### **SYMPOSIUM**

# Rationing Vaccine During An Avian Influenza Pandemic: Why It Won't Be Easy

John D. Arras

Department of Philosophy, University of Virginia, Charlottesville, Virginia

The specter of an avian influenza pandemic poses enormous technical and logistical challenges. For example, how can such a looming catastrophe be avoided? If we cannot prevent it, how can we best mobilize our medical and social resources to effectively blunt its impact? How can we quickly mobilize production of sufficient quantities of effective vaccines and antiviral agents to either prevent infection or mitigate the burden of illness in the infected? While we hope and trust that our scientists and public health officials will do their best to prevent a pandemic, it would be foolhardy to assume they will succeed against such a formidable foe, especially when many of our most distinguished and knowledgeable influenza experts warn that the operative question isn't whether, but rather when, a pandemic will strike. And while virologists in both the public and private sectors are no doubt searching feverishly for new ways to hasten production of effective vaccines, a full-blown pandemic will most likely overwhelm their best efforts. Thus, in addition to posing scientific, technical, and logistical problems, the threat of an avian influenza pandemic

poses equally important ethical problems, the most vexing of which is the age-old question, "Who shall live when not all can live?" In short, how should influenza vaccine and antivirals be rationed in the context of a global pandemic?

In the absence of revolutionary breakthroughs in the design and production of influenza vaccines, we can expect acute shortages of vaccine in the early months of a pandemic. Given current egg-based methods of producing vaccines, experts anticipate a ramp-up period of roughly six months before large quantities of drug will be ready for distribution [1]. Since pandemic influenza strains achieve their global reach by virtue of their novelty and our corresponding lack of immunological defenses against them, it takes time to identify the new strain and design a tailormade vaccine against it. Thus, during the first six months of a pandemic, there is likely to be little or no carefully tailored vaccine available to combat the first wave of influenza. (There may, however, be stocks of generic vaccine on hand, such as the H5N1 vaccine currently being developed at the National Institutes of Health

To whom all correspondence should be addressed: John D. Arras, Department of Philosophy, 512 Cabell Hall, University of Virginia, P.O. Box 400886, Charlottesville, VA 22904. Tel.: 434-924-7863; E-mail: jda3a@Virginia.edu.

[2]. Just how effective such a generic vaccine will be against a specific, newly mutated influenza strain remains to be seen. Preliminary studies indicate that the generic vaccine is effective but only at extremely high doses — a result that does not bode well for widespread distribution during a pandemic [3]. One authoritative source estimates that, during the following six months, worldwide vaccine production would most likely be limited to roughly 1 billion doses. Since we won't have any built-up immunity to this particular strain of influenza, as we do against garden variety influenza strains that circulate among us from year to year, it will most likely require two doses of this vaccine to effectively protect each recipient. This means that only roughly 500 million people, or 14 percent of the world's population, could be effectively immunized during the second half of the pandemic's first year [4, p 1842]. Other authorities estimate that current production capacity in the United States would only yield enough drug in one year to effectively vaccinate about half of the American population [5]. A realistic approach to the threat of pandemic influenza must, therefore, assume that there will be significant shortfalls in vaccine availability, which, in turn, will force us to choose, especially in the early stages of an epidemic, who will live and who will die. We will have to decide not only who gets scarce vaccines, but also who gets (less) scarce antiviral medications, hospital beds, and ventilators. In this paper, I will limit the ambit of my attention to the problem of justice in vaccine distribution. Because such awesome choices are fraught with ethical and political ramifications, it is imperative that we begin drafting and publicly justifying our selection criteria now, well before a pandemic is upon us. The stakes are so high, and the issue so volatile, that the public must come to understand and accept, if only somewhat passively, the rationale for distribution well before an epidemic strikes that

will inevitably stir up social chaos in its wake.

In this paper, I shall argue that the ethical principles governing the distribution of vaccine during the so-called "interpandemic" influenza seasons will be inadequate to deal with the medical, social, and ethical challenges of a genuine avian flu pandemic. Our criteria for just distribution will have to expand to include protection of key personnel and social infrastructures. I shall also argue, however, that once we have articulated these additional criteria, we will have to acknowledge that we lack rational grounds or a social consensus on how to set priorities among them. This conclusion will lead to the further claim that when rational priority-setting among distributional criteria founders in this way, efforts to legitimize rationing during a pandemic should focus on the development of a transparent and democratic process for making such decisions. Even when such a legitimizing process has been deployed, however, rationing will still be difficult due to ubiquitous empirical uncertainties. In short, I shall argue that even though rationing during an avian flu pandemic is potentially legitimate and ethically justifiable, it won't be easy.

## I. RATIONING DURING INTERPANDEMIC FLU SHORTAGES

We already occasionally experience manufacturing disruptions that lead to shortages in vaccine supply during normal, "interpandemic" influenza seasons — the most recent occurring in the fall of 2004 — and the United States and other countries have by now settled upon criteria for vaccine rationing during such periods [6]. One might well ask why we should not simply deploy these same criteria during a genuine influenza pandemic. A comparison of the phenomena of interpandemic and pandemic influenza shows why this would be a bad idea.

