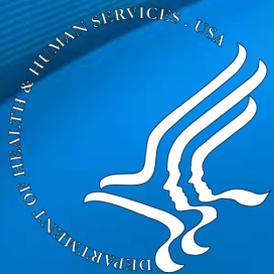


**Risk Assessment of the  
National Emerging Infectious Diseases  
Laboratories  
at the Boston University Medical Center**

**Community Engagement and  
Status Update**

**April 28, 2010**



# Agenda Overview

- **Overview of the Supplementary Risk Assessment:**
- **Concurrent Breakout Sessions (*Conducted Twice*)**
  - **Selection and Analysis of Pathogen Research Scenarios: Proposed Approach**
  - **Modeling of Pathogen Transmission and Health Effects: Proposed Approach**

# Goal of Today's Meeting

- **Update the community on the current status of the risk assessment**
- **Provide an overview of the risk assessment process and methodologies**
- **Offer opportunity for dialogue on proposed risk assessment approach**

# Background

- In 2003, following a scientific merit, peer review process, BU Medical Center was awarded a grant from the NIAID to build a national biocontainment laboratory (NBL) known as the National Emerging Infectious Diseases Laboratories (NEIDL)
- The mission of the NEIDL is to:
  - Serve as a national, state and local public health research resource to address emerging infectious diseases and bioterrorists threats by providing comprehensive, state-of-the-art biosafety level 2, 3, and biosafety 4 (BSL-4) research space
- Law suits filed in State court (July 05) and Federal court (May 06) to stop construction and operation of the NBL



# NIH Blue Ribbon Panel

- **Charge:** Provide scientific and technical advice to guide the agency in responding comprehensively to judicial requests and public concerns regarding the operation of the NEIDL
- **Membership:** ID and ID modeling, public health and epidemiology, risk assessment, environmental justice, risk communications, biodefense, and biosafety
- **Tasks:**
  - Determine additional studies needed to assess potential risks and public health consequences of:
    - Accidental and malevolent releases of infectious agents
    - Exposure to infectious agents in urban vs less populated locations
  - Define the key elements of studies:
    - Infectious agents
    - Scenarios
    - Methodologies
  - Address underlying concept of “worst case”

# Panel's Approach

- **Reviewed background materials:**
  - **Previous studies**
  - **Public input**
  - **Judicial materials**
  - **Epidemiologic and demographic data**
  - **Safety and emergency preparedness plans**
- **To further inform the Panel's analysis, the NIH engaged the NRC**
  - **BRP/NRC Meeting May 2, 2008**
  - **BRP/NRC Teleconference April 7, 2009**
  - **BRP/NRC Meeting March 19, 2010**
- **Continued consideration of comments and feedback received from the public, as well as input from the NIH Advisory Committee to the Director and Council of Public Representatives**

# Blue Ribbon Panel Meetings

- **March 13, 2008**

- Discussed overarching aims and the scope of relevant research
- Federal, state, and municipal officials presented on pertinent research oversight requirements
- Reviewed summary of legal proceedings
- NIH presented an overview of the 2007 draft supplementary risk assessment

- **May 2, 2008**

- Invited the NRC to present their “Letter Report Regarding the Strategies to Address Issues Concerning the 2007 Draft Supplementary Risk Assessments and Site Suitability Analysis for the NEIDL”
- NRC provided additional input regarding the design and development of a subsequent risk assessment

# Initial BRP Meeting with the Boston Communities

May 16, 2008

Massachusetts State House  
Boston, Massachusetts

- Presented the BRP charge and proposed approach to supplementary risk assessment
- Most of meeting devoted to public comment session



# Advisory Committee to the Director (ACD)

- **June 6, 2008**
  - **BRP recommendations regarding study design (agents, scenarios, and methodology) for a supplementary risk assessment were unanimously approved by the ACD**

# **BRP Meeting with the Boston Communities**

**July 16, 2008**

**National Institutes of Health**

**Bethesda, Maryland**



- **Invited members of Boston community, Boston city officials, community researchers, and social justice experts**
- **Explored case studies on community engagement and environmental justice**
- **Roundtable discussion of how to effectively engage communities**

