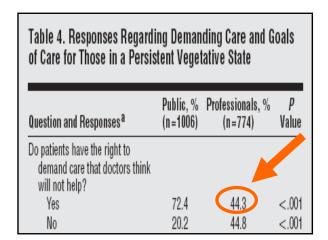
Source: U.S. Census Bureau, 2004, "U.S. Interim Projections by Age, Sex, Race, and Hispanic Origin," https://www.census.gov/ipc/www/usinterimproj/











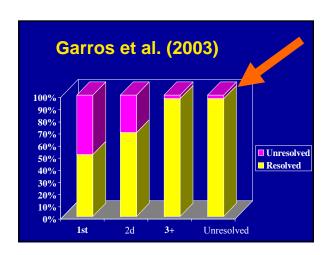
- More palliative care
- More EOL training
- Provider rights
- Financial incentives

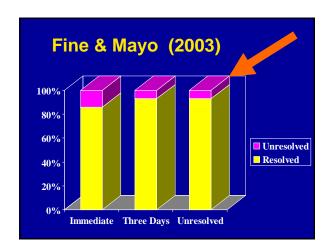
Typical dispute resolution pathway

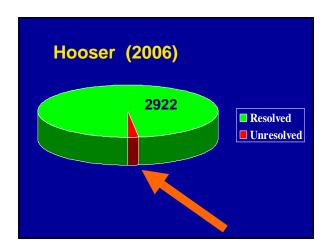
How are futility disputes usually resolved? 1. Surrogate eventually agrees with HCP 2. HCP accedes to surrogate demands 3. Patient dies 4. Patient transferred

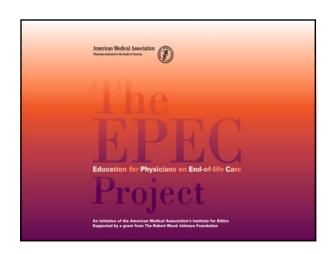
Prendergast (1998)

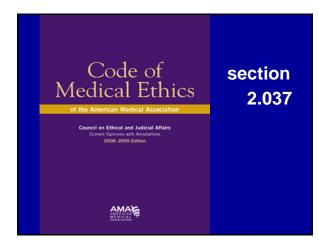
- 57% surrogates immediately agree
- 90% agree within 5 days
- 4% continue to insist on LSMT











- 1. Earnest attempts . . . deliberate over and negotiate prior understandings . . .
- **2. Joint decision-making** should occur . . . maximum extent possible.
- 3. Attempts . . . negotiate . . . reach resolution . . ., with the assistance of consultants as appropriate.
- 4. Involvement of ... ethics committee ... if ... irresolvable.

5.

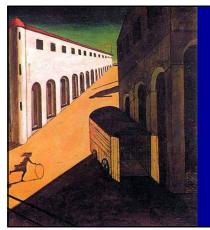
- 6. If the process supports the physician's position and the patient/proxy remains unpersuaded, transfer....
- 7. If transfer is not possible, the intervention need not be offered.



Roadmap (part 2)

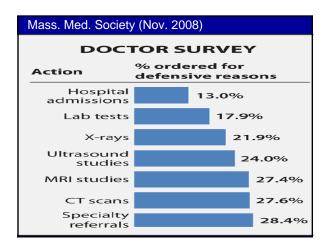
Intractable conflict
Court cases
4 legislative approaches

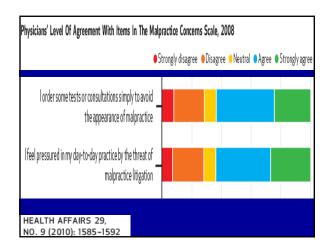
Intractable conflict



Mediation occurs in the "shadow" of the law









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

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

CMAJ 2007;177(10):1201-8

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

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

Reference Committee

October 4-6, 2008

This resolution constitutes a proposal for consideration by the California Medical Association House of Delegates and does not represent official CMA policy.

