

*International Workshop on*  
**Ethical and Legal  
Considerations in  
Mitigating Pandemic  
Disease**

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# **Ethical Considerations in International Preparedness Planning Efforts**

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# Background of This Presentation

- Based around work being done by WHO
- Grows out of my role as Director ETH/SDE, but my comments today reflect my own views, not WHO
- WHO team working on ethical/legal issues is led by Andreas Reis, MD, MA, of the ethics team within ETH
- Project carried out jointly with EPR/CDS, under leadership of David Heymann, aADG/CDS, Mike Ryan, Director EPR, and Keiji Fukuda, head of influenza team

# Where Do Ethical Considerations Fit?

- Workshop has heard about how society and in particular public health professionals have been organized to respond to known and newly emerging pandemics
  - Much can be learned from the past
  - Historical perspectives (smallpox eradication; SARS)
- Present preparedness efforts by Federal government and elsewhere in the region and globally
- With this understanding of the technical we turn to the ethical considerations that arise in planning and response
- These will be examined tomorrow in context of particular mitigation and treatment strategies; this is an introduction

# Variety of Ethical Approaches/Foci

- For people in health-related fields, the most familiar form of “ethics” is a set of principles, often associated with the *Belmont Report* (1978) or *Principles of Biomedical Ethics* by Tom Beauchamp and Jim Childress
- Frames ethical decisions around three/four principles:
  1. Beneficence/Nonmaleficence
  2. Respect for Persons
  3. Justice

# Variety of Ethical Approaches/Foci

- This is a “principlist” form of deontology
  - Is particularly suited to examining what is the right thing for biomedical researchers & clinicians to do with individuals
  - In this context, “Justice” is the least developed principle
- Yet not the only set of principles
  - Alternatives include human rights-based principles, which are framed by obligations in international instruments
  - Such principles focus not on individual actors (health care professionals) but on institutions, particularly governmental
  - Not merely “ethical obligations” but “legal rights”

# Variety of Ethical Approaches/Foci

- Major alternatives to medical deontology, for evaluating the right course of action, are:
  - Virtue ethics
  - Case-based ethics (including casuistry)
  - Consequentialist ethics
- Of consequentialist theories, probably the most influential is utilitarianism
  - Can be purely “results-based” (classical formulation: that which produces the greatest sum of X, such as “happiness” or “well-being”)
  - Can be “rule-based” (that set of rules of action/behavior which usually produce the greatest good, even when specific applications of a rule may not maximize utility)

# Variety of Ethical Approaches/Foci

- Focus of ethics can be on the **content of policies** (e.g., about pandemic preparations and response)
- Alternatively, can focus on the **process** by which policies are established
- One can also incorporate into the principles that will be used **both** duty-oriented and outcome-oriented considerations (e.g., utility AND justice)
- Ethics may coincide with prudential considerations

# Variety of Ethical Approaches/Foci

- Finally, in addition to using ethical principles and analysis to judge the moral rightness of decisions, ethicists can also bring out the values embedded in “technical” decisions
  - For example, a program that aims to “save the most lives” might seem straightforward and free of ethical problems but inherent in that choice could be preference for treating particular group of patients (e.g., those easiest to save) over others, or for life-saving over reduction of over all burden of disease

# Development of Ethical Guidance at WHO

- WHO sets technical norms and standards in many areas involving public health, healthcare, and health research
- Developed through expert consultations and review by WHO's governing bodies
- Sometimes recommendations take the form of guidance
- Ethical analysis can lead to conclusions and recommendations which become part of technical guidance
- **THIS IS THE PATH BEING FOLLOWED FOR PANDEMIC INFLUENZA:** incorporation of ethics into technical guidance

# Ethical Issues Being Addressed

- 1. Equitable access to health care in a pandemic**
  - How to allocate vaccines and to antivirals and hospital care?
  - How to allocate resources (in advance and during the pandemic) between pandemic influenza and other health needs
  - Altered standards for approval of vaccines or drugs for pandemic
  
- 2. Ethical (& human rights) issues in public health actions**
  - Surveillance & information dissemination
  - Measures to prevent animal-to-human transmission (culling, etc.)
  - Quarantine, isolation and social distancing
  - International travel and border control (Int'l Health Regulations)

# Ethical Issues Being Addressed

## **3. Obligations of (and to) healthcare workers in pandemic**

- Which persons are included (only "professionals" or others?)
- Are obligations of healthcare workers dependent on their receiving special protections (a contractual model) or on direct or implied commitments made when they entered the profession?
- How and by whom should obligations be formulated & enforced?

