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INCORPORATING EXPLICIT ETHICAL REASONING INTO PANDEMIC INFLUENZA POLICIES

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Introduction

Since the emergence of the H5N1 highly-pathogenic (avian) influenza threat in 2004,[1] scholars and policy-makers have been actively preparing for a potential pandemic. These five years represented an unprecedented opportunity. Although historically, three to four global pandemics have occurred each century,[2] never before had the world been given prospective warning about such a potentially serious influenza outbreak. This early warning meant that steps could be taken to prevent, or at least mitigate, the health effects of this looming global public health emergency.[3] Social distancing strategies were devised and implemented, medical countermeasures were developed and stockpiled, and careful thought was given to buttressing critical infrastructure from the impending social disruption.[4] Beyond these medical, social, and public health preparedness efforts, scholars and government officials also had an opportunity to grapple prospectively with the ethical impact of preparedness and response activities, with the goal of ensuring that the burdens of disease and benefits of intervention would be distributed equitably.[5]

Unfortunately, these ethical preparedness efforts have been of limited utility to-date. While numerous scholars have identified and explored a range of important ethical issues, data indicate that ethical considerations are not regularly incorporated into actual pandemic preparedness plans.[6] The consequences of this failure have yet to be felt for H5N1, since the virus remains only a potential threat. But with H1N1 influenza (swine origin) rapidly emerging as a real global public health danger, the current situation presents an interesting opportunity to assess how our public health system reacts under pressure, allowing us to ask important questions about how, and to what extent, policy-makers are incorporating ethical considerations into their deliberative processes.[7]

As an example of a situation in which ethical considerations influence policy-making processes, this essay will briefly explore issues surrounding domestic and global H1N1 vaccine allocation decisions. Important policy decisions that influence allocation, such as prioritization of a scarce H1N1 vaccine, require careful balancing of multiple considerations.

The opinions expressed here are the author's and do not reflect the policies and positions of the National Institutes of Health, the U.S. Public Health Service, or the U.S. Department of Health and Human Services.

Decision makers have to weigh epidemiologic and scientific evidence alongside practical and ethical considerations. Policies developed without sufficient ethical discourse run the risk of undermining public trust and cooperation by contributing to a perceived lack of fairness and transparency. This is particularly true when making potentially controversial decisions about how to allocate a demonstrably scarce resource.

Given that the emerging pandemic is still in its early phases, with rapidly shifting surveillance data and assumptions, the goal of this essay is to ask a preliminary set of questions about incorporation of bioethical reasoning into H1N1 policy decisions. After first summarizing current information about the epidemiologic characteristics of the disease and projected vaccine availability, I will focus on two recent U.S. vaccine allocation policies: the domestic allocation recommendations promulgated by the Advisory Committee on Immunization Practices (ACIP), and President Obama's decision to share ten percent of the country's vaccine supply with developing countries. I will demonstrate that while both of these policies are reasonable and appropriate, they could have been better supported by the inclusion of more explicit ethical reasoning. The failure to do so raises serious questions about the fundamental ethical underpinnings of our political actions.

The Current H1N1 Influenza Pandemic

On June 11, the World Health Organization (WHO) declared that the H1N1 threat had become a full pandemic, raising the alert level from phase five to six.[8] Globally, as of the end of September 2009, there have been more than 300,000 laboratory-confirmed cases of the virus with almost 4,000 deaths.[9] These numbers likely represent a substantial underestimation of total cases in the world as many countries focus surveillance and laboratory testing only on persons with severe illness. In the U.S., for example, it is estimated that there have been at least one million cumulative infections.[10] U.S. officials have stopped reporting cumulative data, but surveillance data shows that visits to doctors for influenza-like illness are significantly higher than what would normally be expected during this time of year and have been increasing as summer draws to a close and the fall flu season ensues.[11] Multiple states began reporting widespread influenza activity at the end of summer, which is highly unusual for this time of year.[12]

