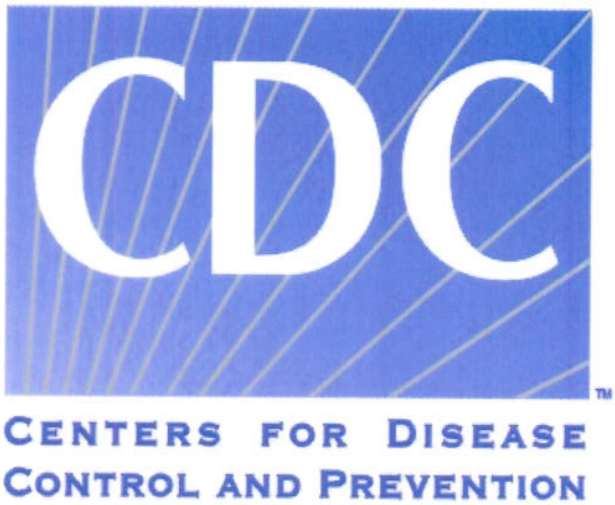
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry



Joint Meeting of the
Ethics Subcommittee of the
Advisory Committee to the Director, CDC
and the
CDC Public Health Ethics Committee
June 26-27, 2008
Atlanta, Georgia

Meeting Summary

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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 June 26 – 27, 2008 at CDC's Distance Learning Auditorium and Auditorium B-3 in the Thomas R. Harkin Global Communications Center, Roybal Campus, in Atlanta, Georgia. Agenda items included review of the outline for the ventilator guidance document and the white paper on emergency preparedness and response, introduction of a new topic relating to unlinked anonymous HIV testing, and updates on various Ethics Subcommittee projects. Meeting participants are listed in Attachment 1.

General Business

- The meeting was called to order at 1:00 pm on June 26.
- Mrs. Vivian Berryhill, a new appointee to the ACD, was introduced to the group.
- It was noted that after the current meeting, Dr. Thomas Hooyman will assume the role of chair of the Ethics Subcommittee.
- Dr. Tanja Popovic, Chief Science Officer, CDC, recognized the following Ethics Subcommittee members who were rotating off of the Subcommittee as of the end of June: Dr. Ruth Macklin, Dr. James Thomas, Dr. Barbara Koenig, and Dr. Robert Levine. She presented certificates of appreciation to retiring members in attendance at the meeting.
- A public comment period was scheduled during each day of the meeting; however, no public comments were offered.

Update: Discussion with the Office of Human Research Protections (OHRP) on the Definition of Research

Lisa M. Lee, PhD, Assistant Science Officer, Office of the Chief Science Officer, CDC, updated the group on CDC's work with the Department of Health and Human Services (HHS) Office of Human Research Protections (OHRP) on the definition of research. The only legal definition of research lies at 45 CFR Part 46, which defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Until 1999, no guidance for determining the difference between

public health research and public health practice (i.e., non-research) existed. CDC created guidance in collaboration with the Office for Protection from Research Risks (OPRR), the precursor to OHRP. CDC's guidance uses the purpose of the activity as the primary characteristic in determining whether the activity is research or non-research. In 2005, OHRP reviewed CDC's guidance and disagreed with several aspects of it. OHRP drafted a new, HHS-wide guidance, the second draft of which was shared for comments in December 2007.

CDC's comments on both drafts of the guidance expressed the agency's appreciation for being included in the development process. CDC articulated concern that the two characteristics used to define research, "systematic" and "generalizable," are insufficient for differentiating research from practice, as nearly all efforts in public health are systematic, and much of public health practice creates knowledge that is generalizable. CDC suggested that the characteristic of the *purpose of the activity* be added to the definition. CDC also agreed that public health practice should be conducted ethically and noted that a process had begun to create a standard guidance for the ethical collection, storage, and use of all data held by public health. The sensitivity and importance of this guidance document has been elevated. HHS agencies that stand to be affected by the guidance were invited to meet with the Deputy Secretary of Health, ORHP, and other HHS officials. Until otherwise directed, CDC continues to use its 1999 guidance when determining whether an activity is public health research or practice..

