

**Joint Meeting of the Ethics Subcommittee of the
Advisory Committee to the Director
Centers for Disease Control and Prevention (CDC) and
CDC's Public Health Ethics Committee**

**November 23, 2009
Teleconference
3:00 – 4:00 pm**

Summary Proceedings

Introductory Remarks and Overview of Meeting Goals

Robert Hood, Chair, Ethics Subcommittee; Public Health Ethicist, Florida Department of Health

Drue Barrett, Designated Federal Official, Ethics Subcommittee

Dr. Hood officially called the meeting to order at 3:00 pm, welcoming those present and thanking them for their time and attendance. Dr. Barrett requested that those on the call send her an email at dbarrett@cdc.gov to acknowledge their attendance for the record.

Dr. Hood offered his welcoming remarks, indicating that the purpose of this teleconference was to review the changes in the ventilator guidance document, discuss its status, and consider approval of the document. He explained that by "approval" they meant that a determination must be made regarding whether there was consensus that the ethical points discussed in the document accurately reflected the general ethical considerations that this subcommittee believes public health officials should consider as they develop their plans. This document will then need to be approved by the Advisory Committee to the Director (ACD). At this time, Dr. Hood called for declaration of any conflicts of interest (COIs) among members of the Ethics Subcommittee. No COIs were disclosed.

Dr. Hood then summarized the proposed changes that were made to the document since the October 15th meeting:

- The definition of a "severe pandemic" was clarified, which is found in the introduction section. Language is now included that states that there is no standard definition of a severe pandemic or list of features to distinguish it from a pandemic, and which sketches out the context that pertains to this document and issue. In the context of this document, a pandemic becomes severe when the demands for treating patients significantly exceed the system's capacity despite attempts to increase surge capacity.
- The heading "General Ethical Principles" was changed to "Basic Biomedical Ethical Principles" (page 9).

- ❑ The heading “Specific Ethical Considerations” remains the same, but a sentence was added that states, “In addition to the basic biomedical ethical principles discussed above, there are a number of more specific ethical considerations that will be useful in guiding decision making about allocation of ventilators. These considerations focus on different approaches to maximizing and distributing benefits (page 11).
- ❑ The concept of “social worth” was clarified (page 13).
- ❑ Language was added to clarify that state and local authority during a public health emergency may vary from jurisdiction to jurisdiction and that officials will need to understand the scope of their authority (page 17)

At this point, the subcommittee members indicated that they were comfortable with the revisions as described.

Dr. Hood then focused on the comments submitted by Dr. Daniels, a member of the Ethics Subcommittee, which were as follows:

- ❑ The definition of a severe pandemic implies that there could be regional variation; this should be clarified in the introduction; discussion points about this comment were as follows:
 - Information was added here about how to define “severe pandemic” and that it may vary by disease, different communities, and / or by different communities or regions experiencing the same disease; perhaps something could be added to the definition that points out that severity may be different within different regions or counties
- ❑ There is some confusion between about how some of the sections fit with each other; Dr. Daniels’ suggestion was to state at the beginning of the section on routine versus emergency practice priorities for ventilator allocation that this and the next two sections pertain to how to modify ethical considerations during a severe pandemic (page 9); discussion points about this comment were as follows:
 - This clarification could easily be made on page 7 at the beginning of the routine versus emergency practice priorities
- ❑ Currently, the document is organized to frame the consequentialist view in terms of maximizing the number of lives saved; Dr. Daniels pointed out that non-consequentialist views could also support maximizing the number of lives saved based on the justification that each life has an equal claim on being saved (page 11, lines 39 and 40); discussion points about this comment were as follows:
 - From a Utilitarian perspective, maximizing the number of lives saved is widely accepted during a public health emergency; Dr. Daniel wanted to clarify that this was also consistent with non-consequentialist views

→ This is simple to edit and can be inserted following the sentence on page 11, lines 39 and 40

→ Dr. Daniels clarified that he would say *some* non-consequentialists views

□ Dr. Daniels commented that the life cycle principle of allocating based on age is not a simple linear function (page 14, lines 33 to 37); discussion points about this comment were as follows:

→ Dr. Daniels clarified that what he meant was that priority is not given to someone 37 years of age over someone 38 years of age; instead what is important are significant differences in age

→ Perhaps a clarifying sentence could be added to point out that prioritization based on the life cycle principle is not a simple linear function of a persons age; the emphasis is on looking for significant differences between groups; Dr. Daniels concurred

Dr. Hood indicated that the document was also circulated among Senior Management Officials (SMOs) from CDC who are stationed in approximately a dozen states, and other leadership at CDC. Comments received were as follows:

□ The SMO from Ohio requested that the discussion include more information about ways to operationalize the document. Discussion points about this comment were as follows:

→ With regard to operationalization or next steps toward implementation, the purpose of this document is to address points to consider; it was never meant to be a specific recommendation regarding triage decisions—these decisions will be made by the states, which the document emphasizes

→ The points made about the scope of the document in the introduction could be restated in the conclusion

→ Perhaps the conclusion could state something about next steps, which include the development of policy decisions by responsible public health officials.

