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Ethical Issues in Public Health ---- Group Assignment Case Study

PANDEMIC FLU IN THE U.S.: ETHICS & THE ALLOCATION OF A SCARCE VACCINE

DIRECTIONS

Part 1: Critique of HHS Policy Recommendations

Students will form small groups of 3-4 people to conduct a public health ethics task force simulation for the influenza vaccine allocation case study described in the following pages. Each group will take on the role of a National Advisory Commission to the President charged with providing advice on the ethical acceptability of a proposed prioritization scheme (pages 3-8) to distribute scarce influenza vaccine in the event of an outbreak of pandemic flu in the U.S.

Each group will turn in a 5 page double spaced policy critique based on its analysis of the case. Your recommendations will be reviewed by your TA, and by members of a group from the alternate discussion section (Part 2 below).

Guidance for the process of your ethical analysis can be found in the assigned readings for sessions #1 through 3.

Examples of the ethical considerations sometimes employed in the allocation of scarce resources that you may wish to discuss in your deliberations are provided in the supplemental information provided with this case (see page 9).

Except for the assigned and recommended readings for the course, you may not consult any published ethical analyses on or related to the topic of the case study.

Your grade for this assignment will be based upon the following criteria:

Length	10 points
Spelling & Grammar	10 points
Clarity	15 points
Organization	15 points
Moral Analysis	50 points

Part 2: Critique of Student Policy Recommendations

In addition to the group assignment described above, you will individually provide a 1-2 paragraph critique of the recommendations developed by a group from the alternate discussion section.

Background

The unprecedented outbreak of the H5N1 strain of the Influenza A virus in birds across Asia and Europe has led to increasing concerns over the threat of an outbreak of pandemic flu in the near future. Pandemic flu can occur when a novel influenza virus emerges and can be efficiently transmitted between humans. As of this writing, the H5N1 virus is known to have infected 121 people in four countries, resulting in 62 deaths over two years. While it is not possible to predict if or when this particular virus will cause a pandemic, history suggests that one or more pandemics will occur in this century. The last three pandemics (1918, 1957, & 1968) respectively killed approximately 40 million, 2 million, and 1 million persons worldwide.

In the event of a pandemic outbreak, vaccinations against the virus will be critical components of any attempt to mitigate the potentially devastating health and societal effects of the disease. In the U.S., it is estimated that it will be between 3 and 6 months after an outbreak of pandemic flu before the first doses of a vaccine against the particular strain of the virus will be available. It is also assumed that two doses per person will be needed in order to provide protection. Once a vaccine is available, it is assumed that the U.S. will have the capacity to produce 3 to 5 million doses (enough for about 1% of the U.S. population) per week.

Because vaccines will be in short supply during a pandemic, the Department of Health and Human Services (HHS) in its Pandemic Influenza Plan has provided guidelines based on advisory committee recommendations concerning the prioritization of vaccine distribution. The stated goals of the priority scheme, and the schemes themselves, are listed on the following pages (3-8).

Imagine that you are a member of a National Advisory Commission appointed by the President to advise him and the public. Your specific charge is to determine whether the guidelines for prioritizing vaccine distribution proposed by HHS are ethically acceptable. You have been asked to:

- 1) Identify moral reasons why groups given low priority may perceive the scheme as unfair.
- 2) Critique the rationales provided by HHS for their recommended priorities to see if important moral arguments in favor of their recommendations are overlooked.
- 3) Recommend changes in the proposed rank ordering if in your commission's judgment any are needed from the standpoint of ethical considerations.

Table 1: Vaccine Priority Group Recommendations¹

Tier	Subtier	Population	Rationale
1	A	Vaccine and antiviral manufacturers and others essential to manufacturing and critical support (~40,000) Medical workers and public health workers who are involved in direct patient contact, other support services essential for direct patient care, and vaccinators (8-9 million)	Need to assure maximum production of vaccine and antiviral drugs Healthcare workers are required for quality medical care (studies show outcome is associated with staff-to-patient ratios). There is little surge capacity among healthcare sector personnel to meet increased demand.
	B	Persons \geq 65 years with 1 or more influenza high-risk conditions, not including essential hypertension (approximately 18.2 million) Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertension (approximately 6.9 million) Persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year (740,000)	These groups are at high risk of hospitalization and death. Excludes elderly in nursing homes and those who are immunocompromised and would not likely be protected by vaccination
	C	Pregnant women (approximately 3.0 million) Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine (1.95 million with transplants, AIDS, and incident cancer x 1.4 household contacts per person = 2.7 million persons) Household contacts of children <6 month olds (5.0 million)	In past pandemics and for annual influenza, pregnant women have been at high risk; vaccination will also protect the infant who cannot receive vaccine. Vaccination of household contacts of immunocompromised and young infants will decrease risk of exposure and infection among those who cannot be directly protected by vaccination.
	D	Public health emergency response workers critical to pandemic response (assumed one-third of estimated public health workforce=150,000) Key government leaders	Critical to implement pandemic response such as providing vaccinations and managing/monitoring response activities Preserving decision-making capacity also critical for managing and implementing a response