The epidemiologic characteristics of an influenza outbreak can change quickly, making it difficult to predict morbidity and mortality. Currently, WHO is estimating a high secondary attack rate, which suggests widespread morbidity.[13] At present, it appears as if H1N1 mortality is similar to that of seasonal influenza, but the possibility that the disease could mutate into a more virulent strain cannot be eliminated.[14]

In the United States, these assumptions relating to mortality rate and likelihood of mutation translate into predictions of infection in thirty to fifty percent of the U.S. population in the next six months.[15] This could result in up to 1.8 million hospital admissions, which would put a significant strain on intensive care units, which already operate at or near capacity.[16] Moreover, assuming average mortality rates, there could be as many as 90,000 U.S. deaths.[17] This mortality would presumably be concentrated among children and young adults, as the majority of cases have been observed in people under the age of eighteen,[18]

and the rate of hospitalization has been highest in children under the age of four.[19] Elevated risk has been observed for infected individuals with certain pre-existing conditions, such as diabetes, hypertension, and respiratory impairment.[20] Pregnant women also appear to be at higher risk.[21] Individuals over the age of sixty-four seem to be at lower risk of getting infected, but remain at elevated risk for complications.[22]

It should be noted that there are approximately 30,000 to 40,000 annual U.S. deaths typically associated with seasonal flu, the majority of which occur in people over sixty-five.[23] The H1N1 morbidity and mortality distributions seem to skew much younger (possibly leading to many more life-years lost).[24] The absolute number of projected deaths, however, does not appear to be as extreme as was feared at the beginning of the outbreak, when a much higher case fatality rate was observed.[25] Nevertheless, it is possible that current assumptions about disease characteristics will turn out to be incorrect.[26] In 1918, the pandemic initially appeared to be mild, only later emerging as a threat that claimed more than fifty million lives, in a much less densely populated and easily travelled globe.[27] It is important to continue preparing using current data, but with the knowledge that the threat could intensify.

H1N1 Vaccine Availability

A key response to an influenza pandemic is a highly matched, widely-available vaccine.[28] Initially, there was serious concern about the timing, availability, and efficacy of an H1N1 vaccine. With current technology, it typically takes approximately six months (if not longer) from the onset of an outbreak for the first doses of vaccine to become available.[29] Given that H1N1 was discovered in April, September/October was the earliest projected date for vaccine distribution, a point in time at which infections would already have begun to increase. There were also concerns about insufficient production capacity.[30] Vaccine supply has been unreliable even for seasonal influenza.[31] The U.S. only has a few producers, and as I will discuss below, there are severe global shortages as well. Furthermore, there was little data on the extent to which medical countermeasures would be efficacious.[32] Until recently, it was thought that two doses would be required, which would have effectively halved availability.[33] Plus, influenza has historically and universally demonstrated the ability to mutate, which raised concerns about a vaccine based on the current strain only providing partial protection against a mutated strain.

Fortunately, vaccine production has proceeded smoothly. Studies show that the vaccine is more efficacious than previously thought. Only one dose is required, effectively ensuring that initial availability calculations will not need to be halved.[34] Furthermore, vaccine doses became available a few weeks earlier than projected, in the first two weeks of October.[35] This heartening news does not, however, obviate the allocation problem. Vaccine is still going to be delivered gradually at first, which very likely will create a perpetual supply shortage through the middle part of the flu season.[36] The Centers for Disease Control and Prevention (CDC) estimates that only 3.4 million doses will be available initially.[37] Eventually, manufacturers should be able to ship up to twenty million doses per week, but it is unclear how long this production run-up will take.[38]

For purposes of discussion, this article assumes that supply of vaccine will exceed demand, at least for the initial stages of the pandemic. This is an appropriate assumption for a number of reasons. First, even if the twenty million dose per week delivery level was reached in mid-October, it would take months before there would be sufficient supply to vaccinate the 159 million Americans identified as being at elevated risk.[39] The number of infections could begin to spike in October or November, meaning that many high risk individuals might not receive vaccine in time. Second, delivery of vaccine does not equal actual administration; logistical challenges will slow down distribution, further limiting early availability. Distribution infrastructure will be spread thin by current plans calling for vaccination of more than half of the U.S. population with H1N1 vaccine, while concurrently running the regular seasonal influenza vaccination programs. Finally, there is a possibility that non-prioritized people will siphon off available supply, further exacerbating potential vaccine scarcity. Individual providers will be responsible for administering most of the vaccine, but they are not bound by the guidelines discussed below, and likely will feel pressured to give vaccine to the worried as well (in this case, vaccine seekers who are not at elevated risk of infection or complication).