WHEREAS, it is still common for physicians who feel non-beneficial or futile treatments are being provided or considered to feel threatened by legal action by the patient's family or other surrogates, and thus continue to provide such care against their best medical judgment; and

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



Court Cases

Damages
Injunctions

Damages

Exposure to civil liability

- State HCDA (incl. fees)
- Battery
- Medical malpractice
- IIED / NIED
- Informed consent
- EMTALA

Criminal liability

• e.g. homicide

Licensure discipline

What is the legal risk from unilateral w/h or w/d 1. High 25% 2. Medium 25% 3. Low, yet material 4. Low and immaterial

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

Burks v. St. Joseph's Hosp., No. 95-CV-002639 (Milwaukee Cir. Ct. 1996), 596 N.W.2d 391 (Wis. 1999).

Providers typically only lose on claims for IIED

- Secretive
- Insensitive
- Outrageous

Luce is confirming the trend of unsuccessful lawsuits against providers

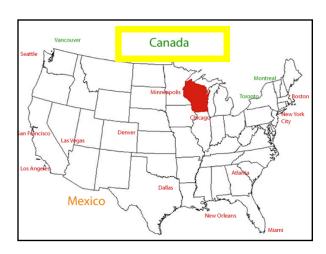


Risk > 0

- Barber (Cal. 1983)
- Manning (Idaho 1992)
- Rideout (Pa. 1995)
- Bland (Tex. 1995)
- Wendland (lowa 1998)
- Causey (La. 1998)

Grossly overstated risks

But **some** real exposure



"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).

"The only fear a doctor need have in denying heroic measures to a patient is the **fear of liability** for negligence . . . where qualified practitioners would have thought intervention warranted."

> Child & Fam. Svcs. v. Lavallee (Man. App. 1997).

But the process itself can be punishment

Even prevailing parties pay transaction costs

Liability averse

Litigation averse too



Providing good, clinically appropriate medicine



Acceding to surrogate demands

Easier to accede to surrogate demands

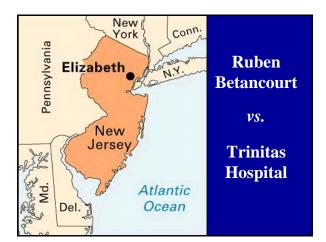
- Patient will die
- Provider will round off
- Nurses bear brunt

But not happy about it

Injunctions

Courts frequently grant **temporary** injunctions to preserve status quo

But patients often die before adjudication of merits



- 73yo male
- PVS
- COPD
- End-stage renal disease
- Hypertensive cardiovascular disease
- Stage 4 decubitus ulcers
- Osteomyeletitus
- Diabetes
- Parchmentlike 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."

Intramural process No consensus **Unilateral withdrawal** DNR order written Dialysis port removed **January 21, 2009** Jacqueline files complaint **January 23, 2009 Court issues TRO February 10, 2009** Court extends TRO January - February 2009 **Evidentiary hearings** Medical expert witnesses Family witnesses

March 4, 2009

Permanent injunction on the merits

August 2009

Appeal: NJHA, MSNJ, NJP, GNYHA

August 13, 2010

Appellate court refuses to reverse



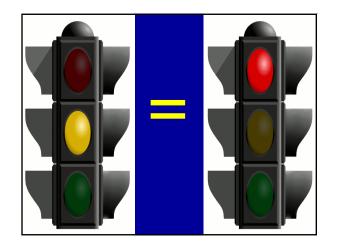


Easier to ask for forgiveness, than to ask for permission

"The Court cannot require a medical advisor to act . . . contradictory to . . . bona fide clinical judgment"

Rotaru v. Vancouver Gen. Hosp., 2008 BCSC 318 (Mar. 13, 2008)

4 Statutory
Approaches









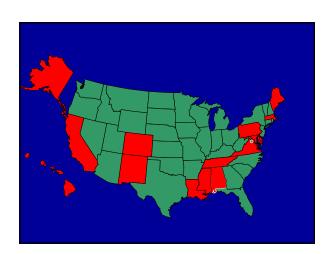
- 1. UHCDA model
- 2. Ontario model
- 3. Texas model
- Conscientious objection

UHCDA model

Statutory approach 1 of 4

New Mexico (1995)
Maine (1995)
Delaware (1996)
Alabama (1997)
Mississippi (1998)
California (1999)
Hawaii (1999)
Tennessee (2004)
Alaska (2004)
Wyoming (2005)





Tenn. Code 68-11-1808(e)

"A health care provider . . . may decline to comply with . . . health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards . . ."

