Security Risk Assessment of HIV, JEE, *B. anthracis*

Risk Assessment for Laboratory Biosecurity and Biosafety
Nashville, TN
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www.biosecurity.sandia.gov

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Hazard vs. Risk

- **Hazard: The way in which an object or a situation may cause harm**
  - A hazard exists where an object (or substance) or situation has an inherent ability to cause an adverse effect
- **Risk: The chance that harm will actually occur**
  - Risk is the chance that such effects will occur
  - The risk can be high or negligible
- **Risk is a function of probability AND consequences**

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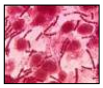
Assessment Methodology

- **Characterize agents (pathogens and toxins) and threats**
  - Evaluate the pathogens and toxins at the facility
  - Evaluate the adversaries who might attempt to steal those pathogens or toxins
- **Evaluate scenarios**
  - Create scenarios
    - Example: a specific adversary attempting to steal and misuse a specific biological agent
  - Determine how the various scenarios could be perpetrated
- **Characterize the risk**
  - Evaluate threat potential and consequences of each scenario
  - Assist in determining acceptable and unacceptable risks, and in developing risk statement or definition
- **The problem should be defined in terms or criteria that are relevant to the problem, understandable, measurable, and non-redundant.**



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Characterize agents and threats

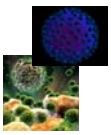
- **Evaluate the pathogens and toxins at the facility**
  - Assess the biochemical properties of the pathogens and toxins to determine how easy or difficult it would be to successfully use them maliciously
  - Assess the potential consequences of malicious use of those pathogens and toxins
- **Evaluate the adversaries who might attempt to steal those pathogens or toxins**

Agent Assessment

- **Consequences**
  - Population Impact
    - Transmission
    - Mortality
    - Morbidity
    - Pre and Post Exposure Countermeasures
  - Economic Impact
  - Psychological Impact
- **Task Complexity**
  - Difficulty of acquiring the agent
  - Difficulty of processing the agent into a suitable quantity in a suitable form for most appropriate dissemination pathway
  - Difficulty of disseminating the agent to cause harm

Agent Assessment
Human immunodeficiency virus (HIV)

- **Consequences**
  - Population Impact
    - There would be a low population impact to a malicious attack with HIV
    - Difficult to transmit
      - Direct contact to mucosal membranes
      - Exchange of bodily fluids through sexual exposure
      - Parenteral
    - The mortality and morbidity of untreated HIV is moderate unless a secondary infection occurs (less then 50% requiring hospitalization with a mortality rate less then 50%)
  - There will be little economic impact or psychological impact to a malicious attack with HIV as it is endemic
- **Task Complexity**
  - Acquisition
    - HIV would be easy to acquire
    - Worldwide distribution
    - No regulation
  - Production
    - HIV is moderately difficult to produce
    - Can be grown
    - Very unstable
  - Dissemination
    - HIV is difficult to disseminate
    - Very unstable in the environment
    - Dissemination via injection or direct mucosal membrane contact



Examples of Biocrimes with HIV

- **HIV: 1987 – 1990**
  - Dr. David Acer, Florida dentist, infects 6 patients with HIV
  - Unclear if deliberate act
- **HIV: October 1998**
  - Richard Schmidt, a gastroenterologist in Louisiana, convicted of attempted second degree murder for infecting nurse Janice Allen with HIV by injecting her with blood from an AIDS patient
- **HIV: January 1999**
  - Brian T. Stewart, a phlebotomist, sentenced to life in prison for deliberately infecting his 11-month-old baby with HIV-infected blood to avoid child support payments

References: Carus WS. 1998. Bioterrorism and Biocrimes: The Illicit Use of Biological Agents in the 20th Century. Washington (DC): Center for Counterproliferation Research, National Defense University; Mohtadi, H. and Murshid, A. 2006. A Global Chronology of Incidents of Chemical, Biological,Radioactive and Nuclear Attacks: 1950-2005, National Center for Food Protection and Defense.

