LEGAL AND ETHICAL ISSUES IN CLINICAL MEDICINE
FALL 2011 –SPRING 2012
SPM 200

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Meeting Times: Lecture/ discussions are integrated into two forum meetings, one each in the fall and spring. Fall forums are held on Monday, Tuesday and Thursday, 1-3PM and Wednesday 2-4PM. Spring forums TBA

FALL SEMESTER
Groups 1-4 November 14, 2011
Groups 5-8 November 15, 2011
Groups 9-12 November 16, 2011
Groups 13-16 November 17, 2011

Meeting Rooms: Learning Center, Large classroom

Course Materials: The cases for group discussions will be provided in handouts at forum discussions.

Course Description: Ethics and Health Law in Clinical Medicine is the second course in a series* designed to emphasize the importance of ethical issues and human values as an integral part of medical education and practice. Building on materials presented in Introduction to Medical Ethics, this course introduces the concept of legal principles in relationship to ethical principles in clinical medical decision making. The goals for consideration of ethical and legal decisions in health care delivery are:

1. To promote the best health care decision making for the individual patient and the health needs collectively of all patients
2. To protect the rights of patients(s), provider(s) and rights of society as a whole.**

*this course follows Introduction to Medical Ethics, the core course for first year medical students and precedes Applied Clinical Ethics, the core course for third year medical students.

** See goals and objectives AAMC Learning Objectives for Medical Student Education Report 1, Guidelines for medical schools, January 1998.
Course Objectives:
1. To recognize ethical and legal issues in medical decision making.
2. To explore the structure and function of law in its relationship to the ethical practice of medicine.
3. To identify ethical and legal principles related to:
   informed consent, end of life decisions, confidentiality, privacy of health information, duty to treat/non compliance, access/allocation/anti discrimination, protection of subjects in clinical research trials, conflicts of interest in health care and medical research, standard of care/professional liability/medical error, professional relationships, public health medicine, managed care/fiduciary duty, professional relationships and institutional policy.
4. To discuss the relationship of ethics and law in clinical decision making.
5. To incorporate and apply this knowledge in making clinical decisions.
6. To identify ethical principles and legal tools relating to public health:
   a. Constitutional power and limits of power to promote community health
   b. Permissive and mandatory statutory laws and administrative regulations to respond to health threats; and
   c. Balance of individual rights of autonomy, privacy and liberty with general welfare.
7. To apply these principles and tools to epidemiology, immunization, screening, medical informatics, substance abuse, reproductive health, wellness and health policy.

Teaching Strategies:
Issues and principles underlying and defining the ethical, legal practice of medicine will be taught using small group discussions of individual case studies, as well as integrated into broad topics of study which will include: epidemiology, immunization, screening, medical informatics, substance abuse, reproductive health, health policy and wellness. Course content will be introduced through a lecture format, studied in small groups and formally applied and presented through student projects.

Student Evaluation:
The course will be graded as pass/fail. Students will be evaluated (1) on their attendance, (2) on their participation in group discussions, (3) on their scores on specific questions included in the comprehensive end-of-semester exam.
COURSE OUTLINE

1. Legal & Ethical Issues in Clinical Medicine

2. Regulation of Practice of Medicine
   - NWS practice standard of care
   - Need to know law to avoid liability

3. Cases
   - Trigger discussion of legal and ethical issues in clinical decision making
   - Illustrate the inseparable interrelationship of medical, ethical, and legal issues in clinical decision making

4. Medical, Ethical and Legal Decision Making
   - Primary medical decision
   - Secondary ethical decision
   - Frequent legal decision

5. Law is the Ethical Minimum
   - Law may set ethical minimum of moral consciousness
   - Starting point for making decisions and developing policies
   - Consideration of underlying law not end per se

6. Legal Rights flow from the American Constitution
   - Rights of:
     Liberty
     Privacy
     Equal Protection
     Due Process

7. Statutory Law
   - Federal laws - anti-dumping statute
   - State laws - legal standard of practice and medical malpractice laws

8. Agency Regulations
   - Legislative bodies delegate authority to implement legislation to agencies
   - Congress delegates to CMS authority to promulgate rules to manage, regulate, and implement Medicare laws

9. Jurisprudence or Case Law
   - Courts have power to decide disputes between parties
   - Courts interpret and apply constitutional, statutory and regulatory law to facts in dispute
   - Court holdings set legal precedents and rules of law for future disputes
Case 1 – Fall Semester  Decision Making for End of Life

An 84-year-old female resides in a nursing home. She has advanced Alzheimer’s disease, is non-verbal and has been confined to bed for several months.

