

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION /  
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**

**October 7-8, 2010**

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**Executive Summary**

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**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**

**Thomas R. Harkin Global Communications Center, Distance learning Auditorium  
Atlanta, Georgia**

Summary of Proceedings

**Thursday, October 7, 2010**

**Introductory Remarks and Overview of Meeting Goals**

*Robert Hood, PhD, Chair, Ethics Subcommittee*

At 1:07 PM on Thursday, October 7, Robert Hood, PhD, Chair, Ethics Subcommittee, called the meeting to order. After introductions, no conflicts of interest among Ethics Subcommittee members were noted.

Harold Jaffe, MD, MA, CDC Associate Director for Science, and David Sencer, MD, MPH, CDC Director from 1966 – 1977, addressed the group regarding the recently-revealed studies conducted in Guatemala in the 1940s. They reported that Wellesly College Professor Susan Reverby discovered the Guatemala study when reviewing the archived papers of Dr. John Cutler, a US Public Health Service (PHS) officer, and Tuskegee Syphilis Study investigator. The work was directed by Cutler and was done with the knowledge of his superiors, including then Surgeon General Thomas Parran Jr. Cutler later became Assistant Surgeon General of the PHS in 1958.

The Guatemala research was conducted by the U.S. Public Health Service with funding from the National Institutes of Health (NIH). The study intended to develop a model for transmission of syphilis, gonorrhea, and chancroid. Initial experiments involved female sex workers, who were intentionally infected with *Treponema pallidum*, and then allowed to expose inmates in the penitentiary in Guatemala City via sexual intercourse. When that proved ineffective, the study changed to direct inoculation of prison inmates, and also expanded to the mental hospital in Guatemala City in order to infect the patients with syphilis. Permission was given from the hospital, which received medical supplies from the researchers in return for participation in the study, but there is no evidence that consent was obtained from the patients. The investigators prepared suspensions with the causative organism for syphilis. The first experiments at the hospital involved dripping suspensions onto the foreskins of the patients. When this approach did not yield effective transmission, the investigators abraded the surface of the patients' foreskins before dripping the suspensions. Higher infection rates resulted. Other patients at the hospital were infected through cutaneous injections, a few were infected through intravenous injections, and a few were infected through inoculation directly into the spinal fluid. These experiments continued for approximately two years in Guatemala. Dr. Cutler summarized the experiments, but never published on them, and the studies were closed in 1948.

Upon discovery of the Cutler papers, CDC reviewed 500 individual patient records from the Guatemala syphilis experiments to determine whether the patients were infected and whether they were adequately treated. This information was passed from CDC to the Department of

Health and Human Services (HHS) and then to the White House Domestic Policy Council. The information was publicly released on Friday, October 1, 2010 through a number of websites.

Dr. Jaffe reported that HHS is in discussions with the Institutes of Medicine (IOM) about conducting a review of the facts of the case, including a search for records in Guatemala. In addition, the President's Bioethics Commission has agreed to form a committee to examine larger questions raised by the revelation of these experiments, especially concerning reparations for affected parties and their families, and a course of action if similar situations should come to light in the future.

### **Discussion Points**

- It was pointed out that at the time of the research that, although the research was known to leadership of the PHS, there was no system in place to provide independent review and oversight of protections for human subjects in research as would occur today.
- It was noted that other government agencies, the military, and academia were involved in similar studies, and that additional studies may come to light. One way to respond to the situation is to conduct a proactive, thorough review of all PHS activities and deal with the consequences immediately.
- Dr. Jaffe pointed out that proactive measures have been taken. CDC has reviewed records from their STD program archives. NIH has reviewed their funding agreements for studies like this one.

It was pointed out that CDC was established in 1946, the year that the Guatemala studies began. The part of the PHS that conducted the studies was the Venereal Disease Research Laboratory in Staten Island, New York. The laboratory was moved to CDC in 1957.

