Brigham and Women's Hospital
Founding Member, Mass General Brigham

Ethical Dilemmas in Pulmonary and ICU Medicine

Kathleen J. Haley, MD
Associate Physician
Department of Medicine, Division of Pulmonary and Critical Care Medicine
Brigham and Women's Hospital
Assistant Professor of Medicine
Harvard Medical School

CONTINUING MEDICAL EDUCATION
DEPARTMENT OF MEDICINE

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Conflict of Interest/Financial Disclosure

- I am a co-investigator on the NIH-funded PrecISE Trial Network and the NIH-funded IDEA trial. Within the last three years, the following companies have provided study drugs for the PrecISE Trial Network: GlaxoSmithKline, Laurel, Sun Pharma, Vifor, Vitaeris/CSL Behring, Vitaflo. The following companies have provided study drugs for the IDEA trial: Organon, Sanofi/Regeneron.

Kathleen Haley, MD

- Pennsylvania State University Medical College
- Medicine Residency and Pulmonary Medicine Fellowship @ NEDH
- Critical Care and Research Fellowship @ BWH
- Assistant Professor of Medicine @ HMS
  - Clinical focus: Critical Care Medicine
  - Research focus: Chronic Critical Illness and Asthma
  - Member of the BWH Ethics Committee
  - Director, Spaulding Cambridge Hospital Ventilator Service

Acknowlegement

- Dr. Martha Jurchak, the director (retired) of the Brigham and Women's Hospital ethics consult service, kindly provided advice and slide material for some of the background information and ICU ethics consults.

Case

- A 78yo man h/o severe COPD on 2L supplemental O2 is admitted to the ICU following intubation for respiratory failure.
- You meet with the patient's son and daughter, who is his healthcare agent, to discuss the next steps in care.
- She states, "We talked about the breathing tube. He said he wouldn't want to live on a machine, but that for a few days that would be different. So, I think he would want the tube right now". Her brother agrees.
- This is an example of what type of decision making?
  - A. Reasonable person
  - B. Consensus decisions
  - C. Synthetic judgement
  - D. Substituted judgement
  - E. Best interests standard

Case

- A 78yo man h/o severe COPD on 2L supplemental O2 is admitted to the ICU following intubation for respiratory failure.
- You meet with the patient's son and daughter, who is his healthcare agent, to discuss the next steps in care.
- She states, "We talked about the breathing tube. He said he wouldn't want to live on a machine, but that for a few days that would be different. So, I think he would want the tube right now". Her brother agrees.
- This is an example of what type of decision making?
  - A. Reasonable person
  - B. Consensus decisions
  - C. Synthetic judgement
  - **D. Substituted judgement**
  - E. Best interest standard

Outline

- Ethical Frameworks and Analyses
- Decisional Capacity/Informed Consent
- Advanced Directives
- Organizational Ethics

Ethics – common frameworks

- Descriptive Ethics – observation of moral reasoning
- Normative/Prescriptive ethics – how to arrive at a moral action
  - Principlist
    - Most commonly used
  - Deontological (duty-based)
  - Teleological (ends-based)
  - Virtue ethics
  - Care ethics
  - Causistry
  - Feminist ethics
  - Narrative ethics

Normative Ethics

- Most frequently used for analysis
- Four basic principles
  - Autonomy
  - Beneficence
    - Personal integrity – truth telling, fidelity, confidentiality
  - Nonmaleficence
  - Justice

Autonomy

- Foundation for
  - General respect for persons
  - Rationale for informed consent
  - Substituted judgement
  - Decisionally capable persons are the site of authority regarding permission for therapy
    - “You are the boss of you”
    - Negative right
- Legal precedence strongly supportive of autonomy, particularly rights to refuse therapy
  - Board tip: When in doubt, look for an option that maximizes the patient’s autonomy

What is a “negative right”