She was diagnosed with carcinoma of the breast 8 years ago, and she underwent a modified radical mastectomy plus radiation therapy. Metastatic disease to both lungs was detected 2 years ago. She did not respond to aggressive chemotherapy and is now receiving only hormonal treatment. The metastases have progressed.

She was admitted to the hospital with a diagnosis of pneumonia. Her respiratory status continued to deteriorate over the next 48 hours, despite broad-spectrum antibiotics. She now requires intubations and mechanical ventilation. It is your opinion that, even if the pneumonia resolves, she will probably never come off the ventilator because of the advanced metastatic disease in her lungs. For this reason you would prefer not to begin ventilator support.

The patient has no advance directives regarding life support. The patient’s husband is deceased and her children have not visited her in the hospital. You are able to contact one of her daughters who wants all life sustaining measures taken.

QUESTIONS:
Q1 - Is the patient competent to make a choice?
Q2 - If the patient is incompetent, how do you decide whether to put her on a ventilator?
Q3 - Is this futile care?
Q4 - Is there a duty to provide futile care?
Q5 - How do we control and standardize decision making?
Q6 – What is a living will, a durable power of attorney, the LA Family consent law?

http://www.legis.state.la.us/
Click on LA laws in left hand column, Law body: RS, Title (40), Section(1299.58.1)
RS - Title 40 Section 1299.58.1 read Part A
RS - Title 40 Section 1299.58.1 read Part B
RS – Title 40 Section 1299.58.2 read (12) and (15)
RS—Title 40 Section 1299.58.3 read Part C
RS – Title 40 Section 1299.58.4
RS – Title 40 Section 1299.58.5

http://MCLNO.org
Click on intranet log on & type in LSUHSC user name & password
Click on MCL Policies- Scroll to #5021 Limitation of Life Sustaining Therapies Including Resuscitation
Case 2 – Fall Semester  Confidentiality and Genetic Information

AB, a 54 year old woman with metastatic breast cancer, had been entered into a research protocol. Although there is a history of breast cancer on her mother’s side, no pathological specimens are available. While testing is underway for mutations in her BRCA1 and BRCA2 genes, the patient died.

The patient has two adult daughters. Shortly after her mother’s death, one of the daughters requests access to her mother’s test results. She explains that she wants this information because it will help her learn whether she carries the same mutation that might have contributed to her mother’s disease. She wishes to learn about her status. If she has the mutation, she is considering undergoing bilateral radical mastectomies to reduce her risk of contacting cancer later in life.

After considerable discussion and consultation, the physician decides to furnish the daughter with information on her mother’s test results. Learning of this decision, the other daughter registers a protest. “There is no way that this decision can be kept away from me, since I’ll learn by sister’s decision if I have a greater risk of developing breast cancer. I object to your releasing this information at this time.”

What should the physician do?

QUESTIONS:
Q1 - Does the physician have a duty to keep information about the mother confidential?
Q2 - What is the duty of the physician when that confidentiality harms a third party?
Q3 - What is the scope of the duty to warn?
Q4 - Can a patient who seeks genetic testing avoid discrimination by employers and health insurers?

http://www.legis.state.la.us/
Click on LA laws in left hand column, Law body: RS, Title (22 & 23), Sections infra
RS – Title 22 Section 1023 Prohibited discrimination; genetic information
RS – Title 23 Section 368 Prohibition of genetic discrimination in the workplace
RS - Title 22 Section 1022 Prohibited discrimination prenatal testing
RS – Title 15 Section 1501 et seq Adult Protective Service, @ Section 1504
RS - Title 9:2800.2 Psych Immunity for warning
Lagniappe: RS - Title 40:1300.12-15
RS – Title 40:1299.40D.1- Authority to test without consent
RS - Title 40: 1064.1 Expedited Partner Therapy
Case 3– Fall Semester - Anti Dumping and Disability Discrimination

A 32-year-old woman who is HIV positive comes to the emergency department of a hospital complaining of right-side abdominal pain. She has fever, tachycardia and severe pain upon palpation in the right lower quadrant with rebound tenderness. She looks acutely ill. Based on her exam and laboratory values you suspect that she has acute appendicitis, and is in danger of rupture. She needs emergent surgery. The patient has no health insurance but attends a free HIV clinic at a University Medical Center only 2 miles away.