□ The Ohio SMO also raised a question about who should be involved in the retrospective review of triage decisions. It was suggested that the team doing the retrospective review should not include the person or team who made the original triage decisions. Discussion points about this comment were as follows:

→ The purpose for this separation is to avoid conflicts of interest such that a separate team would engage in the triage process and another team would review the decisions made during the triage process

- The general context of this comment was to ensure fairness in standards for decisions across areas
- It should be stated explicitly that there is a reason for different teams in that it is important for planning to be done ahead of an incident, for the triage process to be transparent, and for a different team be responsible for retrospective review in order to avoid conflicts of interest
- A comment from CDC leadership requested clarification about how the document would apply; discussion points about this comment were as follows:
 - The intent in writing this document was a recognition that it does not apply to the current situation of pandemic H1N1 as of 11-23-09 because there are not shortages of ventilators in the United States, although a severe pandemic could occur in the future with an additional wave of the current virus or a more severe strain that increases transmission or severity; perhaps clarification of the logic would address this comment
 - Reference is made in the document to the current H1N1 pandemic, with a statement regarding how to handle an increase in severity
 - The request seems to mean simply to clarify the current situation; this could easily be done in the conclusion section
- Concern was expressed by a participant on this call about ventilators being used in the home setting in terms of whether use standards would apply to them (e.g., Could someone be asked to relinquish their ventilator to the hospital ICU?); discussion points about this comment were as follows:
 - This document addresses allocation decisions for shared pools of ventilators in institutions, predominantly held by hospitals, states, and emergency settings. It does not address ventilators in people's homes.
 - There is a section that addresses the fact that, in general, public health has different degrees of legal authority in different states at the state, local, county, and city levels to use private assets during declared emergencies; it will be important for public health officials to understand the scope of their authority

Motion: Ventilator Guidance Document

A motion was made and seconded to approve the ventilator guidance document with the incorporation of the minor revisions suggested. The motion carried unanimously.

Dr. Barrett pointed out that this group has been discussing this document for several months. The goal for today's meeting was to review the final changes and vote on the document in order

to move it forward to the CDC Advisory Committee to the Director (ACD). The Ethics Subcommittee is a subcommittee of the ACD, so everything that this group does must be approved by the ACD. The ACD convenes regularly scheduled meetings that are typically at the end of April and the end of October. However, they are trying to arrange a meeting within the next one to two months. One of the issues the ACD will address during its next meeting will be the ventilator guidance document.

Public Comment

Marcia Baker EIR News Service

Ms. Baker noted that it was stated in the report that the Association for Respiratory Care estimated that there are 65,000 to 105,000 ventilators in the United States. This is a major gap. She wondered how there were no problems now and whether they were just hopeful that a cluster of cases did not occur in a geographic area with very few ventilators. Regarding the group's mandate as a subcommittee, since this is a guidance document, it was not clear why they were not emphasizing building infrastructure so there would be no shortages. Ms. Baker pointed out that there are not even enough beds for 1,000 patients in many parts of the country. There certainly are not enough obstetric facilities. It is important as leaders of this country to reiterate that quality life adjusted years (QALYs) and other such measures should not be the priority.

Maggie Elestwani Texas Collaborative for People with Disabilities

Ms. Elestwani raised three issues/questions: 1) While ventilators in the home were not being discussed at this time, she wondered whether consideration had been given to individuals who already have ventilators who present to the emergency department seeking treatment in terms of recommendations about how that would be addressed; 2) In the discussions engaged in by the subcommittee, she wondered whether there had been a recommendation regarding increasing public/stakeholder engagement in the Ethics Subcommittee process at the state level; and 3) She wondered whether there had been any discussion regarding regional differences and scarce resources within one region, and using a particular protocol or algorithm when other resources existed outside of the region experiencing scarce resources. Though regional differences were addressed earlier, these differences may include access to resources.

Discussion

Dr. Barrett pointed out that CDC had published other guidance. There is a previous pandemic influenza ethics guidance document that is posted on the CDC website. That document addresses the allocation of scarce resources in preparing for pandemic influenza. This document makes the point of the importance of being proactive and prepared for a pandemic in a variety of ways, including developing public health infrastructure. The ventilator guidance document was the result of a request to focus specifically on ventilators and to address how the original pandemic influenza document could be applied to the situation of allocation of ventilators. Many individuals at CDC are working on pandemic influenza preparedness. The mission for this subcommittee is really about setting forth an ethical framework for public health officials who need to make decisions about allocation of scarce resources.

