Responding to Requests for Futile or Potentially Inappropriate Treatments

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Disclosures

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- Gordon and Betty Moore Foundation
- UPMC Innovation Award
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Is Treatment Futile?

- 71 year old man with moderate dementia and severe COPD admitted with respiratory failure, septic shock and multi-organ failure. No advance directive.
  - 6 weeks in ICU
  - Minimally responsive after watershed infarcts
  - Ventilator and dialysis dependent
  - Off pressors; stable vital signs
  - Necrotic digits and pressure ulcers requiring serial debridement.

- Family insists on ongoing treatment, saying “He believes that life is sacred. We think he would choose this life over death”.

Goals

- Explore the nature of these disputes
- Discuss strategies to prevent intractable conflict with surrogates.
- Present new professional society recommendations about how to resolve intractable conflict with surrogates.

Is This an Important Issue?

Original Investigation

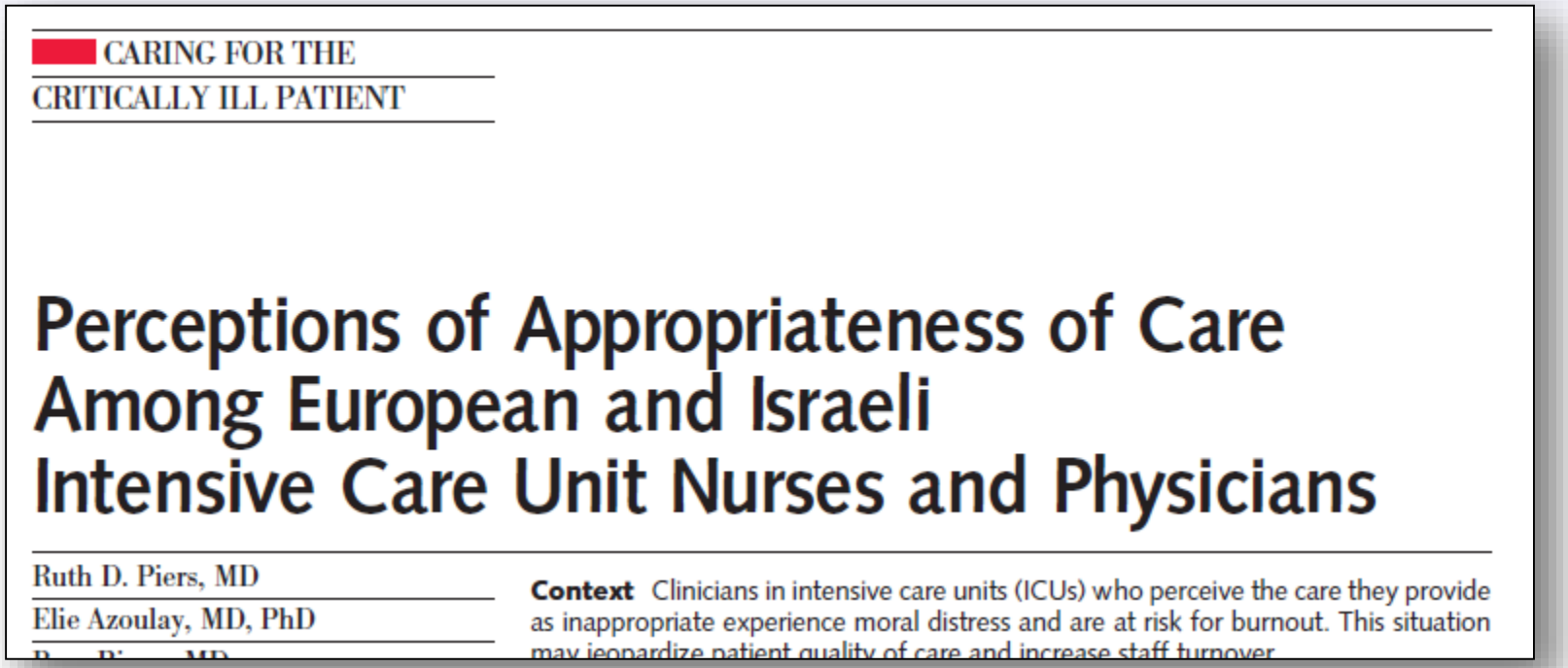
The Frequency and Cost of Treatment Perceived to Be Futile in Critical Care

Thanh N. Huynh, MD, MSHS; Eric C. Kleerup, MD; Joshua F. Wiley, MA; Terrance D. Savitsky, MBA, MA, PhD; Diana Guse, MD; Bryan J. Garber, MD; Neil S. Wenger, MD, MPH

- 11% of patients received treatment perceived as futile.
- $2.6 million over 3 months on treatments perceived to be futile.