## **4. Obligations among countries (& intergovernmental orgs.)**

- How should governments balance their duties to their own population versus to other countries and populations?
- What role can and should international organizations (such as WHO) play in addressing cross-border risks and obligations?

# Process for Developing Guidance

- Each topic being addressed by a Working Group, chaired by an expert:
  1. Equitable Access: Prof. Marcel Verweij (Univ. Utrecht)
  2. Public Health Measures: Prof. Larry Gostin (Georgetown Univ.)
  3. Healthcare Workers' Obligations: Prof. Ross Upshur (U Toronto)
  4. International Responsibilities: Dr. Robert Archer (International Council on Human Rights Policy)
- 35 Working Group members in public health, science, medicine, ethics, human rights, and law from inside & outside WHO (including other intergov'tal organizations)

# Process for Developing Guidance

- Working Groups mostly operating as "virtual committees"
- Technical meeting of all Working Groups, with WHO regional office participation, on 18-19 May in Geneva
- As result, 4 background papers have been revised and set of conclusions and recommendations are being prepared
- These will be used in regional technical workshops and in discussions with countries
- Global Consultation will be held at end of next month

# WHO Process Still On-Going

- Decisions about particular recommendations will not be made until after the October consultation
- I can, however, outline the principles that have emerged from the Working Groups,
  - Substantive (points that Member States should take into account in framing policies)
  - Procedural (manner in which Member States would be advised to arrive at and refine their policies)

# Substantive Principles

- **Principle of utility:** act so as to produce the greatest good
- **Principle of efficiency:** minimize the resources needed to produce an objective or maximize the total benefit from a given level of resources
- **Principle of fairness:** treat like cases alike and avoid unfair discrimination (based on irrelevant or illegitimate characteristic of person or group)
- **Principle of liberty:** impose the least burden on personal self-determination necessary to achieve legitimate goals (broadly, not trade all freedom for security)

# Procedural Principles

- **Principle of transparency:** make information available to affected population, including process and bases of decisions
- **Principle of participation:** involve population affected by policies in the process of formulating objectives and adopting policies, through appropriate institutions & means
- **Principle of review and revisability:** stakeholders should have a means of “appeal” and policies and plans should be subject to review and revision in light of experience
- **Principle of effectiveness:** means to ensure other principles and conditions are actually being met

# I. Access to Health Care: General Issues

- Central issue is fair distribution of resources that are not adequate to provide care for everyone in need, even in rich countries (& dramatically inadequate in poor ones)
- Particular issues concern not only access to antiviral drugs (for prophylaxis or treatment) and vaccines but also treatment for other conditions (emergency and routine surgery, intensive care, primary care)
- Competition for scarce resources begins at PLANNING stage: **people involved in influenza preparation may be taken away from other high-need activities**

# I. Access to Health Care: Standards

- What constitutes fair distribution? Two sets of issues:
  1. **What type of justice is being sought?**
    - **Compensatory** (making up for a special burden the person has suffered—e.g., destruction of poultry to avoid disease-spread)
    - **Distributional** (equalizing the burdens and benefits, which might include factors beyond influenza: who are the worst off?)
    - **Procedural** (the outcome of a fair process)
  2. **What is the basis of comparison?**
    - Well-being, lives (valued how?), social and/or economic impact?

# I. Access to Health Care: Standards

- **Highest visibility issue: prioritizing access to Tamiflu**
  - Healthcare workers? (Professionals? Cleaning staff?)
  - Other “first responders”?
  - Others who provide public services (Safety? Education? Delivery personnel?)
  - Those most likely to sicken and die?
  - Those most likely to survive if treated?
  - Those most likely to spread the disease if not treated?
  - Those most productive for society (young to middle aged workers)?
  - Lives valued equally, or preference to the youngest (“fair innings”)?