As the emergency physician, you contact the surgeon on call. The surgeon suggests that, since the patient is seen at the University HIV Clinic, she should be transferred to the University Hospital’s emergency department. He states that she would be a good case for the residents in the training program there.

QUESTIONS:
Q1 - Does federal anti-dumping statute apply to this transfer?
Q2 - What is EMTALA?
Q3 - What constitutes an appropriate (legal) transfer?
Q4 - Does federal American with Disabilities Act apply?
Q5 – Does Title III, “equal access of persons with disabilities to benefits of public accommodations” apply to this situation?

http://www4.law.cornell.edu/uscode/

Title 42 US Code Section 12182 Americans with Disabilities Act (ADA)
Title 42US Code Section 1395dd Anti Dumping Statute/ EMTALA
Moses v. Providence Hospital and Medical Centers, Inc., 561 F.3d 573 (6th Cir. 2009)
Case 4 – Fall Semester         Clinical Research Ethics/ Informed Consent/ Exploitation

You have recently admitted under your care a 60 year old female patient with early Alzheimer’s disease. In your medical judgment she was competent at time of admission to make her own health care decisions. You invited her to participate in a clinical trial testing a new memory drug to help improve her memory. You were present when the clinical investigator obtained her signed informed consent a few days ago.

When you visit your patient today and ask her if she is ready to begin the study tomorrow, she looks at you blankly and seems to have no idea what you are talking about. What should you do?

QUESTIONS:
Q1 - Is informed consent required for clinical research?
Q2 - Is the prior informed consent valid?
Q3 - If the patient is incompetent, how can she participate in the testing?
Q4 - What is the LSU Institutional Review Board (IRB) and how does it function in clinical research?
Q5 - Does inclusion of this patient as a research subject in study constitute exploitation of vulnerable population?

http://www.access.gpo.gov/
GPO access
Code of Federal Regulations
“21CFR50.20” (search must be enclosed by quotation marks)

http://www.legis.state.la.us/
Click on LA laws in left hand column, Law body: RS, Title 40, Sections infra
RS Title 40 Section 1299.40 et seq. Informed consent
RS Title 40 Section1299.53 Persons who may consent
RS Title 40 Section1299.53 et seq. Persons who may consent
–substitute decision making-default family consent law-also 1299.55 relationship liberally construed; Interim LSU policy-5016; 1299.54 emergency exception; 1299.56 right to refuse;

http://www.lsuhsc.edu/no/research/
- Clinical Trials – Institutional Review Board Guidelines, or
http://www.lsuhsc.edu/no/Administration/rs/irb/
Case 5 - Fall Semester: Overdose of Medication/ Medical Malpractice

A 60 year old man was diagnosed with primary colon cancer five years ago. At that time, his physician performed a colostomy, removing the tumor. Tumor margins were positive and he was treated with chemotherapy. You were his attending oncologist and now readmit this patient with complaints of abdominal pain and signs of abdominal distention.

Exploratory laparoscopy demonstrates diffuse, disseminated peritoneal metastasis. The tumor is not resectable. The treatment options are immunotherapy, chemotherapy or palliative therapy. Data to date on the first two options evidence no likelihood of cure. Patient’s life expectancy is one month.

At bedside of this patient during morning rounds you verbally order chemotherapy. The oncology specialist nurse who is rounding with you writes the order in the chart, misplacing the decimal point on the dosage, resulting in an order 10X the amount that you requested.

