DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention/
Agency for Toxic Substances and Disease Registry

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 25, 2008
Meeting Held by Conference Call

Record of the Proceedings

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Acronyms Used in This Report

ACD	Advisory Committee to the Director
CDC	Centers for Disease Control and Prevention
COTPER	Coordinating Office for Terrorism Preparedness and Emergency Response
DHS	Department of Homeland Security
HHS	Department of Health and Human Services
IRB	Institutional Review Board
MMWR	*Morbidity and Mortality Weekly Report*
OFRD	Office of Force Readiness and Deployment
OSHA	Occupational Safety and Health Administration
PHEC	CDC Public Health Ethics Committee

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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 25, 2008 by conference call. Meeting participants are listed in Attachment 1.

Welcome and Introductions

Thomas Hooyman, PhD, Chair, Ethics Subcommittee, called the meeting to order at 12:00 noon. He welcomed those present, thanked everyone for their participation, and led the group in a round of introductions.

The purpose of this conference call was to review the draft white paper titled, "Ethical Guidance for Public Health Emergency Preparedness and Response: *Highlighting Ethics and Values in a Vital Public Health Service.*" Dr. Hooyman explained that the group should focus on content issues during the call, while any grammatical and typographical issues noted should be emailed to Mr. Jennings or Dr. Arras. He pointed out that if PHEC could come to consensus about content of the document and vote to approve it, it could then be finalized for submission to the Advisory Committee to the Director (ACD) which is meeting on October 30, 2008.

Overview & Discussion

Overview

Mr. Jennings reported that Ethics Subcommittee decided some time ago to develop a white paper to provide a broad ethical framework for public health emergency preparedness planning and response, the 17th draft of which the group would deliberate during this call. The paper attempts to address both the particular types of decisions and ethical dilemmas that public health responders face, and to offer a sense of the ethical importance or dimension of public health emergency planning itself as an enterprise or component of the field of public health.

While a number of sections were already reviewed and commented upon by the previous Ethics Subcommittee members, additional sections have been added, and new Ethics Subcommittee members are reviewing the document for the first time. Since the Ethics Subcommittee's last review of the document, the Executive Summary and Conclusion have been added. Numerous changes were made to the document in response to the last round of comments received during the last Ethics Subcommittee meeting and subsequently from a number of CDC staff members in the interim. The document as it stands, at least in terms of the outline and sections, is now complete. There remain some issues with respect to some of the references in the bibliography, but Mr. Jennings thought that issue could be set aside during the call unless anyone wished to add references that should be included.

In terms of the structure of the document, Mr. Jennings explained that Part I of the document contains the general introduction (Section 1), which states why ethical issues in this area are important. The conceptual framework is then laid out in the form of ethical goals and ethical decision making for emergency planning (Section 2). Sections 3, 4, 5, 6, 7, 8, and 9 constitute Part II of the document and address particular problems that are related to the framework of ethical goals and decision making. These sections address the importance of health, safety, and wellbeing throughout the community; constraints on individual liberty and autonomy; problems of distributive justice and the allocation of scare resources; accommodating special needs and special vulnerabilities among different groups; communication and participation in the planning, follow-up, and recovery processes; special obligations of professionals (e.g., physicians, public health professionals, nurses, and others); and the sense in which public health emergency planning is a responsibility of the government and the community as a whole, as well as each individual.. Part III is somewhat more focused on particular concerns articulated by CDC colleagues. A section is included regarding activities that seem to raise special ethical questions concerning human subjects participation with respect to research in the context of emergency response. A section is also included on special ethical considerations for CDC personnel who are deployed during an emergency response.

