CLINICAL BIOETHICS FOR THE NEW MILLENNIUM

BENJAMIN M. RIGOR, M.D., LL.D*.

Professor & Emeritus Chairman
Department of Anesthesiology
School of Medicine
University of Louisville Health Sciences Center
Louisville, Kentucky, USA

E-mail: bmrigorsrmd @ juno.com

*Certified Educator/Professor of Clinical Bioethics, Humanism & Professionalism on Medicine/Medical Practice
Disclaimer/Disclosure

• I am in the Speaker’s Bureau of the University of Louisville for continuing medical education of physicians, health professionals & for public information.

• Some of my research projects (phases II & III clinical trials) were supported by grants funded by pharmaceutical companies on a competitive basis & I have no financial interests or investment in them.

• The opinions expressed during this presentation are my own and do not necessarily reflect those of the University of Louisville or organized medicine.
Clinical Scenario No. 1

65 yrs. old, white, female, diagnosed with advanced uterine cancer, life expectancy is less than 6 months, cerebral metastasis produced alternate lucid & altered consciousness, matured son & daughter have opposing decisions - son wants everything done including all narcotics & resuscitation efforts - daughter wants to limit narcotics & requests DNR (Do not resuscitate!) orders in the patient’s chart.
Clinical Scenario No. 2

32 yrs. old, male, found positive for HIV antibodies, refuses to inform his wife, “If she finds out, it will destroy our marriage”. Should you notify the wife despite the patient’s objection? Although maintaining patient confidentiality is important, it seems cruel not to warn the wife that she is a risk for a fatal infection!!
Clinical Scenario No. 3

Mrs. R, a 66 yrs. old, widow, Alzheimer disease, lives in a nursing home, does not recognize relatives/friends or respond to questions; requires assistance with dressing, bathing & eating. When still lucid, she told her children/friends, many times, she wanted no “heroics” if she becomes senile! Her son claims, “this is not living!. I don’t want to die plugged into a machine, unable to recognize my family & having to depend on others to take care of me. If I’m like that, just let me die in peace!”.
Clinical Scenario No. 4

Ms. Reyes, RN, is an OR nurse. Mr. Cruz, a 43 yrs. old man, with symptomatic HIV infection was struck by a car while crossing a stop light. He sustained comminuted fx of the rt. femoral shaft. Dr. Ramos, orthopedic surgeon, scheduled him for emergency fixation & intramedullary rod. Miss Reyes refused to scrub/assist Dr. Ramos because during surgery sharp bone fragments (spicules) from the seropositive patient will expose her to an “unacceptable” risk of a potentially lethal disease with no known cure!!
Jose, a senior student in medical school, was taking his final examination in pediatrics. This was a honor examination with no proctors/watchers. John, his classmate, noticed he opened his book/notes during the examination. Jose answered the question promptly, correctly & topped the examination getting the highest grade “honors”. When the Dean gave his farewell address to this class in their last day in school, he announced that Jose is one who will graduate with honors or “cum laude”!!
Mrs. Reyes is a Jehovah’s Witness who is in her last trimester of pregnancy. She went into active labor & delivered a healthy, full-term baby but is now having vaginal bleeding from uterine atony. In spite uterine massage, drugs to make the uterus contract, her HCT dropped to 5.5% & is bleeding continuously. She refuses blood transfusion & Dr. Ramos, her obstetrician said, “I cannot provide care on this patient who might died without the benefit of the badly needed blood transfusion. I am taking care of this patient with one arm tied around my back!!”
BIOETHICAL QUESTIONS

• What are the ethical dilemmas in these case scenarios?
• As the physician/health care professional, what will you do?
• What morality & ethics ought to be for the:
  health care professional?
  patient?
  relatives?
  hospital?
  payer (insurance companies)?
  society & policy makers?
**Milestones – Clinical Bioethics**

<table>
<thead>
<tr>
<th>Ethical Codes</th>
<th>Authors</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hippocratic Oath</td>
<td>Phytagorean or the asclepiads</td>
<td>4th BC</td>
</tr>
<tr>
<td>Medical Ethics</td>
<td>Sir Thomas Percival</td>
<td>1803</td>
</tr>
<tr>
<td>AMA Code of Ethics</td>
<td>Drs. Bell &amp; Hays</td>
<td>1847</td>
</tr>
<tr>
<td>Geneva Declaration</td>
<td>WMA</td>
<td>1947</td>
</tr>
<tr>
<td>Nuremberg Trials</td>
<td>War Crimes Commission</td>
<td>1947</td>
</tr>
<tr>
<td>Helsinki Declaration</td>
<td>WMA</td>
<td>1964</td>
</tr>
</tbody>
</table>

