Requests for Potentially Non-beneficial Treatment

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Disclosure of ABIM Service: Robert Macauley, MD

- I am a current member of the Test-Writing Committee on Hospice and Palliative Medicine.
- To protect the integrity of certification, ABIM enforces strict confidentiality and ownership of exam content.
- As a current member of the Test-Writing Committee on Hospice and Palliative Medicine, I agree to keep exam information confidential.
- ***No exam questions will be disclosed in my presentation.***

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Hippocrates on the Goals of Medicine

Doing away with the suffering of the sick, lessening the violence of their diseases, and refusing to treat those who are overmastered by their diseases, realizing that in such cases medicine is powerless.

History of Futility

- Pre-mid-20th century
  - Physicians simply wouldn't mention/offer things they didn't think would help
- Mid-20th century: Shift toward patient autonomy
  - Recognition of importance of informed consent
    - First in battery law, then in negligence law
    - Coincided with other "rights" movements
- Right to refuse treatment
  - American Hospital Association Patient Bill of Rights (1973)
  - California Natural Death Act (1976)
  - *In re: Karen Ann Quinlan* (New Jersey Supreme Court, 1976)
    - Competent patients have the right to reject medical treatment

Positive and negative rights

- Negative rights are those of non-interference
- Positive rights are *entitlement* rights
  - Which incur the obligation for someone else to assist in acquiring what someone has a "right" to

Extending rights

- The "right to die" was originally a negative right, and some have attempted to expand that to a positive right (i.e., "medical aid in dying")
  - Which we'll cover in the other session
- But here we're talking about extending the negative right to physicians
  - The "right to die" movement was about patients having the right to say no. Do physicians have the same right?

The Futility Movement

- Literature
  - 1987: First reference to “futility”
- Position statements
  - 1986: American Thoracic Society
  - 1987: Hastings Center
  - 1990: Society of Critical Care Medicine
  - 1991: American Medical Association
  - 1994: American Academy of Pediatrics
- Legislation
  - 1999: Texas Advance Directive Act

Texas Advance Directives Act (1999)

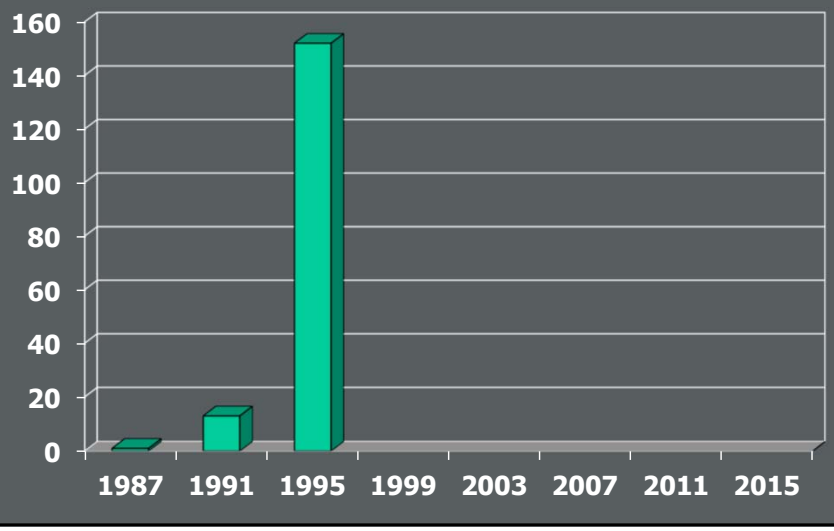
- Hospital ethics committees authorized to function as courts in reviewing requests for “futile treatment”
- Process
  - “Futile” request for treatment is reviewed by hospital ethics committee
  - Family given 48 hour notice to participate in the committee consultation
  - If ethics committee concurs with physician, family has 10 days to identify a facility willing to accept transfer
  - If no transfer after 10 days and no court order for extension, then a unilateral decision to withdraw treatment

No Ethical Obligation to Provide "Futile" Interventions

Physicians are not ethically obligated to deliver care that, in their best professional judgment, will not have a reasonable chance of benefiting their patients. Patients should not be given treatments simply because they demand them.

American Medical Association Code of Medical Ethics (1994)

Medline References to "Futility"



Problems

- Definitions
- Reasoning backward
- Implementation

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Problems

- Definitions
- Reasoning backward
- Implementation

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Medical futility's many definitions

Futility has a "variety of meanings … including the narrow sense -- physiologic inefficacy and inability to postpone death -- and a broad sense -- inability to prolong life for a time, inability to maintain an acceptable quality of life, very low probability of achieving any one of the foregoing."

