Allocating Vaccines and Antiviral Medications During an Influenza Pandemic

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I. INTRODUCTION

Influenza pandemics have been a regular occurrence throughout human history.¹ One difference between contemporary pandemics and those of the past is that today we have the capacity to develop life-saving pharmaceutical interventions in the form of vaccines and antiviral medications. Unfortunately, while these interventions should provide significant benefits to many people, the supply is likely to fall considerably short of the demand. An effective vaccine is unlikely to be available until approximately six months after the onset of a pandemic,² and even after a vaccine is developed, there are unlikely to be sufficient supplies to vaccinate more than a small fraction of the world’s population.³ As for antiviral medications, although the United States is close to reaching its goal of stockpiling eighty-one million treatment courses, the Institute of Medicine estimates that

¹ See John G. Bartlett, Planning for Avian Influenza, 145 ANNALS INTERNAL MED. 141, 141 (2006) (noting that influenza pandemics have typically occurred several times each century).

² See Y. Guan et al., A Model to Control the Epidemic of H5N1 Influenza at the Source, BMC INFECTION DISEASES, Nov. 13, 2007, at 6, http://www.biomedcentral.com/content/pdf/1471-2334-7-132.pdf (concluding that “at most only a third of the global human population may have the chance of getting the vaccine at least six months after the pandemic strain is identified”); see also World Health Org., Avian Influenza Frequently Asked Questions, http://www.who.int/csr/disease/avian_influenza/avian_facts/en/ (last visited Oct. 9, 2009).

³ See Ezekiel J. Emanuel & Alan Wertheimer, Who Should Get Influenza Vaccine When Not All Can?, 312 Sci. 854, 854 (2006) (suggesting that “more than 90% of the U.S. population will not be vaccinated in the first year” of a pandemic); Lori Uscher-Pines et al., Priority Setting for Pandemic Influenza: An Analysis of National Preparedness Plans, 3 PLoS MED. 1721, 1721 (2006) (“At current capacity, we cannot expect to vaccinate more than 14% of the world’s population within a year of a pandemic.”).
more than twice that amount might be needed to treat twenty-five percent of the population and to provide prophylactic treatment to workers likely to be infected on the job. Moreover, it is not even clear if the stockpiled medications will be effective. This year, the dominant strain of the seasonal influenza virus has proven resistant to Tamiflu, the primary stockpiled drug. If similar resistance develops in a pandemic influenza strain, existing stockpiles could turn out to be useless.

The limited availability of vaccines and antiviral medications during a pandemic means that difficult decisions will have to be made about how to allocate these resources. Questions about allocating scarce life-saving resources are not, of course, unique to pandemic situations. For example, the demand for transplantable organs consistently exceeds the supply, and, as a result, complex regulatory systems have been developed to ensure that organs are allocated fairly and consistent with medical need. However, existing systems for allocating scarce resources like organs provide only limited guidance for the type of decisions that will arise during an influenza pandemic. First, during a pandemic, decisions will have to be made under crisis circumstances, in the face of social unrest as well as uncertain and evolving medical information. Regulatory systems will have to be flexible and responsive, and allocation criteria may have to be based on broad generalities rather than case-by-case assessments of individual needs. Second, unlike decisions about allocating organs, the impact of which is felt primarily by individual patients, decisions about allocating vaccines and antivirals will have significant implications for all of society. For example, because influenza is infectious, individuals denied access to vaccines or antivirals will not only have a greater likelihood of becoming ill and dying, but they will also have a greater chance of infecting other persons. Similarly, denials of care to essential service providers, such as health care workers or key government

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7 In the United States, the system of organ allocation is managed by the United Network for Organ Sharing (UNOS), under contract with the Department of Health and Human Services. See generally UNOS: Who We Are, http://www.unos.org/whoweare/ (last visited Oct. 9, 2009).
officials, may increase risks to third parties by undermining society’s ability to mount an effective response to the pandemic. As a result, prioritization systems will have to take into account the externalities of treatment denials, in addition to the impact on the individuals seeking care.

While the details of national pandemic preparedness plans vary, the general approach takes to the question of allocating vaccines and antivirals is substantially similar. Overall, the primary goal is to save the most lives possible, while simultaneously reducing social disruption and economic losses. These are certainly valuable goals, particularly in the context of a crisis in which society’s very existence may be threatened. Yet, underlying the decision to pursue these goals are several contestable value judgments that pandemic planners have not always made explicit. My goal in these brief remarks is to highlight three of these judgments: (1) the view that all individuals’ lives deserve equal protection, regardless of age; (2) the view that individuals in particular occupational categories, especially “health care workers,” necessarily deserve greater protection than the rest of the population; and (3) the general assumption that the goal of prioritization systems should be to maximize aggregate social welfare at the lowest possible cost. These are by no means irrational approaches to the challenge of allocating scarce life-saving resources, but they nonetheless have potentially problematic implications that warrant further discussion.