Huynh T. JAMA IM. 2013
Truog R. JAMA IM. 2013

Not Just a North American Issue



CARING FOR THE
CRITICALLY ILL PATIENT

Perceptions of Appropriateness of Care Among European and Israeli Intensive Care Unit Nurses and Physicians

Ruth D. Piers, MD
Elie Azoulay, MD, PhD

Context Clinicians in intensive care units (ICUs) who perceive the care they provide as inappropriate experience moral distress and are at risk for burnout. This situation may jeopardize patient quality of care and increase staff turnover

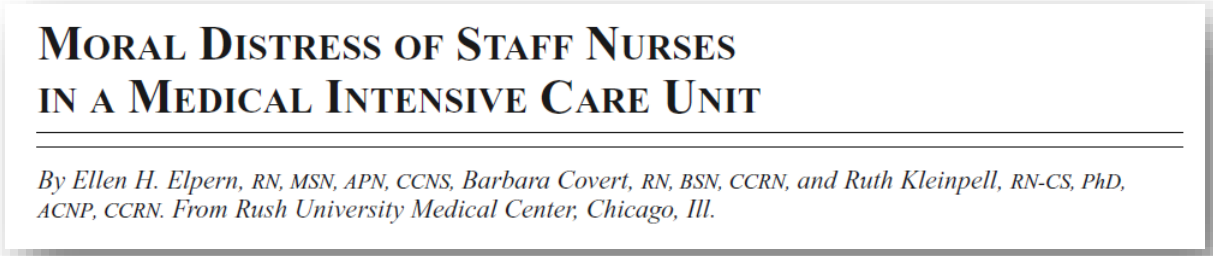
- 16% of clinicians judged that at least one patient under their care was receiving “disproportionately aggressive” treatment in light of the prognosis.

Piers R. JAMA. 2011

Administering "Futile" Treatment Causes Moral Distress

The relationship between moral distress and perception of futile care in the critical care unit☆

Melinda J. Mobley[a], Mohamed Y. Rady[a,*], Joseph L. Verheijde[b], Bhavesh Patel[a], Joel S. Larson[a]



MORAL DISTRESS OF STAFF NURSES IN A MEDICAL INTENSIVE CARE UNIT

By Ellen H. Elpern, RN, MSN, APN, CCNS, Barbara Covert, RN, BSN, CCRN, and Ruth Kleinpell, RN-CS, PhD, ACNP, CCRN. From Rush University Medical Center, Chicago, Ill.

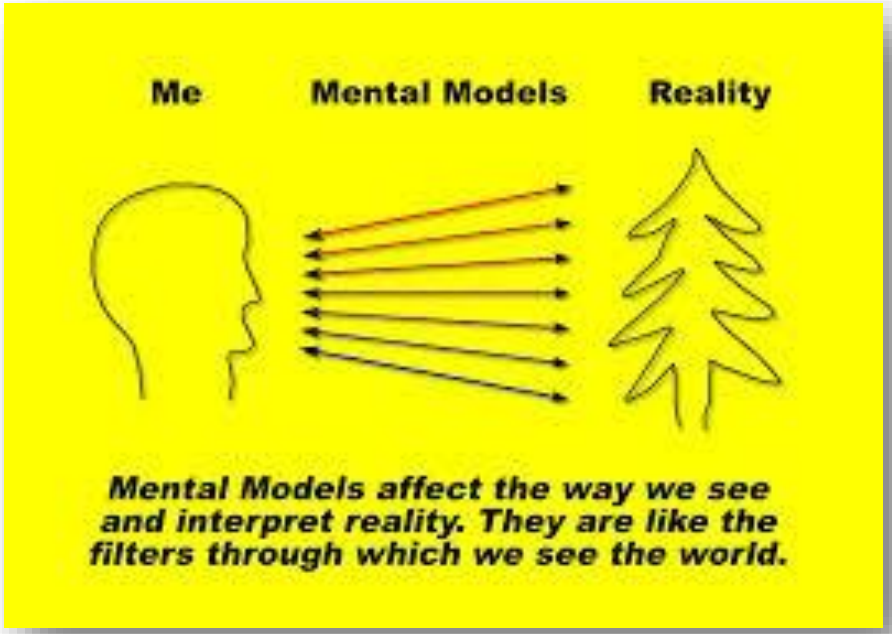
Prevalence and Factors of Intensive Care Unit Conflicts
The Conflicus Study

Élie Azoulay[1], Jean-François Timsit[2], Charles L. Sprung[3], Marcio Soares[4], Kateřina Rusinová[5], Ariane Lafabrie[1], Ricardo Abizanda[6], Mia Svantesson[7], Francesca Rubulotta[8], Bara Ricou[9], Dominique Benoit[10], Daren Heyland[11], Gavin Joynt[12], Adrien Français[2], Paulo Azeivedo-Maia[13], Radoslaw Owczuk[14], Julie Benbenishty[3], Michael de Vita[15], Andreas Valentin[16], Akos Ksomos[17], Simon Cohen[18], Lidija Kompan[19], Kwok Ho[20], Fekri Abroug[21], Anne Kaarlola[22], Herwig Gerlach[23], Theodoros Kyprianou[24], Andrej Michalsen[25], Sylvie Chevret[26], and Benoît Schlemmer[1], for the Conflicus Study Investigators and for the Ethics Section of the European Society of Intensive Care Medicine*

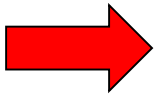
Mobley MJ. Intensive and Critical Care Nursing (2007) **23, 256—263**

The Nature of “Futility” Disputes

A Common Mental Model of Futility



These are ***relatively straightforward, technical judgments***



"I should be allowed to make these decisions at the bedside."

