

ETHICAL GUIDELINES in PANDEMIC INFLUENZA

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This document provides ethical guidance that the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) proposes as a foundation for decision making in preparing for and responding to pandemic influenza. The document was developed in response to a request from CDC that the Ethics Subcommittee address ethical considerations (1) in vaccine and anti-viral drug distribution prioritization and (2) in the development of interventions that would limit individual freedom and create social distancing² (in discourse on pandemic influenza, often referred to as non-pharmaceutical interventions). Although the issue of the duty of health care professionals to provide care during a pandemic was outside the scope of the request, the Ethics Subcommittee believes that this issue is of central importance in pandemic planning and response and should be addressed in a subsequent document. An equally relevant issue, but also beyond the scope of this document, is the importance of providing legal protections for health care providers who, during a declared public health emergency, may be asked to perform services outside of their usual realm of responsibilities or to administer interventions which are not yet scientifically validated. As with many other areas of community or public decision making, ethical issues are frequently encountered in the decision making process. And though difficult decisions are made on a regular basis, the process for decision making, including the framework and reasoning that support ethical choice, may not be clearly articulated. We are acutely aware of the need to have ethical perspectives provide practical assistance and to have these proposed guidelines fully vetted by those involved in the pandemic influenza planning and response process. We offer the following document with both commitments in mind and attempt to articulate the boundaries and underlying ethical premises that can serve as a marker against which to test implementation decisions. In utilizing these guidelines, decision makers at all levels – federal, local, state, tribal, etc. – should continue to exercise their best judgment in particular situations.

I. General Ethical Considerations

- **Identification of clear overall goals for pandemic planning** is essential to making difficult choices. Historically, the organizing principle for resource (antiviral and vaccine) distribution in inter-pandemic years has been the minimization of serious influenza-associated complications, including hospitalization and death. Individuals most at risk of experiencing the serious negative health consequences of hospitalization or death if infected are given priority in receiving influenza vaccinations. The recommendations of two federal advisory committees, the Advisory Committee on Immunization Practices (ACIP)

² Social distancing refers to methods for reducing frequency and closeness of contact between people in order to decrease the risk of transmission of disease. Examples of social distancing include cancellation of public events such as concerts, sports events, or movies, closure of office buildings, schools, and other public places, and restriction of access to public places such as shopping malls or other places where people gather.

and the National Vaccine Advisory Committee (NVAC) reflect this principle.³

However, in pandemic influenza management a second principle – that of preserving the functioning of society – should receive greater priority in decision making than preventing serious complications. Those individuals who are essential to the provision of health care, public safety and the functioning of key aspects of society should receive priority in the distribution of vaccine, antivirals and other scarce resources. Engagement of diverse stakeholders will be essential in affirming this priority, determining who is considered key to the functioning of society, and establishing a distribution strategy that allows for decisions to be made when resources are limited. In any prioritization proposal, it must be clearly acknowledged that maintaining the functioning of society may result in a lack of resource availability to those at high risk of severe medical complications due to pre-existing medical conditions or advanced age.

Affirming this second principle (preserving the functioning of society) raises important conceptual questions about who is valued and how particular services and functions are determined to be “key.” These questions are set in important historical and social contexts involving individuals’ ability to attain “essential” positions given societal barriers and obstacles. Discussion of these questions, while very important in ordinary times, takes on a lower priority when confronted with the urgent demands of preserving society.

- There is a **commitment to transparency** throughout the pandemic influenza planning and response process. The reasoning behind choices made is fully articulated (in language appropriate to particular audiences) and the values and principles justifying those decisions are clearly identified and open for examination. This commitment to clarity and openness, which is based on a deep respect for all individuals and communities involved, exists in balance with the understanding that those with the authority and responsibility of making decisions must often make decisions in a timely manner.
- **Public engagement and involvement** are essential to build public will and trust and should be evidenced throughout the planning and response process. The public is seen as a partner with other experts, with particular attention to vulnerable or historically marginalized members of society. Clear mechanisms must be created for public involvement in planning and for feedback throughout the process.
- Public health officials have a **responsibility to maximize preparedness** in order to minimize the need to make allocation decisions later. (Examples of maximizing preparedness include shortening the time for virus recognition or

³ The NVAC/ACIP recommendations for prioritization of pandemic influenza vaccine are described in the HHS Pandemic Influenza Plan available at <http://www.hhs.gov/pandemicflu/plan/appendixd.html>. Vaccine and antiviral manufacturers, medical and public health workers, and persons at highest risk of influenza complication are identified as priority groups for receipt of pandemic influenza vaccine.

vaccine production, increasing the capacity to produce vaccines or antivirals and increasing the supplies of antivirals.) Proactive planning of response strategies for a pandemic, including the training of staff, is required. This necessarily entails consideration of the full context in which choices are made. Enhancing the available range of prophylaxis and treatment options should decrease the need to focus on scarcity of resources and allocation during a pandemic. Preparedness also includes determining and articulating what rules will govern public health decision making in advance of the time that decision making must commence. Though every specific choice or contingency cannot be foreseen, comprehensible foundational guidelines and procedural action plans provide coherence and direction and build trust.