The Executive Summary more or less reflects the structure of the entire document: the background and introduction to emergency preparedness; the definition; a summary of why ethical considerations are important to this field; the framework itself in bullet point form; and italicized guidelines / recommendations. A struggle with this document pertained to a suitable level of specificity or generality in terms of any recommendations or conclusions made. The document was not designed to serve as a practical manual, field guide, or code of ethics for emergency responders. Instead, the italicized statements sometimes highlight important themes / orientations the document offers to the public health community. There are some more concrete recommendations, particularly with respect to the importance of public participation and engagement in emergency planning and preparedness, and the importance of making advance provisions for special needs and vulnerabilities. The primary goal was to capture the general themes and core ideas of the document itself, using the graphic techniques of italics and bullet points to make this visual acceptable and easy to accommodate. Deliberately, numeric points were not made in order to avoid the misleading tendency to suggest that one item is more important than another. No order of priority is meant to be suggested in the concluding statements.

Discussion Points

- Dr. Besser commended those involved for having done a brilliant job in crafting this document. As he read through it again, he was struck by the richness of the document and was motivated to think about how to utilize this for training materials in order to assist state and local responders' in their preparedness efforts. As a whole, he thought the document would help move forward what is done in preparedness. Given the length of the document, he stressed that the Executive Summary would be critical as a majority of readers would likely focus on this section alone. The remainder of the document will likely be used for particular purposes to delve down into specific areas. With regard to ethical issues for CDC responders, one piece in the section which deals with this that does not seem to be addressed in the Executive Summary regards the ethical appropriateness for CDC responders to make recommendations during a response based on limited information. That is, there may be an ethical problem in not dealing with an issue because CDC responders believe they must have *all* information in order to make a recommendation.

- Given that the Executive Summary may be the only component of the document read by many people, Dr. Bayer expressed concern that it is written at a level of abstraction that leaves some of the strong points too abstract and not specific enough. He was troubled throughout the document with the need to deal with all types of emergency responses (e.g., infectious disease, pandemic threats, natural disasters, et cetera). These different types of events raise different types of ethical questions in terms of planning and intervention. In the document, there is a tendency to move from one to the other to use them as exemplars of broader points. To Dr. Bayer, this confused the ethical question involved. There is a difference between isolating / quarantining someone due to an infectious threat versus dealing with someone who refuses to leave their home in the context of a hurricane. Issues of paternalism, liberty, et cetera take on different meanings in these very different contexts; however, this is not captured by the Executive Summary. If, indeed, people read only the Executive Summary, they will miss some of the important ideas involved in the paper itself. For example, at the top of page 8, there is a very brief reference to the issue of whether an activity is research versus surveillance. This is a hotly contested issue with very different sets of obligations, yet there is no sense of this in the document. For example, people who are part of surveillance operations should not be referred to as human subjects participants.

- Dr. Barrett commented that there had been considerable discussion at CDC about the issue of research versus surveillance, and it was decided not to deliberate this issue in the document but instead the intent was to focus on ethical issues.

- Dr. Lo shared the concern that the document is so inclusive it is difficult to get through. With respect to the Executive Summary, he raised four points: 1) it would be useful to clarify how public health emergency preparedness ethics differs from public health ethics in general; 2) further consideration should be given to whether ethics in the emergency preparedness context is more about minimizing harm rather than providing benefits; 3) a lot of attention is rightly paid to the individual professional responsibilities of CDC personnel; however, an issue that always arises in emergency situations is how public health officials should interact with other government officials who have overlapping or complementary responsibilities, but do not necessarily share the professional ethics of public health officials; and 4) page 5 of

the Executive Summary includes many good ideas, but it is difficult to follow the guidelines / recommendations—consideration should be given to some type of hierarchical structure with more overarching or general guidelines / recommendations. In addition, he did not believe the last three lines in the Executive Summary were the best way to make the point he thought they were attempting to make. Most of the document is saying that public health emergency preparedness is different from ordinary public health. To seemingly reduce this to just more and better public health infrastructure did not seem to do justice to some of the issues. For example, personal physical risk is generally not an issue for CDC personnel in ordinary public health practice.