Tenn. Code 68-11-1808(f)

- (3) . . . make all reasonable efforts to assist in the transfer . . .
- (4) If a transfer cannot be effected, the health care provider . . . shall not be compelled to comply.

16 Del. Code 2508(g)

A health-care provider . . . that declines to comply . . . shall . . .

Provide continuing care, including continuing life sustaining care, . . . until a transfer can be effected

Are there "generally accepted healthcare standards"

1.Yes

2.No



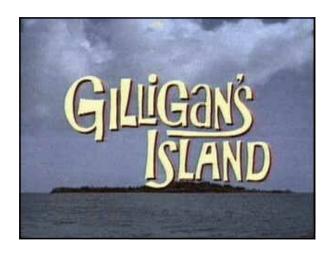
□1 □ 2

"Bad" safe harbor language

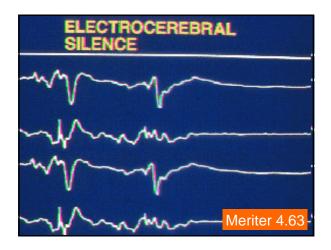
"generally accepted health care standards"

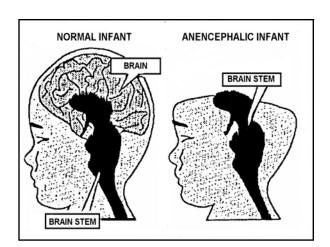
"significant benefit"



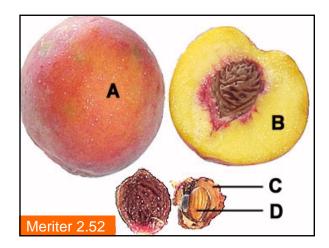


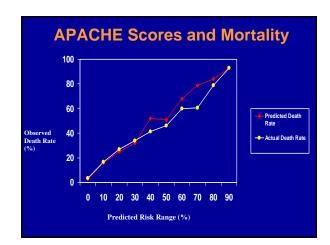
-	











Wide variation in what considered futile

• Some: only when 0%

• Others: as high as 13%

Lantos, Am J Med 1989

What threshold

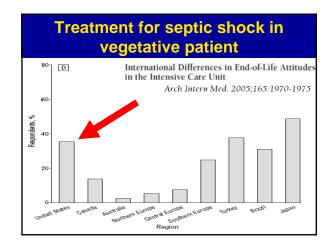
Uncertainty in extrapolating from populations to individuals

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

Bernat 2008

Qualitative Futility

- Benefit burden
- QOL
- Cost per QALY

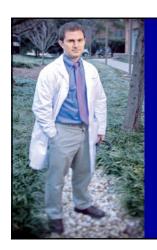


Goals of Medicine

- Cure disease
- Alleviate pain & suffering
- Restore function
- Prevent disease
- Prolong corporeal existence







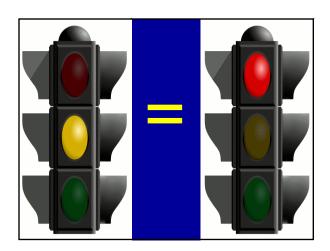
Not just ambiguity

Providers continue to create the "wrong" standard of care

Dan Merenstein 291 *JAMA* 15 (1994)

Result of Ambiguity

- Few futility policies
- Rare "full" implementation



Surrogate selection model

Statutory approach 2 of 4

A proxy shall act in accordance

- 1. "directive . . . decisions"
- 2. "the maker's . . . wishes"
- 3. "maker's best interests"

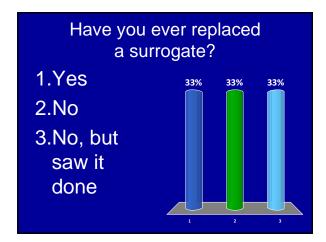
Wis. Stat. 155.20(5)

The health care agent shall act in good faith consistently with the desires of the principal . . . with any valid declaration . . . in the best interests of the principal

Wis. Stat. 155.60(4)

The court may ...