- **Sound guidelines should be based on the best available scientific evidence.**
There is no need to establish rules for the equitable distribution of goods that will not work or to implement public health interventions that are ineffective. This is equally true for vaccines and antivirals as it is for ‘social distancing’ measures. Because the scientific basis for efficacy of particular interventions continues to be studied and models projecting the course of a pandemic are being investigated, sound scientific evidence for proposed interventions may not currently exist. The current knowledge basis should serve as a foundation for ethical guidelines and a commitment to ongoing scientific and ethical evaluation of interventions should be made.
- The United States recognizes its membership in the global community, and the pandemic planning process acknowledges the **importance of working with and learning from preparedness efforts globally**. This recognition is not based simply on the potential of global involvement to benefit U.S. citizens (an “instrumental” reason), but on a deep recognition of the common good⁴ and our interdependence globally. Mechanisms for global involvement and criteria for determining the scope of impact of U.S. decisions should be explicit.
- **Balancing of Individual Liberty and Community Interests**
Pandemic influenza planning, like other public and community health activities, is a cooperative and shared responsibility that balances community and individual interests. During the course of a pandemic, the functioning of society may be threatened. Our moral tradition embodies an understanding that it may be ethically acceptable (or perhaps even ethically mandatory) to suspend some (but not all) ordinary moral rules in such circumstances. For example, limits on individual freedom or choice may be necessary to protect individuals as well as entire communities during pandemic influenza. Yet, individual liberty should be restricted with great care and only when alternative approaches to realizing the goal of weathering the pandemic are not likely to be effective. Suspensions of

⁴ The “common good” refers to the interests of a group or collective that is defined by having in common certain attributes (e.g., location in a geographically-defined community, risk of a specific disease) that create a commonality of interests. Its use in this context reflects an understanding that in the case of an influenza pandemic, all human beings are part of a single collective that has a ‘common good’.

ordinary moral rules should be anticipated and the conditions calling for such suspensions should be specified.

Guiding principles in determining these restrictions include:

- Adopting the least restrictive practices that will allow the common good to be protected.
- Ensuring that restrictions are necessary and proportional to the need for protection.
- Attempting to ensure that those impacted by restrictions receive support from the community (e.g., job security, financial support for individuals and their families, provision of food and other necessities to those who are isolated or placed under quarantine, and/or protection against stigmatization or unwarranted disclosure of private information).

- **Diversity in Ethical Decision Making**

Given numerous historical examples of abuse of individuals, particularly those who are considered vulnerable, in the name of the public good (e.g., involuntary sterilization of the mentally retarded, the U.S. Public Health Service Syphilis Study at Tuskegee, the internment of Japanese-Americans during World War II), public health officials must adequately acknowledge and respond to strong currents of suspicion and distrust of the healthcare system. This acknowledgement is, of course, a part of a much larger healthcare dialogue. Addressing this distrust should be a strong and enduring commitment and not viewed as merely instrumental to inducing individuals to comply with recommendations. Diverse public voices should be involved in determining the need for restrictions and in articulating the ethical justification for these restrictions.

- **Fair Process Approach (Procedural Justice)**

We recommend an approach to justice that focuses on the procedures to be followed with the hope that good procedures will lead to fair outcomes.

Following are the elements of an ideal procedural justice approach:

- Consistency in applying standards across people and time (treating like cases alike).
- Decision makers who are impartial and neutral.
- Ensuring that those affected by the decisions have a voice in decision making and agree in advance to the proposed process.
- Treating those affected with dignity and respect.
- Ensuring that decisions are adequately reasoned and based on accurate information.
- Communications and processes that are clear, transparent and without hidden agendas.
- Inclusion of processes to revise or correct approaches to address new information, including a process for appeals and procedures that are sustainable and enforceable.