- Mr. Jennings noted that the white paper rejects the notion that emergency preparedness is in conflict with other forms of public health. They were carefully attempting in this document not to drive a wedge between emergency preparedness and public health, or between emergency ethics and public health ethics more generally. The idea was to integrate this particular set of activities, planning especially, into the entire array of public health activities practices conducted with and for the community.

- Dr. Arras thought a fundamental issue was to use a different acronym to describe this effort. Mr. Jennings noted that early on it was suggested that a phrase resulting in a four-letter acronym such as Public Health Emergency Preparedness (PHEP) would be more suitable, the committee insisted that all of the terms be utilized. Dr. Arras said he thought they had been collectively wrong about this, noting that it would be easy to change in the final document. Others agreed that the acronym should be simpler.

- Referring to page 37, figure 4.1, Dr. Bayer expressed concern about the “assault on personal liberty” being very tough language. He suggested that “restriction” freedom differed considerably from “assault” and that further consideration should be given to this type of phrasing throughout the document. In addition, the refusal of a person to leave their home during a flood or hurricane does not simply affect that individual. This has implications for the entire community and responders as well. For example, refusal to leave may lead to the necessity of being rescued later. A mandatory removal is not simply to protect the individual, but also is to protect the community from having to intervene later or perhaps to protect children who are made vulnerable by their parents refusing to leave. Many issues are involved (e.g., age, psychological state, illness, et cetera). This is a major issue that requires much greater guidance than is offered in the document. It is important to discuss what mandatory evacuation means, what levels of coercion are appropriate, and how to prioritize such issues. While the document certainly cannot offer an answer for every possible scenario, the reader has the right to expect some guidance on the juncture at which paternalism is justified. The discussion does not have enough “bite.” Even if there are no concrete, agreed upon ethical principles, the document should at least acknowledge that responders and policy makers are going to have to make decisions in these regards and will not have the luxury of saying there are no theoretical resources. Ethics can take them only so far. Moreover, the document is very long. While the reference to Plato is lovely, for example, to the reader of the *Morbidity and Mortality Weekly Report* (*MMWR*) consideration must be give to whether the document will make them feel lifted up or burdened down.

- Dr. Barrett noted that another member of the workgroup raised the issue regarding "assault on liberty" and suggested changing the phrase "assault on liberty" to "perceived loss of liberty."

- Dr. Hood appreciated the opportunity to review and comment on the document, which he found overall to be an important contribution to and synthesis of the literature, particularly with respect to recognizing the areas in which there is not consensus. He concurred with the suggestion to change the phrase "assault on liberty" to another phrase such as "unnecessary restriction on liberty." With respect to the concern about emergencies differing, he suggested inserting a paragraph at the beginning of the document to recognize that there are differences among disasters, but that an all-hazards approach addresses infectious disease, natural, and bioterrorism / radiological disasters and that throughout the document when these are referenced, they are used to illustrate points that are made—not to imply that these three types of disasters are the same or raise the same issues. With regard to the section on research (Section 11, Page 133), Dr. Hood suggested adding language to encourage institutions with Institutional Review Boards (IRBs) to view IRBs as having an emergency preparedness function, encouraging them to have plans in place for emergency response and to train and exercise those plans. He seconded the idea to have CDC facilitate a coordination of review, suggesting the following addendum to Page 133, line 10, ". . . expedited protocols drafted in response to ongoing emergencies, and encourage other IRBs to join efforts to coordinate review during declared public health emergencies." Other federal agencies have not done as much as possible to encourage IRBs to coordinate reviews, so it would be beneficial to signal that here. At the end of the paragraph that begins on Line 20, Page 133, add a sentence to read, "Regardless of whether institutions would like to participate in a centralized review process, IRBs should be included in PHEPR and should plan and exercise their ability to respond to requests for review of research in disaster settings with appropriate expertise in a timely manner." Dr. Hood will email the specific language to Dr. Arras.

- Ms. Berryhill agreed that the language should be kept simple, that the document should not be too lengthy, and that otherwise they were on the right path. With respect to vulnerable populations, she stressed that this document should lay out clear, precise ideas about how to deal with gray areas.

