

LEGAL ISSUES

United States Law

- Two systems—federal and state
- Lawmakers
 - Judges (common law)
 - Legislatures (statutory law)
 - Executive agencies empowered by legislatures (regulatory law)
- Enforcement through
 - Administrative system (licensure suspension or revocation)
 - The civil system (most commonly, monetary judgments, but in the medical context, often an order to take an action or to stop treatment, known as "declaratory or injunctive relief")
 - The criminal system (fines and/or prison)
- End-of-life issues generally addressed through
 - Civil common law (federal or state)
 - Statutory law (usually state)
- Although many important legal principles in end-of-life decision-making are widely accepted among the states, it is important for physicians to become familiar with their state's specific statutes and cases

Resolving Difficult Cases: Role of Law and Ethics

- In any discussion of ethical issues in medicine, legal issues may arise
- Both ethics and the law set norms or standards for conduct
- Law
 - The law often expresses a kind of minimal ethical societal consensus—one that society is willing to enforce through civil judgments or criminal sanctions
 - However, there are areas of conduct that the law does not and cannot address
 - Slow and expensive means of dispute resolution
 - Going to court rarely necessary in end of life situations
- Ethics committees/consultants
 - Clinicians facing difficult decisions concerning patients near the end of life may be aided by consultation with ethics consultants and ethics committees
 - Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) mandates this mechanism to address ethical issues
 - Most health care institutions have ethics consultants or have established ethics committees
 - Role of ethics committees and consultants
 - Develop processes to allow clinicians, patients, and families a forum for the discussion of end-of-life decision-making
 - Provide a mechanism to consider recommendations regarding ethically appropriate choices in a given situation

Informed Consent: Importance

- First, many patients and families (or parents if the patient is a child) who are facing treatment withdrawal
 - May have not been fully informed of the risks and benefits of the therapy at the time it was begun
 - May not have been told that treatment would be withdrawn if the treatment was no longer effective
 - Knowing the burdens of continued treatment, the fully informed patient or surrogate may not elect further treatment

- Second, patients and families who refuse further treatment should be told the consequences of the discontinuation of treatment, just as they are told the benefits and risks of other interventions

Ethics

- Information giving standards
 - Reasonable information-giving is judged partly by
 - What any good professional would give
 - What any reasonable person would want in the same circumstances
 - What this specific patient would want in these circumstances
 - Specific patient goals not legally required
 - Nonetheless, an important ethical goal
- Elements of information
 - Nature of procedure
 - Risks, common or severe
 - Benefits
 - Alternatives
- Consent: As important as information giving, or more so
 - Understanding
 - Must involve proper understanding
 - For example, does the patient understand that the consequence of declining life-prolonging intervention is probably an earlier death?
 - Voluntary and free of coercion

Procedures

- Documentation
 - Usually, health care facilities have a predrafted form that can be used
 - However, documentation is of no risk management benefit if the process was absent or ineffective
- Process of deliberation and shared decision-making
 - Ideally woven into regular clinical interaction
 - Reflects a deliberative relationship in which the physician fosters and advocates for the well-being of the patient, the health care values, and the goals and specific wishes
- Communication of news about the disease and its management is timely and sensitive
- Physicians have direct responsibility for bringing the information into focus before settling on a specific decision together
 - Decisions are significantly determined by external constraints (e.g., insurance carriers, managed care organization's coverage and reimbursement policies)
 - Nonetheless the direct responsibility for informed consent falls to physicians
 - Even with the recent trend of holding plans liable for patient care decisions, the physician remains most directly available to and responsible for patient and surrogate decisions

Treatment Limitation at End of Life: Legal Consensus

- Treatment limitation
 - In the past 2 decades, federal and state courts have decided a number of cases that have established a consensus of important legal principles in end-of-life care
 - Though these principles have not been unanimously adopted by all federal and state courts and legislatures, the consensus that has emerged has been broadly accepted with a distinct minority of exceptions

- Patients may refuse unwanted treatment
 - Patients with decision-making capacity may refuse unwanted medical treatment, even if this may result in their death
 - Based on both the common-law respect for bodily integrity and the liberty interest articulated in the 14th Amendment to the Constitution
 - Cruzan case: Most important expression of this principle was enunciated by the United States Supreme Court
 - Key question was whether an individual has a constitutional right to refuse treatment
 - Other courts affirmed this principle
 - Applies even when patient does not have life-threatening illness

