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# Pharmacy 543

## Introduction to Bioethics

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Autumn 2008

1

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## Outline

- Process of Bioethics
  - Case Presentations
  - Discussion -- whenever
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2

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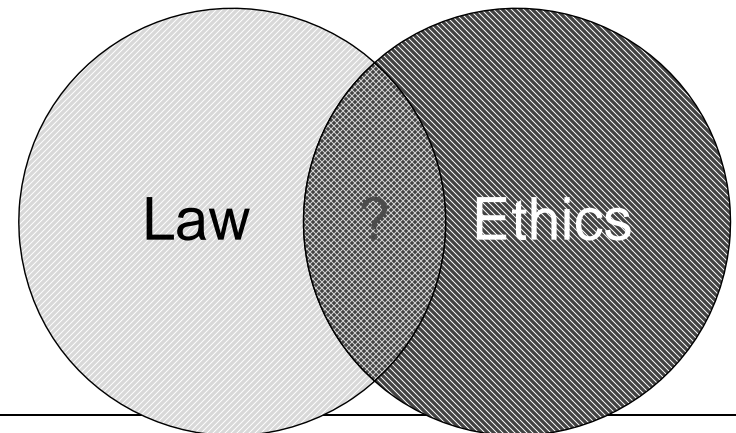
## Why Bioethics

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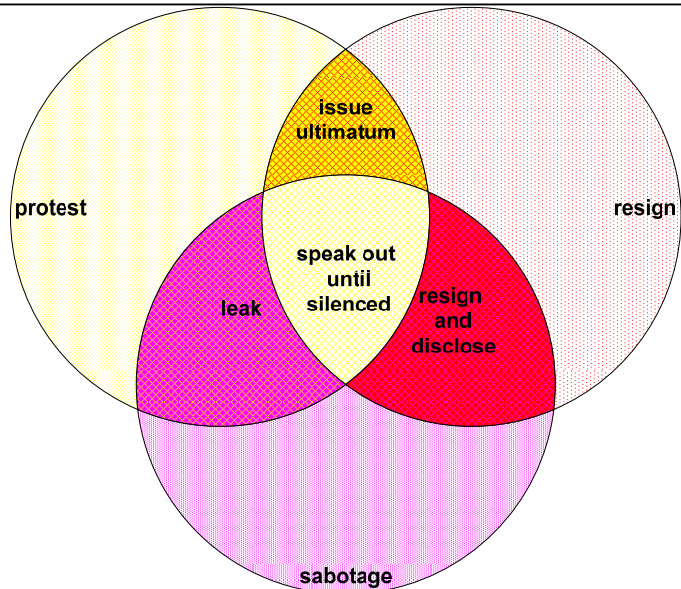
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## Conceptual Model Law & Ethics



4



### Responses to Value Conflicts

from Weimer and Vining, *Policy Analysis: Concepts and Practice*, 3rd Edition, 1998

5

## Why Bioethics 2

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

6

## 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

7

## Terminology

- |                       |                                  |
|-----------------------|----------------------------------|
| ■ nonmaleficence      | ■ virtue                         |
| ■ beneficence         |                                  |
| ■ autonomy            | ■ “root cause”                   |
| ■ justice             |                                  |
| ■ “Georgetown mantra” | ■ <b>clinical considerations</b> |

8

## 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

9

### Hippocratic Oath -- Classical Version

I swear by Apollo Physician and Asclepius and Hygieia and Panacea and all the gods and goddesses, making them my witnesses, that I will fulfil according to my ability and judgment this oath and this covenant:

To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art - if they desire to learn it - without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but no one else.

I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy. In purity and holiness I will guard my life and my art.

I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work.

Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about.

If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.

## 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

11

## 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

12

## terminology (4) [more justice]

- 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

\*Beauchamp & Childress: Principles of Biomedical Ethics, 5th Ed, Oxford, 2001

13

## terminology (5)

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

14

## ... "Turbo Georgetown"

- 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?

15

## Dilemma Tools

- Whose ethics?
- What is (are) the issue(s)?
- Does an issue of law trump?
  
- Principle-based; "lexical" ordering?
- "Clinical" ethics

16

## Terminology (5)

Principle	Virtue
Nonmaleficence	Nonmalevolence, compassion
Beneficence	Benevolence, altruism
Justice	Fairness, empathy
Autonomy	Respectfulness for other persons, compassion

Pellegrino ED The metamorphosis of medical ethics. A 30-year retrospective. JAMA. 1993 Mar 3;269(9):1158-62.