Youngner, "Who Defines Futility?" *JAMA* 1988

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Physiologic

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Physiologic
Qualitative (normative)

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Physiologic
Qualitative (normative)
Probabilistic

Youngner, "Who Defines Futility?" *JAMA* 1988

Futility's Many Definitions

- Physiologic futility
  - The procedure definitely won't achieve its goals
  - E.g., IV medications in an asystolic patient who has refused chest compressions
- Probabilistic futility
  - The procedure is very unlikely to achieve its goals
  - E.g., out-of-hospital CPR
- Qualitative futility
  - Even if the goal is achieved, it may not be worth it
  - E.g., artificial nutrition in a PVS patient

Futility is Defined by the Patient's Goals

- Something is futile if it won't achieve its goal
  - A certain procedure may be "futile" for one patient and not for another
  - E.g., endotracheal intubation may be useful in a patient who wants to survive at all costs, but futile in a patient whose goal is comfort care
- **Futility is inherently a value-laden term.**
  - It's not a question of physiological effect, but rather benefit
  - "Benefit" as defined by the patient

Problems

- Definitions
- Reasoning backward
- Implementation

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Reasoning backward

- If an intervention has a 1:1,000 chance of saving a patient's life
  - Physicians likely would not want to provide it
  - But if it's the patient's *only* chance at survival, the patient/family might well request it
- There are only three reasons not to provide a potentially beneficial treatment
  - Patient/surrogate refusal
  - Rationing
    - Otherwise known as "the R-word" in the United States
  - "Futility"

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Elegant Logic

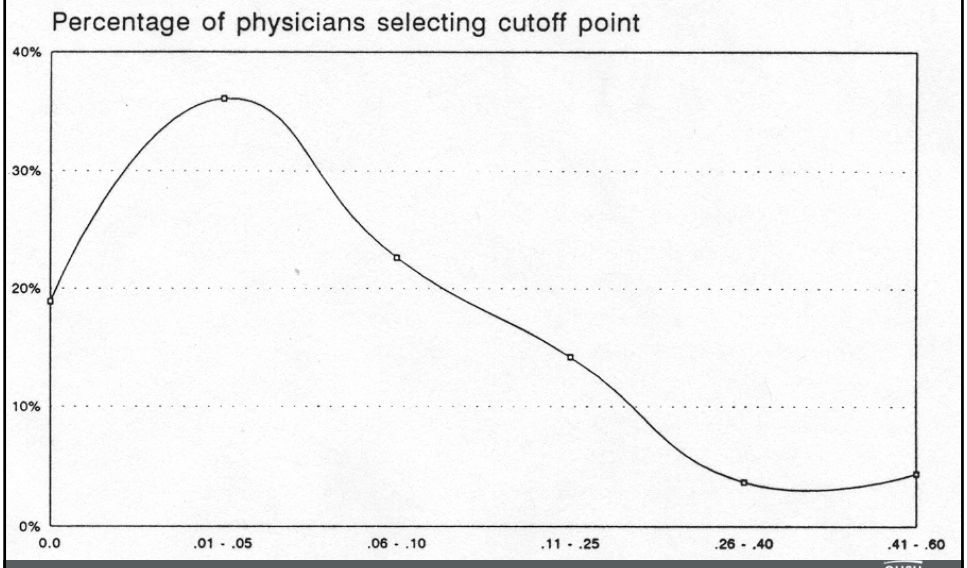
a. Physicians aren't obligated to provide "futile" treatment.
b. Treatment ___ is "futile".
c. I am not obligated to provide ____.

Futility: the "F-word" in medical ethics.

Physicians' Assessment of Futility

McCrary *et al.*, *J Clin Ethics* **5** (1994):100-4

Physicians' Assessment of Futility



McCrary *et al.*, *J Clin Ethics* **5** (1994):100-4

Problems

- Definitions
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"So how's TADA working out?"

— Question I posed over lunch to

Director of
Ethics at large Texas hospital

"Well, if you don't count having to move your family to a secure location under cover of darkness, I'd say pretty well."

