Ethical and Legal Issues in End-of-Life Care

22nd Annual DOME Symposium
“Respecting Community, Reflecting Community”

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Bioethics & the Law

- Technology
- Appropriate use or discontinuation of interventions
- Landmark bioethics cases as benchmarks
- Generally, legal precedent follows medical ethical principles
Resolving Difficult Cases: Role of Law and Ethics

- Both set standards of conduct
- Law = minimal consensus
- Many areas of conduct not regulated by law
- Ethical standards exceed legal obligations
End of Life Care & the Law

- Broad ethical and legal consensus:
  - Informed Consent/Right to Know
  - Treatment limitation
  - Deciding for those who have lost decision making capacity
    - “Burden”
  - Use of opioids

- Lack of consensus:
  - Physician assisted suicide
  - Futility
Informed Consent

- **Elements:**
  - nature, risks, benefits, alternatives, no treatment

- **Information (includes):**
  - burdens of treatment
  - limitation of treatment if ineffective
Informed Consent & Palliative Care – “Right to Know” Laws

- California Right to Know End-of-Life Options Law (2008)
- New York Palliative Care Information Act (2010)
Right to Know End of Life Options Law - CA

- When a health care practitioner makes a diagnosis that a patient has a terminal condition, the health care provider shall, upon the patient’s request
  - provide comprehensive information and counseling regarding legal EOL options, including right to refuse unwanted treatment, or
  - provide referral or transfer, if practitioner does not wish to comply with provision of info

- Chapter 683, California Statutes (2008)
Palliative Care Info. Act – NY (1)

- Requires a health care practitioner to offer to provide palliative care information and end of life options to a patient diagnosed with a terminal illness or condition
  - including but not limited to:
    - the range of options appropriate to the patient; the prognosis, risks and benefits of the various options; and
    - the patient's legal rights to comprehensive pain and symptom management at the end of life

- Where the patient lacks capacity to reasonably understand and make informed choices relating to palliative care:
  - the attending health care practitioner shall provide information and counseling under this section to a person with authority to make health care decisions for the patient
Where the attending health care practitioner is not willing to provide the patient with information and counseling under this section,
- he or she shall arrange for another physician or nurse practitioner to do so,
- or shall refer or transfer the patient to another physician or nurse practitioner willing to do so
Refusal of Medical Treatment

- Right to refuse medical treatment
- Grounded in
  - Law of Battery
  - Informed consent/refusal
  - Liberty Interest of 14th Amendment
Informed Refusal

- Patients should be made aware of consequences of refusal
  - Truman (Calif. 1980)

- Right to refuse medical treatment, including life-sustaining medical treatment
  - Cruzan (U.S. 1990)
Limitation of Treatment: The Consensus

- **Right to refuse any intervention**
  - Ventilators, feeding tubes, blood products
    - Wons (Fla. 1989), Fosmire (N.Y.1990)

- **All patients have right, even incapacitated**
  - Quinlan (N.J. 1976), Cruzan (U.S. 1990)

- **Withholding / withdrawing**
  - not homicide or suicide
  - orders to do so are valid Dinnerstein (Mass. 1978)
  - Courts need not be involved

Limitation of Treatment: The Consensus

- Artificial nutrition and hydration (ANH) = medical treatment that may be refused
  - Majority decision reviewed state cases that equated ANH with medical treatment
  - O’Connor concurrence “artificial feeding cannot be distinguished from other forms of medical treatment
    - Cruzan (U.S. 1990)
Decision Making Capacity

- Vs. Competence
- Elements:
  - understand the information
  - evaluate the consequences and to make a decision
  - communicate the decision
- Assess for each decision
Decision Making for the Incapacitated

- Who should decide?
  - Guardian, health care agent, surrogate

- What standard should be used?
  - Substituted judgment, best interest

- How sure must the decision maker be?
  - Clear evidence, preponderance
Advance Directives

- Living Will - direction to physician
  - Terminal condition or PVS
- Power of Attorney for Health Care - appointment of agent often with direction
  - Any incapacity
Limitation of Treatment: Advance Directives

