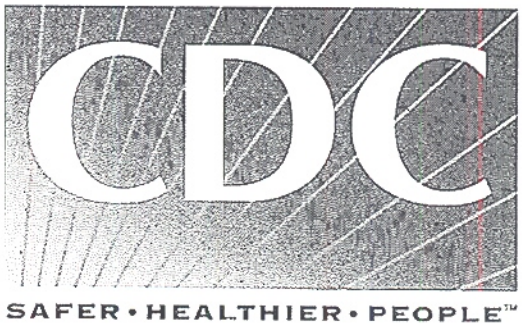


**Advisory Committee to the Director**
**Centers for Disease Control and Prevention**
**Roybal Campus, 1600 Clifton Road, Atlanta, Georgia 30333**

**Teleconference Summary**
**December 14, 2006**

Department of Health and Human Services
Public Health Service

**Summary of the December 14, 2006**
**Teleconference of the Advisory Committee to the Director, CDC**

A teleconference of the CDC Advisory Committee to the Director (ACD) was held on December 14, 2006. The purpose of this meeting was to provide recommendations to the CDC Director on issues addressed by the Ethics and Health Disparities Subcommittees.

**The Ethics Subcommittee** reviewed the ethical guidelines for use in the case of an influenza pandemic in terms of vaccine and antiviral drug distribution and non-pharmaceutical interventions. The grounding ethical considerations of a pandemic included transparency in planning and response processes and maximized preparedness to minimize later allocation decisions. Guidelines must be 1) based on sound science, 2) coordinate with global preparedness efforts, and 3) identify clear overall goals to preserve a functioning society. The latter would ethically allow higher prioritization for immunization and treatment for those responsible to provide health care, public safety and the functioning of key aspects of society. In a pandemic, evidence-*informed* decision making, rather than the more stringent evidence-based decision, is ethically acceptable, being comparable to the 'compassionate use' of treatments not yet rigorously proven.

To balance individual liberty and community interests, the least restrictive practices should be adopted that will allow the common good to be protected; the restrictions must be necessary and proportional to the need for protection; and the critical needs of those affected by the restrictions must be supported by the community. Local autonomy should be honored unless it risks social functioning. Restrictions should be imposed only as needed to be protective and to avoid great harm to the public well-being. Pre-pandemic establishment of a fair, procedural justice mechanism is essential. A clear advance resource distribution plan is critical, with clear explanation of the ethical basis.

The ACD members urged CDC to explore the possibility of legal protection for healthcare professionals providing care outside of their normal practice; advised CDC to use another example than forced vaccination (e.g., limited movement) and to be clear that these are recommendations for voluntary action.

**The Health Disparities Subcommittee** was charged to advise CDC on its objectives, priorities and activities to reduce health disparities. They advised that the starter objectives add "social determinants of health" under "Risk or Threat." They also suggested renaming Criterion D ("Is the objective consistent with CDC's missions, core values and interests?") to read "Importance of CDC role," and that the highest priority be placed on objectives addressing areas of high disparity, high burden, that are feasible to accomplish, and are in CDC's mission.

The Subcommittee approved of CDC's approach to address health disparities in the Goal Action Plans (GAPs) if they are rigorously applied, but also urged CDC to develop explicit time-phased measures and targets. Specific recommendations were to provide the draft GAPs for the ACD/HDS members' review and that of key minority advocacy and

professional organizations, and that the GAPs include specific action items to address the different needs of different populations.

Both documents were approved as edited. The latter would be incorporated and circulated again among the Subcommittee members, and then to the ACD members.

**Minutes of the December 14, 2006 Teleconference of the Advisory Committee to the Director, CDC**

A teleconference of the CDC Advisory Committee to the Director (ACD) was held on December 14, 2006. The purpose of this meeting was to provide recommendations to the CDC Director on issues addressed by the Ethics and Health Disparities Subcommittees.

In the absence of an appointed committee Chair, Dr. Lynn Austin, Chief of Staff, and ACD Designated Federal Officer served in that capacity.

**The Ethics Subcommittee** report was provided by Dr. Robert Levine and Ms. Kathy Kinlaw. The Subcommittee developed ethical guidance for use in the case of an influenza pandemic in terms of vaccine and antiviral drug distribution and non-pharmaceutical interventions. The resulting document provided the ethical points to consider in crafting recommendations. With ACD approval, it would be forwarded to the CDC Director and then publicly disseminated as Ethics Subcommittee recommendations.

