



*Biodefense solutions to protect our nation*

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

***Composite Bio-Risk Management  
“Biological Surety”***

Veterinary Corps  
Director, Biosecurity

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# Terms

*Biodefense solutions to protect our nation*

- 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

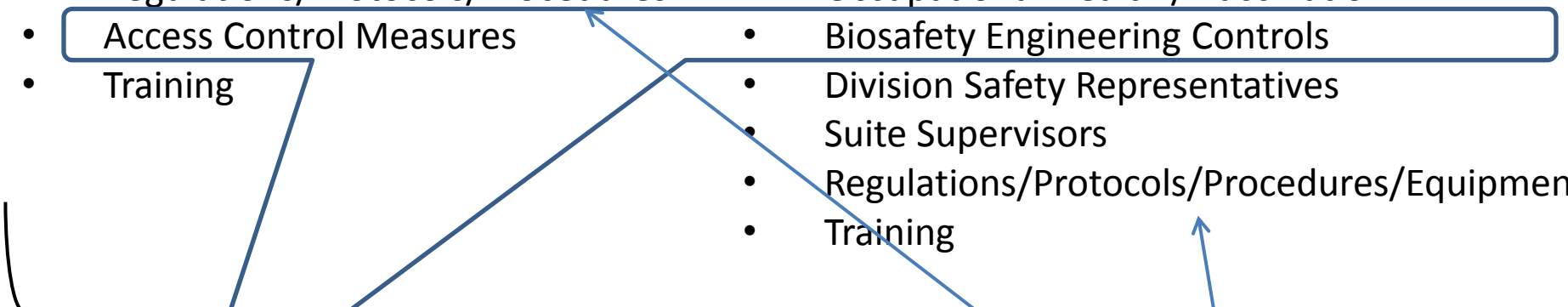
### **Biosafety**

- 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

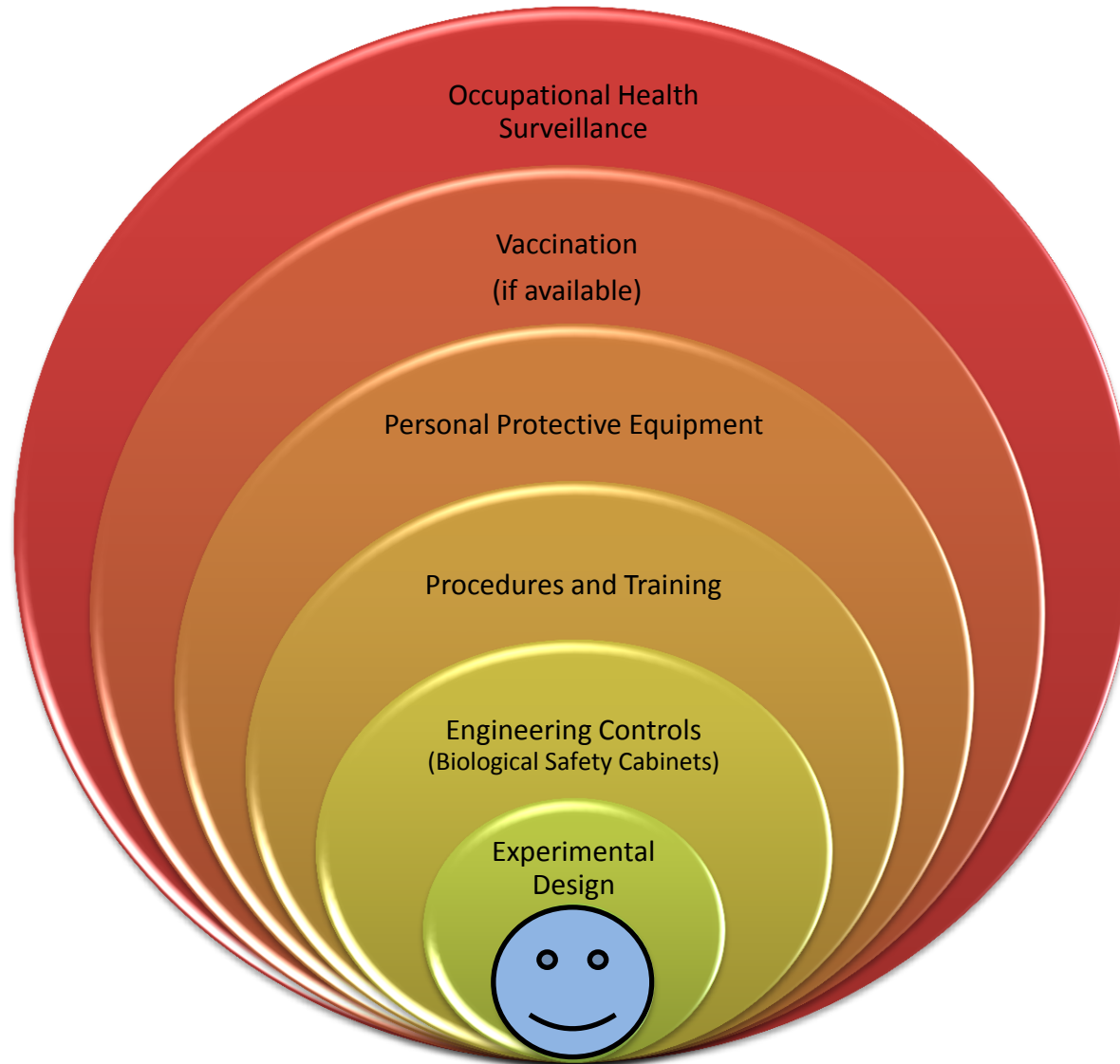
Informed by Science





# ***Biological Hazard Mitigation (Personnel)***

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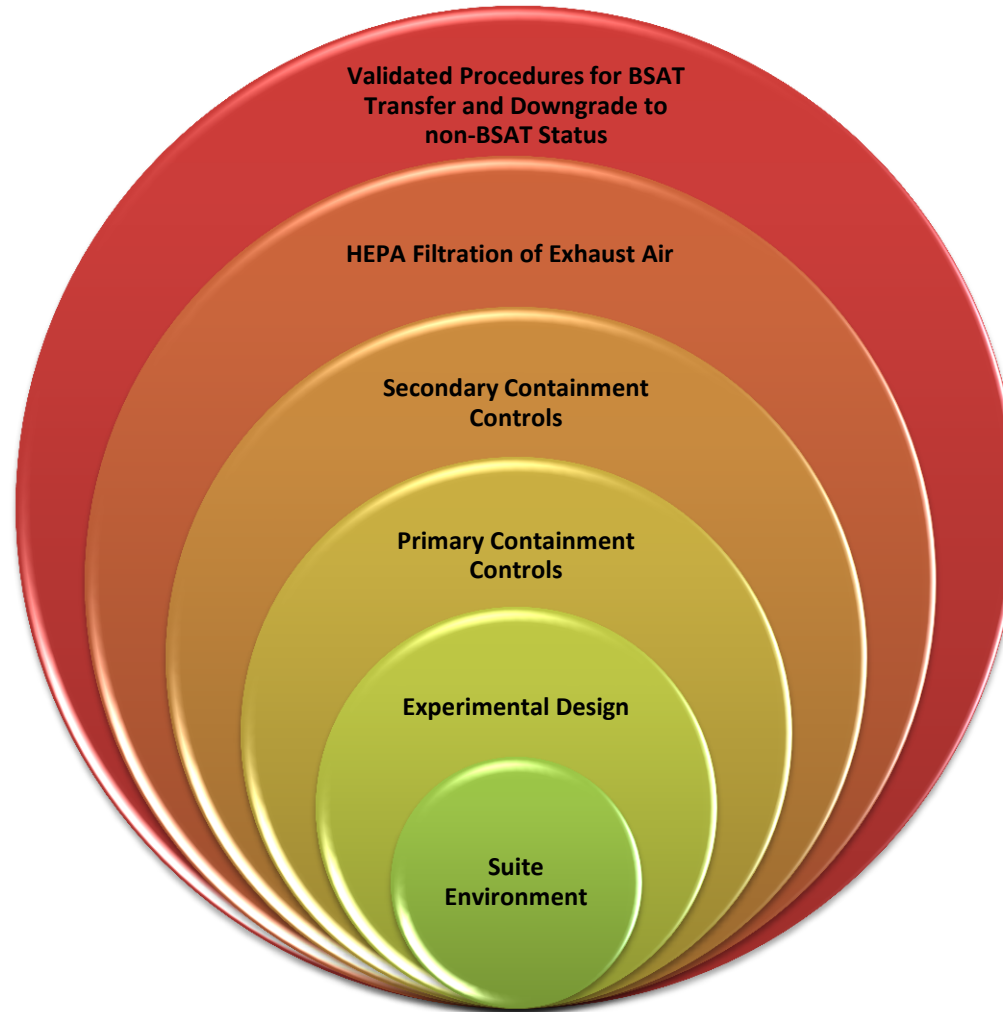




