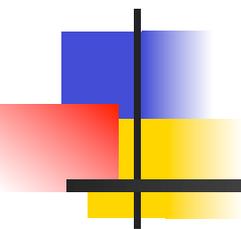
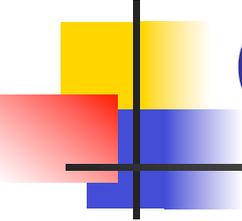


Medical Futility and End of life Care



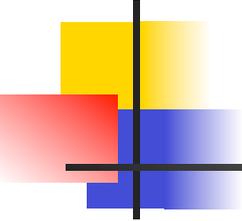
Jeff Kaufhold, MD FACP
2013

Daniel P Sulmasy, OFM, MD, PhD
Director, The Bioethics Institute
New York Medical Center
July 17, 2004



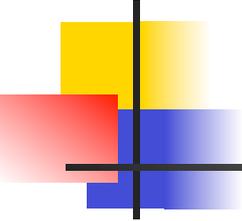
Case

- 76 y.o. female with Multiple Myeloma admitted with Sepsis.
- Heavily pretreated, no further chemo available
- On vent, Pressors
- Daughter wants everything done.



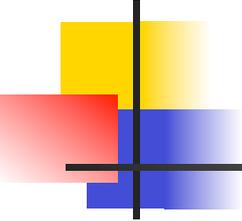
Medical Futility And End of life Care

- History of Futility and futility law
- Religious and Moral Principles
- Probability
- Dealing with the case
 - Establishing a relationship
 - Establishing limits
 - 48 hour waiting period
- Identifying patients who should have the discussion



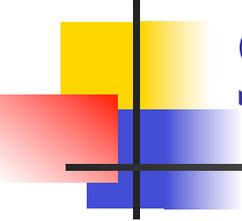
Futility, a History

- Smith Papyrus, 1700 B.C.
 - Entreaty to not intervene if spinal cord is transected
 - This Egyptian papyrus, found in 1900's, references a much older text.



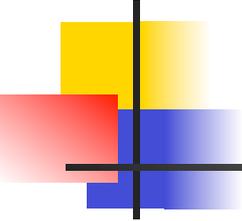
Futility, a History

- Smith Papyrus, 1700 B.C.
 - Entreaty to not intervene if spinal cord is transected
- Hippocrates, 460 – 377 B.C.
 - “On The Art” – the physician should refuse to treat in cases where medicine is powerless



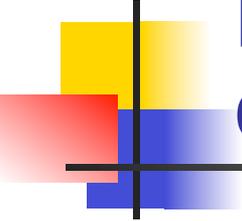
Social norms regarding cancer

- 1950's – call it something else.
- 1960's – Inform pt of diagnosis
- 1970's – Informed consent
- 1990's - Informed Demand



Evolution of Futility

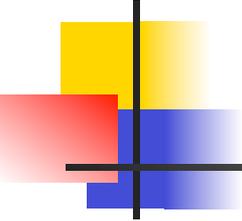
- In the 1970's, doctors would not remove life support even if the family ASKED for it. You didn't die in a hospital without getting CPR first.
- Once there was a safe harbor for withdrawal of care, doctors became comfortable with it.
- The safe harbor came after Quinlan 1976.
- Now called inappropriate care or Nonbeneficial care.



States with statutes regarding physician refusal of nonbeneficial care.

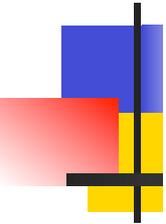
- Alaska, California, Delaware, Hawaii, Maine, Mississippi, New Jersey, New Mexico, Tennessee, Texas and Wyoming.
- All use the Uniform health Care Benefits act as a guide.
- As of 2016

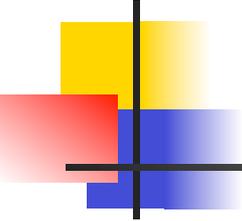
10 States' Laws Address Medical Futility



- All permit healthcare providers to refuse “medically ineffective’ or “medically inappropriate” care.
- All require healthcare providers or facilities to notify the patient or surrogate when proposed treatment is determined to be futile.
- All require that life-sustaining treatment be continued until the patient can be transferred to another facility willing to comply with the patient’s instructions.
- All require assistance in locating and transferring the patient to the other healthcare facility.
 - Managing Patients or Families who demand Medically Futile Care. 2016. Jan Slater Anderson, JD, MBA -Online

