



USAMRMC STRATEGIC COMMUNICATION PLAN MILITARY INFECTIOUS DISEASES RESEARCH PROGRAM (MIDRP)

MISSION

The Military Infectious Diseases Research Program's mission is to conduct a focused and responsive world-class infectious diseases research and development program, leading to the fielding of an effective, improved means of protection and treatment to maintain maximal global operational capability with minimal morbidity and mortality.

BACKGROUND

Infectious diseases historically cause more casualties than enemy fire in deployment to tropical regions. The impact on Service Members range from loss of man-hours to death and can severely hamper combat effectiveness while increasing the logistical burden for diagnosis, treatment and evacuation. The MIDRP manages research for the DOD on naturally occurring infectious diseases with a focus on minimizing disease impact by protecting the Warfighter through development of vaccines, drugs, diagnostics and vector control products. The MIDRP's role is of continuing importance as diseases, such as malaria, dengue, diarrhea and leishmaniasis, continue to adversely impact military operations and the health of Service Members and their families. More than 300 M.D. and Ph.D. level Army, Navy, Air Force, Government Service civilian and contract investigators around the world lead MIDRP research and development efforts.

Infectious diseases such as malaria and human immunodeficiency virus also often impact global political stability, public health and humanitarian concerns. In addition, infectious disease threat changes over time due to shifts in ecological conditions (e.g., climate

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change), reemergence of infectious disease threats (e.g., pandemic flu, multi-drug resistance organisms, rabies), emergence of new threats (e.g., Middle-East Respiratory Syndrome, severe acute respiratory syndrome, Chikungunya, Ebola) and increased focus in certain geographical areas due to operational reasons.

Products under development by the MIDRP not only protect Service Members, but also benefit people living in disease-endemic areas. The MIDRP has supported HIV vaccine research and development since 1985, as HIV remains a significant threat to Service Members deployed overseas and is a major source of regional instability in areas of U.S. force protection.

The MIDRP has successfully developed candidate products from basic science concepts through pilot scale manufacturing and all phases of animal and clinical evaluation. The program particularly excels at translational research, where new products are moved from the technology base to a level where a commercial partner will take the product on to licensure and marketing to the U.S. military and civilian population.

QUESTIONS & ANSWERS

Q *Why are infectious diseases a concern to the military?*

Infectious diseases continue to impact operational forces. Service Members are hospitalized more often for infectious diseases than those who are 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.

Q *What impacts have infectious diseases had in recent operations?*

A Cutaneous leishmaniasis, a disease transmitted by sand flies, had a major impact early in Operation Iraqi Freedom. More than 3,000 personnel were diagnosed with this disease, and many had to be evacuated to the United States for treatment, which impacted treatment facilities. The impact of malaria was seen in Vietnam, where 25 percent of all Army troops suffered with this disease. Malaria still represents the most significant infectious disease threat to deployed Soldiers where malaria

KEY THEMES AND MESSAGES

The discovery and development of vaccines to protect the Service Member are a priority for the MIDRP. Vaccines are often the most durable and cost-effective solution against disease. More than half of the routine vaccines given to Service Members were co-developed by the military.

New drugs for treatment or prophylaxis are continually required to overcome evolving drug resistance. The MIDRP has contributed to the development of most synthetic drugs licensed in the United States for the prevention and treatment of malaria.

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is endemic, as highlighted by the deployment of U.S. Marines to Liberia in 2003, during which 80 of 220 contracted malaria, more than half of whom required evacuation. Diarrheal disease caused by bacteria has also shown significant impact on force readiness due to hospitalization and lost duty days during the Operation Enduring Freedom/Operation Iraqi Freedom.

Q *Why does the military need to conduct infectious disease research?*

A The focus of the MIDRP is to develop countermeasures against diseases our deployed military forces will likely encounter. Most of these diseases are not of concern within the United States. Preventing disease is a force multiplier by keeping people healthy and by enhancing readiness. While the MIDRP shares some common research goals with other research organizations, the military has unique needs that are inadequately addressed by other federal agencies, international programs and private industry.

Q *What are the technical issues with developing medical products?*

A Developing vaccines and drugs is a challenge. Scientists all over the world are still trying to learn the basic biological principles that make them work. Making safe and effective vaccines and drugs as countermeasures for different microorganisms is highly empirical. Vaccine and drug development also is a high-risk, high-cost venture, with most vaccines and drugs failing in human clinical trials. As such, there is a requirement for continued technology development to provide a robust pipeline of new technologies and materials to replace those that have failed.

