



USAMRDC USAMRIID

U.S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASE

MISSION

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

VISION

Advance medical biological defense to protect our military and the nation

BACKGROUND

USAMRIID was established in 1969 by the Office of the Surgeon General of the Army to develop medical defenses against biological warfare threats. The USAMRIID was originally known as the U.S. Army Medical

Unit, Fort Detrick. In 1971, it became part of the U.S. Army Medical Research and Development Command. The Institute has played a key role over the past 50 years as the DoD's lead laboratory for medical aspects of biological defense.

As the only DoD laboratory equipped to safely study highly hazardous viruses that require maximum containment at biosafety level (BSL) 4, USAMRIID is uniquely positioned to develop and maintain biological safety, security, and surety standards to meet multiple levels of regulatory oversight. The Institute also leads the field in developing animal models of aerosol exposure to biological threat agents and in testing vaccines and therapeutics for efficacy in those models. Research conducted at the USAMRIID

leads to medical solutions— vaccines, drugs, diagnostics, and information — that benefit both military personnel and civilians.

The primary research focus of the USAMRIID since its inception has been on highly virulent diseases. USAMRIID scientists focus on the identification and initial development of medical countermeasures to protect military personnel against biological attack. These products include candidate vaccines and drugs, diagnostic capabilities, and medical management procedures to minimize the effects of disease, preserve fighting strength, and maximize return to duty after exposure. Because there are many natural disease threats that could affect deployment of forces into endemic areas, medical countermeasures for those diseases are studied as well.

As the Center of Excellence for DoD medical biological defense research, the USAMRIID's main challenge is to maintain its world-class scientific and technology base while being responsive to its primary customer—the Warfighter.



KEY THEMES AND MESSAGES

The vision of the USAMRIID is “to advance medical biological defense to protect our military and the nation.” The Institute strives to be the nation’s preeminent research laboratory, providing cutting-edge medical research for the Warfighter against biological threats.

While the USAMRIID’s primary mission is to protect the Warfighter, its research has applications that benefit society as a whole, as demonstrated by many Cooperative Research and Development Agreements and other partnerships established with industry, academia, and other government agencies.

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QUESTIONS & ANSWERS

What are the most common biological threat agents?

The most common biological threat agents are those that cause anthrax, botulism, plague, smallpox, ricin intoxication, and nerve damage.

How does USAMRIID define “biosafety level”?

BSL refers to the level of biocontainment precautions that are needed to isolate dangerous biological agents in an enclosed facility. In the United States, the Centers for Disease Control and Prevention (CDC) has specified containment levels ranging from 1 (lowest BSL) to 4 (highest BSL). BSL-4 is required when working with agents that can result in severe to fatal disease in humans for which vaccines or other treatment options are unavailable or with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections.

What are the key features of USAMRIID’s BSL-4 facilities?

USAMRIID’s BSL-4 laboratories are designed with integrated laboratory sterilization systems to process and decontaminate all liquid and solid wastes completely. Exhaust air passes through high-efficiency particulate air filters, rendering all solid, liquid, and air effluents safe before they leave the facility.

A combination of structural integrity, engineering controls, meticulous procedures, and tight security accounts for the outstanding safety record of BSL-4 facilities throughout the decades of their existence. In addition, researchers who work in such laboratories are highly trained and follow rigorous safety procedures.

How does USAMRIID ensure the safety of its workers and the surrounding community?

The first priority is maintaining a safe and secure environment for the workforce and the surrounding community. The USAMRIID’s comprehensive safety

program emphasizes safety training, risk management, continuous compliance, and occupational health screening. The physical security program uses layered security measures to allow only authorized individuals access to the areas in which biological agents are stored or used. These individuals must satisfactorily complete laboratory safety training, physical examination screening and a security background investigation. The personnel reliability program requires that all individuals who have completed the requirements for biological agent access also undergo a personnel records review, a medical evaluation, and an interview with the Certifying Official highlighting individual responsibilities, reliability standards, and reporting requirements. Agent accountability involves inventory control, shipping, transfer and destruction records, and observation of laboratory procedures.