The involvement of diverse voices in pandemic influenza planning and in creating a transparent procedure for decision making is essential. In addition to engaging citizens in general, this process would involve those who are primarily responsible for implementing the pandemic influenza plans (e.g., direct health care providers who would be asked to commit to providing care even in the face of personal risk or the competing needs of their own families.)

A balance between centralized, federal control and state and local community implementation of central guidelines must be effectively struck (see Section II-B, page 10, paragraph 1 for more discussion about the strong presumption in favor of centralized decision making during a pandemic). This process should be especially attentive to historically marginalized communities and those where sensitivity to cultural, racial, religious or other values must be incorporated.

Thoughtful preparation and attention to process will not provide guidance in all specific circumstances. The practice of attending to fair process may provide support for local decision makers addressing unanticipated questions. In addition, these decision makers must be authorized to utilize their best judgment in addressing and resolving particular issues.

II. Addressing Particular Ethical Issues in Pandemic Influenza Planning

A. Allocation of Resources

The distribution of goods should be guided by criteria specified well in advance of any need to apply them. As indicated earlier, the primary goals of the distribution system should be clearly specified. Further distribution criteria should be evaluated according to their ability to contribute to the realization of the primary goals. These further criteria should be directed at maximizing fairness (or equity) in the distribution process.

We have concluded that a classic utilitarian approach to defining priorities, ‘the greatest good for the greatest number,’ is not a morally adequate platform for pandemic influenza planning. We recommend an approach to ethical justification, that, like utilitarianism, evaluates the rightness or wrongness of actions or policies primarily by their consequences, but, we further recommend that planning should take into account other checks (‘side constraints’) grounded in the ethical principles of respect for persons, non-maleficence, and justice. For example, a classic utilitarian approach, which might accept imposing suffering on the few for the greater benefit of all, would be tempered by such principles as:

- Refrain from harming or injuring individuals and communities.
- Equal opportunity to access resources should be assured to those within agreed upon priority groups.
- Respect for individual autonomy by, for example, employment of the least restrictive interventions that are likely to be effective.

Distribution plans should further specify:

- What scarce goods are involved in the distribution plan? The names of the individual vaccines or classes of goods (e.g., antivirals for the purpose of treating or preventing influenza) should be publicly communicated. It would also help to specify what will not be covered by the distribution plan and why (e.g., drugs that treat or prevent certain disorders or conditions that make one more susceptible to contracting influenza.)
- Who (or what agency) will decide about prioritization and distribution? A mechanism for authoritative interpretations of the rules in the case of a dispute or an appeal is needed.
- Who is eligible to be a recipient? (e.g., Will all individuals present in the local community be eligible, regardless of visitor status? Will the local community encourage travelers to return to home communities to receive the scarce resource? Will exceptions be made? If so, why?)
- What morally relevant criteria will be employed to assign higher or lower priorities to groups of individuals or individuals within the determined goal (preserving the functioning of society)? For example, are certain key services more essential than others? Within the organization or group of individuals who provide an essential service, are there justified criteria for determining a further order of priority (e.g., those with more years of experience or those who have dealt with crises in the past)?

Some theoretical distribution criteria that would generally **not** be ethically supported in pandemic influenza planning include:

- To each according to purchasing power.
- To each according to what he or she deserves.
- First come, first served. (Superficially, this may appear to be fair but, de facto, this puts certain groups – such as those who are less likely to be informed or those who have inadequate transportation - at a disadvantage.)
- Criteria, such as race, ethnicity, religious belief, gender, sexual orientation, or IQ, when used to make discriminations that are only invidious and not morally relevant.

In ordinary circumstances, the distribution criterion, ‘to each according to his or her social worth,’ is not morally acceptable. However, in planning for a pandemic where the primary objective is to preserve the function of society, it is necessary to identify certain individuals and groups of persons as ‘key’ to the preservation of society and to accord to them a high priority for the distribution of certain goods such as vaccines and antiviral drugs. Identification of key individuals for this purpose must be recognized for what it is: it is a social worth criterion and its use is justified in these limited circumstances. Care must be taken to avoid extension of the evaluation of social worth to other attributes that are not morally relevant.

Among the goods that must be allocated is the time of health care professionals. It may be necessary to delegate the responsibility and authority to perform procedures and interventions customarily carried out by certain professionals to other individuals. For example, physicians may need to delegate duties to nurses, physicians’ trained assistants,

and other personnel (e.g. retired health care professionals) who may not be part of the customary health care team. Similarly, procedures customarily carried out by nurse practitioners and other health care professionals may also be delegated. Such delegations of authority and responsibility should be carefully planned and suitable training programs should be activated in advance of the pandemic.