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The Rise and Fall of the Futility Movement

BETWEEN 1987 and 1996, the concept of "medical futility" was debated in the medical community with a vehemence that few philosophical concepts elicit. Before 1987, the concept was virtually unrecognized. Interest in the concept peaked in 1995, when 134 articles on the topic were published, and has subsequently waned; a Medline search of the key word "futility" for the year 1999 yielded only 31 articles.

The movement to establish a policy on futile treatment was an attempt to convince society that physicians could use their clinical judgment or epidemiologic skills to determine whether a particular treatment would be futile in a particular clinical situation. The idea was that once such a determination had been made, the physician should be allowed to withhold or withdraw the treatment, even over the objections of a competent patient.

In this article, we analyze the rise and fall of the "futility movement." Broadly speaking, discussions of futility can be grouped into four categories: attempts to define medical futility, attempts to resolve the debate with the use of empirical data, discussions that cast the debate as a struggle between the autonomy of patients and the autonomy of physicians, and attempts to develop a process for resolving disputes over futility.

Futile care in hospitals is still very much an issue, yet doctors today are no more empowered to declare a treatment futile unilaterally than they were 15 years ago.

ATTEMPTS TO DEFINE FUTILITY

end a patient's total dependence on intensive medical care."[1]

Using these definitions, Schneiderman et al. argued that once a treatment has been deemed futile, medical professionals have no ethical obligation to provide it. Their underlying assumption was that just because a treatment has an effect on the patient, it does not necessarily benefit the patient. This distinction between an effect and a benefit became an influential notion. Veatch and Spicer noted, for example, that "in order to establish that care is futile, the clinician must claim that even though the care predictably will have some effect that changes the way that the patient dies, the effect is not beneficial on balance."[9] Critics raised objections and pointed out exceptions to each of the thoughtful definitions offered by Schneiderman et al. and others, and as a result, no consensus was achieved.

Several authors shifted the debate away from definitions of futility to rationing. They believed it would be easier to achieve a consensus about rationing and that it expressed the essential problem — limited medical resources — in a more explicit way.[10-12] Many objected, however, that solutions based on rationing, though potentially viable, addressed a different set of issues. Decisions about futility involved moral judgments about right or good care. Decisions about rationing, in contrast, addressed the question of how limited resources should best be used. Such decisions therefore derived from the principle of distributive justice.

EMPIRICAL ASSESSMENTS OF FUTILITY

Several authors sought consensus by attempting to determine empirically the threshold for a physician's judgment that further treatment would be futile. In various studies, the threshold, expressed in terms of the physician's prediction of the chance of survival, ranged from 0 to 60 percent, although responses tended to cluster around 5 percent.[13-16] Critics argued that the great variability in responses

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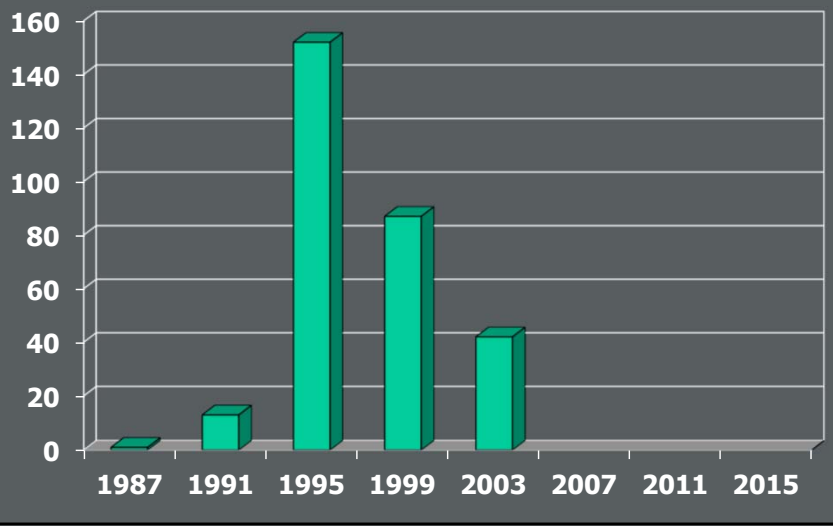

So What Happened?