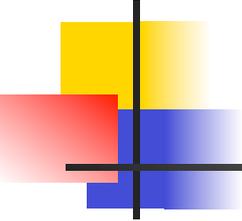
Summary of Provision	AK	CA	DE	HI	ME	MS	NJ	NM	TN	TX	WY
Healthcare institution may decline to comply if the patient's instruction or decision is contrary to the institution's policies.	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Physician may decline to comply if the patient's instruction or decision requires medically ineffective/inappropriate treatment.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Definition of medically ineffective treatment.	✓							✓			
If the physician or facility declines to comply with the patient's instruction or decision, the patient and the person authorized to make healthcare decisions on the part of the patient must be informed promptly.	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
If the physician or facility declines to comply with the patient's instruction or decision, continuing care, including life-sustaining treatment, must be continued until the patient can be transferred to another facility willing to comply with the patient's instruction or decision.	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
The physician or facility must immediately make all reasonable efforts to assist in the patient's transfer to another facility willing to comply with the patient's instruction or decision.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Life-sustaining treatment may be discontinued after a fixed period of time if no other facility is willing to accept the patient.										✓	





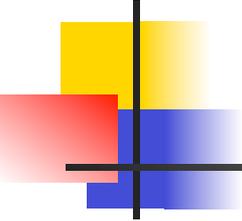
Texas Statute

- Texas Advance Directive Act (“TADA”) sec. 166.046
- “I don’t want people to like Texas. I prefer if they hate and FEAR it.”
 - H Tristan Englehart, PhD.



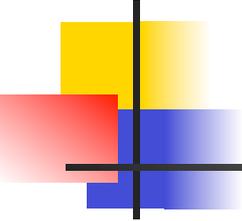
Texas Statute

- A patient may be removed from life support and a doctor may refuse to provide inappropriate treatment to a patient if
 - The doctor believes it is non beneficial
 - Must be confirmed by the hospitals ethics committee.
 - Surrogate has 10 days to try to find another provider.
 - On the 11th day, facility may withdraw treatment even against the surrogates wishes.
 - Doctor has immunity if process is followed.



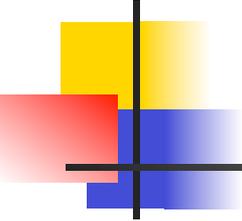
Texas Statute

- Three components:
 - 1. Process establishes a Community standard for the care of that particular case.
 - If no hospital is willing to take the case, it implies that other providers agree further care is futile.
 - 2. Competencies of Doctor and ethics committee members.
 - 3. Cultural Norms
 - Has everything been done?
 - Are ethics comm members biased / acting in the interest of the institution or the patient?



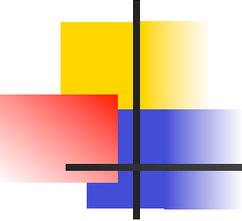
Religious Principles

- Intrinsic Dignity
 - Made in the image of God
- Alien Dignity
 - Relationships define our being.
- Also a fact that we are Finite



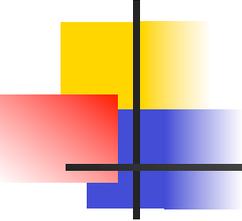
Religious Principles

- Life is a gift, and we are its stewards
- Limits to stewardship
 - Illness is a burden
 - Costs and burden to family/caregivers
 - Futile care need not be given.



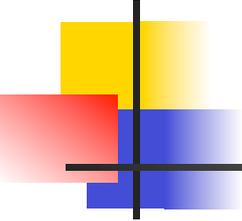
Moral Principles

- No moral obligation to provide futile Tx.
- What is Futile Treatment?
 - Non-beneficial
 - Inappropriate treatment at the end of life
 - What is the real goal?
 - Free of pain and suffering



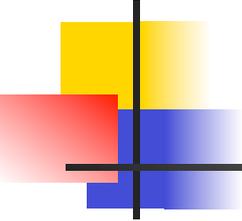
Moral Principles

- What is Futile Treatment?
 - Subjective Futility
 - Patient won't be able to appreciate benefit
 - This is ***not sufficient*** moral argument to withhold therapy
 - Objective Futility (biomedical use)
 - No objective benefit to any observer



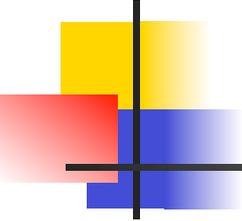
Moral Principles

- Medical Realism
 - There are facts
 - Trained people can make judgements
 - But we are fallible
 - We have to relate the *data* to the *patient*
 - *This is the tricky part of the art.*
 - Requires use of probability.



