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# Prioritizing the Global Biological Threat

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International
BIOLOGICAL THREAT REDUCTION

# Evolution of the Biological Threat

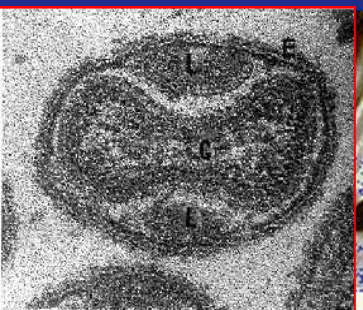
- The biological threat has evolved in concert with
  - Increasing emergence and reemergence of highly infectious disease
  - Rapid advance of biotechnology globally
  - Rise of transnational, asymmetric terrorism
- Evolution in the threat makes crafting and implementing biological threat reduction policies and programs challenging

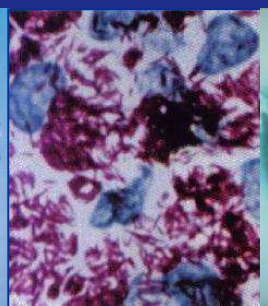
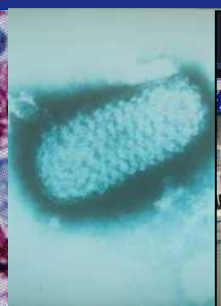
Mt. Merapi, Yogyakarta, Indonesia

# A Paradigm Shift?

- Today, the materials, technology, and expertise necessary to maliciously disseminate infectious disease are more accessible to more people than ever before
  - This trend shows no sign of abating in the future

- Paradigm shift in biological threat reduction
  - Increased threat of bioterrorism (perhaps more than state-based biological weapons proliferation)
  - Increased vulnerability of legitimate bioscience to malicious exploitation
  - Bioterrorists can come from anywhere; legitimate bioscience can be exploited almost anywhere
  - The scope of the problem is truly global




# Global Distribution of Dangerous Biological Materials

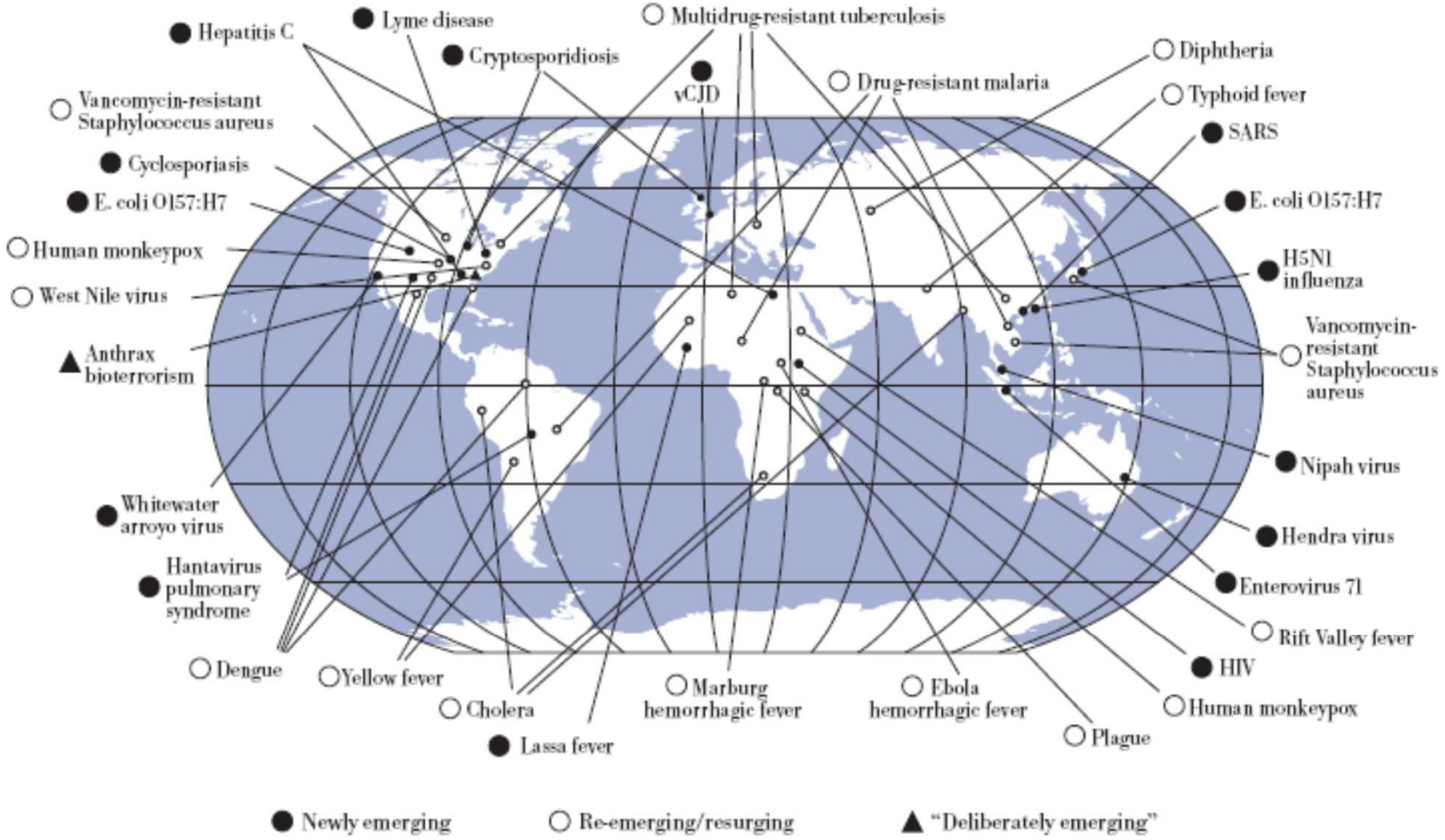
- Increasing emergence and reemergence of highly infectious disease
  - SARS, Nipah, Hendra, etc.
  - Highly pathogenic avian influenza, fear of a global pandemic
  - Research on new viruses occurs beyond areas where disease is emerging
    - HPAI: 8 – 23%, and SARS: 4 – 23%; Latin America is least active and Asia is most (based on survey data)