Although vaccine shortages during interpandemic influenza seasons pose a serious threat to thousands of vulnerable individuals, such "crises" are not generally regarded as a threat to the functioning of society at large. Consequently, rationing strategy during such periods tends to focus rather narrowly on protecting those most at risk for influenza-associated mortality and hospitalization. This approach thus gives highest priority to people over 65 with co-morbid conditions, elderly residents of long-term care facilities, those under 65 with co-morbid conditions, children aged 6 to 23 months, and pregnant women. The CDC's recently published priority ranking also lists health care personnel and the household contacts of children under the age of 6 months. (Direct vaccination of children in this category is not recommended) [6].

A solid social consensus exists with regard to this narrowly focused rationing scheme. There is general agreement that during interpandemic shortages, scarce life-saving medical resources should go to those most in need. No consideration is given here to maintaining the smooth functioning of important social institutions, such as schools, prisons, the courts, or legislatures. Indeed, when the news media report that high-ranking politicians or sports teams have jumped the queue, this behavior tends to be roundly criticized. Although health-care providers are included on the CDC's list, the justification for their inclusion had nothing to do with maintaining the smooth functioning of our medical infrastructure. Given the likely impact of a normal influenza season upon unvaccinated health-care workers. officials at the CDC were not worried about the ability of the health-care system to continue to function. Their primary concern with health-care providers is helpfully telegraphed by this group's proximity on the list to household contacts and outof-home caretakers of children under 6 years. All three of these groups were given

priority because they are potential vectors of influenza transmission to the populations most at risk for influenza-related illness and death. (Imagine the potential impact of a single infected physician or nurse upon the frail, immune-compromised residents of a nursing home.) Thus, the one item on the list that might appear to suggest a social objective, rather than a narrowly medical focus, turns out to represent merely an indirect means of achieving the single goal of protecting the neediest and most vulnerable individuals.

This consensus on the correct rationing principle for interpandemic shortages has important implications for policy. First, agreement on a single rationing principle tends to obviate the need for much attention to the development of fair and/or elaborate procedures for the distribution of scarce resources [7]. If we agree in principle on who should get scarce vaccine, and if our sole criterion is based upon medical considerations, then, assuming serious scarcity, the major procedural question will be how to ensure as far as possible that only the most vulnerable persons actually end up receiving the vaccine. So we will need screening mechanisms carefully designed by medical professionals to exclude younger and healthier persons (e.g., politicians) from receiving priority. Inevitably, some unscrupulous, relatively healthy people will slip through the screen, but those doing the screening will at least know exactly what they are looking for. The philosopher John Rawls called this an example of "imperfect procedural justice"— i.e., a case in which there exists an independent criterion for the correct outcome, but there is no feasible procedure guaranteed to yield it [8, p 86].

Interestingly, given this interpandemic emphasis upon a single agreed-upon criterion of selection — and a corresponding de-emphasis upon the elaboration of some sort of "fair procedure" — those political units (e.g., towns, counties, states) that

resort to non-medical decision procedures in order to achieve a perceived measure of "fairness" might actually be judged as acting in an unprincipled, unjust manner. During fall 2004, for example, the media published accounts of municipalities that responded to the impending shortfall in vaccine supplies by instituting lotteries or first-come, first-served policies at public health clinics. Apparently flummoxed by the magnitude of the shortfall, the intensity of demand from all quarters, and lack of clear guidance from the CDC at that time, some political leaders adopted a seemingly fair procedure that would at least give everyone a fair shot at obtaining an injection. Notice, however, that if we really do have consensus upon a rationing principle such as "protect those most likely to suffer illness or death due to influenza," then resorting to other kinds of procedures like lotteries or town meetings will be either unjust or unnecessary. Since they already agree on the correct principle, and since the fairest process will be predicated upon medical judgments, those attending a town meeting would have nothing to discuss. A lottery, on the other hand, would give equal consideration or an equal chance not only to those who are most vulnerable (e.g., sick nursing home residents) but also to those who are merely somewhat vulnerable (e.g., healthy adults over 65), which would defeat the point of the principle.

Consensus on a rationing principle during interpandemic vaccine shortages also has implications for the locus of decision making. During the 2004 season, a controversy arose regarding the relative desirability of national vs. local decision making. After it became apparent that only half the usual doses would be available due to a manufacturing snafu at Chiron Corporation, local health departments looked to the federal government, and in particular to the CDC, for guidance in allocating their scarce remaining stocks. For its part, the CDC had not yet developed an authoritative priority list and pon-

dered the wisdom of hastily publishing recommendations without a firm factual basis or much time to deliberate carefully. Some CDC officials worried that publishing a priority list in the midst of that flu season, after many local health officials had already made tough but unavoidable choices in distributing vaccine, might have the unintended effect of undercutting local health departments and possibly subjecting them to lawsuits from irate citizens who had been denied vaccination. Abstracting from the crisis atmosphere of that period, we can now ask at our leisure whether centralized federal or diffuse local decision making, or perhaps some complex mix of the two, should govern such rationing choices during interpandemic shortages.