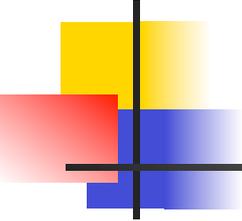
Probability

- Is this patient going to die?
 - Probably.
- Even with treatment?
 - Probably.
- Can you be more specific?
 - Probably.



Probability

- Prognosis is the probability that a patient will respond to tx, plus the probability that the disease will kill them.
- Probability that we use in individual cases comes from objective data about the particulars of the case, plus experience, plus common sense.
 - This process is fallible, but we do the best we can.



Probability

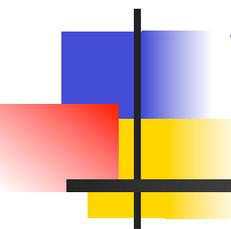
- Three factors:
 - Frequency:
 - Prediction:
 - Strength of belief

- Lets apply to the case:

Probability

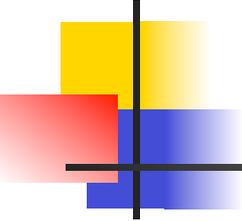
Myeloma with sepsis

- Frequency: (80% of myeloma pts do not wean from vent)
 - Based on studies
- Prediction: (1% likelihood of survival for this pt)
 - Based on Karnovsky score in Onc literature
 - Based on APACHE score in ICU literature
- Strength of belief
 - P value
 - “Reasonable degree of medical certitude”



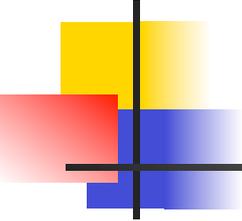
“Ultimately, Ethics is about
What to Do”

Aristotle, 384 – 322 B.C.



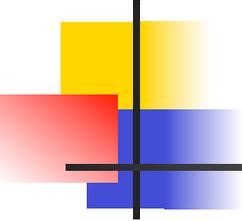
Morality of Futility

- Judgment enters Morality when decision is made about taking action.
 - Actions:
 - Wean from vent?
 - Wean from pressors?
 - Stop Antibiotics?
 - Stop tube feedings/ IV fluids?



Morality of Futility

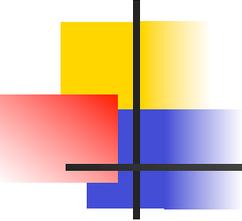
- Judgment enters Morality when decision is made about taking action.
 - Approaches:
 - Pragmatic – does this help the patient?
 - Remember, removing pt from life support may kill them, but might it also stop their suffering?
 - Moral (prudential) – is this the right thing to do?



Back to the Case

Myeloma with sepsis

- Frequency:
 - (80% of myeloma pts do not wean from vent)
- Prediction:
 - (1% likelihood of survival for this pt)
- Strength of belief
 - “Reasonable degree of medical certitude”
- Pragmatic approach
 - CPR will not help pt get better
- Prudential approach
 - Morally wrong to provide inappropriate treatment.



Back to the Case

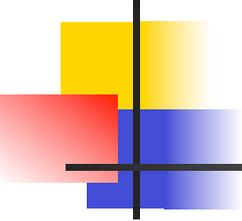
Myeloma with sepsis

- Pragmatic approach
 - CPR will not help pt get better
- Prudential approach
 - Morally wrong to provide inappropriate treatment.
- Recommendation:
 - Make the pt DNR – CC arrest
 - Consider withdrawal of life support
- How do we proceed with the family?

Back to the Case

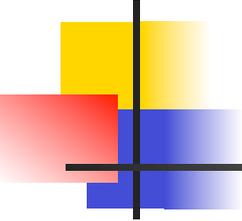
Myeloma with sepsis

- The family in town wants to keep Mom comfortable, and see she is suffering on life support.
- However, the out of town daughter is “in charge” and insists everything be done.
- Cultural barriers arise.
- *Tilden. Nurs Res: 2001, 50;105-115.*
 - *Its Stressful to be the surrogate*
 - Guilt, Ambivalence, Depression, Anger.