Major Discussion Points

- There is no set timetable for the process of guidance development.
- Many of NIH's comments on the draft guidance aligned with CDC's comments.
- Great concern was expressed that the process of developing the new guidance was not more transparent and did not include open discussions with the affected agencies as well as their partners, such as state and local public health departments and agencies.
- Accountability is always required in any public health activity, be it research or practice.
- CDC personnel felt that their opinions had been heard at the meeting of HHS agencies.
- Upon completion, the guidance will be open to a public comment period through the Federal Register; however, CDC feels that the period is not long enough and is not an appropriate mechanism for gathering feedback from affected partners, as comments submitted to the Federal Register are not subject to responses, and the process is not always collaborative. It was further noted that if OHRP arrives at a definition that is acceptable to all parties, then public comment is not likely to have an impact on it.
- CDC will share the document with Ethics Subcommittee members when it is released.
- A good case can be made that "systematic" and "generalizable" quality improvement activities need not be classified as research. It may not be possible to resolve the differences in perspective among the parties involved, so compromise might be found on the grounds of oversight, management, and accountability, rather than definition.
- There is no standard, cross-cutting set of procedures and standards for protecting public health data. State laws govern data protections, and CDC works to create standards and a means for enforcing them for the ethical collection, storage, and use of public health data across the public health enterprise.
- The process is not likely to be affected by a change in administration.
- It was decided that the minutes of the meeting should convey concerns about the closed nature of the process of creating the document and that the discussions might benefit from moving beyond "definitions."
- A better picture of the definitions might come from starting with the values that are being advanced and the level of protection that will be sufficient.

Update: Status of the Public Health Data Collection Project

Dr. Lee presented an update on the Public Health Data Collection Project. All states have laws in place to protect data that are collected through public health activities, but the laws vary widely. Model legislation was formed for public health privacy laws to address the appropriate use of public health data and the appropriate protection and security of public health data, but the model law was not adopted across all 50 states. Several CDC programs have outlined standards to manage data, but the rules and procedures are not consistent. The Ethics Subcommittee provided a foundation of ethical principles to develop and operationalize a project to unify standardized rules and procedures across CDC. CDC staff and external partners are working on this effort. Further, they will track and implement the guidance, adding accountability. The effort will likely take one or two years.

Major Discussion Points

- The Ethics Subcommittee halted its work in this area when OHRP addressed the difference between public health research and practice. CDC hopes to create a document on the standard ethical treatment of public health data independent of the question of research versus non-research.
- Centers within CDC have been inventoried for documents addressing the ethical treatment of data, the use and reuse of data, and the release and re-release of data. Securing agreement on what the uniform standards should be will be a challenge.
- Advancing technologies in collecting medical records and patient information will affect public health data collection, as will using other federal data sources such as the Census and IRS. For now, CDC is focusing on how to treat the data that they get, not on how the data are obtained.
- CDC's Office of Strategic Innovation has addressed the question of personalized health medicine issues as part of a broader national analysis.

Introduce New Topic: Ethical Aspects of Unlinked Anonymous HIV Testing Surveillance and Survey Activities Supported by CDC in International Settings

Terence Chorba, MD, MPH, introduced the group to unlinked anonymous Human Immunodeficiency Virus (HIV) testing for surveillance purposes. This testing has been conducted since the early years of the HIV epidemic. Serosurveillance for HIV infection is used to gather information on prevalence and incidence in a given population; quantify the burden of disease and determine whether public health interventions are best needed in a given population; ascertain where the services will best be targeted; and evaluate the effectiveness of prevention programs.

In many countries, national HIV prevalence estimates are obtained through surveys of sentinel groups, mostly using pregnant women presenting to antenatal clinics or through population-based surveys. USAID has funded Macro International to do demographic and health surveys. The surveys include blood draws for anemia values, syphilis and several other infectious diseases, and HIV seropositivity. These surveys use two testing approaches: with informed consent, and without informed consent. In the United States, CDC conducted HIV surveillance using unlinked anonymous testing without informed consent until the mid-1990s. The practice was discontinued with the widespread availability of voluntary counseling and testing. WHO has issued guidance regarding HIV surveillance in the developing world using unlinked testing with and without informed consent. If CDC continues to perform unlinked anonymous testing without informed consent in these settings, then CDC's domestic and international practices are in

conflict. Ethical concerns have been raised when participants in surveys using unlinked anonymous testing with or without informed consent have not been provided their HIV test results and have not been referred to treatment services. In some settings, treatment services are not available, and in some settings, there is no framework for providing confirmatory testing or follow-up.