II. APPROACHES TO THE ALLOCATION OF VACCINES AND ANTIVIRAL MEDICATIONS IN NATIONAL PREPAREDNESS PLANS

As concerns about the potential for a new influenza pandemic have mounted, many countries have developed pandemic preparedness plans that explicitly address the allocation of vaccines and antiviral medications. In the United States, the Department of Health and Human Services (DHHS) has issued guidelines for the allocation of both vaccines and antiviral medications. For vaccines, the guide-

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8 See infra Part II.
9 See infra Part II.
lines divide individuals into target groups and then, within the target
groups, into tiers. The target groups include: (1) persons who
“maintain homeland and national security”; (2) persons who “pro-
vide health care and community support services”; (3) persons who
“maintain critical infrastructure”; and (4) “the general population.”

The first tier within each group would receive top priority for vacci-
nation. For the occupational groups—i.e., groups one through
three—the first tier includes deployed forces, critical health care per-
sonnel, emergency medical service personnel, and fire and police of-
ficers. For the general population, tier one would be limited to
pregnant women, infants, and toddlers, all of whom are expected to
have a higher risk of dying during a pandemic. After individuals in
the first tier of each group are vaccinated, supplies would be directed
to persons in the second, third, fourth, and fifth tiers.

DHHS has also issued guidance for the use of antiviral drugs. Initial priorities would focus on efforts to contain or suppress initial pandemic outbreaks anywhere in the world and to provide post-
exposure prophylaxis at the border to travelers entering the coun-
try. Then, the bulk of the stockpiled medications would be directed
to persons infected with pandemic influenza who present themselves
for care early in the course of their illness and who would benefit
from antiviral medications. Other priorities include prophylaxis for
health care workers, persons who have compromised immune sys-
tems, and persons living in residential settings such as nursing homes,
prisons, and homeless shelters when outbreaks occur in those set-
tings. The guidelines recognize that existing stockpiles will be insuf-
ficient to cover all of these categories, and conclude that, when sup-
plies are limited, “treating all persons based on assessment of medical
need is considered preferable to targeting certain priority groups for
treatment.” They also recommend that, in situations of limited
supply, treatment should be preferred to prophylaxis because “the

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12 DHHS, VACCINE ALLOCATION PLAN, supra note 10.
13 Id. at 3.
14 Id. at 8.
15 Id. at 6.
16 Id. at 8–9.
17 Id. at 7.
18 See DHHS, ANTIVIRAL USE, supra note 11.
19 Id. at 1.
20 Id.
21 Id.
22 Id. at 16.
need is clear and benefits [are] likely to accrue for those who are treated.”

The DHHS guidance documents are intended to be advisory only. They do not purport to be binding on the state, local, and tribal planners who are the primary audience of the documents. In fact, the vaccine guidance notes that “it is important that plans are flexible as the guidance may be modified based on the status of vaccine technology, the characteristics of pandemic illness, and risk groups for severe disease—factors that will remain unknown until a pandemic actually occurs.”

Other countries’ prioritization plans differ in some respects from the DHHS guidelines, but in general reflect similar considerations. In a 2006 analysis of national pandemic preparedness plans, Uscher-Pines found that the overwhelming focus was on utilitarian factors. Thus, twenty-one plans emphasized the need to reduce morbidity and mortality, while thirteen referred to the maintenance of essential services or the “minimization of social and economic impacts.” Individuals at high risk of infection were ranked consistently at the top of resource allocation schedules. In addition, health care workers and other essential service providers were given priority access in most national plans. Reasons offered for prioritizing health care workers included the fact that such individuals were at increased risk of getting and transmitting infections, that they were necessary for recovery efforts, and that the availability of health care workers would reduce overall morbidity and mortality in society.