Problem 1: Not Straightforward Technical Judgments

- It is exceedingly rare for surrogates in ICUs to request treatments that are strictly futile (i.e., stand *no chance* of achieving their intended goal).

Is Treatment Futile?

- 71 year old man with mild dementia and severe COPD admitted with respiratory failure, septic shock and multi-organ failure. No advance directive.
  - 6 weeks in ICU
  - Minimally responsive after watershed infarcts
  - Ventilator and dialysis dependent
  - Off pressors, “stable” vital signs
  - Necrotic digits and pressure ulcers requiring serial debridement.

- Family insists on ongoing treatment, saying “he believes that life is sacred. we think he would choose this life over death”.

The Actual Ethical Question in 'Futility' Cases Hinges on Complex Value Judgments

- "Are there situations in which the patient's life could be extended (and doing so is requested by the patient/proxy), but doing so would be ethically wrong?"

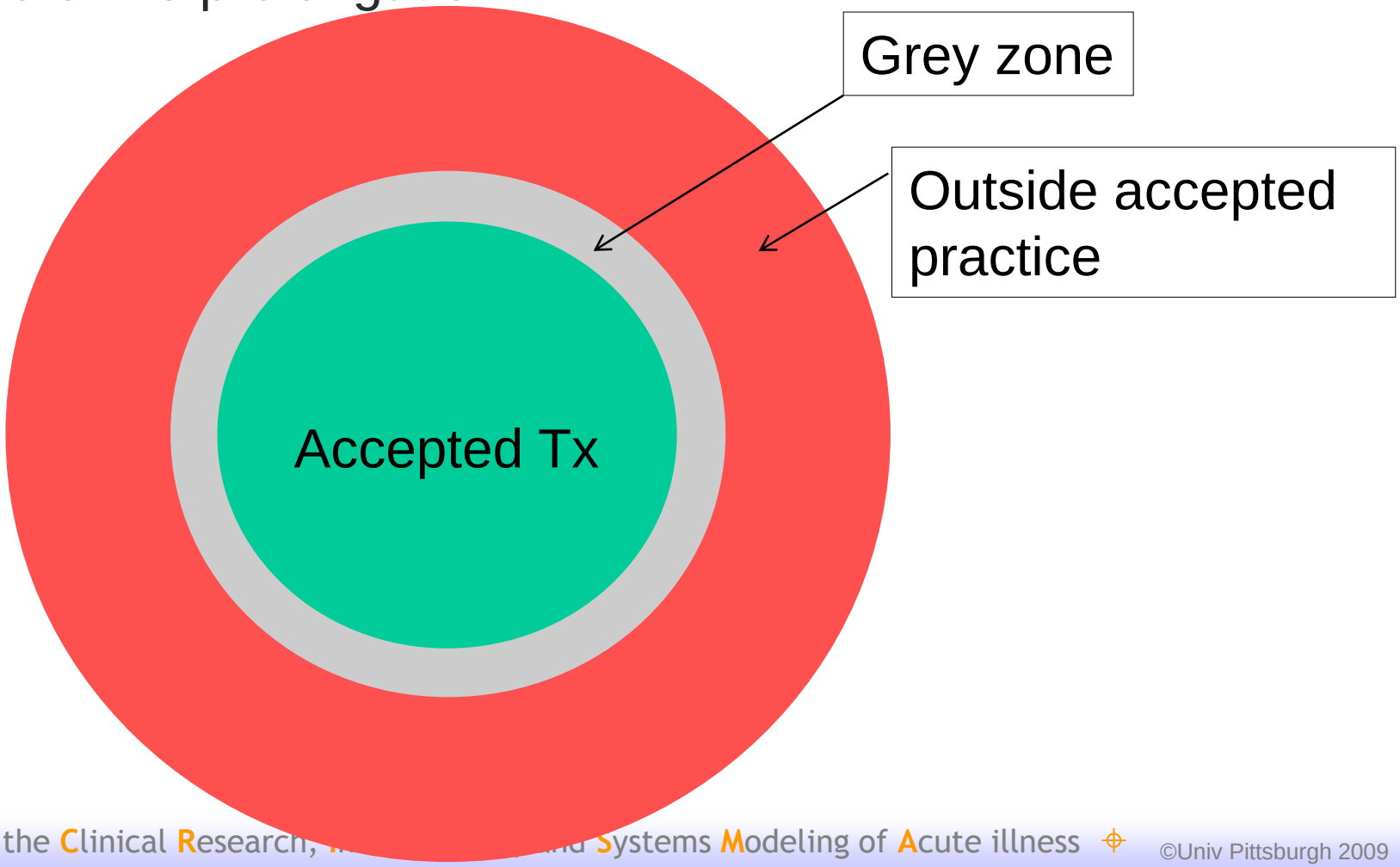
The Relevant Competing Ethical Considerations

- Patients' interest in living according to their values and preferences.
- Physicians' interest in acting in accord with professional integrity.
- Society's interest in just allocation of resources.

