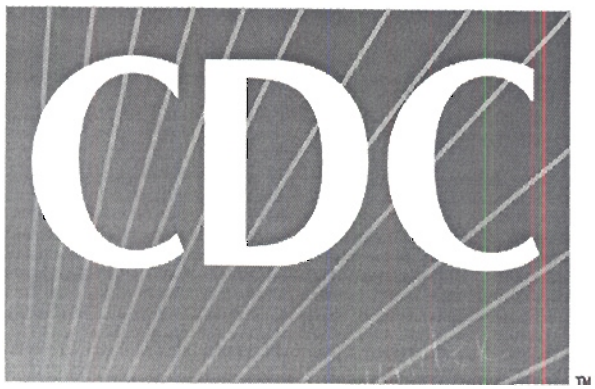
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



CENTERS FOR DISEASE
CONTROL AND PREVENTION

Joint Meeting of the Ethics Subcommittee of the Advisory Committee to the Director, CDC and the CDC Public Health Ethics Committee September 14-15, 2006 Atlanta, Georgia

Record of the Proceedings

TABLE OF CONTENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

JOINT MEETING OF THE
ETHICS SUBCOMMITTEE OF THE
ADVISORY COMMITTEE TO THE DIRECTOR, CDC
AND THE
CDC PUBLIC HEALTH ETHICS COMMITTEE
September 14-15, 2006
Atlanta, Georgia

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a joint meeting of the Ethics Subcommittee of the Advisory Committee to the Director, CDC and the CDC Public Health Ethics Committee (PHEC). The meeting was held on September 14-15, 2006 at CDC's Global Communications Center, Building 19, Room 232, Auditorium B3 in Atlanta, Georgia. Meeting participants are listed in Attachment 1.

Opening Session

Dr. Ruth Macklin, the Ethics Subcommittee Chair, called the joint meeting to order at 8:45 a.m. on September 14, 2006.

Dr. Macklin presented a certificate of appreciation to Dr. Dixie Snider in tribute, recognition and gratitude of his dedicated service and leadership to CDC, the Ethics Subcommittee and PHEC. Dr. Snider gave both groups a sense of direction; emphasized the importance of the guidance these groups provide to CDC; and played a critical role in strengthening public health ethics at CDC. Dr. Snider served in a variety of roles during his distinguished career of public service to CDC over the past 33 years. His final position prior to his recent retirement was as the CDC Chief Science Officer.

Dr. Macklin pointed out that a summary was distributed of Dr. Snider's achievements and contributions to public service over his productive career. The participants applauded Dr. Snider's dedicated leadership and wished him well in his retirement. Dr.

Snider thanked the current and former Ethics Subcommittee and PHEC members for assisting CDC in addressing important and complex issues related to public health ethics. He urged both groups to continue to provide CDC with valuable guidance in this area.

Dr. Macklin also presented a certificate of appreciation, *in absentia*, to acknowledge the valuable contributions, dedicated service and solid support of Dr. Janice Devier to the Ethics Subcommittee and PHEC. Dr. Devier is currently detailed to another area in CDC to focus on pandemic influenza. Dr. Macklin was pleased to announce that Dr. Drue Barrett has assumed the role as the Designated Federal Official for the Ethics Subcommittee.

Pandemic Planning Assumptions and Decision Domains

Dr. Stephen Redd, of the CDC Influenza Coordination Unit, presented ethical issues for the Ethics Subcommittee and PHEC to consider in pandemic influenza preparedness and response. The goals of the federal response to a pandemic to protect human health are three-fold. One, the spread of a pandemic to the United States should be stopped, slowed or otherwise limited. Two, the domestic spread of a pandemic should be limited and disease, suffering and death should be mitigated. Three, the infrastructure should be sustained, the impact to the economy should be controlled, and the functioning of society should be maintained.

The impact of a pandemic would depend on the severity, the available resources to diminish the impact, and the quality of preparedness. Interrelated decisions would include four major factors: (1) the application of healthcare and community infection control measures; (2) prioritization and distribution of medical countermeasures; (3) capacity to make adjustments in the delivery of care; and (4) the content of risk communication campaigns.

The key domains for decision-making are healthcare capacity and non-pharmaceutical and pharmaceutical interventions. The issues that must be considered in these areas include travel and border restrictions and screening; community and infection control interventions; and the prioritization, purchase and allocation of vaccines and antiviral drugs. With non-pharmaceutical interventions, efforts are made to delay the peak of an outbreak, diminish the burden to the healthcare system, and reduce cases.

Models serve as the best source of data for all non-pharmaceutical interventions. A "targeted layered containment" model was developed as an aggressive approach to a pandemic, but these interventions have not been adopted as policy to date. In this

model, schools would be closed to decrease cases among school children, but transmission would most likely be increased in households and neighborhoods. The implementation of voluntary household quarantine with or without household post-exposure prophylaxis (PEP) would decrease intra-household transmission, but would potentially increase the relative importance of transmission in the workplace and communities. Prohibiting sports events and other large outdoor gatherings, halting rapid transit service, and other social distancing efforts could be applied to decrease cases.

Infection control and transmission interventions include N95 respirators and face masks, cough etiquette, hand hygiene, and surface decontamination and disinfection. However, these important components have not been incorporated into models to date. Additional factors that should be considered include plans for secondary effects, the duration of implementation, intervention fatigue, socioeconomic disparities, the impact of sustained absenteeism and economic impacts.

Pre-pandemic vaccines protect against viruses with pandemic potential, are produced during gaps in annual vaccine production, and are matched with a pandemic strain with unknown efficacy. Questions have been raised about the value and specificity of pre-pandemic vaccines. Pandemic vaccines protect against a specific pandemic virus and can only be produced after the pandemic occurs. U.S.-based capacity to produce influenza vaccines is limited.

The seven steps involved with a pandemic vaccination program are production, purchase, prioritization, allocation, distribution, administration and monitoring. A time frame of four to six months would be required to advance from production to distribution. Federal, state and local agencies and manufacturers would be involved at various stages of a pandemic vaccination program.

Strategies to treat pandemic influenza with antiviral drugs are based on the experience in treating seasonal influenza. For treatment, these drugs could shorten the duration of illness; reduce infectiveness and transmission; and decrease pneumonia, hospitalization and death. Antiviral drugs must be administered within 48 hours of the onset of symptoms to be effective. Antiviral drugs can also be used as both seasonal prophylaxis and PEP. The drugs would be effective in preventing illness, but a much larger supply would be required.

Several assumptions have been made in planning for various areas in health care during a pandemic. Of persons who become ill, 50% would seek medical care. The number of hospitalizations and death would depend on the virulence of the pandemic virus. The demand for services would be high and would most likely increase by 25%

during a pandemic. Staff absenteeism would dramatically increase based on outcomes during the 1957-1958 outbreak in the United Kingdom. The availability of critical resources would be limited.