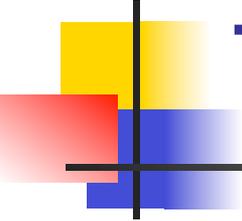
How to proceed Clinically

- Establish relationship with family
- Review case (how did she get here)
- Describe level of illness
- Lay out options
- Establish goals
 - keep her alive until son gets here
 - Maintain comfort no matter what.
- Establish Limits
 - will not resuscitate her if heart stops.



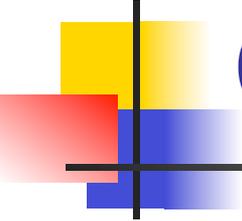
Recommendations

- At the end of your discussion, you should have some recommendations.
- If you ask a family what they want to do, they will generally ask for “everything”. It is much easier for a family to accept limits if the doctor recommends them.



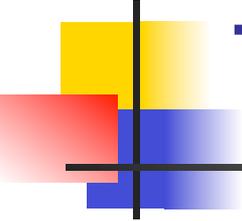
The Ohio 48 hour Rule

- Questions and Comments?
- Recently the 48 hour rule has become the most common issue for local ethics committees.



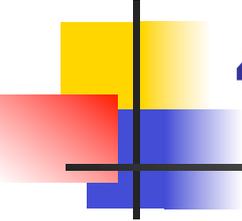
Case

- I had a case once in which a patient that was fully alert and oriented with pulmonary fibrosis had decided he no longer wanted to be on the vent. His family supported his decision. He had been considering this decision for some time. He changed his LOC to DNR-CC and the attending stated he needed to wait 48 hours before turning off the vent... is that required when the individual makes the decision, the patient ended up begging to have the vent turned off prior to the 48 hour window had passed....the physician hesitated but granted the patient's wishes.



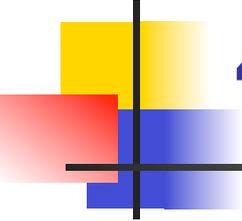
The Ohio 48 hour Rule

- Modified Uniform Rights of the Terminally Ill Act MURTI
- Provides guidance regarding withdrawal of life support in cases where the patient is terminal, has severe brain injury or is in PVS
- The physicians and network have some protection from liability if the 48 hour waiting period is observed.



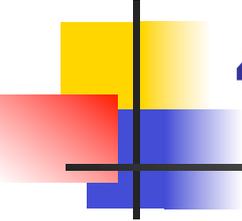
48 hour waiting period

- Must make an effort to contact “priority individuals”.
- Pt should be made DNR.
- Discuss the 48 hour waiting period as part of the process, and make note of the time this is discussed,
- If there is consensus among the decision makers, may proceed with withdrawal from life support at the end of the 48 hour waiting period
- If the waiting period requirement causes conflict, obtain an ethics consult.



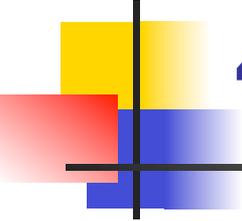
48 hour waiting period

- If there is NOT consensus among decision makers, or if a “priority individual” cannot be contacted, OR if one of the “priority individuals” raises an objection, then a 48 hour waiting period is mandated by Ohio law.
- The purpose of the waiting period is to give time for an objection,
- the objector then must go to Probate Court within 3 business days to request that the spokesperson for the patient be changed.



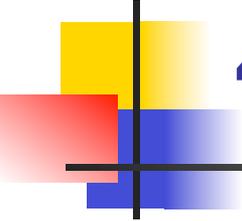
48 hour waiting period

- Interestingly, it appears that this statute is not recognized in Cincinnati, and physicians there are not even aware of it.
-
- The key will be to include early discussion about the 48 hour waiting period with families so they will not be surprised once a decision is made.
-
- We may want to include a discussion about withdrawal at the earliest indication of severe brain injury, so we can choose to start the waiting period while confirmatory testing proceeds.
-
- The law is silent on withholding / withdrawal of dialysis, antibiotics.



48 hour rule - exceptions

- 1. Brain Death declared – Life support will be withdrawn “within a reasonable amount of time” after family notified.
 - There is NO NEED for 48-hour waiting period.
 - There is flexibility for family to gather etc if needed.
- 2. Pt requests withdrawal – If there are no concerns regarding pts state of mind, withdrawal may precede, no need for waiting period. (Analogous to pt withdrawing consent for any other treatment)
-
- 3. In the case where a patient comes into ER and is intubated, then found to have a valid DNR designation, we may elect to withdraw OR wait the 48 hours, as the laws governing these designations conflict.



