Approaching Medical Futility:

Laws that grant physicians and hospital ethics committees final authority to deny patients life sustaining treatment are ethically sound.

Pro

Robert L. Fine, MD, FACP Director, Office of Clinical Ethics and Palliative Care Baylor Health Care System Dallas, Texas

Con

Thaddeus Pope, PhD, JD Associate Professor of Law, Member Health Law Institute Widener University School of Law Wilmington, Delaware



Presenter Disclosures

1) Personal financial relationships with commercial interests relevant to medicine, within past 3 years: Consultant (ethics), VITAS Hospice, Corporate Ethics Committee

2) Personal financial support from a non - commercial source relevant to medicine, within past 3 years:
No relationships to disclose

3) Personal relationships with tobacco industry entities within the past 3 years:

No relationships to disclose



Presenter Disclosures

- 1) Personal financial relationships with commercial interests relevant to medicine, within past 3 years: No relationships to disclose
- 2) Personal financial support from a non commercial source relevant to medicine, within past 3 years:

Honoraria for hospital rounds: HCA, U-NM, U-Manitoba, Kaiser-San Diego Honoraria for education: Am. College Legal Medicine, S. III. Univ.

3) Personal relationships with tobacco industry entities within the past 3 years:

No relationships to disclose

Case One

- 78 year old man with ESRD on chronic HD now vegetative due to severe post-CPR anoxic encephalopathy.
 - Ventilator, ANH and dialysis.
 - Anticipated that the patient will become ventilator independent.
 - Based upon his living will, family demands all interventions including full code status.
- Are the treatments demanded by the family beneficial? Are they medically appropriate? Are they medically futile?

Case Two

- 28 year old Ethiopian Coptic Christian woman with diffuse angiosarcoma involving the liver, lungs, and chest wall.
 - Failed surgery, chemo, and radiation.
 - Now with severe pain/dyspnea.
 - Rx: intubation, chest tubes, pressors, opioids.
 - Unable to communicate and has previously deferred all decisions to her brothers.
 - Transition to "comfort only" rejected by brothers citing religious traditions.
 - Morphine should be stopped because suffering = salvation.
 - Full code status is what God expects of humanity.
- Are the treatments demanded by the family beneficial? Are they medically appropriate? Are they medically futile?

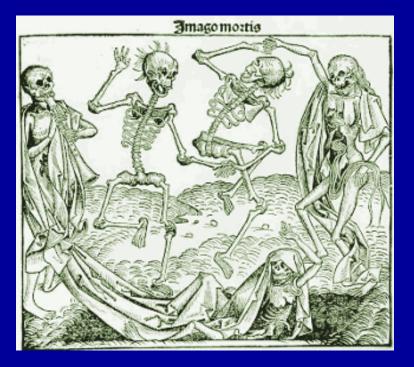
Defining medical futility



John William Waterhouse 1849-1917 The Danaider, 1906 Weisin William Waterhouse

- "Leaky, hence untrustworthy, vain, failing of the desired end through intrinsic defect."
- Gilgamesh and Ecclesiastes.
- "Refuse to treat those overmastered..." *Hippocrates*
- Physiologic and/or qualitative futility - Youngner, 1988
- Quantitative futility Schneiderman, 1990
- Treatments that benefit part of the body vs the whole person -Shuster, 1992
- "Medically inappropriate" or "nonbeneficial"

Defining medical futility



- "The clinical concept futility embodies cannot be eradicated from medicine as long as patients are mortal."
 - E. Pellegrino, Chair, President's Bioethics Commission

TADA Coalition: futility beyond physiology, quality and quantity

- Consider the goals and means of medicine.
- Dialysis "works" physiologically in vegetative patients with renal failure as in case one. Should we provide it? Why or why not?
- Renal transplant would work too. Should we provide it?

- Chest tubes "work" physiologically to relieve pneumothorax in case two, but can't cure the cancer.
 - Because it works physiologically (on one part of the problem), must it be used?
 - If so, how many times and how many tubes?
- If some persons believe pain is a moral blessing, must we leave pain untreated? Why or why not?
 - What if a decision maker asked that a limb be amputated without anesthesia? Would you do it? Why or why not?

Defining medical futility



- The clinical concept futility embodies cannot be reduced to its parts and transcends both pure physiologic futility and pure qualitative futility. It is part of the nature of life.
- "Futility of futilities, all is futility."

Ecclesiastes

Medical futility: We know it when we see it





- The patient cannot recover enough to live free from the medical institutional complex, <u>and</u>
- Is either disproportionately suffering or unable to appreciate the benefit or joy in being alive, <u>and</u>
- Cannot die easily or peacefully without permission.