Supposing that we have a well-founded consensus on a rationing principle exclusively focused on the prevention of morbidity and mortality in the most vulnerable categories of people, the case for local decision-making is greatly attenuated. In many circumstances, policy makers rightly favor localized decision making. Conditions may vary from place to place. The residents of different geographical locations might have different value rankings, and, especially when information concerning particulars is at a premium, only local actors might possess a sufficiently nuanced appreciation of the facts on the ground to make sound decisions. Such is the case, for example, regarding decisions to forgo life-sustaining treatments, which most thoughtful observers believe are best delegated to the involved parties and perhaps local hospital ethics committees rather than to members of the U.S. Senate. During interpandemic flu seasons, however, none of these conditions prevail, so the national government via the CDC seems to be the locus of proper decision making. To be sure, local public health officers and other officials will require discretion in carrying out the recommendations of federal agencies - for example, regarding the number and placement of screening and vaccination sites — but they require no discretion in identifying the proper policy objectives.

Finally, note that vaccine shortages during interpandemic flu seasons are at least somewhat compatible with a private market in vaccines. During ordinary flu seasons, it is at least somewhat "business as usual" in that various health care providers (e.g., hospitals, nursing homes, managed care organizations, local public health agencies, etc.) already will have contracted for their standing orders of vaccine long before a crisis emerges. When a serious shortage looms, such institutions rightly expect their prior contractual agreements to be honored. The problem, of course, is that many other institutions - ranging from corporations to professional sports teams — have also placed standing orders, but few (if any) of their members might satisfy the criteria set forth in the CDC's priority ranking list. In situations such as this, government agencies can wheedle, cajole, and perhaps even threaten such private institutions to cede their stocks of vaccine to those who are truly needy, such as the residents of nursing homes that had the bad luck to have contracted with a defaulting supplier. In cases such as this, the market is a notoriously bad mechanism for achieving just or tolerably fair results. Notwithstanding much urgent talk about the need for fair and equitable dissemination of scarce vaccine stocks in fall 2004, the brute fact was that pre-existing market transactions had already precluded fair and equitable distribution for many highly vulnerable citizens. For rationing to be both equitable and efficient, those doing the rationing (e.g., legislators, public health officials, etc.) must effectively control the resources to be distributed; otherwise, they have no leverage in bringing about desired results. Fortunately, that flu season turned out not to be as devastating as originally predicted, and many virtuous citizens who regularly get flu shots decided to forgo them. So an impending medical and moral crisis was averted, but this close call served to highlight the limits of unfettered markets in the distribution of vaccine.

## II. RATIONING DURING PANDEMICS

When we move from rationing during interpandemic periods to full-scale pandemic rationing, the situation is entirely different. In the first place, there will be much less room for the workings of the free market if or when the United States is engulfed by waves of avian flu. Given the predicted extent of shortages and their implications for large-scale devastation of the population, it will be imperative for the federal government to control all available stocks of avian flu vaccine from the beginning. Naturally, the government will have to purchase these stocks from the private companies that produce them, but we cannot repeat during a pandemic the unfocused, ad hoc, and socially blind workings of the market seen during the last interpandemic crisis, a process that delivered vaccines to the members of Congress and, one suspects, to high-ranking officials of large corporations. This does not mean, however, that the government should control the chain of distribution along its entire length and breadth. There may well be a powerful case for distributing avian flu vaccine not only through public health clinics, but also through private hospitals, managed care organizations, and other private enterprises. The key point is that such decisions must be made by a single entity that controls all available vaccine. They must, moreover, conform to the strictly defined objectives of the vaccination program, and not according to people's willingness and ability to pay.

Another crucial difference between interpandemic and pandemic rationing situations is that the latter may exhibit several (possibly competing) policy goals, whereas the former only featured the single goal of reducing mortality and morbidity within the most vulnerable categories of citizens. The latter policy objective might certainly continue to play a role in the thinking and planning of public health officials during a pandemic, in which case distribution would continue to favor the most medically needy and vulnerable e.g., the elderly and children with co-morbid conditions, such as acute asthma, nursing home residents, and the people (including physicians and family members) who care for them. But this is only one possibility. During the crunch of a genuine flu pandemic, other important objectives for social policy beckon. Before we enumerate and discuss these additional policy goals, some of which supplement a narrow medical focus with a concern for the continued functioning of crucial social institutions, we need to confront an important threshold question: viz, is it ever morally permissible to weigh the social value of various possible recipients and uses of scarce medical resources?

This question was posed at the birth of the modern bioethics movement by Dr. Belding Scribner's development of an arterio-venous shunt for dialysis patients in end-stage kidney failure: viz, who would live when not all could live [9, 10]? According to many observers at the time, one key factor that should count either for or against any given candidate for this scarce, life-saving resource was his or her value to society. It seemed axiomatic to these commentators that if not all could be saved, then the cancer researcher or the church-going mother of four should receive ongoing dialysis rather than the bachelor street sweeper with a drinking problem. From this angle, the best solution to this problem was the formation of a committee with diverse membership, whose job it would be to tote up the potential net social contributions of the various candidates. If there wasn't enough to go around, we should bestow our scarce societal resources upon those most likely to give us maximal "return on investment." Clearly, this position was animated by an unapologetic and unvarnished version of utilitarianism, according to which resources should be distributed so as to maximize social value (e.g., happiness, welfare, the satisfaction of desires, etc.) [11]. According to this view, everyone's gains or losses in welfare would be counted, but the prize would go to those who had the most social value on offer.