- Initially, no evidence that completion changed care

- Subsequently, patients who had prepared advance directives received care that was strongly associated with their preferences
  - 83.2% of subjects who requested limited care and 97.1% who requested comfort care received care consistent with their preferences
Centers for Medicare and Medicaid Services (CMS) final rule rule

- Re: payment
- Advise patients re: advance care planning during annual exam
- Effective Jan. 1, 2011
- Rescinded Jan. 5, 2011
- Physicians not restricted from discussing end of life without payment
Default Surrogate Consent
e.g. Illinois Surrogate Consent Act

- Hierarchy of surrogates able to make medical decisions for non-decisional patients
  - Priority of surrogates = Spouse • Adult child • Parent • Adult Sibling • Adult grandchild • Close friend • Guardian of the estate
    - If dispute, majority rule for children, siblings and grandchildren
  - If decision concerns forgoing life-sustaining treatment, patient must be in terminal condition, permanently unconscious, or incurable or irreversible condition
  - Standards § 40/20(b)
    - N/A to admission to mental health facility, psychotropic medication or ECT (see 405 ILCS 5/1-121.5; 5/2-102; 5/3-601.2, amended 1997)
    - 755 ILCS 40/1 to 40/65, at 40/25 (Smith-Hurd 2007)
Default Surrogate Consent
e.g. California

- Comprehensive Health Care Decisions Act
  - An individual orally designated as surrogate
    - The surrogate has priority over a concurrently appointed health care agent during the period the surrogate designation is in effect.
      - Effective “only during the course of treatment or illness or during the stay in the health care institution when the designation is made, or for 60 days, whichever period is shorter.”
      - N/A to civil commitment, ECT, psychosurgery, sterilization, and abortion.

Surrogate Consent
Decision Making Standards
e.g. California

- A surrogate...shall make a health care decision in accordance with
  - the patient’s individual health care instructions, if any, and other wishes to the extent known to the surrogate
  - Otherwise ... in accordance with the surrogate's determination of the patient's best interest.
    - In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate
      - Cal. Probate Code § 4714 (West 2007)
Surrogate Consent
Decision Making Standards
e.g. California

- Evidentiary standard
  - Preponderance
    • Applies to patients who either are permanently unconscious, executed an advance directive, designated a surrogate, or have a conservator and are conscious but the decision is not intended to result in death
  - Clear and convincing
    • Applies when a conservator seeks to withdraw life-sustaining treatment from a conscious, incompetent patient who has not left legally cognizable instructions for health care or appointed an agent or surrogate for health care decisions
POLST Paradigm

1. Physician Orders on Life-sustaining Treatment
2. Translation of patient wishes into portable pre-hospital physician orders
   - Resuscitation, Intubation, Artificial nutrition and hydration, Antibiotics, Dialysis
3. Widespread adoption
   - Also known by different acronyms depending upon the state in which it has been adopted. New York Medical Orders for Life Sustaining Treatment (MOLST), North Carolina Medical Orders for Scope of Treatment (MOST), West Virginia and Idaho Physicians Orders for Scope of Treatment (POST), and Vermont Clinician Orders for Life-Sustaining Treatment (COLST).

Allegation of Failure to Comply with POLST directions

DeArmond Case 1

Calif.

Emily DeArmond, 18 yo

- Brain Cancer, dependent adult, mother = decision maker
- Calif. POLST completed by primary care physician with mother, includes Do Not Intubate (DNI) Order
- Unresponsive, brought to Kaiser Anaheim ED, Nov. 6, 2011
- Claims ED physician told of POLST & DNI
  - Intubates despite POLST & admits
- Transferred to another Kaiser facility, Lakeview
  - Comfort measures, extubated
  - Died Nov. 7

Suit filed by family for Damages and Injunctive relief

- ED physician new or should have known @ POLST and violated order
- Kaiser failed to educate or establish policies and procedures to follow POLST
Allegation of Failure to Comply with POLST directions