### **Strategy for Supporting State, Tribal, Local, and Territorial Health Departments**

*Robert Hood, PhD, and Leslie Wolf, JD, Ethics Subcommittee Member*

Leadership at CDC has made supporting state and local health departments a priority. To this end, a workgroup of the Ethics Subcommittee has been in talks with state public health officials to understand the ethical issues that they face, how they respond to those issues and challenges, and what resources CDC can offer them. Thus far, one meeting has been held with health officials in regions IV and VI, and one webinar has been held with Regions VII and VIII. The webinar outline includes the following topics:

- Define public health ethics
- Describe CDC's public health ethics activities
- Provide examples of public health issues that commonly present ethics concerns
- Discuss state's key ethical challenges and how these challenges have been addressed
- Discuss ways CDC can support states in their efforts to address public health ethics issues

There has been interest in the topics, and participation has been active and enthusiastic. After only two sessions, it is too soon to identify common themes. However, some preliminary observations about ethics concerns and issues that have emerged include the following:

- Rationing and allocation, whether for preparedness or immunizations
- Data use issues
- Controlling infectious disease: a number of officials raised tuberculosis as a challenging issue
- Immigration
- Medically indicated surveillance and tracking and screening
- Community engagement

Many states do not have a formal mechanism for dealing with public health ethics questions. In some states, workgroups created for addressing ethical issues in pandemic influenza preparedness were taking on other public health ethics issues. Some states are using informal peer-to-peer networks to address public health ethics issues, while others are working on formal relationships with university colleagues. Still other states do not have ethicists available to them and would value a means for having these conversations. There was also a discussion of including ethics mechanisms as part of the public health agency accreditation process. The presence of the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO) in these discussions represents a significant partnership source.

### **Discussion Points**

- The workgroup has been discussing the formation of a public health ethics consortium to establish a networking forum for academic ethicists and public health professionals. Such a forum could assist states in addressing public health ethics issues by bringing people together to deal with specific topics, arranging consultations and trainings, and more. Such a consortium could pool resources of academic and medical centers as well as schools of public health.
- The HHS Regional Health Administrators have played an important role in coordinating the webinars with state health officials and they may serve as important resources for addressing ethics issues in the future. Other potential partners include ASTHO, NACCHO, and SACCHO organizations (State Association of City and County Health Officials).
- Members of the Ethics Subcommittee and PHEC could assist state and local public health officials in discussing public health ethics challenges and in establishing networking opportunities in their areas, perhaps by convening monthly or quarterly conference calls within regions.
- There is a clear need to provide timely help and useful tools to those in the field who face ethical dilemmas. The Ethics Subcommittee could address recurring issues and assemble tools and frameworks as resources to public health practitioners. This would require that the Ethics Subcommittee shift its output from longer documents to more nimble, focused, tailored pieces.
- PHEC has established a mechanism for conducting public health ethics consultations. They do these consultations quickly and produce a 6 to 10 page response document that discusses the problem and gives the program points to consider. Sometimes, the discussion of a topic could be the output, rather than the development of a formal document.

- The Ethics Subcommittee could also act as “matchmaker” to direct those with inquiries toward the available literature written on a given topic or to experts in the field. Further, they could develop case studies to help illustrate ethical questions and to stimulate discussions at the state and local levels.
- Each Center in CDC is encouraged to have a Public Health Ethics Lead and a Public Health Ethics Team. Issues then can percolate through the Center up to PHEC. The Teams within Centers have been established with varying degrees of success.
- Hospitals and public health departments are not necessarily hiring new people, but are rather building ethics capacity within their staff. It is important to create forums for people to discuss public health ethics topics. Helping them develop capacity and infrastructure will make a positive difference.