¹ The committee focused its deliberations on the U.S. civilian population. ACIP and NVAC recognize that Department of Defense needs should be highly prioritized. DoD Health Affairs indicates that 1.5 million service members would require immunization to continue current combat operations and preserve critical components of the military medical system. Should the military be called upon to support civil authorities domestically, immunization of a greater proportion of the total force will become necessary. These factors should be considered in the designation of a proportion of the initial vaccine supply for the military. Other groups also were not explicitly considered in these deliberations on prioritization. These include American citizens living overseas, non-citizens in the U.S., and other groups providing national security services such as the border patrol and customs service.

Table 1 (Continued)

Tier	Subtier	Population	Rationale
2	A	<p>Healthy 65 years and older (17.7 million)</p> <p>6 months to 64 years with 1 high-risk condition (35.8 million)</p> <p>6-23 months old, healthy (5.6 million)</p>	Groups that are also at increased risk but not as high risk as population in Tier 1B
	B	<p>Other public health emergency responders (300,000 = remaining two-thirds of public health work force)</p> <p>Public safety workers including police, fire, 911 dispatchers, and correctional facility staff (2.99 million)</p> <p>Utility workers essential for maintenance of power, water, and sewage system functioning (364,000)</p> <p>Transportation workers transporting fuel, water, food, and medical supplies as well as public ground public transportation (3.8 million)</p> <p>Telecommunications/IT for essential network operations and maintenance (1.08 million)</p>	Includes critical infrastructure groups that have impact on maintaining health (e.g., public safety or transportation of medical supplies and food); implementing a pandemic response; and on maintaining societal functions
3		<p>Other key government health decision-makers (estimated number not yet determined)</p> <p>Funeral directors/embalmers (62,000)</p>	Other important societal groups for a pandemic response but of lower priority
4		Healthy persons 2-64 years not included in above categories (179.3 million)	All persons not included in other groups based on objective to vaccinate all those who want protection

NVAC/ACIP recommendations for prioritization of pandemic influenza vaccine and NVAC recommendations on pandemic antiviral drug use²

Advisory Committee recommendations are presented in this report to provide guidance for planning purposes and to form the basis for further discussion of how to equitably allocate medical countermeasures that will be in short supply early in an influenza pandemic. Two federal advisory committees, the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC), provided recommendations to the Department of Health and Human Services on the use of vaccines and antiviral drugs in an influenza pandemic. Although the advisory committees considered potential priority groups broadly, the main expertise of the members was in health and public health. **The primary goal of a pandemic response considered was to decrease health impacts including severe morbidity and death; secondary pandemic response goals included minimizing societal and economic impacts.** However, as other sectors are increasingly engaged in pandemic planning, additional considerations may arise. The advisory committee reports explicitly acknowledge the importance of this, for example highlighting the priority for protecting critical components of the military. Finally, HHS has recently initiated outreach to engage the public and obtain a broader perspective into decisions on priority groups for pandemic vaccine and antiviral drugs. Though findings of the outreach are preliminary, a theme that has emerged is the importance of limiting the effects of a pandemic on society by preserving essential societal functions.

On July 19, 2005, ACIP and NVAC voted unanimously in favor of the vaccine priority recommendations summarized in Table 1. These votes followed deliberations of a joint Working Group of the two committees, which included as consultants representatives of public and private sector stakeholder organizations and academic experts. There was limited staff level participation from DoD, DHS, and VA. Several ethicists also served as consultants to the Working Group.

A. Critical assumptions

The recommendations summarized in Table 1 were based on the following critical assumptions:

- **Morbidity and mortality** - - The greatest risk of hospitalization and death—as during the 1957 and 1968 pandemics and annual influenza—will be in infants, the elderly, and those with underlying health conditions. In the 1918 pandemic, most deaths occurred in young adults, highlighting the need to reconsider the recommendations at the time of the pandemic based on the epidemiology of disease.
- **Healthcare system** - - The healthcare system will be severely taxed if not overwhelmed due to the large number of illnesses and complications from influenza requiring hospitalization and critical care. CDC models estimate increases in hospitalization and intensive care unit demand of more than 25% even in a moderate pandemic.
- **Workforce** - - During a pandemic wave in a community, between 25% and 30% of persons will become ill during a 6 to 8 week outbreak. Among working-aged adults, illness attack rates will be lower than in the community as a whole. A CDC model suggests that at the peak of pandemic disease, about 10% of the workforce will be absent due to illness or caring for an ill family member. Impacts will likely vary between communities and work sites and may be greater if significant absenteeism occurs because persons stay home due to fear of becoming infected.
- **Critical infrastructure** - - Only limited information was available from which to assess potential impacts on critical infrastructure sectors such as transportation and utility services. Because of changes in business practices and the complexity of networks, information from prior pandemics was not considered applicable.
- **Vaccine production capacity** - - The U.S.-based vaccine production capacity was assumed at 3 to 5 million 15µg doses per week with 3 to 6 months needed before the first doses are produced. Two doses per person were assumed to be required for protection. Subsequent results of an NIH clinical trial of influenza A (H5N1) vaccine suggest that