# BRP Meeting with the Boston Communities

October 14, 2008

Hibernian Hall

Roxbury, Massachusetts

- **Engaged community members in planning of meeting and outreach efforts**
  - Broad multi-media public announcements
  - Evening meeting in local community hall
- **Presented, and sought community input on, draft principles and best practices for community engagement**
- **Heard general comments and perspectives from community members**



# Advisory Committee to the Director

- **December 5, 2008**
  - **Provided a progress update to the ACD on the development of a subsequent risk assessment and BRP activities regarding community engagement**

NRC Committee on Technical Input on the NIH's Draft  
Supplementary Risk Assessment for the Boston  
University National Emerging Infectious Diseases  
Laboratories:

**NIH Requests Input from NRC**

# NIH Requests Input from NRC

- **The NRC Committee met with the BRP on May 2, 2008 to:**
  - **Discuss in greater detail overall concerns about the prior draft supplementary risk assessment**
  - **Provide perspectives on approaches to be taken and issues to be addressed in any future risk assessment**
- **NRC specific conclusions were consistent with the Panel's, validating its emerging findings**

# NRC Perspectives: Range of Scenarios

- **Rather than worst case, two phases of analysis were suggested:**
  1. **Plausible scenarios designed to allow a realistic assessment of risks**
    - Procedural failures
    - Containment systems/ equipment failures
    - Malevolent actions
  2. **Credible high-consequence event for assessment**
- **Include probabilistic statements**
  - Empirically based if possible
- **Include mitigation capability/effects**

# NRC Perspectives (Cont'd): Agent Selection

- **Select a variety of agents for assessment with appropriately diverse transmission characteristics**
- **Clarify for the public and courts what agents and forms of agents will *not* be researched at the NEIDL (e.g. virus that causes small pox)**

# **NRC Perspectives (Cont'd): Consider Outcomes in Light of Agent Characteristics**

- **A risk assessment should analyze multiple outcomes and assess how the characteristics of agents studied in the NEIDL might influence the likelihood of each outcome in the event of a release.**
- **Qualitative analysis of potential outcomes should consider impact of local characteristics (e.g. population density, vector availability, public health infrastructure) on the probability of the various outcomes**
- **Modeling is not mandatory, but qualitative analyses should be used in instances where quantitative modeling is not possible**

# **BRP Recommendations: Agents for Study**

# Agents for Study: Key Attributes

- **Agent attributes:**
  - **Infectivity (primary infection rate, primary routes of human infection)**
  - **Transmissibility (including secondary and tertiary transmission)**
  - **Incubation period**
  - **Infection period**
  - **Pathogenicity**
  - **Mortality rate**
  - **Reservoirs (if known)**
  - **Vectors (if known)**
  - **Availability and efficacy of treatments**

# Agents for Study: Key Attributes

- **External attributes:**
  - Relevance to the site locations (actual and alternatives), especially in terms of reservoirs and vectors
  - Extent of epidemiologic data
  - Availability of sound models for a given infectious disease
- **Recognition as a public health concern and/or studied at the NEIDL**
  - For example, designation as
    - BSL-3 Agent
    - BSL-4 Agent
    - Category A Agent
    - Select Agent
- **Agents to be studied should include variability in contagiousness and infectiousness.**

# Recommendation: Agents for Study

- Risk assessments should be done for the following agents:

- 1918 pandemic influenza virus
  - *Yersinia pestis* (Plague)
  - *Francisella tularensis* (Tularemia)
  - *Bacillus anthracis* (Anthrax)
  - SARS-associated coronavirus
- BSL 3
- Rift Valley fever virus
  - Andes hantavirus
- BSL 3 or 4
- Junin haemorrhagic fever virus
  - Tick-borne encephalitis complex (Russian spring-summer encephalitis) virus
  - Lassa fever virus
  - Marburg virus
  - Ebola virus
  - Nipah virus (*added at the request of BU*)
- BSL 4

NOTE: Agents in RED are CDC and/or NIH Category A Agents and/or Select Agents

# **BRP Recommendations: Scenarios for Study**

# Recommendation: Scenarios

- **Scenarios should:**
  - **Be scientifically accurate and credible**
  - **Be realistic**
    - **Relate to a real incident 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**

