

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

**Meeting of the Ethics Subcommittee of the Advisory
Committee to the Director (ACD),
Centers for Disease Control and Prevention (CDC)**



**Summary Report
October 11, 2012**

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Acronyms Used in this Document

Acronym	Expansion
ACA	Affordable Care Act
ACD	Advisory Committee to the Director
APHA	American Public Health Association
ASTHO	Association of State and Territorial Health Officials
CBP	(United States) Customs and Border Protection
CDC	Centers for Disease Control and Prevention
DFO	Designated Federal Officer
DGMQ	Division of Global Migration and Quarantine
DHS	Department of Homeland Security
DNB	Do Not Board (list)
FACA	Federal Advisory Committee Act
HIA	Health Impact Assessment
HIE	Health Information Exchange
LO	Lookout (list)
MAPP	Mobilizing for Action through Planning and Partnerships
MDR-TB	multi-drug resistant tuberculosis
NACCHO	National Association of County and City Health Officials
NALBOH	National Association of Local Boards of Health
OSTLTS	Office of State, Local, Tribal and Territorial Support
PHAB	Public Health Accreditation Board
PHEC	Public Health Ethics Committee
SOP	Standard Operating Procedure
STLT	State, Tribal, Local, and Territorial
TB	Tuberculosis

Introductory Remarks and Overview of Meeting Goals

Ruth Gaare Bernheim, JD, MPH
University of Virginia
Chair, Ethics Subcommittee

Ruth Gaare Bernheim, JD, MPH (Chair, Ethics Subcommittee) called to order the meeting of the Ethics Subcommittee of the Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC) at 9:08 am on Thursday, October 11, 2012. Drue Barrett, PhD, (Lead, Public Health Ethics Unit, Office of the Associate Director for Science, CDC, Designated Federal Officer (DFO), Ethics Subcommittee), conducted a roll call of Ethics Subcommittee members present and participating via teleconference. A quorum was present, including ACD representative, Ms. Sara Rosenbaum. Dr. George Isham, the other ACD representative joined the call at 9:30 am.

Ms. Bernheim welcomed the meeting participants. The attendees in the room and on the telephone introduced themselves. A list of meeting participants, the meeting agenda, and the list of Ethics Subcommittee workgroup members are included in this document as Attachments A, B, and C, respectively. The PowerPoint presentation used during the meeting is available at the ACD website (<http://wwwlink.cdc.gov/about/advisory/advCharter.htm#Archives>).

Ms. Bernheim welcomed the following new Ethics Subcommittee members:

- Dr. Janice Chilton, M.D. Anderson Cancer Center
- Dr. Alan Melnick, Clark, Cowlitz, Skamania and Wahkiakum Counties, Washington
- Mr. Matthew Stefanak, Mahoning County District Board of Health, Ohio (retired)
- Dr. Ani Satz, Emory University

Ms. Bernheim asked Ethics Subcommittee members to declare any conflicts of interest. No conflicts of interest were declared.

Discuss and Vote: Recommendations Regarding Revision of Standard Operation Procedures for Use of Travel Restriction Tools for Control of Communicable Diseases

Overview of the Proposed Revision to the Standard Operating Procedures

Francisco Alvarado-Ramy, MD, FACP, CAPT, US Public Health Service
Supervisory Medical Officer, Quarantine and Border Health Services Branch
Division of Global Migration and Quarantine
Centers for Disease Control and Prevention

Dr. Francisco Alvarado-Ramy (Supervisory Medical Officer, Quarantine and Border Health Services Branch, Division of Global Migration and Quarantine (DGMQ), CDC) presented the Ethics Subcommittee with an overview of a proposed revision DGMQ is considering for the CDC standard operating procedures (SOP) used when applying public health travel restriction tools (Do Not Board (DNB) and Lookout (LO) Lists). Dr. Alvarado-Ramy's biography and PowerPoint

presentation is included with this document as Attachments D. His PowerPoint presentation is available at the ACD website (<http://wwwlink.cdc.gov/about/advisory/advCharter.htm#Archives>).

Public health travel restrictions are designed to prevent the transmission of serious communicable diseases in the travel setting. Most requests for restrictions originate at the state and local public health agency level. After CDC receives the requests and reviews the facts of the case, the request for action goes through at least two layers of assessment at CDC for approval. The Department of Homeland Security (DHS) also vets each case. To date, these tools have been used exclusively for tuberculosis (TB). They are applied to all persons, regardless of citizenship, legal residency status, or visa status.

Three criteria must be met before a person is placed on the DNB/LO Lists: The person is infectious or likely infectious with a disease that constitutes a public health threat; the person is not adherent with public health management; and the person is at risk of traveling on a commercial flight or traveling internationally. Approximately 80% of persons placed on the list are removed. Removal from the DNB/LO Lists requires one criterion: The person is deemed not infectious.

When determining whether an individual should be placed on the DNB/LO Lists, CDC relies on a decision support algorithm developed by TB subject matter experts. In some instances, a person is no longer infectious and is removed from the lists, but he or she subsequently stops treatment, raising the likelihood of a return to an infectious state and of the development, or worsening, of drug resistance. Approximately 5% of persons on the DNB/LO Lists have been placed on it more than once. It is difficult to determine when a person becomes contagious after stopping treatment for TB. The algorithm offers a grace period before which a person is considered infectious after stopping otherwise-successful treatment. The grace period is based upon the duration of the time that the person was on effective and uninterrupted treatment. In the case of TB that is susceptible to first-line drugs, the grace period is up to 50% of the time that the person was on treatment. Because the consequences of multidrug-resistant TB (MDR-TB) are more severe, the grace period for persons with MDR-TB is up to 25% of the time that the person was on treatment.

CDC and some state health departments are concerned that the existing grace period in the algorithm has resulted in delaying needed public health action. CDC and state health departments have also experienced difficulty in communicating with patients who are located overseas.

DGMQ proposed the following three changes to the DNB/LO SOP:

- Any grace period afforded a person after interrupting TB treatment will be considered a maximum interval. Therefore, a return to the DNB/LO Lists could be sooner.
- Persons located in the US who have ceased treatment after being removed from the DNB/LO Lists will be returned to the lists as soon as public health authorities conclude there is a reasonable risk that the person is infectious. TB patients in the US are monitored by a state or local health department, so CDC receives information fairly reliably when patients become non-adherent.
- Persons living outside of the US will be required to provide regular documentation of continued or completed treatment, or they will be returned to the DNB/LO Lists. Periodic

documentation of treatment adherence is justified by the difficulty in monitoring treatment in a foreign country.

DGMQ also proposed clarification to the decision support algorithm. Although not explicit in every scenario described in the SOP, the algorithm incorporates several factors when assessing infectious risk. These factors include: drug resistance, continuity of care, and suitability of the treatment regimen. The clarification to the SOP will make these factors specific and explicit. The ultimate goal of these changes is to increase flexibility for public health authorities to assess the public health risk of people who are considered for the DNB/LO Lists while balancing individual and community interests.

Ethics Subcommittee Recommendation

Janice Chilton, DrPH, MA, MPH
M.D. Anderson Cancer Center
Chair, Travel Restriction Workgroup, Ethics Subcommittee

Dr. Chilton provided an overview of the recommendation of the Ethics Subcommittee Travel Restriction Workgroup which was tasked with providing input on ethical considerations relating to the proposed revision to the DNO/LO SOP. The workgroup recommendation is included with this document as Attachment E. Dr. Chilton pointed out that in 2009 the Ethics Subcommittee provided input on ethical considerations for the original version of the DNO/LO SOP.

The Travel Restrictions Workgroup proposed the following recommendation:

“The Ethics Subcommittee members are in agreement that the proposed amendment to the SOP is consistent with the ethical considerations outlined in the 2009 Ethics Subcommittee document. Specifically, these revisions are consistent with the ethical obligation to use the least restrictive measures in a manner that is proportional to the threat and minimizes the possibility of adverse consequences. The Ethics Subcommittee members also are in agreement with protecting community interests while respecting individual rights by requiring patients to provide documentation relevant to treatment outcome. Although the Ethics Subcommittee recognizes that requiring persons living outside of the United States to provide periodic documentation of continued or completed treatment imposes a burden, this burden can be justified based on the need to protect the public, which is the goal of the DNB/LO order. It is important that persons placed on the DNB/LO Lists be given sufficient information about their status and the risk they pose to others prior to being placed on the lists. If they have been given this information, then they should bear some responsibility for demonstrating that they have adhered to treatment. The Ethics Subcommittee also noted that the revised language will allow greater flexibility in keeping individuals off the DNB/LO Lists if they are able to provide documentation of treatment.

“The Ethics Subcommittee emphasizes the importance of taking steps to ensure transparency and uniformity in the application of the algorithm used for determining when a person should be added or returned to the DNB/LO Lists (like cases should be treated alike). These criteria should focus on indicators of

infectiousness and should avoid use of social factors as a proxy for treatment adherence.”

The recommendation aligns with the following ethical principles:

- ❑ Protecting community interests while respecting individual rights: the obligation to protect the public’s health while respecting individual autonomy and protecting individual civil liberties.
- ❑ Transparency and clear communication: the obligation to provide an open decision-making process and clear and efficient communication with affected individuals, communities, and others who may be impacted by the public health action.
- ❑ Social and distributive justice: the obligation to treat individuals respectfully and fairly, to minimize group stigmatization, and to fairly distribute risks, burdens, and benefits of public health actions.
- ❑ Global responsibility: recognition of the importance of working in collaboration with international partners to protect the health of the global community.

The Travel Restrictions Workgroup also created two secondary recommendations that pertain to the need for clarity in the proposed revision to the SOP:

- ❑ The Ethics Subcommittee found the wording of the first amendment to be somewhat confusing. We recommend that this section be revised to more clearly state what the program is proposing. The understanding of the Ethics Subcommittee is that the program would like to be able to add or return persons to the DNB/LO Lists even if they have had fewer than 30 days of treatment interruption if there is other information to suggest there is a public health risk.
- ❑ The program should offer guidance to individuals located outside of the United States on how to report documentation of continuing or completed treatment by providing a template that the patient can provide to their health care provider. Also, the frequency of this report should not be onerous and needs to be clarified.

Discussion Points

- There was confusion among the Ethics Subcommittee regarding the clarity of the language of the first proposed change to the SOP. The Travel Restrictions Workgroup understood what the program was asking, but because the language of the program’s proposal was confusing they suggested that the program provide further clarification when the SOP was revised. The program has not yet written the final revised SOP language.
- Dr. Alvarado-Ramy affirmed that the changes refer to returning individuals to the DNB/LO Lists rather than to keeping individuals on the lists. If a person meets the criteria for removal from the lists and then stops treatment that has otherwise been successful, then without testing, there is uncertainty about his or her infectiousness. If the person is unavailable for testing, then CDC has to make a determination about returning him or her to the list with limited data. The intervals of missed treatment should be considered maximum intervals, especially considering drug resistance and previous adherence to treatment. Authorities should be able to act sooner rather than later. Dr. Alvarado-Ramy indicated that about 5% of people who are removed from the lists lapse into non-adherence.

- Dr. Nicole Cohen (Associate Chief for Science, Quarantine and Border Health Services Branch, DGMQ) provided an example of a person with MDR-TB who was lost to follow-up. He had been on treatment for approximately six months, but the treatment was not optimal. According to the algorithm, his grace period was 25% of the time he was on treatment, up to a maximum of 30 days. In this case, 25% of his time on treatment was greater than 30 days. CDC's TB subject matter experts and the health department officials felt that the patient was likely to be infectious, given that his treatment was intermittent and suboptimal; however, the way that the protocol was written did not allow them to place him back on the DNB/LO Lists until the 30-day grace period ended. They hope to avoid similar situations.
- There was discussion regarding whether the proposed SOP changes offer treating physicians and state and local TB controllers more discretion in determining whether a person with active TB is infectious and may or may not travel. The changes could impose more restrictions on personal liberty, but the restrictions could also result in a reduction in the number of persons who are non-adherent with treatment and are returned to the lists multiple times.
- The current SOP sets a minimum standard for noncompliant individuals before a decision is made regarding their return to the DNB/LO Lists in the absence of information about their infectious status. The change to the SOP converts that minimum into a maximum time before the decision is made about returning the person to the lists. There is no new "floor" in the amendment to the SOP because the literature is not definitive on this issue.
- The Travel Restrictions Workgroup's recommendations reflect an understanding of the need for more flexibility in deciding when individuals should be returned to the DNB/LO Lists. However, the workgroup emphasized that individuals should not languish on the lists.
- The SOP change focuses on making decisions in a setting of noncompliance, uncertainty, and the inability to access additional information to determine infectiousness. The proposed change shifts responsibility for documentation onto individuals who have a history of noncompliance and is not necessarily more restrictive. The change in the SOP will affect where the burden of proof lays regarding demonstrating infectiousness status after a period of partial treatment and may result in the same people being placed on the list sooner, which may prevent transmission. Initial placement on the lists places the burden on public health authorities to document infectiousness and potential threats to the community. After a period of noncompliance, the change to the SOP shifts the burden of proof to the individual to prove that he or she is noninfectious in order to be removed from the lists.
- The Ethics Subcommittee discussed potential unanticipated issues that could emerge as the new protocol shifts accountability and responsibility for liberty-limiting restrictions. The workgroup felt that individuals should have guidance and assistance so that providing documentation of noninfectiousness will not be overly burdensome. In addition, the issue of shared responsibility is important when the burden of responsibility shifts from public health authorities to the individual. The person subjected to the exclusion of flying should have a due process or appellate process available to discuss the case.
- It was suggested that the SOP language specifically address whether local and state public health officials are given full discretion to make decisions regarding placing persons back on the DNB/LO Lists. However, it was noted that the ultimate regulatory authority for executing

the DNB/LO Lists is federal responsibility; federal entities fulfill this responsibility in support of a local or state request.

- Mr. Matthew Stefanak (Mahoning County District Board of Health, Ohio (retired), Ethics Subcommittee member) suggested an addition to the program's language. [The suggested addition is underlined in the following paragraph.]

"We recommend making explicit that any time periods for treatment interruption described in the DNB/LO algorithm should be considered maximum off-treatment periods, and earlier addition or return to the DNB/LO may be considered on a case-by-case basis based on public health risk. TB drug resistance, continuity of care, and suitability of treatment regimen are leading factors that CDC will consider when exercising its discretion to add or return an individual to the DNB/LO Lists upon request from local or state health officials. Treatment regimens are evaluated based on American Thoracic Society, Infectious Diseases Society of America and CDC *Treatment of TB* Guidelines."