- We couldn't agree on the definition
- Even if we had agreed on the definition, we couldn't agree on who should apply the definition
- Even if we had agreed on the definition and who should have applied it, we couldn't agree on what to do when people disagreed on the final decision
- So we gave up, and fell back on narrowly defined procedural policies that are rarely used
  - Except in Texas
- Ultimately, our discussion of futility was futile (depending on your definition and who applies it)

Medical Futility in End-of-Life Care (AMA, 2005)

When further intervention to prolong the life of a patient becomes futile, physicians have an obligation to shift the intent of care toward comfort and closure. However, there are necessary value judgments involved in coming to the assessment of futility. These judgments must give consideration to patient or proxy assessments of worthwhile outcomes.

But then people started talking about it again

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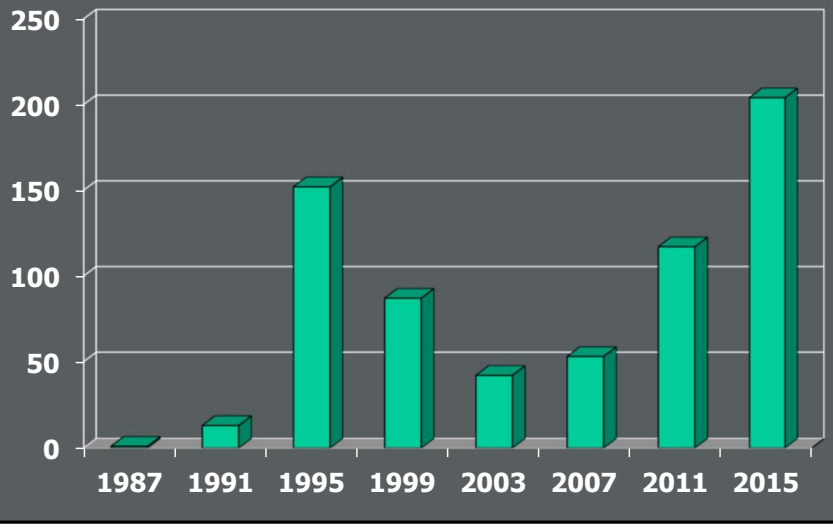
Medline References to "Futility"



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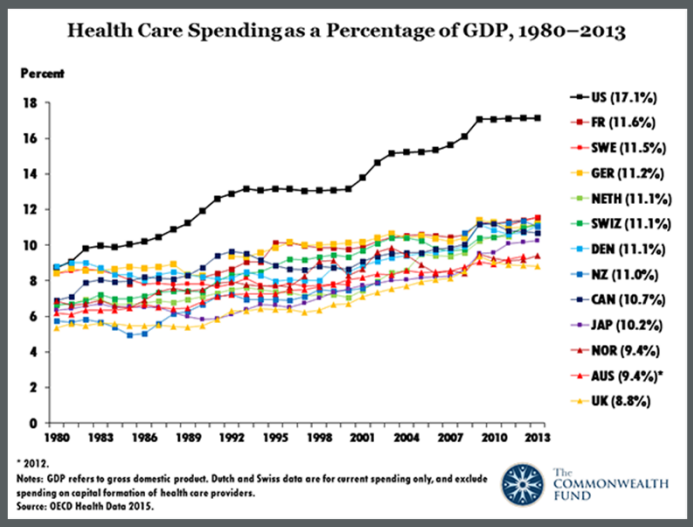
Why are we interested in futility again?



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2015 Consensus Statement

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 Treatment

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

Background: There is controversy about how to manage requests by patients or surrogates for treatments that clinicians believe should not be administered.

Purpose: This multisociety statement provides recommendations to prevent and manage intractable disagreements about the use of such treatments in intensive care units.

Methods: The recommendations were developed using an iterative consensus process, including expert committee development and peer review by designated committees of each of the participating professional societies (American Thoracic Society, American

potentially inappropriate treatments that remain intractable despite intensive communication and negotiation should be managed by a fair process of conflict resolution; this process should include hospital review, attempts to find a willing provider at another institution, and opportunity for external review of decisions. 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 seek procedural oversight to the extent allowed by the clinical situation and need not provide the requested treatment. (3) Use of the term "futile" should be restricted to the rare situations in which surrogates request interventions that simply cannot accomplish

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Consensus recommendation #2

- Use "potentially inappropriate," rather than "futile"
- Advocate for an appropriate treatment plan
- Continued requests should be managed by a fair process
  1. Enlist expert consultation to continue negotiation during the dispute resolution process
  2. Give notice of the process to surrogates
  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

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Consensus recommendation #2

- Use "potentially ~~inappropriate,~~" **non-beneficial** rather than "futile"
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Consensus recommendation #3

Clinicians should not provide "futile" interventions (i.e., those that won't achieve the physiologic goal).