Several key factors must be considered for healthcare planning and preparedness for a pandemic. Appropriate infection control measures must be applied in healthcare facilities, workplaces, communities and homes to limit transmission and delay the spread of a pandemic. Scarce commodities should be allocated. Guidance should be developed for persons seeking health care.

Hotlines should be established for triage to reduce the burden on facilities. Alternative care sites should be selected and logistics should be made to stand up these sites. Solid communications, coordination and collaborations should be developed with all involved entities at federal, state, regional and local levels. Plans should be developed for surge capacity, triage, infection control and the delivery of interventions to staff and patients.

During the joint meeting, Dr. Redd asked the Ethics Subcommittee and PHEC to consider three important issues to assist CDC in producing the best possible guidance: (1) the quality of preparedness to mitigate the impact of a pandemic; (2) the requirement of various policy decisions; and (3) an effective process to reach policy decisions.

In response to a comment, Dr. Redd agreed that a critical need exists for CDC to rapidly provide clear guidance to states on pandemic influenza preparedness and response. He announced that a simultaneous planning process is underway at various governmental levels to address this issue. Dr. Redd also took note of the suggestion to build pandemic influenza capacity in other countries because scientists outside of the United States would most likely detect a pandemic.

Dr. Julie Gerberding, the CDC Director, joined the meeting to give the Ethics Subcommittee and PHEC additional guidance on providing CDC with input on public health ethics issues. CDC has a tremendous operational responsibility in pandemic preparedness and response at federal, state and local levels. Most notably, CDC has been charged with developing a community containment strategy and completing other tasks in the CDC pandemic preparedness and response plan.

Dr. Gerberding indicated that CDC will remain flexible in making decisions and developing policies on pandemic preparedness and response as new knowledge and data are gathered. Most notably, CDC will soon award grants to academic institutions to analyze the science on countermeasures, test hypotheses during the 2006-2007 influenza season, and conduct other activities to enrich the evidence base. CDC will

continually review and evaluate these efforts to improve and expand its pandemic preparedness and response policies and plans on an ongoing basis.

CDC recognizes the need to accelerate its planning efforts due to the vulnerability of the United States to a pandemic and the relevance of pandemic preparedness and response to CDC, public health and the entire nation. Although these efforts are focused on pandemic influenza, the same level of capacity and decision-making would be needed for other threats of a catastrophic nature.

CDC is aware that difficult decisions must be made about the allocation of resources and delivery of services in this context. CDC is also mindful that the decision-making process must be open, transparent and implemented with full inclusion and participation of the public and other stakeholders. As a result, discussions during the joint meeting of the Ethics Subcommittee and PHEC should extend beyond a pandemic. The deliberations should more broadly focus on a process and decisions for other scenarios in the United States when resources are scarce.

Dr. Gerberding acknowledged that concerns have been expressed internally within CDC about efforts to engage ethicists in planning, preparedness, response and decision-making efforts because ethics are not viewed as "science." However, she confirmed that CDC is taking steps to address these concerns by informing staff about the important need for ethics to serve as the foundation for scientific interpretation, application and decision-making. She urged the Ethics Subcommittee and PHEC to focus discussions during the joint meeting on a broader context beyond pandemic influenza to assist CDC in educating staff about the critical role of ethics in science.

Dr. Gerberding concluded her remarks by expressing CDC's deep and sincere appreciation to the Ethics Subcommittee and PHEC for continuing to provide CDC with valuable guidance and expertise on public health ethics issues. She emphasized that CDC would remain committed to this extremely important process.

Overview of Ethical Guidelines in Pandemic Influenza

Ms. Kathy Kinlaw and Dr. Robert Levine are Ethics Subcommittee, members assigned to draft the Ethics Subcommittee's report on ethical guidelines in pandemic influenza, thanked Drs. Barrett and Devier for their valuable assistance in this effort.

Dr. Levine summarized the history of the workgroup's development of the draft ethical guidelines, but he pointed out that the detailed history was distributed to the Ethics

Subcommittee and PHEC members prior to the joint meeting for review. Ms. Kinlaw added that the draft ethical guidelines were also circulated to the advisory groups for review. She and Dr. Levine reviewed the content of the draft ethical guidelines and highlighted the key recommendations in the draft report for the Ethics Subcommittee and PHEC to consider during the discussion. The draft ethical guidelines document is attached at the end of these minutes (see Attachment 2).

The Ethics Subcommittee and PHEC commended Ms. Kinlaw and Dr. Levine in drafting a thoughtful, well written and solid report. Several members made suggestions for the workgroup to consider in developing the next iteration of the ethical guidelines in pandemic influenza.

- The ethical guidelines should reflect a balance between public trust of authority and transparency.
- Pandemic influenza planning efforts should anticipate the differential ability of various groups and individuals in society to cope with and react to a crisis. This approach might minimize perceptions of resentment and injustice after the event.
- The goal of the pandemic preparedness plan should be to mitigate and offset social inequalities instead of delivering messages for each household or family to only be concerned with individual needs during a pandemic, such as stockpiling food and water.
- A clear distinction should be made between the development of policy guidelines and decision-making. For example, county health officers have asked CDC to describe specific actions that need to be taken. Local agencies would then identify approaches and make decisions to conduct these activities.
- The good of society is described as the most important general ethical tenet in allocating medical countermeasures. The basis for this ethical principle should be clearly articulated because the federal government has identified other critical infrastructures. For example, retail stores would play an important role during a pandemic, but would not be critical to the health, safety and survival of individuals during a pandemic.
- The specific order of providing vaccine to certain groups should be specified because a sufficient amount of vaccine will be available in the future to vaccinate all persons. For example, a decision would need to be made on whether high-risk persons should be vaccinated before young children.
- The document should be translated, tailored and formatted for different audiences. Moreover, the eight pages might be too lengthy for certain groups.

- The ethical guidelines should leverage and be consistent with childhood immunization other common public health practices to promote acceptance and understanding by public.
- Caution should be taken in the recommendation to avoid using the classical utilitarian approach to define priorities in pandemic influenza planning. Most notably, state governors and local health departments typically implement this strategy to establish public policy.
- Legal experts should be engaged in further efforts to finalize the ethical guidelines to determine whether healthcare facilities, providers and private citizens would face civil or criminal liabilities in not complying with the recommendations.
- Language in the ethical guidelines that questions the "value" of specific persons to vaccinate during a pandemic should be replaced with the "roles" of these individuals.
- "Common good" should be clearly defined.
- The individual responsibility of citizens and other members of the community to ensure successful outcomes during a pandemic should be discussed, such as stockpiling essential items and adhering to quarantine requirements.
- Caution should be taken in recommending the fair process or procedural justice approach because this strategy will be extremely difficult to execute and operate at state, local and county levels.
- The ethical justification and necessity of the three restrictions on personal freedom on page 7 should be clarified.
- "National origin" should be included as an additional ethically unsupported criterion in pandemic influenza planning.
- Language should be added to the document to clearly point out that the ethical guidelines serve as overarching guidance for central decision-making, but should not be used to support inappropriate behaviors, unproductive decisions, or measures unjustified by science. The statement should also note that certain situations would require persons to make decisions and exercise judgment based on local needs regardless of established procedures.
- "Survival" is a drastic word and should be deleted from the document because the existence of society would not be at stake during a pandemic. However, the document should openly and honestly note that a pandemic has the potential for catastrophic societal consequences. This possibility would justify social worth criteria to ensure the immediate distribution of vaccine or antiviral medication to front-line responders.
- Caution should be taken in characterizing the criteria of social worth, race and gender as "ethically unsupported" or "morally irrelevant" in pandemic

influenza planning. Most notably, these factors have been historically used in influenza vaccine coverage decision-making to identify social determinants of risk and adverse consequences from influenza based on race. These criteria have also been applied to allocate resources from a scientific perspective.