- It was pointed out that this issue is interesting because the available information is imperfect. In these complex cases, especially when there is disagreement among the authorities, having a resource for an ethical consultation would be helpful. Dr. Martin Cetron (Director, DGMQ) agreed that their challenge was decision-making in an uncertain setting. They would welcome a real-time and responsive consultation mechanism. They frequently review their actions and consider tweaks to their guidance. On-going evaluation of their principles and algorithms is important, as is review of practice and implementation to ensure that they are consistent with their principles. Dr. Barrett suggested that the internal CDC Public Health Ethics Committee (PHEC) could provide rapid ethical feedback on a case-by-case basis.
- There was discussion regarding whether the Ethics Subcommittee could support the spirit of the changes in the absence of the exact language of the revised SOP. Dr. Barrett said that the program has not yet changed the SOP. Instead, the program was asking whether there were ethical reasons not to make the proposed change. Regarding process, Dr. Barrett stressed that because the Ethics Subcommittee is a subcommittee of the ACD, all feedback provided by the Subcommittee must go through the ACD. They must generate a recommendation for the ACD to review and comment on, which could then go to the program.
- Dr. George Isham (HealthPartners, ACD Representative to the Ethics Subcommittee) also stated that the Subcommittee may need additional orientation regarding its advisory role. Dr. Isham pointed out that the Ethics Subcommittee should perform an ethical analysis on a given issue and pose recommendations and advice to the ACD. He did not expect the Ethics Subcommittee to approve operational language.
- A motion was made by Mr. Stefanak to approve the Travel Restrictions Workgroup recommendations; however the Ethics Subcommittee did not reach consensus on the recommendation and Mr. Stefanak withdrew the motion. It was clear that The Ethics Subcommittee endorsed the principle of more discretion, but was concerned with protections around the process.
- Dr. Barrett thanked the Ethics Subcommittee for their input. Per Dr. Isham's comment, she suggested that they could spend time in a future agenda discussing the role of Federal

Advisory Committee Act (FACA) committees, which serve in an advisory role, not a regulatory role. The program makes final decisions about its operations. The Ethics Subcommittee is a subcommittee of the ACD rather than a parent committee; therefore, the goal of the Ethics Subcommittee is to address issues that the ACD wishes to address.

- Ms. Bernheim also thanked the Ethics Subcommittee for the discussion, observing that even when a formal vote does not occur, the discussion itself is useful to CDC. She thanked Dr. Isham for his reminder of the role of the Subcommittee, and stressed that they are respectful of their role as a subcommittee of the ACD.

Discuss and Vote: Recommendations Regarding Approaches for Enhancing Collaboration Between Public Health Ethics and Public Health Law

Kenneth Goodman, PhD
University of Miami
Chair, Public Health Law Collaboration Workgroup, Ethics Subcommittee

Dr. Goodman presented a series of recommendations from the Public Health Law Collaboration Workgroup regarding the collaboration between public health ethics and public health law. The workgroup's recommendations are included with this document as Attachment F:

- CDC should continue to collaborate with the Network for Public Health Law to offer its membership training on public health ethics either through webinars or through annual conferences.
- CDC should continue to provide training on public health ethics that includes information on the complementary roles of public health law and public health ethics as part of the training materials CDC is developing for local health officials.
- The Ethics Subcommittee should develop a framework to highlight differences and similarities between legal and ethical issues, including addressing how law and ethics approach issues and clarifying how legal reasoning and ethical reasoning differ. This should include use of cases to illustrate why law is necessary but not sufficient for addressing some public health challenges.
- The Ethics Subcommittee should explore potential additional areas where public health law and public health ethics could work together, including the development of ethics standards for the accreditation process, development of recommendations regarding cross-sectorial collaboration (health in all sectors), and development of procedures for effective community engagement.

Dr. Goodman reported that the workgroup engaged in rich discussions about the relationship between ethics and the law. As public health officials are trained, they are often interested in learning about both their legal and their ethical obligations. These obligations offer teachable moments to illustrate how law is shaped by shared societal values.

The workgroup is committed to making explicit various ways to navigate public health ethics and public health law. Case studies are useful in this work. Precedents set in law may carry more

weight than precedents set in ethics. Cases present opportunities to share problem-solving strategies.

The workgroup recommended the developed of a document that would describe a framework for enhancing collaboration between public health law and public health ethics. The outline for this framework document is included as Attachment G. The sections of the proposed document include the following:

- Overview
- Introduction to public health law
- Introduction to public health ethics
- Similarities and differences between public health law and public health ethics
- Opportunities for symbiosis between public health law and public health ethics
- How law and ethics work together when faced with scientific or policy uncertainty
- How to proceed when law and ethics do not agree or when the law is silent
- Cases to illustrate how to apply the analysis framework

Discussion Points

- Ms. Bernheim, Dr. Drue Barrett Dr. Leonard Ortmann (Public Health Ethics Unit, CDC), and Ms. Leslie Wolf (Georgia State University, Public Health Law Collaboration Workgroup member) reported on a public health ethics training CDC conducted on October 10 as a pre-conference workshop at the Public Health Law Network Conference in Atlanta. The maximum number of 50 people signed up for the four-hour workshop, and more people wanted to attend. The response to the workshop was very positive. The training involved use of case studies that reflect ethical issues encountered in public health practice.
- Ms. Wolf noted that conversations with state and local health officials pointed out that many health officials consult their lawyers when they face ethical issues. This is part of what led the Workgroup to propose the development of a framework for enhancing collaboration between public health law and public health ethics. In addition, many issues need to be addressed by law and ethics simultaneously. The context that frames the ethical dilemma or tension includes the legal framework. It is important to bring the two professions together for conversations that can contribute to practice.

Motion

Dr. Alan Melnick moved that the Ethics Subcommittee endorse both documents from the Public Health Law Collaboration Workgroup: recommended approaches for enhancing collaboration between public health law and public health ethics and the proposed outline for a framework for enhancing collaboration. Mr. Matthew Stefanak seconded the motion. The motion carried unanimously.

Discuss and Vote: Development of Case Studies

Matthew Stefanak, MPH
Mahoning County District Board of Health, Ohio (retired)
Chair, State, Tribal, Local, and Territorial (STLT) Support
Case Development Workgroup, Ethics Subcommittee

Mr. Stefanak presented case studies on a mandatory influenza vaccine program and community health needs assessment (CHNA). The mandatory influenza vaccine program case is included with this document as Attachment H. The CHNA case is included with this document as Attachment I.

Dr. Barrett said that after approval by the Ethics Subcommittee and the ACD, the cases will be included in CDC's training manual that was used at the Public Health Law Conference and has been used with the National Association of City and County Health Officials (NACCHO), the National Association of Local Boards of Health (NALBOH), and the American Public Health Association (APHA). The manual currently includes five cases that were developed outside the Ethics Subcommittee. Additional cases will be developed by the Ethics Subcommittee, and as they are approved, they will be inserted into the manual.

The case study format is standardized. The case begins with a background description and includes discussion questions, a scenario shift, references, and facilitator information. The mandatory influenza vaccine case study describes a nursing home that is considering requiring influenza vaccines for all of its employees. The CHNA second case study is timely, as it addresses the requirement under the Affordable Care Act (ACA) that non-profit community hospitals conduct a CHNA. The case illustrates the potential tension between competing priorities as the health director wants to ensure that the hospital and other partners in the process "walk the talk" of collaborative community health assessment and planning.

Several case studies are in various stages of development, including the following:

- School-based TB screening approaches
- Treatment for multi-drug resistant TB
- Parental refusal to vaccine (pertussis and varicella)
- Public health interventions to reduce intimate partner violence
- Prescription drug abuse
- Consumer product safety (table saw)
- Social determinants of health

The cases that the workgroup will likely finalize next are the vaccine refusal cases. The Ethics Subcommittee's prior work on cases relating to social determinants of health are in a different format, but could be modified to fit the current format. It was also noted that during the April 2012 ACD meeting, the CDC Director expressed interest in the issue of the integration of clinical care and public health. For example, public health surveillance data is collected and identifies problem behaviors, but does not link people back to clinical services to address the behaviors. A case could address ethical issues relating to the integration of public health and clinical medicine.

Discussion Points

- Dr. Barrett indicated that the influenza vaccine case will serve as a model for all of their subsequent cases. The remaining work to be done on the CHNA case is the development of the facilitator information. The facilitator information includes additional questions, points to consider, and a sample ethical analysis.
- Ms. Bernheim acknowledged the important roles that Dr. Isham and Ms. Sara Rosenbaum, ACD representatives to the Ethics Subcommittee, played in creating the CHNA case. The idea for developing this case was based on input from Ms. Rosenbaum during a previous Ethics Subcommittee meeting. The ACA presents opportunities for public health to become more engaged with a range of stakeholders. The Public Health Law Conference workshop attendees mentioned these opportunities and the ways in which public health can be empowered to be more active. The attendees also expressed interest in the advocacy role that public health plays and the moral responsibility and opportunity that public health has in the community.
- Dr. Isham said that the case presents the issues well and is very instructive. The major issues associated with community benefit include a clear understanding of what the law says, versus “what we would like it to say.” The law serves as a base for the conflicts in the example and will help the field understand the context and the issues that arise. The CHNA case illustrates the complementary roles of law and ethics. He complimented the workgroup on the case.
- It was also noted that the timing of the CHNA case is very good. Hospitals are conducting their needs assessments now, and the case will be a useful tool for local health jurisdictions in their deliberations with local hospitals.
- Additional suggestions for case studies included:
 - The use of public health data and the responsibility that public health may have to work with clinical care to address findings in the data.
 - Data flow as part of Health Information Exchanges (HIEs), which integrate the public health and medical systems. Sharing data, especially personal health information, could serve as a basis of a strong case study.
 - As data are collected and analyzed by public health, problems with incidental findings may arise. These problems may be similar to problems that are experienced by personnel who work in genetics or at biorepositories.
 - A case on health impact assessments (HIAs) could be useful for the field. Many local and state officials are conducting HIAs not just on the built environment, but also on policies. There are ethical issues to consider at every step of these assessments.
 - Cases that address disparities and inequity, and how public health’s decisions and policies disparately affect different populations (e.g., homeless populations). There was also discussion of addressing this issue in existing cases by exploring differential effects among various groups.
 - Conflict of interest is a recurrent issue. As public health is encouraged to create new partnerships and find new resources, the relationships can be complicated, and conflict of interest is a critical point.

Motion

Dr. Melnick moved that the Ethics Subcommittee approve the mandatory influenza vaccine case and the direction of the CHNA case. He also recommended leaving the selection of which cases to develop next to the discretion of the workgroup. Dr. Kahn seconded the motion. The motion carried unanimously.

Update: Development of Recommendations Regarding Evaluation of Public Health Ethics Activities and the Development of Accreditation Standards

Ruth Gaare Bernheim, JD, MPH
University of Virginia
Chair, Evaluation Workgroup

Ms. Bernheim reported that the Evaluation Workgroup is addressing one of the most challenging and interesting questions for the field of ethics -- how to evaluate the impact of ethics activities. The workgroup has been focusing on defining public health ethics and establishing why evaluating the impact of public health ethics activities is important. They have developed a model for evaluating public health ethics activities that will be useful for additional work on identifying ethics standards and measures for the public health department accreditation process.

She directed the group's attention to the current draft of the logic model for evaluating public health activities, which includes potential indicators, measures, and data sources. The outcomes are divided into staff, program, organization, and community/public. The draft logic model is provided with this document as Attachment J. The Evaluation Workgroup has had support from CDC's evaluators (Tom Chapel and Craig Thomas) who have provided technical input on the evaluation process.

Discussion Points

- Many organizations approach ethics from the perspective of justifying their decisions to the community. The new approach applies to how an organization and its leadership behave ethically. The community/public health outcome in which the decision-making process is perceived as ethical could be the same for staff, as staff perceptions of trust in the ethical nature of the process can be measured.
- Staff members should be educated and able to apply ethical principles in their everyday work. This point is included in the logic model, but the language could be more direct and clear.
- There was discussion regarding the ethical dimension of "addressing health equity/protection of vulnerable populations" and whether it is more useful to think about "global vulnerability" as opposed to specific populations. It was noted that people are

universally and constantly vulnerable to illness and disability, and the public health model that divides people into certain populations is not helpful. The Ethics Subcommittee discussed differential risks; the impact of environmental and biological factors; and the impact of social determinants of health and tools for resilience. Everyone in society should have access to the same tools and opportunities to maximize their health. When policies target particular groups or populations, people who do not fall into a discrete group get nothing. It was suggested that the logic model could add language to “lift everyone up,” recognizing common vulnerabilities and addressing the question of fair distribution.

- There was discussion regarding how the outcomes in the table parallel the logic model. Additionally, there was concern that the large number of measures pertaining to public health infrastructure may seem burdensome to health departments. It was clarified that health departments will not measure or be held accountable for everything in the model. The logic model is a road map to better articulate the processes and outcomes associated with public health decision-making. The measures in the model are concepts and are not yet true measures.
- There was discussion regarding measuring the amount of bad press on public health decisions. The publicity is good most of the time, and the more times a health department is cited as a trusted and credible source of information, the more likely it is acting in the public interest and acting ethically. Tracking the number of “hits” that the health department receives in the local media may be a better way to measure the impact of its ethics efforts.
- There was discussion about the role of volunteers in public health activities. Certain laws protect volunteers. It was unclear how volunteers would fit into the logic model. One suggestion was to specify whether “staff” includes paid staff and volunteers.
- The Ethics Subcommittee discussed the importance of creating mechanisms by which staff can feel safe reporting or questioning policies or decisions. Anyone who wants access to the ethics committee should have access to it, and a mechanism should be in place to protect the confidentiality of those who request it.
- The Ethics Subcommittee agreed that the logic model is moving in the right direction. The Evaluation Workgroup would refine the model and the measures.
- Ms. Bernheim thanked the Ethics Subcommittee for their input and discussion, indicating that the Evaluation Workgroup would refine the model and the measures. The model is part of a bigger project with PHAB to add ethics to the public health accreditation process.

Update on Ethics and Accreditation

Robin Wilcox, MPA **Chief Program Officer, Public Health Accreditation Board**

Dr. Barrett reminded the Ethics Subcommittee that during the last meeting, Dr. Kaye Bender (President and CEO, PHAB) presented an overview of the accreditation process. They discussed ways in which the Ethics Subcommittee could contribute to developing ethics standards and measures for the health department accreditation process. The report from PHAB to the Ethics Subcommittee can be found at the ACD website (<http://wwwlink.cdc.gov/about/advisory/advCharter.htm#Archives>).

Ms. Wilcox reported that PHAB is determining how to integrate issues of ethics and health equity into the PHAB Standards and Measures. The current version of the Standards and Measures incorporates ethics and health equity, but PHAB intends to revise the Standards and Measures so that ethics and health equity are more visible and specific.

The standards in the PHAB Standards and Measures document are grouped by domain, which correspond with the 10 essential public health services. Each domain includes standards, and each standard includes measures. The document also includes narratives to describe each domain and its importance to public health. Every measure is accompanied by documentation that a health department applying for accreditation must provide. Statements also clarify the purpose and significance of each measure to public health, the community, and public health departments. The Standards and Measures document provides examples of documentation and other tools. Revising the Standards and Measures includes revising the narratives that guide the health departments. The narratives and required documentation guidance have helped introduce new ideas to health departments. For instance, the examples and documentation have helped guide public health departments regarding community health assessments.