Clinicians should not provide "legally proscribed" or "legally discretionary" non-beneficial treatments.

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Consensus recommendation #3

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Consensus recommendation #4

The medical profession should lead public engagement efforts and advocate for policies and legislation about when life-prolonging technologies should not be used.

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Consensus recommendation #1

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

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Steps to prevent "futility" conflicts

Steps to prevent "futility conflicts"

DO

1. Address legal concerns
2. Clarify patient goals
3. Offer recommendations with those goals in mind
4. Take into account burdens as well as benefits
5. Utilize informed assent

DON'T

1. Dwell on treatments which do "not have a reasonable chance of benefiting the patient"
2. Use the F-word

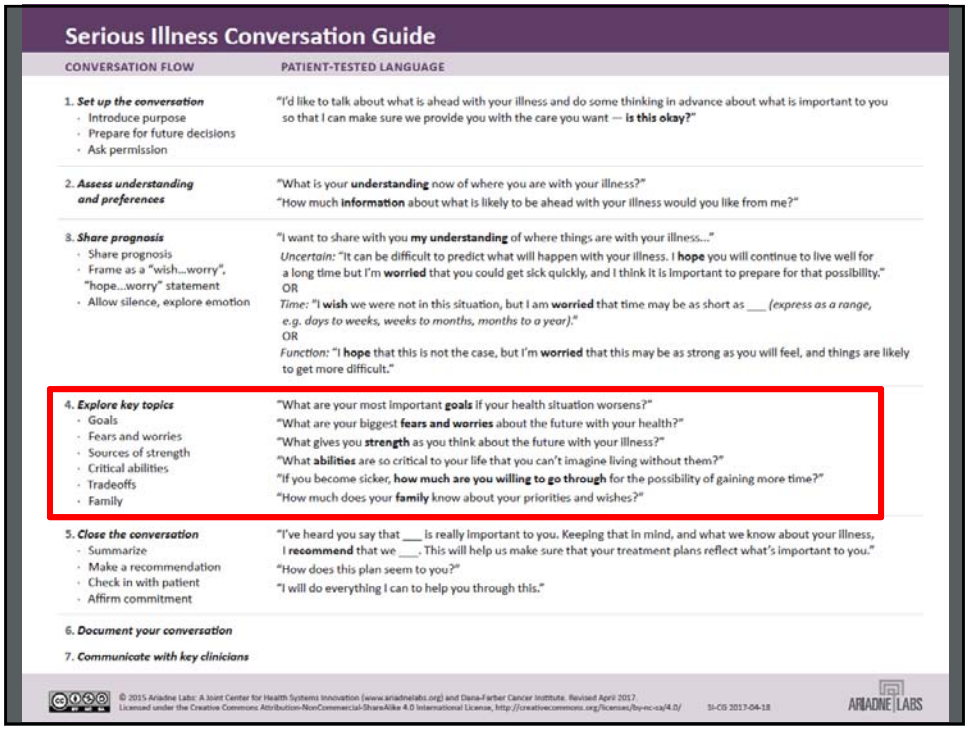
DO address legal concerns

- In the U.S., if a family sues to keep treatment in place, they'll usually win
  - But they usually don't sue
- If a family subsequently sues because treatment was withdrawn and patient died, they generally won't win
  - Unless the physicians were really callous

TM Pope, "Futile or non-beneficial treatment," *J Clin Eth* 2011 (**22**): 277-96.

DO clarify patient goals

- Recognizes that benefit is defined by the patient's goals
- Time-intensive (in the beginning)
  - Time-, effort-, and pain-saving in the end
  - Ideally involves Interdisciplinary Team
- Verify that goals are
  - Real: a specific treatment is rarely a goal in itself
  - Realistic (i.e., achievable)



