Joint Meeting of the
Ethics Subcommittee of the
Advisory Committee to the Director, CDC
and the
CDC Public Health Ethics Committee
November 15 - 16, 2007
Atlanta, Georgia

Meeting Summary
Meeting Summary

Overview
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 (ACD), CDC and the CDC Public Health Ethics Committee (PHEC). The meeting was held on November 15 - 16, 2007 at CDC’s 1825 Century Center Building, Conference Rooms 1 A / B. The goals of this meeting were to:  1) review and provide comment on the concept of shared responsibility for pandemic preparedness; case studies on pandemic influenza; the evaluation of CDC’s public health ethics activities, guidance on public health data collections; and the new draft of the emergency preparedness and response ethics guidance; 2) obtain updates on the status of Department of Health and Human Services (HHS) draft guidance on pandemic influenza vaccine distribution and Ethics Subcommittee efforts to develop guidance on ventilator distribution, CDC development of a web-based public health ethics training course, and a request from Cambridge University Press that CDC edit a book on the ethics of health promotion; and clarify issues relating to member term lengths and the selection of the next Ethics Subcommittee Chair.

General Business
- New Oak Ridge Institute for Science and Education (ORISE) fellow, Neelam Ghiya, was introduced.
- Dr. Mary desVignes-Kendrick and Dr. Georges Benjamin are rotating off of the Ethics Subcommittee. Dr. Gerberding’s letter of gratitude to them for their contributions was read to those present.
- A public comment period was offered during each day of the meeting; however, no public comments were offered.

Pandemic Influenza Issues: Ethics of Shared Responsibility for Pandemic Preparedness
Benjamin Schwartz, MD, Senior Science Advisor, National Vaccine Program Office, HHS, provided the group with background information regarding pandemic influenza issues and issues of shared responsibility, especially as the concept applies to purchasing and stockpiling antiviral drugs. As production capacity for these drugs has increased, new strategies can be employed for prophylactic antiviral drug use. The Secretary of HHS is weighing the concept of “shared responsibility” regarding pandemic preparedness which would distribute responsibility for preparedness among a number of public and private sector partners. Several questions emerge in thinking about shared responsibility for purchasing and stockpiling antiviral drugs: Who should have that responsibility? How should the responsibility be implemented? What ethical questions and issues are raised by the concept of shared responsibility?
Dr. Ruth Macklin, the Ethics Subcommittee Chair, presented an analysis of these questions. The candidates to share the responsibility include the federal, tribal, state, and local governments; public sector organizations; private sector organizations; and individuals and families. Preparation for a public health emergency should be consistent with ethical principles. Potentially relevant concepts and principles include: 1) effectiveness, as defined by an arrangement for the purchase and distribution of antiviral drugs that will result in the best overall public health outcome (a statement that needs further elucidation); 2) efficiency, which addresses both cost and speed; 3) equity or fairness regarding access to the drugs; 4) reciprocity, so that those who assume greater risks receive greater protection; and 5) autonomy. Placing the bulk of the burden on insurance companies to purchase antiviral drugs fails to comply with several ethical principles.

Five conclusions flow from the analysis: 1) National recommendations on antiviral drug strategies (treatment and prophylaxis) must recognize the burden that will be posed and the ethical questions raised in purchasing and stockpiling the drugs. Therefore, those recommendations should be based on the best scientific evidence, the process for developing the guidance should be transparent, and the recommendations should be vetted with those who may bear part of the responsibility for their implementation; 2) Several applicable ethical principles must be considered in assessing policy options, but the overriding principle is that of effectiveness; 3) Autonomy is an important principle in a democratic society, but the public sector will need to assume substantial responsibility either through direct purchase of the antiviral drugs or by facilitating purchase in a way that best assures broad compliance; 4) Devolving responsibility broadly for purchase and stockpiling of antiviral drugs to organizations and potentially to individuals will inevitably violate principles of equity and reciprocity, unless the policy can be strictly enforced or a safety-net created that assures uniform access; and 5) Funds devoted to antiviral drug purchase and stockpiling are likely to be taken from other beneficial uses. A policy that maximizes both efficiency and effectiveness would, from an ethical perspective, be optimal.