Principles of Vaccine Allocation

During a non-pandemic period, allocation of scarce vaccine is generally guided by the goal of reducing morbidity and mortality for those most at risk. But during a pandemic involving a new influenza strain, there is a potential that everyone is at risk, so competing considerations arise. Significant literature has been written on the ethical issues associated with scarce vaccine allocation,[40] and it is not the intention of this article to propose a new framework. Nevertheless, it is worth briefly reviewing some of the most prominent arguments.

Given the assumed scarcity, a number of different criteria can be used to determine how best to allocate H1N1 vaccine. One approach involves a utilitarian focus on maximizing total public health benefit. Obviously, there is a strong imperative to use available resources to save as many lives as possible. This argument, however, can take a number of forms, including prevention, vulnerability, and minimizing mortality. Prevention involves allocating vaccine in such a way as to minimize the spread of infections. This would include strategies such as ring vaccination around an infected region, or vaccinating school children, who have been shown to be a primary driver of seasonal influenza transmission. Allocation based on vulnerability would prioritize individuals based on their risk of getting infected. Minimizing mortality would allocate vaccine to those people most likely to die if infected. Many people have also proposed related utility arguments, such as protecting critical infrastructure/social functioning by prioritizing professions (medical personnel, first-responders, utility workers, etc.) that are necessary to keep society running, thus providing indirect health and safety benefits to the population.[41]

A second approach incorporates principles of equity and justice. Rather than focusing on saving the most lives, this perspective is concerned with ensuring that benefits and burdens are appropriately distributed, particularly when resources are scarce. This cluster of arguments is associated with minimizing discrimination and unfairness, and can lead to

prioritization of those who are worst off.[42] Some of these arguments have garnered wide support. For example, some have argued that reciprocal fairness dictates allocation of vaccines to healthcare workers when their jobs expose them to increased risk of infection. More controversially, some have called for a fair innings approach, prioritizing younger persons who have not had a chance to live through a range of life stages.[43] Others have called for a focus on existing disparities, such as baseline health status or access to healthcare services.[44]

Domestic H1N1 Vaccine Allocation

With these ethical frameworks in mind, the kinds of arguments articulated in the course of the U.S. vaccine allocation deliberations can be analyzed. ACIP, for example, provides guidance on the use of vaccines and related agents.[45] This expert committee reports to the Department of Health and Human Services (DHHS) and CDC. In the ACIP charter, the committee is charged with a number of responsibilities, including an obligation to give advice on —population groups and/or circumstances in which a vaccine or related agent is recommended. [46] ACIP met in late July, 2009, to discuss the allocation of H1N1 vaccine.[47]

The committee articulated a number of considerations that they felt were relevant to making a vaccine allocation decision, including: the severity of an individual's illness and risk for complications, frequency of illness, contribution to the overall burden of severe illness, protection of healthcare system functions, reduction of societal impact, and potential for indirect protection of more vulnerable contacts.[48] Based on these consideration, and assuming full vaccine availability, the committee determined that the following groups should have priority access to vaccination: pregnant women, household contacts and caregivers for children younger than six months of age, healthcare and emergency medical services personnel, persons six months through twenty-four years of age, and only those persons aged twenty-five through sixty-four years who have medical conditions associated with a higher risk of influenza complications, including chronic pulmonary, cardiovascular, renal, hepatic, cognitive, neurologic/neuromuscular, hematological or metabolic disorders, and immunosuppression.[49]