An outside ethics consultation meeting was convened in February 2008 at Columbia University. Its objective was to obtain an outside review of the ethics of HIV surveillance and surveys in which HIV test results are not returned to participants. A family of such surveys is the Demographic and Health Surveys (DHS) that are usually funded by USAID and implemented by Macro International. When the surveys are conducted without informed consent, it is commonly because the testing is conducted on "leftover blood" that was drawn for another reason. Participants are unaware of testing. In the context of Macro International surveys, USAID notes that inherent in the design of the sampling scheme of the DHS surveys is an inability to identify retrospectively the individual from whom the information was obtained. At the meeting, the ethicists were asked to provide recommendations regarding whether it is ethically acceptable to collect samples, test them for HIV, and to withhold test results, whether the tests were administered with or without informed consent. At the end of two days, the ethicists presented a draft set of two recommendations:

- ❑ Unlinked anonymous testing using leftover specimens obtained without informed consent for HIV testing can be ethically justified in some countries, but perhaps increasingly not in others, and the ethical justification depends on facts and circumstances that can change and must be reviewed periodically to determine whether they no longer warrant testing without providing results to the individuals tested. As the AIDS epidemic has evolved, the advent of the widespread availability of rapid testing has made it less defensible to do unlinked anonymous testing using leftover specimens obtained without informed consent for HIV testing in various environments.
- ❑ Withholding test results from samples obtained with informed consent is something for which no ethical justification exists for the purposes of surveillance. Testing samples for HIV without offering to provide participants with their test results is no longer ethically justifiable.

What the program is seeking are well-defined ethical criteria for review and approval on unlinked anonymous testing in the context of HIV serosurveys in international settings supported by CDC.

Major Discussion Points

- There were questions regarding how the speed of testing has ethical significance. Rapid testing returns results in as soon as 20 minutes, eliminating the logistical argument for not returning results to individuals.
- The Program hoped that the Subcommittee would help create an ethical standard to which researchers will be held.
- There was much discussion about what the Subcommittee was being asked to do, and about the process by which the topic was brought to the Subcommittee. The topic must be approved by the Chief Science Officer and the Director of CDC. The Subcommittee (or a Workgroup thereof) will consider the topic and create a charge for the group, if the topic is deemed to need the Subcommittee's input. There was concern that consulting outside ethical groups might circumvent the Subcommittee and the FACA guidelines under which it operates. At the same time, the Ethics Subcommittee should not become an impediment to CDC's communication with others in the ethics community.

- It was clarified that the Subcommittee was not being asked to "second guess" the work of the initial group of ethicists, but to decide whether the Subcommittee should take the issue further. Regarding the convening of outside ethical consultations, it was noted that CDC has a large number of programs, and the Ethics Subcommittee cannot be consulted by each one. The question of whether the Ethics Subcommittee takes up the issue relies on whether the ACD needs their specific recommendations and advice regarding CDC's programmatic operations.
- Other federal agencies, including USAID and the Department of Defense (DOD), were represented at the initial meeting of ethicists. CDC staff members are struggling with what they can and cannot approve for funding.
- Two members of the Subcommittee, Dr. Macklin and Mr. Jennings, were at the meeting, but not representing the Subcommittee.
- Work in this area is urgent, as there is resistance to change among those conducting the surveys, and there are concerns that they will return to "business as usual" until this process comes to resolution.
- The document created by the initial group of ethicists represents a compromise between two extremes: some felt that unlinked anonymous testing was no longer justified, given the availability of antiretroviral medications, while others argued that surveillance data are essential for tracking the epidemic.
- Unlinked anonymous testing for HIV occurred in the domestic population in the mid-1980s. That testing is no longer conducted; however, there are settings in which unlinked anonymous testing in this country does occur.
- CDC staff need to have internal discussions for clarity in order to educate the Workgroup to make a recommendation about the Subcommittee's involvement.

Review and Approve: Ventilator Distribution Guidance Outline

Dr. Kathy Kinlaw described the background of this project. She and Dr. Levine were charged by the Ethics Subcommittee to work on the *Ethical Guidelines for Pandemic Influenza*. Public comments on that document included requests for guidance regarding specific problems, including the distribution of ventilators in the course of a pandemic. The Subcommittee decided to pursue specific guidance on that issue. Dr. Kinlaw and Dr. Levine continue to work on the project, with the help of CDC subject mater experts and PHEC members.

They have developed an outline of points to address in a guidance document. The introduction to the document will discuss its focus and that it is a practical furthering of the original pandemic influenza ethics guidance document that will include cases and examples, not specific policy recommendations. Public health officials should use the guidelines to inform their development of recommendations, policies, and guidelines. The document will adopt a theoretical approach and look for distinctions that may exist between the theories in the overall pandemic influenza guidance and their application to the specific case of ventilation. While utilitarianism is a common approach in public health, it is not the best approach in this case. The document will also address operating principles and the tension between various duties. There will be discussions of issues relating to distributive justice, health disparities, and vulnerable populations. Finally, the document will embrace the concepts of transparency and the importance of hearing diverse voices in planning.