**Major Discussion Points**

- “Payers” include more entities than just private insurance companies. Ultimately, the public health system is a “safety net.”
- Rules of equity state that in the context of an emergency, private payers cannot operate under policies to benefit their subscribers. Distinctions between public and private are broken in a disaster circumstance because the differentiation is counter to fairness and equity. People with insurance, but who have limited benefits, will need to have equal access to drugs.
- “Solidarity” is needed in an emergency. There should be an ethical mandate for coordination and collaboration among the various sectors.
- There was discussion regarding whether more affluent nations should have responsibility for other less developed nations and their stockpiles and if there should be stockpiling for Americans who do not live within the borders of the United States.
- In response to the question about providing antivirals to Americans working abroad, Dr. Schwartz indicated that American companies who operate oversees will need to be responsible for protecting their employees.
- The document needs concrete examples of the potential methods and players in these situations.
- Stakeholders will be engaged in discussions about shared responsibility in purchasing and stockpiling antivirals. The concept includes how widely the responsibility is shared and what the federal government can and should do to overcome barriers.
• The government can purchase antiviral drugs at a much cheaper rate than private insurers or the general public, which raises questions of efficiency.

• “Shared responsibility” can mean shared cost, or it can refer to each sharer’s capacity to make its own decision about how much to stockpile and what to fund, mirroring the United States’ current Medicare, Medicaid, and private insurance system. This approach of “fragmented responsibility” may not be appropriate in this case.

• Dr. Schwartz suggested that for the Ethics Subcommittee input to be useful to the HHS Secretary, their final input on would be needed by mid-December.

• Dr. Barrett reminded the group that all products of the Ethics Subcommittee are required to be approved by the ACD. Dr. Popovic commented that because of the current status of the ACD it may be difficult to obtain their review before the middle of December. Dr. Popovic also emphasized the point that charges to the Ethics Subcommittee should come from the ACD or the CDC Director.

Draft HHS Vaccine Distribution Guidance
Dr. Schwartz presented the draft guidance on prioritization of pandemic influenza vaccine distribution. The document addresses the question of who should be vaccinated earlier in the event of a pandemic. Targeting certain groups for earlier vaccination will support the pandemic response goals to reduce the health, societal, and economic impacts of the pandemic. The document itself and the process by which it was developed followed the ethical principles of transparency, inclusiveness, reasonableness, fairness, societal benefit, reciprocity, and flexibility. Public engagement and stakeholder meetings in Las Cruces, New Mexico; Nassau County, New York; and Washington D.C. were important to the process. The meetings resulted in the same four objectives for the prioritization: protect people who work to fight the pandemic and provide healthcare; protect those providing essential community services; protect those who are at increased risk because of their jobs; and protect children.

Fifty-seven population groups were defined by their occupation, age, and health status. The interagency group rated the extent to which each group met the occupation-related objectives. Then, CDC and external influenza experts rated the extent to which each of the groups met science-based objectives. Weights were applied to the ratings based on the public and stakeholder values. The highest-ranked groups included public health responders, healthcare workers, emergency medical services (EMS) providers, law enforcement, and children. Vaccination will occur by tiers that combine target groups across the four categories, and the structure is defined differently according to pandemic severity. The scheme will be flexible and adaptable to the pandemic situation. Many public health professionals are concerned about placing children high on the priority list, but this placement is consistent with public opinion and with mathematical modeling that suggests that protecting children may reduce the spread of influenza. The draft guidance will be vetted with the public and stakeholders in a comment period, which includes in-person engagement meetings as well as presentations and opportunities for Web-based response. The population estimates will be validated, and implementation options will be considered. Then the “Final Interim Guidance” will be complete, with the understanding that it will be revisited periodically.

Dr. Schwartz presented preliminary results from the public engagement meeting in Milwaukee the previous weekend. Overall, 80% of participants agreed or were neutral regarding the goals of vaccination, 68% agreed or were neutral regarding whether the overall draft plan was reasonable, and 88% agreed or were neutral regarding placing children above the elderly in the vaccination strategy. Several changes were suggested and agreed with by most of the participants. Dr. Schwartz requested that the Subcommittee provide comments in three areas: 1) The ethical principles that underlie the vaccine prioritization strategy; 2) Whether the draft
Major Discussion Points
- The inclusion of community input into the guidance development process was praised, and it was noted that CDC is responding to the values of the American public not just the values of ethicists.
- Planning for different levels of pandemic severity is a strong aspect of this guidance.
- A pandemic will likely evolve over time, influencing the benefits for those who are vaccinated early. People who are not vaccinated early in the event can be protected by other pandemic response measures.
- There was discussion concerning the recent public engagement meeting in Milwaukee, which revealed that a large segment of society feels disenfranchised and suspicious of the government.
- It was noted that in general, recommendations from the public gathered at the community meetings are incorporated into the final guidance based on their feasibility.
- The funeral industry should be included in the critical infrastructure.
- This document’s value hinges on its implementation, and it is crucial that members of each priority group be treated the same.