"direct the ... agent to act in accordance .
.. [or] rescind all powers"



Helga Wanglie (Minn. 1991)



Surrogate decision inconsistent with P preferences



Bernstein v.
Superior Court of Ventura County (Feb. 2, 2009).



Court to
Barbara Howe:



Your own personal issues are "impacting your decisions"

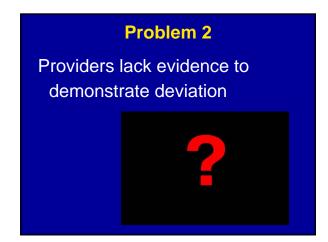
"Refocus your assessment"



Ontario
Capacity
and
Consent
Board

Limitations of surrogate replacement

Problem 1 Surrogates can often demonstrate congruity



If cannot replace the surrogate, then (in those rare cases) just provide the treatment



We still need dispute resolution mechanisms for those intractable cases in which surrogates are "irreplaceable"

Texas model

Statutory approach 3 of 4

You can stop LSMT for any reason if your own hospital's ethics committee agrees

Tex. H&S Code 166.046

- 48hr notice
- Ethics committee meeting
- Written decision
- 10 days
- No judicial review



Tex. H&S Code 166.045

A physician . . . is not civilly or criminally liable or subject to review or disciplinary action . . . if the person has complied with the **procedures** outlined in Section 166.046

TX safe harbor

- Measurable procedures
- Safe harbor protection certain

TN safe harbor

- Vague substantive standards
- Safe harbor protection <u>un</u>certain



Emilio Go<u>nzalez</u>

April 14, 2006

Mg
Gonzales
407 Neches St.

Lockhart, Texas 78644



Dear Ms. Gonzales;

We, the physicians and other members of the healthcare team, appreciate you taking your time to attend the patient care conferences regarding your son.

At the last conference, your son's physician discussed his brain condition and the poor prognosis for any further neurological improvement. As you know, the physicians involved in the care of your son believe that his condition is irreversible and that to continue certain treatments will serve to prolong his suffering without the possibility of cure. We understand that you do not agree with this position and want the hospital to continue to provide all current treatments for your son.

When disagreements of this nature arise, Texas law allows hospitals to call the hospital ethics committee meeting to review whether certain treatments are medically appropriate. A meeting has been called for the Seton Family of Hospitals Pediatric Ethics Committee to consider Emilio Gonzales's care. This meeting will be held on February 16, 2007 at 09:00 a.m. in the 3rd floor boardroom at Brackenridge Hospital of Austin. The physicians providing care for your son, as well as the ethics committee members will attend the meeting. Under Texas law you have the right to attend and participate in this meeting. While that is not legally required, we strongly encourage you to be present for this discussion. You will be given the opportunity to ask questions regarding your son's care and to provide input into the committee's decision-making process.



Step 3: HEC Decision

The Ethics Committee further recommends that

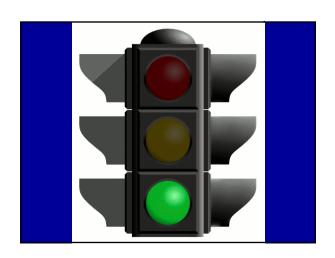
- The treatment plan for the patient be modified to allow only comfort measures (such as hydration, pain control and other interventions designed to decrease the patient's suffering).
- New complications that develop should not be treated, except with additional palliative measures, as appropriate.
- The patient's code status be changed to a DNR.
 Appropriate spiritual and pastoral care resources should be provided to Emilio's mother and family members.

In summary, the consulted members of the Ethics Committee concur with the recommendation by the Attending Physician and patient care with the recommendation by the Attending Physician and patient care team to withdraw aggressive care measures, including use of the ventilator, and to allow palliative care only. The Attending Physician, with the help of the Children's Hospital of Austin, will continue to assist the patient's family in trying to find a physician and facility willing to provide the requested treatment. The family may wish to contact providers of their choice to get help in arranging a transfer.