A pandemic situation involves departures from the 'usual' social expectations. Considerations such as a higher priority assigned to preserving a functioning society can make the normally unacceptable criteria relating to "social worth" valid considerations, and provide a utilitarian justification of interventions and procedures (with "side constraints"). During a pandemic, the centralization of decision-making authority becomes a requirement to ensure access to essentials, and non-pharmacological interventions may have to be evidence-*informed* rather than evidence-based.

The grounding ethical considerations include a commitment to transparency throughout the pandemic influenza planning and response processes and the responsibility to maximize preparedness in order to minimize the need to make allocation decisions later. The latter would involve shortening the time, for example, for virus recognition, proactive planning and crafting of response strategies (e.g., training; rule making for government decisions during a pandemic).

Three practical aspects were stressed: 1) that the guidelines must be based on sound science, 2) the importance of working with and learning from global preparedness efforts, and 3) the need to identify clear overall goals. In an epidemic, that goal would be to minimize death and disability; but in a pandemic, the preservation of the functioning of society would supersede. In that case, immunization and treatment priorities could favor those responsible to provide health care, public safety and the functioning of key aspects of society.

However, that could reduce antiviral availability to those at high risk of severe medical complications. The Subcommittee addressed the ethical consequences of that and the balance, in a pandemic situation, of individual liberty and community interests. Because of these challenges, it is critical that CDC's preparation be transparent and actively engage diverse public voices to determine and justify when restrictions or resource diversions are necessary.

To address these two challenges, the ethicists made several recommendations:

1. To balance individual liberty and community interests, involve diverse public representation in decision making, and use three guiding principles:
    a. Adopt the least restrictive practices that will allow the common good to be protected.
    b. Ensure that restrictions are necessary and proportional to the need for protection.
    c. Ensure that those affected by the restrictions receive support from the community (e.g., job security, financial support for individuals and their families, provision of food and other necessities to those who are isolated or placed under quarantine).
2. Establish a fair, pre-pandemic, procedural justice mechanism to ensure:
    a. Consistency of application across people and time
    b. Impartial and neutral decision-makers
    c. The ability to make adequately reasoned decisions that are based on accurate information
    d. The advance participation in decision-making of those affected by such future decisions and their agreement to the proposed process
    e. An appeals process
    f. Establishment of sustainable and enforceable procedures

While even thoughtful preparation will not provide all the guidance that may be needed, the ethicists hoped that the practice of attending to this will also help to guide actions at the local level, where onsite judgment will be needed.

*Advance preparation for resource allocations* include specified decision criteria, established ethical justification (with evaluation of right and wrong decided by decision consequences), established checks and constraints to protect individuals and justice, and assured equitable access to resources within priority groups. Again, while respect for individual autonomy is important, a pandemic may make acceptable or even mandatory the suspension of normal rules and the normally unacceptable criteria of "social worth" would have a place in a pandemic setting. The ethical issues pertaining to non-pharmaceutical interventions include the necessity of a sound scientific basis for efficacy. However, the exception in a pandemic could also be compared to 'compassionate use' of treatments not yet rigorously proven. This evidence-*informed* decision making is less stringent than that which is evidence-based, but would be satisfactory until full knowledge is available for antiviral efficacy.

A clear advance resource distribution plan is critical (e.g., defining the agency in charge to prioritize/distribute, those eligible to receive, who sets priorities). The ethical criteria should be listed, with particular detail provided on the social worth aspects relating to those individuals with functions critical to preserving social functioning. This prioritizing is justified in limited circumstances, but care must be taken not to extend it to other, not morally justified, attributes. Another aspect that bears attention is that of liability for

healthcare professionals (e.g., nurses) who may be delegated authority to do procedures normally carried out by others (e.g., physicians).

*Advance preparation for social limitations in a pandemic.* With regard to limitations upon personal freedom, interventions could include:

- Isolation or quarantine of individuals and families, social distancing (school closings, cancellation of public events), restricted access to essential public venues (e.g., grocery stores, public transportation, gasoline stations) and flexible work scheduling. This is generally recommended for voluntary compliance.
- Limitation of travel within or between cities and/or local regions is ethically justified.
- There is a strong justification for centralized decision making in pandemic, but local autonomy should be honored unless it risks social functioning (e.g., school closings until the influenza wave has passed). The restrictions should be imposed only as needed to be protective, and when not implementing, they risk great harm to the public well-being. The agencies responsible for restrictions (quarantine) also have a prima facie duty to arrange the provision of critical needs (e.g., food, water), and to protect the restricted individuals' jobs and ability to meet living expenses.

