

**NIH Blue Ribbon Panel to
Advise on the Risk Assessment of the BU
National Emerging Infectious Diseases Laboratories:
Update and Current Status**



**Advisory Committee to the Director, NIH
December 8, 2011**



Topics

- **Brief Background on Origin and Purpose of the Blue Ribbon Panel**
- **Summary of Panel Recommendations**
- **Update on Draft Supplementary Risk Assessment**
- **Next Steps**

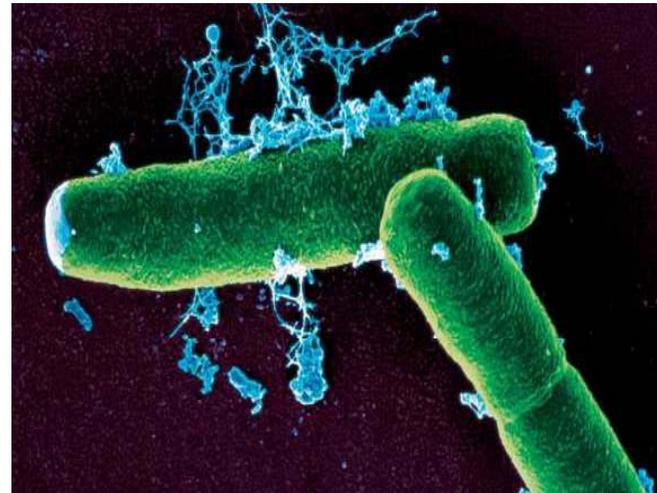
Background

- In 2003, following a peer-review process, Boston University Medical Center (BUMC) was awarded a grant from the National Institute of Allergy and Infectious Diseases (NIAID) for construction of a:
 - **National Biocontainment Laboratory known as the National Emerging Infectious Diseases Laboratories (NEIDL)**



Background

- **The NEIDL would provide essential infrastructure for congressionally mandated programs of biodefense research**
 - Including comprehensive, state-of-the-art biosafety level 2, 3, and biosafety 4 (BSL-4) research space
- **Purpose of the NEIDL:**
 - To assist national, state and local public health efforts in the event of an infectious disease emergency
 - To serve as a national resource for conducting research to help prepare for and guard against such events



Background

- **Prerequisites to the facility's construction**
 - **BU prepared a Final Environmental Impact Report in accordance with the Massachusetts Environmental Policy Act (MEPA)**
 - **NIH completed a Final Environmental Impact Statement for the NEIDL and published a Record of Decision in accordance with the National Environmental Policy Act (NEPA)**

Background

- **Public Concerns**
 - **Safety of having a maximum containment facility in downtown Boston compared to less densely populated area**
 - **Impact of facility on an environmental justice community**
- **Law suits filed in State court (July 05) and Federal court (May 06) to stop construction and operation of the NEIDL**

Background

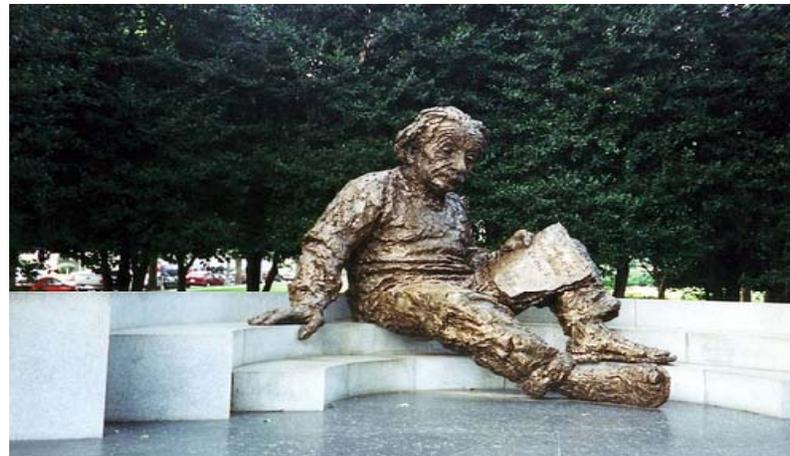
- **In July 06, the Massachusetts Superior Court held that the BU Final Environmental Impact Report (FEIR) failed to:**
 - **Consider any “worst case” scenario “involving accidental or malevolent release of a highly contagious pathogen”**
 - **Analyze whether the “worst case” scenario would be materially less catastrophic if the NEIDL were located in a less densely populated area**
- **Judge voided the State Agency’s approval of the FEIR**
- **The State Agency required BU to submit a supplemental FEIR to address these shortcomings**