# ***Biological Hazard Mitigation*** ***(Environment: Internal and External)***

USAMRIID  
Campus

Fort Detrick



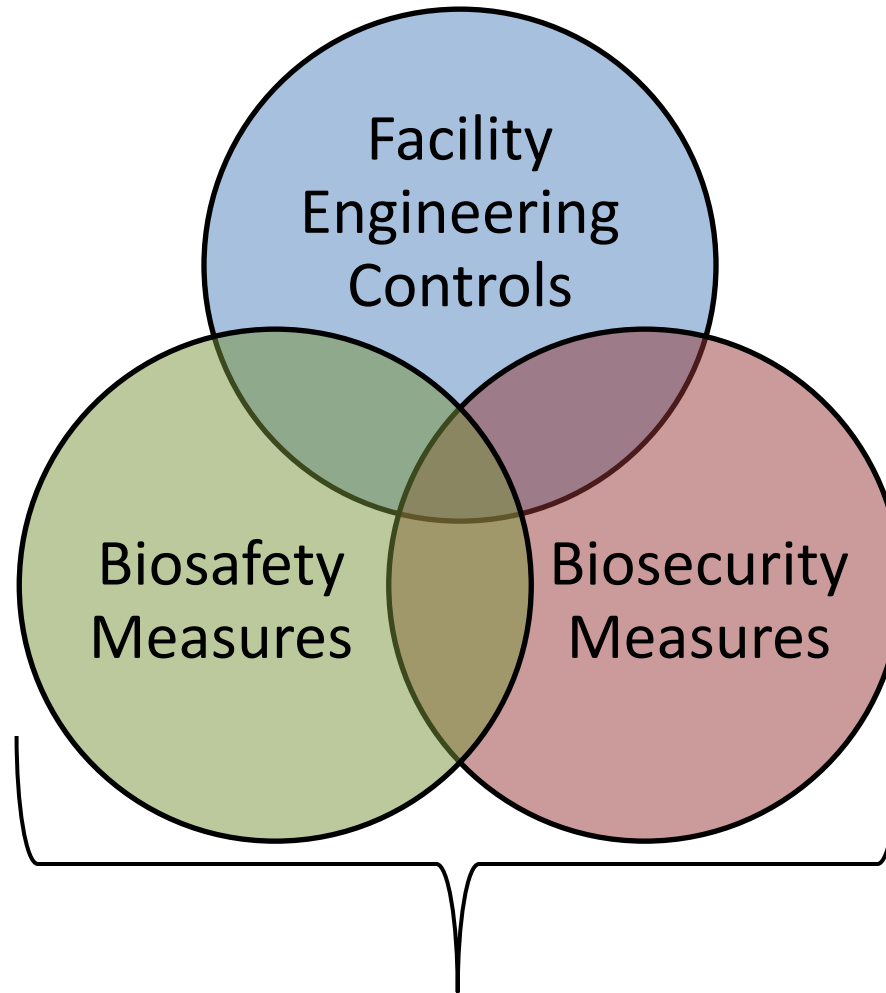
State

Nation

International



# *Synchronization is Critical*



**Risk Mitigation**



# *Synchronization*

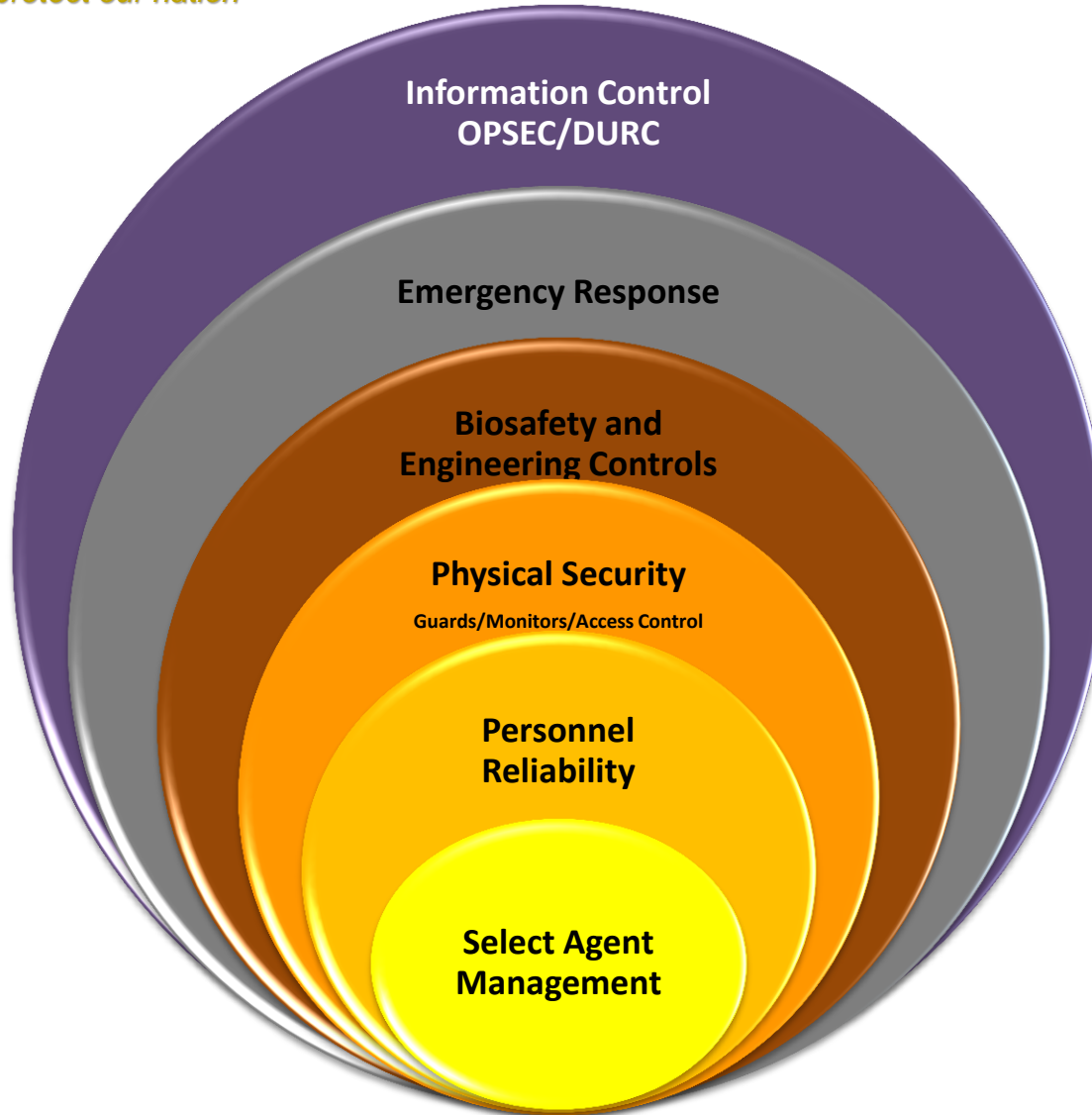
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- Suite Access Forms
  - Personnel must meet all criteria of every office prior to receiving authorization to work independently in restricted laboratory space
- USAMRIID Form 91
  - Suite registration for all infectious agents and toxins
- CDC/APHIS 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***