*Discussion.* The ACD members resoundingly approved of the document, to the extent of terming it a "masterpiece" in considering all the complex variables involved. They appreciated the evidence-informed basis for decision making in a crisis and the flexibility for those providing treatments beyond their normal duties (e.g., those delivering therapies not fully tested). Such personnel should begin such cross-training as soon as possible. While local officials may delegate that authority, they would still be responsible for competent behavior. The ACD concluded that this was a consideration beyond their area, but urged CDC to explore the possibility of legal protection for such healthcare providers.

Dr. McIlhaney was uneasy about text that referred to the possibility of forced vaccination as an example of potential mandatory interventions and advised, to general agreement, the use of another example (e.g., limited movement) and to be clear that these are recommendations for voluntary action. In response to a question about the scope of the document, Ms. Kinlaw clarified that the Ethics Subcommittee had not addressed the ethics related to manufacturers providing adequate supplies and those of the payers involved. They only responded to CDC's focused request to comment on vaccine and antiviral distribution and individual freedom-limiting measures. Dr. Beasley emphasized for the record, especially regarding the discussion of emergency considerations, the enthusiastic endorsement of the ACD to the recommendations, with no reservations.

**VOTE:** Dr. Lappin moved to accept the document with the minor changes as discussed by the committee. With none opposed, ***the vote passed unanimously.***

**The Health Disparities Subcommittee** report was summarized by Dr. Walter Williams, after which Dr. Yancey provided the Subcommittee's recommendations for the ACD's vote.

The Subcommittee was charged to advise CDC on its objectives, priorities and activities to reduce health disparities. A detailed outline was provided of the Subcommittee's meetings with CDC and HHS staff in February, May, June and September. In these, the Subcommittee was updated on CDC's goals implementation, its action plan template and the link between its research guide and the Goal Action Teams. The Subcommittee discussed how the ACD could be actively involved in identifying objectives for the goal action plans. They reviewed CDC's current organizational structure and operational framework; core values and capabilities; strategic imperatives; four overarching health protection goal areas and 24 sub-goals; approach to developing the criteria and starter objectives for the goal action plans; proposed template for the goal action plans; the partner and public engagement process; and important public health events and context that provide a compelling rationale for CDC to seek ways to enhance the health impact of its programs. The National Center for Health Statistics updated them on progress toward the Healthy People 2010 goals, particularly the population-based objectives in goals one and two related to health disparities.

The Subcommittee discussed and ranked the proposed criteria and starter objectives. Dr. Yancey commented on the great and growing need to integrate this work in CDC's overall activities. Of 195 objectives with sufficient data for tracking, only 24 have shown a decreased disparity of ≥10% and these were generally not in the areas of most mortality and morbidity.

*Starter Objectives.* The Subcommittee's recommendations for the starter objectives were as follows:

- Under "Risk or Threat," add "social determinants of health" as an explicit bullet since the criteria do not capture many risk predictors that are related to social structure and that drive health disparities ("social determinants of health").[1] Address, as needed, the issues that relate to the health system (e.g., access, quality, cultural competency, health literacy, language differences). The science and evidence base for the foregoing needs to be expanded accordingly.
- Rename Criterion D ("Is the objective consistent with CDC's missions, core values and interests?") to read "Importance of CDC role." Delineate it further to address its consistency with CDC's mission, how it supports CDC objectives, and its relation to the essential CDC role in support of key partners' missions.
- Place the highest priority on objectives that address areas of high disparities, high burden, that are feasible to accomplish, and are in CDC's mission.

[1] E.g., class; poverty and low wages; discrimination; institutional racism; power/wealth imbalance; economic burdens; social exclusion of race/ethnic groups; lack of access to productive resources, social goods, affordable housing, and quality education; stress and other quality of life issues.