The guidance document will note the following assumptions:

- ❑ During a pandemic, available life-sustaining resources will not be adequate to address all patient needs. The guidelines will only come into play when there are limited resources.
- ❑ Cases of pandemic influenza infection will occur in waves, and most likely a vaccine that will be well-matched will not be available in the first wave. It is anticipated that resources will be overwhelmed in the first wave, and there will be a need to allocate scarce resources such as ventilation.
- ❑ Patients with respiratory failure who are unable to receive ventilation are at risk and likely to die.
- ❑ Interventions will make a difference: if ventilators are available for patients with respiratory problems, then it will help.
- ❑ Decisions about allocation of scarce resources must be made in a broad context. Other events will be taking place, and while the provision of care for ventilation is important, other issues will need to be addressed simultaneously.

The document will include a section on pre-event consideration and planning that will confirm that proper planning is an ethical duty. The original pandemic influenza ethics document shifts the goal away from regular seasonal flu planning, which focuses on minimizing serious complications, hospitalization, and death, to preserving the functioning of society in the case of pandemic influenza. This shift may nor may not hold true in the case of allocating ventilators. In addition, the original guidance raised the question of including some "social worth criteria" to identify those who are important to the functioning of society. The question of when a triage plan should be implemented is important and relates to surge capacity issues. This document, like the original, will address the centralization of decision-making as opposed to allowing local communities to make decisions. Procedural issues and whether all institutions will be mandated to participate will be discussed. The document will also address questions of scope of practice and altered standards. Some healthcare professionals may need to perform procedures that are not under their realm of duty, and others may need training. The question of a "Good Samaritan" protection will be discussed. The next important issue to be covered in the document concerns community participation and whether obligations exist about informing the community. Finally, the outline lists additional topics, including stockpiling, storage, portability, ease of use, sharing of resources, working with composite state and other medical boards to secure permission for cross-training and training for non-traditional personnel.

The document will include a brief statement about obligations to provide for those who are not able to receive mechanical ventilation and address the appeals process for family and patient concerns. Other topics to be discussed in the document include:

- the obligation to collect data for the purpose of research;
- when to decide to end the triage process, whether it is a decision point or a progression;
- the obligation to determine if the triage system failed, and whether and how to make those findings public;
- the ethical obligation of stewardship in the public health context.

Finally, a few special topics the will be discussed in the document include the use of ventilators in pediatric populations and considerations of patients who are chronically on ventilation, such as in nursing homes or home care settings.

Major Discussion Points

- There was discussion about the rationale for not providing specific recommendations about prioritization of ventilator use. Rather than making policy recommendations, they have

chosen to focus on the ethical considerations that should be taken into account by those who make policies. The original pandemic influenza ethics document focuses on the maintenance of societal infrastructure, and it is suggested that certain groups should be placed in priority order; however, specific tiers are not provided. They intend to provide practical advice without "tying the hands" of local officials and decision-makers. Public health officials are considering the ventilator problem as a surge capacity and triage problem. They are considering solutions based on emergency medicine approaches, but there are pros and cons associated with using quantitative measures. From a public health perspective, ventilators are societal resources that should be used to create certain public health outcomes, objectives, and goals, not just pieces of equipment that are owned by a hospital, which is the clinical perspective.

- It was noted that providers as well as patients will be impacted due to scarcity of resources.
- The distinction between the provision of ventilators, which falls under the purview of clinical response, and the public health response, was discussed. This document addresses the provision of clinical care in the context of a pandemic, but resources will be scarce for both clinical care and public health.
- Another conflict arises between the needs of those who are already sick, and those who may soon be sick. It is not inconsistent for different groups to get priority depending on the possibility of recovery. There could be compensatory reasons, such as reciprocity for a healthcare worker who became sick while helping others.
- Public health has a responsibility to establish criteria about how excess ventilators should be distributed and used.
- The issues of centralization and mandatory participation by institutions will likely play out differently in public versus private settings. Different institutions will have different internal authority systems.
- The section on the pre-planning phase should address conducting research in a response setting in which it is not possible to get patient consent.
- It was suggested that the "research" chapter not be included in this document, as it is a separate topic that may need to stand on its own. However there was not agreement on this suggestion.
- There was discussion regarding who makes triage decisions in intensive care units.
- Conversations about medical futility, which involves making decisions about withdrawing ventilation, are needed.
- The idea of what to tell the community, and when, focuses on how much the community will be involved in considerations of how these decisions will be made, and how that involvement will take place.
- In a pandemic, healthcare professionals will be compelled to act above their level of certification. Current thinking supports using people's skill sets to match need. The question of cross-privileging is important; that is, when healthcare professionals move to jurisdictions in which they are not credentialed. There may not be adequate resources for repair and maintenance of ventilators, so early training may be needed.
- The group discussed whether objective criteria affect the implementation of triage and to what extent objective criteria are allowable. There are some objective measures of quality of life. Additionally, there should be clear criteria to indicate when the triage process should begin.
- The document should address whether elective procedures should be disallowed during a pandemic and what, if any, criteria should apply to patients that require mechanical ventilation for other reasons, such as chronic illness.
- The question of withdrawal from mechanical ventilation is very difficult. This document might not be specific, but it can examine how decisions are being made and how to justify