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Agent Assessment Japanese Encephalitis (JEE)

- **Consequences**
  - Population Impact
    - Low ability for transmission
      - Vector transmission
      - Exchange of bodily fluids
    - The untreated mortality is moderate, less then 50%
    - Untreated morbidity is high , 50% or more requiring hospitalization or outpatient treatment
  - There will be little economic impact or psychological impact to a malicious attack with JEE
- **Task Complexity**
  - Acquisition
    - JEE is easy to acquire
    - Worldwide distribution
    - No regulation
  - Production
    - JEE is moderately difficult to produce
    - *Can be grown*
    - *Very unstable*
  - Dissemination
    - JEE is difficult to disseminate
    - Very unstable in the environment
    - Dissemination via injection or insect vectors

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Agent Assessment for *B. anthracis*

- **Consequences**
  - Population Impact
    - Low ability for transmission
    - The untreated mortality is high (50% or more deaths from untreated inhalation anthrax)
    - The morbidity is also high (50% or more people would require hospitalization or outpatient care
  - The economic impact would be moderate for an attack with Anthrax
  - The psychological impact would be high
- **Task Complexity**
  - Acquisition
    - *B. Anthracis* is moderately difficult to acquire
    - Worldwide distribution
    - But regulated by US and other countries
  - Production
    - Anthrax is easy to produce
    - Grows well in a laboratory
    - Environmentally stable
  - Dissemination
    - Anthrax requires some skill for dissemination (moderate)
    - Very stable in the environment
    - Dissemination via aerosolization possible

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Bioterrorism: Anthrax – 1990s

Aerosolization of Bacillus anthracis and botulinum toxin by Aum Shinrikyo

- **Location: Tokyo, Japan**
- **Perpetrator: Aum Shinrikyo Cult**
- **Objective: Apocalypse**
- **Organisms**
  - *Bacillus anthracis*
    - Vaccine strain
  - *Clostridium botulinum*
    - Environmental isolate
    - Avirulent strain
  - Ebola virus
    - Attempted to acquire from Zaire outbreak under guise of an "Humanitarian mission"
- **Dissemination**
  - Aerosolization in Tokyo
    - *B. anthracis*
    - Botulinum toxin
- **Outcome**
  - Leader Asahara was convicted of criminal activity

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Bioterrorism: Anthrax – October 2001

- **Location: More than 60 sites in the US**
- **Perpetrator: Unknown**
- **Objective: Unknown**
- **Organism**
  - *Bacillus anthracis*
- **Dissemination**
  - 4-7 letters sent through postal system
  - 22 confirmed cases of anthrax
    - 11 Cutaneous
    - 11 Inhalational (5 Deaths)
- **Outcome: Perpetrator not yet identified**

"Amerithrax"

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Lab activity

- **Research activities which might make the agents more attractive to an adversary:**
  - Large quantity
  - Increased stability
  - Increased resistance to
    - Treatment
    - Environment
  - Aerosolization studies
  - New infectious routes
  - Greater morbidity or mortality

Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

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Threat Assessment

- **Adversary Motive**
  - Motive characterizes why an adversary would steal a pathogen or toxin.
- **Adversary Means**
  - Means is a characterization of the adversary's technical skills, operational knowledge, and necessary tools required to conduct the scenario
- **Adversary Opportunity**
  - Opportunity characterizes whether an adversary could steal the biological agent covertly or must steal it overtly. This is based on the degree of the adversary's access to the asset.

