

NIH Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Disease Laboratory at Boston University Medical Center

Working Group of the Advisory Committee to the Director

Summary of Public Meeting July 16, 2008

The NIH Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Disease Laboratory (NEIDL) at Boston University Medical Center (BUMC) (Blue Ribbon Panel [BRP or “the Panel”]), a working group of the Advisory Committee to the Director (ACD) of the National Institutes of Health (NIH), was convened for its fourth meeting at 8:00 a.m. on July 16, 2008, at the NIH, Building 31-C, Conference Room 6, Bethesda, Maryland. Dr. Adel Mahmoud (Chair) presided. In accordance with Public Law 92-463, the meeting was open to the public from 8:00 a.m. until 2:00 p.m. on July 16, 2008. Notice of this meeting was published in the *Federal Register* on July 3, 2008 (73 FR 38235). The purpose of this meeting was to discuss foundations for community engagement and partnerships between research institutions and local communities.

Panel Members Present

Donald S. Burke, M.D., University of Pittsburgh
George Friedman-Jiménez, M.D., Bellevue Hospital Center
Margaret A. Hamburg, M.D., Nuclear Threat Initiative
Dennis L. Kasper, M.D., Harvard Medical School/Brigham and Women’s Hospital
Johnnye Lewis, Ph.D., DABT, University of New Mexico
W. Ian Lipkin, M.D., Northeast Biodefense Center/Columbia University
Adel Mahmoud, M.D., Ph.D., Princeton University (Chair)
Thomas H. Murray, Ph.D., The Hastings Center
Mary E. Northridge, Ph.D., M.P.H., Columbia University/*American Journal of Public Health*
Jean Patterson, Ph.D., Southwest Foundation for Biomedical Research
Mark Gregory Robson, Ph.D., M.P.H., Rutgers, The State University of New Jersey
Samuel L. Stanley, Jr., M.D., Midwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research/Washington University in St. Louis
Wayne Thomann, Dr.P.H., Duke University/Duke University Medical Center

Ex Officio Member Present

Rima F. Khabbaz, M.D., Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

NIH Staff Members Present

Amy P. Patterson, M.D., Office of the Director, NIH

Invited Speakers

Klare Allen, Safety Net and STOP the Bio-Terror Lab Coalition
Ruth Barkley, Cathedral United Tenant Organization
Glen Berkowitz, J.D., M.P.A., Community Liaison Committee, Boston Biolab
Barbara Ferrer, Ph.D., M.P.H., M.Ed., Boston Public Health Commission
Elmer R. Freeman, M.S.W., Center for Community Health Education Research and Services, Inc.
Michael Kineavy, M.P.A., City of Boston

Thomas J. Moore, M.D., Boston University Medical Center
David Mundel, Ph.D., Consultant
Carmen Nazario-Vega, M.Ed., Tenants in Victory
Peggy M. Shepard, M.P.H., WE ACT for Environmental Justice
Michael A. Trush, Ph.D., Johns Hopkins Bloomberg School of Public Health

Others

Approximately 58 people attended this public BRP meeting.

I. Welcome and Opening Remarks/Dr. Mahmoud

Dr. Mahmoud, BRP Chair, called the meeting to order at 8:00 a.m. on July 16, 2008. BRP members introduced themselves with name, professional affiliation, and primary area of professional activity.

Dr. Mahmoud reiterated the BRP's charge. He stated that the goal of the meeting was to provide information to the BRP on community engagement, with stakeholders invited to talk about ways and means to have an effective and sustained dialog between BU and the surrounding community.

II. Partnerships Between Research Institutions and the Local Communities: Important Principles, Key Attributes, and Lessons Learned

Presenter: Elmer R. Freeman, M.S.W., Executive Director, Center for Community Health Education Research and Services, Inc.

Mr. Freeman discussed core aspects of building public trust in research. The Council of Public Representatives (COPR) advises the NIH Director along with the ACD, which is composed of scientists. He discussed the history of the COPR, its roles and functions, and the reports it has generated.