DeArmond Case 2

Calif. Physician Orders for Life Sustaining Treatment

- **Sec. 4781.2.**
- (a) A health care provider shall treat an individual in accordance with a [POLST] form.
- (b) Subdivision (a) does not apply if the [POLST] form requires medically ineffective health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.
- (c) A physician may conduct an evaluation of the individual and, if possible, in consultation with the individual, or the individual’s legally recognized health care decisionmaker, issue a new order consistent with the most current information available about the individual’s health status and goals of care.
- California State POLST Legislation (AB 3000 [Statutes 2008, Chapter 266], January 1, 2009.)
“A POLST form presents options for treatments as if they were morally neutral. In fact, they are not…”

“A POLST oversimplifies these decisions and bears the real risk that an indication may be made on it to withhold a treatment that, in particular circumstances, might be an act of euthanasia. Despite the possible benefits of these documents, this risk is too grave to be acceptable.”

Other concerns
- the lack of a patient signature acknowledging that the form truly represents a person’s choices;
- potential conflict with current Wisconsin law and/or other advance care directives (for example, use by minors or their guardians, or use during pregnancy);
- the absence of a conscience clause that protects facilities or practitioners, which cannot follow a POLST treatment order due to the institution’s or person’s moral, ethical, or medical concerns; and
- the immediate effect of the document, even when a person is receiving non-emergency treatment.
“Due to the serious and real threats to the dignity of human life that POLST and all similar documents present, we encourage all Catholics to avoid using all such documents, programs, and materials...”


Advance Care Planning

Communication

- Terminally ill patients who knew they were terminally ill and talked with physicians about preferences were \( \approx 3.5 \) times more likely to have preferences honored
  - 44% of patients who knew they were terminally ill had not had conversation with physician about preferences
Most patients with advanced cancers of the lung or colon do not understand that chemotherapy was unlikely to cure them:
- 69% of those with Stage 4 lung cancer
- 81% of those with Stage 4 colorectal cancer

Accuracy of Surrogate Decision Makers for the Incapacitated

- Patient-designated and next-of-kin surrogates incorrectly predict treatment preferences in 32% of cases
- Neither patient designation of surrogates nor prior discussion of patients’ treatment preferences improved surrogates’ predictive accuracy

- Literature search re: studies on how accurately surrogates predict treatment preferences and efficacy of commonly proposed methods to improve surrogate accuracy.
- 16 studies, 151 hypothetical scenarios and 2595 surrogate-patient pairs.
Family wishes re: life-support decision making

- 55% - Final control of decision
- 40% - Shared decision making
- 5% - MD to decide

  Johnson SK, Bautista CA, Hong SY, Weissfeld L, White DB. An empirical study of surrogates' preferred level of control over value-laden life support decisions in intensive care units. Am J Respir Crit Care Med 2011;183(7):915-921.
From Paternalism to Abdication?

- Early benchmark cases in bioethics
  - Physicians paternalistically overriding patients’ wishes to forgo life-sustaining medical treatment

- Now
  - In life support discussions with surrogates, for approximately half of the decisions that arise, physicians do not provide a recommendation
    - Even when families explicitly ask for a recommendation, only about half of physicians give one.
  - Struggle in training physicians
    - Not tamping down a burgeoning paternalism, but helping them understand their professional role to provide recommendations
      - rather than offering treatment and non-treatment options as mere menu choices
Burden of Surrogate Decision Making for the Incapacitated

- Making treatment decisions has a negative emotional effect on at least 1/3 of surrogates
  - Stress
  - Guilt over the decisions made
  - Doubt regarding whether made the right decisions

- Often substantial; typically lasts months (sometimes, years)
  - Data Synthesis: 40 studies, 29 qualitative and 11 quantitative methods, data on 2,854 surrogates, > ½ of whom were family members of the patient
Quality of Life

I went to do an ethics consult
And found the patient
On a ventilator
The questions was
Withdrawal
IV in neck
Jello on tray
Soaps on tv
Is this what we mean
By poor quality of life?
But the work had been done.

The patient had written
The consult note for me
In sprawling cursive
Slanted upward
On the clipboard
He had framed the problem:
“Last night I thought
All night long.
I don’t want to be a burden
I don’t want to die today.”