- Dr. Piacentino of the National Institute for Occupational Safety and Health (NIOSH) brought forth several comments from NIOSH's staff members who reviewed the document:

    → The general consensus was that the document is comprehensive and very impressive. The comprehensive nature of the document is its strength.

    → Section 8, which discusses public health workers and resonated heavily within his group, adequately describes worker responsibilities in terms of assuming risk. However, the discussion on the employer responsibilities for worker protection did not resonate well. The group pointed out that this section presented the counter argument in terms of society at large having obligations for worker protections, but for whatever reason, the idea of society at large did not seem to translate well within NIOSH. When they look at society's obligation to workers and protection, what they are really discussing is employers' responsibility. NIOSH views those employer

responsibilities in terms of recommendations versus regulations. The group felt that it was important to remind the readers that in addition to having a social obligation, there is also a regulatory obligation. NIOSH staff did not think the discussion captured their need to see worker protection characterized in terms of regulatory responsibilities specifically with the Occupational Safety and Health Administration (OSHA).

→ The document discusses CDC responsibilities during mobilization efforts, but NIOSH staff thought it was important to reiterate CDC's responsibility as an employer to protect its mobilized personnel. While this message may be inferred, NIOSH staff believed that message should be reiterated overtly.

- Mr. Jennings expressed appreciation for NIOSH's review and comments. He suggested that perhaps the employer responsibility comment belonged in Section 9 rather than Section 8, given that Section 9 seemed to be a natural home to make clearer that public / civic / governmental structures as well as private / corporate structures are expected to assume their responsibilities. The burden of Section 9 is that they do not want to have an "every man for himself" philosophy. Regarding Section 11 and CDC deployment, perhaps the intent was not made clear. He was under the impression that a great deal of that section pertained to what CDC as an employer, and organization, owes to its employees in terms of proper training, material support, not being arbitrary in making deployment assignments, providing counseling and support upon return from a deployment, guidance when being told to do something that one believes to be ethically wrong when in the field, et cetera. Mr. Jennings said he would appreciate further suggestions in crafting the right wording if this was not, indeed, clear.

- Dr. Piacentino responded that he did not make clear that the group was suggesting that some of this be included in the Executive Summary as well. This did come through clearly in Section 11.

- With respect to Page 20 and the all-hazards approach, it struck Dr. Lo that there were two issues which needed to be distinguished: 1) emergency versus routine public health; and 2) public health personnel versus people in communities. With respect to the importance of fairness in the implementation of policies, Page 25 addresses how acceptability depends upon both the substance of policies and the process by which they are arrived at. However, as Hurricane Katrina showed, policies that seem facially neutral get implemented in ways that have disparate effects. The notion about fairness depends upon how apparently good policies are implemented. He would like to see more discussion regarding implementation throughout the document.

- Dr. Barrett read into the record the following comments shared by PHEC members who could not attend the call:

  → The term "paternalism" is emotionally loaded, subjective, and may mean different things to different people. It was suggested that this word be replaced with "authoritarian" or "authoritative."

→ There is often a conflict between CDC staff deployed through the Department of Health and Human Services (HHS) Office of Force Readiness and Deployment (OFRD) versus those deployed through CDC. Include some discussion about this in the section dealing with CDC responsibilities. Dr. Barrett noted that information was added to clarify that CDC deployments through the Commissioned Corps differ from deployments directly through CDC, and that perhaps additional language could be added there to address this comment.

- Dr. Bayer thought it would be a major mistake to drop the word "paternalism." Instead, perhaps they need to make very clear what the word means, but the concept is not simply about "authoritative" or "authoritarian." The term "paternalism" carries a special and important meaning in public health. Others agreed. It was suggested that not only should "paternalism" be better defined, but also that the misunderstandings it may cause be addressed as well. While it was suggested that a footnote be included, others thought it should be addressed head on in the text.