Practice

Life is short, the Art is long, opportunity fleeting, experience delusive, judgment difficult. *The Aphorisms of Hippocrates*

TADA and EOL treatment disputes

- Patient must be terminal or irreversible
- Physician recommends withdrawal of "medically inappropriate" treatment and surrogate refuses
- Physician requests review by "an ethics or medical committee" (not defined in the law)
 - Hospital administrators or ethics committees cannot initiate.
- Surrogates receive written explanation of the due process mechanism with at least 48 hours notice.
- Surrogates and treating physicians invited to attend.

- If the review committee affirms the treating physicians, then written report given to the surrogate.
- 10 day search for an alternative willing provider begins.
- If transfer is available, then transfer.
- If no alternative provider found, then life sustaining treatment may be withdrawn on the 11th day unless ...
- The surrogate petitions and convinces a court of law by a "preponderance of the evidence" that if an extension is granted, an alternative willing provider can be found.

Baylor early experience with TADA

- 47 futility consults 2 years post-TADA at Baylor:
 - 37 (78%) resolved with routine ethics counseling
 - 10 (22%) proceeded to the more formal ethics committee review following Texas law
 - 4 cases: ethics committee rejected the notion that further non-comfort treatments were medically inappropriate.
 - 6 cases: a 10-day letter was issued.
 - 3 cases family agreed to stop treatment before 10 days elapsed.
 - 3 cases patients died during 10-day period (without CPR).
 - » Fine RL, Mayo Wm T. Resolution of futility by due process: early experience with the Texas Advance Directives Act. Annals of Internal Medicine. 2003; 138: 743-746.

Statewide experience with TADA

- Five year data from 11 hospitals and two year data from 5 hospitals:
 - Total ethics consults: 2,922
 - Estimated explicit futility consults: 974
 - Total 10-day letters issued: 65
 - 11 patients transferred within 10 days.
 - 22 patients died during the 10 day transfer period.
 - 27 patients had disputed treatment withdrawn.
 - 5 patients either had treatment extended or were transferred later.

Pro

Laws that grant physicians and hospital ethics committees final authority to deny patients life sustaining treatment are ethically sound because...

Promote fidelity to the patient

- Fidelity (to the patient), beneficence, and nonmaleficence are the most important ethical principles intrinsic to Medicine
 - Plato: "No physician, in so far as he is a physician, considers his own good in what he prescribes, but *the good of the patient...*"
 - Hippocrates: We act for "the benefit of the sick ... "
 - Peabody: "For the secret of the care of the patient is in caring for the patient."

Place boundaries on Autonomy

- We live in an Autonomy worshipping culture.
- Patient Autonomy is important but cannot be absolute without destroying the <u>covenantal</u> <u>relationship between physicians and patients</u>.
 - This is especially true when patient autonomy is expressed by surrogates.
 - Surrogates fail to predict patient preference in 1/3 of cases.
 - Surrogates often project own wishes on patients.
- Negative rights outweigh positive rights.

Promote a good secular ethic

- Kant's second maxim: Always treat persons as ends and never as means.
- Buber's relational ideal: Strive to interact with persons in an I-Thou rather than an I-It manner.

Promote the moral integrity of the medical profession

- When conflict with surrogates exists, physicians are more likely to advocate for the patient's best interest once given legal protection.
- Physician defined Beneficence should not be absolute.
 - Ethics committee review checks treating physicians.
 - The alternative willing provider rule checks treating physicians and the ethics committees.

If well constructed and implemented, laws similar to TADA may

- Promote ethical equipoise between unchecked patient autonomy and unchecked physician defined beneficence.
- Counterbalance the tyranny of a dominant family member.
- Counterbalance magical thinking and/or secondary gain of surrogates.

If well constructed and implemented, laws similar to TADA may

- Lift the burden of decision making from surrogate.
- Discourage the American cultural idea that medical treatments should be unlimited.
 - Human medical needs appear infinite.
 - Technology expands to meet needs.
 - The resources to pay will always be finite.
- We cannot control resource utilization in life's last chapter without fundamental cultural change supported by laws like TADA.