17

## 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

18

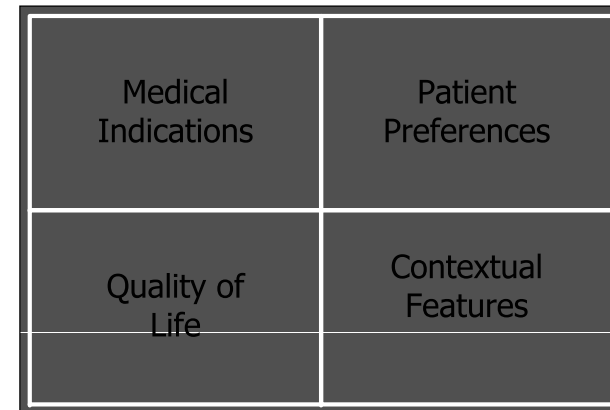
## A Wee “Ethical Dilemma”

- newly available human papillomavirus vaccine (quadrivalent human papillomavirus types 6, 11, 16, 18, recombinant vaccine, Merck)
- cervical cancer-related vs. prevalent types
  - ~ 20 million people are currently infected with HPV in US.
  - > 50 percent of sexually active men and women acquire genital HPV infection at some point in their lives.
  - By age 50, at least 80 percent of women will have acquired genital HPV infection.
  - ~ 6.2 million Americans get a new genital HPV infection each year.
  - ~ 10 of the 30 identified genital HPV types can lead, in rare cases, to development of cervical cancer.
  - For most women (90 percent), cervical HPV infection becomes undetectable within two years.
  - Persistent infection with "high-risk" types of HPV is the main risk factor for cervical cancer.
- **Dilemmas**
  - which HPV types?
  - available at Hall Health?
  - subsidy?
  - mandatory vaccination?
- **Perspectives?**
  - manufacturer
  - FDA (society?)
  - insurers
  - health care providers
  - patients
    - parents
    - 9-12 yo girls
    - 9-12 yo boys

[<http://www.cdc.gov/std/HPV/STDFact-HPV.htm>]

19

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



20

## 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
  
- "utilitarian" ethics; futility

21

## 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

22

## 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

23

## 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

24

## Cases

- Emergency contraception
- Parts for sale
- "Punishing mothers"

25



*"Don't get me wrong, I think the morning-after pill is great. It's just that right now my problem is lining up something for the night before."*

*The New Yorker*, July 23, 1999

26

## 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

27

## COUNTERPUNCH Ethics

provider → NO → patient

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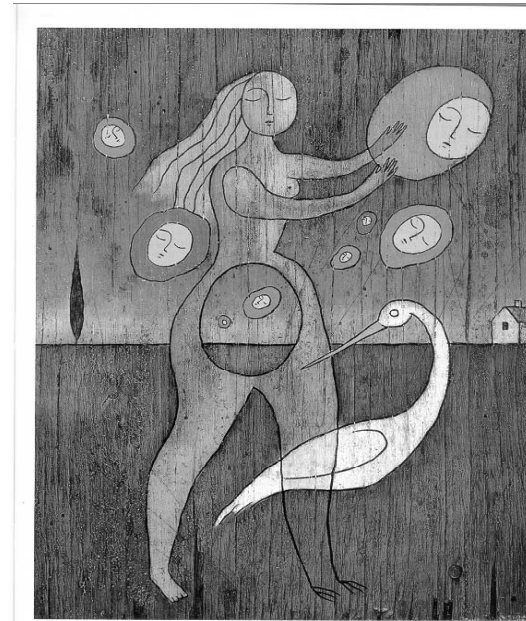
Perspective? Issue(s) of law? Root cause?

28

## 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

29



Mead R. *The New Yorker* 8/9/1999:56

## 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"

30

## Marketplace for Parts

Principle	Virtue
Nonmaleficence	Nonmalevolence, compassion
Beneficence	Benevolence, altruism
Justice	Fairness, empathy
Autonomy	Respectfulness for other persons, compassion

•perspective, issues of law, root cause?

31

## “Punishing mothers” & Avoidable Risks to Children

- McCaughey
- *Whitner v. State*, 492 S.E.2d 777, 780 (S.C. 1997) [cocaine-addicted baby]
- How much should society be able to infringe on a mother’s bodily integrity to protect its interests?

Capron AM Punishing mothers. *Hastings Cent Rep* 1998;28(1):31-3

32

## “Punishing mothers”

Principle	Virtue
Nonmaleficence	Nonmalevolence, compassion
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Justice	Fairness, empathy
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Perspective? Issues of law? Root cause?

33

## 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)

34

## Ethics Resources

- Pub-Med → MeSH Database, “ethics, pharmacy”
- *Hastings Center Report*
- *Cambridge Quarterly of Healthcare Ethics*
- Beauchamp & Childress: Principles of Biomedical Ethics, 5<sup>th</sup> Edition [Oxford]
- Engelhardt: The Foundations of Bioethics, 2<sup>nd</sup> Edition [Oxford]
- Lo: Resolving Ethical Dilemmas [Williams & Wilkins]
- Kushner: Ward Ethics [Cambridge]

35

# Questions

36

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## Points to Emphasize

- Perspective
- Principles
- A tool
- Root cause