That evening you sign the order that the nurse has written in the chart. The order for the medication is sent to pharmacy. It is such a large amount that pharmacy does not have enough in stock and sends a runner to three different hospitals to borrow enough of the drug to fill the order. The nurse who hangs the IV drip and administers the chemotherapy to the patient reports that the solution was the darkest blue that she had ever seen for this drug.

Following the administration of this “therapy” the patients’ health declines rapidly. The patient suffers a cardiac arrest and dies four days later.

QUESTIONS:

Q1 - Has any member of the healthcare team violated the standard of care?
Q2 - What is the medical malpractice law in the state of Louisiana?
Q3 - What are the elements of proof on medical malpractice?
Q4 - What is the legal standard of care, violation of the standard of care, causation, damages, prescription?
Q5 – How can we prevent medical error?

http://www.legis.state.la.us/
Click on LA laws in left hand column, Law body: RS, Title 40 Sections infra
RS – Title 40 Section 1299.41 - 1299.51 LA Medical Malpractice Act
(Law is extensive; it is cited here for your future reference. A summary will be presented in class.)
RS-Title 9 Section 5628 Statute of Time Limitations;
RS -Title 9 Section 4231 Voluntary Arbitration;
RS -Title 40 Section 1299.39.3 Panel during declared State of Emergency;
Case 6- Fall Semester  Good Samaritan Statutes

A 50 year old man is having dinner with his 49 year old wife and four children as they celebrate their oldest daughter’s graduation from UNO at a local restaurant. In the middle of toasting his daughter’s accomplishment, he suddenly notices that his wife is holding her neck and gasping for air. In a frenzy he hurries to her side determined to apply his limited CPR knowledge. Before he can reach her a physician from another table has already begun performing the Heimlich maneuver on her while instructing someone to call for an ambulance.

When the EMT’s arrive, the physician has successfully dislodged the bolus of food from the wife’s trachea. However, she seems to be in severe abdominal pain. The physician rides to the hospital with the wife. At the hospital the wife undergoes abdominal surgery to control internal bleeding. The physical stress of the respiratory rescue has apparently caused the rupture of an abdominal aortic aneurysm.

After learning the nature of his wife’s diagnosis and the cost of the medical care she has needed, the husband is considering filing a malpractice suit against the physician for his rescue at the restaurant.

QUESTIONS:
Q1 - Was it the physician’s duty to act, even though he did not know the woman’s underlying medical history?
Q2 - Does the Good Samaritan statute offer any protection for the physician in this particular case?
Q3 - Does this statute offer a medical student any protection?
Q4 – Is a physician who volunteers professional services at a free clinic protected from professional liability?

http://www.legis.state.la.us/
Click on LA laws in left hand column, Law body: RS, Titles 37 & 9, Sections infra

RS – Title 37 Section 1731 Good Samaritan immunity licensed provider
RS – Title 37 Section 1731.1 Limitation liability during Gov declared state emergency
RS – Title 9 Section 2793 Good Samaritan immunity lay person
RS – Title 9 Section 2799.5 Good Samaritan immunity community health clinic
RS - Title 29 Section 781-792 Uniform Voluntary Health Practitioners Act
POLICY AND PROCEDURES REGARDING
LIMITATION OF LIFE SUSTAINING THERAPIES INCLUDING
RESUSCITATION

POLICY STATEMENT
This policy sets forth guidelines for limitation of life sustaining therapies including resuscitation for adults and children at the Medical Center of Louisiana.

MCL Policy 5021 – Policy and Procedures Regarding Limitation of Life Sustaining Therapies Including Resuscitation was developed by a multidisciplinary committee and approved by the Medical Staff and does not apply to:

- Patients undergoing surgical procedures. (Exceptions for surgical patients may be made if surgery and anesthesia agree to the exception).
- Patients requiring emergency department care in which the wishes of the patient are uncertain.
DEFINITIONS

For the purpose of this policy, the following terms shall be defined as indicated below:

Medical staff physician – the staff physician who has primary responsibility for the treatment and care of the patient.

Life-sustaining procedure – any medical procedure or intervention which, within reasonable medical judgment would serve only to prolong the dying process. A “life-sustaining procedure” shall not include any measure deemed necessary to provide comfort care.

Minor – a person who has not reached the age of majority, which is 18 years old.

