



USAMRMC

STRATEGIC COMMUNICATION PLAN

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND



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 Soldiers ranges from loss of man-hours to death and can severely hamper combat effectiveness while increasing the logistical burden for diagnosis, treatment, and evacuation. MIDRP stresses the importance of keeping forces healthy by preventing disease via the use of vaccines and drugs. Vaccines, antimalarial therapeutics, and diagnostics are the program's primary focus. MIDRP's role is of continuing importance because diseases such as malaria, dengue, diarrhea, and leishmaniasis continue to have an adverse impact on military operations and the health of service members.

Global political stability, public health, and humanitarian concerns are also often impacted by infectious diseases such as malaria and human immunodeficiency virus (HIV). Products under development by MIDRP not only protect Warfighters but also benefit people living in disease-endemic areas. 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.

Key Themes & Messages

- The discovery and development of vaccines to protect the Warfighter are a priority for 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. MIDRP has contributed to the development of most synthetic drugs licensed in the United States for the prevention and treatment of malaria.
- Early diagnosis facilitates prompt, appropriate treatment and aids commanders in the field. MIDRP diagnostics products include fieldworthy 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.

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Q & A

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

A: Infectious diseases continue to impact operational forces. More 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 2,500 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 remains a militarily relevant disease, as evidenced in 2003, when 44 percent of 268 Marines conducting a 2-week mission in Liberia were rapidly rendered ineffective due to malaria. About 40 of them were evacuated to the United States for treatment, and 4 developed severe symptoms. Fortunately, no one died from the infection.

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

A: The focus of 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. Unfortunately, a major focus in much of the civilian research community is on treating and not preventing these diseases. For many diseases in this program, there are no other directed research efforts to develop preventive countermeasures required by our military. Focus on prevention helps maximize the military's ability to accomplish its mission around the world.

Q: *Why is biodefense studied apart from infectious disease? Infectious diseases could be used in biowarfare in regions with entrenched conflict.*

A: Due to safety and security reasons, the biodefense program focuses on diseases that are a real threat as biowarfare agents.

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 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.





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Conducting trials also is impacted by the ability to recruit 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: When H1N1 was an immediate concern, the nation didn't have enough vaccines in supply. How do you ensure there are enough vaccines acquired for an epidemic among military personnel?

A: MIDRP's mission is only research and development.

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

A: Therapeutics, vaccines, diagnostic devices (FDA), and certain other products such as insect repellents (EPA) 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: How helpful are the FDA and EPA?

A: The FDA and EPA processes allow for open discussion between product developers and regulatory staffs. However, due diligence by the agencies is the primary concern, and any concerns for safety or effectiveness can result in programs being justifiably slowed or stopped until these concerns are eliminated.

Q: With many others funding research in areas you cover such as HIV and malaria, why does 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. For example, the international malaria effort is dedicated to preventing death in children in endemic areas so that they can acquire immunity and lead more productive lives, whereas the U.S. military's goal is to prevent troops from becoming ill. These are very different efforts requiring different technologies.

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

A: 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 Inter-agency 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: Do you and your partners abide by animal use guidelines in your research?

A: All animal research is conducted in accordance with procedures described in the *Guide for the Care and Use of Laboratory Animals*. The facilities are fully accredited by the American Association for Accreditation of Laboratory Animal Care International.

Q: Do military personnel or civilians participate as subjects in the research?

A: Yes.

Q: Are research data and results transparent or publicly available?

A: Only unclassified and mature data are available to the public.

Q: How do civilian medicine and military medicine benefit from one another in this research area?

A: Knowledge sharing through collaborations.

Q: What's on the horizon?

A: Recently some new vaccines and diagnostic devices were successfully developed that are ready to be deployed, and lots of new promising candidates are in the pipeline.



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