# Recommendation: “Worst Case” Scenarios

- **State court requested evaluation of “worst case” scenario that involves “risk of contagion arising from accidental or malevolent release of a contagious pathogen.”**
  - **Concept of “worst case”**
    - **Intuitively understood but highly subjective notion**
      - **Therefore “worst case” is a discredited term in the field of risk assessment (e.g., nuclear reactor safety)\***
  - **Variations of the scenarios should address underlying concept: “highly unlikely but still credible high consequence event” \***

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, Public
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, Public
	Suicide bomber/airplane attack/truck with explosives/fire	Public
	Disgruntled or deranged lab worker spreads agents in community	Public

# **BRP Recommendations: Methodology and Analyses**

# Recommendation: Analyses

- **Qualitative analyses:**
  - Should be conducted for all agents and scenarios
- **Quantitative analyses:**
  - Should also be performed in all cases for which sufficient epidemiologic data and validated mathematical models are available
- **Analyses should:**
  - Use proven methods and reflect known epidemiologic data
  - Take into account characteristics of the surrounding community
  - Be transparent regarding any assumptions and sensitivity of analyses

# Recommendation: Analyses

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

# Current Status

# NRC Letter Report: April 20, 2010

- In general, the NRC found the proposed approaches for conducting the risk assessment suitable and well planned
- **Selection of Agents**
  - The agents selected for analysis are appropriate and comprehensive
  - The contractor should not attempt to push modeling further than data for the agents being studied allow
  - NRC strongly supports conducting a qualitative assessment for all 13 pathogens and quantitative analyses for five of the pathogens

# NRC Letter Report: April 20, 2010

- **Modeling**

- **Use of the branching process and compartmental modeling approaches is appropriate, rational, and straightforward**
- **Emphasis should be on sensitivity analysis and carefully examining scenarios with low probability but high consequence**
- **Use data when available and well-documented judgment from experts when data are not available to estimate event probabilities**
- **Uncertainty analyses are generally more qualitative and should be included**

# NRC Letter Report: April 20, 2010

- **Expertise and Capabilities**

- Available expertise on and available to the assessment team is strong

- The NRC is encouraged to see the inclusion of personnel with experience in hospital infection control and infectious disease research, theory, and public health

- **Qualitative Issues**

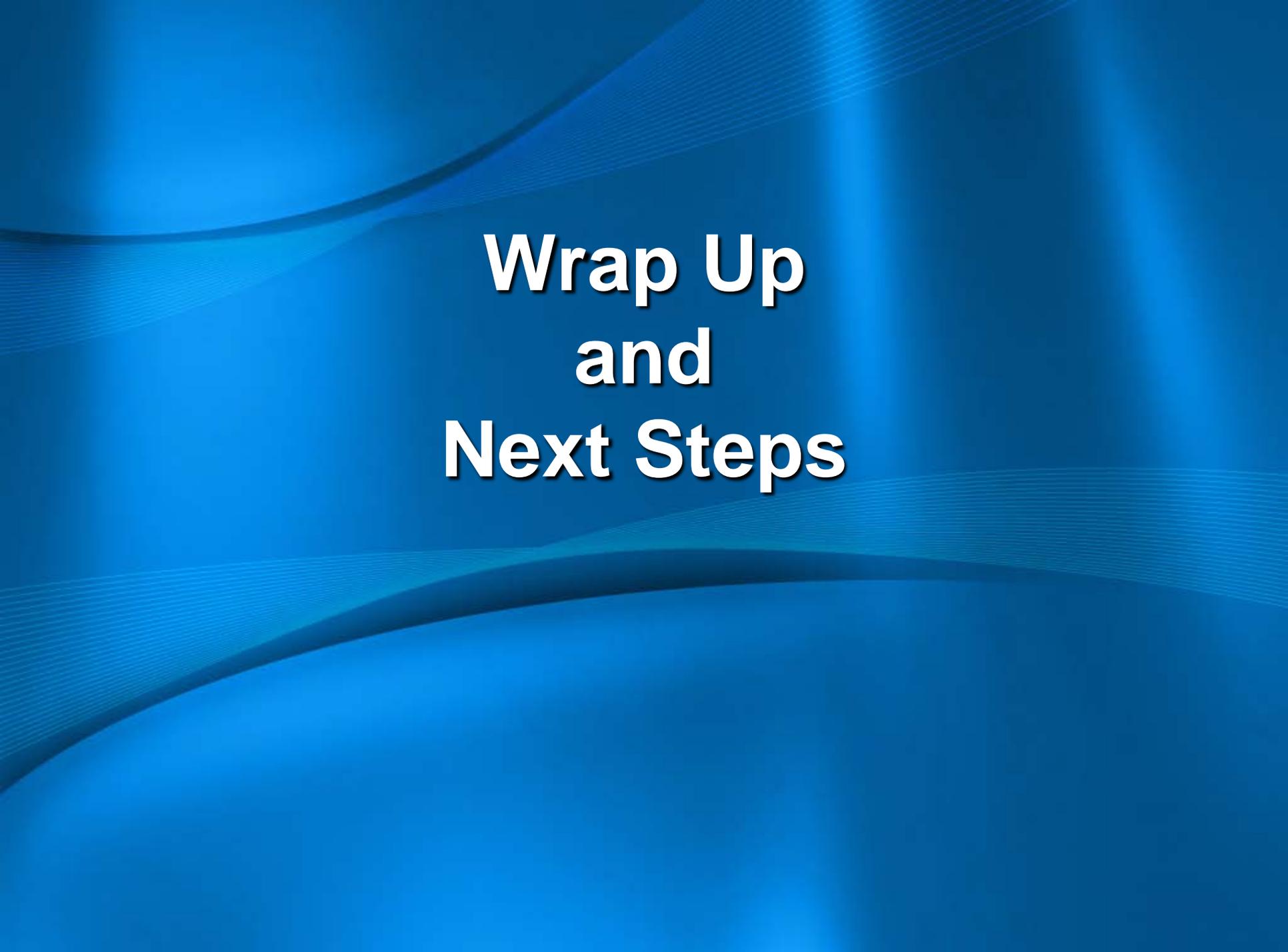
- Focus on vulnerable populations where transmissibility and/or susceptibility may be higher (e.g. immunocompromised individuals)