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# Keys to Success

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- **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



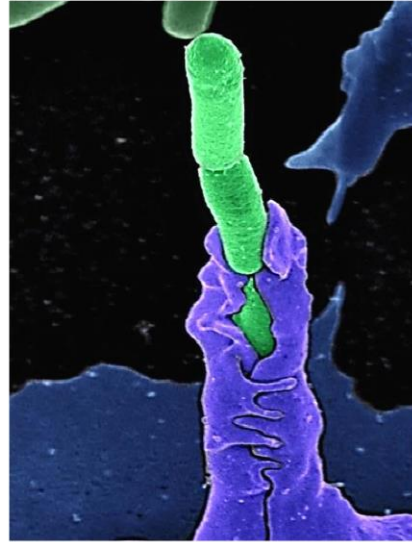
# Mission Essential Task List (METL)



**Prepare for  
Uncertainty**



**Develop, Test & Evaluate  
Medical Countermeasures**



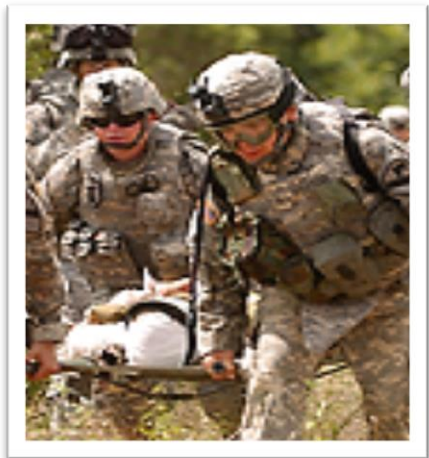
**Provide World Class Expertise  
in Medical Biological Defense**



**Biosafety & Biosecurity**



**Rapidly Identify  
Biologic Agents**



**Train & Educate  
the Force**



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

***Ebola Response***

Neal Woollen DVM, MSS, PhD  
Colonel, Veterinary Corps

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# ***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

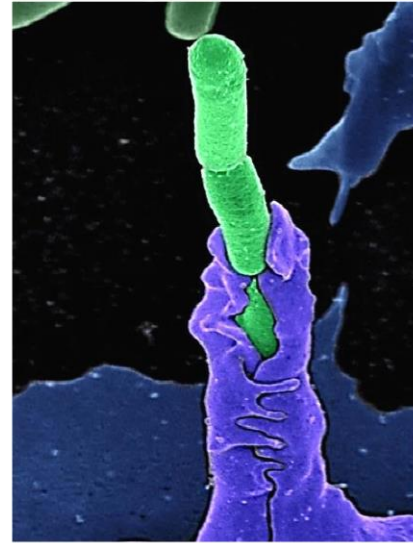




# Mission Essential Task List (METL)



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Uncertainty**



**Provide World Class Expertise  
in Medical Biological Defense**



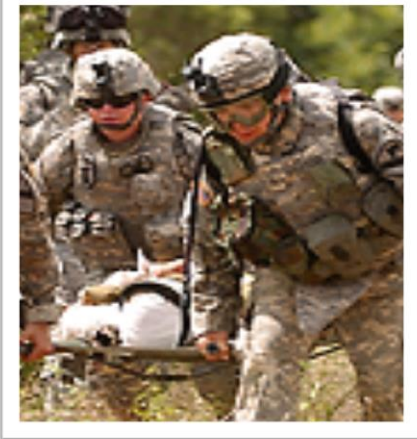
**Rapidly Identify  
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**Develop, Test & Evaluate  
Medical Countermeasures**