PHAB has developed a work plan that includes gathering information and input from a variety of sources. The current Standards and Measures will be revised using a track-changes process and will be vetted with the public health community. There are opportunities to provide ideas and recommendations to PHAB now as the document is being revised. There will also be an opportunity to comment on the first draft of the changes. An advisory committee will guide PHAB in the process. Their goal is to release the revised Standards and Measures in January 2014, and for them to become effective in July 2014.

One of PHAB's strategies for collecting information is the Think Tank. They have convened several Think Tanks, and more are scheduled as part of their work plan. The Think Tanks include groups of experts in a given topic to discuss the state of the art, the state of the field, and other concepts that should be applied to improve the Standards and Measures. An ethics/health equity Think Tank is being planned for January or February 2013, which presents another opportunity for the public health ethics community to provide input.

Ms. Wilcox welcomed and encouraged the Ethics Subcommittee's comments and suggestions for improving the Standards and Measures. PHAB's goal is not to conduct a wholesale revision

of the Standards and Measures; rather, their goal is to strengthen and clarify them, particularly in the areas of ethics, health equity, public health informatics, and communication science.

Dr. Barrett indicated that a conference call with PHAB with representatives from NACCHO and the Association of State and Territorial Health Officials (ASTHO) was scheduled in October to discuss how to best collaborate on the development of recommendations for ethics standards and measures.

Public Comment Period

At 2:01 pm, Dr. Barrett opened the floor for comment from members of the public in the room and on the telephone. No comments were provided.

Wrap Up and Review of Next Steps

Drue Barrett, PhD
Lead, Public Health Ethics Unit
Office of the Associate Director for Science, CDC
Designated Federal Officer, Ethics Subcommittee

Dr. Barrett reviewed the next steps for the Ethics Subcommittee, which included the following:

- The Travel Restrictions Workgroup will revise the recommendations for the proposed changes to the SOPs. They will determine at what point the Ethics Subcommittee should make a formal recommendation to the ACD. Nothing will be presented to the ACD during their October 25, 2012 meeting on this topic.
- The Ethics Subcommittee approved the mandatory influenza vaccine case, and it will be presented to the ACD.
- The Ethics Subcommittee approved the two public health law collaboration documents, and they will be presented to the ACD.
- The Case Development Workgroup will complete the CHNA case and move forward on the other suggested cases.
- The Evaluation Workgroup will address aspects of the logic model and the outcomes that were identified as problematic.
- Ethics Subcommittee members were encouraged to submit specific suggestions for revisions to the evaluation model.
- Any recommendations that the Ethics Subcommittee makes regarding PHAB's Standards and Measures will go through the ACD.

The ACD generally meets at the end of April and the end of October every year. Future Ethics Subcommittee will be timed so that they are held in advance of the ACD meeting, allowing time for documents to be revised before they are presented to the ACD. Because of budget issues, there is a movement toward more virtual meetings. The Ethics Subcommittee typically meets in February, June, and October. The February 2013 meeting will likely be convened virtually. The Ethics Subcommittee may shift to a schedule of meeting twice yearly.

Discussion Points

- Dr. Goodman referred to the proposed evaluation measure of good and bad publicity for public health, and inquired as to whether CDC tracks that information. He observed that good decisions that solve problems well are not newsworthy, and that exposure in the media may give a false impression of an entity.
- Mr. Stefanak commented that good or bad, publicity is good. The publicity is good most of the time, and the more times a health department is cited as a trusted and credible source of information, the more likely it is acting in the public interest and acting ethically. Tracking the number of “hits” that the health department receives in the local media may be a better way to measure the impact of its ethics efforts. His health department utilizes a Google-based news tracking service to track the department’s mentions in a range of media. This information is an indirect way to measure a health department’s presence in its community.

With no further comments offered or questions posed, Ms. Bernheim thanked the meeting attendees for their participation. The meeting was officially adjourned at 2:12 pm.

Certification

I hereby certify that to the best of my knowledge, the foregoing minutes of the October 11, 2012 Ethics Subcommittee meeting are accurate and complete.

Date: Ruth Gaare Bernheim, JD, MPH, Ethics Subcommittee Chair

Attachment A: List of Meeting AttendeesEthics Subcommittee, Advisory Committee to the Director

Ruth Gaare Bernheim, University of Virginia
Janice Chilton, M.D. Anderson Cancer Center
LaVera Marguerite Crawley, Stanford University (phone)
Kenneth Goodman, University of Miami
George Isham, HealthPartners, ACD Representative (phone)
Jeff Kahn, University of Minnesota
Alan Melnick, Clark, Cowlitz, Skamania and Wahkiakum Counties, Washington
Sara Rosenbaum, Georgetown University, ACD Representative (phone)
Jennifer Ruger, Yale University
Ani Satz, Emory University
Matthew Stefanak, Mahoning County District Board of Health, Ohio (retired)

Centers for Disease Control and Prevention

Drue Barrett (Designated Federal Officer, Ethics Subcommittee)
Francisco Alvarado-Ramy (Envision)
Elise Beltrami
Michele Bohm
Marty Cetron (phone)
Nicole Cohen
Catina Conner (phone)
Barbara Ellis
Sonja Hutchins (phone)
Vik Kapil
Mim Kelly
Lindsay Kramer
Leonard Ortmann
Craig Thomas

Members of the Public

Kendra Cox, Cambridge Communications
Bill Sexson, Emory University
Robin Wilcox, Public Health Accreditation Board (phone)
Leslie Wolf, Georgia State University

Attachment B: Meeting Agenda

Meeting of the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC)

Thursday, October 11, 2012
8:30 am – 2:30 pm Eastern Daylight Savings Time

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

Call-in Information: 1-877-928-1204, Pass Code 4305992#

Meeting Agenda

8:30 – 8:45	<p>Introductory Remarks and Overview of Meeting Goals – Ruth Gaare Bernheim, JD, MPH, Chair, Ethics Subcommittee</p> <ul style="list-style-type: none"> • Welcome and introductions • Ethics Subcommittee members declaration regarding conflicts of interest • Overview of meeting goals <ul style="list-style-type: none"> ○ Finalize recommendation regarding “Ethical Aspects of Proposed Amendment of Infectiousness Standard for Travel Restrictions” ○ Finalize mandatory influenza vaccine case and provide update on community health needs assessment case ○ Finalize recommendations regarding approaches for enhancing collaboration between public health ethics and public health law ○ Provide update on progress toward developing evaluation framework and development of ethics accreditation standards
8:45 – 9:45	<p>Discuss and Vote: Recommendations Regarding Revision of Standard Operating Procedures for Use of Travel Restriction Tools for Control of Communicable Diseases</p> <ul style="list-style-type: none"> • Overview of the proposed revision to the standard operating procedures – Francisco Alvarado-Ramy, MD, FACP, CAPT, U.S. Public Health Service, Supervisory Medical Officer, Quarantine and Border Health Services Branch, Division of Global Migration and Quarantine, CDC • Ethics Subcommittee recommendation – Janice Chilton, DrPH, MA, MPH, Chair, Travel Restriction Workgroup
9:45 – 10:00	BREAK
10:00 – 11:00	<p>Discuss and Vote: Development of Case Studies – Matthew Stefanak, MPH, Chair, STLT Support (Case Development) Workgroup</p> <ul style="list-style-type: none"> • Mandatory influenza vaccine case (finalize) • Community health needs assessment case (update)
11:00 – 12:00	<p>Discuss and Vote: Recommendations Regarding Approaches for Enhancing Collaboration Between Public Health Ethics and Public Health Law – Ken Goodman, PhD, Chair, Public Law Collaboration workgroup</p> <ul style="list-style-type: none"> • Recommended approaches for enhancing collaboration between public health law and public health ethics • Proposed outline for a framework for enhancing collaboration between public health law and public health ethics
12:00 – 1:00	LUNCH
1:00 – 2:00	<p>Update: Development of Recommendations Regarding Evaluation of Public Health Ethics Activities and the Development of Accreditation Standards – Ruth Gaare Bernheim, JD, MPH, Chair, Evaluation Workgroup</p>
2:00 – 2:15	Public Comment
2:15 – 2:30	<p>Wrap up and Review of Next Steps</p> <ul style="list-style-type: none"> • Workgroup participation • Proposed dates for 2013 meetings
2:30	Adjourn

Attachment C: Ethics Subcommittee Workgroup Membership

Ethics Subcommittee Workgroup Membership

For October 11, 2012 Ethics Subcommittee Meeting

Travel Restriction Workgroup (established January 2008)

FY2012 Meetings: May 14, 2012, August 16, 2012 and September 17, 2012

Current Members:

- **Janice Chilton, Workgroup Chair, MD Anderson Cancer Center (Ethics Subcommittee Member)**
- Kathy Kinlaw, Emory University
- Robert Levine, Yale University
- Jenifer Ruger, Yale University (Ethics Subcommittee Member)
- Ani Satz, Emory University (Ethics Subcommittee Member)

STLT Support (Case Development) Workgroup (established April 2010)

FY2012 Meetings: November 16, 2011, April 10, 2012, and September 14, 2012

Current Members:

- Ruth Gaare Bernheim, University of Virginia (Ethics Subcommittee Member)
- Alan Melnick, Clark, Cowlitz, Skamania, and Wahkiakum Counties Public Health (Ethics Subcommittee Member)
- **Matthew Stefanak, Workgroup Chair, Northeast Ohio Medical University (Ethics Subcommittee Member)**

Evaluation Workgroup (established October 2011)

FY2012 Meetings: October 26, 2011, January 11, 2012, January 24, 2012, March 1, 2012, March 15, 2012, April 5, 2012, May 4, 2012, August 23, 2012 and September 20, 2012

Current Members:

- **Ruth Gaare Bernheim, Workgroup Chair, University of Virginia (Ethics Subcommittee Member)**
- Alan Melnick, Clark, Cowlitz, Skamania, and Wahkiakum Counties Public Health (Ethics Subcommittee Member)
- Eric Meslin, Indiana University (Ethics Subcommittee Member)
- Matthew Stefanak, Northeast Ohio Medical University (Ethics Subcommittee Member)
- Jennifer Ruger, Yale University (Ethics Subcommittee Member)

Public Health Law Collaboration Workgroup (established March 2012)

FY2012 Meetings: March 12, 2012, April 18, 2012, May 24, 2012 and August 24, 2012

Current Members:

- Ruth Gaare Bernheim, University of Virginia (Ethics Subcommittee Member)
- **Kenneth Goodman, Workgroup Chair, University of Miami (Ethics Subcommittee Member)**
- Jeff Kahn, Johns Hopkins University (Ethics Subcommittee Member)
- Ani Satz, Emory University (Ethics Subcommittee Member)
- Leslie Wolf, Georgia State University

Attachment D: Francisco Alvarado Ramy Biographical Sketch**Francisco Alvarado-Ramy, MD****Supervisory Medical Officer, Quarantine and Border Health Services Branch,
NCPDCID**

Captain Francisco Alvarado-Ramy serves as a supervisory medical officer assigned to CDC's Division of Global Migration and Quarantine. The DGMQ mission is to prevent introduction and spread of infectious diseases in the U.S. and to prevent morbidity and mortality among immigrants, refugees, migrant workers and international travelers. CAPT Alvarado-Ramy supervises medical and epidemiologic support for the quarantine system in the United States. Most recently CAPT Alvarado-Ramy was detailed as Deputy Director of the Community Measures Task Force as one of the pillars of the U.S. government's H1N1 Response.

Dr. Alvarado-Ramy joined CDC in 1999 as an Epidemic Intelligence Service (EIS) officer where he conducted scientific studies and investigated outbreaks related to healthcare-associated infections and other adverse events. He was a member of the CDC response to the anthrax attacks in New York City. As a CDC assignee, he has served as a state epidemiologist. In that capacity he led the development of public policy on the prevention of serious morbidity and mortality from Respiratory Syncytial Virus (RSV) infection, among other accomplishments.

Dr. Alvarado-Ramy received a BS from Tulane University and an MD from the University of Puerto Rico. He completed a residency in internal medicine at the Cleveland Clinic in Cleveland, Ohio. He is certified by the American Board of Internal Medicine. He has been the recipient of national awards, such as the Juan Carlos Finlay Award from the US Public Health Service and the Martha Katz Award from the National Public Health Leadership Institute.

Attachment E: Travel Restrictions Workgroup Recommendations Document**Recommendation of the Ethics Subcommittee, Advisory Committee to the Director,
Centers for Disease Control and Prevention (CDC)¹**

Developed by the Ethics Subcommittee Travel Restriction Workgroup on behalf of the Ethics Subcommittee, Advisory Committee to the Director, CDC²

Approved by the Ethics Subcommittee on _____

Approved by the Advisory Committee to the Director, CDC on _____

**Ethical Aspects of Proposed Amendment of the
Infectiousness Standard for Travel Restrictions****Question to the Ethics Subcommittee:**

State, local and international health officials can request through CDC that the Department of Homeland Security (DHS) place travel restrictions on persons who may be contagious with a communicable disease that poses a serious public health threat. A number of tools are available to restrict travel including the Do-Not-Board and Look Out (DNB/LO) Lists.

The Ethics Subcommittee has been asked to provide input on ethical considerations relating to a proposal by the Division of Global Migration and Quarantine (DGMQ) to amend their standard operating procedures (SOP) for use these travel restriction tools (see Attachment A). This amendment would result in the following revisions to the SOP:

1. Length of time a person has interrupted treatment will be considered on a case-by-case basis when determining if a person should be added or returned to the DNB/LO Lists. The current time period, determined by an algorithm that allows up to 30 days off treatment based on level of drug resistance and

¹ The members of the Ethics Subcommittee include Ruth Gaare Bernheim (Subcommittee Chair), University of Virginia; Janice A. Allen Chilton, The University of Texas MD Anderson Cancer Center; LaVera Marguerite Crawley, Stanford University School of Medicine; Kenneth W. Goodman, University of Miami; George Isham, Health Partners; Jeffrey Kahn, Johns Hopkins University; Alan L. Melnick, Oregon Health and Science University; Eric Meslin, Indiana University; Sara Rosenbaum, George Washington University; Jennifer Prah Ruger, Yale University; Ani Satz, Emory University; and Matthew Stefanak, Northeast Ohio Medical University.

² The members of the Travel Restrictions Workgroup include are Janice Chilton, Workgroup Chair, The University of Texas MD Anderson Cancer Center (Ethics Subcommittee member); Kathy Kinlaw, Emory University; Robert Levine, Yale University; Jenifer Ruger, Yale University (Ethics Subcommittee member); and Ani Satz, Emory University (Ethics Subcommittee member).

duration of prior treatment, will be considered the maximum; however, the revision would allow people who have interrupted treatment for shorter periods than indicated by the algorithm to be put back on the DNB/LO Lists if they are at high risk of infectiousness. Factors that will be considered when assessing risk include TB drug resistance, continuity of care, and suitability of treatment regimen.