*Gen. Telford Taylor* (Informed Consent)
Nuremberg Code of Ethics

- Voluntary consent
- Expected beneficial outcome
- Prior animal experimentation
- Avoidance of horror & pain
- Avoidance of risk & disablement
- Less risks than benefits
Nuremberg Code of Ethics

• Risk is not >humanitarian importance
• Proper preparation & adequate facilities to protect the subject
• Scientifically qualified researchers
• Subject can retract consent
• Obligation to stop the experiment
Modern Crisis – Clinical Bioethics

• 1950 – 1960 – The Tuskegee Experiments!!

• 1962 – Shana Alexander’s “They decide who lives, who dies”. Allocation or rationing of hemodialysis, Seattle, WA.

• 1973 – Drs. Duff & Campbell – Deliberate decision to withhold treatment to 43 babies, Yale-New Haven Hospital, CT.

• 1976 – New Jersey Supreme Court – Right of Karen Ann Quinlan’s family to withdraw medical treatment!!

• 2006 – The Terri Schiavo “fiasco”!!
Definitions – Clinical Bioethics

• **Morality** – Beliefs & practices of people about behavior & character toward other people, institutions, society, other life forms & inanimate objects.

• **Ethics** – The disciplined study of morality.

• **Bioethics** – What morality ought to be for health care professionals, patients, institutions, payers & policies.

• **Ethonomics** – Recognize the validity of economic & material constraints in health care.
Definitions – Clinical Bioethics

• **Autonomy** – Freedom to choose & implement one’s own decision, free from deceit, constraint, coercion & duress (**Self-determination**).

• **Beneficence** – Duty to promote the health & welfare of the patient over & above other considerations, while attending & honoring their personal autonomy.

• **Physical/Mental Capacity** ("**Competence**") – Freedom from disability; sense of well being & in control of all faculties & thought processes – Decision-making ability.
Definitions – Clinical Bioethics

- **Non-maleficence** – Not to inflict harm, evil, injury or wrong to the sick (“*Do no harm!*”).
- **Justice** – Equal must be treated equally.
- **Advanced Directives** – Advance desires of the patient on the progression of care while still competent.
- **Healthcare Surrogate** – Patient advocates who enforces the advanced directives.
- **Paternalism** – Imposing your own views & values to the patient.
Definitions – Clinical Bioethics

• **Compassion** – Acknowledge & respond to the suffering & distress of the patient.

• **Fiduciary** – A person serving as a trustee, in respect of confidence & trust & the scrupulous good faith & candor.

• **Self-effacement** – Virtue requiring health care professionals to ignore irrelevant differences between health care workers & patient & their responses to these differences.

• **Substantive Justice** – Outcome of distribution of scarce resources, who gets what as due the patient.
Challenges – Clinical Bioethics

- The manage care era.
- Changing demography of patients.
- **Medicine is now a business!**
- Advocacy for consumers ("Naderism").
- Advances in computers & technologies.
- Health care expenditure is limited!
- Human experimentations & clinical trials.
- Clinical bioethics & the law.
Challenges – Clinical Bioethics

• Sharing of health care costs.
• Legal entanglements & litigious society.
• Demand for advanced directives & autonomy.
• Governmental control & regulatory policies/bodies.
• The non-cognitive/communicative patient.
• Manpower crisis in health care.
• HIV-AIDS & new/other endemic diseases.
Challenges – Clinical Bioethics

• End-of-life, assisted suicide, withdrawing or withholding care & treatment.
• Dealing with mental health issues.
• Propensity for human & medication errors of the health professionals.
• The For-Profit-Hospitals & “penny pinching”.
• Moral distress & dealing with suffering.
• Justice & distribution of scarce resources.
• Militancy & advocacy in medicine.
Ethical Dilemmas in Pain Management

- End-of-life scenarios.
- Acts of omission or commission.
- The “narcotic seeking” patient!
- Animal experimentations ("Pain & horror").
- The non-cognitive/communicative patients.
- The Hospice/Palliative Care environment.
- Therapeutic use of non-conventional or alternative medicine, devices & modalities.
- Paternalism by the health care providers!
Basic Theories of Bioethics