### **Ethical Considerations for Patient Notification Following Infection Control Lapses**

*Joseph Perz, DrPH, Team Lead, Ambulatory and Long Term Care, Prevention and Response Branch, Division of Healthcare Quality Promotion, CDC, and*

*Alice Guh, MD, MPH, Medical Officer, Prevention and Response Branch, Division of Healthcare Quality Promotion, CDC*

Drs. Perz and Guh provided an overview of CDC’s work on patient notification following infection control lapses. The Division of Healthcare Quality Promotion (DHQP) is often called upon to evaluate infection control breaches for bloodborne pathogen transmission. They also provide consultations to health departments and affected facilities and assistance in outbreak investigations involving healthcare-related transmission of bloodborne viruses and in assessments of infection control breaches when there is no clear evidence of disease transmission. In contexts of outbreak investigations when there is known transmission of bloodborne pathogens, there is a duty to warn patients, so the decision to notify patients and to recommend testing is relatively straightforward. Situations in which an infection control lapse is identified in a healthcare setting in the absence of known disease transmission present more uncertainty regarding whether patient notification should occur and whether testing should be recommended. There is little guidance in this area, and it can be particularly challenging for providers and public health officials.

To address some of the challenges and ethical issues associated with these situations, DHQP conducted several activities:

- Development of a framework for evaluating infection control breaches
- Summarizing patient notification events that have occurred in the United States from 1999 through June 2010 in which patients were advised to get tested for bloodborne pathogens
- Conducting focus groups to evaluate patients’ preferences for notification
- Convening a stakeholder meeting in December 2009 to identify best practices for notification
- Requesting a public health ethics consultation through CDC’s Public Health Ethics Committee

DHQP developed a qualitative approach to risk assessment of infection control breaches in healthcare settings. The key points of the document include framing the problem in terms of risk of bloodborne pathogen transmission and determining when notification is warranted and

when testing should be recommended. Various stakeholders should be involved in the decision process. It is important to engage public health early in the process. There are potential harms in notification and testing.

If possible, breaches should be classified as either:

- Category A: A lapse that occurs within the context of known disease transmission, or one that is identified in the absence of evidence of transmission, but a lapse that historically has been shown to be associated with bloodborne pathogen transmission. When a Category A breach occurs, the decision to notify patients and to recommend testing is warranted.
- Category B: A lapse that has never been shown to be associated with bloodborne pathogen transmission. In this category, the lapse risk is uncertain, but is felt to be less than a Category A breach. In situations involving these breaches, multiple factors should be considered, involving participation of stakeholders to determine whether notification should occur and whether to recommend testing.

If the decision for notification and testing is made, then several communication and logistical issues should be considered. They include:

- Developing appropriate and adequate communication materials
- Deciding who should do the notifying and testing
- Working with media issues and public inquiries

DHQP also conducted a review of patient notification events that occurred in the United States from 1999 through June 2010 in which patients were advised to get tested for bloodborne pathogens because of exposure in a healthcare setting. The review showed that notification events occurred more frequently, and their magnitude has increased, in recent years. The review highlighted the need for increased oversight and greater attention to basic infection control as well as the need to identify best practices for conducting patient notifications as well as for the management of positive test results. There is also need for a consensus-based approach to risk assessment, especially for Category B breaches.

In addition, DHQP conducted six patient focus groups in Atlanta and New York to obtain feedback on patient notification and to assess participants' knowledge and awareness of safe injection processes. Additionally, DHQP held a stakeholder meeting that included representatives from health departments and other federal agencies as well as advocacy groups. The meeting focused on identifying best practices for notification and on discussing the ethical issues and dilemmas surrounding notification. As a follow-up to the meeting, DHQP requested an ethics consultation with the CDC PHEC and had a chance to speak with ethicists outside CDC.

Through these processes, DHQP has solidified its approach for Category A breaches. There is general consensus that there should be notification and a recommendation for bloodborne pathogen testing in these breaches. Since DHQP published the document, thinking has evolved regarding Category B breaches. Because of increasing demand for transparency in healthcare, there is a movement toward patient disclosure. Increasingly, they are finding that in Category B breaches, the default course of action may be to disclose, with or without recommendation for bloodborne pathogen testing.