Update on Development of Ventilator Guidance
Dr. Kinlaw described progress on the development of a ventilator guidance to accompany the Ethical Guidelines for Pandemic Influenza. Guidance has been developed for ventilator use in a variety of settings, most notably from New York state. The new document should emphasize an ethical framework for decision-making about ventilator distribution however it will not include any specific recommendations regarding prioritization schemes. Drs. Kinlaw and Levine will act as the core Ethics Subcommittee representatives for this effort, and they plan to prepare a draft outline by January or February 2008.

Major Discussion Points
- The document should address the need for adequate supplies and the possibility of technical solutions, such as using ventilators for multiple people at the same time.
- The document should address the use of hand-bagging ventilators and the need to “cross train” personnel to be prepared in case the ventilator operators fall ill. Maintenance of the ventilators should be addressed, as well as “cross-training” technicians.
- The document should focus on priorities of allocation to first responders and healthcare personnel who may contract influenza and require ventilation.
- The document could consider the concept of alternate care as part of ventilator prioritization.
- The problem of ventilator allocation includes “medical futility” and questions of whether to remove patients who are on ventilators, but who have poor prognoses, from the ventilators to provide for someone who has fallen ill with influenza. Rotating patients among existing machines is another problem. These issues have been addressed in the arena of dialysis.
- It was noted that many ventilators are owned by private entities, which raises legal issues regarding who is in control of their allocation. Should ventilators be considered community resources when most of them are owned by better-funded facilities? State or local policies will likely be needed to govern distribution.

Review of Case Studies on Pandemic Influenza
Dr. Kinlaw introduced the proposed case studies, which will serve as another addendum to the original guidance regarding ethical issues and pandemic influenza. The case studies focus on the implementation of community strategies for mitigating pandemic influenza and address
issues of limits on individual freedom and creating social distancing. Their instructional goals and objectives include an obligation to maximize possible benefits and to minimize possible harms. Transparency and inclusiveness are important, as well as balancing individual freedom and the public good. The case studies could be offered in different educational settings and contexts, and so the materials should be flexible. Ideally, the cases would be presented by a facilitator to a group, and then discussion could occur.

**Major Discussion Points**
- It was noted that there may be too many questions after the second scenario. Further, the questions should better address concerns about stigmatization. Members of the Subcommittee commented that the second scenario seemed unrealistic.
- Questions that are more science-based as opposed to ethics-based could be removed or consolidated.
- With changes in the language used, the case studies could be useful for public engagement as well as for training CDC and state and local public health personnel.
- The goal of the case studies is to focus on rather than on providing “right answers” for the ethical standards. A cohesive and holistic discussion at the end of each study would be helpful. In addition, a “facilitator’s guide” may be a useful tool.

**Update on Development of a Web-Based Foundational Public Health Ethics Course**
Dr. Charles Magruder briefed the group on the development of a foundational level public health ethics curriculum. The Office of Workforce and Career Development (OWCD) received funding to pursue this project. PHEC is making recommendations for the curriculum’s content, and then subcontractors will create the training module. In a series of meetings, the PHEC Education Subcommittee addressed the issue of competence from several perspectives, the possibility of using the Collaborative Institutional Training Initiative as an initial framework, the necessary steps in ethical decision-making, the importance of case studies in considering those steps, and the importance of using a basic vocabulary of moral discourse.

The course should combine approaches and be relevant to public health practitioners inside and outside of CDC. It should be relevant to all CDC staff, not just scientists. In building the curriculum, the Education Subcommittee will first evaluate already-existing public health ethics curricula. The Web-based course will focus on basic public health ethics concepts. Additional money will be sought to develop more advanced training. Dr. James Thomas and Mr. Bruce Jennings are engaged in this effort.