Background

- **Federal court requested that NIH address:**
 - “Public health consequences of the accidental release of communicable Category-A (including BSL-4) pathogens”
- **In response to concerns raised by the court and public comments, NIH published for public comment Draft Supplementary Risk Assessment and Site Suitability Analysis (DSRASSA) of the NEIDL (July 07)**
 - Focused primarily on potential impacts of the release of several BSL-4 agents into the community under various scenarios

Background

- Viewing the DSRASSA as potentially relevant to its decision-making process, the Massachusetts Environmental Protection Agency asked the National Research Council (NRC) in 2007 to review the prior draft risk assessment
 - **Critical of methodology used to analyze risk**
 - Not transparent
 - Not validated through peer review



Establishment of Blue Ribbon Panel

- To guide the agency in responding comprehensively to the judicial requests and concerns expressed by the public and the NRC, NIH established the **Blue Ribbon Panel** in March 2008 as a Working Group of the ACD:
 - 16 members
 - Expertise in ID, public health and epidemiology, risk assessment, environmental justice, risk communications, biodefense, biosafety, bioethics, and ID modeling

BRP Roster

Chair

Adel Mahmoud, M.D., Ph.D.

Professor, Molecular Biology
Princeton University

Members

Donald Burke, M.D.

Dean, Graduate School of Public Health
University of Pittsburgh Medical Center

Stephen Eubank, Ph.D.

Deputy Director of Network Dynamics and
Simulation Science Laboratory
Virginia Polytechnic Institute

Vicki Freimuth, Ph.D.

Professor, Grady College of Journalism and
Mass Communication, University of Georgia

George Friedman-Jimenez, M.D.

Assistant Professor, Environmental Medicine
New York University School of Medicine

Margaret Hamburg, M.D.

Senior Scientist
Nuclear Threat Initiative (*thru 5/09*)

Karen Holbrook, Ph.D.

Senior Vice President for Research, Innovation
and Global Affairs, University of South Florida

Dennis Kasper, M.D.

Professor of Microbiology and Molecular Genetics
Harvard Medical School

Johnnye Lewis, Ph.D., D.A.B.T.

Director, Community Environmental Health Program
University of New Mexico (*thru 9/10*)

Ian Lipkin, M.D.

Director, Center for Infection and Immunity
Mailman School of Public Health
Columbia University (*thru 11/10*)

Thomas Murray, Ph.D.

President, The Hastings Center

Mary Northridge, Ph.D., M.P.H.

Professor, Clinical Sociomedical Sciences
Mailman School of Public Health, Columbia University

Jean Patterson, Ph.D.

Chair, Department of Virology and Immunology
Southwest Foundation for Biomedical Research

Mark Robson, Ph.D., M.P.H.

Professor, School of Environmental and
Biological Sciences, Rutgers University

Samuel Stanley, M.D.

President, Stony Brook University

Wayne Thomann, Ph.D.

Assistant Research Professor
Duke University Medical Center

Charge to the Panel

- **BRP to advise on:**

Studies to assess any potential public health risks associated with the operation of the National Emerging Infectious Diseases Laboratories and to assess strategies for mitigating these risks



Task

- **Determine what additional studies are needed to assess potential risks and public health consequences of:**
 - Accidental and malevolent releases of infectious agents
 - Exposure to infectious agents in urban versus less populated locations
 - Define the key elements of studies: agents, scenarios, and methodologies
- **Review background materials:**
 - Previous studies
 - Judicial materials
 - Safety and emergency preparedness plans
 - Epidemiologic and demographic data
 - Public input

Consultation with the NRC

- To further inform the Blue Ribbon Panel's (BRP) analysis, the NIH commissioned the NRC committee that reviewed prior draft supplementary risk assessment to suggest approaches to risk assessment
 - April 2008 NRC report noted that:
 - BSL-4 facilities have been operated safely in both urban and rural settings
 - Selection of sites for high-containment labs should be supported by detailed analyses and transparent communication of information regarding possible risks