Recognizing the potential supply problems discussed above, ACIP suggested the potential need for further prioritization. In the event of a vaccine shortage, ACIP recommended that vaccine be given to a more precisely-targeted high priority group, including pregnant women, household contacts of infants under six months of age, healthcare professionals and emergency responders who would have direct contact with patients or infectious materials, children aged six months through four years, and children aged five to eighteen years old with chronic medical conditions.[50]

Incorporating Ethical Reasoning Into the ACIP Guidelines

These guidelines have been relatively non-controversial, but questions remain about the extent to which they adequately incorporate a range of ethical considerations. Scholars have proposed a number of frameworks for evaluating the incorporation of ethics into pandemic preparedness policies, and vaccine allocation in particular.[51] Of particular relevance is a framework developed by a panel of public health officials, ethicists, and clinicians who were

convened by the Hastings Center and the Providence Center for Health Care Ethics.[52] This expert panel identified a number of ways in which pandemic plans might not adequately incorporate ethics. First, plans may articulate priority lists without justifying or explaining why those groups should be given preferential access to a scarce resource. Second, plans may fail to acknowledge equity concerns, such as existing disparities (e.g., income, health status, or access to healthcare). Third, plans may fail to differentiate between public health ethics and clinical ethics. While more detailed analysis is required in subsequent scholarship, this framework can be instructive as an initial way of measuring the extent to which the ACIP guidelines have carefully considered a range of ethical issues.[53]

The ACIP guidelines appear to do a reasonably good job of delineating a set of priority populations and justifying this decision. The guidelines clearly explain that the priority groups are based on an underlying principle of minimizing the burden of illness.[54] One can further separate the committee's articulated goals into two categories, each of which is supported by sound justification and robust epidemiologic data. The first group of goals is aimed at directly minimizing morbidity and mortality; prioritization groups are selected on the basis of severity of illness, risk for complications, frequency of illness, and contribution to the overall burden of severe illness.[55] Based on the most recent epidemiologic data, this means that the vaccine should first go to people at high risk for infection and/or complications (i.e., pregnant women, adults with certain pre-existing conditions, children under five years of age).[56] The second group of goals is aimed at preventing ancillary harm by preserving social functioning through protecting healthcare system functions, reducing societal impact, and indirectly protecting vulnerable populations.[57] This set of goals translates to the prioritization of people who can help others (i.e., caregivers of young children and healthcare personnel).

While the choice of priority groups is well justified, corresponding attention does not seem to have been paid to the second prong of the Hastings analysis. A close examination of the relevant published documents reveals no evidence of discussion about non-disease minimizing concerns, such as equity, non-discrimination, and pre-existing disparities. To demonstrate this point, I conducted an informal content analysis of the guidelines, building on earlier research regarding the incorporation of ethics into H5N1 preparedness plans. In a 2007 study, researchers conducted an analysis of all existing federal and state influenza pandemic plans to ascertain the frequency of a defined set of ethically relevant terms.[58] Their analysis revealed a notable absence of ethical language, leading the researchers to criticize the plans for failing to —[a]rticulate the underlying ethical values or principles that would enable states to rethink or refine the priorities. [59] Adapting their methodology, I searched both the published MMWR article detailing the official ACIP recommendations, as well as the final recommendation document presented at the July 29, 2009, ACIP meeting, finding no instance of any ethical term as a result of this search. While content analysis cannot demonstrate whether particular discourse actually occurred, the presence or absence of certain words can serve as a proxy for direct evidence of ethical reasoning. In this case, the complete absence of relevant language provides strong support for the claim that there was little discussion of non-disease minimizing concerns.