- Right to refuse
- Not a right to have treatment of choice

Decisional Capacity

- Distinct from “competency”
  - Competency is a specific legal term
  - Capacity refers to the ability to make choices regarding therapy
- Capacity requires
  - Knowing available choices
  - Appreciating consequences of available choices
    - Weigh the burdens and benefits of the choices
  - Indicate a choice
- Required for informed consent
- Difficult to assess with casual conversation
- A continuum instead of an absolute state
  - Capacity is decision-specific
  - Disorder of thinking doesn’t necessarily preclude competency

Two sticking points

- A person with capacity has the right to make a “wrong” decision
- Capacity can be difficult to assess
  - Rapid assessment can be made in the clinic or at the bedside
    - Several tools can help to gauge cognition
    - However, cognition is not sole determinant
  - Casual conversation usually inadequate to fully assess capacity for major decisions with large burdens
    - Psychiatry consultation can assist with capacity evaluation
    - Neurocognitive testing can give details of cognition
    - Outpatient clinic providers have the advantage of longitudinal relationship that can give greater insight than the in-patient assessment.

Advance Directives

- Honors autonomy when patient unable to participate
- Surrogate Decision Maker
  - Surrogate is anyone speaking for a patient
  - Health care agent is a legally recognized surrogate designated using health care proxy form
  - If health care agent isn't designated
    - Most states have defined hierarchy, generally next of kin
    - 4 states do not have defined hierarchy: MA, MO, NE, RI
    - If no next of kin, synthetic judgement is used
    - States frequently limit surrogate's authority to specific decisions
      - Some do not allow research consent
      - Generally, autopsy consent is allowed

Advanced Directives

- Advance Care Planning: Patient Self-Determination Act of 1990
  - Federal Statute
  - All states have Advance Directives laws
- Options for patients:
  - Living will – not recognized as binding in all states
  - Orders for life sustaining technology (MOLST, POLST, LaOLST)
  - Available resources: Nonprofits, state/national bar and medical societies, state governments
- Utility frequently limited in practice
  - Hard to anticipate specific questions
  - Work best to give general guidance about goals and wishes

Healthcare Agents

- The outpatient setting provides an opportunity to review
- Health Care Proxy/Durable POA for Healthcare
  - Legal, but simple, document
  - Healthcare agent does not need to be related to patient
  - Copies with chart, agent, Primary healthcare provider
  - Healthcare decisions during life (autopsy permission varies by state)
  - Same prerogatives regarding health information as patient
  - Basis for decisions
    - Patient's clearly stated wishes
    - Substituted judgment
    - Best interests of the patient

Beneficence and Nonmaleficence

- Beneficence
  - Do good
- Nonmaleficence
  - Avoid doing bad

Justice/Fairness

- Always a consideration
  - Usually more in the background
  - Occasionally more prominent
    - Patient/family monopolizing staff resources
    - Insurance limitations
- Recent sharper focus due to COVID-19 pandemic
  - Can be very contentious
  - Why???

Why the Contention?

- Definitions
  - Just: guided by reason and fairness, moral rightness
  - Justice: free from bias, dishonesty or injustice

- The problem:
  - Elements of justice have subjective components
  - Justice therefore modulated by framework and perspective

What Was Different?

- Pre-pandemic
  - In-hospital resource supply generally sufficient
  - Health disparities importance more of a systems, policy level
  - Many providers thought the system was fundamentally sound
- The pandemic changed this
  - Major concerns about essential in-hospital resource availability
    - Hospitals planned to allocate resources
  - Interaction of COVID-19 and health disparities
    - Brought fairness to the forefront
    - Raised questions about the fairness of the system
    - Raised questions about allocation plans

What Are the Implications?