III. ASSESSING THE PLANS: AGE, OCCUPATIONAL CATEGORIES, AND THE PRIMACY OF SOCIAL UTILITY CONSIDERATIONS

Existing prioritization plans share several common characteristics. I highlight here three features of these plans that I believe warrant greater attention. First, the plans all seek to save the most lives possible without distinguishing between the value of lives based on

23 Id.
24 DHHS, VACCINE ALLOCATION PLAN, supra note 10, at 1.
25 Id.
27 Id. at 1723.
28 Id.
29 Id.
30 Id. at 1723–24.
individuals’ ages. Second, they prioritize certain occupational groups, most commonly health care workers, but they often do not clearly define the contours of these categories. Finally, they reflect the general view that maximizing aggregate social welfare should be the primary consideration in allocation decisions, despite the potential impact of such an approach on socially disadvantaged groups.

A. All Lives Are Equal, Regardless of Age

Existing plans for both vaccines and antiviral drugs seek to identify persons at the greatest risk of infection and death from the pandemic influenza virus and to ensure that these individuals have the greatest chance of receiving prophylaxis and treatment. The implicit judgment is that, when resources are scarce, the primary goal should be to save as many lives as possible. Some commentators have argued that such an approach is consistent with utilitarian ethical theories because, during a pandemic, the number of lives saved is the best measure of the aggregate social good. The view that all lives are equally deserving of protection can also be seen as consistent with egalitarian principles, insofar as it rests on the assumption that all individuals have inherently equal worth.

Yet, a serious weakness of treating all lives as inherently equal is that such an approach ignores commonly held intuitions about the implications of aging. In particular, the argument can be made that the value of additional life declines over the course of an individual’s lifespan. This is why the death of a young person is typically perceived as tragic, whereas the death of someone who has already lived a full life is not.

The idea that young people’s lives are deserving of greater protection than the lives of older persons is sometimes referred to as the “fair innings” argument, which is based on the idea that everyone de-
serves to live through all the “innings,” or phases, of life. According to one formulation of this argument, “[o]lder persons will have had many more opportunities in their life than persons who die at young age and therefore, when we can save some but not all, it is fair to save younger people first.” The fair innings argument reflects the view that fairness does not necessarily mean that everyone should have equal access to the same amount of resources, but that everyone should have an equal chance to live a complete life.

The pure version of the fair innings argument would give the greatest preference to the youngest members of society—i.e., infants—on the ground that they have the most years of life ahead of them. A variation of the argument, proposed by Ezekiel Emanuel and Alan Wertheimer, would balance the amount of time a person has left to live against the amount of time the person has already invested in living.

With this “investment refinement” to the standard fair innings argument, a 20-year-old person would have greater priority than an infant “because the older individuals have more developed interests, hopes, and plans but have not had an opportunity to realize them.” Emanuel and Wertheimer note that, during a pandemic, their approach would direct resources to individuals in the age cohorts at highest risk of infection during the 1918 Spanish flu.

The insight that additional life years have diminishing value as individuals become older poses a serious challenge to the view that the goal of resource allocation should be to save as many lives as possible without attention to age. However, age-based prioritization systems also raise concerns of their own. First, even if we were to agree that the number of years a person has left to live is a relevant criterion for allocating vaccines and antivirals, age is not always an accurate proxy for life expectancy. Factors such as genetics, health status, and lifestyle also play important roles. Thus, basing prioritization decisions solely on age would not necessarily result in saving those people with the greatest number of years left to live. Second, any

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33 See id. at 10; see also Alan Williams, Intergenerational Equity: An Exploration of the “Fair Innings” Argument, 6 HEALTH ECON. 117, 119 (1997).
34 Verweij, supra note 32, at 10.
35 Emanuel & Wertheimer, supra note 3, at 854–55.
36 Id. at 855.
37 Id.
38 See Michael M. Rivlin, Why the Fair Innings Argument Is Not Persuasive, BMC MED. ETHICS, Dec. 21, 2000, at 4, http://www.biomedcentral.com/content/pdf/1472-6939-1-1.pdf ("It is in fact not possible for two patients to have an identical condition, bearing in mind the differences between both of a medical and, just as importantly, a
official policy that treats the lives of those closer to death as less deserving of protection creates the danger of reinforcing biases and discrimination against the elderly.

These concerns, however, are not a sufficient justification for completely excluding age from prioritization decisions. While age may not correlate perfectly with life expectancy for every individual, it is undeniable that, on average, there is a strong correlation between the number of years one has lived and the number of years one has left. In general, prioritization systems are based on the aggregate impact of particular factors on a population level, even though individual exceptions to these general patterns will inevitably occur. For example, pregnant women are given top priority for vaccines in the DHHS plan because, on average, they face a higher risk of dying if they become infected.\(^39\) The average correlation between pregnancy and mortality is sufficient to justify the heightened priority, even though the correlation does not mean that every single pregnant woman who becomes infected during a pandemic would necessarily die.