**Major Discussion Points**
- It was recommended that the product be accessible to a number of target audiences and be translated into other languages.
- There was discussion regarding whether the curriculum should be Web-based, since ethical concepts benefit from discussion. It was pointed out that in order for the training to be available to a cross-section of CDC staff, the curriculum needs to be web-based; however, it may be possible for groups to go through the curriculum together and discuss it, or for “chat rooms” to be created as a medium for discussion.

**Update on Edited Book on Ethics of Health Promotion**
Dr. Barrett informed the group that Cambridge University Press approached them to develop an edited book on the ethics of health promotion. A small workgroup within the PHEC has considered this question. On November 20th, they will acquire input from the Center Leadership.
Council regarding whether this project is worthwhile. The book would include new articles and cover a wide variety of topics under the umbrella of health promotion.

**Major Discussion Points**
- It was suggested that a book grow out of the internal and external committees’ work and agenda, not from an outside source. Further, there may not be a market for such a book.
- The topic of health promotion is worthy of the Ethics Subcommittee’s consideration. A book could increase awareness of public health issues that CDC and its external partners face.
- There were concerns expressed related to the Subcommittee’s work, which is in the public domain. A published book would be for profit. Discussion centered around whether CDC can receive royalties and whether the book authors could receive compensation.
- It was suggested that CDC publish a book itself through its own mechanisms or that the Ethics Subcommittee consider publishing its white papers in a book-like series.

**Ethical Considerations for Public Health Data Collections: Review of Draft Ethics Guidance Document**

Dr. Macklin introduced a working draft of the “Ethical Guidance for the Collection, Use, Storage, and Dissemination of Public Health Data.” She noted that the structure could be altered for clarity. The document was originally intended to provide ethical guidance regarding non-research data, since abundant guidance exists for research and there is a lack of overarching direction for non-research data. However, Dr. Lisa Lee, the requestor for this document recommended expanding it so that the document was relevant to both research and non-research data collections. This is because the ethical standards that apply to managing and keeping data are the same for research and non-research and sometimes the line between research data and non-research data is not clear, so all should be treated similarly and ethically. Further, the federal regulations that govern research do not address some topics, so individual Research Ethics Committees or IRBs often create their own rules.

The paper includes an introduction and establishment of the need for the document in such areas as informed consent, disclosures, and information sharing. The paper describes public health practice and the various protections that already exist, some of which overlap or even conflict. The paper describes the major categories of public health practice data collection: surveillance and registries, field investigations, emergency response, contract tracing, and evaluation. Emergency response does not fall under research, but a sub-category includes research that may be conducted in the context of an emergency response. A section of the paper will address the collection of human biological materials. Recommendations from the National Bioethics Advisory Commission (NBAC) report on human biological materials in 1999 could be adapted for this document. A section of the paper addresses legal considerations relevant to data collections and data releases. Details of laws and regulations will be included as an annex to the document.

Part Two of the paper lists ethical considerations and guiding principles for public health data collection, storage, and use. The list of twelve Principles of Ethical Practice of Public Health, endorsed by the APHA, is included. The next section addresses data collection. Some principles are different in research and non-research contexts. For example, in research settings, the presumption is in favor of consent, where in non-research, open questions remain regarding when consent should be obtained, and whether obtaining consent is practicable and feasible. Other parts of the paper refer to data storage and the use of data for purposes other than for which it was initially collected. Dr. Macklin offered the ethical guidance statements on page 15 as a model or example for the guidance statements at the end of each of the sections.