Physician – a physician or surgeon licensed by the Louisiana State Board of Medical Examiners, and granted clinical privileges by the Medical Executive Committee and appointed by the Hospital.

Futile therapies – therapies, that within reasonable medical judgment, are not considered to be of benefit to the patient and are not usually indicated unless they alleviate pain or suffering or support personal dignity.

Limitation of life sustaining therapies - withdrawal and withholding of therapies.

Permanent con-cognitive state of comatose-state – a state in which there is no reasonable medical possibility of ever achieving a cognitive state of conscious perception.

Guidelines for Limitation of Life Sustaining Therapies Including Resuscitation for Adults

ETHICAL PRINCIPLES

A. The ethical basis for limitation of life sustaining therapies including resuscitation must be the sound medical judgment that further medical treatment for the primary disease is futile and does not benefit the patient. Limitations of life sustaining therapies include withdrawal and withholding of therapies and there is no ethically significance difference between the two.

B. When patients are mentally competent adults, they have the legal Right to accept or refuse any treatment proposed by their physicians and their wishes must be recognized and honored by their physicians. The right to refuse therapy may be modified in the pregnant patient because of the presence of the fetus. Physicians are not required to apply medically
inappropriate treatments to patients. The patient is to be informed of the right to execute an Advance Directive. Please refer to MCL Policy 0024 – Policy and Procedure Governing Advance Directives for detailed procedures.

C. Patients who experience unexpected cardiopulmonary arrest for known or unknown causes and who are not known to have refused resuscitation should have resuscitation measures performed.

D. Age, mental disease, mental retardation and chronic disease capable of being treated or palliated should not be grounds for an order not to resuscitate.

E. Life sustaining medical therapies are not indicated if one or more of the following circumstances is present unless those therapies alleviate pain or suffering or support personal dignity. Under the following clinical circumstances life sustaining therapies are usually considered futile:

- the patient imminently and irreversibly dying.
- the presence of a permanent non-cognitive comatose state such as coma or the persistent vegetative state.
- The therapy is virtually futile in terms of survival and under the circumstances is associated with significant burden to the patient (e.g. comply or painful therapy being used on a patient who will probably die despite therapy in the judgment of the medical staff physician).

F. If a non-pregnant patient meets brain death criteria, life sustaining therapies should be discontinued within 24 hours of the determination of brain death if organ procurement is not a consideration.

G. The decision to limit therapies including resuscitation does not remove from the physician the responsibility to maintain the comfort of the patient, nor does it necessarily preclude active therapy of the patient’s primary disease. Comfort of the patient should include warmth, physical and social comforting and freedom from pain even if administration of analgesia may unintentionally hasten death. At no time is it permitted to administer a medical or surgical therapy with the intent to cause or hasten the patient’s death.

MECHANISMS
A. Comprehensive evaluation of the patient’s medical condition is mandatory prior to
A decision to limit life sustaining therapies or resuscitation. Appropriate consultation among medical and surgical specialists should be sought when indicated.

B. Every effort should be made to determine the patient’s preference and to discover if the patient has an advance directive.

- In the instance of progressive illness, discussions should be held with the patient prior to specific need in order to ascertain a sense of the patient’s wishes.

- Discussions with the family in order to legal succession, or an appointed guardian, should seek to determine the patient’s wishes if the patient is unable to communicate his/her wish: or, if he/she has not executed an advance directive.

- The physician has the ultimate ethical and legal responsibility of making the clinical judgment not to resuscitate or to limit medically futile therapies. The decision should be made in consultation with the patient and/or family.

C. When the decision to not resuscitate or to limit therapies has been made, the order should be written in the patient’s chart and the basis for the order, as well as documentation of pertinent discussions, should be placed as part of the patient’s medical record. The DNR and Limitation of Life Sustaining Therapies Worksheet (see Exhibit 1, immediately following this document) should be completed and placed on the chart.