2. Persons located in the United States who have ceased treatment or been lost to follow-up after being removed from the DNB/LO Lists will be returned to the Lists as soon as public health authorities conclude there is a reasonable risk that the person is infectious.
3. Persons living outside of the United States will be required to provide periodic documentation of continued or completed treatment or they will be returned to the DNB/LO Lists.

Background:

The federal government through the Centers for Disease Control and Prevention (CDC) Division of Global Migration and Quarantine (DGMQ) has the authority to use restrictive means to protect the public's health by preventing the importation and spread of infectious diseases into the United States. The implementation of this authority has the potential to raise ethical issues relating to the threshold for use of travel restriction tools and the appropriateness of these tools in terms of fairness, use of the least restrictive means, due process, and issues of privacy.

The current criteria for placing a patient with an infectious illness on a DNB List takes into account the infectiousness of the illness, the intent of the patient to travel, and whether the patient has demonstrated a likelihood to be non-compliant with public health recommendations for the prevention and control of disease spread. The majority of patients diagnosed with infectious illnesses, such as tuberculosis (TB), are voluntarily compliant with public health recommendations for preventing the spread of illness (e.g., taking medications, isolating self at home, using protective gear such as masks when traveling to and from treatment).

In 2009, the Ethics Subcommittee provided input on ethical considerations relating to the DGMQ travel restriction SOP (see Attachment B). Our previous input outlined a number of ethical considerations that should guide the use of the SOP. As pointed out previously, the use of these restrictions limit individual autonomy, or the freedom to make one's own decisions about when and how to travel. Respect for individual autonomy is deeply embedded in U.S. culture and reflects our cherished belief in the inherent dignity and worth of the individual and the understanding of each individual's general right to non-interference. However, government may, and in many other contexts does, legitimately restrict freedom when the actions of individuals place others at risk. In imposing restrictions, officials should ethically justify their actions by carefully weighing and fairly balancing the potential benefits and harms that might accrue to the affected individuals and communities. Public health officials have the ethical obligation to use the least restrictive measures in a manner that is proportional to the threat and minimizes the

possibility of adverse consequences. It is especially important to establish procedures that ensure the fair and impartial application of restrictions and the protection of individuals' privacy and the confidentiality of their information.

Issues related to the proposed amendment

State and CDC public health officers have been faced with situations where, against public health recommendations, individuals do not continue treatment after attaining noninfectious status. Partial treatment of TB causes the individual to revert to an infectious state and poses a risk for development, or worsening, of drug resistance. Treatment of TB with acquired drug resistance may require the use of more toxic and costly second-line medications, prolong the necessary duration of therapy, limit the availability of effective treatment options, and promote transmission of resistant strains.

When a patient undergoing treatment for TB stops treatment against medical advice or is lost to follow-up, it is challenging to make an absolute determination of when the patient likely reverts to being contagious. In the absence of clinical testing, there is insufficient published evidence to make an indisputable determination of infectiousness. In the current DNB/LO algorithm, an individual is not considered infectious immediately after stopping treatment for TB. For example, if the interruption is less than one half the duration of treatment received and patient does not have multidrug-resistant TB (MDR-TB), the patient may travel. For patients with MDR-TB, if the interruption is less than one quarter the duration of treatment received, up to a maximum of 30 days, the patient may travel. This guidance has a caveat in that prior treatment should have been uninterrupted. In those instances, the DNB/LO algorithm allows for an even shorter acceptable interruption.

The DNB/LO algorithm is a critical guide for public health officials. However recent experience in applying this algorithm has indicated a need to clarify the guidance and its nuances to better inform public health decision-making regarding individuals considered for placement on DNB/LO list. These changes should result in improved protection of persons from TB when they travel on air conveyances and in the U.S. land borders without undue burden on individuals with TB.

Recommendation of the Ethics Subcommittee, Advisory Committee to the Director:

The Ethics Subcommittee members are in agreement that the proposed amendment to the SOP is consistent with the ethical considerations outlined in the 2009 Ethics Subcommittee document. Specifically, these revisions are consistent with the ethical obligation to use the least restrictive measures in a manner that is proportional to the threat and minimizes the possibility of adverse consequences. The Ethics Subcommittee members also are in agreement with protecting community interests while respecting individual rights by requiring patients to provide documentation relevant to treatment outcome. Although the Ethics Subcommittee recognizes that requiring persons living outside of the United States to provide periodic documentation of continued or completed treatment imposes a burden, this burden can be justified based on the need to protect the public, which is the goal of the DNB/LO order. It is important that persons placed on the DNB/LO Lists be given sufficient information about their status and the risk they

pose to others prior to being placed on the lists. If they have been given this information, then they should bear some responsibility for demonstrating that they have adhered to treatment. The Ethics Subcommittee also noted that the revised language will allow greater flexibility in keeping individuals off the DNB/LO Lists if they are able to provide documentation of treatment.

The Ethics Subcommittee emphasizes the importance of taking steps to ensure transparency and uniformity in the application of the algorithm used for determining when a person should be added or returned to the DNB/LO Lists (like cases should be treated alike). These criteria should focus on indicators of infectiousness and should avoid use of social factors as a proxy for treatment adherence.

This recommendation aligns with the following ethical considerations:

- Protecting community interests while respecting individual rights — *the obligation to protect the public's health while respecting individual autonomy and protecting individual civil liberties.*
- Transparency and clear communication — *the obligation to provide an open decision-making process and clear and efficient communication with affected individuals, communities, and others who may be impacted by the public health action.*
- Social and distributive justice — *the obligation to treat individuals respectfully and fairly, to minimize group stigmatization, and to fairly distribute risks, burdens, and benefits of public health actions.*
- Global responsibility — *recognition of the importance of working in collaboration with international partners to protect the health of the global community.*

In addition, the Workgroup made the following secondary recommendations:

1. The Ethics Subcommittee found the wording of the first amendment to be somewhat confusing. We recommend that this section be revised to more clearly state what the program is proposing. The understanding of the Ethics Subcommittee is that the program would like to be able to add or return persons to the DNB/LO Lists even if they have had fewer than 30 days of treatment interruption if there is other information to suggest there is a public health risk.
2. The program should offer guidance to individuals located outside of the United States on how to report documentation of continuing or completed treatment by providing a template that the patient can provide to their health care provider. Also, the frequency of this report should not be onerous and needs to be clarified.

Attachment A

Input from the Division of Global Migration and Quarantine regarding Proposed Amendment of Infectiousness Standard for Travel Restrictions September 11, 2012

Background

Two federal travel restriction tools, the Do Not Board (DNB) action and the Lookout (LO) action, limit travel for individuals who pose a serious public health threat. The DNB action entails the inclusion of an individual who is suspected or confirmed to be contagious with a communicable disease of public health importance on a list that precludes the individual from obtaining a boarding pass for any commercial domestic flight or for any commercial international flight arriving in, or departing from, the United States. The LO action does *not* prevent travel but places a public health alert message on the individual's record located in TECS (not an acronym), which is usually linked to a passport, visa or other border entry document. TECS is owned and managed by Customs and Border Protection (CBP), a component of the U.S. Department of Homeland Security (DHS), and is an information-sharing platform designed to screen and process individuals arriving into the United States at ports of entry (seaports, airports and land border crossings). The LO record prompts CBP staff, in collaboration with CDC quarantine program officers, to conduct a public health inquiry and evaluation of such individuals when they attempt to enter the United States. Persons included on the public health DNB list also are routinely assigned a LO record.

Under DHS statutory authority, the DNB tool may be used to prevent the boarding of any person who may pose a public health threat to other passengers or crew if permitted to board a commercial flight. Whereas the LO tool may be used to alert CBP staff at any point of entry. To date both tools have been used exclusively for persons with suspected or confirmed infectious tuberculosis (TB). TB transmission, which occurs via the respiratory route, has been documented during commercial air travel. Persons with TB can remain contagious for long periods, especially when infected with resistant strains, and they can also be infected without being contagious or without realizing it.

Three criteria are required to add an individual to the DNB/LO (likely infectious with a communicable disease that poses a risk during travel; nonadherence³ or unawareness of diagnosis; and likely will attempt to board a commercial aircraft). To determine when a person with TB is likely infectious, CDC relies on an algorithm developed by agency TB subject matter experts (SMEs), and reviewed by National TB Controller Association members. The initial assessment for contagiousness is derived from existing general guidance on prevention of TB transmission as well as guidance specific to air travel. These are 1) clinical, radiographic, and microbiologic (e.g., sputum smear microscopy and culture results) evaluation; 2) treatment adequacy (based on drug susceptibility testing, treatment regimen, and duration); and

³ Adherence is the extent to which a person's behavior matches treatment, infection control and other care management recommendations provided by clinicians and public health officers.

3) mycobacteriologic response to treatment (as determined by subsequent microbiologic evaluation). This initial assessment has been agreeable to state and local health departments who have initiated DNB/LO action consultations.

CDC public health officers regularly review persons on the DNB/LO to decide whether they are eligible for removal. Since DNB/LO are tools intended to prevent transmission of disease during travel, resolution of the first criterion for placement on the lists – infectiousness – is considered the sole criterion for removal. A finding of noninfectiousness serves as a bright-line test for removal from travel restrictions. An individual who has been removed from the DNB/LO may be returned to the DNB list and a LO reissued if the individual once again meets the three criteria for DNB/LO placement. Individuals who have been on DNB/LO have shown risk for travel and have been nonadherent, therefore a second DNB/LO listing usually faces a lower evidence threshold for these two criteria. Under current CDC Standard Operating Procedures, individuals who were noninfectious at the time of the DNB/LO removal, may be relisted once it is believed that they have reverted to a state of likely infectiousness.

Program Parameters

The DNB/LO are public health protection tools, designed to prevent transmission of serious communicable diseases in the travel setting; they are not public health management tools aimed at compelling adherence to treatment. Although persons placed on DNB and LO may show improvement in adherence to treatment of disease, this is not the intended use of the tools. However, improvement in adherence to treatment among persons placed on the DNB and LO may be a secondary benefit. The DNB/LO are also not tools to manage immigration.

Issues

State and CDC public health officers have been faced with situations where, against public health recommendations, individuals do not continue treatment after attaining noninfectious status. Partial-treatment of TB causes the individual to revert to an infectious state and poses a risk for development, or worsening, of drug resistance. Treatment of TB with acquired drug resistance may require the use of more toxic and costly second-line medications, prolong the necessary duration of therapy, limit the availability of effective treatment options, and promote transmission of resistant strains.

When a patient undergoing treatment for TB stops treatment against medical advice or is lost to follow-up, it is challenging to make an absolute determination of when the patient likely reverts to being contagious. In the absence of clinical testing, there is insufficient published evidence to make an indisputable determination of infectiousness. In the current DNB/LO algorithm an individual is not considered infectious immediately after stopping treatment for TB. For example, if the interruption is less than one half the duration of treatment received and patient does not have multidrug-resistant TB (MDR-TB), the patient may travel. For patients with MDR-TB, if the interruption is less than one quarter the duration of treatment received, up to a maximum of 30 days, the patient may travel. This guidance has a caveat in that prior treatment should have been uninterrupted. In those instances, the DNB/LO algorithm allows for an even shorter acceptable interruption.

The DNB/LO algorithm is a critical guide for public health officials. However recent experience in applying this algorithm has indicated a need to clarify the guidance and its nuances to better inform public health decision-making regarding individuals considered for placement on DNB/LO list. These changes should result in improved protection of persons from TB when they travel on air conveyances and in the U.S. land borders without undue burden on individuals with TB.

Revision of DNB/LO Infectiousness Determination

We propose to refine the infectiousness determination used by CDC to make DNB/LO decisions. The changes described in recommendation #1 apply to individuals new to DNB/LO as well as those who would be returned to DNB/LO listing. They pertain to the substantive determination of infectiousness.

1) We recommend making explicit that any time periods for treatment interruption described in the DNB/LO algorithm should be considered maximum off-treatment periods, and earlier addition or return to the DNB/LO may be considered on a case-by-case basis based on public health risk. TB drug resistance, continuity of care, and suitability of treatment regimen are leading factors when assessing public health risk. Treatment regimens are evaluated based on American Thoracic Society, Infectious Diseases Society of America and CDC *Treatment of TB Guidelines*.

Logistic Changes

The changes described in #2 (persons in the US) and #3 (persons abroad) relate to procedural changes in the logistics of infectiousness determinations and apply only to individuals being assessed for their potential return to the DNB/LO listing (i.e., they do not apply to persons being considered for DNB/LO for the first time).

2) Individuals located within the United States— If a state or local health department informs CDC that a person removed from DNB/LO has ceased treatment against advice or has been lost to follow-up, the person should be returned to the DNB/LO as soon as public health authorities conclude there is a reasonable risk that the individual is again infectious. This assessment will reflect the maximum off-treatment approach incorporated into the algorithm and the consideration of public health risk (as outlined in recommendation #1).

3) Individuals located outside of the United States— After being removed from DNB/LO, an individual must provide periodic documentation (e.g., every 3 months – a specific proposed interval has not been identified) of continuing or completing treatment for TB that US public health authorities consider trustworthy. This requirement may be waived in circumstances where this information is available without extraordinary effort from a reliable source (e.g., a foreign public health authority, a panel physician contracted to the U.S. Department of State, or a U.S. embassy). If public health authorities in the United States learn that an individual overseas has stopped treatment, or if the person fails to provide documentation of adherence, he or she may be considered infectious and returned to DNB/LO if U.S. authorities conclude that a public health

risk to other passengers or crew during air travel may reasonably exist. The requirement for periodic documentation of treatment adherence is justified by the difficulty in monitoring treatment in a foreign country. Under such circumstances, an absence of appropriate documentation of continued treatment adherence may be considered a more relevant factor in determining likely infectiousness than off-treatment periods or other public risk factors, such as drug resistance.

Summary:

Based on our experience the proposed refinements to the DNB/LO protocol will:

1. Provide increased flexibility for public health authorities to assess public health risk for individuals on a case by case basis who are considered for DNB/LO
2. Identify requirements for individuals located outside of the US to document treatment adherence
3. Clarify that any time periods for treatment interruption described in the DNB/LO algorithm should be considered maximum off-treatment.

Attachment B

Ethics Subcommittee, Advisory Committee to the Director⁴ Recommendation for Ethical Considerations Section for Inclusion in the CDC Document - “Requesting Department of Homeland Security Assistance for Control of Communicable Diseases: Standard Operating Procedures”

Developed by the Ethics Subcommittee Travel Restriction Workgroup on behalf of the Ethics Subcommittee of the Advisory Committee to the Director⁵

Approved by the Ethics Subcommittee on April 7, 2009

Approved by the Advisory Committee to the Director, Centers for Disease Control and Prevention on September 1, 2009

⁴ Members of the Ethics Subcommittee who approved this recommendation include John Arras, PhD, University of Virginia; Ronald Bayer, PhD, Columbia University; Vivian Berryhill, National Coalition of Pastors’ Spouses; Vanessa Northington Gamble, MD, PhD; Robert Hood, PhD, Florida Department of Health; Bruce Jennings, MA, Centers for Humans and Nature; Kathy Kinlaw, MDiv, Emory University; Bernard Lo, MD, University of California, San Francisco; Nancy Kass, ScD, Johns Hopkins University; and Leslie Wolf, Georgia State University.