- Justice may be more aspirational than achievable
  - Not a rationale for complacency, but instead humility
- Elements are rarely absolute
  - Fairness is impacted by context
  - Considerations of fairness will have blind spots
  - Any system open to charge of unfairness

- What to do? Recommendations:
  - Enlarge resource amount
    - When feasible can be a powerful approach
  - Transparency about analysis framework
    - Board tip: Frameworks will be good targets for questions
  - Willingness to revisit based on stakeholder concerns

Case Update

- The patient's status remains tenuous.
- You have received several emails about the patient's family from the ICU staff.
  - They have visited once in the week since his admission.
  - They frequently argue with nursing about the use of sedation.
  - Last night, a family member asked why lung transplants hadn't been brought up by the ICU team.
- The nurse manager discusses the family issues with you and states that she does not think the healthcare agent is making good decisions for the patient.

Question

- The action to take next is to
  - A. Petition the court to change the healthcare agent
  - B. Ask your social worker to schedule a family team meeting
  - C. Discuss the nursing concerns with the patient's daughter
  - D. Call an ethics consult
  - E. Arrange for a transfer to a different unit

Question

- The action to take next is to
  - A. Petition the court to change the healthcare agent
  - B. Ask your social worker to schedule a family team meeting
  - **C. Discuss the nursing concerns with the patient's daughter**
  - D. Call an ethics consult
  - E. Arrange for a transfer to a different unit

Managing Discord

- A consensus plan among providers is vital
- Proactive, frequent family meetings with predetermined clinical milestones help to decrease discord
- If significant discord, get outside opinion and/or increase family support
  - Involve healthcare provider with long-term relationship
  - Ethics consult
  - Social services
  - Patient/family relations referral
  - Chaplaincy
- If intractable discord refer to hospital policy
  - Following policy does not prevent lawsuits, but does support the reasonableness of the healthcare provider's action

Communicate, Communicate, Communicate

- Apparent discord frequently arises in setting of confusing or insufficient communication
- Identify agreed upon issues and goals first, then move to areas of disagreement
- Reframe issues as shared opportunity to work toward mutually held goals

Case, Continued

- You learn the following at the family meeting:
  - Work schedules have prevented family visits
  - The family thought the ventilator wasn't painful
- You bring up tracheostomy
  - The daughter states, "If he can't go home, he wouldn't want to go on like this". Her brother agrees.
- The discussion moves to possible extubation to comfort care. The patient's son states, "We can't do that. Taking away the machine will kill him." Which of the following is true?
  - A. Ethically, stopping an intervention is the same as not starting it.
  - B. Extubation to comfort care requires review by hospital lawyers
  - C. Extubation to comfort care requires an ethics consult
  - D. Sedatives cannot be increased after extubation to comfort care
  - E. Extubation to comfort care requires family consensus

Case, Continued

- You learn the following at the family meeting:
  - Work schedules have prevented family visits
  - The family thought the ventilator wasn't painful
- You bring up tracheostomy
  - The daughter states, "If he can't go home, he wouldn't want to go on like this". Her brother agrees.
- The discussion moves to possible extubation to comfort care. The patient's son states, "We can't do that. Taking away the machine will kill him." Which of the following is true?
  - **A. Ethically, stopping an intervention is the same as not starting it.**
  - B. Extubation to comfort care requires review by hospital lawyers
  - C. Extubation to comfort care requires an ethics consult
  - D. Sedatives cannot be increased after extubation to comfort care
  - E. Extubation to comfort care requires family consensus

Guardians and Minors

- Minors have a sliding scale for decisional capacity
  - If below the age of consent, assent is still required
- Legal guardians
  - Laws and roles vary by state
  - More constrained than health care agent
    - Psychiatric treatment may need separate guardian
    - Court approval may be required for consideration of end-of-life decisions

Research and Conflict of Interest

- Conflict of interest arises when a physician has dual roles
  - For example, an attending physician who has an actively enrolling clinical trial
- Usually managed by excluding the treating physician from recruiting patients into their own clinical trials
- The ethical issues raised by conflicts of interest:
  - Balance of risks and benefits
  - Informed consent can be problematic
  - Surrogate decision makers are limited from consenting for research in some states