Notwithstanding its intuitive plausibility to many observers, the social value criterion was subjected to withering criticism at the time of the Seattle allocation experiment, and it was subsequently abandoned by both clinicians and social policy experts in the area of organ transplantation [12]. According to the influential Protestant moral theologian Paul Ramsey, deciding who should live or die according to judgments of social worth necessarily violates the equal intrinsic worth of every human being [13, p 253]. To say that the cancer researcher or the banker is more valuable to society than a disabled single man on welfare, and thus that the former should live while the latter should die, is, argued Ramsey, "to presume to make a (nearly) total estimate of a man's life" [13, p 259], and thus to make a repugnant and indefensible judgment. Repugnant because such a judgment denies what most religions and liberal political philosophies steadfastly insist upon: viz, that each of us is, respectively, either a child of God morally equal in God's eyes, or a citizen of a democratic polity deserving of equal concern and respect. Indefensible, because we lack the epistemological resources to know who is more socially worthy than whom. What if the single man on welfare devotes himself to the well-being of his neighbors, while the banker turns out to be a selfish tyrant, ruining the lives of his workers and family? Ramsey concluded that, in the ordinary run of such tragic choices, the only way to acknowledge our equal worth as human beings was to decide who would live on the basis of a random decision procedure, such as a lottery.

Ramsey conceded, however, that there might be some highly unusual social circumstances in which judgments of social worth could be morally permissible. In two of Ramsey's examples, war and catastrophic triage situations, human beings are reduced to a state of affairs in which a single overarching social goal e.g., defeating the enemy or saving those who can be most easily saved following a natural catastrophe — effectively eclipses all other concerns. Thus, during World War II, it was decided that the scarce stocks of the newly developed "magic bullet," penicillin, would go first to soldiers "wounded in brothels" rather than on the battlefield. During the North African campaign of 1943, the myriad values and goals ordinarily littering the social landscape were reduced to a single imperative: Get as many troops into battle as soon as possible in order to defeat the German army. Here the great plurality of social values and criteria for selection boil down to a "focused" concern "where objectives were closely defined" [13, p 257]. In such desperate straits, social worthiness can and should, Ramsey conceded, be both effectively measured and deployed as a decisive criterion for life and death decisions. He maintained, however, that dire straits of this severity were a rare social occurrence and continued to advocate his principle of random selection for the vast majority of "tragic choice" situations, including the rationing of dialysis machines and transplantable organs.

Although they routinely claim many thousands of lives each year, bringing untold grief to those left behind, interpandemic flu seasons do not bring society to its knees; they do not count as exceptions to Ramsey's general rule against the deployment of social worth criteria. Although many die, life goes on for the vast majority of citizens, and the variegat-

ed infrastructure of society remains intact. Our field of vision thus remains highly pluralistic rather than "focused" upon a single overarching social imperative, and so it makes sense to avoid social value criteria. But the specter of a genuine avian flu pandemic may well provide us with yet another example of a catastrophic situation so drastic and so threatening to the fabric of society as to legitimate the limited use of social value criteria.

Consider in this connection the havoc wreaked by the infamous "Spanish flu" pandemic of 1918. This was an exceptionally lethal virus that killed with frightening speed and efficiency. Young adults, a category usually spared by most interpandemic flu viruses, were singled out for particularly harsh treatment. It is estimated that as many as 8 to 10 percent of all young adults then living in the world were felled by this virus. Five hundred thousand Americans and as many as 50 million deaths worldwide have been attributed to the Spanish flu. As the historian John M. Barry, puts it, this flu killed more people than any other outbreak in human history. It "killed more people in a year than the Black Death of the Middle Ages killed in a century; it killed more people in twenty-four weeks than AIDS has killed in twenty-four years" [14, p 4-5]. Military bases with their cramped, fetid quarters provided ideal growth conditions for the virus and were quickly decimated. In the city of Philadelphia, it took only 10 days for the epidemic to explode from one or two deaths per day to hundreds of thousands ill and hundreds dropping dead. Federal, city, and state courts closed down, and all public meetings were banned. Swaths of black crepe, indicating a death in the house, hung everywhere in every neighborhood. "People were dying like flies," one observer noted, "every other house had crepe over the door" [14, p 223]. There were not nearly enough doctors and nurses to attend to the ill, as if their paltry defenses at the time would have made any difference against that virus, nor were there enough undertakers to bury the mounting toll of dead.