⁵ The Ethics Subcommittee representatives on the Travel Restrictions Workgroup are Kathy Kinlaw and Vanessa Northington Gamble. CDC representatives on the workgroup are Francisco Alvarado-Ramy, Jessica Apps, Drue Barrett, Clive Brown, Nicole Cohen, Jan Devier, Laurie Dieterich, Richard Dixon, Gail Horlick, Susan Hunter, Curi Kim, Charles Magruder, Ashley Marrone, Thomas Navin, Marcy Neumann, Leonard Ortmann, Anne Sowell, and Mark White. Robert Levine, Yale University, served as a consultant to the Travel Restrictions Workgroup.

Ethical Considerations

The restrictions on travel described in this Standard Operating Procedure (SOP) document⁶ raise a number of ethical challenges. These restrictions limit individual autonomy, or the freedom to make one's own decisions about when and how to travel. Respect for individual autonomy is deeply embedded in U.S. culture and reflects our cherished belief in the inherent dignity and worth of the individual and the understanding of each individual's general right to non-interference. However, government may, and in many other contexts does, legitimately restrict freedom when the actions of individuals place others at risk. In imposing restrictions, officials should ethically justify their actions by carefully weighing and fairly balancing the potential benefits and harms that might accrue to the affected individuals and communities. Public health officials have the ethical obligation to use the least restrictive measures in a manner that is proportional to the threat and minimizes the possibility of adverse consequences. It is especially important to establish procedures that ensure the fair and impartial application of restrictions and the protection of individuals' privacy and the confidentiality of their information.

To ensure fairness, CDC has developed a set of standards to determine when to impose or rescind the application of the Department of Homeland Security (DHS) travel restriction tools. Though travel restrictions are federal tools, health departments⁷ usually initiate a request to restrict the travel of individuals located within or recently departed from the United States, while a U.S. embassy or consulate or foreign Ministry of Health might do so for individuals located outside the United States who wish to enter the United States. Use of these tools may pose unique, sometimes unforeseen challenges. Consequently, CDC and its partners in other federal agencies and in state, local, tribal and territorial (SLTT) governments strive to apply these tools carefully. Decisions to use these tools are guided by scientific evidence and subject-matter expert advice, and embody efforts to balance the obligation to protect the public's health against the obligation to respect individual autonomy. CDC and its partners deliberately attempt to avoid stigmatizing or blaming individuals or groups, and instead focus on treating these individuals and groups with respect and dignity, including those individuals who have been non-adherent with public health recommendations.

CDC, in collaboration with its partners, seeks the most appropriate and measured response to protect public health. In some cases, public health officials have decided to forgo placing travel restrictions on an individual after federal and SLTT officials had collectively determined that there was no threat to the traveling public. However, the ultimate decision whether to proceed with a travel restriction action rests with CDC.

CDC and its partners endeavor to remove individuals from the Do Not Board (DNB) list as soon as possible. Once initiated, a CDC request to remove an individual from the DNB list generally takes 24 hours to execute. Immediately upon an individual's removal from the DNB list, the entity reporting the case to CDC will notify the individual, who will receive, via certified mail, a

⁶ The Standard Operating Procedures document refers to a CDC document titled "Requesting Department of Homeland Security Assistance for Control of Communicable Diseases: Standard Operating Procedures." This "Ethical Considerations" document will be included as a section in the SOP document.

⁷ Includes state, local, tribal, and territorial health departments.

“removal notification letter” from the quarantine station (QS) assigned to the case (SOP Appendix 4).

The development of this SOP demonstrates CDC’s commitment to ensuring that all staff involved in implementing travel restriction tools have an understanding of the relevant policies and procedures and of the ethical framework that should guide decision making about use of the tools. A systematic consideration of the ethical framework helps to ensure that the procedures are implemented fairly and in a manner that minimizes harms. CDC has an obligation to provide training to all relevant staff on the use of this SOP and to provide support on addressing ethical issues that may arise in the implementation of the tools.

When acting under these SOP, CDC staff should weigh ethical considerations relevant to public health practice. A description of some of these ethical considerations and examples of how they apply to the use of travel restrictions are listed below.

Protecting community interests while respecting individual rights — the obligation to protect the public’s health while respecting individual autonomy and protecting individual civil liberties.

Respect-for-person involves treating individuals as autonomous agents and respecting their individual opinions and choices. Public health practice focuses on the health of populations and on protecting the common good. This focus often raises conflicts between protecting individual rights and protecting community interests. This conflict is especially apparent in public health actions taken to protect the public against infectious illnesses, where the focus is on controlling the spread of disease and on promoting other community interests, such as eliminating disease and reducing health disparities based on race and ethnicity, place of birth, or other social factors. The use of the travel restriction tools described in this SOP is a case in point, which involves limiting an individual’s autonomy in regard to freedom of movement in order to protect the public’s health.

CDC attempts to honor the individual choice as long as it does not endanger the health of others. For example, foreign nationals with multi-drug resistant tuberculosis (MDR-TB) could voluntarily decide to return to their countries of residence to receive medical treatment once public health officials determine that they are no longer contagious, even if the officials believe that adequate treatment for MDR-TB may not be available in an individual’s country of residence. In such cases, CDC or health departments in the United States would provide information about available treatment options and would coordinate transfer of care with the national and local health officials in the individual’s country of residence. In this example, the individual would also be informed that, if after leaving the United States completion of treatment could not be documented, he or she would be placed back on the DNB and/or Lookout lists due to the risk of reverting to a contagious state following the interruption of treatment.

- **Proportionality** — *the obligation to use public health actions that are proportional and appropriate for the nature of public health threat.*

Use of the least restrictive/intrusive interventions that will achieve the public health objective is ethically required. In cases where isolation orders issued by SLTT health departments will suffice to prevent an individual from traveling, or where public health officers may convince an individual to voluntarily comply with recommendations not to travel, CDC recommends that these actions be taken before travel restrictions are considered. For example, in cases where U.S. citizens or legal permanent residents travel outside of the United States before they are known to be contagious, CDC recommends that the health department first work with the individual and his or her family to coordinate treatment in the foreign country prior to use of travel restrictions. Similarly, if after a period of treatment an individual on the DNB list is determined to be non-contagious, but the health department has concerns about compliance during the remainder of the treatment course, CDC recommends the issuance of SLTT treatment orders and the lifting of federal travel restrictions as soon as the treatment orders are in place. In order to respect the authority of SLTT health departments who have jurisdiction for the control of infectious diseases, CDC relies on SLTT health officials to communicate with individuals and their families. This approach is also less intrusive, as typically these health officials already have an established relationship with the individual. However, when required, CDC will facilitate such communications, for example by coordinating international telephone calls.

To the extent possible and where appropriate, CDC will consider suggestions for travel based on a modification of policies, practices, or procedures, or by the provision of auxiliary aids or services after consultation with relevant subject matter experts to ensure that any such modification does not pose a direct threat to the health or safety of others. In addition, it may be possible to make arrangements for alternative safe options for travel, such as driving in a private vehicle. However, the individual should be counseled regarding the risk of transmission to others in the community or workplace following prolonged, close contact. For this reason, travel restrictions are generally used in conjunction with voluntary or mandatory isolation orders issued by the SLTT health department.

- **Social and distributive justice** — *the obligation to treat individuals respectfully and fairly, to minimize group stigmatization, and to fairly distribute risks, burdens, and benefits of public health actions.*

One approach to ensuring justice is to rely upon fair procedures in the hope that fair procedures will result in fair outcomes. Elements of procedural justice include consistency in applying standards across people, places, and time, having impartial and neutral decision makers, ensuring that those affected by decisions have a voice in decision making, treating those affected with dignity and respect, ensuring that decisions are adequately reasoned and based on accurate information, establishing clear and

transparent communication with the public, and developing processes for addressing new information and for raising concerns or appealing decisions.

The purpose of this SOP is to ensure that travel restrictions are imposed fairly and without bias. For example, wealthy individuals are not entitled to greater than average benefits based on their perceived status and people with more education are not allowed fewer restrictive measures out of an assumption that they will be more adherent in following directives. Travel restrictions should be based solely on clinical and public health information and never on the individual's financial status or group membership (e.g., ethnicity, race, religion, gender, or citizenship). CDC strives to have all individuals under isolation orders or travel restrictions receive the best available care, although treatment decisions, such as where a patient receives medical care, are usually made by the SLTT health department. CDC conducts a review of each case involving use of travel restrictions to ensure that the restrictions continue to be necessary. This review is conducted on at least a monthly basis and often more frequently (e.g., every two weeks). Additionally, CDC has established a procedure for informing affected persons of their right to request a review of their case if they feel they have been placed on travel restrictions in error.

- **Beneficence — *the obligation to do no harm and to maximize possible benefits and minimize possible harms.***

The principle of beneficence creates an obligation to secure the well-being of individuals while pursuing the primary objective of preserving the public's health. In the interests of pursuing the public's health one must avoid the deliberate infliction of harm to others. There are times, however, when fulfilling the goal of preserving the public's health causes burdens and, at times, harms, to others. In the process, however, we must minimize these burdens and harms to the extent possible. Of particular relevance for this SOP is the obligation to use relevant, reliable, and valid data to protect the public from exposure to infectious diseases while ensuring that ill individuals receive appropriate medical care and are treated in ways that minimize harms or burdens. The use of travel restrictions has the potential to result in adverse consequences for those affected. For example, individuals on travel restrictions might be harmed financially. CDC is committed to working with organizations to assist restricted individuals in mitigating potential hardships that may result from the inability to travel. Such assistance may include contacting the individual's local embassy or consulate, requesting assistance from the Department of State or Department of Homeland Security regarding visa issues, or requesting that an airline defer fees. CDC will additionally work to ensure that travel restrictions are removed as soon as clinical and laboratory evidence indicates that the individual is no longer contagious.

The development of this SOP in itself exemplifies a commitment to beneficence. CDC seeks to ensure that travel restriction tools are implemented fairly and in a manner that minimizes harms. This SOP provides information to staff involved in implementing travel restrictions about the relevant policies and procedures and the ethical considerations that should guide decision making about use of the tools. As stated previously, CDC has an obligation to provide training to all relevant staff on the use of

this SOP and to provide support on addressing ethical issues that may arise in the implementation of the tools.

- **Transparency and clear communication** — *the obligation to provide an open decision-making process and clear and efficient communication with affected individuals, communities, and others who may be impacted by the public health action.*

The ethical requirements of transparency and clear communication are based on respect for affected individuals and communities. Transparency also facilitates accountability in the development and implementation of policy concerning travel restrictions. Clearly articulating the reasoning behind public health recommendations and the values and principles justifying those actions is essential to building public will and trust. Good communication is more than simply providing factual information; it should be a two-way exchange and must be both culturally and linguistically appropriate, such as described in the National Standards on Culturally and Linguistically Appropriate Services (CLAS mandates)⁸. There should be clear and transparent policies and procedures that define who has responsibility for decision making, who will be accountable for ensuring the appropriate use of travel restrictions, and what procedures will be put in place for reviewing decisions. It is essential that individuals diagnosed with infectious illnesses of public health concern be notified at the time of diagnosis of the need to avoid travel on public conveyances, the reason for such avoidance, and the potential consequences of not following public health recommendations including the potential for federal travel restrictions. CDC has developed educational materials for distribution to public health partners that can be used for patient education about the travel restrictions tools described in this SOP.

- **The responsibility to maximize preparedness and to work collaboratively with other public health agencies to address public health threats** — *the obligation to put into place procedures and resources that allow for the most efficient and effective actions to protect the public's health, while ensuring that involved public health officials share in decision making as appropriate for each agency's scope of authority.*

Health officials have an obligation to work together in advance to ensure that persons placed on travel restrictions receive appropriate care for their illnesses. CDC works closely with public health partners and other agencies to ensure shared responsibility for the appropriate management of contagious individuals. Preparedness also requires having policies in place and providing training to personnel so they are knowledgeable about the policies and understand how the policies are to be implemented. This may also include specific training about the importance of ethical considerations in implementing travel restrictions.

⁸ Detailed information about CLAS mandates can be found at <http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlID=15>

The development of these SOPs is meant to ensure that there is agreement between CDC and the DHS on the appropriate use of travel restriction tools. In addition, procedures have been put in place to examine specific incidents of concern, for example the failure of travel restrictions to prevent a contagious individual from boarding a commercial aircraft, or the improper restriction of an individual not on the on the DNB list, in order to identify and correct weaknesses in the system.

As previously indicated, travel restrictions are federal tools; however, they are mostly initiated at the request of a SLTT health department for individuals located within or recently departed from the United States, or by a U.S. embassy or consulate or foreign Ministry of Health for individuals outside of the U.S. borders who wish to travel to the United States. CDC will often facilitate communication between agencies to ensure that the best possible care is provided to individuals on travel restrictions. For example, in the case of a U.S. citizen diagnosed with tuberculosis in a foreign country who desires repatriation to complete treatment, CDC will work with U.S. embassies, treating physicians, and foreign Ministries of Health to ensure that treatment and diagnostic testing are in accordance with U.S. standards. CDC also facilitates the shipment of laboratory specimens to state laboratories in the United States in order to expedite diagnostic testing required for removal of travel restrictions.

- **Global responsibility — *recognition of the importance of working in collaboration with international partners to protect the health of the global community.***

This ethical consideration is based on recognition of the common good and of the interdependence of the global community. CDC works with the Department of State and its network of embassies as well as foreign Ministries of Health to ensure international cooperation in preventing the global spread of infectious diseases. Canadian and Mexican authorities are routinely notified whenever the U.S. authorities place an individual on travel restrictions. Cases which fall under the jurisdiction of the International Health Regulations (IHR) are reported to World Health Organization (WHO). For example, if U.S. authorities became aware of a U.S. citizen who had been diagnosed with MDR-TB in a foreign country and subsequently defied treatment recommendations and travel restriction orders by traveling to a neighboring country, CDC would notify the involved countries and would report the case to WHO in accordance with the IHR.

- **Respecting individuals' privacy while protecting the community – *the ethical obligation to protect individuals' privacy and the confidentiality of their individually identifiable data⁹ by collecting and sharing only the minimum information necessary to ensure the public's health.***

⁹ For the purposes of this document, individually identifiable information is defined as data that directly identifies an individual (e.g., name, social security number) or data that when combined with other information can reasonably be used to identify an individual (e.g., by linking to another database).

Implementing the travel restriction tools described in the SOP raises a number of ethical concerns about protecting individuals' privacy and the confidentiality of their individually identifiable data. Threats to privacy and confidentiality should be minimized by collecting and disclosing only the minimum information necessary to ensure the public's health and by sharing this information with partner agencies in a secure fashion. There are a number of state and federal laws and regulations that govern the confidentiality of medical and public health records. A discussion of legal considerations regarding privacy protection and technical safeguards for protecting the security of individually identifiable information are presented in Appendix 1.