Problem 2: No Substantive Rules

'Grey Zone' Cases

- There are no clear, widely accepted criteria for when clinicians should refuse to provide treatments that hold some chance of life prolongation.



Problem 3: Wide Variability in Clinicians' Moral Judgments

Perceptions of Appropriateness of Care Among European and Israeli Intensive Care Unit Nurses and Physicians

Ruth D. Piers, MD
Elie Azoulay, MD, PhD
Bara Ricou, MD

Context Clinicians in intensive care units (ICUs) who perceive the care they provide as inappropriate experience moral distress and are at risk for burnout. This situation may jeopardize patient quality of care and increase staff turnover.

- In ~85% of cases, there was disagreement within the clinical team about whether the treatment was inappropriate.

Piers R. JAMA. 2011

The Influence of Physician Race, Age, and Gender on Physician Attitudes Toward Advance Care Directives and Preferences for End-Of-Life Decision-Making

Eric W. Mebane, MD,[*†‡] *Roy F. Oman, PhD,*[‡§] *Leo T. Kroonen, BA,*[¶] *and Mary K. Goldstein, MD*[†‡]

15% of African American and 2.5% of Caucasian **physicians** preferred aggressive treatment in the context of PVS.

Mortality associated with withdrawal of life-sustaining therapy for patients with severe traumatic brain injury: a Canadian multicentre cohort study

Alexis F. Turgeon MD MSc, François Lauzier MD MSc, Jean-François Simard BSc, Damon C. Scales MD PhD, Karen E.A. Burns MD MSc, Lynne Moore PhD, David A. Zygun MD MSc, Francis Bernard MD, Maureen O. Meade MD MSc, Tran Cong Dung MD MSc, Mohana Ratnapalan HBSc, Stephanie Todd BSc MBT, John Harlock MD, Dean A. Fergusson PhD; for the Canadian Critical Care Trials Group.

M B. CARTER,

Physic

Care Units

Caroline M. Quill, M.D., M.S.H.P.[1-2]

Sarah J. Ratcliffe, Ph.D.[3]

Michael O. Harhay, M.P.H.[2-3]

Scott D. Halpern, M.D., Ph.D.[2-5]

Problem #4: Substantial Inaccuracy in Physicians' Prognostications

Power and limitations of daily prognostications of death in the medical intensive care unit

William Meadow, MD; Anne Pohlman, MD, PhD; Laura Frain, MD; Yaya Ren, JD; John Paul Kress, MD; Winnie Teuteberg, MD; Jesse Hall, MD

Objective: We tested the accuracy of predictions of impending death for medical intensive care unit patients, offered daily by their professional medical caretakers.

Design: For 560 medical intensive care unit patients, on each medical intensive care unit day, we asked their attending physicians, fellows, residents, and registered nurses one question: "Do you think this patient will die in the hospital or survive to be discharged?"

Results: We obtained >6,000 predictions on 2018 medical intensive care unit patient days. Seventy-five percent of MICU patients who stayed ≥4 days had discordant predictions; that is, at least one caretaker predicted survival, whereas others predicted death before discharge. Only 107 of 206 (52%) patients with a prediction of "death before discharge" actually died in hospital. This number rose to 66% (96 of 145) for patients with 1 day of corroborated (i.e., >1) prediction of "death," and to 84% (79 of 94) with at least 1 unanimous day of predictions of death. However, although positive predictive value rose with increasingly stringent prediction criteria, sensitivity fell so that the area under the receiver-operator characteristic curve did not differ for single, corroborated, or unanimous predictions of death. Subsets of older (>65 yrs) and ventilated medical intensive care unit patients revealed parallel findings.

Conclusions: 1) Roughly half of all medical intensive care unit patients predicted to die in hospital survived to discharge nonetheless. 2) More highly corroborated predictions had better predictive value; although, approximately 15% of patients survived unexpectedly, even when predicted to die by all medical caretakers. (Crit Care Med 2011; 39:474–479)

KEY WORDS: prognostication; medical intensive care unit; clinical predictions; medical intensive care unit survival

"Approximately 15% of patients survived unexpectedly, even when predicted to die by all treating clinicians."

Meadow W. Crit Care Med; 2011

Problem #5: The Context of Vulnerable Patients

- Patients typically too sick to engage physicians in conversation about their values and preferences.
- Patients generally have no ability to choose their physician in acute critical illness.
- Limited ability to independently seek out alternative clinicians.