48 hour waiting period

There are 3 different forms to cover the various scenarios:

Notification record for a patient with a living will

Consent to withhold/ withdraw LST for a patient with a DPOA-HC

Consent to withhold/ withdraw LST for a Non-declarent by a priority individual (for patients without LW or DPOA-HC)

These forms are available in the MICU and SICU at GVH.

NOTIFICATION RECORD
for a patient with a
LIVING WILL

Name of Patient: _____ (the "Patient")

NOTE: After the decision is made to withdraw/withhold life-sustaining treatment as directed by a Living Will and prior to carrying out the wishes of the patient, the attending physician is required to make a good faith effort to notify any person(s) designated in the Living Will of the decision. If there is no person designated in the Living Will to be notified, the highest Priority Individual (or group of individuals if it is a class), as listed below, should be made. After notification, or the reason why notification was not successful, is documented, any action to withhold/withdraw treatment must wait for 48 hours before initiation to allow the notified person(s) time within which to tell the attending physician that they object to the decision. Once the physician is notified of any objection, the objecting person has two (2) business days within which to file a complaint with the Probate Court, and if filed, no further action may be taken to withhold/withdraw life-sustaining treatment until further order of the Court. If no objection occurs within the 48 hours, the withdraw/withhold of life-sustaining treatment may be initiated to the extent consistent with the Patient's wishes as reflected in the Living Will.

Complete the information below regarding the Patient's designee and Priority Individuals and document all notifications and attempts to notify.

Person(s) designated in Patient's Living Will, if any:

Name:	Relationship:	Phone #:
1 st designee/Priority Individual: _____	_____	_____
2 nd designee/Priority Individual: _____	_____	_____

Name:	Relationship:	Phone #:	Order of Priority Individuals:
_____	_____	_____	1. Person listed in Living Will (Listed above)
_____	_____	_____	2. Legal Guardian
_____	_____	_____	3. Spouse
_____	_____	_____	4. Adult Children
_____	_____	_____	5. Parents
_____	_____	_____	6. Adult Siblings

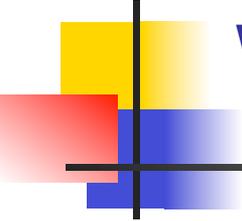
Notification Results / Attempted Notification Results (INCLUDE: Acknowledge understanding; agreement to proposed course of action; voiced objections; inability to notify an individual, including manner of attempted notification):

Date/Time:	Priority Individual(s):	Results of Notification:	Notified by:
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Each of the undersigned is an adult of sound mind and has given consent voluntarily and in good faith

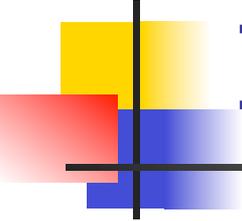
Signature: _____	Relationship to Patient: _____	Date/Time: _____
------------------	--------------------------------	------------------

Witnessed By: _____	Printed Name: _____	Date/Time: _____
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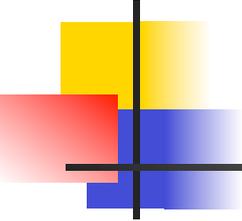
Who should have a discussion

- How do we identify which patients would benefit the most from a discussion about end of life care/ DNR?
- What criteria could we use?
- What are other people doing?



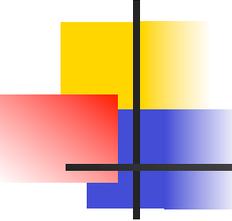
Impact of End of Life Care

- 80% of healthcare dollars are spent in last year of life.
- There will need to be a discussion with the public about what is reasonable care and what is unreasonable.
- There is some basis for this.



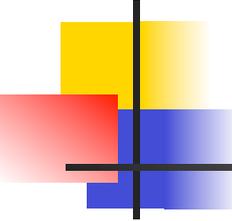
Britain's NIHCE Commission

- Sets policy on acceptable treatments which will be covered by National Health Insurance. Balances efficacy with cost.
- Based on a calculation of Quality Adjusted Year of Life Saved (QALY).