- **Risk Communication**

- Risk assessment should be clear, accessible, and transparent to non-scientists, or be accompanied by a summary version that is comprehensive and easily accessible to lay reader

# Breakout Sessions

	<b>Group A (Salon F)</b>	<b>Group B (Salon H-K)</b>
<b>7:15 pm – 8:15 pm</b>	<b>Selection and Analysis of Pathogen Release Scenarios: Proposed Approach</b>	<b>Modeling of Pathogen Transmission and Health Effects: Proposed Approach</b>
<b>8:30 am – 9:30 pm</b>	<b>Modeling of Pathogen Transmission and Health Effects: Proposed Approach</b>	<b>Selection and Analysis of Pathogen Release Scenarios: Proposed Approach</b>

The background is a vibrant blue with a series of flowing, wavy lines that create a sense of movement and depth. The lines are darker in some areas and lighter in others, giving it a three-dimensional appearance.

# **Wrap Up and Next Steps**

# NIH Blue Ribbon Panel

to Advise on the Risk Assessment of the  
National Emerging Infectious Diseases Laboratories  
at Boston University Medical Center

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## Providing Scientific and Technical Advice to the NIH

**The NIH Blue Ribbon Panel (BRP)** provides scientific and technical advice to the NIH, through the Advisory Committee to the Director, as the agency responds to the comments and concerns voiced by state and federal courts, the local community, the National Research Council, and the general public regarding the construction and operation of a national biocontainment laboratory at Boston University Medical Center. [Read more details about the NIH BRP.](#) ...

### Announcements

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#### Project Update

*June 2009*

Welcome to the redesigned NIH Blue Ribbon Panel Web site. New features include easier navigation; a Project Update section (you're reading it right now), which will highlight recent progress; and an updated version of the Frequently Asked Questions. As always, we welcome your feedback and comments on the Web site and activities of the Panel. You may send comments to [BRP\\_NIH@od.nih.gov](mailto:BRP_NIH@od.nih.gov).

The development of the supplementary risk assessment is now under way. Since the earliest planning stages, NIH has been working to ensure that the assessment would be comprehensive and that the concerns of the Boston Community would be fully considered. Toward that end, NIH is seeking advice from the independent Blue Ribbon Panel throughout the design and conduct of the study.

#### News & Information

Read our key documents and news releases

#### Meetings

Review Webcasts and key documents from past meetings; view future meetings schedule

#### FAQs

<http://nihblueribbonpanel-bumc-neidl.od.nih.gov>

# Written Comments

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