An Alternative Mental Model

- *"These are controversial, value-laden judgments that inevitably must be addressed, but we should proceed with great care when doing so."*

AMERICAN THORACIC SOCIETY DOCUMENTS

An Official ATS/AACN/ACCP/ESICM/SCCM Policy Statement: Responding to Requests for Potentially Inappropriate Treatments in Intensive Care Units

Gabriel T. Bosslet, Thaddeus M. Pope, Gordon D. Rubenfeld, Bernard Lo, Robert D. Truog, Cynda H. Rushton, J. Randall Curtis, Dee W. Ford, Molly Osborne, Cheryl Misak, David H. Au, Elie Azoulay, Baruch Brody, Brenda G. Fahy, Jesse B. Hall, Jozef Kesecioglu, Alexander A. Kon, Kathleen O. Lindell, and Douglas B. White; on behalf of The American Thoracic Society *ad hoc* Committee on Futile and Potentially Inappropriate Care

This Official Policy Statement of the American Thoracic Society (ATS) was approved by the ATS, January 2015, the American Association for Critical Care Nurses (AACN), December 2014, the American College of Chest Physicians (ACCP), October 2014, the European Society for Intensive Care Medicine (ESICM), September 2014, and the Society of Critical Care Medicine (SCCM), December 2014

http://www.atsjournals.org/journal/ajrccm

Bosslet G. AJRCCM 2015

Variability Across Existing Professional Society Guidelines

Prof. Society	Terminology	Approach to Resolution
ATS (AJRCCM 1991)	"A life-sustaining intervention is **futile** if reasoning and experience indicate that the intervention would be highly unlikely to result in meaningful survival for that patient."	None required
SCCM (Crit Care Med 1997)	"Treatments should be defined as futile only when they will not accomplish their intended goal, i.e. treatments that have no beneficial physiologic effect."	A procedural approach (unspecified) should be pursued that adheres to accepted conceptions of procedural fairness
AMA (JAMA 1999)	No definition provided	The disputed treatment should be provided unless/until a 7-step oversight process is completed and supports clinicians' claim.

Participants

Participating Professional Societies

- American Thoracic Society
- Society for Critical Care Medicine
- American Academy of Critical Care Nurses
- American College of Chest Physicians
- European Society of Intensive Care Medicine

Medicine

- Gabriel Bosslet
- Gordon Rubenfeld
- J. Randall Curtis
- Dee Ford
- Elie Azoulay
- Jozef Kesecioglu
- Molly Osborne
- Jesse Hall
- David Au
- Brenda Fahy
- Douglas White

Pediatrics

- Robert Truog
- Alexander Kon

Nursing

- Cynda Rushton
- Kathy Lindell

Public/patients

- Jill Raleigh
- Cheryl Misak

Law

- Thaddeus Pope

Bioethics

- Bernard Lo
- Baruch Brody

Methods

- Iterative consensus process involving a multi-disciplinary committee and representatives from each of the 5 participating professional societies.
  - Literature review
  - Review of existing professional society guidelines
  - Iterative in-person meetings and tele- and web-conferences over 2 years to reach consensus on key recommendations.
  - Writing committee drafted policy statement and iteratively revised in response to committee member comments.
  - Each professional society's ethics committee reviewed and approved the document.
  - External peer review.
  - Final approval by Board of Directors of each society.

Three Main Groups of Recommendations

- **Recommendations for:**
  - **Terminology** to describe disputes.
  - **Preventing** intractable disputes between clinicians and surrogates.
  - **Resolving** intractable disputes.

Guiding Considerations of the Policy

1. The policy will necessarily entail value judgments, which should be made explicit.

2. Neither individual clinicians nor families should be given authority to make unilateral decision.

3. Clinicians should not simply acquiesce to requests they believe are harmful to the patient or violate professional integrity.

4. In response to intractable conflict, the process of decision making should satisfy basic aspects of procedural fairness.

Recommendation

The term "potentially inappropriate" should be used, rather than "futile," to describe treatments that have at least some chance of accomplishing the effect sought by the patient, but clinicians believe that competing ethical considerations justify not providing them.

The term "futile" should only be used in the rare circumstance that an intervention simply cannot accomplish the intended physiologic goal.

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Contrasting Potentially Inappropriate Treatment (PIT) & Futile Treatment

	Ethical Justification for Refusal	Examples
PIT	Physician believes that administering the requested treatments would **violate professional integrity**. Reasons might be • that the treatment is highly unlikely to be successful, • is highly burdensome or unseemly, • is extremely expensive, or • is intended to achieve a goal of controversial value.	Ongoing use of life support in a patient who has widely metastatic cancer, multi-organ failure, and is ventilator dependent.
Futile interventions	Ineffectiveness in achieving physiological goals	Antifungal medications to treat MI; CPR in a patient with livedo reticularis and rigor mortis.

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Futile interventions	Ineffectiveness in achieving physiological goals	Antifungal medications to treat MI; CPR in a patient with livedo reticularis and rigor mortis.

Why Use the Term 'Potentially Inappropriate Treatment'?

Nudging Clinicians Toward a New Mental Model

- The word 'potentially' signals that the judgments are preliminary rather than final, and need some sort of verification.
- The word 'inappropriate' conveys more clearly than the word 'futile' that the assertion being made by clinicians is a value-laden claim rather than a technical one.
  - Tends to promote rather than cut off reason giving.