any criteria. The document should also include a statement about euthanasia and palliative care.
- The document should establish a foundation of the difference between a public health community decision versus an individual clinical care decision.
- Part of the challenge of centralization stems from the difficulty of interfacing with existing oversight if a larger authority overrides local responsibilities.
- The processes have to be simple and easily understood so that people can move quickly and instinctively into their roles.

Update: Ethical Guidelines for Use of Traveler Restrictions

Clive Brown, MD, Acting Associate Director for Science, Division of Global Migration and Quarantine, National Center for Preparedness, Detection, and Control of Infectious Diseases, CDC addressed the group about his Division's mission and challenges that it faces, especially after the recent high-profile case of a traveler who tested positive for TB.

Some people will comply voluntarily with requests to avoid travel or to isolate or quarantine themselves while others will not. There is a need to determine the best ethical approach in situations where persons will not comply with these requests. CDC relies on a number of federal and other partners at various ports of entry to the United States to help enforce its regulations.

Public health authorities have two main tools available from DHS: "Do Not Board" and "Lookout." Persons on the "Do Not Board" list are not allowed to check in for flights that are inbound to, or outbound from, the United States. In order to be placed on this list, a person must be infectious and pose a public health threat, must be a threat for noncompliance, and have an intent to fly commercially. CDC and DHS determine whether the criteria are met and then the person is placed on the list. The "Lookout" designation does not necessarily stop a person from boarding a flight, but it does "flag" the individual, who is provisionally held at the port of entry until quarantine staff can review the case. Based on the review, the person may continue his journey or may be required to visit the local health department. Several issues have arisen: Different regulations in different states; the balance between law enforcement and healthcare standards; using the least restrictive means of detainment, depending on the compliance of the individual; and the process must be transparent to avoid the suspicion that individual rights are restricted.

The Ethics Subcommittee was asked to assist in reviewing CDC's standard operating procedures. The Division has established a case review mechanism for ethical issues that arise in cases. The Subcommittee is also asked to address issues raised by the "action report" from last year.

Major Discussion Points

- There was discussion of how travel restrictions work in cases of land entries.
- Regarding the question of using public health authority for reasons other than public health, such as for restraining people, it was noted that public health personnel and policies and procedures should be addressed primarily, if not exclusively, to acting for public health reasons. Public health works because of public trust.
- Any time CDC seeks to enforce or carry out quarantine or isolation orders, it is necessary to involve other federal agency partners, as CDC is not an enforcement agency. The issue of

sharing records would not exist if CDC had the capacity and resources to do the work alone, but because they have to collaborate, they have to work to best protect individuals' privacy.

- Additional public health education will lead to more voluntary compliance. Certain elements affecting quarantine issues have changed recently. The Subcommittee might discuss possible responses when people choose not to follow restrictions.
- It was noted that an Ethics Subcommittee member would have to be added to the Workgroup since Dr. Levine was rotating off.
- There are many ways into the country other than by air, this guidance seems to focus on air travel. It was suggested that the Workgroup consider whether the guidance is truly capturing the need.
- In general, the idea of using restriction on travel as tool of infectious disease control is fraught with the potential for injustice and discrimination.
- The topic of using the "least restrictive means" is very important, particularly in light of historical abuses of individual freedom.
- Not specific to this topic, concern was raised that the more topics that are brought to the Subcommittee, the more likely it is that they will become a "bottleneck" to resolving ethical issues. Dr. Barrett pointed out that each of the Centers has been encouraged to create public health ethics teams so that they can address public health ethics issues at the Center level without having to bring all issues to the CDC Public Health Ethics Committee or the Ethics Subcommittee of the Advisory Committee to the Director..

Review and Approve: White Paper on Emergency Preparedness and Response

Mr. Jennings reviewed the process of creating drafts of the White Paper on Emergency Preparedness and Response. The current draft includes all of the paper's section, with two exceptions: an Executive Summary and a concluding/recommendations section. Sections One through Eight have been commented on by the Subcommittee and the Emergency Preparedness and Response Workgroup through several iterations. The meeting focused on reviewing Section Four (the Justice section), and two new sections: Section Nine, concerning issues with conducting research activities during emergencies, and Section Ten, concerning special ethical considerations for CDC personnel.