Step 4: Attempt transfer

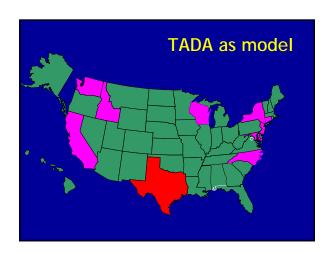


Texas: the good



Ontario	Texas
Fast	Fast
Judicial review	No judicial review
Independent	Not independent
Rules & procedures	No rules
Only for bad proxies (not Golubchuk)	For all disputes









Resolution 505-08 TI	ITLE: LEGAL SUPPORT FOR NONBENEFICIAL TREATMENT DECISIONS
Author: H Hugh Vincent, MD; William Andereck, MD Introduced by: District 8 Delega	tion
Endorsed by: District 8 Delegation	on Reference Committee E
	October 4-6, 2008
	proposal for consideration by the California Medical Association legates and does not represent official CMA policy.
Resolution 506-09 T	ITLE: END-OF-LIFE CARE AND FUTILE TREATMENT
Author: Larry A. Bedard, MD	
Introduced by: Larry A. Bedard	, MD
Endorsed by:	Reference Committee
	October 17-19, 2009

	WASHINGTON STATE MEDICAL ASSOCIATION HOUSE OF DELEGATES	
		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	
	WASHINGTON STATE MEDICAL ASSOCIATION HOUSE OF DELEGATES	
		Resolution: A-2 (A-10)
Subject:	WSMA Opinion on Medical Futility in End-of-Life (Care
Introduced by:	Shane Macaulay, MD, Delegate WSMA Board of Trustees	
Referred to:	Reference Committee A	



RESOLUTION 1 - 2004

(read about the action taken on this resolution)

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.

Texas: the bad and the ugly

Few **substantive** criteria for identifying inappropriate EOL treatment

Without substantive criteria, we must resort to procedural criteria

Intractable value conflict



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

Is the TADA process fair?

20% 1. Very fair

20% 2. Somewna

^{20%} 3. Neutra

^{20%} 4. Somewhat unfair

5. Very unfair

Procedural defects recognized

Tex. S.B. 439 (2007)

Tom Mayo, Ga. St. U. L. Rev. (2009)

Due Process

- Notice (48hrs)
- Opportunity to present
- Opportunity to confront
- Assistance of counsel
- Independent, neutral decisionmaker
- Statement of decision with reasons
- Judicial review

No time to evaluate all these aspects of due process

Basically, providers should give patients what they give themselves

E.g. Peer review

E.g. Licensure actions

Who Makes the Decision?

Intramural institutional ethics committee

But the HEC is controlled by the hospital

•			
•			
•			
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TADA recognizes need for some "independent" check

- Requires HEC review
- Prohibits referring physician from serving on HEC

But the current mechanism is **not** sufficient

TADA is **silent** on HEC composition

No community member requirement, like IRB

Lack of transfer is **not** external review

COI

More documented

More targeted



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Conflict of interest (\$\$\$)

- Ruben Betancourt (NJ)
- Brianna Rideout (PA)
- James Bland (TX)
- Kalilah Roberson-Reese (TX)

Conflict of interest (other)



Statement of Decision

- Provide rationale
- Factual basis
- Considered, supported

But decisions are of variable quality

Issues that were identified and considered:



- The treatment team is in agreement that this per terminal and irreversible condition which will result in his death.
- There is significant concern that this patient is suffering from pain related to his clinical condition.
- Dr. Wilson, Emilio's current attending physician, other physicians and other members of the patient care team believe Emilio is suffering and that the burdens associated with his current plan of care far outweigh any benefits that Emilio may be receiving.

MEMORIAN

Dear Mrs. Ella Davis and Family:

This is to inform you of the decision of the Medically Inappropriate/Futile Treatment Review Committee that met on January 21, 2009 at 5:30 p.m. As a reminder, this Committee was composed of independent clinicians who had not been involved in the treatment of Mr. Davis or any bioethics consult that was requested.