The risk that an age-related prioritization system would exacerbate ageism is certainly a serious consideration. However, the significance of this risk may depend on how a system of age-related preferences is implemented. For example, giving a bump up in priority to broad categories like “adolescents” and “young adults” may pose less of a risk of fostering biases against the elderly than a sliding scale approach in which each additional year of life is treated as a negative. For this reason, the World Health Organization has recommended that, if countries choose to incorporate age-related considerations in vaccine and antiviral allocation systems, such categories should “rely on broad life stages, rather than ranking individuals based on differences of only a few years.”\(^40\)

B. Membership in Particular Occupational Categories Justifies Priority Access to Resources

A consistent feature of national pandemic preparedness plans is the prioritization of certain occupational categories, particularly health care workers. The logic of this approach is that, if individuals

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\(^{39}\) See supra note 16 and accompanying text.

who are essential to the pandemic response effort become ill and die, many more people are likely to die as a result. Thus, saving essential workers means that everyone will be better off.

As a general matter, it is hard to argue with the general idea of giving preferential treatment to individuals who are genuinely essential to the pandemic response effort. In fact, even commentators who are strongly opposed to the use of general “social worth” criteria in resource allocation decisions approve the preferential treatment of individuals necessary to respond to crisis situations. Paul Ramsey, for example, argued that “we should be indiscriminate in the care we provide—just as God makes the rain fall on the just and the unjust alike,” but that in a “focused community” in which survival of the group is the primary objective, favoring those who contribute essential functions can be seen as a legitimate goal.\(^{41}\)

Giving priority in resource allocation to essential health care workers is particularly justifiable if those individuals will have to assume greater-than-normal risks to their own health in order to carry out their job responsibilities. For example, health care workers who are exposed to influenza patients are likely to face a significantly greater risk of infection than the general population.\(^{42}\) Offering these workers protection against infection may be a necessary incentive to get them to agree to work.\(^{43}\) In addition, providing access to vaccines and antivirals to individuals who expose themselves to life-threatening risks as part of the pandemic response effort can be justified by the ethical principle of reciprocity, which states that those who make sacrifices for the benefit of society have a greater claim to benefits from society in return.\(^{44}\)

Nonetheless, basing preferential treatment on specific occupational categories is problematic because the categories are inherently broad and may be difficult to contain within reasonable limits. For


\(^{42}\) See Carl H. Coleman, Beyond the Call of Duty: Compelling Health Care Professionals to Work During an Influenza Pandemic, 94 IOWA L. REV. 1, 9 (2008) (noting that “[h]ealth care professionals who participate in the pandemic response effort are likely to face a significantly greater risk of infection than the rest of the population,” and that, during the Severe Acute Respiratory Syndrome (SARS) epidemic of 2003, health care professionals accounted for nearly twenty percent of confirmed SARS cases worldwide).

\(^{43}\) See id. at 42 (arguing that health care professionals who volunteer to work during a pandemic should receive priority access to vaccines and antivirals).

\(^{44}\) See WORLD HEALTH ORGANIZATION, supra note 40, at vi.
example, should the category of “health care worker” include only professionals with unique life-saving abilities, such as infectious disease specialists, or should it include anyone who works in a setting that provides health care—including, for example, janitorial staff or members of the billing department? If the goal is to ensure the continued functioning of hospitals and other health care providers, then arguably anyone necessary to the maintenance of that institution would have a claim to priority access. Yet, if anyone who works in a health care institution is entitled to priority, it will be hard to justify differential treatment for others who provide equally valuable societal benefits, such as day care providers, bus drivers, or sanitation workers. In other words, unless the concept of “essential worker” is limited to an extremely narrow category of lifesavers, any distinctions that are drawn may be perceived as arbitrary and hence unfair.

Reflecting these concerns, the New York State Task Force on Life and the Law recommended against prioritizing health care workers and other first responders for access to ventilators during a pandemic.\(^\text{45}\) According to the Task Force, if ventilators are in short supply, prioritizing health care workers could mean that anyone who is not a first responder would lack a realistic chance of having access to ventilators.\(^\text{46}\) The Task Force also pointed out that prioritizing health care workers could lead to “the appearance of favoritism, in which those who devised the rationing system appeared to reserve special access for themselves.”\(^\text{47}\)

Rather than giving priority access to broad occupational categories, planners should develop more finely tuned criteria for identifying individuals whose services are genuinely essential. Any expansion beyond these narrow criteria should depend on a showing that an individual will be required to assume greater-than-normal risks as a result of performing services that will benefit the greater social good.