Dr. Arras described changes to Section Four. The changes include new material on process. Utilitarianism should not be a stand-alone political philosophy for public health ethics. Balance is needed between claims of efficiency and claims of fairness or equity. There is no canonical way to resolve those disagreements, and there should be a legitimate procedure for addressing them. The preconditions for "legitimate decisions" include publicity or transparency, an appeals process, the offering of relevant reasons, and democratic participation, or the involvement of stakeholders.

Section Eight describes the normative basis of research in public health. Public health researchers see their patients as the society at large rather than individuals. Therefore, this section amends traditional ethical analysis to assert that the root of research ethics in public health is not the fiduciary relationship between doctors and patients, but the moral equality of all humans, who should not be used merely for scientific purposes for reasons they could not accept. The root of research ethics is the claim that all people are free and equal and deserving of equal respect. The section describes an ethical framework for assessing the ethics of public health research in the context of disaster. Several benchmarks for ethical research are listed, such as the importance of social value, fair subject selection, which includes vulnerable populations, consent, and the possibility of therapeutic misconceptions. Another piece of this

section is devoted to institutional review. In the case of a disaster, IRB review procedures could limit some research projects. Planning should include thought about ways in which researchers might respond to the problem of time constraints. One possibility is for researchers to develop "just in case" protocols, thinking ahead to typical emergency situations and crafting protocols for effective response. Another possibility is centralizing the IRB process to improve efficiency and to respond to concerns about over-taxing certain vulnerable populations that might be subjected to repeated studies.

Section Ten of the document addresses CDC directly, focusing on the experience of deployed CDC staffers in the response phase. CDC's deployment role can be complicated as it interacts with a number of state and local authorities, organizations, and partners as well as with other agencies. Ethical issues in deployment often arise because of the difference between "responsibility" and "authority." CDC people may have information and knowledge that others do not have, and they may have a sense that they are responsible for ensuring that people are protected in certain ways, but they often only have the power to advise, not to make things happen. The section also addresses questions of CDC's roles and interaction before deployment, psychological support after returning, interacting on the ground, and communications issues as well as policy and agency issues for CDC in terms of the deployment process and function. The stance of CDC should be to support good science, information, and openness.

Major Discussion Points

Process/Changes to Section Four

- There is disagreement about the form that public participation should take. Some commentators view public participation as crucial for legitimacy, while others do not consider this public as a form of democracy. Public participation in the preparedness planning process is one of the themes of the White Paper, and it provides an original contribution to the literature on this topic. The paper argues consistently for both ethical and practical reasons for including people in planning. Groups are working on engaging under-represented minorities in this process. The text would benefit from discussion of "who counts" as the "public." To what extent can they be confident that the people selected to contribute to decision-making are truly representative, or whether they are simply the "loudest voices" for any given interest group?
- One of the largest contributions of this document concerns the issue of public engagement. Providing ethical underpinnings for public engagement, as well as the practical issues of ease of implementation, is a major contribution of this paper.
- The field of emergency preparedness and response is grounded in limited science, so it is critical that the ethical guidelines are practical and useful.
- It was suggested that Sections Four and Eight of the document be combined. Section Four discusses allocation of resources and justice, focusing on distributive questions, but does not address the personal responsibility associated with being a member of the community and personal responsibility for one's health.
- The Internet should be included as a major form of community engagement, and the document can address whether input through the Internet is fair and reliable and whether it systematically draws from certain groups of the population.
- It was recommended that the section on vulnerable or "special needs" populations include a discussion of socially-created or geographical vulnerabilities, not just physical disabilities. The social construction of vulnerability unites the disability perspective with other perspectives, such as ethnic and marginalized minorities. The term "special needs" includes

more than those who are handicapped: it extends to those who do not comprehend well or read well, and to others.

- There was discussion concerning whether some of the phrasing in the document should be "toned down" to avoid precise recommendations and potential future litigation. It was decided that guidelines are not automatically implemented due to competing priorities or resource constraints. The Subcommittee should not feel restrained about its recommendations.
- There was discussion concerning how all people in an emergency are affected or considered vulnerable. Even the most wealthy are affected by disasters. All interdependencies and vulnerabilities must be recognized. Examples in this area might be useful.
- The notion of cross-coordinating or collaborative databases among federal agencies was discussed. Public health may have a responsibility to begin to judiciously and ethically bridge those databases to prepare for a disaster. There are many negative aspects of database integration, including intrusions on privacy. However, if pre-planning includes sharing information, then the process of responding to a disaster could be made easier. It was also noted that while large databases are available with a great deal of information, community needs assessments are being conducted by volunteer levels at neighborhood levels.