A flu pandemic threatening anything resembling the devastation of 1918 would no doubt qualify as an exception to Paul Ramsey's rejection of social value criteria. In the United States alone, hundreds of thousands would perish, key social institutions (e.g., the courts, prisons, legislatures) would be crippled, and commerce would grind to a halt in many cities. Air travel, a primary medium for the spread of such viruses, would be suspended for weeks, if not months, thereby throwing the whole industry into a financial tail spin. Confronted by the looming threat of such a pandemic, our usual commitment to the equal moral worth of each citizen would predictably and justifiably yield to a social value perspective narrowly focused on survival and the minimization of social disruption. At such a perilous juncture, it would be reasonable for those in charge of the national welfare to consider the following possible goals:

### (1) Protection of the most vulnerable

For example, children and the elderly, those with co-morbid conditions, their caregivers, etc. As we have seen, this goal, which focuses attention on the medically worst off group, constitutes the sole objective of current government policy during periods of interpandemic flu. During an epidemic of pandemic flu, however, this important goal may well have to be weighed and balanced against other values and social priorities. Thus, in addition to upholding the value of social equality and the equal worth of every person, society may have to engage in trade-offs with some of the following social goals.

## (2) Protection of key personnel in health care, public health and safety, and crisis response infrastructures

Whereas current government interpandemic rationing policy does include health care workers providing direct support to infected or highly vulnerable persons, the rationale for their inclusion, as we saw above, rested exclusively on their role as potential vectors of the disease to vulnerable populations. During a pandemic, however, both the categories of key workers and the rationale for their inclusion would expand to encompass explicitly social goals, such as the maintenance of crucial health-related infrastructures. Thus, in addition to those health care workers directly caring for patients, our priority list would also include vaccine manufacturers and key public health personnel on both the national and local levels, as well as front-line crisis responders, including personnel from the Department of Homeland Security. This list could be expanded to include key elected officials with administrative responsibilities for managing social crises, such as the U.S. president, key cabinet officers, state governors, etc.

# (3) The protection of key social functions — including transportation, fire and police departments, food production, utilities, and undertakers

Some key sectors of the economy, such as trucking, obviously play a role in the distribution of crucial medical supplies such as vaccines and anti-viral drugs. Clearly, these sectors would have priority during a flu pandemic. Nevertheless, many crucial, non-health related social functions would be threatened during a pandemic. As we saw during hurricane Katrina, natural catastrophes can overwhelm the usual bulwarks of law and public order. Police and fire personnel, as well as members of the National Guard, might thus be high on our priority list. Depending on the mortality rate of a given pandemic flu virus, even undertakers might be singled out for preferential treatment under a vaccine rationing plan. The plausibility of such a scenario is graphically underscored in Barry's account of the 1918 outbreak in Philadelphia: "But the most terrifying aspect of the epidemic was the piling up of bodies. Undertakers, themselves sick, were overwhelmed. They had no place to put the bodies ... The city morgue had room for thirty-six bodies. Two hundred were stacked there. The stench was terrible ... No more bodies could fit. Bodies lay in homes where they died, as they died, often with bloody liquid seeping from the nostrils or mouths ... Corpses were wrapped in sheets, pushed into corners, left there sometimes for days, the horror of it sinking in deeper each hour..." [14, p 223-4].

### (4) Maximization of economic benefits

Supposing that one were inclined to maximize the economic benefits flowing from the deployment of vaccines and antivirals, and supposing that the greatest economic cost exacted by a flu pandemic would be attributable to massive loss of life in the healthy working population, then planners might reasonably target vaccines at a broad swath (e.g., 40 to 60 percent) of healthy workers in the general adult population [15]. While traditional criteria for vaccine priority tend to be explicitly "Hippocratic" in nature, this ordering of priorities would be dictated entirely by cost-benefit analysis — more specifically, by an analysis of the costs associated with a catastrophic shutdown of major industries, such as air travel, telecommunications, food production and distribution, tourism and entertainment, and so on.

### (5) "Fair innings"

Another controversial rationing principle with a credible claim to justification is rationing by age. According to this view, those who have already reached old age and thus enjoyed their "fair innings" should receive lower priority for vaccines and other scarce resources than those who have yet to live a full life. Thus, even though relatively healthy persons over the age of 65 might be at greater risk for influenza-related morbidity and mortality than healthy children, teens, and young

adults, the fair innings principle would give priority to these latter groups. Although this principle reaches many of the same conclusions as rationing according to social value, its rationale is very different. While some appeals to age-based rationing, like the economic maximization scheme described directly above, are grounded in utilitarian calculations of the likely social benefits of immunizing various competing age cohorts, the fair innings argument, focusing as it does on securing for everyone an equal opportunity to live a full life, is actually grounded in a concern for fairness and justice [16-18].

## III. WHY PANDEMIC RATIONING WILL BE SO DIFFICULT

In a pandemic flu situation, the four policy goals enumerated above — i.e., protection of the most vulnerable individuals, of key health-related personnel, of important societal infrastructures, and, finally, the achievement of maximal social utility — would all be on the table as possible options for key decision makers. But not all of these goals are mutually compatible. The protection of the most vulnerable would obviously allot highest priority to the elderly debilitated residents of nursing homes. Living in close proximity to scores or hundreds of other patients, most with already compromised immune systems, these residents are clearly at highest risk for infection and death. On the other hand, because they are no longer working, their deaths would not exact great economic costs. In addition, precisely because their immune systems are already often severely compromised, giving nursing home residents first priority will not amount to an efficient use of scarce vaccine stocks. So a policy focused upon the protection of the most vulnerable would inevitably threaten at least two other worthy goals - viz, maximizing both economic value and the purely medical effectiveness of the vaccine.