\(^{46}\) Id. at 27.

\(^{47}\) Id. at 28. The Task Force noted that, although it rejected giving priority to health care workers for access to ventilators, the considerations might be different for decisions about vaccines and antivirals. See id.
C. Promoting Aggregate Social Welfare and the Impact on Vulnerable Populations

A general concern with utilitarian-based approaches to the allocation of scarce life-saving resources is that they may conflict with other important societal values, particularly the values of equality and non-discrimination. The problem is that, if the primary goal is ensuring that resources are deployed in the most cost-effective manner possible, entire segments of the population may end up receiving nothing. For example, developing a mechanism for delivering vaccines and antiviral medications to hard-to-reach rural populations will inevitably cost more than using those resources in concentrated urban settings. Sending resources to developing countries, and helping those countries deploy those resources in the absence of well-developed health care infrastructures, will entail similar inefficiencies. In general, many of the most vulnerable segments of society would suffer under a system that focuses primarily on the cost-effective deployment of resources, including individuals who are home bound or who have significant mobility restrictions, individuals whose literacy or linguistic limitations prevent them from being easily reached with public service messages, and individuals who face barriers in access to health care because of membership in stigmatized social groups.

The impact of utilitarian-centric resource allocation policies on vulnerable populations is particularly problematic in light of the fact that individuals who are economically and socially disadvantaged would probably suffer the greatest burdens of an influenza pandemic. According to one recent study, if the next pandemic has mortality patterns comparable to the 1918 Spanish flu, ninety-six percent of deaths will occur in the developing world. Moreover, during the Spanish flu, individuals from “lower social classes and [socially] oppressed groups had substantially higher mortality rates than the dominant or ruling population” in both wealthy and developing countries. Despite these concerns, the authors of the study found that no country had systematically identified vulnerable populations in the context of pandemic response efforts. Rather, discussions of vulnerability have been limited to individuals at “increased biological or

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50 Id.
51 Id. at 35.
medical risk of” infection or death.\textsuperscript{52} Only two of the plans surveyed even mentioned “the barriers that the poor and other disadvantaged people are likely to face in securing access to vaccines and antiviral[ ]” medications.\textsuperscript{53}

In other contexts, we already accept that the pursuit of social utility must be tempered with equality-based considerations. For example, Robert Veatch points out that our system for allocating organs explicitly rejects several inequitable criteria that would make sense from a purely utilitarian perspective.\textsuperscript{54} For example, the system does not rely on HLA antigen matching for kidney transplantation, in part because such an approach would systematically favor white over black organ recipients.\textsuperscript{55} Similarly, the allocation system ignores “reliable data showing that people of a certain age, race, income group, and gender [do] predictably slightly better” as kidney recipients.\textsuperscript{56} Veatch also argues that efforts to promote wider geographical regions for organ sharing also reflect “a victory for the justice perspective” over defenders of pure efficiency approaches, as broad geographic distribution “tends to favor equality of access, based on need, over efficiency.”\textsuperscript{57}

Even the most ardent supporters of taking equality considerations into account in resource allocation decisions do not deny that maximizing social utility is an important ethical value. The question is ultimately one of balance—i.e., we must decide “how far [we] are willing to have the overall level of health of the community reduced in order to reduce inequalities in the distribution of health.”\textsuperscript{58} At some point, attempting to compensate for economic and social disadvantages by deploying greater resources to vulnerable populations can itself be seen as inconsistent with respect for equality if the greater resources devoted to the vulnerable make it impossible to care for other segments of society. Yet, in order to strike this balance, the conflict between utility and equality must first be acknowledged. Existing preparedness plans do not even take this first step.

\textsuperscript{52} Id.
\textsuperscript{53} Id. at 37.
\textsuperscript{55} Id.
\textsuperscript{56} Id. at 240.
\textsuperscript{57} Id.
\textsuperscript{58} Williams, supra note 33, at 122–23.
IV. CONCLUSION

Existing plans for allocating vaccines and antivirals during a pandemic are rational responses to a problem with no ideal solution. Yet, several aspects of these plans deserve further consideration, particularly with respect to the role of age, the relevance of occupational categories, and the impact of utility-based considerations on vulnerable populations. While no plan can perfectly resolve the competing considerations, it is essential that the trade-offs are made explicit and subject to broad public deliberation. This symposium has served a valuable role in fostering this kind of discussion.