D. The order should be periodically reviewed in light of clinical events.

IMPLEMENTATION

a. The medical staff physician or the house officer physician, in consultation with the medical staff physician, will write the (Do Not Resuscitate – DNR) or limited therapy order in the patient’s medical record. It is the physician’s responsibility to assure that the meaning of the order is discussed with and understood by the health care personnel caring for the patient.

b. The medical staff physician or house officer physician will document the basis of the DNR or limited therapy order in the progress notes of the patient’s medical record.

c. The medical staff physician will place a note in the progress notes of the patient’s medical record documenting concurrence with the DNR or limited therapy order if the order was written by the house officer physician. If the medical staff physician is not present, the house officer physician will document concurrence of the medical staff physician with the order. The
medical staff physician will write a brief note or cosign the house officer physician’s note within 72 hours of the order.

d. The limitation of therapy or Do Not Resuscitate (DNR) order should be reviewed by the medical staff physician and house officer physician whenever the patient’s clinical status changes to determine its continuing appropriateness.

e. The DNR and Limitation of Life Sustaining therapies Worksheet should be completed and placed on the patient’s medical record. It is not necessary to obtain the signature of the patient and/or the patient’s family member if there is good documentation of discussion content in the patient’s medical record.

MECHANISM OF REFERRAL TO THE HOSPITAL ETHICS COMMITTEE

f. A representative of the Hospital’s Ethics Committee is on-call at all times and may be reached through the Hospital operator. Please refer to MCL Policy 5053 – Policy and Procedures for Consulting the MCL Ethics Committee for detailed procedures.

g. It is the responsibility of the medical staff physician to request the Ethics Committee review of cases which involve considerations within the purview of the Ethics Committee.

h. Request for review may also be made by family members, clergy as well as medical and paramedical personnel involved directly or indirectly in the care of the patient.

i. Request for review by outside agencies must come through the Medical Director’s office.

j. In all cases reviewed by the Ethics Committee, every attempt is made to maintain confidentiality of patient’s identity.
MEDICAL CENTER OF LOUISIANA AT NEW ORLEANS

DNR AND LIMITATION OF LIFE SUSTAINING THERAPIES WORKSHEET

I. PURPOSE

Do Not Resuscitate (DNR) Orders and Limited Therapy Orders should be considered with life sustaining therapies are medical or ethically constrain dictated. Medical and ethical contraindications to life sustaining therapies are summarized on the following page of this worksheet and can be further reviewed in MCL Policy 5021 Limitation of Life Sustaining therapies Including Resuscitation. In such circumstances, the following format for limiting therapies is recommended. Alternative approaches may be acceptable under appropriate circumstances. Patients with advance directives should be treated in accordance with MCL Policy 0024 - Policy and Procedures Governing Advance Directives. Please refer to MCL Policy 5011 – organ Donation for brain death criteria.

II. POLICY

All patients at MCL will be provided full resuscitation and intensity of care unless otherwise indicated by the attending physician. Therapies which are medically indicated, alleviate pain and suffering or which support the personal dignity of the patient will be provided unless refused by the competent patient.

III. DNR AND LIMITED THERAPY OPTIONS (Check those that apply)

Limitation of resuscitation and care orders must be written, signed and dated on the physician’s order sheet. The medical or ethical contradiction(s) to therapy must be documented in Section IV.

Withdrawal of treatment is not ethically different from withholding of treatment.

1. “DO NOT RESUSCITATE” – No cardiopulmonary resuscitation, no intubations, and no defibrillation, no life sustaining drugs.

2. LIMIT RESUSCITATION TO:  (SPECIFY)________________________

3. LIMITATIONS OF OTHER THERAPIES (SPECIFY) ________________

4. This patient has executed an Advance Directive (Refer to MCL Policy 0024):

5. Other:  (specify) ________________________________________________

IV. The medical and/or ethical contraindication to life sustaining therapies in this patient are:  (This section must be filled in).

The indication(s) for limiting or withdrawing therapy should be documented in the progress notes and appropriate orders should be written on the physicians order sheet.

V. DISCUSSION DOCUMENTATION

Participants present, date(s) of discussion and content including medical or ethical contra indication(s) to therapy should be noted in the medical record. Document discussion content with the patient and/or family should be put in the medical record. A representative of the Ethics Committee should be notified of withdrawal/withholding decisions affecting infants and children as per MCL Policy 5021 Limitation of Life Sustaining therapies Including resuscitation.