

Pandemic Influenza Summit: Ethical/Legal Concerns

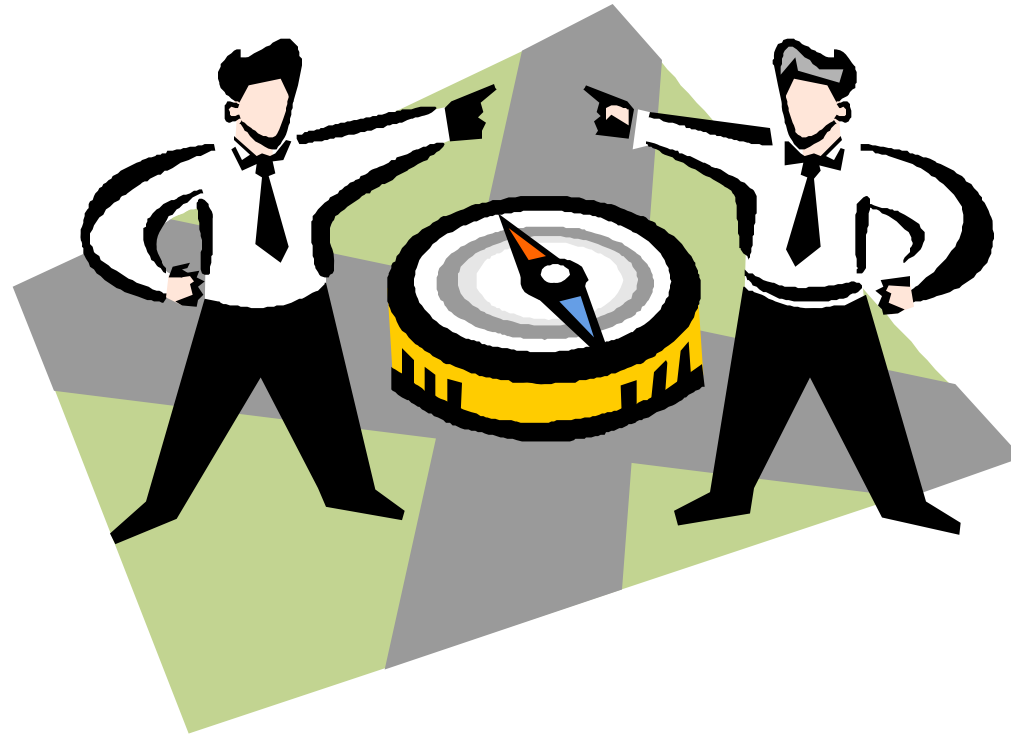
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Session Objectives

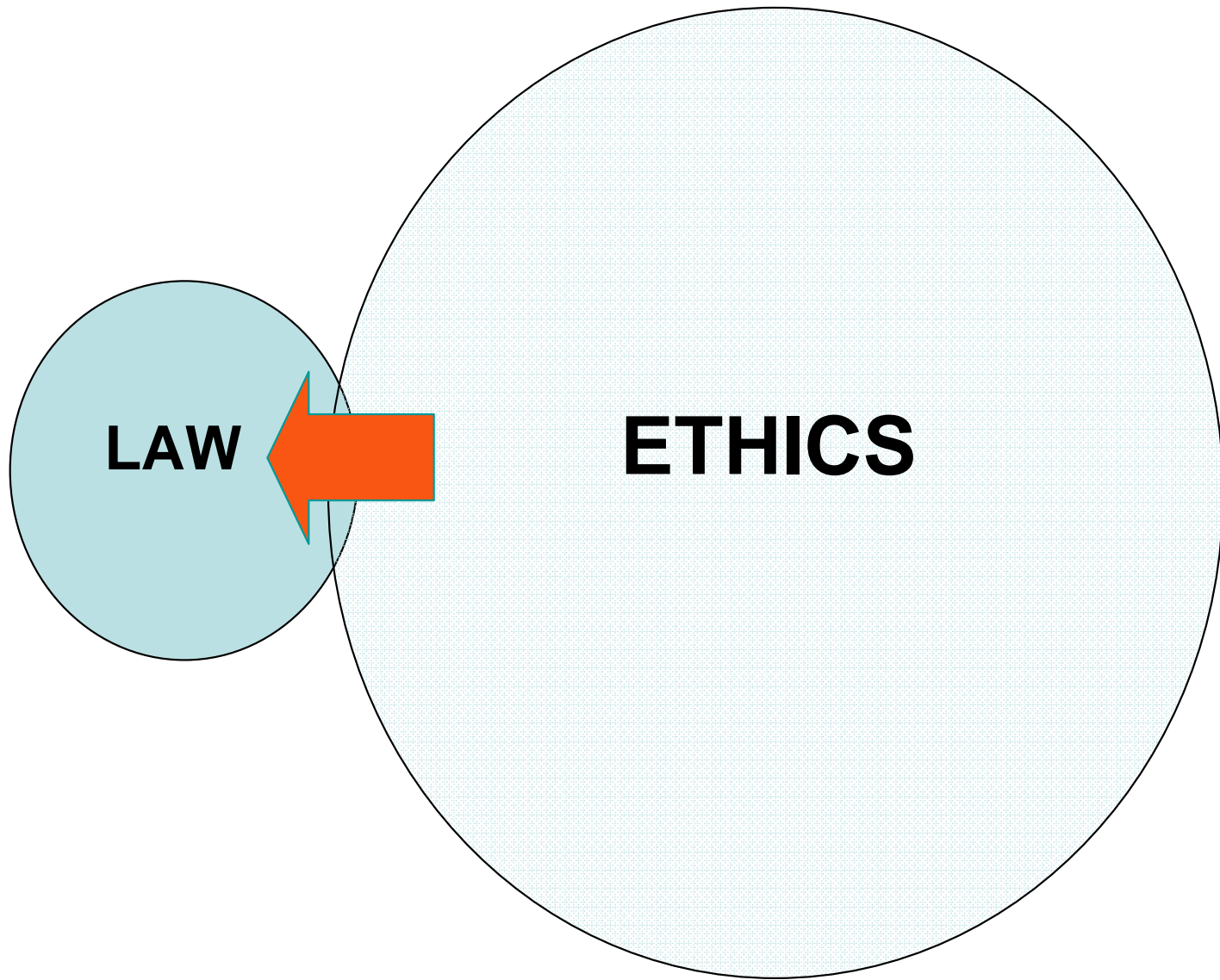
- Consider the relationship between law and ethics
- Propose a legal and ethical framework to deal with pandemic influenza issues
- Review some key legal and ethical issues in preparedness planning for pandemic influenza