- More laboratories working with dangerous pathogens because of heightened concern about bioterrorism
  - Increased US NIAID funding for research on dangerous pathogens and toxins
  - Increased US Government (and other western, developed countries) demand for vaccines and therapies for bioterrorism-related infectious diseases

# Global Distribution of Dangerous Biological Materials - Examples

- ***Bacillus anthracis*: World Anthrax Data Site categorizes 14 countries as being "hyperendemic" for anthrax**
  - **Turkey, Tajikistan, Myanmar, Niger, Chad, Ethiopia, Zambia, Zimbabwe, Togo, Ghana, Cote d'Ivoire, Liberia, Sierra Leone, and Guinea.**
  - **A large number of countries in Africa and Asia are considered "endemic"**
  - **Very few countries are considered anthrax-free**
- ***Burkholderia mallei***
  - **Some Middle Eastern countries (Turkey, Syria, Iraq, Iran), South Asia (Pakistan and the Indian subcontinent), Southeast Asia (Burma, Indonesia, Philippines), parts of China and Mongolia, and Africa. The Balkan states and former Soviet republics may also still have *B. mallei*.**
  - **Glanders is sporadic in Europe and the Americas**
- **Foot-and-Mouth Disease virus**
  - **Endemic in Asia, Africa, most of South America, and parts of Europe.**
  - **High prevalence throughout Africa (exceptions in southern African nations of Zimbabwe, Namibia, Botswana, and South Africa).**
  - **FMDV is endemic in many South American nations, except for Chile, Uruguay, Argentina, Paraguay, and southern states of Brazil.**
  - **OIE considers just 32% of countries free of virus.**
- **MDR *Mycobacterium tuberculosis***
  - **Most likely present in every country. Regions of the world with the highest burden of MDR-TB include Eastern Europe, Southeast Asia, sub-Saharan Africa and the Western Pacific region.**

# Global Distribution of Dangerous Biological Materials - Examples




Adapted from Morens, D.M., et al. 2004. The Challenge of Emerging and Re-emerging Infectious Diseases. *Nature* 430:242–49.

