UNITED STATES ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES (USAMRIID)

Composite Bio-Risk Management “Biological Surety”

Veterinary Corps
Director, Biosecurity
Terms

• Difference in terms can create confusion, but both employ principles of biosafety and biosecurity to create a safe work environment and maintain control and accountability of high consequence pathogens

• non-DoD (interagency and international): Bio-risk Management
  – Traditional emphasis on Biosafety
  – Increasing emphasis on Biosecurity

• DoD (Army): Biological Surety
  – Surety emphasizes both Biosecurity and Biosafety
Risk Mitigation
(Programmatic Elements)

Biosecurity
- Personnel Reliability
- Select Agent Management
- Information Control (OPSEC/DURC)
- Armed Guard Force
- Camera Monitors/Recording
- Regulations/Protocols/Procedures
- Access Control Measures
- Training

Biosafety
- Biosafety Professionals
- Safety Committee
- BSL3/4 Subcommittee
- IACUC Committee
- Institute Biosafety Committee
- Occupational Health / Vaccination
- Biosafety Engineering Controls
- Division Safety Representatives
- Suite Supervisors
- Regulations/Protocols/Procedures/Equipment
- Training

Emergency Response
Facility Controls
Informed by Science
Biological Hazard Mitigation
(Personnel)

- Occupational Health Surveillance
- Vaccination (if available)
- Personal Protective Equipment
- Procedures and Training
- Engineering Controls (Biological Safety Cabinets)
- Experimental Design

Smiley face icon
Biological Hazard Mitigation
(Environment: Internal and External)

Validated Procedures for BSAT Transfer and Downgrade to non-BSAT Status

HEPA Filtration of Exhaust Air

Secondary Containment Controls

Primary Containment Controls

Experimental Design

Suite Environment

USAMRIID Campus

Fort Detrick

State

Nation

International
Synchronization is Critical

Risk Mitigation

Facility Engineering Controls

Biosafety Measures

Biosecurity Measures
Synchronization

Biodefense solutions to protect our nation

• Suite Access Forms
  – Personnel must meet all criteria of every office prior to receiving authorization to work independently in restricted laboratory space

• USAMRIID Form 91
  – Suite registration for all infectious agents and toxins

• CDC/APHIS Form 1
  – BSAT registration form; information received from all offices and submitted through CDC Responsible Official

• USAMRIID Form 11
  – Prior to any samples leaving USAMRIID, authorization must be granted by biosafety and biosurety offices, as well as science division chief

• 24-hour on-site staff for Facilities and Security
  – Monitor all critical facility control systems, personnel entry, and activities

• 24-hour conference line for managing emergent situations
  – Utilized to rapidly assess situation with maximal SME input and determine immediate course of action

• Emergency Management Exercises
  – Synchronizes response from affected internal and external entities
USAMRIID Integrated Process

Biodefense solutions to protect our nation

Information Control
OPSEC/DURC

Emergency Response

Biosafety and Engineering Controls

Physical Security
Guards/Monitors/Access Control

Personnel Reliability

Select Agent Management
Keys to Success

Biodefense solutions to protect our nation

• Command Emphasis
• Right people in key positions
  – Understand both the regulatory requirements and the science
  – Personnel who can integrate science with regulatory requirements to find suitable, feasible, and acceptable solutions to challenges
• Integrated execution that synchronizes effort and minimizes stovepipe mission execution
  – Insuring that all key stakeholders have input to key processes and input to key decisions
  – Cross-talk is regular and natural
• Biosafety and Biosecurity awareness of ongoing research
Mission Essential Task List (METL)

Prepare for Uncertainty

Rapidly Identify Biologic Agents

Provide World Class Expertise in Medical Biological Defense

Develop, Test & Evaluate Medical Countermeasures

Biosafety & Biosecurity

Train & Educate the Force
UNITED STATES ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES (USAMRIID)

Ebola Response

Neal Woollen DVM, MSS, PhD
Colonel, Veterinary Corps
Mission and Vision

Mission
Provide leading edge medical capabilities to deter and defend against current and emerging biological threat agents

Vision
To be the leader in the advancement of medical biological defense with world renowned experts dedicated to protecting our military forces and the nation

Medical Biological Defense Insurance Policy for the Nation
Ebola’s Unique Challenges
“An Atypical Mission”

Natural Reservoir Unknown
• Difficult to break cycle of human contact with natural reservoir if reservoir is unknown
• Fruit bats suspected, but not proven / Bush meat is considered an elevated risk

No Approved Therapeutics / Vaccines / Diagnostics
• Requires Emergency Use Authorization (EUA) of Investigational Products
• Required materiel solutions not in mass production and readily available

Rapid Diagnostics for Patient Management
• Clinical signs and symptoms similar to other diseases
• Informs patient isolation decisions, patient care strategy, therapeutics selection, and public health strategy
• Number of laboratory assets required for timely sample analysis

Infection Control
• Low infectious dose necessitates increased level of emphasis on protective barriers; elevated protective posture for Ebola is not part of core skill training
• Patient care, patient transport, sample management, sample analysis, waste management, relief worker safety, protecting the public (personnel returning from Liberia)
Ebola’s Unique Challenges
“An Atypical Mission”