Law and Ethics



Law and Ethics

- Ethical questions arise when the exercise of preference somehow affects the welfare of others
- Law is normative and a codification of societal ethics
- Classic tension: does law drive ethics? **OR** are ethical concerns the source of law?
- Law and ethics are best approached as intersecting domains, especially when we deal with novel issues and lack ready guidance



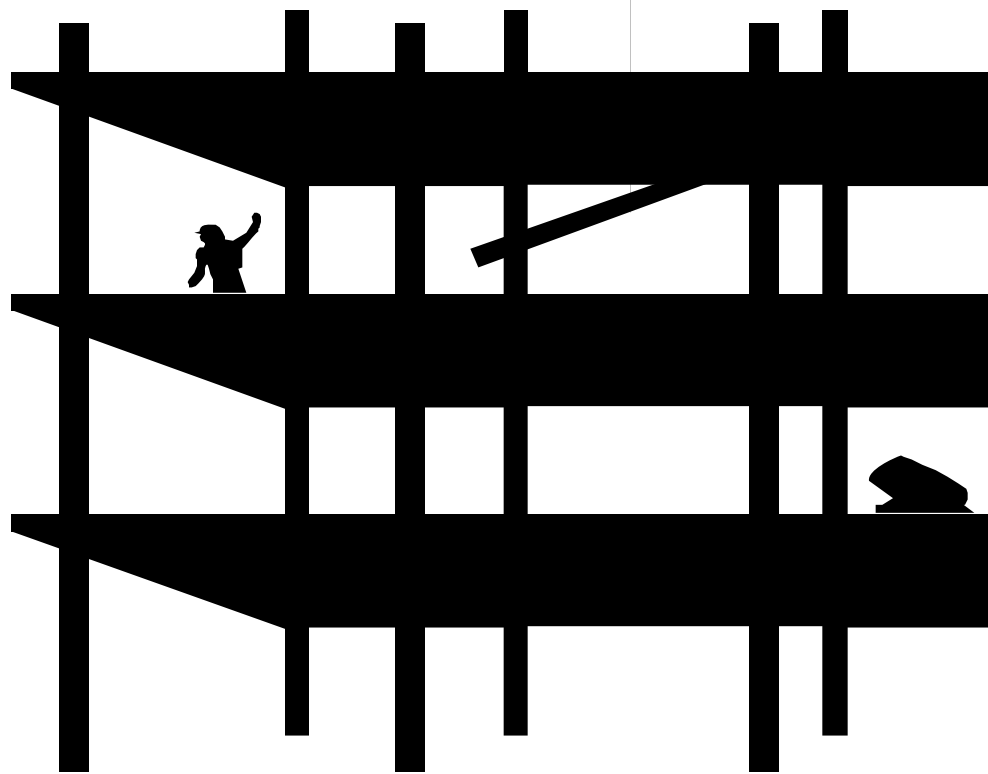
Law and Ethics (2)