How Should We Manage Conflicts about Potentially Inappropriate Treatment?

The Gist

Intensive communication

Expert consultation

Fair process of dispute resolution

AMERICAN THORACIC SOCIETY DOCUMENTS

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Recommendation 1

Institutions should implement strategies to prevent intractable treatment conflicts, including proactive communication and early involvement of expert consultation.

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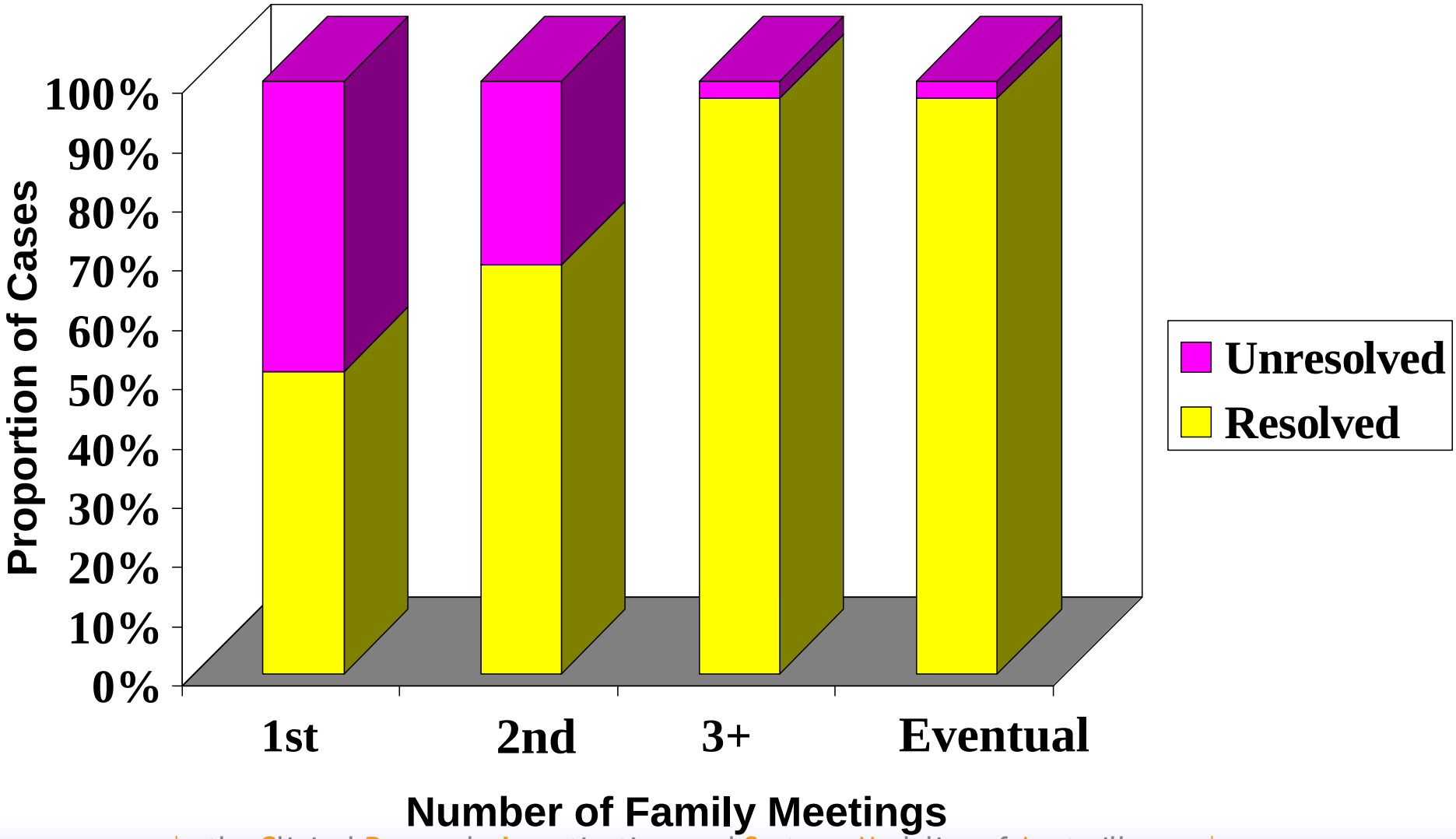
The Vast Majority of Disagreements are Resolved Without Unilateral Action

Garros et al. (2003); Prendergast (1998)



Goal: Prevent Low-level Conflict from Becoming Intractable Conflict

- Involve experts early to prevent “solvable” conflicts from becoming entrenched and intractable.