Q *Why can't these products be developed faster?*

A Besides the technical issues, major constraints on making vaccines and drugs are the high costs of development and the need to conduct human clinical trials in a safe and acceptable way. The ability to move forward in clinical testing is dependent on demonstrating that the vaccine/drug is safe in both short- and long-term studies. Conducting trials also is impacted by the ability to recruit

KEY THEMES AND MESSAGES

(cont. from previous)

Early diagnosis facilitates prompt, appropriate treatment and aids commanders in the field. MIDRP diagnostic products include field-worthy devices to diagnose human infections and determine if insects are carrying infectious agents transmissible to humans.

Many militarily relevant infectious diseases are transmitted by biting insects and other arthropods. Vector control products include personal protective devices (such as insect repellents, insecticides and bed nets) to prevent mosquitoes, ticks and sand flies from biting Service Members.



subjects into the trials and to complete the studies. Compiling, verifying and analyzing clinical trial results require considerable time. The next required clinical trial is often dependent on completing a previous trial that may take 1 to 4 years to complete, and U.S. Food and Drug Administration (FDA) licensure often takes many months of evaluation after trials are completed.

Q *What roles do the FDA and Environmental Protection Agency (EPA) play in medical product development?*

A Therapeutics, vaccines, diagnostic devices and certain other products, such as insect repellents are, by law, regulated by the U.S. Government to ensure the products are safe and effective. Safety concerns are the primary driver for the guidelines and processes in place to ensure individuals and the environment are not harmed by the products being developed and marketed. In recent years, the level and complexity of regulatory oversight have increased significantly, resulting in longer development times.

Q *With many others funding research in areas you cover, such as HIV and malaria, why does the DOD need to conduct this type of research?*

A The DoD must protect its forces from diseases that may impact the ability to complete missions. This does not necessarily align with the needs of the public health community, where most efforts are directed at reducing mortality rates. The goal of developing a malaria vaccine is one example. The focus of the international community is to develop a malaria vaccine that will prevent death in young children and pregnant women in areas of the world where prior malaria infections provide some natural immunity. MIDRP scientists actively support these efforts through many collaborations. The military, however, needs a malaria vaccine that will protect Service Members with no prior natural immunity to avoid mission-degrading illness. Preventing death in children and keeping Soldiers healthy and effective are distinct goals requiring different research strategies.

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Q *Why does the MIDRP have an anti-diarrhea program?*

A Diarrhea continues to be a major problem for deployed personnel. It can cause serious dehydration and crippling disease, which impacts the ability to accomplish a mission. Some affected troops are placed on restricted duty or hospitalized for treatment. Historically, some diarrhea outbreaks have resulted in entire units becoming nonoperational.

Q *What are the program's interactions with outside research efforts/outside funding organizations?*

A The MIDRP has many successful governmental and commercial partnerships, such as Cooperative Research and Development Agreements, the Small Business Innovation Research Program, Congressional Special Interest-appropriated funding and Interagency Agreements. Critical to the development of any vaccine or therapeutic is the involvement of a commercial partner that has the ability to manufacture and market medical products to those who need them. The high cost of product development usually can only be recovered, and the product sustained by having a commercial market for the product. In addition, the basic research and concept development for new products involve both academic and governmental research organizations that are critical for intellectual input and for providing critical research capabilities not always available at military laboratories.

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Q *What are the contributions of the MIDRP?*

A **Drugs:** The MIDRP has contributed to the development of most synthetic drugs licensed in the United States for the prevention and treatment of malaria. Next-generation antimalarial drugs include tafenoquine and an intravenous formulation of artesunate.

Diagnostics: MIDRP diagnostic products include field worthy devices to diagnose human infections (e.g., malaria and cutaneous leishmaniasis) and to determine if insects are carrying infectious agents transmissible to humans (e.g., west nile and dengue fever viruses).

Vector Control: Vector control products include personal protective devices (e.g., insect repellents, insecticides and bed nets) to prevent mosquitoes, ticks and sand flies from biting Service Members. Additional products include computer-based systems that identify potential disease-carrying insects.

Q *Where can I learn more about the MIDRP?*

A Additional information about the MIDRP can be found at: <https://midrp.amedd.army.mil/>