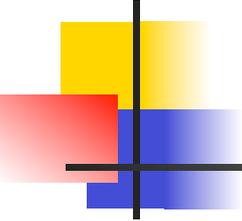
QALY

- Quality Adjusted Life Year is the measurement of cost of treatment per year of life saved assuming that time is of reasonable quality (not in nursing home or bedridden).
- Can use this to rank treatments for both efficacy and cost.



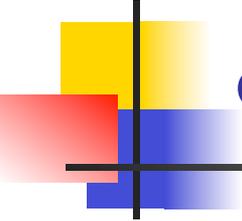
QALY

- NICE current threshold range is \$28 - 42,000 per QALY.
- US surveys suggest a level around 40-100,000 per QALY.
- Recent oncology survey suggests oncologists are comfortable with \$280,000 per QALY.



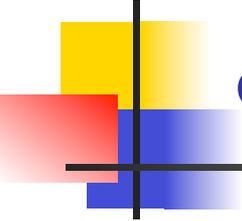
Expense of Treatment

- Oncology drug treatment consumes 40% of Medicare Prescription Drug cost
 - Medicare Payment Advisory Commission
 - Report to Congress: Variation and Innovation in Medicare. June 2003.



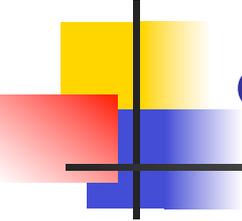
National Debate on Priorities at End of Life

- This is a loaded issue: see the hysteria raised by the claims of death panels which came from a provision to pay physicians to have a discussion about EOL with their patients.



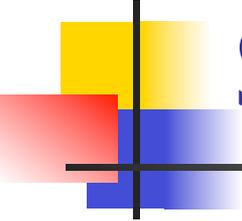
National Debate on Priorities at End of Life

- Do we want a “Good Death” surrounded by family and friends?
- Death with Dignity?
- Do we want any and all treatments, even if many of them don't help?
- Do we want to be good stewards of our healthcare resources, so there will be something left to take care of our children?



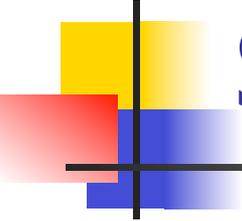
National Debate on Priorities at End of Life

- The Clinical Effectiveness Review (CER) Commission could guide a public debate about End of Life care.
- One of the treatments that is offered at the End of Life is CPR and resuscitation.
- While dramatic, it often does not help the patient, and can cause harm.



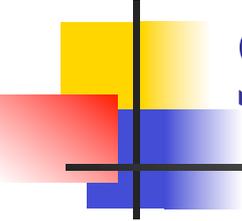
Survival after resuscitation

- On TV 1980 90 %
 - 2008 75 %
- Surveys of people over 65:
 - Estimate 59% success rate
 - Would want CPR 41 %
 - After explanation of procedure and success rates : 10 % would still want CPR



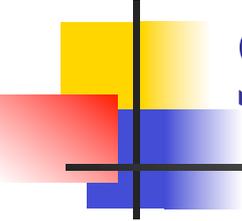
Survival after resuscitation

- TV portrayals of CPR are mostly binary—full recovery or death—with little attention given to survival to discharge or long-term disability. TV patients also tend to be younger and experience cardiac arrests because of trauma, unlike real-world CPR recipients, who tend to be older and have longstanding heart and lung disease.
- NY Times, July 2014, Dhruv Khullar, MD



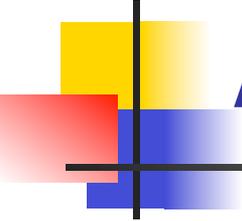
Survival after resuscitation

- Incidence of cardiac arrest: 1 per 1200 admissions
- Hospital Survival Rates:
 - Witnessed in CCU 30-40 %
 - Rest of Hospital 15-20 %
 - Sepsis in the ICU 3 %
- OUT of Hospital Arrest 3 %
- With other End Stage Disease: < 1%



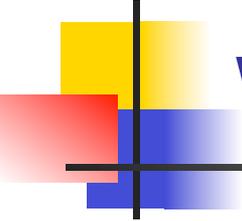
Survival after resuscitation

- Hospital Rates:
 - Incidence of cardiac arrest: 1 per 1200 admissions
 - GVH Deaths reviewed 2005
 - 100 death charts reviewed
 - Approx. 70 of the patients were made DNR before they died. Some were resuscitated one or more times before made DNR.
 - Dr Kaufhold QA review



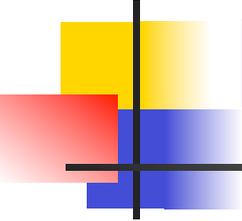
Family Understanding of Advance Directives

- 78% of pts with life-threatening illness would prefer to have physician and family make the decision for them.
- 30% of surrogates incorrectly interpret their loved ones written instructions.
 - Am Med News, Jan 12, 2009 pg 8.
 - The Physician Surrogate Relationship. Arch. Int Med. June 11, 2007.