- The workgroup should clearly state its ethical approach in reconciling the conflict between scientific and moral criteria.
- The document should more clearly reflect the entire U.S. population, particularly American Indians/Alaska Natives in extremely remote locations with limited access to care.
- CDC should clearly articulate the purpose, use and dissemination plan of the ethical guidelines by state and local agencies.
- New language should be added to the document to address professional responsibility in the context of epidemic disease.
- The document should clearly distinguish between "sex" and "gender" and should also articulate whether "age" would be an additional ethically unsupported criterion in pandemic influenza planning.
- The ethical guidelines should address the global impact of a pandemic in developing or low resource countries, but the document is tailored to American audiences.
- New text should be added to the document about the potential for citizens to distrust the government based on a perception that public health officials are not sufficiently zealous in protecting community interests and sacrificing individual liberty when necessary.
- The document should acknowledge that CDC or other federal agencies may have no role or authority at the local level during a pandemic. Guidance should be provided on engaging communities in open and honest dialogue about this possibility. Most notably, roles, responsibilities and decision-makers should be clearly identified.
- The document should focus on populations that are at greatest risk of becoming infected or developing disease.
- The document should raise the possibility of expanding authority to nurses and physician assistants to perform certain procedures during an emergency.
- The document should clearly distinguish between the roles of state and local agencies during a declared public health emergency.
- The document should clearly distinguish between priorities that should be established in the protection of individuals versus society or the critical infrastructure during the planning and preparedness decision-making process.
- The document should include more language on "human rights."

- CDC should develop an evaluation process to assess compliance with the ethical guidelines in pandemic influenza. Efforts should also be made to track situations in which the ethical guidelines were used and the effectiveness of the document.
- The document should acknowledge the critical role of ethical guidelines in medical equipment in addition to vaccines and antiviral drugs.
- Strong efforts should be made to reach consensus about the shift in priorities that will occur during a pandemic to preserve an infrastructure or retain an emerging society.

Ms. Kinlaw and Dr. Levine thanked the Ethics Subcommittee and PHEC for providing valuable input on the draft ethical guidelines in pandemic influenza. They encouraged the members to submit additional comments and language to strengthen the document. They confirmed that the comments were noted and would be considered during their draft of the next iteration. Ms. Kinlaw and Dr. Levine made several remarks in response to some of the comments.

- "Transparency" does not require that open meetings be held to engage the entire public. Instead, transparency requires that the bases and general rules of the decision-making process are made available to the public.
- Ethicists are limited in providing specific guidance on ethical issues during a pandemic, such as whether retail stores should remain open or closed or if children versus high-risk adults should be vaccinated. The role of an ethicist is to provide advice on ethical issues that should be considered during the decision-making process. The actual decisions to take action must be made by those who have a thorough knowledge of the relevant scientific facts as well as the authority to make such decisions. However, ethicists can be very helpful in the implementation of ethical guidelines by working with the decision-makers to assist them in articulating clearly the goals, principles and values during a pandemic.
- The ethical guidelines define the "utilitarian approach" as evaluating the moral rightness of an act to determine its ability to produce good or acceptable consequences. All healthcare policies are consequential or utilitarian to some degree and do not tolerate the sacrifice of some persons for the greater good of the public at large.
- Ethical guidelines must be practical and relevant to actions that can be taken at state and local levels. "Idealistic standards" could then be described in an appendix, footnotes or a companion paper to the document.

- The next iteration of the ethical guidelines will provide clearer and more specific language on race and gender as "morally irrelevant" criteria in pandemic influenza planning.
- Input will be solicited from state and local agencies to ensure that the ethical guidelines document is useful to decision makers.
- New text on the potential for individuals to make judgments and the fact that decision-making would most likely occur in situations of uncertainty would be a solid addition to the document.

Dr. Barrett pointed out that the ethical guidelines will be submitted to ACD for review as recommendations to the CDC Director. The ethical guidelines could serve as guidance for CDC's existing pandemic influenza documents and activities, but could also be applied to other areas. The document will be posted on the CDC web site.

Dr. Macklin summarized the next steps in revising the draft ethical guidelines in pandemic influenza. Ms. Kinlaw and Dr. Levine agreed to continue to lead this effort. The next iteration of the draft ethical guidelines would reflect comments and suggestions made by the Ethics Subcommittee and PHEC during the joint meeting, but the members should feel free to submit additional changes to Dr. Barrett at dhb1@cdc.gov. The members should particularly inform the authors about language in the document that is too technical for the target audience to ensure these terms are clarified.

Dr. Macklin also asked CDC to provide the workgroup with clearer guidance in revising the draft ethical guidelines, such as developing a comprehensive document or limiting its scope, breadth and level of detail to the initial charge of the Ethics Subcommittee.

CDC's Role in Emergency Preparedness and Response (EPR)

Dr. Richard Besser, Director of the CDC Coordinating Office of Terrorism Preparedness and Emergency Response, provided an overview of CDC's EPR activities. At the interagency level, the National Response Plan serves as an all-hazards approach to organize the federal response in a coherent manner, provides a framework for emergency response, and identifies the roles and responsibilities of each federal agency during an event.

At the department level, the Department of Homeland Security (DHS) has overarching authority for directing and coordinating EPR activities. HHS has responsibility for medical services and the public health components of EPR activities under Emergency Support Function 8. At the agency level, HHS gives CDC broad authorities to conduct

EPR activities, including public health surveillance, infection control, and activation of the Strategic National Stockpile (SNS) during national disasters..

CDC views public health preparedness as a continuous process in improving the health system to detect, respond to, recover from and mitigate consequences of terrorism and other health emergencies. CDC takes an all-hazards approach to preparedness by building interrelated systems to respond to pandemic influenza, natural disasters, bioterrorism and other emergencies. CDC's vision and mission in this effort are the protection of persons, public health preparedness, and the prevention of adverse consequences.

CDC acknowledges that time is of the essence during an emergency because health protection requires rapid and effective detection, science, communication, integration and actions. CDC established nine preparedness goals to conduct activities before, during and after an event. These goals include traditional public health actions to prevent, detect, report, investigate, control, recover and improve response. CDC's support to states and agency-wide funding in the area of preparedness are aligned with its nine preparedness goals.