Schiedermayer DL. Quality of Life, in
Burden of Surrogate Decision Making for the Incapacitated

- Patients often telegraph wishes in short aphoristic statements
  - “No heroic measures”
  - “Do everything”
  - “No machines”
  - “I don’t want to be a burden”

- But once patient is non-decisional, family and others left to interpret and apply
Burden

- To family
- To caregivers
- To larger community
  e.g. religious or cultural
- Dependent upon patient wish to not be a burden, and
- Family members’ determination of weight of burden and willingness to bear
- May minimize, thwarting patient’s wish not to be a burden
- Rare cases, may overstate
Burden

- Including the burden to others as a factor to be weighed in decision making
  - “Normally one is held to use only ordinary means – according to the circumstances of person, places, times and culture – that is to say means that do not involved any grave burden for oneself or another.
  - A stricter obligation would be too burdensome for most people and would render the attainment of the higher, more important good too difficult. [Emphases added]

  - Pope Pius XII, Address to an International Congress of Anesthesiologists: Basic Principles.
    http://www.lifeissues.net/writers/doc/doc_31resuscitations.html
Burden

- Wish not to be a burden is strong
  - 38% of those who chose physician assisted suicide allowed under Oregon Death with Dignity Act
  - expressed a concern about being a burden for family, friends, and caregivers
  - Vs. inadequate pain control or financial implications
Opioids in End of Life Care

- Use in Palliative Care
- Principle of Double Effect
- Experience with
  - Medical examining boards
  - Criminal prosecutions
Pain Relief & Medical Boards

Board actions vs. physicians

- Perception of risk >> actions

Opioids in End of Life Care: Criminal Prosecutions

- Homicide prosecutions post pain management for dying patients
- Perception >> number of prosecutions
- 1990-1998 (Post Cruzan):
  - 5 MDs charged, 3 tried, 2 convictions (one reversed on appeal) = only one conviction* (KCl bolus - State v. Wood Okla. 1998)
  - Acquittal for one case of succinyl choline administration - jury accepts palliative care defense (State v. Pinzon-Reyes 1997)

  - * Wood conviction reversed on appeal (US v Wood 10th Cir. 2000)
End of Life: Criminal Prosecutions

  - (1) withdrew vent without reversing neuromuscular block in 81 y.o. man in ED with presumed stroke,
  - (2) fentanyl & midazolam administration to 78 y.o. woman with metastatic Ca p family asked for better pain control; family interpreted ambiguous remark as intent to cause death
  - (convicted for two deaths, reversed on appeal)
End of Life: Criminal Prosecutions

  - (succinyl choline administered on video to man w/ ALS, convicted 2000, affirmed on appeal, released 2007)

- **Weitzel (Utah Trial Ct. 2000/2002)**
  - Psychiatrist orders morphine for patients with senile dementia, 5 deaths in 16 days
  - Defense: all five terminal dementia
  - Convicted,
  - New trial granted after prosecution withheld expert opinion that care was standard and not criminal, acquitted
Prescription Drug Abuse

- Narcotics = most widely prescribed drugs in the United States
  - 1998 → 2008
    - = 400% increase in prescription drug abuse
  - 1994 → 2003
    - Rxs for “Controlled Substances” = 22M → 354M
    - ED visits for misuse prescribed & OTC 500K → 1M
    - Admissions for misuse = 40K → 300K
    - Deaths ≈ 5K → 14K
  - 2008 Deaths = 15K
  - 2009 Deaths = 16K
    - Methadone accounts for almost a third of deaths
    - 31.4% OD deaths; 1.7% of 257M Rx
Drug Enforcement Administration (DEA)

- Federal agency charged with oversight of controlled substances
  - Harrison Narcotic Act 1914
  - Controlled Substances Act 1970
- 2006 actions re: physicians
  - 735 investigations of physicians opened ($\approx 1/1,000$)
  - 71 physicians arrested for crimes related to “diversion” ($\approx 1/10,000$)
    - 735,000 physicians in active practice (est. 2000)
Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act

- Pain relief vs. fear of prosecution
  - Twenty-one Health Organization and DEA, 2001
- Undertreatment = serious problem
- Guidelines = safety unless “knowingly and intentionally” prescribed drugs for illegitimate reasons; quantity not
- Incorporated into FAQs posted on DEA website
DEA & Pain Relief (2)