² Taken from Appendix D of the HHS Pandemic Influenza Plan, 2005. Available <http://www.hhs.gov/pandemicflu/plan/>

higher doses of antigen will be needed to elicit a good immune response; thus, the assumptions made by the committee could potentially substantially exceed the amount of vaccine that would be produced.

Definitions and rationales for priority groups

1. Healthcare workers and essential healthcare support staff

a) Definition

Healthcare workers (HCW) with direct patient contact (including acute-care hospitals, nursing homes, skilled nursing facilities, urgent care centers, physician's offices, clinics, home care, blood collection centers, and EMS) and a proportion of persons working in essential healthcare support services needed to maintain healthcare services (e.g. dietary, housekeeping, admissions, blood collection center staff, etc.). Also included are healthcare workers in public health with direct patient contact, including those who may administer vaccine or distribute influenza antiviral medications, and essential public health support staff for these workers.

b) Rationale

The pandemic is expected to have substantial impact on the healthcare system with large increases in demand for healthcare services placed on top of existing demand. HCW will be treating influenza-infected patients and will be at risk of repeated exposures. Further, surge capacity in this sector is low. To encourage continued work in a high-exposure setting and to help lessen the risk of healthcare workers transmitting influenza to other patients and HCW family members, this group was highly prioritized. In addition, increases in bed/nurse ratios have been associated with increases in overall patient mortality. Thus, substantial absenteeism may affect overall patient care and outcomes.

2. Groups at high risk of influenza complications

a) Definition

Persons 2-64 years with a medical condition for which influenza vaccine is recommended and all persons 6-23 months and 65 years and older. Excludes nursing home residents and severely immunocompromised persons who would not be expected to respond well to vaccination.

b) Rationale

These groups were prioritized based on their risk of influenza-related hospitalization and death and also their likelihood of vaccine response. Information from prior pandemics was used whenever possible, but information from interpandemic years was also considered. Nursing home residents and severely immunocompromised persons would be prioritized for antiviral treatment and/or prophylaxis and vaccination of healthcare workers and household contacts who are most likely to transmit influenza to these high risk groups.

3. Critical infrastructure

a) Definitions and rationale

Those critical infrastructure sectors that fulfill one or more of the following criteria: have increased demand placed on them during a pandemic, directly support reduction in deaths and hospitalization; function is critical to support the healthcare sector and other emergency services, and/or supply basic necessities and services critical to support of life and healthcare or emergency services. Groups included in critical infrastructure are needed to respond to a pandemic and to minimize morbidity and mortality, and include the following sectors:

- Persons directly involved with influenza vaccine and antiviral medication manufacturing and distribution and essential support services and suppliers (e.g., growers of pathogen-free eggs for growth of vaccine virus) production activities
- Key government leaders and health decision-makers who will be needed to quickly move policy forward on pandemic prevention and control efforts

- Public safety workers (firefighters, police, and correctional facility staff, including dispatchers) are critical to maintaining social functioning and order and will contribute to a pandemic response, for example by ensuring order at vaccination clinics and responding to medical emergencies
- Utility service workers (water, power, and sewage management) are prioritized as the services they provide are also essential to the healthcare system as well as to preventing additional illnesses from lack of these services unrelated to a pandemic.
- Transportation workers who maintain critical supplies of food, water, fuel, and medical equipment and who provide public transportation, which is essential for provision of medical care and transportation of healthcare workers to work and transportation of ill persons for care
- Telecommunication and information technology services critical for maintenance and repairs of these systems are also essential as these systems are now critical for accessing and delivering medical care and in support of all other critical infrastructure.
- Mortuary services will be substantially impacted due to the increased numbers of deaths from a pandemic and the fact that impact will be high in the elderly, a growing segment of the population

4. Public health emergency response workers

a) Definition

This group includes persons who do not have direct patient care duties, but who are essential for surveillance for influenza, assessment of the pandemic impact, allocation of public health resources for the pandemic response, development and implementation of public health policy as part of the response, and development of guidance as the pandemic progresses.

b) Rationale

Persons in this sector have been critical for past influenza vaccine pandemics and influenza vaccine shortages and little surge capacity may be available during a public health emergency such as a pandemic.