Why are infectious diseases a concern to our military?

Infectious diseases continue to impact operational forces to the point where Service Members are more often hospitalized for infectious diseases than for being wounded in combat. Infectious diseases also place a significant burden on the medical logistical system for people requiring treatment or hospital space. The loss of personnel to infectious diseases reduces operational readiness and effectiveness by requiring replacement troops.

What are some of the key contributions of the USAMRIID?

USAMRIID has made significant advances in the areas of vaccine development, drug development, diagnostics, and training and education. In addition, the Institute has led the way on animal model development, conducting the first-ever, foundational Good Laboratory Practice studies in BSL-4 laboratories; these studies were recognized by FDA as the basis for testing of any future medical product designed for Ebola virus treatment.

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KEY THEMES AND MESSAGES, continued

The Institute’s six core competencies are: biological agent research; rapid identification of biological agents; testing and evaluation of medical countermeasures; training and educating the force; preparing for uncertainty; and maintaining safety, security, and surety standards.

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QUESTIONS & ANSWERS, continued

What are some of the key contributions of the USAMRIID?

Vaccines: USAMRIID performed the pivotal Phase 3 clinical trial that led to FDA approval of a new smallpox vaccine, proving its enhanced safety and efficacy over the current product. The Institute also performed all nonhuman primate studies to evaluate the protective efficacy of a new Ebola virus vaccine. USAMRIID also has developed vaccine candidates for anthrax, ricin toxin, and hantaviruses.

Drugs: The USAMRIID develops and screens promising therapeutics and re-purposes antibiotics for biodefense. The Institute performed pivotal efficacy studies to support FDA’s expansion of the indication to use moxifloxacin and ciprofloxacin to treat plague; executed all key studies for the first small-molecule treatment to be FDA-approved for smallpox; and identified a novel synthetic Ebola therapeutic.

Diagnostics: The USAMRIID continuously develops and fields diagnostic capabilities to fill operational gaps, and pre-positions data packages with the FDA to support faster turnaround during outbreaks or contingencies. USAMRIID also serves as one of only three National Laboratories in the CDC’s Laboratory Response Network, or LRN.

Training and Education: The USAMRIID conducts the Medical Management of Biological Casualties Course, which has trained thousands of military and civilian health care providers in recognizing and treating the signs of biological agent exposure. (The course is offered in partnership with the U.S. Army Medical Research Institute of Chemical Defense, which covers similar material geared toward chemical agent exposure.) The USAMRIID also offers the Field Identification of Biological Warfare Agents course, which trains laboratory personnel who conduct diagnostic

testing in a field setting, and the Outbreak Response Course, which offers active duty military and civilian healthcare personnel the necessary tools for planning, training, recognition and response to infectious diseases that could potentially cause public health crises or overwhelm the ability of medical facilities to respond.

How does the USAMRIID define a “biological threat agent?”

A variety of agents can be used in a biological attack. Some agents cause infectious diseases that can spread in populations (e.g., smallpox) while other agents are only dangerous when an individual comes into direct contact with them (e.g., anthrax).

What is “bioterrorism,” and how does it differ from other types of attacks?

“Bioterrorism” is defined as the intentional use of germs or harmful biological substances (i.e., biological threat agents) to cause widespread fear and illness. Acts of bioterrorism often are not recognized immediately since they do not typically involve an explosion or other obvious signs. Therefore, it may take health care workers some time to determine that a disease is spreading through a population in a particular area. Nuclear, chemical, and radiation attacks differ from bioterrorist attacks in that they are designed to release dangerous substances into the air and the surrounding environment and result in immediate damage.

How did the USAMRIID contribute to the worldwide response to the Ebola virus outbreak that began in 2013 in Western Africa?

The USAMRIID significantly contributed to almost every therapeutic, vaccine and diagnostic product developed or used in this devastating outbreak. The USAMRIID also spearheaded the provision of personnel, training and diagnostic laboratory support to the Liberian Institute for Biomedical Research on a continuous rotational basis.