Dr. Besser's summary of CDC's key EPR activities is summarized below.

- The CDC Director's Emergency Operations Center (DEOC) was created in 2003 to respond to public health threats, natural disasters and other major events. DEOC is responsible for overall coordination of CDC's assessment, preparedness, response, recovery and evaluation before and during public health emergencies.
- The SNS is a national repository of countermeasures, antibiotics, antiviral drugs, chemical antidotes and medical equipment. The SNS is designed to deliver critical medical assets to the site of a national emergency within 12 hours of the decision to deploy them.
- The Select Agent and Toxins Program regulates the possession of biological agents and toxins that have the potential to pose a severe threat to public health and safety.
- The Laboratory Response Network (LRN) is a national network of approximately 150 laboratories throughout the country that perform testing for bioterrorism agents. LRN provides laboratory diagnostic capacity to respond to biological and chemical terrorism and other public health emergencies and as such, serves as a critical infrastructure for both terrorism and natural events.
- Biowatch was established in 2003 as an early warning system to rapidly detect trace amounts of biological materials in the air. Sampling is

underway in several cities throughout the country. CDC, DHS and the Environmental Protection Agency collaborate in the Biowatch system.

- BioSurveillance enables early event detection and health situational awareness with real-time clinical data from hospitals. BioSurveillance allows public health agencies at federal, state and local levels to simultaneously access health data to analyze syndromes; visualize time series and patient line listings on geospatial maps; and make queries as needed.

CDC participated in major responses over the past five years. The investigation of severe acute respiratory syndrome (SARS) was a successful collaboration between epidemiology and laboratory science. Of approximately 800 CDC staff who were activated to serve on the SARS response, about 100 were deployed to assist with domestic and international investigations and approximately 80 were deployed to assist the World Health Organization. CDC's laboratory activities in the global SARS response included transporting and processing approximately 3,000 specimens from 27 countries. The CDC laboratory played a key role in virus isolation, characterization, and diagnostic test development and deployment.

Hurricane Katrina resulted in CDC's largest response to a natural disaster to date. CDC deployed about 700 staff to four states; provided technical assistance to state and local health departments; developed and delivered health and safety messages; used the SNS to deploy medical supplies and establish federal medical stations; conducted environmental, public health and mental health needs assessments; and performed disease surveillance activities. CDC is continuing to assist residents with reoccupation and rebuilding efforts in response to Hurricane Katrina.

CDC immediately responded to the 9/11 terrorist attacks on the World Trade Center. The SNS was deployed with 50 tons of pharmaceuticals, medical supplies and equipment. CDC closely collaborated with the New York City Department of Health to assess hospital capacity, evaluate needs, and develop a comprehensive worker health and safety program. CDC coordinated efforts with other public health and law enforcement agencies at federal, state and local levels to identify potential cases and characterize exposures in response to the anthrax attacks that caused the infection and death of 27 persons.

Dr. Besser was extremely pleased that the Ethics Subcommittee and PHEC are focusing on ethical issues related to pandemic influenza and the broader area of EPR. He emphasized that the expertise of the Ethics Subcommittee and PHEC would be essential to CDC providing guidance.

Dr. Besser provided additional comments about ethical issues in EPR based on questions and comments by the Ethics Subcommittee and PHEC members.

- Several ethical issues that are essential to pandemic influenza also apply to EPR, such as the allocation of scarce resources. The development of a framework for ethical decision-making in EPR would be extremely important.
- CDC would greatly benefit from input on ethical research, such as appropriate actions to take during an emergency if informed consent and a full Institutional Review Board (IRB) process were not possible. Ethical research during an emergency should particularly focus on principles to protect vulnerable populations.
- Guidance by the Ethics Subcommittee and PHEC on ethical issues in EPR should include appropriate times to suspend civil liberties to (1) control an outbreak; (2) quarantine airline passengers to avoid the importation of infection into the United States; and (3) enforce state and local laws to ensure public health, individual rights and appropriate ethical values.
- CDC acknowledges that staff at federal, state and local levels would need to be trained with specific skill sets and properly supported to operate in an ethical manner during an emergency or disaster. However, CDC needs assistance from ethicists in identifying and articulating these skill sets to provide training to the public health community.
- CDC should compile and review lessons learned from the anthrax investigation to provide training to the field on ethical issues. For example, the delivery of care and other responses to the anthrax outbreak varied based on location and population.

Public Health Ethics in Emergency Response

Ms. Micah Milton, of CDC, reported on meetings held with CDC staff to obtain diverse perspectives on the ethical aspects of CDC's role in emergency response activities. CDC staff who were deployed to Hurricane Katrina identified the following ethical issues that should be considered during an event: (1) preparedness for deployment; (2) individual and agency duties and responsibilities during deployment and emergency response; (3) coordination and communication; (4) professional competency; (5) competing obligations or concerns; and (6) research ethics.

CDC emergency response leaders indicated that it would be helpful to have additional guidance regarding the following ethical issues pertinent to emergency response: (1)

the need for rapid decision-making often with insufficient information; (2) the importance of transparency and clear communication; (3) achievement of common good while protecting vulnerable populations, individual rights and community interests; (4) allocation of scarce resources; (5) priority of public health practice versus research; (6) a balance between fulfillment of regular and special duties during deployment; (7) interagency conflicts and disagreements; (8) professional competency specific to emergency response; and (9) transparency and fairness in selection of staff for deployment.

In preparation for the joint meeting of the Ethics Subcommittee and PHEC, a workgroup of Ethics Subcommittee members, PHEC members and CDC staff with responsibility for EPR activities prioritized the following ethical issues: (1) conflict of values and perspectives among agencies; (2) allocation of scarce or valuable resources; (3) social and distributive justice in the prioritization of public health response; and (5) appropriateness of conducting research during emergency response activities.

The workgroup members agreed it would be useful to focus on three key questions during the joint meeting. One, is it ethical for CDC to conduct research during emergency situations? Two, under what conditions or circumstances should CDC conduct research during emergency situations? Three, what strategies can CDC apply to ethically conduct research during emergency situations? Ms. Micah pointed out that CDC provided the advisory group members with three case scenarios to guide the discussion: "mission creep," "balancing act," and "not enough to go around."

Dr. John Arras and Mr. Bruce Jennings, the Ethics Subcommittee members who served on the workgroup, reviewed several areas of ethical concern relating to emergency response. These included:

- "Professional competency." Several CDC staff who were deployed during Hurricane Katrina personally believed they were helpless or under-prepared.
- "Delivery of quality medical care." The extent to which lower standards of care are accepted during an event should be addressed (i.e., the necessity to permit certain persons to perform medical procedures they are not usually authorized to do - for example, authorizing nurse practitioners to treat fractures).
- "Interagency relationships." Strategies should be developed for CDC to address potential concerns that arise with personnel from other agencies at federal, state and local levels during emergency events.
- "Research." Decisions should be made on conducting research during an emergency. Interventions cannot be improved without solid studies;

however, research might be questioned during a catastrophic event that involves massive morbidity or mortality. The public might also perceive research during this type of event as a diversion or exploitation of the situation.