5. Persons in skilled nursing facilities

a) Definition

Patients residing in skilled nursing facilities. Not included in this group are persons in other residential settings (e.g., assisted living) who are more likely to be mobile, in a setting that is less closed, and have decentralized healthcare.

b) Rationale

This group was not prioritized for vaccine because of the medical literature finding poor response to vaccination and occurrence of outbreaks even in the setting of high vaccination rates. Other studies have suggested that vaccination of healthcare workers may be a more effective strategy to prevent influenza in this group. Further, surveillance for influenza can be conducted in this group and antiviral medications used widely for prophylaxis and treatment. Ill visitors and staff should also be restricted from visiting nursing home facilities during outbreaks of pandemic influenza. This strategy for pandemic influenza vaccine differs from the inter-pandemic vaccination strategy of aggressively vaccinating nursing home residents. The rationale considers several factors: 1) these populations are less likely to benefit from vaccine than other groups who are also at high risk; 2) other prevention strategies feasible for this group are not possible among other high-risk groups; 3) the overall morbidity and mortality from pandemic is likely to severely impact other groups of persons who would be expected to have a better response to the vaccine; and 4) a more severe shortage of vaccine is anticipated.

6. Severely immunocompromised persons

a) Definition

Persons who are undergoing or who have recently undergone bone marrow transplantation and others with severe immunodeficiency (e.g., AIDS patients with CD4 counts <50, children with SCID syndrome, recent bone marrow

transplant patients). The numbers of persons in these categories is likely much smaller than the anticipated number assumed in tiering above, but sources for more specific estimates have not been identified.

b) Rationale

These groups have a lower likelihood of responding to influenza vaccination. Thus, strategies to prevent severe influenza illness in this group should include vaccination of healthcare workers and household contacts of severely immunocompromised persons and use of antiviral medications. Consideration should be given to prophylaxis of severely immunocompromised persons with influenza antivirals and early antiviral treatment should they become infected.

7. Children <6 months of age

a) Rationale

Influenza vaccine is poorly immunogenic in children <6 months and the vaccine is currently not recommended for this group. In addition, influenza antiviral medications are not FDA-approved for use in children <1 year old. Thus, vaccination of household contacts and out-of-home caregivers of children <6 months is recommended to protect this high-risk group.

C. Other discussion

There was substantial discussion on priority for children. Four potential reasons were raised for making vaccination of children a priority:

- At the public engagement session, many participants felt that children should have high priority for vaccination.
- Children play a major role in transmitting infection, and vaccinating this group could slow the spread of disease and indirectly protect others.
- Children have strong immune systems and will respond well to vaccine whereas vaccination of the elderly and those with illnesses may be less effective.
- Some ethical frameworks would support a pediatric priority. ACIP and NVAC did not make children a priority (other than those included in tiers, because of their underlying diseases [Tiers 1B and 2A] or as contacts of high-risk persons [Tier 1C]) for several reasons:
 - Healthy children have been at low risk for hospitalization and death in prior pandemics and during annual influenza seasons.
 - It is uncertain whether vaccination of children will decrease transmission and indirectly protect others. Studies that show this impact or mathematical models that predict it rely on high vaccination coverage that may not be possible to achieve given limited supplies in a pandemic.
 - The committees recognize that this is an area for further scientific work; that children may be a good target population for live-attenuated influenza vaccine (FluMist®) if it is available; and that education of the public will be needed to provide the rationale for the recommendations. HHS Pandemic Influenza Plan

Ethical Considerations in Scarce Resource Allocation *

Medical Success (Effectiveness) - - priority given to those most likely to achieve a good outcome

Medical Need - - priority given to those most in need of medical intervention

Public Health Utility - - achieving the least morbidity/mortality possible given the resources available (maximizing good health/survival with the available resources)

Immediate Usefulness - - priority given to those with special skills that could be used to serve the common good in the immediate circumstance

General Social Value - - priority given to those who are considered by society to have the greatest social worth (past or future)

Principle of Conservation - - priority given to those who use proportionally less resources

Responsibility for Dependents - - priority given to those who have primary responsibilities to dependents (parents, nursing home attendants, etc.)

Generally Neediest - - priority given to those considered most helpless or generally neediest in society

None if not all - - no one should be saved if not all can be saved

Queue - - priority given on a first-come, first-served basis

Random Selection - - allocation determined by chance (a lottery, for example)

Ability to Pay - - priority given to those who can pay for the resources

Merit based - - priority given to those who have earned it due to past actions

NOTE: The above considerations are not necessarily mutually exclusive. You may develop a position based on one principle, or you could develop a position which attempts to balance many principles.

For example, you may develop a position which favors use of the “Medical Need/Effectiveness” principle until a certain point in the pandemic, at which time the “Ability to Pay” principle may become primary for you.

* Adapted from Gerald Winslow’s work, Triage and Justice (1982)