Promising practices of public involvement and community engagement include using a variety of approaches to obtain as much input as possible, involving the community/public and governance and policymaking bodies such as institutional review boards and boards of trustees, and taking advantage of existing relationships and partnerships.

Lessons learned from strategic partnerships include that the public maintains a general mistrust of scientists, that science is often political and driven by self-interest, that public engagement changes people, and that public involvement in science and biomedical research is inevitable.

Presenter: Michael A. Trush, Ph.D., Johns Hopkins Bloomberg School of Public Health

Dr. Trush offered a laboratory scientist's perspective on community relationships and outreach. He noted that building trust and communication is the most significant issue and is the key ingredient in building positive community relationships. Dr. Trush illustrated his points with three examples: Wagner's Point in Baltimore, a bus depot in a Baltimore neighborhood, and demolition of the East Baltimore Biotech Park.

To get to know its surrounding community, an institution should conduct an inventory of the community, looking for assets such as businesses, churches, and leaders; discern who lives in the community and appreciate the culture of those residents; identify community leaders; and recognize and understand the needs of the community. An institution should include the community in all aspects of a proposed project (including the initial planning), be prepared to be flexible, be respectful of the community's culture, and deliver on its promises. Evaluating progress and processes and returning to the participating community with interim findings are also important.

Presenter: Peggy M. Shepard, M.P.H., WE ACT for Environmental Justice

Ms. Shepard discussed her work in Harlem and north Manhattan communities for 20 years, in which she helped mobilize communities with regard to sewage treatment plants and diesel bus bins. Her method is to organize proactively to create community benefits; Ms. Shepard is currently negotiating a community development agreement with Columbia University Health Services.

Community risk perceptions are based on personal risk evaluations, and communities rarely derive any benefits, such as jobs, from the construction of biosafety laboratories. When risks and benefits are not evenly distributed, conflict is inevitable. A growing mistrust of expert knowledge exists, especially in science. In most instances, the public is generally left out of policymaking, and progress cannot be made if residents are not included in reaching solutions.

BRP Discussion

BRP members discussed with the presenters whether and how institutional change can occur, the lack of real benefits but the perception of real risk when research laboratories are built, tangential benefits to the community that BU might want to pursue (e.g., parks and schools), and building trust between BU and the community.

Final Speaker Comments/Responses

Mr. Freeman noted that one of BU's challenges is that the building is already there. Institutional expansion in every major city in the northeast United States is a problem; as more land is taken off the property tax rolls, residential tax rates increase and make it more expensive to live in that city. BU must offer tangential benefits to residents.

Dr. Trush opined that the NIH has moved away from public health as its research mission. The community around the NEIDL knows what they would like to have around them; BU should engage them and listen to them.

Ms. Shepard noted that there is not enough oversight or inspection and that mayors in many cities are encouraging bioresearch facilities as economic development. Academic research institutions are expanding, and as landowners, this expansion creates tension. These institutions can provide benefits that are created in concert with community residents, such as social service facilities, dental clinics, and affordable housing. All communities know what they need and are willing to voice those needs.

III. Foundations for Community Engagement: Trust and Transparency

Presenter: Barbara Ferrer, Ph.D., M.P.H., M.Ed., Boston Public Health Commission

Dr. Ferrer discussed building effective partnerships to promote and sustain healthy communities. She noted that public health work can be accomplished effectively only through the use of partnerships; preventing disease must include partnerships with people who get those diseases. Without information from the community, serious mistakes are made in policies and initiatives. Dr. Ferrer focused on two examples—building Neighborhood Peace Councils (NPCs) and community involvement in a citywide working group to establish policies regarding biological research laboratories.

NPCs were targeted to four poor neighborhoods in Boston that had higher rates of violent crime than other Boston neighborhoods. The purpose of these NPCs was to provide an opportunity for residents and local agencies to work together to build a safe and vibrant neighborhood by ensuring the provision of city services, supporting civic engagement, and ensuring accountability. Goals included defining a neighborhood vision, building relationships, constructing solutions, and creating opportunities for youth involvement. Successes included a reduction of violent crime in the first 4 months in each NPC

neighborhood, visible improvements in each of the four neighborhoods (street signage, cleanliness, and lighting), establishment of resident leadership, and activities sponsored by the NPC.