**Major Discussion Points**

- There was discussion regarding the possibility for public health research to provide benefit to the individuals from whom data are collected. While subjects may receive benefits, for instance program evaluation or an epidemic investigation, public health research’s purpose is to develop information that will benefit the welfare and rights of all members of the community from which the subject pool was drawn.
- Additional discussion concerned whether and how to obtain informed consent in a scenario like 2007’s tuberculosis-infected traveler flying on an airplane. Data were collected from his fellow passengers, and clarity is needed regarding informing them of their potential risk and in collecting data or information from them. Other questions concerned storing data and information and using it in another context.
- A number of nuances were mentioned, such as how to work in international settings with different norms, what to do when obtaining informed consent does not make logistical or economic sense, and how to de-identify data as part of surveillance and then obtain consent.
- Without specific examples and focus, the document may be too large and therefore unhelpful. The federal government and state- and local-level agencies have different needs, and this document should be useful in the field.
- It was suggested that information is not limited to data collected as part of a study. Different types of information are managed by different rules and regulations. Although state laws exist to protect data, they vary widely.
- Rather than serving as a coercive document, this paper should include principles to empower people who make decisions about data collection on a daily basis.
- Comments were made regarding the need for epidemiologists in particular to have complete and timely data. Informed consent can introduce bias and make data less useful. Perhaps the document should specify precise settings in which consent should not be needed, such as in records, and address what happens in a face-to-face collection of information.
- Public health officials have an ethical obligation to use all of the available data to the fullest to protect the community. This guidance document should help people interpret what they can and should do with data given the variability among state laws.
- A structure was suggested for the document: It could include the categories of public health data collection activities, definitions and terms that apply to public health data collection activities, legal considerations, and the ethical obligations, questions, and considerations that arise in public health data collection activities. These obligations differ according to the audiences. Each section could include case examples to capture specific nuances, tension, conflicts, and resolutions.
- Also suggested was that the document include a section on personal responsibility and a discussion of the concept of “presumed consent.” There was debate regarding whether personal responsibility would be a useful topic to include in a document focused on public health professionals, and the idea of “presumed consent” may be dangerous. A section could discuss the obligations of citizenship, which would be helpful for practitioners.
- It was noted that it is difficult to truly de-identify data in this electronic age, especially when data is linked to genomic information.
- Regarding the NBAC recommendations made in 1999, concern was expressed that many elements of thinking and of the science have changed since then; therefore, this may not be an appropriate resource.
- Rules governing data collection differ not only from state to state, but on a case-by-case basis. The rules in an outbreak event are different from the rules that govern routine surveillance. Framing the document by data function could be helpful.
- While it is not possible to write an algorithm to apply to each state and local health department, the document can include general statements of support for those on “the front
lines” as they make daily judgments. Group consideration is needed for many of these issues, such as suspending the need for consent. When events transpire too quickly to assemble a group, a description of general circumstances in which it would be appropriate to override the expectation of consent would be helpful.

- It was recommended that the document consider community harms and group harms, as well as identifiable personal information. The document could address the most likely harm versus the worst possible harm that is likely to arise from ethically inappropriate use, storage, and dissemination of public health data.
- With the current wording regarding whether it is possible to obtain consent, some practitioners may construct the collection process so as not ask for consent at all. People who practice public health should be ethical, but the statement should still be clarified to remove doubt.

**Review of Proposed Evaluation of CDC’s Public Health Ethics Activities and Post-Public Health Ethics Consultation Evaluation**

Dr. Barrett introduced two evaluation instruments that are intended to assess CDC staff’s awareness of public health activities and their thoughts about the impact and value of those activities. Further, the instruments will assess CDC staff’s ability to use the concepts of public health ethics. A baseline assessment as well as repeat surveys could be administered via the Web. A wide range of CDC employees will be targeted.

**Major Discussion Points**

- The Subcommittee made several suggestions regarding the wording and language of the evaluation tools.
- It was suggested that the follow-up to the consultation evaluation determine why the respondent decided to request a consult and whether they would seek a public health ethics consultation again.
- The self-evaluation section could include additional indicators of capacity, such as whether the respondent agrees or disagrees with established concepts in public health ethics or whether the respondent is familiar with the APHA Code of Public Health Ethics or read articles about public health ethics.
- A survey structure that included scenarios could better assess the respondent’s abilities.
- The instrument would benefit from input from someone experienced in questionnaire design and from someone experienced in sampling.
- The evaluation could be based on the “stages of change” behavioral model. However, tools based on this model are usually lengthy and should be task-specific.
- It was recommended that the questionnaire include a preamble to define and clarify public health ethics so that it is not confused with scientific ethics.
- The survey should be piloted with different groups within CDC.
- The purpose of the document is to assess awareness that PHEC exists and of its activities as well as staff feelings about their own skills in addressing ethical issues. This purpose will be made clear at the outset. The survey results will inform PHEC’s future activities and help identify areas and topics for further training.
- Pre-assessments should take place before training sessions.
- The group discussed “fear of ethics” and the perception that ethics equates to ideology.