# Global Distribution of Technologies

- Governments in many countries consider life sciences and biotechnology a priority
  - Brazil, Malaysia, Pakistan, Poland, and Turkey have invested significant resources
  - Argentina, Egypt, Moldova lack adequate funds for systematic growth of biotech sector
- Key dual-use, second-hand equipment readily available in Asia and Middle East
  - Autoclaves
  - Bioreactors/fermenters
  - Biosafety cabinets
  - Centrifuges
  - DNA and peptide synthesizers
  - Freeze dryers
  - Large-scale cryogenic storage devices
  - Shaker incubators

| Research technique | % of all respondents using technique |
|---|---|
| Classical PCR | 64% |
| ELISA | 57% |
| Electrophoresis | 56% |
| Sequencing | 35% |
| RFLP | 22% |
| SNP | 8.4% |
| Microarrays | 7.6% |
| RNAi | 7.8% |
| Chimeras | 5.3% |
| SAGE | 1.8% |

Table shows data from 2007 SNL survey of life scientists in Asia, Latin America, Middle East, and Eastern Europe

Data from a DHS and DOE sponsored SNL projects in 2007

# Global Distribution of Technologies: Containment Laboratories

- **Examples of BSL4 expansion globally**
  - Almost 40 BSL4 labs either planned, in construction, or operational worldwide today*
  - US: BSL4 capacity is in the process of expanding by a factor of ten*
  - India: Currently one operational BSL4 (Bhopal) and building two additional BSL4 labs (Pune and Hyderabad)

- **Examples of BSL3 expansion globally**
  - Singapore: In 2003, they had just three, but now have at least 15 operational
  - Indonesia: In 2005, they had two BSL3s (vaccine production), but now have at least six for research and diagnostic purposes
  - Egypt: Currently has no BSL3 labs (except US's NAMRU-3), but planning to construct at least six BSL3s in immediate future
  - Brazil: Have just finished a network of 12 BSL3s in Ministry of Health, and seven BSL3s in Ministry of Agriculture
  - World Bank currently funding over 40 lab construction projects (majority BSL3) for AI


*Gigi Kwik et al., "High-Containment Biodefense Research Laboratories," Biosecurity and Bioterrorism, 5:1, 2007

# Global Distribution of Expertise

- **Human capital is often a major limitation in a country's efforts to build a sustainable biotechnology sector**
  - **Brain drain a significant problem for most, with notable exceptions of Pakistan and Turkey**
  - **But sophisticated research is conducted in many countries, including Argentina, Brazil, Egypt, Malaysia, and Poland**

- **Of eight countries studied, all conduct at least some sophisticated research utilizing modern technologies (Moldova hardest to ascertain)**
  - **All have investigated drug-resistance**
  - **Scientists in Argentina, Brazil, Egypt, Malaysia, Poland, and Turkey have conducted research that could be considered "dual-use" as defined in Fink Report**

- **Most explicit knowledge is readily available in open literature, but tacit knowledge can be more elusive**

**Data from a DHS-sponsored SNL project in 2007 studying the bioscience sector in eight countries around the world.**

# Existing Oversight Mechanisms for Control of Materials, Technologies, and Expertise

- International
  - Biological Weapons Convention
    - Focused on reducing threat of state proliferation
    - No verification protocol
  - World Health Organization (and Food and Agriculture Organization)
    - Laboratory Biosafety Manual, 3rd edition, 2004
    - Laboratory Biosecurity Guidance, 2006
  - Australia Group export controls
    - Limited to some biological technologies and materials
    - Primarily focused on reducing threat of state proliferation
- National
  - Few countries have implemented substantive regulations and standards; very little oversight
  - Most countries rely entirely on international guidelines

# Reducing the Global Biological Threat

- Spread of materials, technology, expertise is truly global in scale
- To reduce the threat of terrorists exploiting and misusing legitimate bioscience, many countries need the capability and capacity to control the containment and use of dual-use materials, technology, and expertise
- The scale of the problem is arguably immense
  - How can policy makers decide where and how to invest limited threat reduction resources?
- USG needs an assessment methodology to analyze the dynamic, complex factors that drive the bioterrorism threat globally, and to help prioritize limited threat reduction resources

# Prioritizing the Global Biological Threat

- **In 2007, US Department of State's Biosecurity Engagement Program (BEP) tasked Sandia's International Biological Threat Reduction (IBTR) with**
  - Developing a methodology for characterizing the biological threat at a country level
  - Prioritizing a group of countries based on biological threat
  - Establishing metrics for measuring effectiveness of biological threat reduction activities