- 2004 - DEA removal of FAQs
  - Concerns by pain medicine experts and 30 attorneys general

- 2005 - DEA Clarification
  - More concerns

- 2006 - DEA Notice of Rule Making
  - No definitive guidelines for prescribing controlled substances
  - Cannot modify or expand through endorsement of guidelines
  - DEA does have authority to determine whether prescription issued for a legit medical purpose within CSA and DEA regs.
    - Pain & Policy Studies Group
      - http://www.painpolicy.wisc.edu/DEA/index.htm
2006 - DEA & physician reluctance re: pain relief

- "The longstanding requirement...that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way...cause any physician to be reluctant to provide legitimate pain relief."

DEA – The New Approach

- In the past decade, “the [DEA] has tried a variety of tactics with limited success, from arresting hundreds of doctors to closing scores of pharmacies.”
- Now putting pressure on distributors [intermediaries between drug makers and pharmacies].
- “In response, the distributors are scrambling to limit their liability by more closely monitoring their distribution pipelines and cutting off some customers.”
REMS for Long-Acting Opioids

Risk Evaluation and Mitigation Strategy (REMS)
- Approved July 2012; Available by March 31, 2013
- FDA-approved educational materials for providers & patients
  - Dangers (& Signs) of abuse & addiction
  - >70% of those who abuse Rx pain meds obtain from friends or relatives (usu. with permission & free)
- Applies to approx. 30 meds
  - Hydromorphone, oxycodone, morphine, oxymorphone, methadone, fentanyl (transdermal) and buprenorphine (transdermal)
- Participation in educational program NOT mandatory
Doctors Petition FDA to Change Labeling of Narcotics

- Physicians for Responsible Opioid Prescribing
- For long-term, non-cancer pain
  - Cleveland Clinic, Mayo Clinic, Public Citizen
- Risks = addiction, overdose, resp. suppression, falls, fxs, sleep apnea, cognitive impairment
- Limit of 100mg/day MS & 90 days for non-cancer pain
  - 14 tabs Vicodin, 13 tabs of Percocet
Physician Assisted Suicide

- No constitutional right
  - Glucksberg, Vacco
- States free to develop laws
- Oregon & Washington (referenda), Montana (Sup. Ct.)
  - Failed efforts: NH, HI, NY, CT, MA
    - GA Sup. Ct. voids, legislature passes new statute
Physician Assisted Suicide: Oregon Experience

- 14 year experience (1998-2011)
  - 596 deaths (∼0.3% of deaths)

- Top reasons
  - Loss of autonomy (91%)
  - Loss of activities enjoyed (88%)
  - Loss of dignity (83%)
  - Loss of bodily functions (54%)
  - Burden for family, friends, caregivers (36%)
  - Not pain, finances, out of state

Physician Assisted Suicide: Washington & Montana

- **Washington**
  - Referendum I-1000 similar to Oregon law
  - Passed 59% (Nov. 2008)

- **Montana**
  - No statutory or public policy basis for prohibition of physician-assisted suicide, effectively permitting the procedure
    - (Baxter, Montana 2009)
  - No regulation
Physician Assisted Suicide: Washington Experience

- 2 year experience (2009-2011)
  - 240 deaths

- Top reasons (2009-2011)
  - Loss of autonomy (90/100/87%)
  - Loss of activities enjoyed (87/91/89%)
  - Loss of dignity (64/82/79%)
  - Loss of bodily functions (52/41%/)
  - Burden for family, friends, caregivers (28/23%/)
  - Inadequate pain control or concern (36/25%/)
  - Not finances

Physician Response to Requests for PAS (1)

- Clarify the request
- Determine the root causes
  - Fear of psychosocial, mental suffering, future suffering, loss of control, indignity, being a burden
  - Depression
  - Physical Suffering
Physician Response to Requests for PAS (2)

- Affirm your commitment to care for the patient
- Address the root causes of the request
- Affirm the patient’s control over treatment decisions and legal alternatives for control and comfort
- Seek counsel from colleagues
  - Education on Palliative and End of Life Care (EPEC) Curriculum, 1999, 2003
“Do Everything”

Everything that might:
- Prolong life?
- Relieve suffering?
- What if can’t maximize both? How balance?