**Discussion of Ethics Subcommittee Member Term Lengths and Chair**

Dr. Barrett informed the group that in order to make the term ending dates for members of the Ethics Subcommittee consistent with the term ending dates for members of the ACD, terms will now end on June 30th rather than December 31. The first group of members to rotate off of the Subcommittee will end their tenure on June 30, 2008. Additional recommendations for new
members for the Subcommittee were welcomed. The next Subcommittee chair will be Dr. Tom Hooyman who will serve as chair until his term expires on June 30, 2009. It is anticipated that three meetings will be scheduled in 2008, two of them occurring before the end of June. Dr. Macklin will chair the first of these meetings, and Dr. Hooyman will take over as chair at the second meeting in order for him to benefit from the presence of Dr. Macklin on the Subcommittee for his first meeting as chair.

**Major Discussion Points**

- It was noted that the Subcommittee would benefit from the addition of members who work at the state and county level.
- The option of appointing a co-chair or a vice-chair during the year to provide continuity was proposed, since Dr. Hooyman will only serve as chair for a year before rotating off of the committee.
- Dr. Barrett expressed that she hoped to give new members as much time on the Subcommittee as possible and not to face rotations of large numbers of Subcommittee members at once. When the ACD members are officially appointed, then two ACD members will be selected to serve on the Ethics Subcommittee. It is also possible to bring members who have rotated off the Ethics Subcommittee back as consultants if their expertise would be useful for completion of a specific project.


Mr. Jennings explained that since their last meeting, Sections One, Two, Three, Five, Six, Seven, and Eight of the document have been “polished” and edited. Section Four on allocation of resources is new material. The working group is considering a draft of Section Nine on research. They have not begun writing Section Ten, which will address the special ethical issues of CDC personnel. Dr. Arras offered “highlights” of Section Four, indicating that it discusses why deliberating about ethics and justice issues in the course of disaster is difficult and the importance of making these deliberations during advance planning. Issues of justice for the recovery phase should be considered in this phase as well. There are conflicts between planning for the worst possible case, which will require expensive and dedicated stockpiling, versus developing a sound public health infrastructure. Further, until the disaster hits, it is not possible to know how bad it will be. Another potential conflict exists between achieving efficiency versus equity. A number of issues still remain, such as maximization. There does not appear to be consensus regarding the sacrifices in efficiency that are “worth it” to focus attention on groups who are worse off or vulnerable. When faced with a number of possible solutions to a distributive problem, and all solutions seem to be sufficiently just, then a process should create a “fair” definitive solution to yield legitimate, acceptable conclusions. The process might include: transparency in decision-making; the need for those who are part of the discussion to focus on relevant, important matters rather than sectarian interests; and an appeals process.

**Major Discussion Points**

- One of the commissioned papers will address fundamental tensions and different values that people in society hold regarding stockpiling. A deliberative, democratic procedure is needed for stockpiling. The commissioned paper includes six elements of fair process, whereas the White Paper narrative describes three. Linking those six elements of fair process to the activities that take place in determining answers to the stockpiling question may be more helpful in implementation than just a listing of tensions.
- Each chapter could benefit a wider audience if it included recommended practices. For instance, each chapter could delineate which decisions are made at upper levels, which decisions need to be made locally, and which decisions cannot be foreseen, so a
mechanism should be in place to make those decisions when the time comes. The
document can address who should be represented in the decision-making group, as well as
the skills, authorities, and training they need to have.