Dr. Hood added that the emphasis on planning in the influenza and ventilator documents is geared toward a recommendation that states, local jurisdictions, cities, and territories should work to increase resilience in their current systems through their planning process. Having resilience means having the resources to address these types of questions.

With respect to the issue of the number of ventilators, Dr. Barrett noted that the point the subcommittee was attempting to make in this document was that it really applies to a time during which a pandemic is so severe that the supply and resources are overwhelmed. At this point, the current H1N1 pandemic has not become a severe situation such that it is overwhelming current resources. The scope of this document will be further clarified in the conclusion.

Dr. Barrett also pointed out that the document addresses the issue regarding uniform decision criteria versus local flexibility. It suggests that there be coordination among the various levels (e.g., federal, state, local, territorial, tribal) and that there should be consistency across regions in order to ensure fairness. However, the document acknowledges that there may be a need for flexibility between different areas. Regarding the issue of public engagement, this document emphasizes the importance of public engagement throughout the document. CDC has also been involved in a public engagement process on pandemic planning, and has done so on a number of issues such as use of vaccine and use of community interventions. CDC recognizes the importance of public engagement.

There was further discussion about the importance of building public health infrastructure and the best way to do this given our current economic situation and efforts at health reform. Dr. Barrett reiterated that the document does address the importance of building infrastructure and being prepared for the next emergency. The document also refers to the need to balance pandemic preparedness requirements with other health care and public health needs.

Action Items / Next Steps

- Make minor revisions to the document as discussed during this call
- Submit the document to the ACD (date to be announced)
- 2010 Meeting Dates:
 - February 18-19
 - June 17-18
 - October 7-8

With no further business posed or comments raised, the meeting was adjourned by Dr. Hood at 4:00 pm.

Certification

I hereby certify that to the best of my knowledge, the foregoing minutes of the November 23, 2009 Ethics Subcommittee meeting are accurate and complete.

[Signature on file]

12/18/2009

Date

Robert Hood, PhD
Chair, Ethics Subcommittee, Advisory
Committee to the Director

Attachment 1: List of Attendees

Ethics Subcommittee, Advisory Committee to the Director

Ruth Gaare Bernheim, JD, MPH, University of Virginia
Ronald Bayer, PhD, Columbia University
Vivian Berryhill, ACD Member, National Coalition of Pastors' Spouses
LaVera Marguerite Crawley, MD, MPH, Stanford University
Norman Daniels, PhD, Harvard University
Robert Hood, PhD, Ethics Subcommittee Chair, Florida Department of Health
Nancy Kass, ScD, Johns Hopkins University
Bernard Lo, MD, University of California, San Francisco
Jennifer Prah Ruger, PhD, MSc, Yale University
Pamela Sankar, PhD, University of Pennsylvania
Leslie Wolf, JD, MPH, Georgia State University

Centers for Disease Control and Prevention

Drue Barrett, Designated Federal Official, Ethics Subcommittee
Elise Beltrami, NCPDCID, PHEC Member
Peter Briss, CDC Acting Associate Director for Science
Melanie Duckworth, CDC Senior Management Official, Florida Department of Health
Debralee Esbitt, COTPER, PHEC Member and Ventilator Workgroup Member
Karen Gavin, NCEH, PHEC Member
Neelam Ghiya, OCSO, PHEC Member
Susan Hunter, CCID, PHEC Member
Annie Latimer, NCDH/ATSDR, PHEC Member
Alexandra Levitt, NCPDCID, Ventilator Workgroup Member
Eileen Malatino, COPTER, Ventilator Workgroup Member
Mary Neumann, NCHHSTP, PHEC Member and Ventilator Workgroup Member
Leonard Ortmann, OWCD, CDC-Tuskegee Public Health Ethics Fellow
Lauretta Pinckney, NCHHSTP, PHEC Member
Jean Randolph, NCPDCID (for Debra Levy, Ventilator Workgroup Member)
Von Roebuck, CDC Media Relations

Members of the Public

Marcia Baker, EIR News Service
Elaine Catloth, KDFW-TV, Dallas/Ft Worth
Maggie Elestwani, Texas Collaborative for People with Disabilities
Barbara Fain, Massachusetts Department of Health
Sherri Fink, ProPublica
Josh Gerstein, Politico
Matt Grubbs, Fox Channel, Dallas Affiliate
Robert Levine, Yale University, Consultant to the Ventilator Workgroup
Joe Shapiro, NPR
Lou Suloss, New York Department of Hygiene
Andrew Zajac, Chicago Tribune/Los Angeles Times