

CDC Program Response to the External Peer Review of Foodborne Illness Detection and Investigation in Multistate Outbreaks

On April 16-17, 2009, an external peer review of CDC's foodborne illness detection and investigation in multistate outbreaks took place in the Division of Foodborne Bacterial & Mycotic Diseases in Atlanta, GA. The panel members included:

- Robert E. Brackett, PhD, Senior Vice President, Chief Science & Regulatory Affairs Officer Grocery Manufacturers Association
- Paul R. Cieslak, MD, Manager, Acute & Communicable Disease Prevention, Oregon Public Health Division
- Jeff Farrar, DVM, PhD, MPH, Branch Chief, Food & Drug Branch, California Department of Public Health
- Vicki S. Freimuth PhD, Professor, Department of Speech Communication, Grady College of Journalism & Mass Communication, University of Georgia
- Craig Hedberg, PhD, Professor, University of Minnesota School of Public Health
- Marguerite Neill, MD (Chair), Associate Professor of Medicine, Alpert Medical School of Brown University
- Jim Pearson, PhD, Director, Division of Consolidated Laboratory Services, Virginia
- Dean G. Sienko, MD, MS, Medical Director, Ingham County Health Department, Michigan

Participating observers also included:

- David Acheson, Associate Commissioner for Food, FDA
- Elisabeth Hagen, Acting Deputy Assistant Administrator, FSIS
- Kirk Smith, DVM, PhD, Supervisor, Foodborne Diseases Unit, MN Department of Health
- Frank Yiannis, Vice President of Food Safety, Wal-Mart Stores, Inc.

Purpose of this review

Recent multistate outbreaks of foodborne illnesses have highlighted a range of complex issues. The purpose of this review is to provide feedback to CDC on how to improve processes and activities associated with multistate foodborne outbreaks as distinct from smaller, more temporally and/or geographically localized clusters of illness.

Listed below are the key findings and recommendations made by the panel and a response from the program. The external review panel's complete report is attached to this summary.

Summary of Key Points & Major Recommendations

1. **There is an urgent need for a significant culture change in food safety activities at CDC. The current culture appears isolated from external partners and resistant to change.**

We are committed to providing the highest level of support to our state, local and federal partners in an open and transparent manner. We have made several recent changes in leadership of the foodborne illness response program that will allow the division to reassess this program with a fresh perspective. The new Acting Director of DFBMD has many years of experience in leading foodborne outbreak investigations and working closely with local, state and federal partners. The new Acting Deputy Director for DFBMD has worked for many years at FDA and brings valuable cross-organizational experience to the program. The outbreak response function has been elevated from a team within a branch to a stand-alone branch (see item 6 below).

We will continue to support, activity participate in and adopt recommendations from the Council to Improve Foodborne Outbreak Response (CIFOR), which constitutes a partnership among CDC, the Council of State and Territorial Epidemiologists (CSTE), the National Association of County and City Health Officials (NACCHO), the National Environmental Health Association (NEHA), the Association of Public Health Laboratories (APHL), the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA).

We will continue to support and enhance OutbreakNet, the national network of local, state and federal public health officials responsible for foodborne diseases surveillance and outbreak response and PulseNet, the national molecular subtyping network for foodborne disease surveillance. The 5th annual meeting of OutbreakNet was recently held, in conjunction with the 13th annual PulseNet meeting, with over 250 attendees participating in seminars, panel discussions and training aimed at improving foodborne diseases surveillance and outbreak response.

CDC and FDA have initiated a working group among food safety leaders in both agencies with regularly scheduled meeting for closer coordination and communication. CDC, FDA and FSIS plan to expand the co-location of staff, on an ongoing basis and during outbreaks, to increase inter-agency capacity and coordination.

See also #4

2. Coordination of multi-state foodborne outbreaks does not appear to be a top-level priority based on the lack of adequate support. Effective national leadership by CDC in food safety requires infrastructure and resources within CDC commensurate to the task.

We have reorganized the structure of the Enterics Diseases Epidemiology Branch into two branches; one responsible for outbreak response and prevention, the other for enteric diseases surveillance and epidemiologic research. The outbreak response branch will have more focused role in outbreak response. The outbreak response branch is currently recruiting 2 additional doctoral level staff members and plans to further build capacity in the future.

CDC has proposed a food safety budget initiative for FY2011. The proposed funds will strengthen food safety capacity at CDC and increase support for local and state partners in foodborne diseases surveillance and outbreak response.

We will strengthen our partnership with FDA and FSIS to more effectively utilize combined resources (see also #4 and #5 below)

3. The placement of food safety programs within CDC's organizational structure is not commensurate with their public visibility and is incongruous with the high-level food safety personnel in other agencies and commercial entities; higher-level managers at CDC need to engage more fully in food safety issues.

We will continue to engage the CDC director in our progress in meeting the recommendations for this program review and other activities within the food safety program. He has reviewed the CDC food safety program response to this review. He and the Acting Deputy Director for Infectious Diseases recently briefed HHS Secretary Sebelius on CDC roles and responsibilities and plans in Food Safety at CDC. We expect to provide routine updates on food safety program progress and plans to the CDC director on an ongoing basis.

The NCZVED Director acts as the agency representative on the President's Food Safety Workgroup, which will continue to monitor progress at CDC, FDA, FSIS and other agencies to enhance food safety in the U.S. Within NCZVED, the Food Safety Office has been elevated to an office within the NCZVED office of the director.