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Threat Environment

- **Aspects which might increase the overall threat to the facility:**
  - High incidence of crime in area
  - Activist groups
  - Local or national political instability
  - Internal discontentment among laboratory staff



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Creation and Evaluation of Scenarios

- **Create Scenarios**
  - Specific pathogen or toxin
  - An individual or group of individuals who wish to steal a pathogen or toxin from a bioscience laboratory
  - The theft of a pathogen or toxin
- **Screen Agents and Adversaries**
  - Remove assets and adversaries which do not pose a significant threat

EMUR – Extreme Malicious Risk Group

HMUR – High Malicious Risk Group

MMUR – Moderate Malicious Risk Group

Asset	Adversary	Action
EMUR	Insider	Theft of the pathogen or toxin
EMUR	Terrorist Group	Theft of the pathogen or toxin
EMUR	Colluding Terrorist Group	Theft of the pathogen or toxin
HMUR	Insider	Theft of the pathogen or toxin
HMUR	Terrorist Group	Theft of the pathogen or toxin
HMUR	Colluding Terrorist Group	Theft of the pathogen or toxin
HMUR	Single Terrorist	Theft of the pathogen or toxin
MMUR	Insider	Theft of the pathogen or toxin
MMUR	Single Terrorist	Theft of the pathogen or toxin

Table 3. Scenarios in a Full Biosecurity Risk Assessment

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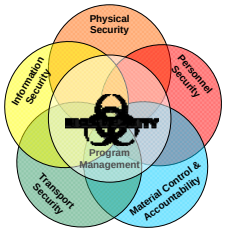
Vulnerability Assessment

- **In the context of a biosecurity risk assessment, this vulnerability assessment entails reviewing the existing implementation of the biosecurity components:**
  - Physical security
  - Personnel security
  - MC&A
  - Transport security
  - Information security
  - Program management



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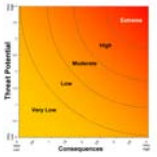
Characterize the Risk

- **Evaluate threat potential and consequences of each scenario**
  - Agent task complexity
  - Adversary attributes
  - Site vulnerability
- **Assist in determining which scenarios represent acceptable risks and which represent unacceptable risks**
- **Assist in developing a definition to articulate the objectives of the biosecurity system**
  - Deny
  - Contain
  - Deter



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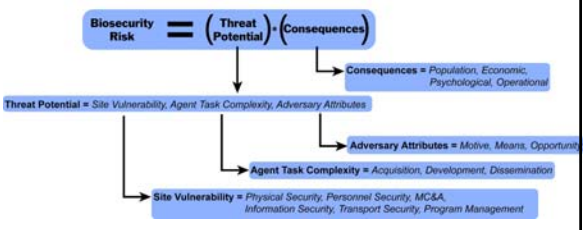
Evaluate Threat Potential and Consequences of Scenarios



Reference: Laboratory Biosecurity Handbook,
by Reynolds M. Salerno, Jennifer Gaudioso
CRC; 1 edition (June 20, 2007) ISBN-10: 0849364752

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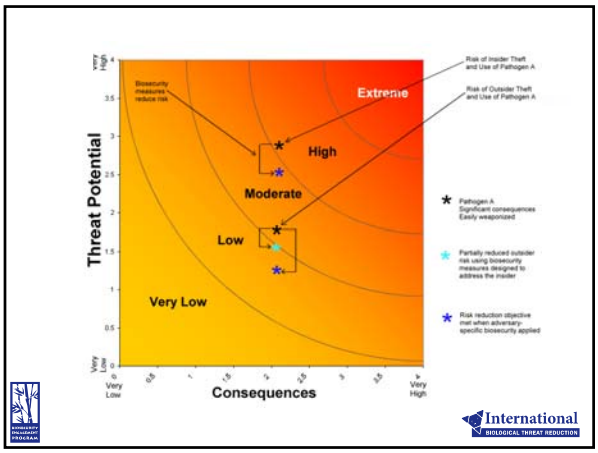
Threat Potential
Very High
Very Low
Consequences
Very Low
Very High
Extreme
High
Moderate
Low
Very Low
Biosecurity measures reduce risk
Risk of Insider Theft and Use of Pathogen A
Risk of Outsider Theft and Use of Pathogen A
Pathogen A Significant consequences Easily weaponized
Partially reduced outsider risk using biosecurity measures designed to address the insider
Risk reduction objective met when adversary-specific biosecurity applied
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