# HSPH Hypothetical for Massachusetts Department of Health

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For the past several months, there has been sustained human-to-human transmission of a novel strain of avian influenza A with genetic components of human influenza in several countries around the world. Your community was first affected three weeks ago, and since then there have been over 500 cases and 50 deaths. Oseltamivir phosphate is the only drug that may effectively reduce mortality of ill patients and limit infection of exposed persons. However, supplies of oseltamivir are limited, and hospitals across the country are independently making decisions to govern allocation of antivirals within their institutions. In your community, the four major academic medical centers have recently established four different protocols regarding prioritization of access to care:

# Hospital A

Recognizing the importance of protecting its workforce in order to minimize absenteeism and ensure continuous response capacity, Hospital A has decided to use its remaining cache of oseltamivir for **prophylaxis of staff** who are exposed while caring for influenza patients.

# Hospital B

In an effort to save its very ill patients, Hospital B has decided to reserve its remaining cache of oseltamivir for **treatment of the sickest** influenza patients. This approach is consistent with the usual practices of providers at Hospital B, who are accustomed to focusing primarily on treatment. Hospital B is relying on airborne infection isolation and personal protective equipment, namely N-95 respirators, gloves, and gowns to protect its staff, and is not using oseltamivir for prophylaxis.

# Hospital C

In order to maximize survival rates, Hospital C has decided to reserve its remaining cache of oseltamivir for **treatment of the patients most likely to benefit**, namely those who present within 48 hours of disease onset. As this prioritization plan will result in faster depletion of the antivirals, Hospital C is relying on airborne infection isolation and personal protective equipment, namely N-95 respirators, gloves, and gowns to protect its staff, and is not using oseltamivir for prophylaxis.

# Hospital D

Assuming that its cache of oseltamivir will soon be depleted regardless of distribution strategy, Hospital D is using the antiviral for **prophylaxis of exposed staff and treatment of all probable and confirmed cases**, regardless of severity. This is the most comprehensive approach, but Hospital D will reach limitations most quickly.

# Questions for Discussion

1. Taken independently, is each hospital's strategy to distribute its cache of oseltamivir fair and reasonable?
2. Viewed in the context of the community, what are some potential challenges that may arise as a result of different institutions utilizing these different strategies?
3. Which of these options should be employed when prioritizing the allocation of limited resources?
4. What factors should govern this decision? Should this decision be made at the hospital-level? At the community-level, led by public health officials? By the state department of public health? At the national-level?
5. What are some prospective actions the community could take to avoid reaching this point? Who should be involved in this process? Who should make the decisions? Should the state department of public health mandate that hospitals unify their actions?

# I. Access to Health Care: Risk of Treatment

- **A special issue: allocation of risks rather than benefits**
- Subjects in clinical trials of vaccines (or drugs)
  - Accelerated technical and ethical review process
  - Possible decision to approve interventions under interpretations of standards that differ from usual
- Would healthcare workers be obliged to accept vaccination (compare to soldiers undergoing mandatory vaccination against possible biowarfare agents)?
- Connection to general issue of “frontline” workers’ risks.

# I. Access to Health Care: Conclusions

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- Clear that PROCESS will be very important in dealing with allocation decisions
  - Information, participation, transparency & revisability are key
- Standards need to be articulated, publicly debated and justified as to how priorities will be set
- Greatest barrier to success may be public skepticism about fairness—or perception of actual discrimination (particularly a risk when discrimination against particular groups already occurs)

# II. Public Health Interventions

- Types of public health measures
  - Quarantine of exposed persons
  - Isolation of sick persons
  - Social distancing
  - Border control
  - Personal hygiene
- Do we have evidence on which will work, at what cost, in containing pandemic influenza or limiting its impact?
- If not, how make comparison with burdens on individuals?

## II. Public Health Interventions

- Clear that PROCESS will be very important in dealing with interventions that seem to trade off individual freedom for potential benefit to health of the public
- Relationship to “allocation”: public control over drugs and vaccines to allow them to be used for public benefit?
- Coordination with international authorities (surveillance and reporting under IHR; cooperation on travel and trade)
- Least restrictive alternative in selecting interventions, made by people with authority to act on solid evidence

# III. Obligations of/to Healthcare Workers

- Unique skills and privileges of healthcare professionals create prima facie obligations to provide needed care
- Level of risk that individuals are willing to countenance is a matter of personal choice, but choices that harm social interests may be subject to sanctions
  - Need to take into account many factors (ways that disease is actually spread; other obligations that healthcare workers may have to family or others)
- Issue: what are obligations of non-professionals who may also be placed at increased risks (in clinics & hospitals).