Organizational Ethics

- Addresses issues around how a clinic or hospital manages ethical questions
  - Moves from individual case concerns to more general facility concerns
  - Examples
    - Transplantation for international patients
    - Instituting a new technology
    - Are criteria for transferring patients set by medical need or financial considerations?
    - Resource allocation for outpatient clinics
      - Should resources be specifically designated toward efforts to improve outreach to underserved neighborhoods?
      - How can resource allocation be used to decrease healthcare disparities?
- Analyses are similar to interpersonal ethics, but the focus is on the “macro” level

Take-Home Points

- The ethical principles of autonomy, beneficence, nonmaleficence, and justice provide the most common framework to analyze ethical issues
- Therapeutic advances means issues of informed consent and decisional capacity are common in the clinic
- Advance directives are best started as an outpatient
  - Choosing a healthcare agent is an important first step
  - Allows patients to guide care based on their goals

Question 1

- The concept of “substituted judgment” is best described by
  a. The medical team substituting for the patient by deciding what is in the patient’s best interests
  b. The designated surrogate decision maker using their best understanding of how the patient would decide for themselves as the basis for decisions
  c. The medical team substituting for the patient lacking a surrogate decision maker by using the “reasonable person” standard
  d. The care instructions outlined in a conversation guide such as the “Five Wishes” or a living will
  e. The court-appointed guardian using their understanding of the patient’s best interests as a basis for decisions

Question 1

- The concept of “substituted judgment” is best described by
  a. The medical team substituting for the patient by deciding what is in the patient’s best interests
  b. <u>The designated surrogate decision maker using their best understanding of how the patient would decide for themselves as the basis for decisions</u>
  c. The medical team substituting for the patient lacking a surrogate decision maker by using the “reasonable person” standard
  d. The care instructions outlined in a conversation guide such as the “Five Wishes” or a living will
  e. The court-appointed guardian using their understanding of the patient’s best interests as a basis for decisions

Explanation for Question 1

- “Substituted judgment” is the concept of having a proxy agent make a decision based on their understanding of what the patient would choose for themselves. It is a mechanism whereby the autonomy of an decisionally incapable patient can still impact decisions around medical therapies. Substituted judgment is the most commonly used method of choosing among therapeutic options, regardless of whether the surrogate decision maker is a healthcare agent or legal guardian. However, there are limitations to this approach, particularly since patients generally cannot anticipate all the issues around their illness in advance. A living will or previously written outline of a patient’s values and therapeutic goals, such as those found in the “Five Wishes” documentation, can provide important additional guidance.
- The “best interest” or “reasonable person” standard for decision-making can be used if there is no information regarding how the patient would choose for themselves.
- In practice, decision making is extremely complex, and a shared decision model, where the medical team provides guidance to the health care agent, is frequently successful.

References for Question 1

- TL Beauchamp and JF Childress. Principals of biomedical ethics, 6th edition. New York: Oxford University Press, 2009.
- A Torke, GC Alexander, J Lantos. Substituted judgment: the limitations of autonomy in surrogate decision making. J Gen Intern Med 2008;23: 1514 – 17.

Question 2

- Your patient, Mr. Jones, is a 54 yr old man who has resp failure due to end-stage COPD and pneumonia. His respiratory status is tenuous, and he is deeply sedated on the ventilator in the ICU. His family asks you to start an evaluation for lung transplantation. You tell his family that he is not a candidate for this procedure. They insist on the evaluation, saying, “he is a fighter”, “he would want everything to live”, “then he could be home, and he’d hate being in a nursing home”. The best course of action is

A. Consult the lung transplant team for an expedited evaluation since the patient’s family has requested this.
B. Refuse to order the consult since it is not medically indicated.
C. Obtain an ethics consult to help manage the disagreement around goals
D. Arrange a family meeting to provide education and obtain clarity about the patient’s goals and recent quality of life
E. Consult Palliative Care to assist this family with coming to terms with this patient’s life-threatening illness