The attending and consulting physicians of Mr. Davis presented the clinical case to this Committee, after which the Committee and family were given the opportunity to ask questions. After reviewing the medical record and having had all questions asked and answered, the Committee is in agreement with the attending physician that the current artificial life sustaining interventions are medically inappropriate. Please see the enclosed documentation.

We understand that the patient advocate has given you information from the Texas Advance Directive Act regarding the right to seek transfer of the patient to another facility and the listing from the TDSES registry of healthcare providers.

If we can be of further assistance please let us know.

Sincerely,

Harold Kurlander, MD Review Committee Chair

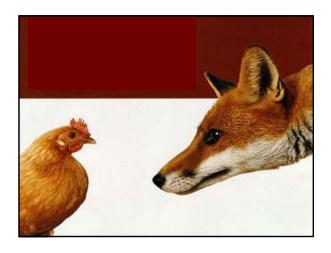
Robert Herman , MD

MODITORING

TADA is **silent** not only on substantive criteria but also on procedures and methodology

- *E.g.* quorum
- *E.g.* voting







Conscientious Objection

Statutory approach 4 of 4





Termination: normally

- Sufficient notice to find alternative
- Medical Board may require ~30 days

Termination: life-and-death

"free to refuse . . . upon providing reasonable assurances that basic treatment and care will continue"

Couch (N.J.A.D. 2000).

Del. Code 2508(e)

"... provider may decline to comply ... for reasons of conscience."

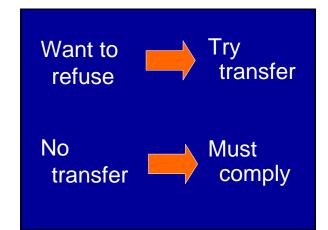
Del. Code 2510(a)(5)

... provider ... not subject to civil or criminal liability or to discipline ... for ... [d]eclining to comply . because ... conscience ...

Del. Code 2508(g)

[If] decline to comply . . .

(2) Provide continuing care, including continuing life sustaining care, . . . until a transfer can be effected



Cal. Probate Code 4736

(c) Provide continuing care . . . until a transfer can be accomplished **OR** until it appears that a transfer cannot be accomplished.



Idaho Code 18-611

No health care professional . . . shall be civilly, criminally or administratively liable for . . . declining to provide health care services that violate his or her conscience

in a life-threatening situation . . . professional shall provide treatment and care until an alternate health care professional capable of treating the emergency is found.

Miss. Code 41-107-5

A health care provider has the right not to participate, . . . violates his or her conscience.

. . .

No emergency exception
No duty to refer

Looking Forward



Without legal support to w/d or w/h openly and transparently, some do it covertly.

PROPORTION OF PHYSICIANS ($n=726$) WHO WI LIFE-SUSTAINING TREATMENT ON THE BASIS OF MEDIC	THHELD CAL 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%)

Avoid intractable conflict

Better ACP

 Most patients do not want overly aggressive treatment

More ethics resources

- Because they work

Better communication

Clinical Practice Guidelines

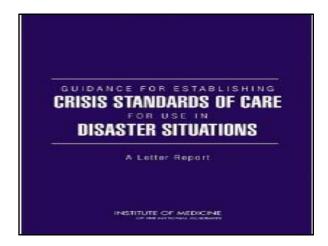
CPG linked to **new** safe harbors

CPGs make **existing** safe harbors effective











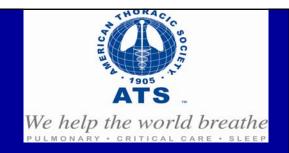
Multi-institutional
ethics committee
Medical society
Specialized agency

- Malpractice panel
- Licensure board





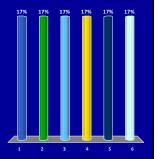




Statement on futility and goal conflict in end-of-life care in ICUs revising the 1991 policy statement

Solution with most promise?

- 1. Better ACP
- 2. Better communication
- 3. CPGs
- 4. TADA
- 5. Surrogate selection
- 6. Reimbursement incentives



Thank you