Serious Illness Conversation Guide

CONVERSATION FLOW	PATIENT-TESTED LANGUAGE
1. ***Set up the conversation*** · Introduce purpose · Prepare for future decisions · Ask permission	"I'd like to talk about what is ahead with your illness and do some thinking in advance about what is important to you so that I can make sure we provide you with the care you want — **is this okay?**"
2. ***Assess understanding and preferences***	"What is your **understanding** now of where you are with your illness?" "How much **information** about what is likely to be ahead with your illness would you like from me?"
3. ***Share prognosis*** · Share prognosis · Frame as a "wish...worry", "hope...worry" statement · Allow silence, explore emotion	"I want to share with you **my understanding** of where things are with your illness..." *Uncertain:* "It can be difficult to predict what will happen with your illness. I **hope** you will continue to live well for a long time but I'm **worried** that you could get sick quickly, and I think it is important to prepare for that possibility." OR *Time:* "I **wish** we were not in this situation, but I am **worried** that time may be as short as ___ *(express as a range, e.g. days to weeks, weeks to months, months to a year).*" OR *Function:* "I **hope** that this is not the case, but I'm **worried** that this may be as strong as you will feel, and things are likely to get more difficult."
4. ***Explore key topics*** · Goals · Fears and worries · Sources of strength · Critical abilities · Tradeoffs · Family	"What are your most important **goals** if your health situation worsens?" "What are your biggest **fears and worries** about the future with your health?" "What gives you **strength** as you think about the future with your illness?" "What **abilities** are so critical to your life that you can't imagine living without them?" "If you become sicker, **how much are you willing to go through** for the possibility of gaining more time?" "How much does your **family** know about your priorities and wishes?"
5. ***Close the conversation*** · Summarize · Make a recommendation · Check in with patient · Affirm commitment	"I've heard you say that ___ is really important to you. Keeping that in mind, and what we know about your illness, I **recommend** that we ___. This will help us make sure that your treatment plans reflect what's important to you." "How does this plan seem to you?" "I will do everything I can to help you through this."
6. ***Document your conversation***	
7. ***Communicate with key clinicians***	

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ARIADNE LABS

DO offer recommendations based on those goals

- Recommend treatments that are consonant with the patient's goals
  - Apply expert knowledge and perspective
- Seek confirmation, engage in dialogue
- Not paternalistic
  - Recognizes physician's fiduciary responsibility

DO take into account burdens as well as benefits

- Most potentially non-beneficial treatment also incurs suffering or loss of meaning

DO utilize informed assent

- Provide full information about risks and benefits
- Convey specific recommendations about medically proposed course
  - Inform patient/family that they are entitled to accept medical team's recommendations
  - Clearly indicated that patient and family are entitled to disagree

Curtis and Burt, "The Ethics of Unilateral DNR Orders," *Chest* **132** (2007)

DON'T dwell on non-beneficial treatments

- We don't need to focus on things we're <u>not</u> going to be doing for the patient
  - Instead focus on what we will be doing, to help achieve the patient's goals
- How did CPR become a universal human right?
- Cautions
  - Focus on individual patient (not rationing, one patient at a time)
  - Requires significant self-reflection to determine bias (a.k.a. "qualitative futility")

Categories of disclosure

1. Withholding treatments that patients/families are not likely to expect for the patient's specific condition
   - Ex lap for dying patient is MSOF
2. Withholding treatments that are clearly not indicated but that most patients/families have come to expect
   - CPR
3. Withdrawing a therapy no longer indicated

Assent required

Curtis and Burt, "The Ethics of Unilateral DNR Orders," *Chest* **132** (2007)

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DON'T use the F-word

- We might think we know what we mean by it
  - Although we probably don't
- But to patients and families, it sounds like we're saying, "It isn't worth our effort to try to save this patient."

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Thank You

Case

- A 78-year-old patient with oxygen-dependent chronic obstructive pulmonary disease presents to the Emergency Department in acute respiratory distress. He has no advance directive and no family is present. He is intubated and admitted to the ICU.
- When his family arrives, they state that he is a “fighter” and has pulled through defied gloomy expectations in the past.
- They identify his primary goals as living at home and not being dependent on other people.
- They demand maximal treatment.