- Surrogate decision-making
 - Patients who lack capacity to make decisions have the same rights as those who have capacity
 - However, different manner to exercise these rights
 - Authorized surrogate decision-makers may make decisions to limit treatment for patients who lack decision-making capacity using standards as discussed below

- Withholding/withdrawing life-sustaining medical treatment
 - Not homicide or suicide
 - Courts have drawn a distinction between
 - Intentionally causing a patient's death
 - Allowing a patient to die as a result of the withdrawal of life-sustaining treatment
 - Legal consensus that both withdrawing and withholding treatment, if not wanted by the patient or ineffective, can be justifiable
 - Orders to do so are valid
 - Courts have also upheld the validity of DNR (do-not-resuscitate) and other treatment limitation orders
 - No limitations on the type of treatment that may be withheld or withdrawn
 - Courts rejected distinctions between "ordinary" and "extraordinary" treatment
 - Thus, ventilator withdrawal that may result in death is permissible
 - Even parenteral nutrition and hydration may be withheld or withdrawn under the same conditions as any other form of medical treatment
 - Physicians should provide the patient (or parents if the patient is a child) with
 - Information about his or her situation
 - Description of choices about all treatments
 - Assistance with decision-making
 - Physicians should not automatically assume that ventilators, feeding tubes, or other life-prolonging treatments are required

- Courts need not be involved
 - Principles are established in legal doctrine
 - Physicians should feel comfortable applying them
 - Few situations that cannot be resolved by physician in collaboration with patient and family
 - Only rarely does limitation of life-prolonging treatment at the end of life require court intervention

Deciding for the Patient without Decision-Making Capacity: Legal Devices

Determining and Declaring Decision-Making Incapacity

- Few patients with life-threatening illnesses retain decision-making capacity until the moment of their death
 - Most patients endure some period of incapacity
 - Limitation of life-sustaining treatment possible for patients who lack decision making capacity
 - However, it is necessary to first
 - Determine incapacity
 - Arrange for proxy decision-making

- Court of law may determine a patient to be incompetent and appoint a guardian to make important decisions, including those concerning health care, for the patient
- Many patients who have not been declared incompetent by a court may nonetheless have problems with their capacity to make health care decisions
- 3 elements of the capacity to make health care decisions
 - First, ability to comprehend or **understand** the information about the medical problem
 - Appreciate the impact of the disease
 - Consequences of various options for treatment, including forgoing treatment
 - Second, ability to **evaluate** the options
 - Compare risks and benefits of each option
 - Deliberate in accord with the patient's own values
 - Make choices that are not irrational
 - Maintain a consistent choice over time
 - Third, the patient should be able to **communicate** his or her choice
- Generally, determination of the capacity to decide on treatment must relate to:
 - Individual abilities of the patient
 - Requirements of the task at hand
 - Consequences likely to flow from the decision
 - Thus, when the consequences for well-being are substantial, there is a greater need to be certain that the patient possesses the necessary level of capacity
- A lack of decision-making capacity may be caused by any break in the chain of decision-making
 - Ability to understand, to reason and evaluate, and to communicate a decision
 - Obviously, patients in a coma, infants, young children and the profoundly mentally disabled lack decision-making capacity for all medical decisions
 - Some other patients, such as those at the end of life with significant metabolic abnormalities, some disorientation, or early dementia may retain some degree of decision-making capacity
 - Physicians taking care of patients at the end of life should make a determination of the patient's decision-making capacity before presenting the patient with significant health care decisions
- Declarations of incapacity can be done through
 - Formal, legal statement
 - Simply recording evaluation of the primary physician or psychiatrist in medical record (usual method)
 - Recorded evaluation should document the basis for declaring the patient incapacitated
 - Record of the patient's lack of decision-making capacity as determined by 2 physicians
 - May be required before a power-of-attorney for health care can be activated
 - Most declarations of incapacity should be for
 - Limited scope of the decision at hand
 - Record should indicate limitations to the scope
 - Subsequent decisions require reevaluation

Decisions for the Incapacitated: Two Criteria Used by Courts to Decide Life-Sustaining Treatment

- Determination that treatment would not be in the **best interests** of the patient
 - For example, one court applying the test determined that for a patient in a persistent vegetative state, it is not in the patient's best interest to continue treatment
- Proxy's **substituted judgment** to determine whether the patient would have wanted treatment withheld if he or she had been competent
 - Takes into account the patient's subjective wishes
 - Application of advance directives uses the substituted judgment criterion