Unresolved issues and remaining challenges include:

- How to determine whether disclosure and testing recommendations should be made in Category B breaches
- How to create a standard protocol for risk assessment of Category B breaches
- Roles and responsibilities in breach situations, especially with the public health's duty to investigate
- Who should notify and conduct testing, as the process is resource-intensive
- Historical breaches and investigations
- Management of patients with positive test results
- Communication issues, including determination of patients' expectations and preferences (e.g., regarding disclosures without recommendation for testing) and appropriate timeline for disclosure
- Narcotics diversion

### **Discussion Points**

- An article written by Rutala and Weber took a quantitative approach to risk assessment, but did not provide clear guidance regarding a level of risk that would trigger action. It also acknowledged that other considerations should be made in patient notification, such as the risk perception of involved stakeholders, potential legal considerations, and more.
- It is important to separate notification and testing, as they can be considered separately.
- The CDC public health ethics consultation was very helpful, as it reinforced DHQP's thinking on how to approach the breaches and helped them define their next steps. It also fostered continuing dialogue with the ethics community. The consult team supported DHQP's approach to Category A breaches and recommended that the default for Category B breaches should be notification, but that this should be determined on a case-by-case basis. The consult team emphasized the need to engage the public and to gather additional information on patients' preferences regarding notification. The consult team also noted the importance of language and terminology used in notification (e.g., how the exposures are described, and how risk is described). They recommended conducting research on how to standardize the language and encouraged building upon stakeholder input in the process. The consult team concluded that CDC has a duty to prevent these incidents in the future.
- Regarding Category B breaches, CDC needs to collaborate more closely with other stakeholders and hold an informed discussion about the challenges presented by these breaches.
- In Category B incidents in which there is not a known precedent for transmission, the Division felt that the risk is hypothetical and very low. They must weigh that risk against the risk of harm of notification.
- Drs. Perz and Guh clarified that focus group participants were aged 45 through 69, and they all had health insurance. There was an attempt to have racial, ethnic, and gender diversity. They are discussing a proposal to examine under-represented populations to learn about their communication needs and perceptions. There could be ethical issues involved with notification letters for different populations. Translation services will be needed as well.

- Based on personal communications, DHQP has learned that some institutions may have regretted losing control of the messaging, especially in the media. Some departments felt they could have communicated better and wished for systems that could have made notifications easier and to assist the facilities and patients. CDC might have an obligation to step in to help with better definitions, language, and terminology.
- The healthcare community at large may not appreciate the risk involved with Category A breaches. The need for notification may be understood, but there are concerns regarding the resources needed to do it well and the responsibility for notification, testing, and follow-up.
- DHQP has promoted such strategies as increased oversight of basic infection control standards across healthcare settings. They emphasize Standard Precautions and basic control measures that represent minimum standards in all settings where care is provided. They agree that there is an ethical obligation on the part of public health practitioners to promote this kind of prevention work.

### **Public Comment Period**

Brenda Robertson spoke via phone. She is a nurse at Grady Memorial Hospital in Atlanta. She expressed interest in the comments about the public health consortium around ethical issues. She deals with ethics in her daily practice, and she felt that such a consortium would be helpful.

### **Friday, October 8, 2010**

#### **Review of Day One Discussions**

Dr. Hood called the meeting to order at 9:04 AM. Dr. Lo joined the meeting via phone at 9:10 AM, giving the group a quorum.

#### **Discussion Points**

- The group discussed how to select Ethics Subcommittee members to participate in PHEC ethics consultations. It was agreed that Dr. Barrett should continue to use her discretion when deciding which Subcommittee members to contact for consultations.
- The Ethics Subcommittee is of greatest help when it addresses CDC priorities. It can also assist in building capacity at the state, local, tribal, and territorial levels.
- Different products from the Subcommittee may suit different topics. The Subcommittee can direct CDC staff or state officials toward existing literature or experts in the field. They can create reports with broad recommendations or case studies.
- The webinars could have different formats, such as information and capacity-building or a private forum for state and local officials to speak with outside experts regarding a specific problem.