The recommendations also fail to adequately address the third prong, concerning the distinction between clinical and public health ethics. The former involves a focus on what is best for the individual patient, while the latter considers what is best for the whole community. These two perspectives can often conflict, and the most appropriate vaccine allocation guidance will address this potential tension by giving clinicians relevant decision-making tools. Notably, however, the guidelines include no discussion of prioritization within the target groups. If an individual clinician is faced with a vaccine shortage, and has multiple high priority patients, no guidance is given regarding which of the prioritized populations should be given preferential access.[60] Failure to articulate a detailed ranking of priority groups places clinicians in a situation where they are forced to make their own fair allocation decisions that potentially could be at odds with what is best from a public health perspective. How should the clinician with one dose at hand decide whether to vaccinate the fifty-year old emergency room doctor or the three-year old child with a chronic pulmonary condition?

These critiques should not be read as a complete rejection of the ACIP guidelines. The guidelines effectively identify priority groups that, if targeted first, will minimize the overall impact of the H1N1 outbreak. This kind of prioritization certainly represents an important and relevant form of ethical reasoning. At the time these guidelines were published, however, it was still unclear when and how much vaccine would be available; early shortages were certainly possible. In this context, additional ethical considerations should have been discussed and publicly articulated. The lack of explicit discussion of ethical issues masked the hard allocation choices associated with scarce vaccine supply. Criteria designed to produce the greatest benefit are an appropriate starting point for allocation decisions, but they become inadequate when there is insufficient supply to protect the entire population of prioritized indicated patients (159 million).

As discussed above, there are a range of values (equity, justice, non-discrimination, etc.) that are also important. These considerations take on particularly increased relevance in situations of severe shortages. If everyone at elevated risk cannot be protected, careful thought must be given to procedures for allocating vaccine in an equitable and non-discriminatory manner. Given the controversial and subjective nature of these ethical considerations, and the resulting winners and losers, it might be impossible for an entity such as ACIP to stake a formal position. The absolute omission of any reference to these concepts, however, does the public a disservice. Real discourse about concepts like equity, justice, and non-discrimination should have been included in the articulated guidance for a number of important reasons. Such discussion, for example, can serve as a tool for clinicians and public health officials faced with real world allocation decisions. Discussion of these ethical considerations can serve as a cue to encourage public engagement about distribution and allocation priority setting under situations of product scarcity. Inclusion of a broader range of ethical considerations can also bolster public trust and can avoid a perceived lack of fairness, particularly under the social pressures created by an active pandemic outbreak.

Global H1N1 Vaccine Allocation

Beyond domestic vaccine allocation decisions, it is also important to analyze the U.S. role in global vaccine allocation. While the U.S. likely will have sufficient vaccine supply eventually, global availability of H1N1 vaccines remains uncertain. Based on initial WHO assumptions in May 2009, a maximum of approximately five billion doses could potentially be produced in twelve months, but only if several assumptions are met.[61] While the vaccine manufacturing process appears to have gone reasonably well, the WHO recently down-graded their total global vaccine production estimate to three billion doses in the next twelve months.[62]

Even if this supply estimate is achieved, distribution is extremely concentrated. Influenza vaccine production is concentrated in a handful of countries. Specifically, eighty-five percent of the world's supply of influenza vaccine is produced by companies located in eight industrialized countries: France, Germany, Italy, the Netherlands, the United Kingdom, the United States, Canada, and Australia.[63] Only thirty-five percent of all seasonal doses reach developing countries and there are serious concerns about the distribution of H1N1 vaccine.[64] While manufacturers are taking some positive steps, such as expressing a willingness to implement tiered pricing and committing to donation of 150 million doses, most of the vaccine currently being produced has already been purchased by developed nations.[65]

Given this reality, a number of scholars and advocates have articulated strong arguments in favor of a more equitable distribution of vaccine.[66] Their arguments can be divided into two rough categories. Some have argued that distributive justice requires a more equitable global distribution of H1N1 vaccine, based on the principle that all lives have equal value. These arguments focus on the fact that national wealth, rather than need, has become the predominant allocation criteria. Accordingly, —rich countries have a responsibility to stand in line and receive their vaccine allotments alongside poor countries, even if they have paid for their vaccine before others could do so. [67] International organizations argue that the world's poorest nations will bear a disproportionate burden of suffering from the disease. Mortality rates will be higher because of inadequate healthcare systems and existing co-morbidities, and the resulting social disruption could harm the fragile economies and infrastructures of these countries, leading to further health impacts.[68]