Shared Decision Making in ICUs: An American College of Critical Care Medicine and American Thoracic Society Policy Statement

Alexander A. Kon, MD, FCCM[1,2]; Judy E. Davidson, DNP, RN, FCCM[3];
Wynne Morrison, MD, MBE, FCCM[4]; Marion Danis, MD, FCCM[5]; Douglas B. White, MD, MAS[6]

Table 2. Recommended Practices for Improving Communication and Support for Surrogates in the Intensive Care Unit

Systems-level interventions
- Conduct regular, structured interprofessional family meetings (63–68)
- Integrate palliative care and/or ethics teams into ICU care for difficult cases (11, 14, 68–71)
- Provide printed educational materials to family (66, 67, 72, 73)
- Maintain dedicated meeting space for ICU family meetings

Clinician-level skills
- Coordinate an effective ICU family meeting
  - Establish consensus among treating clinicians before the meeting (68, 74)
  - Use a private, quiet space for family meetings (68, 74)
  - Introduce all participants
  - Use patient/family-centered communication strategies (*see below*)
  - Affirm nonabandonment and support family decisions (12, 75)
- Provide family-centered communication
  - Elicit surrogates' perceptions first (76)
  - Use active listening skills and deliver information in small chunks (77, 78)
  - Respond to questions and check for understanding of key facts (12, 76, 79)
  - Acknowledge and address emotion (13, 68, 75, 79, 80)
  - Support religious/spiritual needs and concerns (68, 81)
- Foster shared decision making (15–17, 68, 82)
  - Assess clinical prognosis and degree of certainty
  - Evaluate surrogate preferences for decision-making responsibility (18, 19, 21, 22)
  - Elicit the patient's treatment preferences and health-related values (83)

Crit Care Med. 2016

Ddx: Causes of Persistent Disagreement

Informational?

- Simple misunderstandings about prognosis
- Lack of awareness about comfort-focused pathway

Emotional/Interpersonal?

- Overwhelming grief
- Conflict within family
- Distrust of physicians' predictions
- Reluctance to act according to patient's values

Moral?

- Deep moral disagreement about what is in the patient's best interest

Intensive communication

Expert consultation

Fair process of dispute resolution

Effect of Ethics Consultations on Nonbeneficial Life-Sustaining Treatments in the Intensive Care Setting

A Randomized Controlled Trial

Lawrence J. Schneiderman, MD
Todd Gilmer, PhD

Context Ethics consultations increasingly are being used to resolve conflicts about life-sustaining interventions, but few studies have reported their outcomes.

- Intervention: ethics consult vs. usual care
- Setting: adult ICUs in 7 hospitals
- Patients: 551 patients "in whom value-related treatment conflicts arose"
  - Identified by nurses; reviewed by PI
  - Cross-over: 67/278 in intervention and 77/273 in usual care

Schneiderman, JAMA 2003; 290:1166

Outcome of Ethics Consult

	Intervention	Control	p value
Enroll to death:			
Hospital (days)	8.7	11.6	0.01
ICU (days)	6.4	7.7	0.03
Mortality(%)	62.7	57.8	0.20

No data on bereavement outcomes, patient-centeredness of care, decision quality.

Schneiderman, JAMA 2003; 290:1166

Proactive palliative care in the medical intensive care unit: Effects on length of stay for selected high-risk patients

Sally A. Norton, PhD, RN; Laura A. Hogan, MS, RN, ACHPN; Robert G. Holloway, MD, MPH; Helena Temkin-Greener, PhD, MPH; Marcia J. Buckley, MS, RN, BC-PCM; Timothy E. Quill, MD

Norton S. Crit Care Med 2007

The effect of a family support intervention on family satisfaction, length-of-stay, and cost of care in the intensive care unit

Wayne Shelton, PhD; Crystal Dea Moore, PhD; Sophia Socaris, MD; Jian Gao, PhD; Jane Dowling, PhD

Sheldon W. Crit Care Med 2010

PERSPECTIVE

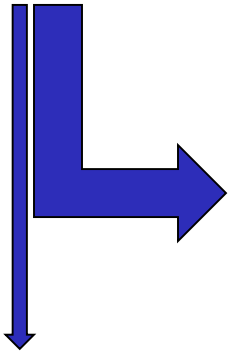
Resolution of Futility by Due Process: Early Experience with the Texas Advance Directives Act

Robert L. Fine, MD, and Thomas Wm. Mayo, JD

Table 1. **Rules for Resolving Futility Cases under the Texas Advance Directives Act, 1999**

1. The family must be given written information about hospital policy on the ethics consultation process.
2. The family must be given 48 hours' notice and be invited to participate in the consultation process.
3. The ethics consultation committee must provide a written report detailing its findings to the family.
4. If the ethics consultation process fails to resolve the dispute, the hospital, working with the family, must try to arrange transfer of the patient to another physician or institution willing to give the treatment requested by the family.
5. If after 10 days (measured from the time the family receives the written summary from the ethics consultation committee) no such provider can be found, the hospital and physician may unilaterally withhold or withdraw therapy that has been determined to be futile.
6. The patient or surrogate may ask a state court judge to grant an extension of time before treatment is withdrawn. This extension is to be granted only if the judge determines that there is a reasonable likelihood of finding a willing provider of the disputed treatment if more time is granted.
7. If the family does not seek an extension or the judge fails to grant one, futile treatment may be unilaterally withdrawn by the treatment team with immunity from civil and criminal prosecution.