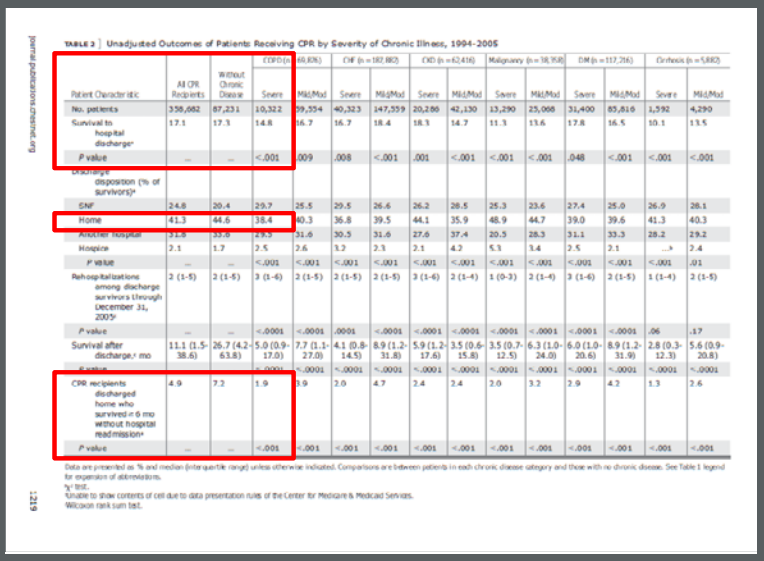

TABLE 3 | Unadjusted Outcomes of Patients Receiving CPR by Severity of Chronic Illness, 1994-2005

Patient Characteristic	All CPR Recipients	Without Chronic Disease	COPD (n = 68,836)		CHF (n = 182,882)		CKD (n = 62,416)		Malignancy (n = 38,958)		DM (n = 117,216)		Cirrhosis (n = 5,882)	
			Severe	Mild/Mod	Severe	Mild/Mod	Severe	Mild/Mod	Severe	Mild/Mod	Severe	Mild/Mod	Severe	Mild/Mod
No. patients	358,082	87,231	10,322	29,554	40,323	147,559	20,286	42,130	13,290	25,068	31,400	85,816	1,592	4,290
Survival to hospital discharge*	17.1	17.1	14.8	16.7	16.7	18.4	18.3	14.7	11.3	13.6	17.8	16.5	10.1	13.5
P value	...	...	<.001	.009	.008	<.001	.001	<.001	<.001	<.001	.048	<.001	<.001	<.001
Discharge disposition (% of survivors)*														
SNF	24.8	20.4	29.7	25.5	29.5	26.6	26.2	28.5	25.3	23.6	27.4	25.0	26.9	28.1
Home	41.3	44.6	38.4	40.3	36.8	39.5	44.1	35.9	48.9	44.7	39.0	39.6	41.3	40.3
Another hospital	31.8	33.6	29.5	31.6	30.5	31.6	27.6	37.4	20.5	28.3	31.1	33.3	28.2	29.2
Hospice	2.1	1.7	2.5	2.6	3.2	2.3	2.1	4.2	5.3	3.4	2.5	2.1	...†	2.4
P value	...	...	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	.01
Rehospitalizations among discharge survivors through December 31, 2005‡	2 (1-5)	2 (1-5)	3 (1-6)	2 (1-5)	2 (1-5)	2 (1-5)	3 (1-6)	2 (1-4)	1 (0-3)	2 (1-4)	3 (1-6)	2 (1-5)	1 (1-4)	2 (1-5)
P value	...	...	<.0001	<.0001	.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	.06	.17
Survival after discharge,‡ mo	11.1 (1.5-38.6)	26.7 (4.2-63.8)	5.0 (0.9-17.0)	7.7 (1.1-27.0)	4.1 (0.8-14.5)	8.9 (1.2-31.8)	5.9 (1.2-17.6)	3.5 (0.6-15.8)	3.5 (0.7-12.5)	6.3 (1.0-24.0)	6.0 (1.0-20.6)	8.9 (1.2-31.9)	2.8 (0.3-12.3)	5.6 (0.9-20.8)
P value	...	...	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001
CPR recipients discharged home who survived n 6 mo without hospital readmission*	4.9	7.2	1.9	3.9	2.0	4.7	2.4	2.4	2.0	3.2	2.9	4.2	1.3	2.6
P value	...	...	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001

Data are presented as % and median (interquartile range) unless otherwise indicated. Comparisons are between patients in each chronic disease category and those with no chronic disease. See Table 1 legend for expansion of abbreviations.
*χ² test.
†Unable to show contents of cell due to data presentation rules of the Center for Medicare & Medicaid Services.
‡Wilcoxon rank sum test.

Stapleton et al., "Long-term Outcomes After In-Hospital CPR in Older Adults With Chronic Illness," *CHEST* 2014; 146(5): 1214 – 1225.

Case

1. What questions should you ask?
2. What treatments should be offered?
3. What treatments should *not* be offered?
4. What do you do if the family does not concur with your recommendations?