Another set of arguments focus on self-interest and national security as justification for distributing vaccine more widely. These arguments are predicated on the fear that concentrated vaccine distribution will leave whole regions unprotected, resulting in the rampant spread of the pandemic. Unfettered transmission of the disease could cause it to mutate, becoming much more virulent and possibly rendering existing medical countermeasures ineffective. This mutated strain could then pose a direct threat to formerly vaccine-protected countries. As an official from WHO noted, —there needs to be a recognition that the whole world is affected by this pandemic and the chain is only as strong as its weakest link. [69]

The United States recently announced that it would donate ten percent of its vaccine supply to needy countries, in concert with other developed countries and the WHO.[70] While this may be viewed as an admirable decision, it is important to examine the articulated reasoning behind this policy.[71] Are we sharing vaccine out of a moral obligation to the world's most vulnerable, or are we simply doing what is in the country's best interest?

While it is impossible to know what reasons were articulated during the closed decision-making process, the official announcement of the decision is illuminating. In this memo, the White House declares that —diseases know no borders and that the health of the American people is inseparable from the health of people around the world. [72] The announcement goes on to cite limiting the spread of disease, and reducing the risk of a more virulent strain emerging, as key reasons for this decision.[73] Interestingly, it is stressed that this decision will not impact the availability of vaccine in the United States, particularly since only one dose will be required and supply will be on hand earlier than expected.[74]

The United State's decision to share vaccine is an equity promoting action that commendably demonstrates a willingness to cooperate as part of a global community. Rather than frame the decision in terms of global distributive justice, however, the official announcement focuses on a national security rationale for sharing vaccine. Overall, the tone is inward looking, stressing the benefits to Americans (and the minimized costs).[75] This is in contrast to the more cosmopolitan justice perspective voiced by a number of scholars cited above. But does this matter? It would be reasonable to argue that the reasoning behind a policy is less important than the nature and effect of that policy. It would also be defensible to explain the lack of explicit ethical reasoning as resulting from practical and political considerations. From a statist perspective, government has a responsibility to its citizens first and foremost, and arguments to that effect will carry the most weight. Particularly from a partisan political perspective, democratic strategists must worry about arguments that this policy represents a lack of commitment to protecting the American public. Such attacks can more easily be deflected if the policy is based on a self-interest rationale.

Even though these political and practical concerns are legitimate, I would argue that a failure to include an explicit ethical justification for sharing vaccine globally sends an unfortunate message—the United States only shares resources when it is convenient and advances our national interests. This was an opportunity to set a more idealistic standard. There will be future pandemics, and a more nuanced ethical justification for sharing vaccine under current conditions could have created a precedent for the next big public health threat, when it might be harder for individual countries to justify sharing their limited resources with less fortunate nations. Furthermore, explicitly incorporating the concept of global justice into this decision-making process would have demonstrated that such ethical reasoning can be a valid basis for making policy, potentially broadening the fundamental underpinnings that can be used to support subsequent political actions and policy decisions.

Conclusion

Responding to an influenza pandemic requires the careful balancing of practical, ethical, and political considerations, in an environment characterized by uncertain and constantly

shifting epidemiologic and scientific evidence. The past five years have been spent anticipating this kind of situation, and the goal of this analysis was to demonstrate that despite this preparation, when faced with a manifest public health threat, our ethical response was lacking. This is not to say that the policies discussed above were inappropriate; both the ACIP guidance and the decision to share vaccine globally are fundamentally sound from both a scientific and utilitarian perspective. Nevertheless, they represent a lost opportunity to articulate more nuanced ethical reasoning that explicitly utilizes the principle of equity as the basis for a policy decision. Saving the most lives is an appropriate ultimate goal for pandemic response, but it is important to base policy decisions on more than just utilitarian and scientific arguments. Arriving at the right outcome is only part of the equation; decisions must be supported by a set of principled rationales that can be generalized to subsequent situations. History demonstrates that the world will regularly be faced with pandemics, some of which will have the potential to cause widespread morbidity and mortality. Systematically incorporating ethical reasoning into policy-making processes will help to ensure that the benefits and burdens of future pandemics are equitably distributed.