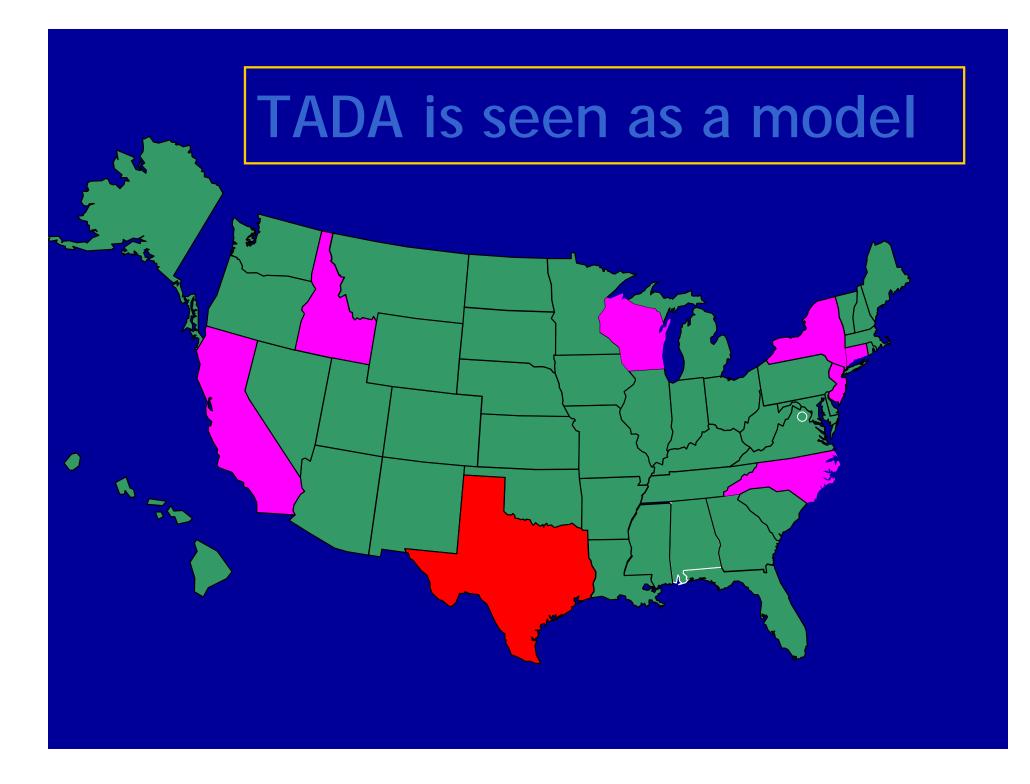
Con

Laws that grant physicians and hospital ethics committees final authority to deny patients life sustaining treatment <u>are not</u> ethically sound because... There are few substantive criteria for identifying inappropriate EOL treatment

- E.g. Brain death
- E.g. Anencephaly
- E.g. Physiological futility

Without substantive criteria, we must resort to procedural criteria

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



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

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

Neutral Decision Maker

Who Makes the Decision?

Intramural institutional ethics committee

But the HEC is controlled by the hospital

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 CO

More documented

More targeted



Conflict of interest (\$\$\$)

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

Conflict of interest (other)

Solution: External Review

Not a court Medical profession itself But not intramural

Models Multi-institutional ethics committee Medical society **Specialized agency** Malpractice panel Licensure board







Statement of Decision

Purpose 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 I 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.



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 TDSHS registry of healthcare providers.

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

Sincerel Harold Kurlander, MD

Review Committee Chair

Robert Herman , MD Review Committee Facilitator

Memorial Hermann Memorial City Medical Center Decision of the Medically Inappropriate Treatment Review Committee
Date JAMARY 21, 2009 Time 7%M Patient Name MAURICE DAVIS Medical Record # 38646326-8370
Patient Name_MAURICE_TAVISMedical Record # 38646326-8370
Background: MULTIPLE CVA'S, MULTISSSTEM'EAILURE, SEPSIS, UNRESPORTSIVE
Intervention(s) under review: <u>DIALYSTS, LAB, MEDICATION'S EXCERT COMPART MEASURES</u> MONITORING
Committee's conclusion: The committee unanimously affirms the following intervention(s) is/are medically Inappropriate treatment in this case: <u>PIAUXIS, LAB, MENICATIONS ARCENT COMPORT METASURES</u> , MINITORING

TADA is silent not only on substantive criteria but also on procedures and methodology – E.g. quorum - E.g. voting

Typical Analysis Patient-centered concerns Autonomy » Preferences » Values Best interests » Suffering » Dignity

Most intractable disputes are religionmotivated



Surrogate Decision Makers' Responses to Physicians' Predictions of Medical Futility

Lucas S. Zier, Jeffrey H. Burack, Guy Micco, Anne K. Chipman, James A. Frank and Douglas B. White

Chest 2009;136;110-117; Prepublished online March 24, 2009;

Balancing against religion No formula, algorithm Justification must: Substantially advance -A "compelling" interest -Not patient oriented **Integrity**? - Staff distress ?

– Stewardship ?

Questions