# III. Obligations of/to Healthcare Workers

- Linked with obligations of healthcare professionals are social obligations to them if they are placed at greater-than-community levels of risk by their role.
  - If provision of care raises greater risk for healthcare workers, this is legitimate ground to provide them with preferential access to prophylaxis and treatment (on grounds that are narrower than general “social benefit” because they are directly related to the ability of health system to cope with pandemic).
- Voluntary participation (superogatory act) should be preferred to mandated participation (obligatory act), and in all cases working conditions should be made as safe as is reasonably feasible.

# III. Obligations of/to Healthcare Workers

- Planners need to engage local and national professional associations in advance, to obtain agreement within these groups about how professional duties relate to actions that will be expected in case of pandemic.
  - These statements should be agreed through a process that is transparent.
  - There should be opportunities for professionals to hear from general community about its expectations.
  - Particular need for advance clarity if any sanctions will be applied.

# IV. National/International Issues Related

- Principal obligations rest on—and principal response will come from—national governments
- But the epidemic is global, so international action needed
  - International surveillance organized under new IHR (being voluntarily implemented in advance of 2007 effective date)
  - WHO expert advice and standards (including ethics)
- Focus of concern: persons who are especially vulnerable
  - Determined on biological grounds (infants, young people, infirm)
  - Determined also by political circumstances: ability of national authorities to organize protection and response

# Responsibilities May Be Ethical (or More)

- UN Charter—purposes of UN include "To achieve international cooperation in solving international problems of a . . . humanitarian character" (Art. 13).
- Universal Declaration of Human Rights guarantees respect for economic, social and cultural rights (including matters of health) "indispensable for human dignity" and proclaims that they should be realized "through national effort and international cooperation" (Art. 22).

# Responsibilities May Be Ethical (or More)

- International Covenant on Economic, Social and Cultural Rights: "Each State Party . . . undertakes to take steps individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present covenant," which include the promotion of health and the prevention, treatment and control of epidemics (Art. 12)
- Other commitments: Millennium Declaration, etc.

# Difficulties with these Commitments

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- They are vague on how they will be implemented, either individually or collectively
- They are focused on long-term development, not emergencies
- They provide no criteria for judging how a state should assess the extent of its obligations or to whom such obligations attach
- Governments more likely to act if others are acting

# Difficulties in Responding Internationally

- Practically, states' ability to respond appropriately depends on degree to which
  - They are **aware** of a problem and the threat it poses
  - They possess **knowledge** (expertise and technology) that enables them to control the problem and the threat it poses; &
  - They possess the financial, logistical and administrative **capacity** to act effectively.
- Morally, states' obligation to respond depends on
  - Extent to which capacity exceeds reasonable projection of its own population's needs
  - An organized international response exists
  - Recipient countries have set up effective and equitable systems

# Conclusions

- The key to an ethically responsible and appropriate response is advance planning, including communication
- Part of communication is recognizing scarcity & resulting need for collective allocation and personal responsibility
  - Engage the public in what Irving Janis termed “the work of worrying”
- Governments in countries first affected will act responsibly by surveillance and international reporting
- Governments with greater resources are more likely to respond to coordinated efforts, planned in advance

# Conclusions

- All of the ethical issues are species of “individual vs. group”
  - Interests of country A vs. interests of community of nations
  - Interests of people to be vaccinated vs. “the herd”
  - Interests of person who wants access to Tamiflu (and may be prepared to pay for it) vs. interests of those who “have priority”
  - Interests of subjects in clinical trials vs. interests of people who will receive drug/vaccine after approval process
- Ethical dilemmas are typically matters of “choice among goods” rather than avoidance of wrong (cf. human rights)
  - Reasoning, publicly debated, may lead to varied outcomes but test is not incontrovertibility but public understanding/acceptance