- In addition, Dr. Barrett read into the record an e-mail sent by Dr. Vanessa Northington Gamble, an Ethics Subcommittee member who was unable to participate in today's meeting.

  Because of a longstanding commitment for NIH, I will not be able to take part in today's meeting. However, I wanted to let you know my concerns about the meeting. I think that it is important to discuss the document, but do not think that we should vote final approval today. As some of you know, I had some major concerns about the previous draft because of how it inadequately dealt with the issue of vulnerable populations, particularly racial and ethnic minorities and the poor. As I informed Tom [Hooyman] and Drue [Barrett], other commitments and travel have made it impossible for me to closely review a 200-page document to see if my concerns have been addressed. Furthermore, I think that we have not done much to solicit public comment on this important document. Merely placing an announcement in The Federal Register is not enough. Given the impetus for this document I think that it would be in CDC's best interest to demonstrate that we have attempted some community engagement. What has not been made clear to me is why we need to vote on this today. If it is necessary to go forward at this time, I will have to vote no and ask the document only include the names of the committee members who have approved it. Again, sorry that I will not be to be on the conference call today.

- Dr. Barrett reminded the Ethics Subcommittee members that there had been previous discussions in the Ethics Subcommittee meetings about when the most appropriate time would be to engage in public comment for this document. Internally at CDC, it seemed to make sense to conduct a public engagement process at a later time when the document may be used to generate policy decisions. The current plan was to distribute the document for public dissemination through a special supplement of the *MMWR* in order to obtain wide discussion and input.

- With respect to procedures for moving the document forward, Dr. Barrett pointed out that all decisions made by Ethics Subcommittee must be made within a public forum. If members were confident that the authors would handle their suggestions suitably, they could vote to approve the document. This was done with the pandemic flu document. They also had the option to table the vote and schedule another meeting to further review the document after the suggested changes were made. However, she cautioned that the deadline to act was set for Friday, October 10th in order to finalize it for submission to the ACD in time for their

October 30th meeting. There would need to be consensus on the final document to be submitted to the ACD rather than submitting a document to ACD that they planned to revise further.

Public Comment

No public comments were offered.

Wrap Up, Adjournment, and Certification

In conclusion, the members agreed to table their vote until they could review revised document which addressed the suggested changes. Mr. Jennings and Dr. Arras agreed to make the revisions by October 2nd, using the "track changes" function in order to help the members focus on those areas in which revisions are made.

A conference call will be convened the week of October 6th to engage in a discussion and vote on the revised document, which should allow ample time to submit the final document to the ACD [Note: Subsequent to this conference call, the next conference call was scheduled for October 9th from 12 p.m. to 2 p.m. EST].

Motion

A motion was made and seconded to adjourn the meeting. With no further business posed, Dr. Hooyman officially adjourned the meeting at 1:30 pm eastern daylight savings time.

October 23, 2008
Date

I hereby certify that to the best of my knowledge, the foregoing minutes of the September 25, 2008 Ethics Subcommittee meeting are accurate and complete.

Thomas Hooyman, PhD, Chair
Ethics Subcommittee, ACD

Attachment 1: List of Attendees

Ethics Subcommittee, Advisory Committee to the Director

Arras, John
Bayer, Ronald
Berryhill, Vivian
Hooyman, Thomas (Chair)
Hood, Robert
Jennings, Bruce
Lo, Bernard

Centers for Disease Control and Prevention

Barrett, Drue (Designated Federal Officer, Ethics Subcommittee)
Besser, Rich
Dixon, Richard
Durant, Tonji
Campbell, Scott
Ellis, Barbara
Esbitt, Deborah
Garza, Roberto
Ghiya, Neelam
Latimer, Annie
Malilay, Josephine
Fred Murphy
McDonald, Daniel
Piacentino, John

Members of the Public

Brewer, Katie (American Nursing Association)
Maskay, Manisha (Tarrant County Public Health Department, Texas)
Meyer, Wolf (European Commission)