While most of these goals individually represent plausible policy options, as would various permutations and combinations among them, it is highly unlikely that any one value or any single combination of values will emerge as uniquely and obviously correct. Part of the problem stems from our epistemological limitations. We will often not have sufficient information to choose among various key players representing health care, the public health system, government, or the economic infrastructure. Who among them is truly "indispensable"? Which will have the greatest impact on stemming the rising tide of the pandemic or maintaining social stability? In all likelihood, we just won't have complete answers to such empirical questions, although we can be quite confident about the crucial importance of some groups, such as front-line emergency medical and public health personnel.

But this epistemological embarrassment won't be the worst of our problems. In addition, there's the equally embarrassing fact that we apparently lack a canonical value ordering that would allow us to prioritize, weigh, and balance the available policy goals and values already on the table before us. How, for example, should we weigh and balance the competing goals of protecting the most vulnerable and safeguarding our key health and security infrastructures? In the value ordering of many people, protecting the most vulnerable should have top priority, especially when compared with, say, the maximization of economic efficiency, but at what cost? The vulnerable certainly won't be protected if our public health infrastructure collapses.

Here's a related problem: How should we weigh and balance the competing goals of protecting the most vulnerable and achieving the best results in terms of lives saved per dose of vaccine? We all might agree that the debilitated elderly in nursing homes deserve protection, but what if the very fact of their immunological debilitation means that they will be extremely

inefficient hosts for the vaccine? What if focusing our attention on the debilitated elderly means that we won't be able to save thousands more younger and healthier people whose bodies could put the vaccine to better use and who perhaps have a stronger claim based upon the fair innings principle [19]? Should we then abandon the elderly completely, giving them no chance at the vaccine, or should we rather allot them a major (or minor) portion of the vaccine, fully realizing that our commitment to protecting this vulnerable population will have serious costs in terms of other lives lost? Questions of this sort go to the heart of the rationing problem, yet we lack both a rational decision procedure and a clear political consensus on how best to answer them. (For a worthy initial attempt at grappling with these difficult problems, see the suggested priority schemes of two federal committees advising the Department of Health and Human Services at www.hhs.gov/pandemicflu/ plan/appendixd.html. Additional information concerning the U.S. government's preparations for an avian flu pandemic, see the National Strategy for Pandemic Influenza: Implementation Plan, available http://www.whitehouse.gov/homeland/nspi implementation.pdf).

Norman Daniels and James Sabin have acknowledged in their recent work the baffling nature of such fundamental questions at the very heart of the health care rationing project. They have concluded that, in the absence of canonical answers to them, the legitimacy of political decision-making about scarce life-saving resources depends upon the fairness of the processes through which they are made [20]. In contrast to the sort of rationing problem posed by interpandemic flu, a situation in which we share a solid consensus on the correct principle, pandemic flu confronts us with multiple values, goals, and principles, all of which are to some extent plausible, but none of which (or no combination of which) is obviously rationally correct. For Daniels and Sabin, this failure of reason leads directly to an emphasis on fair procedures for settling on public policies. Although this is no place for a full examination of their theory of fair process, these authors stress the importance, inter alia, of publicity (rationales must be publicly accessible), of broadly intelligible and acceptable reasons (rather than sectarian appeals), and of mechanisms for challenge and dispute resolution. If such fair procedures are not followed. Daniels and Sabin contend, political choices may well be reasonable and sound, but they will not be viewed as legitimate by the people subject to them. This is, I would argue, a crucial consideration for medical and public health leaders who would suggest rationing principles favoring members of their own professions. Although a highly plausible case can be made for vaccinating front-line doctors, nurses, and public health officials in a context of pandemic flu, we must keep in mind that such a rationing principle does override or violate (even if justifiably) Paul Ramsey's principle of equal moral worth. In the absence of a well-planned process of sharing information, deliberation and consensus building with the public, such a recommendation may well strike many people as a case of well off medical types helping themselves to the lion's share of a scarce lifesaving resource. In this connection, it appears that the Canadians, who have already deployed an ambitious consensusbuilding project on pandemic flu preparations, are already well ahead of the U.S. [21].