Consideration of the ethical issues raised above is an important component of the procedures described in this SOP. A systematic consideration of these ethical issues will ensure that CDC's public health recommendations are appropriate, measured and fair and that the public's health is protected while individual rights are respected. CDC has established the Public Health Ethics Committee (PHEC) and procedures for conducting public health ethics consults. PHEC can serve as a resource to CDC staff as they implement this SOP. More information about PHEC can be found at <http://www.cdc.gov/od/science/phec/>.

Appendix 1
Legal and Technical Considerations for Protecting Privacy and the Security of
Individually Identifiable Data

Legal Considerations Regarding Privacy Protection

A number of privacy laws, regulations and policies, as well as technical and administrative safeguards have been developed to protect individually identifiable information, including the:

- Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule,
- Privacy Act of 1974, and
- Privacy Act Regulations.

The HIPAA Privacy Rule¹⁰ regulates the use and disclosure of individually identifiable information by health plans (e.g., Medicare, Blue Cross), health care clearinghouses, and health care providers who transmit information electronically (referred to as covered entities). CDC is not a covered entity; however, many of its partners are covered entities. The HIPAA Privacy Rule generally permits providers to disclose individually identifiable health care information without the consent of the individual to public health authorities who are authorized to collect or receive such information for public health practice, including the prevention and control of disease and public health surveillance, investigations, and interventions. CDC is considered a public health authority and therefore could receive such information from an entity governed by HIPAA.

The Privacy Act of 1974¹¹ and the Privacy Act Regulations¹² govern the use and disclosure of individually identifiable information of U.S. citizens and lawful permanent residents, whose records are maintained by federal agencies in a system of records¹³. The Privacy Act Regulations authorize CDC to disclose individually identifiable information without consent if there are compelling circumstances affecting the health or safety of the individual. The Privacy Act requires agencies to publish the permitted routine uses for such information in a System of Records Notice (SORN) in the *Federal Register*¹⁴. The SORN also serves to provide notice to the public about the categories of individuals and information maintained.

The disclosures of individually identifiable information described in this SOP are made in accordance with the Privacy Act and established routine uses for information in the Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71 SORN¹⁵. An example of a

¹⁰ 45 CFR Parts 160 and 164

¹¹ 5 U.S.C. § 552a

¹² 45 CFR Part 5b

¹³ A system of records is a group of records under control of the agency from which the information is retrieved by the name of the individual or another identifier.

¹⁴ A system of records is a group of records under control of the agency from which the information is retrieved listed by the name of the individual or another identifier.

¹⁵ Federal Register; 13 December 2007, Vol. 72, No. 239/Notices, pp. 70867-70872.

routine use is the disclosure of airline flight manifest information containing passenger names and contact details to SLTT health departments for the purpose of evaluating travelers potentially exposed to an active case of TB. In this case the information is shared outside of HHS for a purpose that is compatible with the stated purpose in the SORN for which the information was originally collected. The SORN permits disclosures to SLTT health departments, medical and public health authorities, the Department of Homeland Security, and others to restrict travel of those who pose a public health threat.

Although the Quarantine- and Traveler-Related Activities SORN does not mandate notification of individuals placed on the DNB list, it is CDC best practice that the Quarantine Station of record send a certified letter with a return receipt requested (SOP Appendix 3) to all individuals placed on the DNB list, regardless of citizenship or immigration status. That letter should be sent within two business days after the individual is placed on the DNB list. Such notification may be waived in certain circumstances, if requested by law enforcement authorities, if deemed necessary to protect the public, or if address is unknown. Besides the written notification, CDC asks SLTT health departments to verbally notify the individual of the DNB action, its consequences, the criteria necessary to be removed from the travel restriction list, and how they are able to assist the individual in meeting the removal requirements.

Technical Safeguards for Protecting the Security of Individually Identifiable Information

Any exchange of individually identifiable information contemplated in these SOP must be protected through secure means. In an effort to strengthen security and decrease processing times, the CDC Emergency Operations Center (EOC) and Division of Global Migration and Quarantine (DGMQ), through the Travel Restriction and Intervention Activity (TRIA), are working to use CDC's Secure Data Network (SDN) to transmit DHS Assistance Requests from the TRIA representative to the EOC and from the EOC to the HHS Secretary's Operations Center (SOC) and the DHS National Operations Center (NOC). When this mechanism is operational, the TRIA representative will upload the DHS Assistance form in electronic format to the Epidemic Information Exchange (Epi-X) that automatically prompts the EOC to retrieve. The document will similarly be sent to recipients at the SOC and NOC. Intra-agency transmission of information may either occur via Epi-X or existing secure systems within each agency.

If protected information must be provided to an individual or agency without access to Epi-X, this information will be transmitted via mail, telephone, secure facsimile, or electronically in an encrypted or password-protected format. All partner agencies and individuals communicating individually identifiable information regarding travel restrictions should receive training regarding the need to maintain the security of such information.

Attachment F: Recommendations for Public Health Law and Public Health Ethics Collaboration

Recommendation of the Ethics Subcommittee, Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC)¹⁶

Developed by the Ethics Subcommittee Public Health Law Collaboration Workgroup¹⁷ on behalf of the Ethics Subcommittee, Advisory Committee to the Director, CDC

Approved by the Ethics Subcommittee on _____

Approved by the Advisory Committee to the Director, CDC on _____

Recommended Approaches for Enhancing Collaboration between Public Health Law and Public Health Ethics

1. CDC should continue to collaborate with the Network for Public Health Law to offer its membership training on public health ethics either through webinars or through annual conferences.
2. CDC should continue to provide training on public health ethics that includes information on the complementary roles of public health law and public health ethics as part of the training materials CDC is developing for local health officials.
3. The Ethics Subcommittee should develop a framework to highlight differences and similarities between legal and ethical issues, including addressing how law and ethics approach issues and clarifying how legal reasoning and ethical reasoning differ. This should include use of cases to illustrate why law is necessary but not sufficient for addressing some public health challenges.
4. The Ethics Subcommittee should explore potential additional areas where public health law and public health ethics could work together, including the development of ethics standards for the

¹⁶ The members of the Ethics Subcommittee include Ruth Gaare Bernheim (Subcommittee Chair), University of Virginia; Janice A. Allen Chilton, The University of Texas MD Anderson Cancer Center; LaVera Marguerite Crawley, Stanford University School of Medicine; Kenneth W. Goodman, University of Miami; George Isham, Health Partners; Jeffrey Kahn, Johns Hopkins University; Alan L. Melnick, Oregon Health and Science University; Eric Meslin, Indiana University-Purdue University; Sara Rosenbaum, George Washington University; Jennifer Prah Ruger, Yale University; Ani Satz, Emory University; and Matthew Stefanak, Northeast Ohio Medical University.

¹⁷ The members of the Public Health Law Collaboration Workgroup include Ruth Gaare Bernheim, University of Virginia (Ethics Subcommittee member), Kenneth Goodman, Workgroup Chair, University of Miami (Ethics Subcommittee member), Jeff Kahn, Johns Hopkins University (Ethics Subcommittee member), Ani Satz, Emory University (Ethics Subcommittee member), and Leslie Wolf, Georgia State University.

accreditation process, development of recommendations regarding cross-sectorial collaboration (health in all sectors), and development of procedures for effective community engagement.

Attachment G: Proposed Framework for Collaboration Between Public Health Law and Public Health Ethics

Recommendation of the Ethics Subcommittee, Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC)¹⁸

Developed by the Ethics Subcommittee Public Health Law Collaboration Workgroup¹⁹ on behalf
of the Ethics Subcommittee, Advisory Committee to the Director, CDC

Approved by the Ethics Subcommittee on _____

Approved by the Advisory Committee to the Director, CDC on _____

Proposed Outline for a Framework for Enhancing Collaboration between Public Health Law and Public Health Ethics

1. Overview of the structure of the document
2. Short introduction to public health law
 - a. What do laws do for decision makers?
 - i. Generally define authority and the boundaries for lawful action which:
 1. establish limitations on particular agency powers
 2. provide starting points, not conversation stoppers, for discussion of public health action
 - ii. Can point to underlying common ethical principles or social consensus often based on these principles
 - b. *Police Powers*
 - i. Defined: Powers exercised by the states to enact legislation and promulgate and enforce regulations that protect the public health, welfare, and morals, and that promote the common good.
 - ii. Examples:
 1. Investigations of infectious disease outbreaks
 2. Childhood vaccinations as condition for school entry

¹⁸ The members of the Ethics Subcommittee include Ruth Gaare Bernheim (Subcommittee Chair), University of Virginia; Janice A. Allen Chilton, The University of Texas MD Anderson Cancer Center; LaVera Marguerite Crawley, Stanford University School of Medicine; Kenneth W. Goodman, University of Miami; George Isham, Health Partners; Jeffrey Kahn, Johns Hopkins University; Alan L. Melnick, Oregon Health and Science University; Eric Meslin, Indiana University; Sara Rosenbaum, George Washington University; Jennifer Prah Ruger, Yale University; Ani Satz, Emory University; and Matthew Stefanak, Northeast Ohio Medical University.

¹⁹ The members of the Public Health Law Collaboration Workgroup include Ruth Gaare Bernheim, University of Virginia (Ethics Subcommittee member), Kenneth Goodman, Workgroup Chair, University of Miami (Ethics Subcommittee member), Jeff Kahn, Johns Hopkins University (Ethics Subcommittee member), Ani Satz, Emory University (Ethics Subcommittee member), and Leslie Wolf, Georgia State University.

3. Ban on distribution of free cigarette samples in areas around schools and other places frequented by minors
 4. Involuntary detention of persons with certain communicable diseases
 5. Property seizure and destruction to control toxic substance threats
 - c. Substantive U.S. constitutional limits on government action
 - i. *Jacobson v. Massachusetts* framework
 1. Public health necessity
 2. Reasonable means
 3. Proportionality
 - a. Burden must be reasonable to anticipated benefit (least restrictive alternative)
 4. Harm avoidance
 - a. Should not impose undue health risk on the subject
3. Short introduction to public health ethics
 - a. Basic principles
 - i. Ethical principles and moral norms particular to the practice of public health
 - ii. Study of, or deliberation about, moral norms that should guide public health decision-making
 - b. A process for identifying, analyzing, and resolving ethical issues in public health
 - i. Steps in ethical analysis
 1. Analyze ethical issues
 2. Evaluate the ethical dimensions of the alternate courses of public health action
 3. Provide justification for public health action
4. Discussion of how law and ethics resemble and differ from each other
 - a. Similar decision making processes – both consider facts, evaluate options, justify decisions
 - b. Different parameters - laws establish floor for decision making; ethics is more aspirational (tells you what “ought” to be done); law based on statutes and regulations, ethics based on moral norms and values
5. Discussion of how law and ethics work together faced with scientific or policy uncertainty
 - a. *Lawyer* may be unable to provide advice about what one *ought* to do
 - i. Where law does not require or prohibit
 - ii. And no legal precedent to guide
 - iii. Limit of *professional* role
 - iv. However – litigation experience with client may provide attorney with opening to advise on the “oughts”
 - b. *Ethics* may help in thinking through options
 - i. Identifying options
 - ii. Delineating justification for or against options

6. Discuss of how to proceed when law and ethics do not agree or when law does not provide adequate direction
7. Examples of how law and ethics can work together – include a series of questions that considers both legal and ethical issues; include cases to illustrate how to apply analysis framework.

Attachment H: Mandatory Influenza Case Study

Recommendation of the Ethics Subcommittee, Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC)²⁰

Developed by the Ethics Subcommittee STLT Support (Case Development) Workgroup²¹ on behalf of the Ethics Subcommittee, Advisory Committee to the Director, CDC

Approved by the Ethics Subcommittee on _____

Approved by the Advisory Committee to the Director, CDC on _____

Case Study: Mandatory Influenza Vaccination for Health Care Personnel

Disclaimer: This case study is solely an educational exercise and does not necessarily reflect the position of Centers for Disease Control and Prevention on this issue.

Background

Influenza tops the list of vaccine-preventable diseases for morbidity and mortality. From 1976-2007, influenza virus infections annually caused between 3,349 to 48,614 deaths in the United States, an average of 23,607 influenza-related deaths annually.¹ Despite the availability of a safe vaccine that prevents illness in healthy adults less than 65 years of age, uptake remains low.²

Individuals 65 years of age and older have higher risks for influenza complications, hospitalization, and death, accounting for approximately 90% of deaths attributed to pneumonia and influenza.^{1,3} Among elderly nursing home residents, the group most susceptible to flu complications, the flu shot has significantly reduced flu related deaths and hospitalizations.³ However, questions about the vaccine's effectiveness remain. One systematic review found that on average the vaccine only has about a 60% efficacy.⁴ The vaccine has reduced efficacy in older persons and in people with compromised immune systems. Nevertheless, the current

²⁰ The members of the Ethics Subcommittee include Ruth Gaare Bernheim (Subcommittee Chair), University of Virginia; Janice A. Allen Chilton, The University of Texas MD Anderson Cancer Center; LaVera Marguerite Crawley, Stanford University School of Medicine; Kenneth Goodman, University of Miami; George Isham, Health Partners; Jeffrey Kahn, Johns Hopkins University; Alan Melnick, Oregon Health and Science University; Eric Meslin, Indiana University; Sara Rosenbaum, George Washington University; Jennifer Prah Ruger, Yale University; Ani Satz, Emory University; and Matthew Stefanak, Northeast Ohio Medical University.

²¹ The members of the STLT Support (Case Development) Workgroup include Ruth Gaare Bernheim, University of Virginia (Ethics Subcommittee Member), Alan Melnick, Clark, Cowlitz, Skamania, and Wahkiakum Counties Public Health (Ethics Subcommittee Member), Matthew Stefanak, Workgroup Chair, Northeast Ohio Medical University (Ethics Subcommittee Member).

recommendation calls for all persons 6 months of age and older, including health care personnel (HCP), including night, weekend, and temporary staff, to receive the influenza vaccine.^{3,5}

Several studies suggest that compared to voluntary strategies, mandatory vaccination policies can increase and maintain vaccination levels among HCP.^{6,7} However, such studies often compare mandatory vaccination with passive, voluntary programs. Other more comprehensive approaches may include mandatory-offering of vaccine by employers and outreach/education of HCP in combination with the use of signed HCP declination statements, as is done with hepatitis B vaccination.⁸ Such comprehensive programs have also led to high compliance rates and raise fewer liberty concerns, but may be more costly to implement than mandatory vaccination policies. There continues to be a debate about whether vaccinating HCP benefits patients. Despite the success of various approaches, there continues to be scientific uncertainty about whether vaccinating HCP benefits patients, with some reports indicating benefit, especially in nursing homes, and other reports concluding that there is no evidence of effectiveness.^{9-11,}

In the United States, opposition to vaccine mandates has a long history that has decisively shaped the legal precedents regarding public health.¹² Although courts generally have upheld public health's police powers in regard to vaccination, they have also established due process requirements and limits to those powers.¹³ These limits include requirements that there be a public health necessity, that reasonable means must be employed to address it, and that the burdens imposed on individuals must be proportional to anticipated benefits. The scientific uncertainty surrounding the benefits of vaccinating HCP has implications for meeting the proportionality requirement. In 2010, a class action lawsuit filed by HCP in South Carolina challenged a mandatory flu vaccination requirement as an unreasonable invasion of privacy.¹⁴ Other recent attempts to mandate vaccination in private institutions have been challenged in court successfully and have resulted in due-process alternatives to mandatory vaccination such as requiring surgical masks for those who come into direct contact with patients.¹⁵

Medical professionals have an obligation first to do no harm in regard to their patients. That includes protecting their own health in order to protect the health of their patients. Vaccinations are one way to protect one's health. The influenza vaccine presumably would be most important for HCP who provide direct care to patients at high risk for influenza complications, such as residents of nursing homes and long-term-care facilities.^{3,4} Currently, though, over a fourth of HCP in nursing homes and long-term-care facilities lack health insurance.¹⁶ In the rare event they experience an adverse reaction to the vaccine and subsequently lose time from work, they would incur out of pocket expenses as well as face the possibility of lost wages. The lack of health insurance underscores the low pay, part-time employment, and low status of many staff members employed by nursing homes and long term care facilities who may be non-professionals. Their lack of professional standing raises questions about whether professional obligations should apply.