• Principles of beneficence & respect for autonomy are the ethical obligations in clinical practice.
• There is a greater balance of good over harm ("Do no harm!").
• Health care professionals, patients, relatives, hospitals, payers & the society have ethical obligations.
• Patient should respect the autonomy of the health care professional & vice versa.
• Patient’s rights are justifiably limited when health resources are scarce!!
Basic Theories of Bioethics

- Ethical analysis & arguments are basic tools of ethics – clear, consistent, coherent, applicable, adequate & reliable.
- Different patients have different levels or intensity of needs & care.
- Universal access to basic & decent minimum of health care resources!
- With scarcity of resources, the patient’s interest & welfare must prevail!
Basic Theories of Bioethics

• Patients have ethical obligation to be prudent savers for their own health cost!!

• Patients & health care professionals have ethical obligations not to impose on family members & other care givers unreasonable long term care burden!!

• There is competing sources of morality in a multicultural & pluralistic society.

• Ethical & moral issues should be incorporated in health care policy debates & laws.

• Distribution of scarce resources – justice prevails.
Informed Consent

- Decision-making capacity – Competence!
- Understanding & comprehension.
- Voluntariness – Not deceived or coerced.
- Authorization & documentation.
Competence

- Patient makes/communicates a choice.
- The patient appreciates the following:
  - Medical situation & prognosis.
  - Nature of the recommended care.
  - Alternative course of care/therapy.
  - Risks, benefits & consequences of each alternative.
- Decision is consistent with pt. values & goals.
- Decision did not result from delusions.
- Patient uses reasoning/logic to make a choice.
Deception & Non-Disclosure

- Elicit family’s concern.
- What does the patient want?
- Future contingencies for information withheld.
- Dilemma if information is disclosed!
- Exhaust other alternatives.
- Is the health benefit at stake?
Confidentiality - Exceptions

• Protection of the 3rd parties – Infectious diseases, STDs, DUI, HIV, etc.

• Injuries by weapon, crimes, terrorism, etc.

• Notification of public health officials.

• Protecting from child- & elder-abuse & domestic violence.

• The patient insists & is aware of consequences of disclosure.
Quality of Life

• Symptoms of the illness & side effects of treatment.
• Patient’s functional ability to perform ADL, i.e., walking, grooming, shopping, meals, etc.
• Patient’s experiences of happiness, pleasure, pain & suffering.
• Patient’s independence, privacy & dignity!!
Clinical Bioethics & the Law

• **Law cannot provide definitive answers to every ethical dilemma!**
• Some actions might be prohibited by law but considered ethical or vice versa.
• Law sets only a minimally acceptable standard of conduct.
• **Courts are not optimally suited to make medical decisions!!**
• **Courts are the tribunal of last resort.**
• Over-reliance on “what is legal” can undermine careful, complete & subtle ethical analysis.
Health Care Justice

• No one has unlimited right to health care!!
• No one has a just claim to marginal, non-costworthy health care benefit.
• Health care needs of the young maybe favored over older people who had achieved natural life span.
• Health care professionals must deliver the best quality of care at all times regardless of the ability of the patient to pay or their resources.
Health Care Justice

• The social worth of the individual is irrelevant in determining just claims to needed health care.

• A reformed health care system need to be universal & global & not fragmented & exclusionary!!

• We are normally obligated to eliminate waste before rationing beneficial health care.
What is Futility?

• Intervention(s) has/have no pathophysiological rationale.
• Active interventions had already failed.
• The likelihood of success is very small (<1% success).
• No worthwhile goal of care can be achieved.
• Quality of life is unacceptable!!
• Prospective benefit is not worth the resources (expenditures) required.
Patient’s Best Interest

• Understand patient’s perspectives.
• Address misunderstanding & concern.
• Persuade & encourage the patient.
• Negotiate a mutually acceptable plan of care.
• In the non-cognitive patients, use proven tools & guides of/for care.
• Ultimately, let the patient or health care surrogate decide.
Ethics in Research & Publications

• Fabrication & falsification of research results.
• Plagiarism.
• Ghost writing & honorary authorships.
• Redundant publications.
• Ethical obligations of peer reviewers.
• Ethical responsibilities of journal editors.
Ethical Responsibilities – Health Care Professional