Section Eight: Research

- A distinction should be made between the kinds of data collecting activities that are clearly research, but are epidemiologic in nature, which could be expedited by an IRB.
- Making a distinction between predictable and unpredictable contexts will be helpful for the document.
- Research is important in a crisis, but individuals may not respond well to suggestions of research unless information is shared with them before the fact so the community might be more open to participating in research.
- If there is conflict between the value of getting research done and the value of rescuing people in an emergency, the goals of saving people should always take priority.
- It was suggested that this section on research might need to be removed from the document, as was suggested for the Ventilator guidance document. However, this suggestion was not agreed upon as the Subcommittee was asked to provide guidance on ethical considerations for conducting research in response settings.
- There was concern that this document makes recommendations that OHRP will not agree with. For the Subcommittee to be consistent and not aligned with OHRP's stance, then the document will need to make a sharp distinction between epidemiologic, or practice, research, and clinical research. The epidemiologists at CDC definitely conduct research, and it is often generalizable because CDC's "patient" is a group of people. The document can clarify that it will not delve into the discussion of the definition of research. A series of focus documents will accompany this paper, and one of those documents will focus on research. Specific concerns about wording in the document were discussed. The document can acknowledge the major debates regarding research versus practice and that the intention of the research section is not to make the definition, but to offer ethical guidelines for when research is conducted.
- There was discussion regarding whether an individual has an ethical obligation to participate in research during a public health crisis. In a non-crisis situation, communities may see and understand this need. There was discussion about "presumed consent" in a crisis situation. There are issues concerning vulnerability and histories of past abuses. Further, the definition of "emergency" is fluid.

- Conflicting professional obligations were discussed. CDC staffers in disaster settings have been asked to respond in a clinical role when they were not prepared to do so. In some cases, people felt conflicting obligations, such as working through CDC policies and procedures versus engaging with people and helping to save lives. CDC has a public health mission, but individuals from CDC can be deployed to provide care and rescue.

Section Ten

- Section Ten should expand and clarify comments on the issue of responsibility versus authority. Another area for expansion is the conflict that people in the field often feel between providing individual care and responding to the population. CDC's primary role in the field is population health and improving the health of the community, but people are often torn by the needs of individuals, and ethical guidance is needed to support the mental health and resiliency of the responder workforce. The issue of making decisions and recommendations with limited or incomplete information would benefit from additional clarification in the document. An agency-wide ethical issue concerns political deployments. The document could address ethical obligations during recovery. Further, what are the ethical obligations of CDC personnel who are not normally responders, but who have skills that could be used during a response?
- There was discussion regarding whether all CDC personnel are obligated to apply their skill sets in public health in an emergency response. The issue involves a commitment to the institution and its mission that goes beyond one's usual role. The relationship between the employer and employee could be examined, as could the idea of vocation versus profession. While there may be well-defined roles and responsibilities, some activities may have to be voluntary and not mandated.
- There is a perception on the part of state-level personnel in emergency responses that CDC will come and overrule decisions or "take over" sites.
- The document would be presented at the October 30th meeting of the ACD, and a Subcommittee conference call would occur prior to that meeting for final approval of the document. The White Paper will be published in a special supplement of the MMWR, accompanied by the five focus papers commissioned by COTPER.

Information: CDC / Tuskegee University Public Health Ethics Fellowship

Mehran Massoudi, PhD, MPH, Chief Science Officer, Career Development Division, Office of Workforce and Career Development, updated the group on the CDC/Tuskegee University Public Health Ethics Fellowship. During the observance of the ten-year anniversary of the Presidential apology for the U.S. Public Health Service (PHS) Syphilis Study at Tuskegee, Dr. Julie Gerberding announced that CDC and Tuskegee University would develop a visiting fellowship program designed to promote the study and application of ethics in public health practice and research and to foster collaborations between university faculty and students and CDC staff. During the two-year fellowship, the faculty fellow will work with the Office of the Director and at least one other CDC program to address current issues in public health ethics. The initial faculty fellow will also help to develop a student program to create an opportunity for Tuskegee University students to gain experience in examining ethical issues in the practice of public health. Future faculty fellows will have a role in mentoring students, and it is anticipated that future faculty fellows and students will be selected not just from Tuskegee University, but from other Historically Black Colleges and Universities (HBCUs), and subsequently from other universities. The financial support of the faculty and student fellows is a joint venture between the fellows' home institution and CDC. The first fellow has been selected and will undergo orientation at CDC in August and begin his two-year stint in the fall.