Case Description

Fairview Nursing Center, a 120-bed nursing home, employs 175 staff members. In the most recent year, 92% of its patients received influenza vaccines. Vaccination rates among

employees, however, have lagged far behind, averaging only 40% in recent years. To increase vaccination uptake, the nursing center began offering influenza vaccination free of charge and at a convenient time and place at the nursing center for all staff members. The voluntary free vaccination program has been in place for several years. Despite this effort, vaccination levels remained well under the U.S. Healthy People 2010 target of 60%, and lie even further below its 2020 target of 90%.

Because of the poor track record of voluntary vaccine programs at Fairview Nursing Center, the director is considering requiring influenza vaccination for all employees in advance of the next flu season. The director plans to provide the influenza vaccine free of cost and will require that those who receive the influenza vaccine outside of the organization submit documentation of their vaccination. The director believes that only medical exemptions should be allowed.

The Fairview director has contacted you, the local health director, for your input on whether a mandatory influenza vaccine policy should be implemented at the nursing center.

Discussion Questions

1. Must any legal considerations be taken into account such as laws or regulations mandating or prohibiting the mandatory influenza vaccinations for HCP?
2. Which stakeholders should be considered in deciding if a mandatory influenza vaccine policy should be implemented? What values and perspectives do these stakeholders bring to this issue?
3. How does scientific information about the efficacy and effectiveness of the influenza vaccine and mandatory versus voluntary approaches to vaccination impact the advice you will give the nursing center director? What are the alternatives to mandatory vaccination for HCP?
3. How would you advise the nursing center director on how to explain the rationale behind the final policy decision to the following groups?
 - individual nursing center employees
 - other nursing center management
 - nursing center patients
 - HCP employee union representatives
 - the surrounding community

Scenario Shift:

1. How might the following policy provisions change your views:

- In addition to medical exemptions, the policy permitted non-medical exemptions on religious or philosophical grounds.
- Employees faced termination for vaccination refusal in the absence of an acceptable exemption.

2. How would your advice change:

- If an influenza outbreak occurred within the nursing center?
- If the seasonal influenza vaccine turned out to be poorly matched to the circulating viruses?

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Information for the Facilitator Mandatory Influenza Vaccination for Health Care Personnel

Additional Facilitator Questions

1. Do HCP have an occupation-specific obligation to be vaccinated against influenza for their own protection, just as police or firefighters may be required to use personal protective devices, carry firearms, or assume other obligations that “go with the territory” of the job? Why or why not?
 - If obligations exist, do these obligations depend on whether they were made clear to employees at the time of initiation of employment?
 - If so, should different enforcement procedures apply, depending on whether an employee signed a contract before or after initiation of the new policy?
 - Should such obligations extend to all nursing center staff or just those designated as HCP?
2. Given the rarity of adverse reactions to the flu vaccine, should any special considerations be given to uninsured HCP who have concerns about adverse reactions to a vaccine?
3. What effects on worker morale or employee relations might a mandatory vaccine policy have?
4. Given legal precedent for mandating vaccination for largely untreatable and deadly epidemics, such as during the 1905 smallpox epidemic, how does the seasonal influenza in the 21st century compare to those previous epidemics in terms of mandating vaccination?
5. Should nursing home facilities institute mandatory influenza vaccine policies, if they have not implemented a comprehensive influenza prevention program (i.e., measures including hand washing policies, segregating patients who have influenza symptoms, etc.)?

Points to Consider

Arguments in favor of a mandatory influenza vaccine policy:

- Just as public health has a mandate to protect the public’s health, the nursing center director has a primary responsibility to protect the health of the residents and arguably the contractual authority to do so.
- Requiring vaccination for HCP could be seen as part of the nursing center director’s responsibility to provide a safe environment for workers.

- Because elderly nursing home residents are a vulnerable population with high susceptibility to influenza and its complications, protecting them should be a high priority that trumps other concerns.
- Health care personnel have a professional obligation to “do no harm” and to act in the patients’ best interest. They also need to take precautions to protect their own health so that they can increase their capacity to provide care during influenza outbreaks.
- Patients have the right to expect that HCP will take reasonable precautions to protect them from developing nosocomial illness.
- Several studies have found that mandatory policies achieve higher coverage than voluntary ones and therefore can better protect the nursing home residents.

Arguments against a mandatory influenza vaccine policy:

- The lack of professional standing and part-time status of many HCP raise the question of to what extent professional or occupational obligations apply to them.
- Competent adults, including HCP, are generally considered to have the right to make their own healthcare decisions, including the decision whether to accept or decline a medical intervention such as a vaccination.
- As the efficacy of the vaccine is estimated to be about 60%, it may not provide enough health benefit to justify its necessity and reasonableness.
- Scientific uncertainty prevails about whether mandatory vaccination policies benefit patients.
- Mandatory policies may not always be effective; local circumstances, such as social attitudes and employee relations, may influence their effectiveness.
- In recent years, some mandatory influenza vaccination programs have been successfully challenged in court.
- The absence of similar or appropriate restrictions on visits by relatives of residents could be construed by employees as both unfair and inconsistent with the policy of preventing the spread of influenza.

- Mandatory vaccination places undue burden on HCP who lack insurance, should they suffer an adverse reaction to the vaccine.
- A mandatory vaccination policy may alienate HCP and damage workplace relationships.

Ethical Analysis

The primary decision maker in this case, a nursing center director, has asked a local public health director for input regarding a proposed mandatory vaccination policy. From a utilitarian perspective, the public health director must weigh, amidst scientific uncertainties, the putative health benefits of high HCP vaccination rates against the likelihood of adversely impacting employee relations by unilaterally imposing mandatory vaccination. The economic costs associated with addressing employee opposition, moreover, must be weighed against more expensive comprehensive approaches that accomplish the same health goal. The director, then, must ultimately determine the threshold of cost savings that would justify implementing an unpopular mandate. These considerations illustrate the inherent difficulty in utilitarian analysis which seeks to balance competing scientific, ethical, and economic values. This case also typifies the kind of conflicts between individual liberty and the greater good that frequently arise in public health practice. Here, this conflict plays out in a private nursing facility, where ambiguity exists about the professional standing and obligations of HCP. As a result, the case also illustrates difficulties that public health officials encounter when they attempt to apply public health standards and values to other sectors or jurisdictions.

One might be tempted to argue that, given the minimal risk the flu vaccination poses, any liberty harms or restrictions are minimal in relation to potential benefits of the vaccination policy. But both sides of this utilitarian argument can be challenged. Because liberty is tied to notions of self-determination, the individual's own determination of the degree of risk matters. Although, scientifically considered, the risk of adverse effects is minimal; the fraught history of vaccine refusal illustrates the divergence between scientific assessment and public perception of risk. Public perception of risk often follows heuristics, evolutionarily evolved rules of thumb that generally help us respond quickly to complex situations. However, these intuitive rules sometimes create hard to dispel cognitive biases. Compelling someone to undergo a risk generally magnifies the perception of its magnitude, and so is viewed as a substantial affront to liberty. These considerations suggest that the nursing center director should first attempt to get buy-in for the vaccine policy from HCP through discussion or negotiation rather than impose a unilateral policy that would have more warrant in the face of an imminent flu outbreak.

The *Principles of the Ethical Practice of Public Health* obligates public health practitioners to make special efforts to protect vulnerable populations such as nursing home residents.¹ That code also obligates practitioners to act in a timely fashion on the basis of scientific evidence. Moreover, it obligates them to act even when lacking definitive evidence, if conditions demand, in order to protect the public. A strong evidence base tends to limit the range of acceptable public health action to the implementation of standards of care or standard interventions. Conversely, the lack of a strong evidence base, especially in the context of urgent demands, tends to extend the range of permissible responses. These considerations are relevant to this case. Although

vulnerable populations deserve special protection, both the medical rationale for mandating vaccination and the justification it offers for restricting liberty are dependent upon the strength of the evidence that vaccinating HCP provides benefits to the residents. Because of uncertainty of the scientific evidence, the nursing center director should consider a broader range of policy or intervention options to address the legitimate concerns about preventing flu in these residents. Moreover, the nursing center director should explore options in a more democratically participatory fashion that could serve to mitigate the fallout that unilaterally imposing a mandate would likely create. Such a recommendation aligns with the public health obligation to engage stakeholders whom policies directly affect as a way to build trust. Having the trust of the nursing center employees would extend the range of feasible options.

The absence of a scientific mandate also underscores the importance of providing a clear justification for decisions, especially those that entail liberty restrictions. As mentioned in the background information, justification for mandatory vaccination has legal precedent, although both procedural and substantive limits restrict that mandate. Regarding procedural limits, although a free, voluntary vaccination program has been in place for several years at the nursing center, other than allowing for medical exemptions, no due process procedures are proposed for those who might object to the policy. Regarding substantive limits, if it cannot be demonstrated that vaccinating HCP benefits residents, then the intervention arguably is neither necessary nor reasonable, nor would it demonstrably benefit residents in proportion to burdening HCP.

Turning from legal to ethical justification for restricting liberty, the relevant ethical basis in this case is Mill's harm principle, which states that preventing direct harm to others is the only justification for restricting liberty in a democratic society.² While providing benefit is not tantamount to avoiding harm, the benefit to residents of vaccinating HCP largely consists in avoiding the harm of contracting influenza. Here, too, inability to demonstrate harm prevention undermines the justification for restricting liberty.

Mandating vaccination for HCP but permitting residents to have contact with non-HCP, such as family members or other visitors, medically undermines the policy, while unfairly discriminating against HCP. Such obvious gaps in preventive measures, along with the peremptory imposition of a mandate could make leadership seem to be more concerned about appearances rather than real solutions. This perception is likely to negatively impact employee relations, which could adversely impact the overall quality of care at the nursing center. These considerations also point to the advisability of exploring the more comprehensive policies the case mentions. Although such policies may be more expensive, they may in the long run also be more feasible and effective. In addition, to expose HCP, many of whom are uninsured to the risk, however slim, of an adverse reaction to the vaccine and the attendant out of pocket expenses and lost wages is unfair on the basis of the reciprocity principle. This principle, which applies to individual members of the public whose liberty is restricted for the sake of a greater good, calls for compensating these individuals as a *quid pro quo* for their sacrifice.³ But the relevance of this principle is uncertain, because the context is not the public at large but a health organization where employees presumably have higher professional obligations.

A number of professional organizations endorse the idea that HCP have a professional and ethical responsibility to receive annual influenza vaccinations as a condition of employment and professional privileges, but few states have mandatory requirements for influenza vaccinations as a condition of employment and professional privileges.⁴ Professional standing generally entails higher standards of obligation and training than those of the non-professional. The rationale for these higher standards lies in the vulnerability of the clients with whom professionals deal. Historically, the *quid pro quo* for meeting these higher standards consisted in the greater prestige and social standing of the professional. Getting vaccinated, then, goes with the territory of being an HCP, just as wearing personal protection equipment goes with the territory of being a firefighter. Protecting themselves from influenza in turn helps HCP fulfill their primary duty as health providers, namely, *primum non nocere*, first do no harm; in this case, avoidable harm to a vulnerable patient. However, many HCP in nursing homes are low-status, low-paid hourly employees, often part-time and lacking health insurance, and with little training compared to other health professionals. The lack of training, status, and *quid pro quo* that normally accompany professional standing likewise call into question the validity of these professional standards of obligation.

Although, based on the weight of evidence, CDC and ACIP recommend that all HCP receive influenza vaccine, the lack of scientific certainty regarding the vaccine's benefits to the nursing center residents weakens the ethical justification. Moreover, the questionable professional standing of many HCP in nursing homes, makes it problematic to apply the mandate ethically on the basis of professional obligations. However, the absence of scientific certainty also opens up the way to exploring additional options, which might become more feasible to implement in the context of democratically engaging HCP to build trust. In the end, recommending greater dialogue with stakeholders and more comprehensive measures is not a retreat from public health values and objectives but a different way of realizing them.

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Attachment I: Community Health Needs Assessment Case Study

Recommendation of the Ethics Subcommittee, Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC)²²

Developed by the Ethics Subcommittee STLT Support (Case Development) Workgroup²³ on behalf of the Ethics Subcommittee, Advisory Committee to the Director, CDC

Approved by the Ethics Subcommittee on _____

Approved by the Advisory Committee to the Director, CDC on _____

Case Study: Community Health Needs Assessment and the Patient Protection and Affordable Care Act

Disclaimer: This case study is solely an educational exercise and does not necessarily reflect the position of Centers for Disease Control and Prevention on this issue.

Background

The new Patient Protection and Affordable Care Act (ACA) revises the conditions that nonprofit hospitals must satisfy in order to qualify for federal tax-exempt status and now requires tax-exempt hospitals to develop strategies to improve community health based on a community health needs assessment (CHNA). By statute, the CHNAs must take into account input from “persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health.” In addition, a hospital’s CHNA must be made “widely available to the public.” Also, ACA implementation policies (issued by the IRS and Department of the Treasury) offer important further guidance about the CHNA and identify “five required elements of the CHNA’s planning assessment phase that must be described in the CHNA report released to the public: the *community served*, the *process and methods* used to conduct the assessment, a the *sources and dates of the data used*, the

²² The members of the Ethics Subcommittee include Ruth Gaare Bernheim (Subcommittee Chair), University of Virginia; Janice A. Allen Chilton, The University of Texas MD Anderson Cancer Center; LaVera Marguerite Crawley, Stanford University School of Medicine; Kenneth Goodman, University of Miami; George Isham, Health Partners; Jeffrey Kahn, Johns Hopkins University; Alan Melnick, Oregon Health and Science University; Eric Meslin, Indiana University; Sara Rosenbaum, George Washington University; Jennifer Prah Ruger, Yale University; Ani Satz, Emory University; and Matthew Stefanak, Northeast Ohio Medical University.