Question 2

- Your patient, Mr. Jones, is a 54 yr old man who has resp failure due to end-stage COPD and pneumonia. His respiratory status is tenuous, and he is deeply sedated on the ventilator in the ICU. His family asks you to start an evaluation for lung transplantation. You tell his family that he is not a candidate for this procedure. They insist on the evaluation, saying, “he is a fighter”, “he would want everything to live”, “then he could be home, and he’d hate being in a nursing home”. The best course of action is

A. Consult the lung transplant team for an expedited evaluation since the patient’s family has requested this.
B. Refuse to order the consult since it is not medically indicated.
C. Obtain an ethics consult to help manage the disagreement around goals
D. <u>Arrange a family meeting to provide education and obtain clarity about the patient’s goals and recent quality of life</u>
E. Consult Palliative Care to assist this family with coming to terms with this patient’s life-threatening illness

Explanation Question 2

- The statements provided by this patient's family indicate that they do not share the medical team's understanding of the patient's current clinical status and prognosis.
- The reasons for this are unclear. A family meeting will help to develop a common understanding and forge a mutually acceptable plan based on the patient's goals and values
- Depending on the outcome of the meeting, ethics and/or palliative care consultations may be indicated, but it is too early at this point to know if these services will be helpful.

References for Question 2

- NG Wysham et al. Long-term persistence of quality improvements for an intensive care unit communication initiative using the VALUE strategy. J Crit Care 2014; 29: 450 – 54.
- A Lautrette et al. A communication strategy and brocure for relatives of patients dying in the ICU. N Engl J Med 2007; 356: 469 – 78.
- JJ Sanders, JR Curtis, JA Tulsky. Achieving goal-concordant care: a conceptual model and approach to measuring serious illness communication and its impact. J Palliat Med 2018; 21(S2): S17 – 27.

Question 3

- Your 40yo clinic patient has advanced breast cancer including lymphangitic spread that has been causing progressive dyspnea. She is currently on a protocol regimen for chemotherapy. What is true about her management?
    A. Opiods to manage dyspnea should be written by her oncologist
    B. Palliative Care consultation may be a useful adjunct to her chemotherapy
    C. Discussing her cancer as a cause of her worsening dyspnea will worsen her anxiety level
    D. Noninvasive ventilation will be a useful intervention for this patient
    E. A frank discussion of her prognosis could only proceed with her oncologist's permission

Question 3

- Your 40yo clinic patient has advanced breast cancer including lymphangitic spread that has been causing progressive dyspnea. She is currently on a protocol regimen for chemotherapy. What is true about her management?
  - A. Opiods to manage dyspnea should be written by her oncologist
  - **B. <u>Palliative Care consultation may be a useful adjunct to her chemotherapy</u>**
  - C. Discussing her cancer as a cause of her worsening dyspnea will worsen her anxiety level
  - D. Noninvasive ventilation will be a useful intervention for this patient
  - E. A frank discussion of her prognosis could only proceed with her oncologist's permission

Explanation for Question 3

- Although consultations for palliative care services are frequently reserved for patients at the end of life, palliative care specialists can positively impact patient care throughout their illness.
- Palliative care consultation, with aggressive symptom management during chemotherapy, was associated with increased survival in patients with metastatic lung cancer.
- Physicians should be trained to be sensitive to the patient's emotions during end-of-life conversations. These discussions are not usually associated with worsening distress: <5% of patients report severe stress associated with discussing end of life issues. A multidisciplinary approach is recommended.

References for Question 3

- RE Bernacki; SD Block; for the American College of Physicians High Value Care Task Force. Communication about serious illness care goals: a review and synthesis of best practices. JAMA Intern Med 2014; 174 (12): 1994 – 2003.
- JS Temel, et al. Early palliative care for patients with metastatic non-small-cell lung cancer. N Engl J Med 2010; 363: 733 – 42.
- EJ Emanuel et al. Talking with terminally ill patients and their caregivers about death, dying, and bereavement: Is it stressful? Is it helpful? Arch Intern Med 2004; 164: 1999 – 2004.