Once Care is limited, Families Accept withdrawal of Care Better.

- Stuttering course of withdrawal is associated with higher family satisfaction.
- The decision takes longer when there are more family members or if a spiritual advisor is involved.
 - Gerstel, Engelberg. Duration of withdrawal of life support in the ICU and association with family satisfaction. *AM J Resp Crit Care Med.* 2008, 178(8): 798-804.



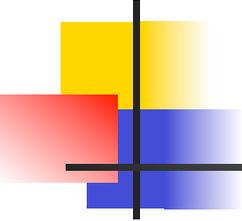
Which patients should be having the discussion?

- Pts with End Stage Diseases should consider limits to care, such as DNR orders.
- Patients with these conditions do not survive resuscitation. (1% survival to hospital discharge.)
- Therefore CPR etc is Futile or Nonbeneficial care
- These conditions are chronic and expensive.

Patients who should discuss Limits to care

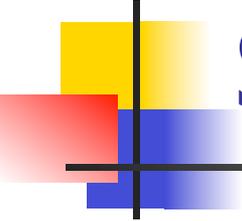
Patients with End Stage Diseases:

- Terminal Cancer
 - (I.e. no further curative treatment planned)
- End Stage Heart disease
 - EF <15%, Defibrillator placement.
- End Stage Renal Disease
- Advanced Dementia.
 - PEG tube placement. Low Karnovsky score (<70).
- End Stage Lung Disease
 - Home oxygen
- End Stage Liver Disease
 - Bilirubin over 5.0



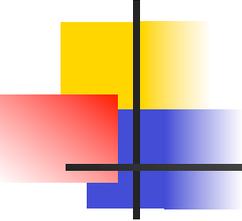
Limits to Care - Controversy

- Social issues also need to be addressed:
 - Chronic Noncompliance must have consequences to the patient:
 - Result in Hospice referral?
 - discontinuation of treatments such as Dialysis?
 - bar from recurrent hospitalization?
 - There will also need to be protection for Providers
 - Noncompliant pt may not sue for bad outcome.
 - Noncompliant pt data not counted against the quality “scorecard” .



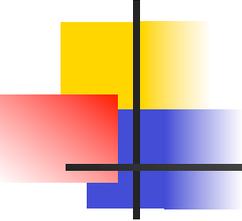
Summary

- History of Futility and futility law
- Religious and Moral Principles
- Probability
- Dealing with the case
 - Establishing a relationship
 - Establishing limits
 - 48 hour waiting period
- Identifying patients who should have the discussion



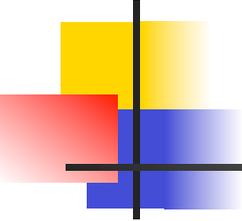
Praying for a Miracle

- Affirm that this is OK
- Bear witness in faith, resurrection
- God is present and answering all our prayers, even if a miracle doesn't come
- Recognize the miracles that have already taken place in the patient's life or the patient's care.



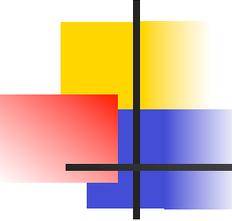
Praying for a Miracle

- A man is in his house in New Orleans before Hurricane Katrina.
- The city sent around a bus before the storm to take residents to a safe place, but he refused, saying “God will protect me”.



Praying for a Miracle

- The national guard sent around a boat during the storm to rescue the man, but he refused, saying “God will look after me”.
- When he was on the roof of his house, the Coast Guard sent a helicopter to rescue him, but he refused, saying “God will save me”.



Praying for a Miracle

Finally, he finds himself in front of heaven, and sees God. He asks God "why didn't you save me?"

And God said, " I sent you a bus, I sent you a boat, I sent you a helicopter! How do you think they found you?"