- There was discussion regarding whether the Subcommittee was a consulting, reactionary body, or whether it might generate a list of emerging issues for CDC to consider. Advisory committees respond to the needs and priorities of CDC and help guide decision-making on important issues. The Subcommittee could have a role in prioritizing the topics that emerge as common themes from the webinars and meetings with the states. Further, the Subcommittee can advise state health officials and others on issues they may not have considered.

### **Status of the Ventilator Document**

*Drue Barrett, PhD, Designated Federal Official, Ethics Subcommittee, ACD, Centers for Disease Control and Prevention*

The ACD reviewed a draft of the Ventilator Document at their April 2010 meeting and made comments on how to improve it. They pointed out that the document might be more useful with broader input, perhaps from people who will make decisions regarding ventilator allocation.

A preamble was added in order to more clearly define how the document was to be used. The document is not intended to provide triage guidance or to determine who should or should not receive a ventilator. Rather, it focuses on ethical points to consider for those who will create mechanisms for making those decisions. The preamble also added clarification regarding the concept of having uniform guidance versus having local flexibility. Dr. Barrett presented options for document dissemination and for obtaining broader feedback which include the following:

- Forward the document to the network established by the Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases in their work on preparedness issues
  1. 9 grantees who have already addressed ethics issues as part of developing crisis standards of care plans
  2. Multiple stakeholders – health care, public health, emergency management
- Forward the document to the Office of Public Health Preparedness and Response ( OPHPR) pandemic influenza grantees
  1. 62 grantees (50 states; 8 territories, 4 cities (Wash DC, NYC, Chicago, LA
  2. Mention opportunity to comment on the document in a weekly newsletter OPHPR sends out to the public health program directors and during the monthly ASTHO calls
- Forward the document to the NACCHO Preparedness, Pandemic Influenza, and Infection Control Workgroups
- Forward the document to members of the ASTHO Preparedness and Infection Control Policy Committees
- Present the document during the ASTHO sponsored meeting of the Public Health Preparedness Directors (presented by Dr. Robert Hood on September 21, 2010)
- RADM Helminak forwards the document to National Hospital Preparedness Project Awardees

### **Discussion Points**

- State officials struggle with how to have productive discussions on these difficult topics with the public. Some states may need tools to help with their public engagement efforts. This may be an area where the Ethics Subcommittee can provide input.
- The ventilator document was initially called a “guidance,” which may have contributed to confusion about its intent. It is a “points to consider” document: state officials and the public will have to have a voice in how it is implemented.

The ACD will meet on October 28, 2010 and Dr. Hood will present the proposed dissemination plans for the ventilator document. The Ethics Subcommittee will have an opportunity to review any comments received on the document and to revise the document if they feel it is appropriate. If the comments point to the need for more specific details about how to implement ventilator triage plans during a severe pandemic, which is outside the scope of this ethical considerations document, this issue will need to be addressed by CDC rather than by the Ethics Subcommittee.

### **Refresher Course on FACA Rules**

*Terry Wheeler, BS, Acting Team Lead, Ethics and Financial Disclosure Team, Federal Advisory Committee Branch, Management Analysis and Services Office, CDC*

Mr. Terry Wheeler gave the group an overview of the ethics rules that apply to special government employees that serve on Federal Advisory Committees (FACA). As a special government employee (SGE), Subcommittee members are federal employees and are covered by ethics rules and criminal conflict of interest statutes. The statutes are under Title 18 of United States Code, Sections 203, 205, 207, and 208. In addition to the criminal statutes, the conduct of SGEs is governed by a series of ethics rules called “Standards of Ethical Conduct.” SGEs are responsible for completing the OGE 450 Confidential Disclosure Report and submitting it for review on an annual basis. Further, SGEs complete the HHS 697, the Foreign Activities Questionnaire, and submit it for review.