B. Ethical Guidelines Regarding Social Distancing and Restrictions on Personal Freedom for Managing Pandemic Influenza

In the management of a pandemic, it will often be prudent to employ procedures and interventions that will limit the freedom of movement of individuals or create conditions of social distancing. In general, the proposed use of such interventions and procedures should be in the form of recommendations for voluntary action. Requirements for mandatory liberty-limiting and social distancing interventions should be imposed only in cases in which voluntary actions seem unlikely to be effective. This point notwithstanding, the remainder of this section is concerned primarily with circumstances in which mandatory liberty-limiting and social distancing interventions are being considered.

As noted earlier, sound guidelines should be based on the best available scientific evidence. Ideally, the validity of liberty-limiting and social distancing interventions would be established in a manner similar to that employed for pharmacological interventions, through carefully controlled research. However, in most cases this will not be possible, particularly in the circumstances of a pandemic. Indeed, in the course of a pandemic, it may be necessary to employ some interventions which have little or no scientific support. The model we recommend is that of ‘evidence-informed’ decision-making, a model that is somewhat less rigorous than ‘evidence-based’ decision making but something that has to do until more satisfactory validation becomes available.

Liberty-limiting and social distancing interventions include the following:

- Isolation of individuals infected with or ill with influenza.
- Quarantine of those thought to have already been exposed, including family members and others in close contact.
- Closing schools, cancellation of public events (e.g. sports events, concerts), and closing public venues such as shopping malls, restaurants, museums, theaters, etc. as mechanisms to decrease social contact that may lead to the spread of influenza.
- Restricting access to public venues deemed more “essential” such as grocery stores, public transportation, and gasoline stations.
- Providing guidance on office practices and/or flexible work scheduling that decreases potential for exposure.
- Limiting travel within or between cities/local regions.

Is Restricting Personal Freedom in Managing Pandemic Influenza Justified?

Implementing any of these interventions involves restricting personal freedoms that are strongly held and highly valued in U.S. society. The ethical concept of individual autonomy, or the freedom to make one’s own decisions, is deeply embedded in U.S.

culture. Respect for individual autonomy is founded on the inherent dignity and worth of the individual and the understanding of each individual's general right to non-interference. Therefore justification for any restrictions on individual freedom must be carefully considered.

Legitimate restrictions on individual freedom may occur if, in exercising one's freedom, one places others at risk. An individual does not have the right to injure another or to take someone's property merely because she or he wishes to exercise her or his freedom. Additionally, implicit in membership in society, is an obligation to abide by certain ethical and legal constraints in order to enjoy the benefits of membership in that society (e.g., security, health-care, general welfare). These "constraints" actually provide the conditions under which personal freedom and flourishing are possible. Thus restrictions essential to the common good, including the public health, of society may be imposed on each member of society. Even so, these restrictions on personal freedom must always be carefully considered and justified.

Procedural Conditions in Restricting Personal Freedom

In Section II-A, we set forth criteria for an acceptable system for allocation of resources, including some characteristics of satisfactory distribution plans and unacceptable distribution criteria. These allocation considerations are equally applicable to developing guidelines regarding restrictions on personal freedom and other non-pharmaceutical interventions for managing pandemic influenza.

The process for decision making about restrictions should be well thought out in advance. Both the decision makers and the criteria that will be used to determine when restrictions will be implemented should be specified. The group that specifies the decision makers and the criteria should be seen by all types of stakeholders as representative or otherwise acceptable. The group that is involved in implementing the policies, educating the public and hearing objections should also be seen as representative or otherwise acceptable. A reasonably diverse infrastructure that includes voices across racial, cultural, community, providers and recipients of care, etc. should be involved in planning, understanding the process, and conveying the process throughout the community. In pandemic influenza, centralization of decision making may be important in creating fair and equitable restrictions that will apply across communities. A process should be in place for objections to be heard, restrictions appealed, and for new procedures to be considered prior to implementation.

As in other areas of pandemic influenza management, transparency about the process is essential and communication about restrictions should begin early in the planning process. The public should be clearly informed that restrictions on personal freedom are anticipated, that these limitations may be important to the individual's own protection, and that they are also necessary to limit the spread of disease throughout the community. Communication should encourage individuals to partner with their communities and society at large in controlling influenza transmission. Information should be provided thoughtfully, balancing when information should be shared with protection of privacy and public trust.