Major Discussion Points

- Concern was expressed regarding when the fellowship is opened to institutions other than Tuskegee University. Some universities may not have the resources to be able to send a fellow to the program. There should be discussions regarding how to ensure that academic leadership at these institutions will want their faculty to participate.
- The fellow's involvement with the Subcommittee was discussed.

Update: Status of Projects, Documents, and Ethics Subcommittee Membership

The Partnership project has shifted focus to address the specific concept of partnering with vaccine manufacturers in studies of adverse events from vaccines. The Immunization Safety Office is now the lead requestor, and as the program is in transition, the project is on hold for the present.

The Genomics project has also been put on hold. The lead writer for the best practices document of how to integrate genomics into public health practice has changed positions within CDC. The CDC National Office of Public Health Genomics (NOPHG) is focusing on issues of how to use NHANES data for genomics. A student intern took up the task of reviewing CDC research protocols that collect human genetic data in order to identify the practices used. When NOPHG is able to identify staff to work on the project, the genomics project will be revisited.

The document on shared responsibility for stockpiling antiviral medications was approved at the May 1st meeting of the ACD, and when HHS signs off on it, the document will be released as a public document and posted on the CDC Website.

Four new members of the Subcommittee were identified including Ronald Bayer of Columbia University, Nancy Kass from the Johns Hopkins Bloomberg School of Public Health, Bernard Lo of the University of California, San Francisco, and Robert Hood, with the Florida Department of Public Health. Their terms will begin on July 1, 2008.

There was discussion about procedures for bringing items to the Subcommittee. The Subcommittee serves to advise the CDC Director, and topics are approved by the Chief Science Officer. It was pointed out that the procedures document for the Ethics Subcommittee addresses how topics are brought to the Subcommittee.

Action Items and Meeting Wrap-Up

The following action items emerged as a result of the meeting:

1) Two new representatives from the ACD will be added to the Ethics Subcommittee, one of whom will be Mrs. Vivian Berryhill. Dr. Barrett will work with the ACD Executive Secretary to identify a second ACD representative.

2) The definition of research: Concern was expressed by members of the Ethics Subcommittee regarding the lack of transparency and secrecy surrounding discussions with OHRP on the definition of "research." The minutes should convey this concern.

3) Unlinked Anonymous Testing for HIV: The Subcommittee will convene a workgroup to address the issue of unlinked anonymous HIV testing for surveillance in developing countries. However, this will occur after further clarification is provided regarding what the CDC Director wishes to receive from the Subcommittee and after further discussion within the agency regarding their stance on the issue. Bruce Jennings and Ruth Macklin (as a consultant) agreed to serve on this workgroup. Ronald Bayer will also be asked to join the workgroup.

4) Travel Restrictions Project: The workgroup will hold future discussions of specific cases involving travel restrictions as well as review a document being developed by CDC in collaboration with the Department of Homeland Security on standard operating procedures for issuing travel restrictions. Ethics Subcommittee representatives on this workgroup will be Kathy Kinlaw and Vanessa Gamble. Robert Levine will continue in a consultant capacity.

5) White Paper on Emergency Preparedness and Response: A final review of the document will occur in September after which the document will be submitted to the Advisory Committee to the Director of CDC for review at its October 30th meeting.

6) Partnership Project: This project will resume after the move of the Immunization Safety office in finalized and staff from that office are able to devote attention to this project. Tom Hooyman will continue as the Ethics Subcommittee representative on this workgroup. In addition, Robert Hood will be asked to join the workgroup to replace James Thomas who is retiring from the Subcommittee.

7) Ventilator Guidance Document: Kathy Kinlaw and Robert Levine (as a consultant) will begin the writing of this document. Bernard Lo will be asked to join this workgroup.

8) There was discussion concerning Subcommittee infrastructure and possible "bottlenecks." The Subcommittee has produced well-thought-out documents, but the process of creating them has been long. Other mechanisms for addressing ethical issues at CDC are needed. CDC is developing procedures so that the internal Public Health Ethics Committee consulting teams will feel more comfortable with the public health ethics consultation process. The Ethics Subcommittee has moved away from focusing on CDC capacity-building issues. However, as not all CDC Centers have well-formed public health ethics teams, there may need to be more discussion regarding the role of the Ethics Subcommittee in developing ways to speed the capacity building process.

9) It was determined that the next meeting day would be November 13-14, 2008. Proposed dates for 2009 meetings (approximately February, June, and October) would be suggested.

With no further business brought before the Ethics Subcommittee or PHEC, Dr. Macklin adjourned the meeting at 12:00 PM on June 27, 2008.

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

9/24.08
Date

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