

What makes the Military Infectious Diseases Research Program (MIDRP) Unique?

An overview of MIDRP efforts



Mission. The mission of the Military Infectious Diseases Research Program (MIDRP) is to protect the U.S. military against naturally occurring infectious diseases via the development of FDA-approved drugs, vaccines and diagnostics, and EPA-approved vector control systems. Although the military has been very successful in this undertaking, diseases such as malaria, dengue, diarrhea, and leishmaniasis continue to adversely impact military operations and the health of service members and their families.

Objectives. 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. 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 malaria infections provide some natural immunity. MIDRP scientists actively support these efforts through many collaborations. However, the military 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.

Other MIDRP objectives which are not addressed by other programs include development of:

- adenovirus vaccines to protect recruits in basic training from acute respiratory disease
- new, FDA-approved drugs to prevent malaria in non-immune service members (as opposed to development of drugs to treat malaria in persons residing in developing countries, where U.S. licensure and prophylactic drugs are not priorities)
- HIV/AIDS vaccines to protect the U.S. military against HIV strains found outside the U.S.
- a second generation Japanese encephalitis vaccine to protect service members and others traveling to Asia, which will replace the vaccine being withdrawn from the market
- Rapid diagnostic tests for leishmaniasis (one of many tropical diseases where there is little national interest outside of DoD)

Other MIDRP programs focus on scrub typhus, hemorrhagic fevers, and other deadly viruses found overseas. These are diseases of DoD interest yet minimal research efforts exist within other national research programs.



“Because, if we fail to protect them, who will protect us?”
CDR Meg Ryan

Past Success. The value of prophylactic drugs and vaccines to protect service members against infectious diseases has been obvious to the military since General George Washington inoculated his army to protect against smallpox. The U.S. military has been quite successful at creating vaccines and drugs. Since the passing of the 1962 Kefauver-Harris Drug Amendment, which requires medical products to be safe and efficacious, the military has been a partner in the development of seven different vaccines licensed in the U.S. or 25 percent of all novel vaccines and more than half the vaccines routinely given to protect our service members. Further, the military has contributed to the development of nearly all synthetic drugs licensed in the U.S. for the prevention and treatment of malaria (see separate MIDRP information paper, “An Overview of Licensed Products”). For decades, the DoD was the only federal agency developing new prophylactic and therapeutic drugs and vaccines for tropical diseases. However, today, an infectious disease threat anywhere in the world threatens the U.S. population at large. This natural biological threat has resulted in increased funding to other Federal agencies, but DoD infectious diseases research funding has been decreasing in real terms.

Capabilities. More than 300 MD and PhD level Army, Navy, Air Force, Government service civilian, and contract investigators lead MIDRP projects. These research professionals are stationed at major infectious diseases research laboratories in Maryland - the Walter Reed Army Institute of Research, the Naval Medical Research Center, and the United States Army Medical Research Institute of Infectious Diseases- , and overseas - Peru, Egypt, Kenya, Thailand, and Indonesia with smaller detachments in Nepal, Uganda, Tanzania, Nigeria, Cameroon and Ghana. The U.S. military has stationed

uniformed scientists in the tropics for more than 100 years, and with active overseas laboratories in place for as long as 58 years. Military scientists live and work in the tropics to study the disease threats in naturally affected populations. Countermeasures and candidate solutions are studied through all phases of development including field testing. These military scientists serve as goodwill ambassadors, and contribute to the development of health and science infrastructure in these tropical countries. Enduring relationships between tropical DoD facilities and ministries of health, international healthcare facilities, and local healthcare providers and researchers are of great value to the U.S. at a time when diseases such as SARS and avian influenza are potential global threats. The global MIDRP military presence provides a real-time early warning system in the identification and assessment of new and reemerging disease. Data from around the world is collected, analyzed, and immediately disseminated to military leadership and other agencies by the military's Global Emerging Infections System (GEIS).

The MIDRP is vertically integrated with full-spectrum capabilities that include basic science (discovery and the knowledge base to solve problems encountered later in development), pre-clinical optimization, and advanced animal model development. Clinical trials expertise for early Phase 1 testing of drugs and vaccines through large (e.g. 42,000 volunteers for hepatitis A vaccine, and 62,000 volunteers for Japanese encephalitis vaccine) pivotal Phase 3 trials in developing nations is an especially valuable asset of the MIDRP. The DoD has high containment laboratories, pilot Good Manufacturing Practice (GMP) compliant bioproduction facilities, and FDA regulatory expertise in the U.S. and in many international settings.

As important as the talented researchers, modern facilities and sophisticated equipment is the MIDRP's proven capability to develop 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" to move a new product 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 civilians. GlaxoSmithKline, sanofi-pasteur, Barr Pharmaceuticals, Pfizer, and many other corporations have confidently partnered with the DoD and provided the additional resources needed to get products to market. One of the MIDRP's major strengths is the recognition by industry collaborators of its neutrality (lack of profit motive) as it pursues its service mission. The trust that this engenders facilitates collaborations that could not otherwise be contemplated, allowing the sharing of trade secrets and the testing of many promising new technologies. These unique partnerships drive scientific discovery at a pace rarely achieved by the private sector.

The DoD receives approximately \$70 million of appropriated funds annually for infectious diseases research – less than 2 percent of the National Institutes of Health total spending on infectious diseases and immunology research. DoD maximizes the use of limited resources by partnering with other federal agencies, non-governmental organizations, and the pharmaceutical industry to focus on the unique infectious disease research and prevention needs of the U.S. military.

What others think. The following comments are extracted from two Institute of Medicine reports (Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance [2004]; and Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military [2002]).

"The Walter Reed Army Institute of Research (WRAIR), through the United States Army Medical Research and Materiel Command (USAMRMC), is the leader in the United States for the development of new antimalarial drugs. Drug resistant malaria is considered a major military threat as well as an American public health issue. Military personnel, tourists, consultants, Peace Corps volunteers and State Department employees traveling to, or residing in, malaria endemic areas owe their safe travel to malaria endemic areas to the U.S. Military."

"Military scientists have a notable record of accomplishments when it comes to vaccines, including primary or significant roles in the development of vaccines against meningococcal meningitis, hepatitis A, Japanese encephalitis, and other dangerous infectious diseases. Partly because of the success of the DoD research programs, the public and even DoD nonmedical research personnel know little about them or the threats that their products have ameliorated."