Acknowledgments

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18. Dawood, Fatimah S., et al. Emergence of a Novel Swine-origin Influenza A (H1N1) Virus in Humans. New Eng J Med. 2009; 360:2605, 2611. [PubMed: 19423869] . These findings are based on a sample size of 642 patients. As the authors of this article note, clinical recommendations will evolve as additional epidemiologic data is collected.
19. CDC MMWR. 2009 H1N1 Flu: Situation Update. Oct 30. 2009 available at http://www.cdc.gov/H1n1flu/update.htm
20. National Center for Immunization and Respiratory Diseases. Use of Influenza A (H1N1) 2009 Monovalent Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2009. available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm?s_cid=rr5810a1_e [hereinafter NCIRD]
21. Id.
22. CDC MMWR, *supra* note 10.
23. President's Council of Advisors on Sci. & Tech., *supra* note 15, at 2.
24. *Id.* at 13.
25. *Id.* at vii.
26. Id.
27. Taubenberger et al., *supra* note 7.
28. *See generally*, Gostin, Lawrence O.; Berkman, Benjamin E. Pandemic Influenza: Ethics, Law, and the Public's Health. Admin L Rev. 2007; 59:121.
29. WHO. Pandemic Influenza Vaccine Manufacturing Process and Timeline. Aug 6. 2009 available at http://www.who.int/csr/disease/swineflu/notes/h1n1_vaccine_20090806/en/index.html
30. *See* Gostin and Berkman, *supra* note 28, at 128.
31. Id.
32. Zhu, Feng-Cai, et al. A Novel Influenza A (H1N1) Vaccine in Various Age Groups. NEJM. Oct 21.2009 online. 10.1056/nejmoa0908535
33. Doreen, Jennifer C. Guidance on H1N1 Vaccine Dosage. Wall St J. Sep 22.2009 :D2.
34. Id.
35. Randall, Tom; Gale, Jason. Swine Flu Shots to Start in Three Weeks as U.S. Cases Spread. Bloombergcom. Sep 13. 2009 http://www.bloomberg.com/apps/news?pid=20601124&sid=asYlPo7IOFqw
36. Pollack, Andrew; McNeil, Donald. NY Times. Oct 26. 2009 A Nation Battling Flu, and Short Vaccine Supplies; p. A1
37. Fox, Maggie. CDC, Reuters. Sep 18. 2009 First U.S. H1N1 vaccine will be nasal spray.
38. Id.
39. *See* Pollack and McNeil, *supra* note 36, at A1.
40. See, e.g., Zimmerman, Richard K. Rationing of Influenza Vaccine During a Pandemic: Ethical Analyses. Vaccine. 2007; 25:2019, 2019. [PubMed: 17258359] Miller, Mark A., et al. Prioritization of Influenza Pandemic Vaccination to Minimize Years of Life Lost. J Infectious Diseases. 2008; 198:305, 305. [PubMed: 18558871] Emanuel, Ezekiel J.; Wertheimer, Alan. Who Should Get Influenza Vaccine When Not All Can? Science. 2006; 312:854, 854. [PubMed: 16690847] Wynia, Matthew K. Ethics and Public Health Emergencies: Rationing Vaccines. Am J Bioethics. 2006; 6:4, 4.Arras, John D. Rationing Vaccine During an Avian Influenza Pandemic: Why It Won't Be Easy. Yale J Biol and Med. 2005; 78:283, 283.Verweij, Marcel. Equitable Access to Therapeutic and Prophylactic Measures. :5–28.WHODiscussion Papers. Chapter 12008; available at http://www.who.int/csr/resources/publications/cds_flu_ethics_5web.pdf
41. *See, e.g.*, Verweij, *supra* note 40.
42. Id.
43. Emanuel and Wertheimer, *supra* note 40.