“Everything”
- Cognitive: Incomplete understanding/ Reassurance best medical care/ reassurance all life-prolonging treatment
- Affective: Abandonment/ Fear/ Anxiety/ Depression
- Spiritual: Vitalism/ Faith in God’s will
- Family: Differing Perceptions/ Conflict/ Dependents
Discussion re: Everything

1. Understand what “everything” means to patient
2. Propose a philosophy of treatment
   - E.g. Balance of burdens and benefits
3. Recommend a plan of treatment
4. Support emotional responses
5. Negotiate disagreements
6. Use harm-reduction strategy for continued requests for burdensome treatments that are unlikely to work
   - Clinicians should still exercise clinical judgment
"Jobs died of respiratory arrest"

“Steve Jobs’ immediate cause of death was respiratory arrest, as cancer spread to other organs in his body, his death certificate reveals”

- BBC News
Futility

- Lack of consensus
  - Wanglie, Baby K, Gilgunn

- Goal? / Objective benefit?

- 2nd opinion/ Ethics consultation/ Transfer of care

- No obligation to provide futile treatment
  - AMA Code of Ethics § 2.037
Futility - Regional Efforts

- Guidelines for the Use of Intensive Care in Denver (GUIDE)
- Houston Citywide Policy on Medical Futility
  - Prohibit unilateral decision making
  - Process, including multidisciplinary committees
  - Transfer if no resolution
- Individual hospital policies
If a physician in Texas concludes that continuing life-sustaining medical treatment (LSMT) for a terminally or irreversibly ill patient is futile:

- Family given 48 hr. notice/opportunity for ethics review by ethics committee
  - Texas Advance Directives Act of 1999
Futility: Texas Law (2)

- If committee agrees LSMT futile and family objects
  - LSMT continued for 10 days while attempts to transfer to alternative provider
  - If no alternative provider found, then only comfort treatment must be provided
  - Courts may grant an extension if there is reasonable evidence that an alternative provider can be found during this extension
    - Texas Advance Directives Act of 1999
Futility - Texas Experience

- Baylor University Medical Center

- 1 year before law v. 2 years after law
  - Futility consultations 14 v. 47
  - EC agreement 14 v. 43
  - Family agreement 12 v. 37
  - Family refusal 2 v. 6

- Changed conversation by conceptual and temporal boundaries

- Forces physicians to think carefully about concept
Futility Developments

“End of Futility?”
- 1995 = 134 articles on Medline
- 1999 = 31 articles

Not!
Challenges to Consensus re: Ineffectiveness & Futility

- “If family members or legal surrogates for the patient want every possible measure taken to keep the patient alive, professionals should comply with this request.”

- “[F]utile CPR has a limited but legitimate place in the practice of medicine”
  - 2 year old boy w/ large frontal encephalocele
  - “At the time we began our resuscitation efforts, I believed that this child was beyond suffering, whereas the psychological needs of his parents were both clinically and ethically significant.”
If, in the well grounded judgment of the attending physician and a staff physician consultant, life-sustaining medical treatment would be futile, the attending physician may write an order withholding or withdrawing the treatment after notifying the patient or other responsible individual.
A life-sustaining medical treatment should be considered “futile” if it cannot be expected:

- To restore or maintain vital organ function or
- to achieve the expressed goals of the patient when decisional

Life sustaining medical treatment includes:

- CPR, mechanical ventilation, artificial nutrition and hydration, blood products, renal dialysis, vasopressors, or any other treatment that prolongs dying
Consultation with Palliative Medicine, Social Services, and Chaplaincy, as appropriate is strongly encouraged
  – If there are remaining questions, the physician should consult the Ethics Committee

If the patient (or surrogate disagrees), the attending physician should consider transfer to
  – Another attending physician
  – Another facility
Froedtert Hospital Futility Policy

- If transfer not feasible, further life-sustaining medical treatment may be withdrawn
- Attending must inform Office of Sr. VP for Medical Affairs *orally and in writing* when this policy is invoked
  - Froedtert Hospital Policy MSP.0011