The major success of the citywide working group was passage and implementation of biosafety regulations. Boston is the only city in the Nation that regulates biosafety level (BSL)-3 and BSL-4 laboratories and bans BSL-4 research with recombinant deoxyribonucleic acid (DNA). In addition, this group organized a structure for ongoing oversight of BSL-3 and BSL-4 laboratories.

Dr. Ferrer noted that Boston has a unique opportunity to address issues related to research with unknown components while paying significant attention to the safety of workers and residents.

Presenter: Michael Kineavy, M.P.A., Chief of Policy and Planning, City of Boston

Mr. Kineavy discussed the general efforts of the City of Boston to promote community engagement and noted that Boston Mayor Thomas M. Menino considers BU to be one of the most responsive institutions in Boston.

Before city approvals were granted for the NEIDL and after the proposed project was vetted, the city required satisfactory answers to the following questions:

- Was the voiced opposition to the project representative of neighborhood opinion?
- Was there merit to the opposition's issues?
- Has the opposition been given the opportunity to state its case in an open and fair manner?
- What are the safety considerations with regard to the project?
- What mitigation measures are needed to ensure that the City of Boston and its neighborhoods are compensated adequately for the additional burden the project may place on the community?

Mr. Kineavy explained that a credible, scientifically valid risk analysis is needed to advance the NEIDL project and to assure community residents that the laboratories within the NEIDL will be safe. Unless the risk analysis suggests differently, the city's position remains that the project bears true merit if BU can operate the facility safely.

Presenter: David Mundel, Ph.D., Consultant

Dr. Mundel discussed strategies for rebuilding trust and creating transparency. He noted that research in many domains demonstrates that trust and open communication are necessary for effective, cooperative decisionmaking and information sharing.

The history of public debate and deliberations regarding the proposed NEIDL indicates that trust was, at best, low at the beginning and became much lower over time. Community concerns were trivialized, questions from the community remained unanswered, promised information was not provided, inadequate risk assessments were repeatedly quoted rather than corrected in subsequent documents, and communication was accomplished primarily through written reports and oral presentations rather than through conversations and discussions.

Given this history, Dr. Mundel offered six suggestions for the BRP to transmit to the NIH Director, in the form of needed actions, analyses, and processes.

Presenter: Glen Berkowitz, J.D., M.P.A., Member, Community Liaison Committee, Boston Biolab

Mr. Berkowitz noted that his home is about 1,000 feet from the NEIDL site and that his comments were not officially sanctioned by either the neighborhood or BU. He was appointed to the Community Liaison Committee (CLC) in 2006. Between 2004 and 2006, what was planned as a hotel became the NEIDL, without the public process that has been employed on other occasions.

BU deserves credit for its appointments to the CLC, including known opponents. The educational forums planned and offered by the CLC were not well attended, because most people are resigned that the BSL-4 laboratory will open in the NEIDL. A large number of community members are neutral about the BSL-4 laboratory, but little knowledge has been gained while the court cases remain pending.

Mr. Berkowitz suggested that BU open the NEIDL laboratories at the BSL-2 and BSL-3 levels only and then work to build trust with the community, putting off the opening of the BSL-4 laboratory. He then offered the story of “Cinda and Helaine,” two activists who were so put off by being disenfranchised by BU that they no longer participate in the community involvement process. Nonetheless, a large group of community members look forward to hearing the new risk assessment and the results of the BRP’s deliberations.

Presenter: Thomas J. Moore, M.D., Associate Provost and Director, Office of Clinical Research, BUMC

Dr. Moore explained that BUMC is the affiliation of the BU School of Medicine and the Boston Medical Center (which was Boston City Hospital until a merger in the 1990s). The mission of the BUMC remains to provide care regardless of an individual’s ability to pay, and therefore BUMC is a major provider of care to Boston’s underserved communities. Benefits to the community provided by BUMC include a cancer screening unit, a medical outreach van that provides health care and clothing for homeless people, an elderly home visit program, a food pantry that feeds 4,000 people per month, and scholarship support for CityLab Academy, which acquaints students with science.

