Pharmacy 543
Introduction to Bioethics

Autumn 2006

Outline

- Process of Bioethics
- Case Presentations
- Discussion -- whenever

Why Bioethics

- Ethics helps you decide what you *ought* to do
- Your understanding of the law informs you about what you *must* or *must not* do

Conceptual Model

Law & Ethics
Why Bioethics 2

- explored through cases
- “normative” ethics representing standards of right or good action

Why Bioethics 3

- Tools for approaching “dilemmas”
  - Institutional, societal bioethics committees; IRBs, NIH (required training)
  - a moving target: whose ethics?
    - In reviewing cases, consider
      - would your conclusions be different
        - at a different time
        - in a different social context

Terminology

- nonmaleficence
- beneficence
- autonomy
- justice
- virtue
- “root cause”
- clinical considerations
- “Georgetown mantra”
Terminology (1)

- **nonmaleficence** -- “First of all, do no harm”
  - <L> *maleficus* evil-doing
  - Hippocratic tradition
  - chemotherapy example
  - double effect
- **beneficence** -- duty to help others
  - <L> *beneficium* service, kindness
  - risk to self vs. benefit to another

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Terminology (2)

- **autonomy** --
  - self (*auto*) rule (*nomos*)
  - the autonomous person acts in accordance with a freely self-chosen and informed plan
  - agency
  - competence
  - respect for autonomy; confidentiality
  - informed consent

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Terminology (3)

- **justice** -- fairness and equality, including access and rationing (budgets)
- **natural lottery**
  - fair opportunity
  - entitlement

Engelhardt HT Jr, Rie MA Intensive care units, scarce resources, and conflicting principles of justice. JAMA 1986 Mar 7;255(9):1159-64
What is a “just” system for distributing society’s “goods”? to each person …
- an equal share*
  - according to need
  - according to effort
  - according to contribution
  - according to merit
- according to free-market exchanges (Rawls)

- Oregon’s health plan
- AMCP Guideline for Formulary Submissions


Virtue -- the way you do things
- compassion
- discernment
- trustworthiness
- integrity
- means vs. ends argument

Many ethical dilemmas occur when you run out of options, given some set of societal norms
- euthanasia
- abortion
- emergency contraception

- Is there a “root cause” that could be “fixed” to eliminate the dilemma?
- Are there clinical issues that have contributed to the dilemma?

Whose ethics?
What is (are) the issue(s)?
Does an issue of law trump?
Principle-based; “lexical” ordering?
“Clinical” ethics
### Terminology (5)

<table>
<thead>
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### Class Approach to Ethical Dilemmas

“9 things”
1. perspective (patient, caregiver, etc.)
2. beneficence
3. nonmaleficence
4. autonomy
5. justice
6. virtue
7. issues of law
8. root cause
9. clinical

### 4-Box Method after Jonsen, et al.: Clinical Ethics

- **Medical Indications**
  - Patient’s medical problem; hx, dx, prognosis
  - Acute/chronic; critical/emergent/reversible
  - Tx goals
  - Probabilities of success
  - Alternate plans in case of tx failure
  - How can this patient be benefited/harm avoided through proposed care
- **Patient Preferences**
- **Quality of Life**
- **Contextual Features**

### Medical Indications

- “utilitarian” ethics; futility
**Patient Preferences**

- What has the patient expressed about preferences for treatment
- Has the patient been informed of benefits and risks, and understood and given consent
- Patient's capacity, evidence of incapacity
- Advanced directives
- If the patient is incapacitated, who is the appropriate surrogate? Is the surrogate using appropriate standards?
- Is patient unable or unwilling to cooperate with treatment
- Is patient's right to choose being respected to the extent possible in ethics and law

- autonomy

**Quality of Life**

- What are the prospects with/without treatment for return to patient's "normal" life
- Are there biases that might prejudice the provider's evaluation of the patient's quality of life
- What deficits are the patient likely to experience with successful treatment
- Is the patient's present or future condition such that continued life might be judged undesirable by them
- Plan and rationale to forgo treatment
- Plans for comfort/palliative care

- beneficence / nonmaleficence

**Contextual Features**

- Are there family issues that might influence treatment decisions
- Are there provider issues that might influence treatment decisions
- Are there financial/economic factors
- Are there religious/cultural factors
- Is there any justification to breach confidentiality
- Are there problems with allocation of resources
- What are the legal implications of treatment decisions
- Are there any provider/institutional conflicts of interest

- justice, autonomy, root cause

**Cases**

- Emergency contraception
- Parts for sale
- "Punishing mothers"
BEWARE THE COUNTERPUNCH

WHAT HAPPENS WHEN A PRESCRIPTION OFFENDS A PHARMACIST'S BELIEFS?

- Michelle Crider, 28, was speechless.
- The pharmacist had just said, "No."
- The married mother of a two-year-old daughter, Crider was concerned that she might become pregnant after having intercourse with her husband. She called her doctor, who prescribed a so-called morning-after formula: four birth-control pills to prevent implantation of a fertilized egg .... Then the doctor called Crider back: the pharmacy manager at Longs Drug Store in Temecula, California, had refused to fill the order, citing his moral beliefs.

Time 1997;149:17

COUNTERPUNCH Ethics

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Perspective? Issue(s) of law? Root cause?

Other “no’s”

- “dis-approval” of RU486
- acquisition of a local (county) hospital by a religious order (access to abortions)
- excluding BCPs as a pharmacy benefit
  - Now an issue of law in Washington
- excluding “lifestyle” drugs from a pharmacy benefit
Eggs for Sale
Wanted: Highly accomplished young women willing to undergo risky, painful medical procedure for very large sums

$50,000 athletic SAT’s > 1400 > 5’10’’

Marketplace for Parts

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• perspective, issues of law, root cause?

“Punishing mothers” & Avoidable Risks to Children

- McCaughey
- How much should society be able to infringe on a mother’s bodily integrity to protect its interests?

“Punishing mothers”

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Recent Stuff

- Won’t dispense/stock
- Counterfeit drugs (San Diego)
- Assisted suicide
- Cost of drug therapy
- Steroids & sports
- Oxy-contin hillbilly heroin
- Ephedra → methamphetamine
- Conflict of interest
- Pharmacogenomics

- Contaminated [adulterated] betamethasone (Walnut Creek, Spartanburg)
- Diluted drugs (Kansas City)
- Third world clinical trials
- Homeopathic therapies
- Compounding sterile preparations and informed-consent
- Confidentiality of Rx files
- Withholding prescriptions (pain management)

Ethics Resources

- Pub-Med → MeSH Database, “ethics, pharmacy”
- Hastings Center Report
- Cambridge Quarterly of Healthcare Ethics
- Lo: Resolving Ethical Dilemmas [Williams & Wilkins]
- Kushner: Ward Ethics [Cambridge]

Questions