**Biosafety & Biosecurity**



**Train & Educate  
the Force**

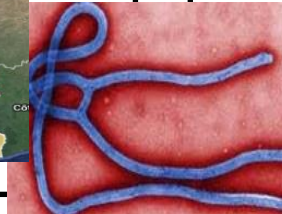




# USAMRIID Ebola Outbreak Support

## 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



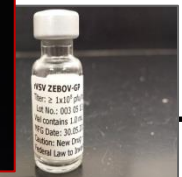
## Subject Matter Expertise

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



## 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



**Rapid mobilization of high-impact capabilities**



# Positive Outcomes and Challenges

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## 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:

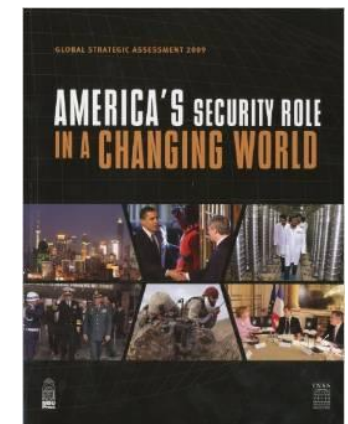
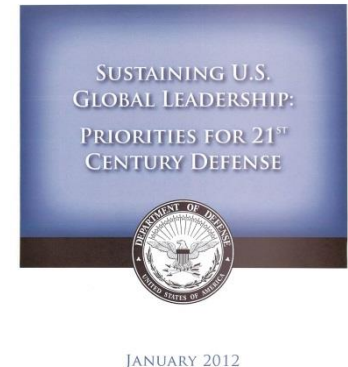
- Diverting research resources to outbreak response strains the workforce; necessitates supportive concurrence from higher headquarters and funding agencies
- Logistical challenges at the LIBR (deteriorating infrastructure, resupply, sample security/viability, process changed numerous times)
- Level 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



# Future Relevance to US Military of Lessons Learned from Current Ebola Outbreak

## Biodefense solutions to protect our nation

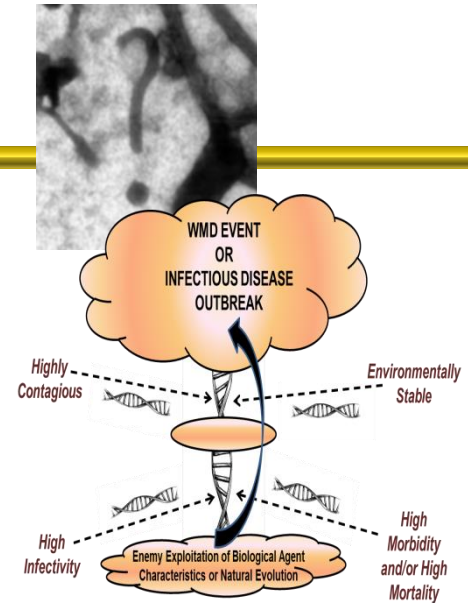
- “The global security environment presents an increasingly **complex set of challenges and opportunities** to which **all elements of U.S. national power** must be applied.” (p. 1)
- Primary Missions of the U.S. Armed Forces
  - #10, “**Conduct Humanitarian, Disaster Relief, and Other Operations.....U.S. 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*



# **USAMRIID**

*Biodefense solutions to protect our nation*

***Uniquely prepared to support  
our military forces and the nation***

*"Serving to Heal....Honored to Serve"*