Recommendations from BRP

- **Additional studies should be performed to address judicial requests and public concerns:**
 - **Use proven methods and reflect known epidemiologic data**
 - **Clearly describe methods, sensitivity of methods, assumptions, final results, and interpretation of results**
 - **Take into account characteristics of the surrounding communities**

BRP Recommendation: Agents for Study

- **Agents to be studied should include those that are:**
 - Highly transmissible, highly pathogenic, and higher case fatality rate
 - Highly transmissible, pathogenic, and lower case fatality rate
 - Poorly transmissible but highly pathogenic, and higher case fatality rate
 - Vector-borne and relevant to the sites to be assessed
- **Epidemiologic data should be used when available**
- **Agents should be recognized public health threats**
 - i.e., designated as a select agent or category A agent, likely to be studied in the NEIDL, and/or listed by the public as an agent of concern

List of 13 Pathogens Studied in Risk Assessment

- **BSL-3**

- 1918 pandemic influenza virus
- *Yersinia pestis*
- *Francisella tularensis*
- *Bacillus anthracis*
- SARS-associated coronavirus
- Rift Valley fever virus

- **BSL-3 or 4**

- Andes hantavirus

- **BSL-4**

- Junin haemorrhagic fever virus
- Tick-borne encephalitis complex (Russian spring-summer encephalitis) virus
- Lassa fever virus
- Marburg virus
- Ebola virus
- Nipah virus

BRP Recommendation: Scenarios

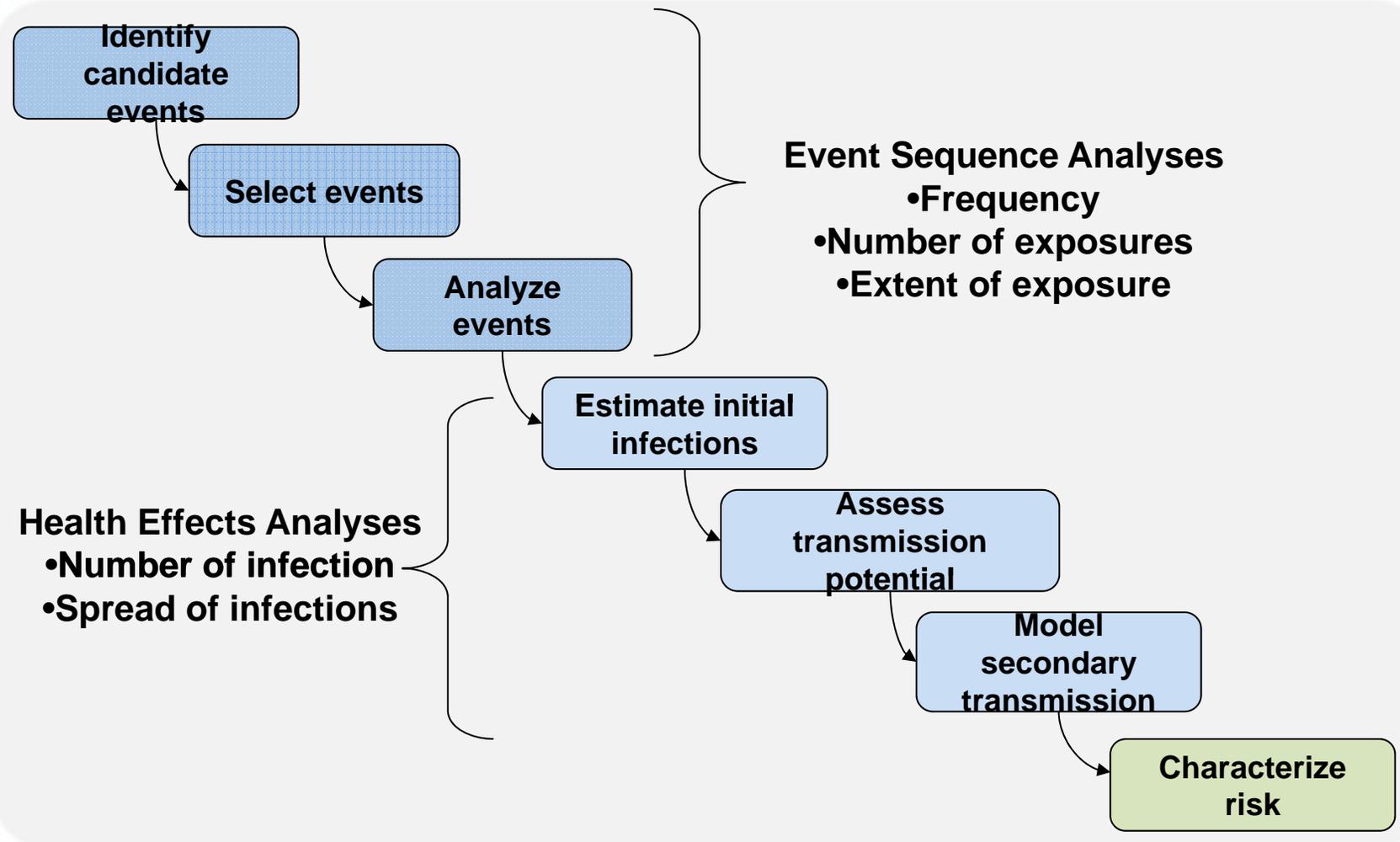
- **Scenarios should:**
 - **Be scientifically accurate and credible**
 - **Be realistic**
 - **Relate to a real case if possible**
 - **Include agents that are recognized as a public health concern**
 - **Include releases of infectious agents into the community that are representative of what could occur through:**
 - **Accidental release**
 - **Malevolent action**