Question 4

- Your are a researcher in interstitial lung disease. Your lab has recently developed an agent that performs well in a rodent model. Your patient, a 75yo man with IPF, saw an article about this work in the paper, and asks you about trialing it in clinic. What would be true about an investigational agent developed by your research lab regarding use in your clinic patients?

  A. You would need an IRB-protocol before any medication could be used in your clinic population.

  B. Your patients could not participate in a trial testing a drug developed in your research lab since that would represent a conflict of interest.

  C. “Compassionate release” could be used as to give your patients access to this new therapy prior to IRB approval.

  D. Recruiting from your own clinic would be the best way to ensure that you have all the pertinent details of the subjects’ medical history.

  E. “Compassionate release” could be used for any of your patients who were critically ill in the ICU.

Question 4

- Your are a researcher in interstitial lung disease. Your lab has recently developed an agent that performs well in a rodent model. Your patient, a 75yo man with IPF, saw an article about this work in the paper, and asks you about trialing it in clinic. What would be true about an investigational agent developed by your research lab regarding use in your clinic patients?

  A. <u>You would need an IRB-protocol before any medication could be used in your clinic population.</u>

  B. Your patients could not participate in a trial testing a drug developed in your research lab since that would represent a conflict of interest.

  C. “Compassionate release” could be used as to give your patients access to this new therapy prior to IRB approval.

  D. Recruiting from your own clinic would be the best way to ensure that you have all the pertinent details of the subjects’ medical history.

  E. “Compassionate release” could be used for any of your patients who were critically ill in the ICU.

Explanation Question 4

- All novel investigational agents that have not yet been approved for use in humans require review by the hospital Institutional Review Board (IRB) and an approved protocol before they can be used in human subjects
  - IRB approval is not necessarily required for novel uses (“off-label” use) of previously approved medications
  - New technology requires an “investigational device” (IND) approval
- The principal investigator should not recruit their own patients, since this would be a conflict of interest: the physician would have the dual role of treating physician and researcher. However, these patients may participate in the trial if they are recruited by a co-investigator, and the research treatment assignment is randomized and masked.
- “Compassionate release” refers to the use of an investigational agent outside of the IRB-approved inclusion criteria and is done on a case-by-case basis.

Reference Question 4

- EJ Emmanuel, D Wendler, C Grady. What makes clinical research ethical? JAMA 2000; 283: 2701 – 11.

Bibliography

- R.D. Truog et al. Recommendations for end-of-life care in the intensive care unit: A consensus statement by the American College of Critical Care Medicine. Crit Care Med. 2008, vol 36, pp 953 – 963
- A. Lautrette et al., A communication strategy and brochure for relatives of patients dying in the ICU. New Eng J Med 2007, vol 356: pp469-478
- J.T. Berger et al., Surrogate decision making: reconciling ethical theory and clinical practice. Annals of Int Med 2008, vol 149 pp 48 – 53
- R.D. Truog et al., Pharmacologic paralysis and withdrawal of mechanical ventilation at the end of life. New Eng J Med 2000, vol 342 pp508 – 511
- M.J. Silveira et al., Advance directives and outcomes of surrogate decision making before death. New Eng J Med 2010, vol 362 pp1211-1218
- E.W. Ely et al., CAM-ICU; Crit Care Med 2001

Conflict of Interest/Financial Disclosure

- I am a co-investigator on the NIH-funded PrecISE Trial Network and the NIH-funded IDEA trial. Within the last three years, the following companies have provided study drugs for the PrecISE Trial Network: GlaxoSmithKline, Laurel, Sun Pharma, Vifor, Vitaeris/CSL Behring, Vitaflo. The following companies have provided study drugs for the IDEA trial: Organon, Sanofi/Regeneron.