- "Actual research versus research-like activities." A clear distinction should be made between these two activities. "Actual research" could have a direct bearing on the quality of medical and other services provided to victims of an emergency. "Research-like activities" could strengthen knowledge and enhance the basis for emergency response in the future.
- "Mission creep." Situations in which the conduct of research would be ethical or reasonable during an emergency should be identified.
- "Resources." The extent to which public health officials could share valuable resources with groups that were not involved in the research project should be determined. Criteria should be established to distribute goods and triage services during an emergency.
- "Acceptable losses." Effective messages should be created to address this issue because the public health community is extremely uncomfortable with the concept of acceptable losses during an emergency.

Dr. Arras and Mr. Jennings raised the possibility of PHEC compiling key points from the Ethics Subcommittee's discussion to provide CDC staff with education and training on public health ethics in emergency response. These resources could then be expanded as case studies or commentaries and distributed for use in the field. However, these efforts would be in addition to the development of an analytic white paper or report with standards, guidelines and principles of public health ethics in emergency response.

Dr. Arras and Mr. Jennings also highlighted key points from three case scenarios to guide the discussion. The "mission creep" case scenario involved a shelter where CDC provided support following Hurricane Katrina at the request of state and local officials. CDC leadership asked staff to report data in a specialized manner, but the request created tension in the field. CDC personnel believed that the request diverted from their on-the-ground emergency duties.

One "balancing act" case scenario involved an ice storm in which CDC staff conducted a study on carbon monoxide poisoning in hospitals. CDC obtained consent from state government officials to perform the research, but tension still developed due to issues about the jurisdiction of agencies.

Another "balancing act" case scenario involved health effects after a major tropical cyclone. CDC initiated a study on diarrheal disease. No evidence was produced to

determine whether the cyclone actually caused diarrhea or if the diarrhea was endemic. This case emphasized the need to identify responsibility for providing the burden of proof in conducting research during a disaster.

The "not enough to go around" case scenario involved a household study to assess community needs after Hurricane Katrina and determine if neighbors of designated households could also submit claims to receive benefits.

Comments and recommendations by the Ethics Subcommittee and PHEC on CDC's role in public health ethics in emergency response are outlined below.

- Immediate needs during an emergency should be addressed before academic, research or future needs. Public health officials should never prioritize research over rescue or mitigation efforts during an event. This approach would promote public trust of the agency and transparency with respect to guidance issued by the government in the future.
- New rapid ethical review procedures should be developed to allow research in emergency settings.
- The need for a new paradigm or concept of public health officials operating in and responding to an emergency should be resolved. CDC could use its influence with professional societies, academic institutions and other groups in this effort to change the face of public health.
- Priority research questions that would need to be answered during an event should be identified prior to an emergency.
- Research should be designed to track and monitor victims of an emergency, such as former New Orleans residents who relocated to various parts of the country following Hurricane Katrina.
- Emergency response decisions should be informed by both ethics and quality science.
- Ethical decisions that should immediately be made during an event should be established before an emergency.
- Communities should be engaged in the decision-making process prior to an event to build trust.
- Strong efforts should be made to (1) identify specific ethical issues that would arise during an emergency; (2) determine roles and responsibilities in addressing these areas; (3) develop strategies to prepare staff to respond to ethical issues; and (4) evaluate these actions to inform future research.
- Collaborations should be established with other federal agencies that have more experience than CDC in emergency response and have developed policies or laws to address this issue. For example, some federal

agencies have already created standards for triage, distribution of scarce resources, and expansion of credentials to other providers during an emergency.

- Existing state and local laws on quarantine and other issues that govern the manner in which state and local health officers have authority to function during an emergency should be compiled and reviewed.
- A different mind set for emergency response should be promoted by providing solid training, a clear mission and a defined chain of command.
- Procedures that have already been established to pre-approve protocols, rapidly conduct research, and answer research questions during an event should be used to define CDC's role in emergency response.
- A combined approach of providing services to persons in need and conducting research during an emergency should be considered.
- Specific situations where research would be appropriate and warranted should be described prior to an emergency, such as testing the effectiveness and use of a vaccine during an outbreak. However, these standards should also outline appropriate times to conclude a study after an emergency, particularly if the research becomes complex, counterproductive or costly; increases the risk of harm to participants; or delays the response.
- Specific ethical principles or guidelines should be established to conduct research during an emergency, such as whether the research would benefit the affected population, add value to the community, or harm the study population. The ethical principles should be used to educate and train CDC staff in the field.
- Specific actions should be taken prior to an event in preparation of conducting studies and asking research questions during an emergency. A long-term strategy should be implemented to build trust in communities throughout the country and enhance state and local capacity.
- Studies should be conducted during an emergency because public trust would significantly decrease if important research opportunities were not explored.
- Clear guidance should be provided to the field on boundaries of research, practice, and quality improvement activities.
- Consideration could be given to development of a broad framework document that discusses public health ethical issues in emergency response. This would augment and complement the guidelines being development for pandemic influenza.
- A framework should be developed for the Ethics Subcommittee and PHEC to discuss all ethical issues. Specific areas that warrant separate discussions should then be identified.

Dr. Besser strongly encouraged the Ethics Subcommittee to develop a white paper on public health ethics in emergency response similar to the ethical guidelines in pandemic influenza. He described four areas where input by the members would be most valuable to CDC: (1) triage of services; (2) allocation of scarce resources; (3) ethical principles in conducting research in an emergency setting; and (4) ethical issues in developing and storing countermeasures. Dr. Besser offered to meet with the Ethics Subcommittee to advance this activity.

Drs. Barrett and Macklin described next steps in providing guidance on CDC's role in public health ethics of emergency response. Dr. Arras and Mr. Jennings agreed to continue to lead this effort. It was recommended that the Ethics Subcommittee and PHEC engage in additional discussions during future meetings to make a clear distinction between program evaluation, public health practice, surveillance and research during an emergency.

A workgroup will be formed with representation by Ethics Subcommittee and PHEC members to meet with and engage in ongoing communications with Dr. Besser. The new workgroup would be charged with: (1) identifying the best strategy or model to provide CDC with guidance on the public health aspects of its role in emergency preparedness and response; (2) assisting CDC in determining specific ethical questions relevant to emergency preparedness and response; and (3) identifying areas where science is needed to inform ethical decisions in emergency preparedness and response, such as interacting and developing trust with the community.

Public Comment Period

Dr. Macklin opened the floor for public comments; no attendees responded.

With no further discussion or business brought before the Ethics Subcommittee or PHEC, Dr. Macklin recessed the joint meeting at 5:05 P.M. on September 14, 2006.

Review of Outstanding Issues

Dr. Macklin reconvened the joint Ethics Subcommittee and PHEC meeting at 8:38 A.M. on September 15, 2006. She opened the floor for CDC and the Ethics Subcommittee to review and discuss outstanding issues related to the draft ethical guidelines in pandemic influenza and public health ethics of emergency response.