### **Discussion Points**

- The OGE 450 forms are collected throughout the year. The Ethics Subcommittee’s forms are due in June.
- There was discussion about the new Web-based system.
- If individual circumstances change during the year, they should be reported to Drue Barrett, the Subcommittee’s Designated Federal Officer.

### **Public Comment Period**

No public comments were made during this session.

**Procedural Issues and Meeting Wrap up**

2011 Ethics Subcommittee meetings will be held on:

- February 17-18, 2011
- June 16-17, 2011
- October 5-6, 2011

**Certification**

I hereby certify that to the best of my knowledge, the foregoing Minutes of the October 7-8, 2010 Ethics Subcommittee Meeting are accurate and complete.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Robert Hood, PhD  
Ethics Subcommittee Chair

## Attachment 1: List of Attendees

October 7, 2010  
1:00 – 5:00 pm Eastern Daylight Savings Time

### Meeting Participants:

#### Ethics Subcommittee, Advisory Committee to the Director

Ronald Bayer, Columbia University  
Ruth Gaare Bernheim, University of Virginia (phone)  
LaVera Marguerite Crawley, Stanford University (phone)  
Robert Hood, Chair, Florida Department of Health  
Nancy Kass, Johns Hopkins University (phone)  
Bernard Lo, University of California, San Francisco (phone)  
Pamela Sankar, University of Pennsylvania  
Marion C. Wheeler, ACD Member, Strategic Consultant  
Leslie Wolf, Georgia State University

#### Centers for Disease Control and Prevention

Drue Barrett (Designated Federal Officer, Ethics Subcommittee)  
Mary Ari  
Elise Beltrami  
Cynthia Cassell  
Cheryl Coble  
Catina Conner  
Lindsay Feldman  
Amelia Feuss  
Ibrahim Garba  
Neelam D. Ghiya  
Natalie Gonzalez  
Sean D. Griffiths  
Alice Guh  
Gail Horlick  
Heather Horton  
Ruth Jajosky  
Mim Kelly  
Jim Kucik  
Kimberly Lane (phone)  
Lisa M. Lee  
Bryan Lindsey  
Josephine Malilay (phone)  
Mehran Massoudi (phone)  
Ron Otten  
Joseph Perz  
John Piacentino (phone)  
Tanja Popovic  
Joan Redmond Leonard (phone)  
Joseph Rush  
Melissa Schaefer  
Salaam Semaan  
Dixie Snider  
Anne Sowell

Carmen Villar  
Eli Warnock (phone)

Members of the Public

Brenda Robertson, Emory University

October 8, 2010  
9:00 am – 12:30 pm Eastern Daylight Savings Time

**Meeting Participants:**

Ethics Subcommittee, Advisory Committee to the Director

Ruth Gaare Bernheim, University of Virginia (phone)  
LaVera Marguerite Crawley, Stanford University (phone)  
Norman Daniels, Harvard University (phone)  
Robert Hood, Chair, Florida Department of Health  
Bernard Lo, University of California, San Francisco (phone)  
Pamela Sankar, University of Pennsylvania  
Marion C. Wheeler, ACD Member, Strategic Consultant  
Leslie Wolf, Georgia State University

Centers for Disease Control and Prevention

Drue Barrett (Designated Federal Officer, Ethics Subcommittee)  
Cynthia Cassell (phone)  
Barbara Ellis (phone)  
Debraelee Esbitt (phone)  
Lindsay Feldman  
Amelia Feuss  
Ibrahim Garba  
Neelam D. Ghiya  
Sean D. Griffiths (phone)  
Gail Horlick  
Sonja Hutchins (phone)  
John Iskander  
Mim Kelly  
Lisa M. Lee (phone)  
Bryan Lindsey  
Eileen Malatino (phone)  
Josephine Malilay (phone)  
Kathleen McDuffie (phone)  
Mary Neumann (phone)  
Ron Otten  
Tanja Popovic  
Joan Redmond Leonard (phone)  
Stevenson Richardson (phone)  
Eli Warnock  
Terry Wheeler