*Goal Action Plans (GAPs).* The Subcommittee approved CDC's approach to address health disparities in the GAPs if they are rigorously applied, but also urged CDC to develop explicit time-phased measures and targets. The Subcommittee's specific recommendations were as follow:

- Provide the draft GAPs for the ACD/HDS' review.
- Explicitly invite review of the draft criteria and feedback via the CDC Website, by key minority advocacy and professional organizations.
- Include in the GAPs specific action items to address the different needs of different populations (i.e., differing by race/ethnicity; SES; age; gender; disability; sexual orientation and gender identity; geography, etc.)

*Discussion.* Dr. Bender appreciated the Subcommittee's work and robust discussions and hoped that the recommendations would accelerate the changes needed to reduce health disparities. Dr. desVignes-Kendrick strongly supported the recommendations.

Dr. Austin asked for clarification of the last phrase about CDC support of partners' missions, which may be more limiting than CDC's overall goals to protect health.

- Dr. Yancey reported much Subcommittee discussion about incorporating stakeholder input and gaining ownership by some stakeholders of the processes underway. That pertains directly to the marginalization of the groups where disparities are concentrated, which may less automatically accept expert opinion than do more affluent communities.
- Dr. desVignes-Kendrick agreed, adding the hope that CDC would facilitate meetings with appropriate departments of housing, employment, etc., and do broad educational outreach to achieve the hoped-for outcomes.
- On the following day, Dr. Benjamin reported more discussion to also build the goals into another overarching document on health disparities. In this case, he explained, the Subcommittee was trying to say that many things that are important to do, need not be led by CDC, but CDC should be a part of it. Dr. Austin agreed, adding that the reverse is also true, in areas where CDC should lead and needs the support of its partners.

Dr. Austin then asked, in the recommended priorities (high priority, burden, etc.) of the GAPs objectives, if the often-used phrase "greatest impact on health overall" would link to the priorities listed. Specifically, she asked for clarification that what CDC does with its resources to produce the greatest impact on health is not limited to the four of the Subcommittee's focus. Dr. Williams explained that those simply were the criteria the Subcommittee was asked to examine, but in synergy, they would provide the greatest impact. Dr. Yancey raised, as an example, the need for sufficient information to make good decisions. In assessing the benefit of expanded transit versus more walking/biking trails, the latter may appear to be the best health promoter. But the former would have a much greater effect on the populations of most disparity, who have little leisure time for exercise.

**Vote.** Dr. desVignes-Kendrick moved the committee accept these recommendations and Dr. Beasley seconded the motion. *All were in favor and none opposed and the motion*

*passed unanimously*. It was agreed that, as before, the recommendation would be advanced to CDC. Dr. Austin agreed to sign the recommendations as DFO, given the successful vote on the motion.

**Concurrence.**
On the following day, another call was held with Dr. Georges Benjamin, who was fully apprised of the recommendations of the two Subcommittees. Dr. Benjamin had, in fact, provided input to both documents. He stated his agreement with the ACD members' comments and minor edits, and added his concurrence to the unanimous vote of the committee.

**Closing Discussion.**
Dr. Austin reported that Dr. Gerberding had been reviewing the ACD membership's composition and was seeking to enlarge the committee to ensure good cross-representation from multiple areas.

*Public comment* was requested, to no response.

The edits to the documents would be incorporated and circulated again among the Subcommittee members, and then to the ACD members.

Attendance
December 14, 2006, CDC/ACD Teleconference

ACD members:

- R. Palmer Beasley
- Joel Bender
- Mary desVignes-Kendrick
- Debra Lappin
- Sandra Mahkorn
- Joe McIlhaney
- Antronette Yancey

CDC:

- Lynn Austin
- Drue Barrett
- Priscilla Patin
- Thayes Carswell
- Peg Haering
- Stephanie Miles-Richardson
- Steve Redd
- Walter Williams

Consultants:

- Kathy Kinlaw, Emory University
- Robert Levine, Yale University
- Ruth Macklin, Albert Einstein College of Medicine

Other participants:

- Daniel Glucksman, International Safety Equipment Association
- Marie Murray, Recorder
- Robin Stombler, Auburn Health Strategies

December 15, 2006:

ACD member: Georges Benjamin

CDC:

- Lynn Austin
- Drew Barrett
- Walter Williams
- Priscilla Patin

I hereby certify that the foregoing summary of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) meeting held on December 14, 2006 is accurate and complete to the best of my knowledge.

Lynn Austin, Ph.D., Acting Chair

3/26/07

Date