Pandemic Influenza

Dr. James LeDuc, of CDC, thanked the Ethics Subcommittee for its tremendous efforts in drafting the ethical guidelines in pandemic influenza. Dr. LeDuc suggested that the Ethics Subcommittee retain the current scope of the pandemic influenza document, with the possible exception of adding language on the allocation of scarce medical equipment and other resources.

Dr. Macklin summarized written comments that were submitted following the discussion on the previous day. One commenter emphasized that the law plays an important role in ethical guidelines. Although the pandemic influenza document was not intended to serve as legal guidance, she advised the Ethics Subcommittee to take the following actions to strengthen the report: (1) reference existing legal authorities in federal, state and local jurisdictions; (2) clarify the role of the guidelines; and (3) show a stronger relationship to current legal frameworks.

The commenter further noted that state and local governments have developed detailed guidelines on appropriate strategies and proper times to close schools, isolate infected persons or take other extreme measures. These standards are typically codified in regulations. Governmental agencies also have established procedures to address actions that deprive citizens of protected rights.

Additional comments by the Ethics Subcommittee and PHEC members on the ethical guidelines in pandemic influenza during the follow-up discussion are outlined below.

- The caveat of "in accordance with applicable law" could be included in the document as a footnote or endnote.
- Ms. Kinlaw and Dr. Levine could collaborate with CDC staff to revise the document with the proper legal context.
- Strong efforts should be made to ensure that the inclusion of legal principles in the document does not divert from the focus on ethical issues.
- It might be useful to conduct a literature search to determine if documents on legal issues in pandemic influenza planning have been developed.

- Key outcomes from the upcoming IOM meeting should be compiled and reviewed because both legal and ethical issues in pandemic influenza will be addressed at this event.
- A new statement should be included to emphasize that the role of legal issues in pandemic influenza is recognized, but the document is intended to provide ethical guidance. The new language should also clearly distinguish between law and ethics. Footnotes should be added to cite relevant literature on legal issues.
- A process should be established to present the document to ACD for endorsement.
- Existing state and local laws should be thoroughly reviewed to increase the utility of the document at state and local levels. Legal advice should be solicited from the CDC Office of General Counsel in this effort.

Dr. Levine thanked the Ethics Subcommittee and PHEC for providing additional comments on the draft ethical guidelines in pandemic influenza. However, he noted that he and Ms. Kinlaw would need a succinct list of action points in addition to the meeting minutes to draft the next iteration of the document because the comments and suggestions were substantial. Dr. Levine confirmed that he and Ms. Kinlaw would make every effort to respond to the action points.

Emergency Preparedness and Response

Additional comments by the Ethics Subcommittee and PHEC members on ethical guidelines in emergency preparedness and response during the follow-up discussion are outlined below.

- The document should not just focus on issues that are specific to public health ethics in emergency response at this time. Instead, emphasis should be placed on identifying issues across public health that may arise in the future.
- The document should emphasize that the current human subjects protection system is not designed for disaster planning and emergency response. However, an "IRB-like" committee should be established to address specific categories of ethical issues during an event, such as carbon monoxide poisoning or an anthrax outbreak. The IRB-like committee could develop and vet guidelines for these situations prior to an emergency and target the recommendations to public health practitioners and researchers.

Dr. Macklin noted that several Ethics Subcommittee members expressed a strong interest in monitoring the ongoing activities at the federal level to revise and clarify the common rule on research with human subjects. Some members also raised the possibility of ACD submitting formal public comments to emphasize the need to modify the common rule. The Ethics Subcommittee could play a role in this effort by searching the literature, developing a white paper, and forming a workgroup to specifically focus on the common rule.

Future Direction of the Ethics Subcommittee

Dr. Richard Dixon, the PHEC liaison to the Ethics Subcommittee, summarized telephone conversations that he and Dr. Barrett had with each Ethics Subcommittee member to obtain their views on the functioning of the Ethics Subcommittee. The members expressed dissatisfaction with the role of the Ethics Subcommittee in CDC's public health ethics program. However, the members acknowledged the importance that CDC has placed of CDC's public health ethics activities.

The members identified the following problems: (1) a slow pace in making progress; (2) a stronger focus on infrastructure, procedural and administrative matters rather than substantive issues; (3) a lack of clarity about the role, scope and function of the Ethics Subcommittee; and (4) confusion and complexity associated with both an internal and external advisory group on public health ethics.

The members described three major activities the Ethics Subcommittee should conduct. Professional consultation and advice should be provided about ethical issues of CDC's programs. Assistance should be provided to educate CDC staff about public health ethics. CDC's infrastructure should be built to support an internal public health ethics program. Several members expressed uncertainty about the provision of recommendations or advice to CDC as individuals or a collective group and the role of the Ethics Subcommittee in the consultation process.

Dr. Dixon described areas where the members most frequently requested clarification during the telephone conversations.

- The formal role of the Ethics Subcommittee and its relationship to PHEC should be clearly defined.
- Functional activities of consultation should be separated from the focus on education and infrastructure.
- Decisions should be made on whether the Ethics Subcommittee would be expected to respond to CDC's direct questions or if the members would have flexibility in addressing other issues.

Dr. Barrett added that the Ethics Subcommittee was established with a broad charge, but efforts could be made to develop more formal language. She announced that CDC is developing documents to clearly outline the framework and procedures associated with consultations.

Dr. Barrett confirmed that CDC is informing each center about the existence of the Ethics Subcommittee. Input is being gathered from staff on substantive issues the members should address in the future. Dr. Barrett also informed the members that CDC is in the early stages of developing a database to track public health ethics consultations and issues.

Dr. Arras reported on discussions he and Dr. Barbara Koenig had with members on the future direction of the Ethics Subcommittee. The members overwhelmingly expressed enthusiasm for and commitment to the public health ethics process. However, the members were also deeply frustrated by the unclear role, elementary activities, and under-utilization of the Ethics Subcommittee.

The members agreed to serve on the Ethics Subcommittee based on an assumption that consultations would be held with CDC leadership on cutting-edge issues, but the meetings typically focused on elementary education and infrastructure building. Some members believed that CDC is discouraging the Ethics Subcommittee from focusing on politically sensitive issues.

Despite these concerns, most members were encouraged by recent events, such as including a discussion on the future direction of the Ethics Subcommittee on the current agenda and assigning Dr. Barrett to provide support and leadership on a full-time basis. Dr. Gerberding's attendance at the meeting on the previous day showed her commitment to the process. Dr. Arras asked the members to focus the discussion on an appropriate model for the Ethics Subcommittee that would balance education, consultation and infrastructure building.

The Ethics Subcommittee thanked CDC, Dr. Arras and Dr. Koenig for having discussions with all of the members to obtain their perspectives. This effort demonstrated that CDC is extremely interested in improving the Ethics Subcommittee and advancing its public health ethics activities. Several members made specific suggestions on the future direction of the Ethics Subcommittee.