²³ The members of the STLT Support (Case Development) Workgroup include Ruth Gaare Bernheim, University of Virginia (Ethics Subcommittee Member), Alan Melnick, Clark, Cowlitz, Skamania, and Wahkiakum Counties Public Health (Ethics Subcommittee Member), Matthew Stefanak, Workgroup Chair, Northeast Ohio Medical University (Ethics Subcommittee Member).

consultation process the hospital employed in order to secure input from both representatives of the community and persons with special knowledge or expertise in public health, a *prioritized list of community health needs identified and the process for prioritizing such needs*, and *other community assets* for meeting these prioritized needs.”

These requirements to qualify for tax-exempt status create an opportunity to improve community health by ensuring that hospitals understand the needs of their communities and by improving coordination of hospital community benefits with other efforts to improve community health. The concept of what constitutes a community benefit for purposes of tax-exempt status has evolved. Prior to 1969, Internal Revenue Service policies specified that the provision of charity care (i.e., care for which no compensation could be expected) was a required element of tax exemption, although IRS policy afforded hospitals a fair degree of latitude in establishing the amount of charity care they would provide. The 1969 IRS revision broadened the permissible range to include such activities as education, research, and activities that promote community health. At the same time, the IRS did not maintain precise definitions of community benefit, nor did the agency maintain a detailed method for collecting information about the size and scope of hospital community benefit activities. As with many other IRS policies, whether hospital activities involve a “community benefit” turns on the “facts and circumstances” of any particular case.

In 2011, the IRS provided further guidance and defined community benefit expenditures as consisting of several distinct categories of activities: financial assistance to the uninsured; expenditures in connection with hospital participation in Medicaid and other means-tested public insurance programs that pay less than the reasonable cost of care; expenditures in connection with health professions education and health research; expenditures in connection with community health improvement activities; and expenditures in connection with certain “community-building” activities when these activities can be shown to be interventions that are known to improve community health.

Of particular interest is the term “community health improvement services,” which the IRS defines as “activities or programs, subsidized by the health care organization, carried out or supported for the express purpose of improving community health.” IRS policies thus recognize that the concept of community benefit includes not only health care but also population-based activities that can improve overall health, and the agency also notes that “[s]ome community building activities may also meet the definition of community benefit” when they rest on an evidence base linking the activity to improvements in community health. The following examples of community building activities are offered: physical improvements and housing such as housing rehabilitation for vulnerable populations such as removing harmful building materials (e.g., lead abatement), neighborhood improvement and revitalization, housing for vulnerable populations upon inpatient discharge, housing for seniors, and parks and playgrounds to improve physical activities; economic development activities such as assisting in small business development and creating employment opportunities in areas with high joblessness rates; community supports such as child care, mentoring programs, neighborhood support groups, violence prevention, disaster readiness and public health emergency preparedness and community disease surveillance “beyond what is required by accrediting bodies or government entities”; environmental improvements to address “environmental hazards that affect community health such as alleviation of water or air pollution,” the safe removal or treatment of garbage and waste products, and other activities to protect the community from environmental hazards (other than expenses made to comply with legal requirements); leadership development and training for community members such as training in conflict resolution, civil, cultural, or language skills, and medical interpreter skills; coalition building such as community coalitions to address health and safety issues; community health improvement advocacy such as efforts to support policies and programs to safeguard or improve public health, access to health care services, housing, the environment, and transportation; and workforce development, including recruiting physicians and other health professionals to underserved areas.

Case Description

Russell County Hospital, a critical care facility in a rural area of State X, partners with other regional hospitals to form an 8-county health care network that features a trauma unit, a maternity unit, and a cancer center. The hospital serves as the primary community hospital for Russell County, which has a total population of 150,000. Two years ago, the health department of Russell County undertook a community health needs assessment and planning process guided by MAPP (Mobilizing for Action through Planning and Partnerships), a strategic planning tool developed by the National Association of County and City Health Officials (NACCHO) and the Centers for Disease Control and Prevention (CDC).

The Russell County Hospital's vice president for nursing was on the community executive board for the MAPP process and actively participated in the 16-month-long process that included community focus groups, in-depth data collection and analyses about the community's health and demographic status, interviews with the leaders of many local agencies and not-for-profit organizations, and citizen forums. Based on all quantitative and qualitative information, the MAPP community executive board identified the following 3 strategic issues as the county's health priorities: 1) infant mortality prevalence and disparity among different ethnic and racial groups; 2) mental health, including substance abuse, and 3) chronic disease prevention, focusing on reducing the prevalence of obesity and tobacco use.

Six months ago, as a final stage of the MAPP process, the health department worked with community leaders to establish community workgroups for each of the 3 priorities. A number of Russell County Hospital staff and health care professionals are participating on workgroups, along with a wide range of community stakeholders. The workgroups were charged with finding ways to address the community's health priorities, including securing new sources of funding, marshaling new energy and efforts to bring together various stakeholders to work together and pool their current resources, and establishing new programs and services. An initial challenge for community leaders in Russell County, including for-profit and not-for-profit organizations and the health department, has been how to allocate the limited funding and limited staff resources among the workgroups, and for each workgroup, how to identify and select the most important projects.

With these community efforts underway, the health department director has learned that the Russell County Hospital marketing department just completed its own community needs assessment (evidently, recommended by the legal counsel for the regional hospital network in order to satisfy the requirements of ACA). Based on the marketing department's assessment, the hospital is considering a new coronary care unit, given the increasing burden of stroke and cardiovascular disease in the county, as well as a new emergency department at the far end of the county that would also address increased demand and competition from another hospital for emergency services in Russell County and two other counties in the regional network.

While the health department director understands that Russell County Hospital would want to do its own community needs assessment, she also believes it is important for the hospital to consider the health priorities identified by the community through the MAPP initiative. She had asked to present the MAPP final report to the Russell Hospital board of directors a few months ago, but had not heard back from them.

The health department director, who knows about the new ACA CHNA requirements, has now decided to schedule a meeting with the hospital CEO to describe the MAPP process. Her goal for the meeting is to strengthen the relationship between the health department and the hospital and catalyze new opportunities for collaboration for community health benefit. While she understands that the ACA gives public health a

formal voice in the community benefit process, she thinks there are ethical issues that arise in exercising that voice: how to be involved and collaborate with the hospital on assessing, planning and setting community priorities, in a way that integrates community values and public health perspectives.

As the health department's coordinator for the MAPP process, you have been tasked by the health department director to develop the presentation for the hospital CEO about MAPP and the priority-setting process, incorporating public health ethical principles and community values. You have brought together some community leaders and public health professionals for a discussion to help plan the presentation.

Discussion Questions

1. Who are the major stakeholders in the case, and what values, goals, and perspective does each bring to the discussion?
2. What are the moral responsibilities of the respective stakeholders in regard to conducting a needs assessment and addressing it?
3. How might their goals and perspectives come into conflict and what are some of the ethical tensions?
4. What are the public health perspectives and ethical principles that are relevant?
5. What are ethical principles that might provide guidance for all stakeholders?
6. What criteria should be used to determine the community's needs and how to address them?
7. What would be the important considerations for partnering with the hospital to collaborate on strategic planning and goal setting, especially in regard to the consensus recommendations?
8. What might be a good process to accomplish the prioritization and transparency goals suggested under the new ACA guidelines and policies?

[NOTE: Facilitator information , including additional questions, points to consider, and sample ethical analysis, need to be developed.]

Attachment J: Draft Evaluation Logic Model

Recommendation of the Ethics Subcommittee, Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC)²⁴

Developed by the Ethics Subcommittee Evaluation Workgroup²⁵ on behalf of the Ethics Subcommittee, Advisory Committee to the Director, CDC

Approved by the Ethics Subcommittee on _____

Approved by the Advisory Committee to the Director, CDC on _____

Proposed Framework for Evaluating the Impact of Public Health Ethics September 26, 2012

Proposed Outline:

1. Introduction to public health ethics and why it is important (to be developed)
2. Why evaluating the impact of public health ethics activities is important (to be developed)
3. Inclusion of ethics standards and measures as part of the health department accreditation process (to be developed)
4. Recommended model for evaluating ethics activities (see below)
 - a. Logic model for anticipated public health ethics activities
 - b. Potential indicators/measures and data sources

²⁴ The members of the Ethics Subcommittee include Ruth Gaare Bernheim (Subcommittee Chair), University of Virginia; Janice A. Allen Chilton, The University of Texas MD Anderson Cancer Center; LaVera Marguerite Crawley, Stanford University School of Medicine; Kenneth W. Goodman, University of Miami; George Isham, Health Partners; Jeffrey Kahn, Johns Hopkins University; Alan L. Melnick, Oregon Health and Science University; Eric Meslin, Indiana University; Sara Rosenbaum, George Washington University; Jennifer Prah Ruger, Yale University; Ani Satz, Emory University; and Matthew Stefanak, Northeast Ohio Medical University.

²⁵ The members of the Evaluation Workgroup include Ruth Gaare Bernheim, Workgroup Chair, University of Virginia (Ethics Subcommittee member), Alan Melnick, Clark, Cowlitz, Skamania, and Wahkiakum Counties Public Health (Ethics Subcommittee Member), Eric Meslin, Indiana University (Ethics Subcommittee Member), Matthew Stefanak, Northeast Ohio Medical University (Ethics Subcommittee Member), Jennifer Ruger, Yale University (Ethics Subcommittee Member).

Logic Model Applied to Public Health Ethics Activity (bold elements focus of evaluation)

<u>Activities</u>	<u>Staff Outcomes</u>	<u>Program/Org Outcomes</u>	<u>Community/Public Outcomes</u>
<ul style="list-style-type: none"> • Establish and support a public health ethics infrastructure • Provide training • Publish and disseminate info • Develop guidance documents/code • Provide PH Ethics reviews, consults, recommendations (consistent with key ethical dimensions and quality attributes)* 	<p><u>Staff</u></p> <ul style="list-style-type: none"> • Have increased awareness and knowledge about what constitutes an ethics issue • Think about ethics and ethical choices in a systematic way • Can analyze and resolve ethical issues • Know the resources available to get assistance with an ethics issue 	<ul style="list-style-type: none"> • Programs establish their own standing mechanism for addressing ethics issues (consistent with key ethical dimensions and quality attributes)* • Programs establish mechanism for identifying and engaging key community stakeholders as appropriate for the issue • Staff and programs <u>use</u> ethics guidance and consult services 	<ul style="list-style-type: none"> • Staff and programs make ethical decisions (consistent with key ethical dimensions and quality attributes)* • Staff/leadership have justification for hard and controversial decisions • PH decision-making process is perceived as ethical • PH decisions are more positively perceived by public and stakeholders leading to increased public credibility and trust • PH policy and programs are better or “sounder”: <ul style="list-style-type: none"> ○ responsive ○ targeted ○ meet needs • Improved PH and health outcomes/ reduced adverse outcomes

Outside/Moderating Factors

Public Health Ethics Activity: Potential Indicators/Measures for Outcome Components

Outcome Component (from Logic Model)	Indicator/Measure	Data Collection Method/Source	Comments/ Challenges
Program/Community Outcome Measures			
Staff and programs make ethical decisions consistent with key ethical dimensions and quality attributes*	Proportion of decisions that have gone thru the health department's or program's established processes which pass benchmarks for key ethical dimensions and quality attributes	Expert/objective review of sample of decisions using checklist/content analysis Information submitted as part of the health department accreditation process Feedback from key external stakeholders (e.g., community members of the ethics committee)	Consider using "just policy" template suggested by G. Poland Consider how to assess how ethics is incorporated into day-to-day decision making across the organization
Programs establish their own strong standing mechanisms for addressing ethics issues	Proportion of program-specific ethics review processes that meet benchmarks for key quality attributes listed below Assessment of how ethics committee recommendations are acted upon by the health department	Expert/objective review of components of process using checklist/content analysis Review of policy statements to assess impact of ethics recommendations	Consider using "just policy" template suggested by G. Poland
Programs establish mechanism for identifying and engaging key community stakeholders as appropriate for the issue	Number of stakeholder or community engagement efforts Inclusion of community members on health department ethics committee	Review of emails or meeting minutes for evidence of stakeholder involvement and community engagement	
Activity Process Measures			

Outcome Component (from Logic Model)	Indicator/Measure	Data Collection Method/Source	Comments/ Challenges
Establish and support a public health ethics infrastructure	Presence/absence of the following key components of an ethics infrastructure: <ul style="list-style-type: none"> • Public health ethics training available • Percent of staff members who have completed ethics training • Guidance documents and other information on public health ethics issues disseminated to health department staff • Process put in place for providing ethics review, consults, and recommendations • If ethics committee established, number of meetings and number of recommendations issued • Staffing of ethics activity • Budget for ethics activity 	Expert/objective review of components of process using checklist/content analysis (assess through document review) Review of ethics committee meeting minutes	May want to delineate a series of stages or levels for ramping up an ethics process as experience, training success and buy-in occur
Activity provides public health ethics reviews, consults, and recommendations	Degree to which the Department's established ethics process meets benchmarks for key ethical	Expert/objective review of components of process using checklist/content analysis	Consider using "just policy" template suggested by G. Poland

Outcome Component (from Logic Model)	Indicator/Measure	Data Collection Method/Source	Comments/ Challenges
	dimensions and quality attributes*		
Outside/Moderating Issues			
Leadership support for public health ethics activity	<p>See measures above under “Establish and support a public health ethics infrastructure”</p> <p>Assessment of program staff perception of leadership support for public health ethics activity and recommendations for building ethics activity</p>	<p>See methods above under “Establish and support a public health ethics infrastructure”</p> <p>Anonymous employee survey</p>	
Economic factors, such as ...	TBD	TBD	
Political factors, such as ...	TBD	TBD	
Social factors, such as ...	TBD	TBD	

Key Ethical Dimensions for Making Decisions

- Weighing benefits vs. harms, costs, and risks of a decision
- Considering rights, values, interests, and needs of individual communities vs. obligation to protect the public good
- Using least restrictive measures necessary to protect the common good
- Ensuring fair distribution of public health benefits/burden
- Addressing health equity/protection of vulnerable populations
- Working towards social justice

DRAFT

Key Quality Attributes of an Ethical Process

- Is open, honest, and transparent
- Makes explicit the facts, values, principles and assumptions used
- Prioritizes values according to a fair, inclusive process; judicious weighing of competing values and goods
- Allows for fair hearing of the interests, values, and perspectives of all
- Consistently applies standards across people and time (treating like cases alike)
- Appropriately engages stakeholders in decision making
- Involves affected, informed, experienced and neutral individuals and representatives of communities
- Provides information to affected stakeholders in a timely manner and in culturally and linguistically appropriate ways
- Uses best available scientific evidence
- Monitors and evaluates the process to allow for updating, revision, or correction of procedures in the light of new info, questions, criticisms, etc.