- Some aspects of this document parallel the document on preparation for pandemic
influenza, and the documents will be stronger if they use similar language.
- It was suggested that Section Eight, which deals with civic obligations and personal
responsibility, become part of a preamble or framework for the entire document. The ideas
in the section create a unique way of looking at emergency preparedness and response.
- It was suggested that each section include summary bullets or questions for discussion at
the end. These summary bullets could address the skills, policies, and groups needed and
where the ethical principles come into play.
- Advice regarding ethically sound, democratic decision-making would be helpful.
- Transparency and an appeals process are key elements of the preparedness phase, but
may not come into play in disaster response.
- The document could address the concept of inherent community capacity and infrastructure.
- It was suggested that the paper more systematically address transparency in each of the
three phases of preparedness, response, and recovery. Accountability and the appeals
process could be described as well.
- The Subcommittee considered whether the document on allocation of ventilators would be
appropriate for inclusion in this document. Ventilator guidance is being developed as an
addendum to the pandemic influenza preparedness document because of the respiratory
nature of the illness.
- The pandemic influenza document claims that maintaining critical infrastructure should be
the highest priority during pandemic influenza, which is a society-wide disaster. If there is a
shift in thinking between the pandemic influenza and the emergency preparedness
documents, then this shift should be explained. In a catastrophic event, the ordinary
principles and priorities may not be as important, and principles of efficiency and protecting
public infrastructure might take precedence.
- Two categories of resources are scarce in an emergency event: 1) consumables such as
vaccines and antivirals, and 2) non-consumable, reusables such as ventilators. Depending
on the disaster, the non-consumable reusables may be different, but principles for allocation
may be similar. Personnel may also be a scarce resource, and allocation of personnel is an
important topic to cover, particularly in the response mode. Another resource allocation
question in a pandemic will be the use of antivirals for CDC personnel. Practical advice
about the process for reaching conclusions would be helpful.
- Discussion centered around the previous day’s presentation on public engagement on the
HHS influenza vaccine prioritization guidance. It was recommended that the emergency
preparedness document consider the degree of consistency or inconsistency between
community feedback regarding resource allocation, feedback from healthcare workers, and
government priorities.
- CDC is in discussion regarding the best specific publication venue for the White Paper and
the five commissioned papers.
- The “Conclusions and Recommendations” could serve as the document’s “take-home
messages.” There was discussion regarding the differences between this section and an
Executive Summary, which could be more discursive and stand separately from the rest of
the document. Alternatively, the Executive Summary could outline the document’s purposes
and content while the conclusion could include practical bullets and recommendations as
well as a narrative.
- It was suggested that the document include a figure or chart to identify the three phases of
planning, response, and recovery, and fill in abbreviated notions and recommendations that
are appropriate to each phase.
• It was suggested that the document include “next steps” or articulate specific gaps that need to be addressed.

**Action Items**

Nine action items emerged from the meeting:

1. **Shared responsibility document:** The Subcommittee will wait to hear from Dr. Popovic regarding whether it will be possible to obtain ACD review of the document in a timely fashion that would allow the document to be considered as part of HHS’ deliberation about the concept of shared responsibility. If review and approval by the ACD cannot be completed before the end of the year, pieces of this document could be used in connection with the Subcommittee’s other work. If it appears that ACD review can be scheduled in December, Ethics Subcommittee members will be asked to provide their comments on the document by Wednesday, November 21\textsuperscript{st}. Dr. Macklin will, in consultation with Dr. Barrett and Dr. Schwartz, revise the document.

2. **Ventilator guidance:** Material will be ready for review by the Subcommittee’s next meeting.

3. **Case studies:** Dr. Levine, Dr. Kinlaw, and Mr. Jennings will provide advice to the CDC members who are writing the case studies.

4. **Educational tools:** The committee will not engage in action items pertaining to the educational tools.

5. **Public health data collection document:** Subcommittee members and CDC personnel will provide cases and other materials. Dr. Gamble, Dr. Macklin, Dr. Barrett, and CDC members of the working group will revise and modify the draft in light of the meeting’s discussion. Dr. Koenig added that OHRP’s work regarding the research-practice divide might help them as they build their document. Dr. Barrett indicated that she will work with Dr. Lisa Lee to clarify the scope of the document.

6. **Evaluation instrument:** The instrument will be revised in light of suggestions made at the meeting. CDC will undertake some of the additional steps suggested at the meeting, such as selecting a sample, piloting the new instrument, and consulting an expert in questionnaire design.

7. **Emergency preparedness and response paper:** Dr. Arras and Mr. Jennings will incorporate the day’s discussion into the next draft, including structural changes, and add the new material. It may be useful in the next draft to highlight which material is new so they can focus their review on these sections. Mr. Jennings clarified that Sections Nine and Ten would be new material.

8. **Next meetings:** Subcommittee members should send known conflicts for February, early March, and June to Dr. Barrett.

9. **Additional suggestions for new Subcommittee members:** Dr. Barrett will re-send the list of names that have already been suggested, and if Subcommittee members have additional suggestions, then they are welcome to send them in.
Closing Session
With no further business brought before the Ethics Subcommittee or PHEC, Dr. Macklin adjourned the meeting at 3:00 PM on November 16, 2007.

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

02.04.08
Date

[Signature]
Ruth Macklin, Ph.D.
Chair, Public Health Ethics Subcommittee