- The consultative role of the Ethics Subcommittee should be to identify, clarify, and analyze ethical issues to formulate preferred options and recommendations.

- The function of the Ethics Subcommittee should be to identify ethical issues for CDC to consider. The members are not charged with resolving ethical issues for application in epidemiology, science and CDC's other activities. However, the members of the Ethics Subcommittee could serve as a resource on ethical matters.
- A formal educational process should be developed to focus on certain topics. This approach would strengthen the efficiency of the Ethics Subcommittee in developing consultative reports.
- Joint meetings with both advisory groups should be used as a forum to address important policy issues.
- The Ethics Subcommittee and CDC leadership should engage in a dialogue to clearly define a process to resolve ethical issues.

Ethics Subcommittee Procedural Issues

Drs. Barrett and Macklin provided details about members' length of service on the Ethics Subcommittee. During a previous meeting, the members drew lots to serve for a total of two or three years. This approach was taken to ensure that the terms of the original members would not expire at the same time. The original timeline would mean that half of the members would be rotating off the Subcommittee at the end of 2006. Because it was felt that change of membership at this time would be disruptive, all members were offered one more year of service, thus bringing the terms to three or four years. A question was raised regarding the ability to serve beyond four years. Dr. Barrett indicated that it was her understanding that four years was the limit but she would ask for guidance from the CDC Committee Management Office.

Dr. Barrett opened the floor for a discussion on the extension of Dr. Macklin as the Ethics Subcommittee Chair. Dr. Macklin, the current chair, and Dr. James Thomas, a potential nominee for the new chair, recused themselves from the discussion and vote.

Concerns raised by members of the Ethics Subcommittee are outlined below.

- Some members expressed dissatisfied due to perceived underutilization of the Subcommittee. Dissatisfaction would be minimized if the Ethics Subcommittee had better communications with CDC leadership and progress was made in addressing important ethical issues.
- The Ethics Subcommittee has no strong linkages to decision-makers who establish CDC policy. A chair with strong interest in and close ties to the public health community might result in more success in reaching and accessing CDC leadership.

- Having a chair who also served on the ACD would facilitate communications.

As the result of the discussion, it was agreed that Dr. Macklin should continue to serve as the Ethics Subcommittee Chair for an additional year. Specific actions to select a new chair should be taken prior to the expiration of Dr. Macklin's term in December 2007. A document describing the terms of reference for the Ethics Subcommittee should be developed. The Ethics Subcommittee should clearly articulate and communicate its expectations of the chair.

Drs. Macklin and Thomas rejoined the meeting and were informed of key outcomes from the discussion. Dr. Macklin agreed to continue to serve as the Ethics Subcommittee Chair.

Ethics Subcommittee Action Items

Dr. Macklin led the members in a review of action items and potential future agenda items that were raised over the course of the meeting.

Action Items

- Dr. Barrett would poll the members by e-mail to determine availability for three meetings in 2007 (in February, June and September). The e-mail communication would also convey the following messages. (1) The members would be asked to confirm their interest in attending a full 1.5-day meeting. (2) The beginning and end times of the 2007 meetings would be clearly stated. Members would be urged to make a commitment to attend each meeting in its entirety. The departure of members on day 2 of the meeting eliminates the ability of the Ethics Subcommittee to maintain a quorum and vote on important issues.
- Dr. Barrett would provide the Ethics Subcommittee with budget information to allow the members to prioritize activities, such as commissioning white papers, outreaching to stakeholders, or reviewing ethical and legal principles.
- Dr. Barrett would facilitate the formation of Ethics Subcommittee workgroups for the members to focus on and advance specific activities.
- Dr. Barrett would facilitate coordination, collaboration and communications between the Ethics Subcommittee and PHEC members in the ongoing development of the ethical guidelines in pandemic influenza and the document on public health ethics in emergency response.

Potential Topics for Future Meeting Agendas

- Discussion to distinguish between public health practice and public health research. CDC would also need to engage its Office of the Chief Science Officer in this effort because this office has lead responsibility in research determination issues.
- Overview of public health ethics in genomics research. Dr. Koenig volunteered to collaborate with CDC as the Ethics Subcommittee lead in this effort.
- Overview of public health ethics in CDC's partnerships with industry, for-profit groups and non-profit organizations. Dr. Macklin volunteered to collaborate with CDC as the Ethics Subcommittee lead in this effort with assistance from Ms. Kathy Kinlaw.
- Continued review and discussion on ethical guidelines in pandemic influenza and public health ethics in emergency response.
- Discussion on terms of reference for Ethics Subcommittee members.
- Report on CDC's database to track public health ethics consultations.
- Report on efforts to identify areas of interest where members and CDC staff could partner to fulfill the Ethics Subcommittee's education and consultative roles.
- Presentation on a joint PHEC/Steering Committee proposal to inform leads in each CDC center that the Ethics Subcommittee is available to provide staff with external expertise on public health ethics.

Closing Session

Dr. Macklin thanked the Ethics Subcommittee and PHEC members for providing outstanding input and contributing their valuable time to the joint meeting.

With no further discussion or business brought before the Ethics Subcommittee or PHEC, Dr. Macklin adjourned the meeting at 12:07 P.M. on September 15, 2006.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

11.27.06
Date

Ruth Macklin, Ph.D.
Chair, Public Health Ethics Committee

ATTACHMENT 1

List of Participants

Ethics Subcommittee Members
Dr. Ruth Macklin, Chair
Dr. John Arras
Dr. Georges Benjamin
Dr. Mary des Vignes-Kendrick
Dr. Vanessa Gamble
[via conference call on 9/15/06]
Dr. Thomas Hooyman
Mr. Bruce Jennings
Ms. Kathy Kinlaw
Dr. Barbara Koenig
Dr. Robert Levine
Dr. James Thomas

PHEC Members
Timothy Barrett
Roger Bernier
Fred Bloom
Karen Bouye
Sally Brown
Christine Casey
Cynthia Clark
Steven Coughlin
Richard Dixon
Sandra DeShields
Rachel Eidex
Barbara Ellis
Michael Grayson
Mary Leinhos
Bryan Lindsey
Aun Lor
Charles Magruder
Micah Milton
Mary Neumann
Stephanie Rutledge
Anne Sowell
Benedict Truman
Rachel Weiss
Mark White

Ethics Subcommittee Designated Federal Officer
Drue Barrett

Other CDC Representatives
Dr. Julie Gerberding, CDC Director
Dr. Dixie Snider, Chief Science Officer (Retired)
Adeyelu Asekun
Richard Besser
Karen Cleveland
Cecilia Curry
Michael Doney
Shahul Ebrahim
Deborah Esbitt
Kay Golan
Richard Goodman
Susan Gorman
Penina Haber
Sharon Katz
Richard Klomp
Paula Kocher
Lisa Koonin
James LeDuc
Lisa Lee
Sherline Lee
Deborah Levy
Anthony Martin
Tony Moulton
Joe Mulinare
Philip Navin
Anita Patel
Nicki Pesik
Tanja Popovic

Oona Powell
Stephen Redd
Desiree Robinson
Benjamin Schwartz
Thomas Shimabukuro
Nicole Smith
James Stephens
Eli Warnack
Joni Young

Members of the Public

Ms. Anna DeBlois (Association of State and Territorial Health Officials)
Dr. Paul Etkind (National Association of County and City Health Officials)
Dr. Richard Hopkins (Council of State and Territorial Epidemiologists)
Dr. Jim James (American Medical Association)
Dr. Donald Williamson (Association of State and Territorial Health Officials)

Attachment 2

Draft Ethical Guidelines in Pandemic Influenza (August 8, 2006 Draft)

This document describes ethical tenets and principles that the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention propose as a foundation for decision making in preparing and responding to pandemic influenza. 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. The following statements are provided 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.