We will continue to directly engage the NCZVED Associate Director for Policy and Associate Director for Communications in all food safety policy and communication activities and plans.

The Director and Deputy Director, DFBMD will be directly involved in division activities in food safety and interactions with officials in other agencies and commercial entities.

4. Coordination with state and local agencies continues to be a weakness and seems intractable, as it has been discussed for years. There needs to be better coordination of information with state and local partners as well as federal regulatory agencies; the emphasis should be on a “partner” approach to streamline multi-state outbreak investigations.

(20) We will conduct a general review of legal and policy issues surrounding data sharing with regulatory and industry partners to determine how to share confidential but not classified information. By June 30, 2010 we will review our data use agreements and consult with CDC’s Offices of Surveillance, Epidemiology and Laboratory Services (proposed), Office of State and Local Support (proposed), Office of the Chief Science Officer, Office of the General Council, and the National Center for Health Statistics to identify policy implications and restrictions to data sharing. We will work with our partners to clarify, change, or develop new data use agreements. We will launch a restricted web-based data portal to provide confidential or sensitive data to approved users.

(22) We will engage with regulatory partners earlier in the investigative process and exchange personnel at different levels in the agencies to strengthen relationships, improve collaboration, and increase dialogue. By June 30, 2010 we will establish multi-disciplinary outbreak response teams and develop rules of engagement and identify roles and responsibilities during different phases of outbreak investigations. We will work with FDA to develop a schedule for staff rotations between agencies.

(23) We will build successful interagency cooperation before outbreaks occur. We will continue to exchange personnel during outbreaks and by June 30, 2010 we will develop a formal orientation program for visitors. By June 30, 2011 we will incorporate short-term projects for EIS officers to work on at FDA and we will implement longer-term exchanges of personnel between CDC and various parts FDA, including CFSAN, CVM, and ORA.

(28) We will develop resources that allow states and CDC to enter, share and view data in real time to allow better access for states and epidemiologists to CDC databases. We have recently launched a web-based, public-use data set that includes information from our National Outbreak Reporting System. By June 30, 2010 we will survey state and local end users to evaluate the accessibility and utility of the current PulseNet library and make revisions to improve accessibility, availability and utility. We will collaborate with USDA FSIS on their Predictive Analytics Project to combine pathogen information with sophisticated algorithms to show geo- and temporal-spatial relationships.

5. Conducting interviews in a timely manner remains the single most critical deficiency in large outbreak investigations. CDC must implement bold, new approaches that reward aggressive, complete, and timely investigations by state and local partners and holds them accountable for slow investigations.

(1) We will create OutbreakNet Sentinel Sites, a network of state and local agencies that will perform aggressive outbreak investigations and develop advanced epidemiological methods. We have already started a pilot program with APHL and provided funding for three sites for limited, one-year projects. We are currently forming a steering team for OSS, which will include regulatory partners. By September 30, 2010 (funds permitting) we will award funding to an additional four sites and by June 30, 2011 we will implement and optimize rapid epidemiological investigation methods in these four OSS sites.

(2) We will develop standard operating procedures or other criteria to determine which clusters of foodborne outbreaks to investigate. By December, 2009 we will complete an internal review of our SOPs and a cluster assessment project. By June 30, 2010 we will pilot automated tools to rapidly visualize epi and lab data associated with clusters and complete the FoodNet working group project on cluster evaluation. We will implement evaluation and monitoring plans based on established metrics and baselines.

(4) We will measure lag times between requests to complete interviews and time of completion and upload to CDC and we will apply pressure to states that are tardy to encourage timely completion of investigations. By June 30, 2010 we will implement and assess performance measures for interview completion during multistate outbreaks and work with states to take corrective action. We will share results with state and local partners during investigations, in after-action reports, and at OutbreakNet annual meetings.

(5) We will prepare after-action reports and conduct thorough evaluations of outbreak investigations as part of a continuous improvement process. We will continue our policy of conducting peer reviews of ongoing investigations and we will solicit feedback from state and local participants. We will explore the possibility of expanding the OutbreakNet annual meeting to include review and evaluation of recent outbreaks. We will develop and teach case studies of challenging and complex outbreak investigations to improve our response capabilities and train new staff.

6. In order to more fully evaluate the results of outbreak investigation and control activities, the responsibility to maintain and analyze outbreak surveillance data should be separated from the responsibility to investigate outbreaks.

(35) The former Enteric Diseases Epidemiology Branch was reorganized on October 1, 2009. The outbreak response function is now separate from the data analysis function. We believe this change will allow the data analysis team to focus on timely completion of periodic surveillance reports since they will no longer be encumbered by emergency response obligations. Similarly, the outbreak response team will be able to adopt a more operational stance and provide stronger support to state and federal partners.

7. Internal IT problems within CDC continue to substantially impact food safety activities in CDC, especially in the area of large foodborne outbreak investigations. New, available technologies are not being used to meet CDC food safety needs. A much greater emphasis, with high level support, must be placed on addressing and solving these IT issues.

We are seeking high level support from CDC to improve our IT capabilities. Our EOC is currently exploring ways to improve IT support and is considering the purchase of computer assisted telephone interview software to improve response. We will engage CDC's new office of surveillance to develop new outbreak management tools and explore options for joint development with federal agency partners. By June 30, 2011 we will assess tools and techniques from OutbreakNet Sentinel Sites and implement those that are proven to be effective at improving our response capabilities.