Biomedical Challenge to Warfighter, Veteran and Civilian: Emerging Infectious Diseases – A Global Challenge

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UNCLASSIFIED
**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 Biodefense Insurance Policy for the Nation*
Core Competencies

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
COLLABORATIVE AGREEMENTS
(Total: approx. 700; A few examples shown below:)

• **IAA** (Interagency Agreements)
  - BARDA
  - MCS
  - CDC
  - DHS
  - FDA
  - NIAID
  - USDA

• **MTA** (Material Transfer Agreements)
  - Emory University School of Medicine
  - VaxDesign Corporation
  - Xoma Corp.
  - Boston University
  - Albert Einstein College of Medicine

• **CRADA** (Cooperative Research and Development Agreements)
  - Sarepta Therapeutics
  - Columbia University
  - Gilead
  - Harvard University
  - Bayer
  - Novartis Vaccines and Diagnostics
  - University of Texas Medical Branch

• **IA** (International Agreements)
  - Public Health Agency of Canada
  - Institut Pasteur
  - Vivalis S.A.
  - University of Madras
  - Dstl Porton Down

*Key conduit to new technologies for the CBDP*
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
- 38 Mobile Training Teams – short notice training and education to 4800 personnel deployed to West Africa

Medical Countermeasures (MCM)
- Developed and/or evaluated leading Ebola MCM candidates
- 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

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
ACCOMPLISHMENTS

— Trained Liberian Institute for Biomedical Research (LIBR) personnel to safely conduct Ebola virus diagnostic testing

  • Prior to successful transition, USAMRIID maintained organic staff since the start of the outbreak

  • Part of the Defense Threat Reduction Agency’s Cooperative Biologic Engagement Program

— Established first forward-deployed genomic sequencing capability at LIBR to support Ebola outbreak response.

  • Allows near real-time monitoring of viral evolution as the outbreak progressed and continues today

ACCOMPLISHMENTS

- Developed DoD EZ-1 Ebola virus diagnostic assay

  • First Ebola diagnostic assay to be given Emergency Use Authorization (EUA) by FDA during the Ebola virus outbreak

  • Administered qualification and proficiency testing for all DoD and state Public Health laboratories

  • Developed at USAMRIID

- Pre-positioned data packages for 73 other diagnostic assays in the event of another declared emergency

- Provided Ebola diagnostic testing support for all Ebola patients treated at the National Institutes of Health, Special Clinical Studies Unit in Bethesda, MD
ACCOMPLISHMENTS

– Rapidly advanced Gilead Sciences GS-5734 small-molecule therapeutic from conception to initiation of Phase I clinical trials in only 9 months for treatment of Ebola virus infection

  • Used on compassionate basis to treat Scottish nurse infected with Ebola virus while working in Sierra Leone

– Successfully tested single monoclonal antibody Ebola therapy

  • 100% effective against lethal Ebola virus challenge in monkeys
  • Multiple-antibody "cocktails" used to treat Ebola virus infection
  • Studies support development of a single antibody therapy
  • Could considerably shorten regulatory review and approval timelines
ACCOMPLISHMENTS

- Completed pivotal animal efficacy studies to meet FDA “Animal Rule” requirements for treatment of inhalational and bubonic plague, and inhalational anthrax using the already-licensed drug moxifloxacin

  • Drug repurposing for additional treatment options maximizes use of government resources and significantly shortens acquisition timelines

- Established BSL-4 Good Laboratory Practice (GLP) testing & evaluation capability at USAMRIID

  • USAMRIID is the only lab with this capability
Uniquely prepared to support our military forces and the nation