Another important difference between interpandemic and pandemic flu follows from this discussion. We saw above how consensus on a moral principle for rationing in the context of interpandemic flu rendered otiose much of the debate over the locus of decision making. If we all (or most of us) agree on a single principle of distribution, then our usual preference for local decision making over the

ruminations of distant government bureaucrats loses most of its force. In a context of reasonable disagreement over a host of plausible principles and their various permutations in combination, however, local approaching differences in intractable questions may well come to the fore. In theory, at least, officials in Maine and California may have a different take on how such goals as protecting the vulnerable, securing the best medical results, safeguarding infrastructures, and achieving maximal economic benefit should be ranked and combined with other goals. So in order for such decisions to acquire legitimacy in the eyes of the public, it may well take more than an edict from the federal government coming out of Atlanta. On the other hand, such political theoretic considerations will have to be balanced against the real world demands of efficiency in the context of an emerging flu pandemic. Since it would only take weeks or even days for a virulent avian flu virus to begin to wreak havoc across the globe, this would not be the time for leisurely democratic deliberation in uncoordinated town meetings. Such rationing decisions will either have to be made long before a pandemic strikes, or they will have to be left to centralized government actors and agencies in the thick of the battle. The former course is obviously preferable to the latter, but does our society have the will to confront well ahead of time such potentially harsh but uncertain realities? Recent events in New Orleans indicate otherwise.

In addition to our epistemological limitations and our lack of consensus on key values, pandemic rationing decisions will be hampered by much uncertainty. An avian flu pandemic may come in the near future, but then again it may not. How much of our national treasure should we devote to hedging against this possibility? Advance planning will also be stymied by uncertainty about the virus itself and its effects. Until an avian viral strain breaks out into the human population, we won't

know exactly how virulent it is. The Spanish flu strain of 1918 killed roughly 2.5 percent of its victims, which doesn't sound like much until vou recall that it struck one-fifth of the world's population. Garden-variety flu viruses, by contrast, only kill one-tenth of 1 percent during a normal influenza season [22, p 7]. A great deal obviously hangs on where a new strain of avian flu would fall on this continuum between worldwide catastrophe and business-as-usual. Planning for pandemic rationing will also be hampered by uncertainty about the virus' age-specific fatality rate. Even if we have decided well ahead of time through legitimate processes of democratic deliberation to devote a certain percentage of vaccine stocks to protecting the most vulnerable members of society, we won't know exactly who the most vulnerable are until the virus strikes. Ordinarily, the elderly and small children are most at risk from flu viruses, but the 1918 flu primarily targeted young adults. Since pandemics by definition are driven by new viral strains against which we have no built up immunity, we won't know how bad they are going to be or who is going to be hardest hit until the epidemic is well under wav.

These uncertainties will pose serious problems for any rationing scheme we could possibly devise. Because we cannot predict either a strain's virulence or its affinity for certain age groups, public health officials will have to be exceedingly attentive to its patterns of infectivity and mortality and be willing to alter pre-established rationing strategies in the middle of the crisis. This will be especially problematic with regard to the threshold question of whether any given epidemic merits the overriding of our standard concerns about equal moral worth and subsequent deployment of social value criteria. Suppose a strain of avian flu does break out into the human population but is comparatively weak, resembling more the strain of Hong Kong flu in 1968 than the Spanish flu of

1918. How bad will it have to be before we jettison our governing norms of equality and start giving preference to health care professionals, politicians, and truck drivers bearing stocks of vaccine? Just because we agree that social value criteria can legitimately be invoked in a genuine social crisis doesn't mean that we will unerringly know when one is upon us. A false positive judgment here would lead to the unnecessary and morally problematic abandonment of a crucially important social norm bearing on the moral equality of all citizens. A false-negative judgment, on the other hand, would lead to misplaced complacency and social chaos.

I close this review of moral difficulties attendant upon pandemic rationing schemes with two additional related considerations. First, any ethical rationing scheme for pandemic influenza must plan effectively to counterbalance our society's well-documented tendency to give short shrift to minorities and the poor. As hurricane Katrina amply demonstrated, in our society the rich and well-placed command resources and the high ground, while the poor suffer, die, and are swept away. We saw this pattern repeated during the last interpandemic rationing crisis in Fall 2004. In spite of all the urgent talk of distributing scarce vaccine equitably among the most vulnerable, the wealthy and powerful unerringly found their way to the vaccine through the medium of the market and the power of political office. Crisis planners would thus do well to keep the somber lessons of Katrina firmly in mind as they devise distribution strategies for vaccine and anti-virals during a flu pandemic.

Finally, in addition to the problem of the poor at home, there is the problem of global poverty and lack of access to medical resources in developing countries. Notwithstanding the urgency of problems on the domestic front, we nevertheless must consider what obligations we (and other advanced industrialized nations) have toward the distant needy. Numerous principles of moral and political philosophy converge on the moral necessity of doing more, much more, than we currently do to help those suffering from starvation, malnutrition, and stunted lives abroad. Whether the analysis focuses on the utilitarian-inspired principles of beneficence and common decency, a strong principle of global distributive justice, considerations of rectification for past and ongoing wrongs, or a relatively weak principle of assistance to burdened societies derived from John Rawls' last work, the conclusion is the same: our current efforts to stem the tide of poverty, malnutrition, and premature death in the developing world are pitifully lame [22, 23]. If this conclusion encompasses an obligation to provide the world's poor with drugs to combat HIV, why would it not also include an obligation to make flu vaccine available to those who cannot afford it? Clearly, this is not a burden that the U.S. can or should alone. Other technologically advanced and wealthy nations must join forces to create vastly expanded capacity to manufacture vaccines. This moral imperative will be extremely difficult, if not impossible, to carry out if we follow the usual pattern of waiting for the epidemic to happen before kicking our pharmaceutical machinery into high gear. Now that a generic vaccine for the H5N1 avian flu virus has been successfully developed, however, we will not have to wait that long, even though this vaccine might not be as effective as one tailor made for an emerging pandemic.