He characterized the community outreach regarding the NEIDL as the largest ever undertaken by BU, with information being shared via an e-mail list and many public meetings, plus a visit to a BSL-4 laboratory in an Atlanta neighborhood and the formation of the CLC. Indications that active opposition is no longer widespread include a lack of requests to speak since 2006 and low attendance at CLC educational forums. The nature of emerging infectious disease research is stigmatized, and the benefits are not easy to demonstrate. The presence of ongoing court cases provides a disincentive to discuss the salient issues, as opponents to the BSL-4 laboratory believe they can win through litigation.

BU is committed to improving its community relation strategies in the future and has hired consultants to assist in this effort.

Presenter: Klare Allen, Member, Safety Net and STOP the Bio-Terror Lab Coalition

Ms. Allen stated that the few residents attending this BRP meeting should not be viewed as representing the entire community surrounding the NEIDL. She reiterated that the BRP should meet in Boston, at a day and time that is convenient for people who work, to discuss concerns with the community.

Specific points made by Ms. Allen included:

- Community members have tried for 6 years to talk to Boston Mayor Menino, but they have been ignored.
- There have been laboratory accidents and incidents, and some safety procedures did not work right. This BSL-4 facility will work with deadly pathogens, and residents cannot afford any mistakes.
- The CLC has been hard to deal with. Advertisements about its educational programs have not been seen.
- BU and the NIH have done a poor job of risk assessment.
- The Manhattan Project model should be used instead of building BSL-4 laboratories around the country.

- The city and the State are not prepared for a safety-related incident at the NEIDL. For example, the fire department is not getting relevant training, and residents are not aware of how to evacuate.
- In 2007 Safety Net wrote and submitted a community plan at the request of a judge.

Presenter: Carmen Nazario-Vega, M.Ed., Tenants in Victory

Ms. Nazario-Vega discussed the history of residential developments in the area surrounding the NEIDL and presented residents' past and current concerns, which center on affordable housing, safe neighborhoods, jobs, and desired services.

She noted that there have not been enough outreach meetings and noted especially the lack of written and verbal communication in Spanish.

Presenter: Ruth Barkley, Member, Cathedral United Tenant Organization

Ms. Barkley reiterated Ms. Allen's invitation to the BRP to come to Boston for an evening meeting, so that community members can express their opinions about the BSL-4 laboratory. She explained that the community wants changes that focus on safe, sanitary, and decent housing.

Ms. Barkley also expressed concern about anthrax research at the NEIDL.

BRP Discussion

BRP members discussed with the presenters how the prior laboratory accident at BU would have been handled if current regulations had been in place, the use of recombinant DNA at the BSL-4 research level, neighborhood priorities as viewed by community residents, and the definition of biodefense.

Public Comment

Sue Gracie, a resident of Brookline, Massachusetts, and a representative of the Women's International League for Peace and Freedom, talked about the escape of a monkey that was never found from an AIDS laboratory in California. This laboratory accident resulted in the community residents rejecting a BSL-4 laboratory for their city.

IV. Panel's Next Steps/Dr. Mahmoud

Dr. Mahmoud stated that the next task of the BRP is to formulate a set of recommendations about how to accomplish the risk assessment. These recommendations will be shared with the ACD for its consideration and eventual transmission to the NIH Director.

V. Adjournment

Dr. Mahmoud adjourned the meeting at 2:00 p.m. on July 16, 2008.

[Note: This summary is based on notes taken at the meeting by a science writer and NIH staff members. More detailed information will be available in the minutes of this meeting. Actions approved by the BRP are considered recommendations to the ACD; therefore, actions are not considered final until approved by the ACD.]

Additional information about this Blue Ribbon Panel can be found at: <http://nihblueribbonpanel-bumc-neidl.od.nih.gov/index.htm>.

Attachment: Roster NIH Blue Ribbon Panel

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