I. General Ethical Tenets

- There is a **commitment to transparency** throughout the pandemic influenza planning and response process. The reasoning behind choices made is fully articulated and the values and principles justifying those decisions are clearly identified and open for examination. The public understands and expects this commitment to clarity and openness, which is based on a deep respect for all individuals and communities involved.

- **Public engagement and involvement** is essential and the obligation to build public will and trust is 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 are 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[1]. 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

[1] Examples of maximizing preparedness include shortening the time for virus recognition or vaccine production, increasing the capacity to produce vaccines or antivirals and increasing the supplies of antivirals.

advance of the time that decision making must commence. Though every specific choice or contingency can not be foreseen, comprehensible foundational guidelines and procedural action plans provide coherence and direction and build trust.

- **Sound guidelines must be based on sound science.** 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[2].

- 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 tenet is not simply based on the potential of global involvement to benefit U.S. citizens (an "instrumental" reasoning), but on a deep recognition of the common good and our interdependence globally. Mechanisms for global involvement and criteria for determining the scope of impact of U.S. decisions should be explicit.

- **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. ACIP, NVAC, and CDC 2005 recommendations reflect this principle.

  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[3]. Again, engagement of diverse stakeholders will be essential in affirming this priority,

---

[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 evens 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.

[3] 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. When confronted with the urgent demands of preserving society during a pandemic, discussion of these questions takes on a lower 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 well-ordered 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.

- **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. Limits on individual freedom or choice may be necessary to protect individuals and the community as a whole during pandemic influenza. Yet, individual liberty should only be restricted with great care and when alternative approaches to realizing the goal of weathering the pandemic are not likely to be effective.

  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 Tuskegee Study of Untreated Syphilis, 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 and addressing the distrust should be a strong and enduring commitment and not be simply instrumental to having individuals comply with recommendations. Diverse public voices should be involved in determining the need for restrictions and in articulating the ethical justification for these restrictions.

  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.
  - Ensuring 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).

- **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..[4] A thoughtful process

[4] Elements of a fair process approach include 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

involving diverse voices in the process of 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 process (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 addressed (see Section II.B, page 7, paragraph 2 for more discussion about the strong presumption in favor of centralized decision making during a pandemic). This process has special obligations to historically marginalized communities and those where sensitivity to cultural, racial, religious or other values must be incorporated.

II. Addressing Particular Ethical Issues in Pandemic Influenza Planning

A. Allocation of Goods such as Vaccines and Antiviral Medications

The distribution of goods (in distributive justice theory these are called 'intrinsically non-moral goods') should be guided by criteria which are specified well in advance of any need to apply them. As indicated earlier, the primary goal 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 goal. These further criteria should be directed at maximizing fairness (or equitability) in the distribution process.

We propose that a classical utilitarian approach to defining priorities, 'the greatest good for the greatest number,' is not adequate to pandemic influenza planning. 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.
- Within agreed upon priority groups, equitable opportunity or access to resources.
- Respect for individual autonomy by, for example, employment of the least restrictive interventions that are likely to be effective.

During the course of a pandemic, the survival of society may be threatened. It is recognized as part of our moral tradition that it is (may be) ethically acceptable to suspend some (but not all)

---

voice in decision making and agree to the proposed process in advance; 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; procedures that are sustainable and enforceable.

moral rules in such circumstances. For example, we would not ordinarily find it ethically acceptable to force people to submit to influenza vaccination. But in a pandemic, we might justify that the health of the community at large is dependent upon all at risk being vaccinated (similar to the current required vaccination of school-age children). Such suspensions of ordinary moral rules should be anticipated and the conditions calling for such suspensions should be specified.

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 are needed.
- Who is eligible to be a recipient? (e.g., American citizens? American residents as of a certain date?) Will any resources be set aside for people who are not identified as eligible recipients or who are residents of countries other than the US?
- 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 **not** be ethically supported in pandemic influenza planning include:

- To each according to their social worth.
- To each according to what he or she deserves.
- To each according to purchasing power.
- First come, first served. (Superficially, this may appear to be fair but, de facto, this puts certain underprivileged populations at a disadvantage.)
- Among the unacceptable criteria are those such as race and gender because they are not morally relevant.

B. Ethical Guidelines Regarding Restrictions on Personal Freedom in Non-Pharmaceutical Interventions for Managing Pandemic Influenza

A sound scientific basis for the effectiveness of non-pharmaceutical interventions serves as an important prerequisite for the employment of any intervention that entails restriction of personal freedom. This requirement parallels the requirement for demonstration of efficacy of

pharmaceutical interventions.

Nonpharmaceutical interventions include such measures as:

- 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. These mechanisms are often called "social distancing" measures.
- 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 non-pharmaceutical interventions involves restricting personal freedoms that are strongly held and highly valued in U.S. society. The ethical concept of individual autonomy, or one's ability to be self-governing, 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 an 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 is 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
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 determining restrictions and in communication about these, particular attention should be given to communities that have been marginalized and/or have a past historical experience of discrimination. Similarly, particular attention should be given to individuals and communities where cultural, religious, or other values/beliefs may be impacted by restrictive measures.

In pandemic influenza there is a strong justification for centralization of decision making versus decision making occurring in every local community 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.)

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. In determining these measures there must be substantial evidence that:

- The liberty-limiting measure will achieve its intended goal.
- 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., too expensive).
- Failure to implement the measure is likely to result in grave harm to the survival 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[5].

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 ensure that mechanisms are in place that provide the impacted population, their family members, and other dependents with adequate access to food water, and other essential services. Mechanisms must also be put in place that protect restricted individuals' jobs and their ability to meet economic obligations (mortgage, rent, paying utilities, etc.

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 needs requires careful reflection and examination throughout the management of an influenza pandemic.

---

5 Philosopher John Rawls' concept of the "veil of ignorance" can shed light on this point. If every decision maker were in the "veil of ignorance" in which everyone's real world socioeconomic status, health status, abilities and life plans were unknown, each decision maker would be inclined to create a society in which all were treated fairly, including the least well off, so that when unveiled, none would be at risk of living an intolerable life.