### CONCLUSION

I have argued in this paper that the ethical challenges posed by a possible pandemic of avian flu are nearly as formidable as the scientific and public health challenges. Assuming a high degree of mortality associated with the viral strain, a genuine pandemic would claim millions of

lives worldwide and threaten the integrity of key medical, public health, social, and political infrastructures. A pandemic on such a scale would justify the temporary abandonment of our traditional commitment to the principle of equal moral worth and the concomitant embrace of social value criteria for health care rationing. But no sooner do we admit the justifiability of such criteria than we realize that we lack a canonical rank ordering of them and their many possible permutations. In the absence of social consensus on priorities, adhering to fair processes becomes critical for the public legitimation of rationing scarce life-saving resources, especially when health care providers and public health officials play a major role in allotting flu vaccines and anti-viral medications to themselves. Whatever rationing principles are ultimately forged within a context of public democratic deliberation, we will still be faced with the difficulty of deploying them under conditions of debilitating factual uncertainty. Finally, the rationing principles we develop must remain vigilant against the ever-present temptation to discriminate against the poor and dispossessed, whether here at home or in the far reaches of the developing world.

Acknowledgements: The author thanks his longtime colleague and friend, Sam Gorovitz, for pointing out several substantive problems and stylistic infelicities in the penultimate draft of this paper.

### REFERENCES

- 1. Palese P. Making better influenza virus vaccines? Emerg Infect Dis. (Accessed 2006 Jan at http://www.cdc.gov/ncidod/EID/vol12no01/05-1043.htm.)
- Ganguli I. Flu vaccines: looking beyond eggs. Scientist. (Accessed March 31, 2006 at http://www.the-scientist.com/news/display/23259/.)
- 3. Butler D. Bird flu vaccine not up to scratch: Positive results of little practical use, experts warn. (Accessed August 10, 2005 at http://www.nature.com/news/2005/050808/pdf/050808-9.pdf.)
- 4. Osterholm MT. Preparing for the next pandemic. NEJM 2005;352;1839-42.

- Schwartz B and Gellin B. Vaccination strategies for an influenza pandemic. J Infect Dis 2005;191;1207.
- Centers for Disease Control. Tiered use of inactivated influenza vaccine in the event of a vaccine shortage. MMWR 2005;54:749-50.
- Daniels N. How to achieve fair distribution of ARTs in 3 by 5: fair process and legitimacy in patient selection. Background paper: Consultation on equitable access to treatment and cadre for HIV/AIDS. WHO, Geneva, Switzerland, 26-27, 2004.
- Rawls J. A Theory of Justice. Cambridge, Massachusetts: Harvard University Press; 1971.
- 9. Jonsen AR. *The Birth of Bioethics*. New York: Oxford University Press; 1998.
- Alexander S. They decide who lives, who dies. Life Mag 1962 reprinted in Arras, J. and Hunt, R. *Ethical Issues in Modern Medicine*. Palo Alto, California: Mayfield Publishing Company; 1977, pp 409-24.
- Rescher N. The allocation of exotic medical lifesaving therapy. Ethics 1969;79; 173-86.
- Childress JF. Ethical criteria for procuring and distributing organs for transplantation.
  J Health Polit Policy Law 1989;14;87-113.
- Ramsey P. The Patient as Person. New Haven, Connecticut: Yale University Press; 1970.

- 14. Barry JM. *The Great Influenza*. New York: Viking; 2004.
- Meltzer MI, Cox NJ, and Fukuda K. The economic impact of pandemic influenza in the United States: priorities for intervention. Emerg Infect Dis 1999;5:659-71.
- Emanuel E. and Wertheimer A. Who should get influenza vaccine when not all can? Science 2006;13:854-5.
- 17. Daniels N. *Am I My Parents' Keeper?* New York: Oxford University Press; 1987.
- 18. Callahan D. *Setting Limits*. New York: Simon & Schuster; 1987.
- 19. Rosenthal E. Studies find flu vaccine and antiviral drugs fall far short. NY Times 22 Sept 2005; p 1.
- Daniels N and Sabin J. Setting Limits Fairly. New York: Oxford University Press; 2002.
- 21. Public Health Agency of Canada. Canadian Pandemic Influenza Plan. http://www.phac-aspc.ge.ca/cpip-pclcpi/
- 22. Kolata G. Flu: The Story of the Great Influenza Pandemic of 1918 and the Search for the Virus that Caused It. New York: Simon and Schuster; 1999.
- Chatterjee DK. The Ethics of Assistance: Morality and the Distant Needy. Cambridge: Cambridge University Press; 2004
- 24. Mandle J. *Global Justice*. Cambridge, Massachusetts: Polity Press; 2006.