Guardianship

- Traditionally, if the patient has made no other provisions, the mechanism for making both medical and nonmedical decisions for incapacitated patients has been to establish a legal guardian, that is, a person with legal guardianship
- End-of-life decision-making for patients who have never had decision-making capacity (e.g., infants and young children, or developmentally disabled adults) generally requires an individual who is legally able to act in the patient's best interest, such as a parent or guardian
- Additionally, federal regulations (so-called Baby Doe regulations) apply to end-of-life decisions made for infants and newborns
- But this mechanism has a number of disadvantages for the average life-threateningly ill patient
- The guardianship process is often slow and costly for the patient or family
- Moreover, the guardian is normally expected to make decisions using the traditional best interest standard, which does not always rely on the patient's previously expressed preferences
- For the parent/guardian of a mature adolescent patient, the conversations eliciting the patient's wishes are difficult
- Consequently, they may not have taken place
- For most adult patients at the end of life, legal guardianship is an option of last resort for making health care decisions. It may, for instance, be used if the proxy is clearly acting against the patient's interests and needs to be replaced

Advance Directives

- Over the past 2 decades, courts and legislatures have recognized legal tools called "advance directives" as valid indicators of patients' previously expressed desires
- Terminology may be confusing
 - The process of discussion, documentation, and implementation of wishes is termed **advance care planning**
 - The most common of the advance directives are:
 - **Living will**--a form of instructional directive to limit life-sustaining medical treatment in the face of a life-threatening illness
 - **Durable power-of-attorney for health care**--an appointment of a health care agent or proxy to make decisions according to the incapacitated patient's preference
 - Other types of instructional directive include
 - Personal letters
 - Values history
 - Medical directive
 - Advance directives give immunity from successful prosecution to physicians who, in good faith, follow the directive
 - Advance directives
 - Statutory documents created by state legislatures
 - Advisory documents that act as evidence of patient wishes
 - Binding under common law beyond state borders
 - Moreover, state legislatures may direct that health care providers honor other states' advance directives
 - As a result of the **Patient Self Determination Act**
 - States are required to recognize at least 1 form of advance directive
 - Hospitals are required to inform patients of their right to refuse medical treatment and to make advance directives (see Module 1: Advance Care Planning)

Surrogate Decision-Making

- Majority of individuals do not complete advance directives
- As a result, a number of states have enacted surrogacy laws (e.g., Illinois)

- Under these laws, patients without advance directives who become incapacitated may have a decision-maker
 - Appointed from a list of eligible individuals, including a spouse, family member, or others as prescribed by statute
 - The hierarchy of the individual's eligibility may vary from state to state
 - Legal recognition to a process that many physicians used in the past when no one had been appointed as guardian—namely, turning to the person most likely to be recognized as the appropriate representative of the patient
- In states without surrogacy laws, physicians often rely informally on next-of-kin hierarchy
 - Once a surrogate is identified, he or she must determine the patient's wishes regarding end-of-life treatment
 - Where the patient has advance directive, this may only entail interpreting the directive
 - Most states require surrogate to determine that it is more likely than not that the patient would have made a particular health care decision
 - Known as *the preponderance of evidence standard*, expressed as "more probable than not"
 - Some states require a higher degree of certainty
 - Clear and convincing evidence
 - Higher standard than preponderance of the evidence that the patient would have chosen a particular course of action
- The difficulty in determining whether verbal expressions of health care preferences meet these standards reinforces the importance of written advance directives
 - For example, a general comment made by the patient that he or she "would never want to live as a vegetable"
 - Does not give a great deal of guidance as to whether to discontinue life support after an accident that leaves the individual with significant brain damage, but not in a persistent vegetative state

Appropriate Use of Opioids in End of Life Care: Developing Consensus

- Palliative care and hospice concepts developed in response to ethical mandate that patients and families should receive care that
 - Relieves suffering
 - Improves the quality of their lives
- Both depend on the appropriate use of opioids to relieve pain, shortness of breath, and other symptoms
- The federal Drug Enforcement Agency and state licensure and drug regulation agencies charged with enforcing laws concerning controlled medical substances, such as opioids
 - Traditionally, these agencies monitored physicians' prescriptions for opioid use
 - In the past, many physicians and regulators were overly concerned about problems associated with substance abuse and addiction
 - Today, growing awareness by regulatory bodies of the role of opioids in medical practice
 - Lessening concerns about addiction when physicians prescribe opioids
- **Principle of double effect** recognizes the difference between
 - Provision of adequate treatment that unintentionally hastens death
 - Provision of medication that intentionally causes a patient's death
- Physicians have responsibility to be aware of realistic risks associated with treatments (e.g., the minimal risk of death associated with opioids when prescribed appropriately for pain relief)
- Physicians should feel comfortable providing medication, including opioids
 - Using accepted dosing guidelines to alleviate a patient's pain and suffering
 - Even if unintended secondary effect might risk hastening patient's death