47 consults for TADA process



37 consults (78%) resolved collaboratively with ethics consultation

10 cases to TADA process

Fine RL *Annals of Internal Medicine*. 2003; 138: 743-746.

How Should We Manage Intractable Disagreements about Potentially Inappropriate Treatment?

Options

1. Give patients/families all authority
2. Give physicians all authority.
3. Pursue a procedural dispute resolution strategy.

Approach 1: Give Families All Authority

Ethically unsustainable

- Confuses positive and negative rights. Patients' rights to demand treatments far weaker than their rights to refuse treatment.
- Ignores ethical importance of respecting professional integrity.
- May result in unfair distribution of scarce resources.

Practically problematic

- May worsen quality of dispute resolution in cases that are not intractable.

Strong Emotional Barriers to Stopping Life Support

- If families “have all the power”, this may fail to encourage the hard emotional/moral work needed to authorize treatment withdrawal when doing so is consistent with patient’s values.

White DB. JAMA. 2012

Approach #2: Give Individual Physicians All Authority

Ethical concerns

- Risks unwarranted variability and arbitrary decisions.
- Is inconsistent with democratic ideals for fairly resolving conflicts about fundamental interests.

The Importance of Procedural Fairness

- When there is deep disagreement and important interests are at stake, the process of decision-making takes on added ethical importance.

- Characteristics:
  - Oversight by legitimate body
  - Unconflicted decision makers
  - Transparency
  - Appeals to reasons that all can accept as relevant
  - Accountability
  - Opportunity for review and appeal

Daniels N. BMJ. 2003

Give Individual Physicians All Authority

Ethical concerns

- Risks unwarranted variability and arbitrary decisions.
- Is inconsistent with democratic ideals for fairly resolving conflicts about fundamental interests.
- May subtly disincentivize the hard work of finding a negotiated agreement.

"…Physicians and patients bring their own vulnerabilities to the decision-making process. Both are authors and victims of their own individual conflicting motivations, interests and expectations."

Katz J, The Silent World of Doctor and Patient, 1984, p. 102

Intensive communication

Expert consultation

Fair process of dispute resolution

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Recommendation 2

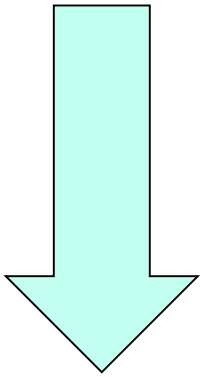
The term "potentially inappropriate" should be used, rather than "futile," to describe treatments that have at least some chance of accomplishing the effect sought by the patient, but clinicians believe that competing ethical considerations justify not providing them. Clinicians should communicate and advocate for the treatment plan they believe is appropriate. Requests for potentially inappropriate treatment that remain intractable despite intensive communication and negotiation should be managed by a fair process of dispute resolution.

Bosslet G. AJRCCM 2015

Last Resort: Process-based Approach to Dispute Resolution

Claim by clinician:
potentially inappropriate treatment

Fair process



Determination:
- Permissible treatment
- Inappropriate treatment

Ethical Justifications for a Procedural Approach to Dispute Resolution

- To diminish the possibility that natural human limitations (bias, ignorance, or idiosyncratic beliefs) impact patients' well-being.
- To conform with democratic ideals for resolving conflicts involving fundamental interests.
  - Transparency, legitimacy, accountability, opportunity for appeal.
- To give clinicians a sanctioned mechanism to challenge demands for interventions they believe are unwise.
- To protect vulnerable patients by putting in place 'process protections' similar to those available to patients in other clinical contexts.

Recommendation 2

Managing Requests for Potentially Inappropriate Treatment

1. Give notice of the process to surrogates
2. Continue negotiation during the dispute resolution process
3. Obtain a second medical opinion
4. Obtain review by an interdisciplinary hospital committee
5. Offer surrogates the opportunity to transfer the patient to an alternate institution
6. Inform surrogates of the opportunity to pursue extramural appeal
7. Implement the decision of the resolution process

Recommendation 3

Managing Requests for Physiologically Futile Interventions

- Clinicians need not provide physiologically futile interventions.
- They should carefully explain the rationale for their refusal.
- If disagreement persists, clinicians should obtain expert consultation to assist in conflict resolution and communication.
- There should be retrospective hospital review of all cases.

Conclusions

- Managing requests for potentially inappropriate treatment is deceptively complex.
- Prevention of intractable conflict is the most promising strategy to improve care.
  - System level interventions to improve communication
  - Early involvement of expert consultants
- For intractable disputes, a stepwise conflict resolution process is the least bad alternative currently available.

University of Pittsburgh Critical Care Medicine

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Recommendation 3b:
Managing Requests for PIT in Time Pressured Situations

- When time pressures make it infeasible to complete all steps of the conflict resolution process and clinicians have a high degree of certainty that the requested treatment is outside accepted practice, they should endeavor to achieve as much procedural oversight as the clinical situation allows and, if there is agreement, should refuse to provide the requested treatment

- All such cases should be undergo prompt retrospective review by a hospital committee.