Type of Scenario	Examples	Sources
Mechanical or Power Failure	Lab Equipment failure	NRC
	Loss of power	Public
	Malfunction of solid and liquid waste disposal systems	Public
Transportation Accident	Transportation Accident	Federal Court
Security Failure	Site security failure	NRC
	Personnel security failure	NRC
Exposure via Fomites or release of Vectors	Fomites bearing transmissible agents	Public
	Vector-borne agent release	NRC, Public
Human Errors	Procedural errors resulting in inadvertent infection (e.g., mislabeled tubes)	NRC, Public
	Infection not diagnosed early and spreads in community, esp. via public transportation	Public
Malevolent Actions	Malevolent actions	NRC, State Court
	Suicide bomber/airplane attack/truck with explosives/fire	Public
	Disgruntled or deranged lab worker spreads agents in community	Public

BRP Recommendation: Analyses

- **Analyses should address:**
 - Risk of agent release
 - Probability of occurrence
 - Any uncertainty in critical parameters used
 - For any value selected for use, the range of published values
 - Available public health interventions
 - Comparative risks at urban, suburban, and rural sites
 - Evaluate health issues at all sites
 - What happens when safety measures and emergency plans do and don't work

Event-Based Supplementary Risk Assessment



Supplementary Risk Assessment : Consultation

- **Supplementary Risk Assessment considers input from the public**
 - **May 16, 2008 (Massachusetts State House)**
 - **July 16, 2008 (Bethesda with community representation)**
 - **April 28, 2010 (Hibernian Hall)**
 - **October 5, 2010 (Roxbury Community College)**



*Massachusetts State House,
Downtown Boston*



*Hibernian Hall,
Roxbury*



*Roxbury Community
College*

Supplementary Risk Assessment : Consultation



NATIONAL ACADEMY
OF SCIENCES

- **NRC provided input at key milestones in the drafting of the Supplementary Risk Assessment**
 - **May 2, 2008 (Bethesda)**
 - **March 19, 2010 (Bethesda)**
 - **September 22, 2010 (Bethesda)**
 - **November 2, 2011 (Bethesda)**

BRP Analysis of the Draft Supplementary Risk Assessment

- **The BRP has carefully reviewed the draft supplementary risk assessment throughout its development**
 - **This study is unprecedented in its scope, depth and complexity. The study utilized widely accepted and validated methods.**
 - **The scenarios described in the risk assessment used real-life data and experience to the maximum extent possible.**
 - **The BRP believes that this is the most scientifically sound, rigorously conducted study that is possible at this point.**
 - **Finalize draft risk assessment for public review**

Agency Next Steps

- **Release of the Draft Risk Assessment for Public Comment (early 2012)**
- **Public Meeting in Boston (February 2012)**
- **Review of Public Comments and Finalizes draft Risk Assessment**
- **Court Review and Ruling**