Dead Body Management
• General procedures are not tailored for handling bodies infected with highly infectious pathogens

Managing Public Perception and Reaction
• Liberian public had to welcome U.S. military presence
• U.S. public had to accept risk of personnel returning from mission

Operating in a VUCA Environment
• Volatile, Uncertain, Complex, Ambiguous
• Requires Joint, Interagency, Intergovernmental, Multinational (JIIM) solution
  • Requires synchronization of effort and harmonization of objectives

Standard Materiel Solutions And Procedures: Inadequate
**USAMRIID Experience with Ebola**

**Legacy Research Program**
- USAMRIID leverages basic science platforms and high level containment capabilities to conduct basic science investigations of high-consequence pathogens such as Ebola to advance the development of medical countermeasures to mitigate the threat (bioterrorism, accident, natural)

**Kikwit Outbreak: 1995**
- Personnel augmented an international team conducting field investigations to identify the natural reservoir

**Cote D’Ivoire WHO Field Investigation: 1996**
- Unique field study that looked at high canopy species of animals, not sampled from previous studies
- Field laboratory for necropsy and immunohistochemistry and immunocytochemistry sample analysis
Mission Essential Task List (METL)

1. **Prepare for Uncertainty**
2. **Rapidly Identify Biologic Agents**
3. **Provide World Class Expertise in Medical Biological Defense**
4. **Develop, Test & Evaluate Medical Countermeasures**
5. **Biosafety & Biosecurity**
6. **Train & Educate the Force**
USAMRIID Ebola Outbreak Support

Cooperative Biological Engagement Program

- Host nation support in Sierra Leone & Liberia prior to Operation United Assistance
- Diagnostic and genomic capabilities at the Liberian Institute for Biomedical Research

Operation United Assistance

- 20 Mobile Training Teams – short notice training and education to 4800 personnel deployed to West Africa
- Laboratory Training

Medical Countermeasures (MCM)

- FDA Emergency Use Authorization for Ebola Zaire diagnostic test
- Diagnostic test adapted for Military Working Dogs
- Laboratory Response Network Ebola diagnostic support
- Clinical trial support for leading Ebola MCM candidates
- Leading Ebola MCM candidates developed and/or evaluated at USAMRIID

Subject Matter Expertise

- Armed Forces Medical Examiner Staff training
- Animal studies to determine Ebola infectivity after death
- 24/7 consultation supporting operational and command requests

Rapid mobilization of high-impact capabilities
Positive Outcomes and Challenges

Positive impacts / Aspects to sustain:

- Data availability to support investigational product Emergency Use Authorization process provides diagnostic and therapeutic solutions that are otherwise not available
- Research laboratory flexibility rapidly put resources on providing solutions for real-world problems
  - Validated need to maintain contingency response capability in research laboratory
- Established an enduring early Ebola diagnostic capability that did not exist for Liberians or relief workers; informs supportive care decisions to improve prognosis
- Leveraged existing training programs and in-house subject matter expertise to immediately provide quality input to planning and readiness for deploying forces
- Just in time training was effective; may be necessary for unique low-frequency missions
- Program of Instruction (POI) development, review, and approval was rapid and enhanced quality of product

Challenges / Aspects to improve:

- Diverting research resources to outbreak response strains the workforce; necessitates supportive concurrence from higher headquarters and funding agencies
- Logistical challenges at the LIBR (deteriorating infrastructure, resupply, sample security/viability, process changed numerous times)
- Level of host nation engagement at the LIBR (host nation personnel availability)
- Training had to be delivered to units, not yet equipped with PPE; required MTT to carry all training supplies
“The global security environment presents an increasingly complex set of challenges and opportunities to which all elements of U.S. national power must be applied.” (p. 1)

Primary Missions of the U.S. Armed Forces
- #10, “Conduct Humanitarian, Disaster Relief, and Other Operations……U.S. forces possess rapidly deployable capabilities, including airlift and sealift, surveillance, medical evacuation and care, and communications that can be invaluable in supplementing lead relief agencies, by extending aid to victims of natural or man-made disasters, both at home and abroad…..” (p. 7)

Pandemics: State Fragility’s Most Telling Gap? By Frederick M. Burkle, Jr.
- “A nation-state’s capacity to govern effectively faces no stiffer test than its ability to manage infectious disease crises.” (p. 105)
- “75 percent of epidemics during the last three decades have occurred in countries where war, conflict, and prolonged political violence have crippled their capacity to respond, leaving their neighbors and the world vulnerable.” (p. 106)
- “Epidemics and pandemics are always public health emergencies. They easily elude a compromised health system and can rapidly cause confusion, fear, and chaos, and send populations fleeing across unprotected borders.” (p. 106)
Prepare for Uncertainty

- Robust biological threat agent technology base
- Active diagnostic and surveillance systems
- Rapid sequencing of unknowns
- High-throughput drug screening & drug development
- DNA vaccine & neutralizing antibody development
- Re-purpose FDA approved drugs for biothreat indications
- Pre-Emergency Use Authorizations in place
- Imaging technologies (PET, CT)

Rapid response to emerging threats
Uniquely prepared to support our military forces and the nation