In pandemic influenza there is a strong justification for centralization of decision making. This is a departure from the customary mode of public health decision making which occurs at the local, state, or tribal level by standards of their own choosing. General maxims and criteria for restrictions on personal freedom would be supported by (1) equity and by (2) the need to preserve the functioning of society across communities, including the tracking of disease. Local autonomy in decision making should be honored where there is no evidence to support a belief that centralization of decision making will contribute substantially to preservation of the functioning of society and where the easing of restrictions is proportional and reasonable in particular communities (e.g., uniform duration of school closing may not be reasonable in communities where the influenza wave has already ended). Local decision makers should be prepared to make their reasoning transparent in these situations; they must be authorized to use their best judgment and supported in their efforts to do so.

When are restrictions on personal freedom ethically justified?

In enacting any measure where personal freedom is limited, the least restrictive, effective measure should be taken. Enactment of these measures should be based on the best available scientific evidence that:

- The liberty-limiting measure will achieve its intended goal.
- The limitation is proportional and no less restrictive measure is likely to be as effective. An exception to this criterion may be justified if the less restrictive measure would be unduly burdensome (e.g., either too expensive or the agency responsible for implementation lacks the resources or expertise to implement).
- Failure to implement the measure is likely to result in grave harm to the functioning of society or to the well-being of the public. For example, if quarantine is enacted, the duration of the quarantine should be clearly informed by transmission characteristics and should be as short as is medically justifiable. Home quarantine should be honored where reasonable and desired, and monitoring/surveillance should be as non-intrusive as is reasonable. We should continually be asking what justifies one further restrictive step.

Restrictions on personal freedom should be equitably applied. It should be exceedingly clear why particular individuals or communities are being restricted and that the criteria that justify a restriction would be equally applied to any and all individuals meeting these same criteria. Care must be taken to avoid stigmatization of individuals or groups. Additionally, a process for questioning, appealing, and revising liberty-limiting measures should be in place and accessible when the level of urgency during a crisis makes this realistic.

When closure of public venues is being considered, determination must be made of which public venues are more essential in maintaining the functioning of society and may need to remain open with some constraints on level of access (e.g., grocery stores may need to remain open with some new mechanism for distribution that safeguards both fair access and decreased potential dissemination of disease, such as maximum order amounts or a delivery service). Other examples of possible “essential services” are public

transportation systems and gasoline stations.

Agencies responsible for imposing restrictions such as quarantine, isolation or other limitations must take into consideration the fact that the impacted population, their family members, and other dependents will require adequate access to food, water and other essential services. Such agencies should attempt to secure access to these requirements for the affected parties. Similarly, they should attempt to provide protection of the restricted individuals' jobs and their ability to meet economic obligations such as mortgage, rent, paying utilities, etc.⁵

There should be no unwarranted invasions of privacy and the mechanisms for maintaining confidentiality of private information should be secure. Where information sharing is important to protecting the public health, measures that safeguard personal, private information should be in place and support should be given to ill individuals, family members, and others potentially stigmatized by real or potential illness.

Throughout this process, respect for individual freedom must continue to be an extremely high priority. Translating this respect also involves serious acknowledgement of a past history of neglect and abuse of personal freedom in multiple U.S. health care programs – all with the best of public health intentions. This history is not taken lightly; the ability to restrict individual freedom to protect the common good requires careful reflection and examination throughout the management of an influenza pandemic.

Closing Statement

This document seeks to provide a framework of ethical considerations to guide decision makers at all levels in preparing for and responding to pandemic influenza. As such, these guidelines are not narrowly prescriptive, but recognize the need of decision makers in particular communities or regions to transform this guidance into specific decisions. Ethical decision making assumes that such judgments will be based on current scientific knowledge, that effectiveness of interventions is carefully assessed, and that transparency of the process is evident. As specific decisions in particular communities are considered, processes should be in place for identifying which ethical issues were addressed, how guidelines were utilized, how decisions impacted the affected community, and what lessons can be shared with other decision makers. In this way these guidelines will continue to be an interactive, working document.

⁵ It is beyond the scope of our mandate to specify which agencies should have decision-making authority regarding liberty-restricting measures. We do not mean to suggest that such agencies are responsible for the provision of necessary goods and services. Rather, they should attempt to ensure that some agency stands prepared to provide such goods and services. In some cases they may be unable to do so. This should not be seen as an absolute barrier to implementation of the liberty-restricting measure. Rather, this should be treated as a serious cost in the analysis of the balance of costs and anticipated benefits necessary to determining whether implementation of the liberty-restricting measure is justified.

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