44. As I will discuss below, a number of scholars and advocates have approached the allocation issue from a global perspective, arguing that distributive justice requires a more equitable distribution of worldwide vaccine resources.
45. CDC. Advisory Committee on Immunization Practices – Charter. Apr. 2008 available at http://www.cdc.gov/vaccines/recs/acip/downloads/charter-april08-march-2010.pdf
46. Id.
47. CDC. Meeting of the Advisory Committee on Immunization Practices – Agenda. Jul 29.2009 available at http://www.cdc.gov/vaccines/recs/acip/downloads/agenda-jul09.pdf. Unfortunately, detailed minutes of their deliberations have yet to be released. The committee has ninety days to make these publicly available, and as of this writing, they had not yet been published. This analysis is based on currently available summary information. As such, this is only a preliminary discussion; further analysis is required once complete information is available.
48. *See supra* note 20; Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices – Influenza Vaccine Workgroup Considerations. Jul 29.2009 available at http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-jul09-flu/11-Flu-Fiore.pdf
49. *See supra* note 20.
50. Id.
51. *See e.g.*, Kass, *supra* note 5; Berlinger and Moses, *supra* note 5; Uscher-Pines, *supra* note 5; *White Paper Series*, *supra* note 5.
52. Berlinger and Moses, *supra* note 5.
53. *See* Chan, *supra* note 3, at 2.
54. NCIRD, *supra* note 20.
55. Id.
56. Id.
57. Id.
58. Thomas et al., *supra* note 6. This list included terms such as accountability, autonomy, collaboration, competence, confidentiality, consent, disparity, diversity, duty, egalitarian, ethic, equality, fair, harm, inclusive, just, liberty, moral, obligation, participation, privacy, representation, responsive, responsibility, right, transparent, trust, and utilitarian.
59. *Id.* at S29.
60. Id.
61. WHO. Pandemic Influenza Vaccine: Current Status. Sep 24. 2009 available at http://www.who.int/csr/disease/swineflu/notes/pandemic_influenza_vaccines_20090924/en/index.html
62. Id.
63. Gostin and Berkman, *supra* note 28, at 129. In a pandemic with a higher case fatality rate, it is possible that governments will nationalize the vaccine industry, refusing to export any of their nationally produced vaccines until domestic demand is satisfied. However, given the moderate nature of this pandemic, this concern can be set aside.
64. Id.
65. Yamada, Tadataka. Poverty, Wealth, and Access to Pandemic Influenza Vaccine. New Eng J Med. 2009; 361:1129. [PubMed: 19675324]
66. *See, e.g.*, Yamada, *supra* note 65; Gostin, Lawrence O. Global Goal for Vaccine Quest. The Weekend Australian Observer. Aug 8.2009 :12.MacDonald, Noni. H1N1 Influenza Vaccine: Global Access for a Global Problem. Canadian Med Assn J. 2009; 181:123.Karron, Ruth A.; Faden, Ruth R. A Moral Obligation: Should the U.S. Produce Enough H1N1 Flu Vaccine to Help Developing Countries? The Baltimore Sun. Aug 17.2009 ; *White Paper Series*, *supra* note 5.
67. Yamada, *supra* note 65.
68. Syal, Rajeev. The Observer. Sep 20. 2009 Swine Flu Could Kill Millions Unless Rich Nations Give £900M; p. 5
69. Id.
70. Brown, David. Wash Post. Sep 18. 2009 U.S. to Donate 10 Percent of Swine Flu Vaccine to WHO; p. A1

71. Press Release, Office of the Press Sec'y. President Announces Plan to Expand fight Against Global H1N1 Pandemic. Sep 17. 2009 available at http://www.whitehouse.gov/the_press_office/President-Announces-Plan-to-Expand-Fight-Against-Global-H1N1-Pandemic/
72. Id.
73. Id.
74. Id.
75. The announcement also mentions saving lives as a broad goal of this policy, but this single mention is outweighed by the overwhelming self-interest rhetoric.