Physician Assisted Suicide: A Matter of State Law

- Perhaps no other end-of-life ethical issue has generated as much controversy as physician-assisted suicide

- Ethical and legal consensus that patient refusal of life-sustaining medical treatment is not suicide
- However, provision of medication with intent to produce death is considered to be assisting suicide
- All states except Oregon have laws that make assisting a suicide by anyone (including physicians) a criminal offense
- Recently, some patients and physicians have argued that suicide with the assistance of a physician should be available for
 - Patients who have advanced life-threatening illnesses
 - Who have decision-making capacity
- In 1997, United States Supreme Court held that there is no federal Constitutional right to assisted suicide
 - In doing so, it reaffirmed the distinction between
 - Withholding or withdrawing life-sustaining treatment
 - Versus assisted suicide
 - Decision leaves open the possibility that state supreme courts will find a state constitutional right, or, more likely, that states will develop a statutory right
 - Oregon has followed the latter route and has legalized physician-assisted suicide

Futility: Lack of Consensus

- Another controversial issue in end-of-life care is the process for determining when medical interventions are no longer effective
 - Especially when medical personnel and the patient or surrogate disagree about the decision
 - A number of cases suggest that this issue is still undergoing development in judicial analysis
- To guide the process, some general principles can be drawn from medical practice and case law:
 1. Physicians should be careful when thinking that a treatment may be "futile"
 - In decision-making when a treatment under consideration may seem to be futile, the physician should ask, "futile for what goal?"
 - That goal should be defined by the patient or surrogate (or parents if the patient is a child) in conjunction with the physician
 2. Physicians' recommendations for limiting treatment should be based as much as possible on
 - Objective determination of ineffectiveness, for the accepted goal
 - Rather than subjective opinions about the worth of the intervention or of the patient's continued life
 - Where there is concern or question, a second clinical opinion about the potential effectiveness of treatment may be both beneficial and necessary
 3. Where the patient or family disagrees with the physician's judgment
 - Ethics consultation
 - Committee review may be advisable
 4. If there is continued disagreement
 - Facilitate transfer of the patient when feasible to another health care practitioner or health care facility
 - Willing to continue or cease treatment (see Module 9: Medical Futility)
 5. If transfer to another physician or institution is not possible, the intervention need not be offered

- In cases where futility comes up
 - Commonly a major component of unsuccessful communication and strained relationships
 - Try to keep communication good, listen well, convey information effectively, and keep an empathic approach
 - In several studies a correlation exists between quality relationships and reduced malpractice rates, not only in futility cases but in general

Confidentiality

- Confidentiality concerns not usually different for patients facing the end of life
- No major legal differences
- In general, confidentiality should be broken if the absence of information puts an identifiable third party at risk of major damage
- Reporting requirements demand that certain infectious disease diagnoses be reported to public health authorities

Role of Professional and Institutional Counsel

- Physicians have responsibility to make ethical decisions in the care of patients at the end of life within the law that governs their medical practice
 - While ethics committees and consultation may consider legal aspects
 - Ethics committees do not act as legal advisor to physician and should not be mistaken as such
- Broad legal consensus on much of end-of-life treatment
- Some state variations remain (e.g., standards of certainty that surrogates must demonstrate in making decisions)
 - Some difficult legal issues remain unresolved (e.g., futility)
- In addition, if the physician works in a managed care organization that has set limits on care that the patient or family disagrees with
 - Physician may have to choose to advocate for one party over the other
 - Physician may also face incentives and disincentives to make decisions that run counter to the patient's wishes
 - But, although there is a duty to the institution, including possibly a contractual one
 - Physician carries the direct responsibility for patient care
 - May have more legal risk than the institution if the patient's care is compromised
- When physicians are uncertain as to the approaches to resolving a given case
 - Legal counsel may be sought
 - Important for the physician to recognize that hospital counsel represents the health care institution
 - May not focus on the needs of the individual physician
 - In addition, legal counsel's primary duty is to protect the client from legal liability, not necessarily to facilitate ethical practice

National Cancer Institute grant (R25 CA76449) to Sara J. Knight, Ph.D., at the Robert H. Lurie Comprehensive Cancer Center provided the funding for the development of this program. This material was adapted from the EPEC project (Education for Physicians on End-of-life Care).