- Increasingly, physicians, researchers, policymakers, and the public face numerous ethical quandaries which the law is often ill-equipped to address
- These emerging legal/ethical problems are not dealt with in existing codes of conduct and are not explicitly stated in laws or rules
- Hence we need a framework within which to consider emerging issues (e.g., stem cell research, pandemics, nanotechnology)

Important Consideration

- Far too often ethics is narrowly viewed as moral guidance directed to what is **right** and **wrong**
- Actually the usual domain of ethics deals with really tough, competing choices involving **right** versus **right**
- Each side (preference) is rooted in basic, core values: choosing between two goods!

Legal and Ethical Framework



How Do We Proceed?

- Fully recognize that there are different approaches to ethical decision-making and our multi-cultural society is informed by a wide range of ethical values
- Reference the existing legal framework and legislation as well as guiding legal principles
- Surface legal and ethical frameworks best suited to these emerging issues
- Need for practicality: scenario planning

Ten Substantive Values to Guide Ethical Decision-Making

- Individual liberty
- Protection of the public from harm
- Proportionality
- Privacy
- Duty to provide care
- Reciprocity
- Equity
- Trust
- Solidarity
- Stewardship

Five Procedural Values to Guide Decision-Making

- Reasonable
- Open and transparent
- Inclusive
- Responsive
- Accountable

Guiding Legal Principles

- Existing State and Federal Laws
 - Isolation and Quarantine
 - Surveillance/Testing
 - Limitation on Liability
 - Licensure/Credentialing

Guiding Legal Principles (2)

- Constitutional Principles/Individual Rights
 - Equal Rights/Non-discrimination
 - Due Process
 - Liberty
 - Privacy

Legal and Ethical Issues



Some Key Issues

- Healthcare workers' duty to provide care during a communicable disease outbreak
- Restrictions on liberty in the interest of public health
- Priority setting, including the allocation of scarce resources, such as vaccines, antiviral medicines, and equipment

Duty to Provide Care: Legal Considerations

- Negligence/Standard of Care
- Non-Abandonment/EMTALA
- Limitations on Liability

Duty to Provide Care: Ethical Considerations

- Duty to care for the sick and injured is a primary obligation for healthcare workers:
 - The ability of physicians and healthcare workers to provide care is greater than that of the public, thus increasing their obligation to provide care
 - By freely choosing a profession devoted to care for the ill, they assume risks
 - The profession has a social contract that calls on members to be available in time of emergency

Restrictions on Liberty: Legal Considerations

- Surveillance
 - Consent to testing
 - Reporting
 - Privacy Rights
- Isolation and Quarantine
 - Who can impose and how is it enforced?
 - Due Process Rights
 - Who is authorized to release?
 - Non-Discrimination
 - Duty to provide basic needs (food, shelter, clothing, medical care)
- Other
 - Travel and import bans
 - School closings and prohibition of mass gatherings

Restrictions on Liberty: Ethical Considerations

- Federal, state, and local governments may need to limit three basic personal freedoms: mobility, freedom of assembly, and privacy
- Inherent ethical tension:
 - Autonomy is a form of personal liberty of action in which the individual determines his/her course of action in accordance with a plan of his/her own choosing
 - The Common Good describes a specific “good” that is shared and beneficial to all. It presupposes that one is willing to place limits on personal autonomy in order to promote the general welfare

Priority Setting: Legal Considerations

- Non-discrimination
- When can treatment be mandated?
 - Mandatory vaccines for healthcare workers (i.e., small pox)
- Right to refuse treatment

Priority Setting: Legal Considerations (2)

- When should liability be limited to increase supply?
 - Manufacturers of vaccines and antivirals
 - Healthcare workers and volunteers
 - Administrators and other decision makers
- When should regulatory requirements be lifted to increase supply?
 - Expedited FDA approval
 - Off-label use of drugs
 - Reciprocal credentialing of healthcare workers
 - Volunteers

Priority Setting: Ethical Considerations

- Priority-setting processes (“rationing” or “resource allocation”) will mean that current societal expectations about access to healthcare (“distributive justice”) will have to change in light of a public health crisis of major proportions
- Principle of Subsidiarity is intended to ensure that decisions are taken as closely as possible to the citizen and that constant checks are made as to whether action at the community level is justified in the light of the possibilities available at national, regional or local level

Ethical/Legal Work Group Assignment

1. Refer to the scenarios found in your program packets
2. Launch into an ethical/legal workup to deal with the questions and issues raised in the scenario
3. Utilize the “Guide for Decision-Making,” “Substantive Values,” and “Procedural Values” as tools