• Compassion, honesty & integrity.
• Protect & promote patient’s interest.
• Maintain competence & skill.
• Fiduciary (trustee) of the patient.
• Self-sacrifice & self-effacement.
• Respect for beneficence, autonomy & self-determination.
• Equitable allocation of scarce resources.
Ethical Responsibilities – The Patient

• Cooperate & expedite informed consent & care plans.
• Respect autonomy of the health care providers.
• Not to impose long term care burdens to the family & other “caregivers”.
• Justifiable limited right of claims on scarce health care resources.
• Be prudent savers for their own health care costs.
• Know about human experimentation & refusal to participate.
Ethical Responsibilities – Health Care Institution

• Fiduciary responsibilities – protects & promotes beneficence-based interests.
• Financial stability & solvency!!
• Professional character & competency of the health care professionals & the staff.
• Contractual obligations & entitlements.
• Tutor third parties on fiduciary roles.
• Survival & excellence of the institution
Ethical Responsibilities – The Society

• Maintenance of health & basic needs.
• Equal treatment – access, availability, extent, intensity of service, etc. (Justice)
• Preserve fiduciary character of the health care professionals & the institutions.
• Accept & appreciate changes in health care concepts & technology.
• Ease burden & decrease possibility of medical litigations.
Preamble – AMA Code of Ethics

• Competent with compassion & respect for human dignity.
• Honesty with patients & colleagues.
• Respect for the law & authority.
• Respect for the rights of the patient, colleagues & other health care professionals (Confidentiality!).
Preamble – AMA Code of Ethics

• Study, apply advance scientific knowledge & advances in medicine.
• Obtain consultation & use talent of others & specialists.
• Provide appropriate patient care without bias.
• Contribute to activities to improve community, the society, humanity, etc. (civic & philanthropic).
The Patient’s Bill of Rights

• Considerate & respectful care.
• Complete medical information, charts, bills, etc.
• All information to give informed consent.
• Refuse treatment to the extent permitted by law & know all the consequences.
The Patient’s Bill of Rights

• Privacy concerning medical care.
• Confidentiality of all records & communications.
• Reasonable response for services.
• Relationship with other health care & educational entities.
• Know human experimentation & refusal to participate
Guiding Principles – End-of-Life

• Respect the dignity of patient & caregivers.

• Be respectful of the patient’s & family’s wishes.

• Use appropriate therapies consistent with the choice(s) of the patient/legal surrogate.

• Ensure pain alleviation & management of other physical symptoms/distress.
Guiding Principles – End-of-Life

• Recognize, assess & address psychological, social & spiritual problems/conflicts.
• Access to therapies that will improve quality of life.
• Access to palliative & hospice care.
• Respect patient’s right to refuse treatment.
• Recognize MD’s/caregiver’s responsibility to forego futile or useless or unproven treatments or modalities.
Approach to Clinical Dilemmas

- Clarify the facts of the case – Clinical situation, primary decision maker, concerns, values, etc.
- Analyze the ethical issues – Apply ethical guidelines.
- Address psychosocial, emotional, spiritual, financial (economic), etc. issues.
- Negotiate to reach agreement.
- Seek assistance/consultation, if needed.
THE GEORGETOWN MANTRA*

• BENEFICENCE

• NON-MALEFICENCE

• INDIVIDUAL AUTONOMY

• JUSTICE

Answers to the Ethical Scenario

• Competence of the patient – There are moments when she is lucid. She should be able to decide for herself.

• The 2 children were not appointed as her health care surrogates.

• Since she is competent, her autonomy must be respected.

• She should be pain-free until death (6 months)!!

• Patient should have agreed to have a DNR (“Do not resuscitate”) order since she is still competent!
The patient became comatose. She still feels pain by showing non-cognitive signs of pain. She has advanced directives. Her husband is her surrogate.

– Answers to Questions –

1. Her husband makes all the decisions in consultation with the children & the Ethics Committee of the hospital.

2. The husband can authorize optimal amount of narcotics to relieve pain till death.

3. The husband can sign the DNR order after consultation with the health care providers, the children & the Hospital Ethics Committee.
“We who remain silent while patients suffer, fail on our duty to patients & deprive the organization & colleagues of important information necessary to reduce liability & improve performance. We accelerate our own burn out, hastening the day when we can no longer respond to the emotional needs of others or experience the joy of patient care & the practice of our profession!”

Suggested Reading List

Suggested Reading List

Suggested Reading List