- **It is hoped that this methodology will help the USG justify *where, why, and how* to apply its biological threat reduction resources most efficiently and effectively**

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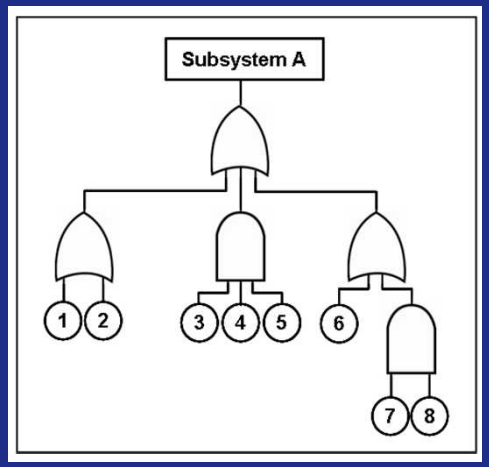
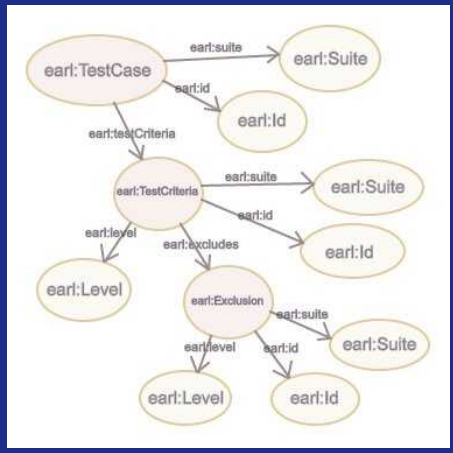
# Global Biological Threat Assessment Methodology Requirements

**Need a systematic, standardized approach for evaluating complex and dynamic data**




- State the Problem
- Formulate the approach – determine the method(s)
  - Qualitative, quantitative
- Collect data / Interview experts
- Build the model
- Run base case in the model
- Conduct sensitivity analysis
- Record results
- Document model



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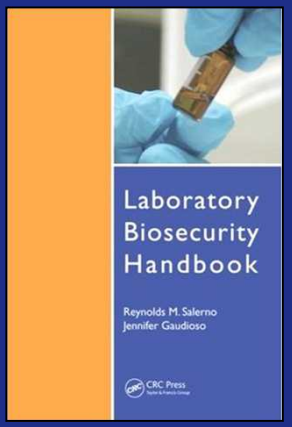
# Examples of IBTR Assessment Models to Assess Range of Biological Threats

- Global Biological Threat Prioritization
  - Bioscience
  - Terrorism
  - National Issues
- Risk of theft of a biological agent from laboratory
  - Consequences of specific agent
  - Site vulnerability
  - Threat
    - Includes agent potential to be used maliciously
- Risk of accidental exposure in a laboratory of a biological agent
  - To individual(s) in laboratory
  - To individuals in facility
  - To community
    - Primary exposure
    - Secondary exposure
  - Consequences of specific agent
  - Likelihood of a specific agent
  - Likelihood based on laboratory work
  - Likelihood reduced based upon biosafety practices and procedures

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# Conclusions - I

- Latent threat is growing: materials are widely distributed, and technology and expertise are spreading globally
  - Large collections of viable and virulent agents in diagnostic and clinical facilities, not just research facilities
  - Dangerous pathogens are often not used in Biosafety Level 3 and 4 (high containment) facilities
  - Rapid expansion of high containment capacity throughout world
    - Increasing reliance on engineered solutions for reducing safety risks
    - Policies, procedures, and practices (people) receive less attention
    - Little appreciation for operational and maintenance costs
    - Few countries with oversight mechanisms in place for work with dangerous pathogens

# Conclusions - II

- Critical for USG biological threat reduction programs to
  - Articulate a standard, repeatable method for assessing the biological threat in various countries
  - Allocate its resources in a manner proportional to the risk (what countries, and what activities)
  - Demonstrate how it measures the effectiveness of its threat reduction policies and activities

# IBTR Program Area and Contact Info

**Laboratory Biosafety, Biosecurity, and Biocontainment**

**Infectious Disease Diagnostics and Control**

**Training and Workshops**

**Policy, Regulatory, and Guidelines Support**


**Assessments and Analysis**

**IBTR Program Contact Info:**
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