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Mention of any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government and shall not be used for advertising or product endorsement purposes. The mention of companies by name is solely for the purpose of representing Command collaborations and should not be implied as endorsement.

Introduction



Nilitary Infectious Diseases

Combat Casualty Care

> Military Operational Medicine

Clinical and Rehabilitative Medicine

Medical Chemical and Biological Defense

> Advanced Technologies

> > Logistics

Appendices

Opera Mod Clinical an Rehabilitati Medicine Medical Chemical and Biological Defense

Advanced Technologies

USAMRMC

The nation's military forces may be called to serve anywhere in the world during times of conflict or in peacetime. Among the threats our forces face are injury from combat operations, exposure to chemical or biological warfare agents, environmental extremes, and endemic diseases not common in the United States. To provide Warfighters defenses against these hazards and sustain their health is the goal of the U.S. Army Medical Research and Materiel Command (USAMRMC).

A complex and diverse organization, the Command sustains the health and fighting ability of Soldiers, Sailors, Airmen, and Marines through its programs in medical research, medical materiel development, medical logistics, and development of new technologies to improve military health care on the battlefield. The Command is engaged in a broad spectrum of activity, from basic research in the laboratory to innovative product acquisition and the fielding and life-cycle management of medical equipment and supplies for deploying units.

Six laboratories make up the Command's core science and technology capability. They are centers of excellence in specific areas of biomedical research, staffed by highly qualified military and civilian scientists and support personnel. A large extramural contract research program and numerous Cooperative Research and Development Agreements (CRADAs) with leading research and development organizations in the civilian sector complement the Command's in-house science and technology capabilities.

Five additional USAMRMC subordinate commands focus on Command requirements, such as medical materiel development, logistics, and contracting, to complete the life-cycle management of medical materiel.



This portfolio provides a comprehensive listing of the products USAMRMC provides or plans to deliver to protect and treat Warfighters who serve the nation. Products the Command develops fall into the following groups in this portfolio: Military Infectious Diseases, Combat Casualty Care, Military Operational Medicine, Clinical and Rehabilitative Medicine, Medical Chemical and Biological Defense, Advanced Technologies, and Logistics. An overview of each group's mission and challenges precedes the group's current product listing.

The section that begins on page xiv entitled "Work With Us" offers additional insight on how researchers and businesses can develop working relationships with the Command. For example, one product may take the Small Business Innovation Research (SBIR) route, another may be the result of a CRADA.

Products are described as completed, promising, or future. Completed products in the portfolio are examples of the Command's success stories. They have made it through the advanced development process and into the procurement system and can be purchased by units. Promising products are those closest to being put in a service member's hands. These are products that have crossed the boundary from the laboratory to advanced development. For example, vaccines and drugs in clinical trials and devices that are being evaluated and modified to fit users' needs are considered promising. One caveat is necessary here: When a vaccine or drug moves to the different phases of clinical trials, planners expect certain fail rates. For example, half of the drugs in Phase 1 trials do not make it to Phase 2, and a third do not make it from Phase 2 to Phase 3. Future products are in basic research in the laboratories. Some are in their early stages; some are awaiting funding to make the leap into advanced development.

Appendix A also provides valuable information on the Command's products. To give the reader an appreciation of advances the Command's scientists have made over the years, it lists licensed technologies from USAMRMC laboratories and the patents the Command holds or held before they expired. Appendix B provides a list of acronyms that are used throughout the book.



Combat Casualty Military Operatio Clinical and Rehabilitative Medicine

Medical Chemical and Biological Defense

Advanced echnologies

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U.S. Army Research Institute of Environmental Medicine

U.S. Army Medical Research Institute of Chemical Defense

USAMRMC Headquarters

6th Medical Logistics Management Center Congressionally Directed Medical Research Programs Telemedicine and Advanced Technology Research Center U.S. Army Center for Environmental Health Research U.S. Army Medical Materiel Agency U.S. Army Medical Materiel Development Activity U.S. Army Medical Research Acquisition Activity

U.S. Army Medical Research Institute of Infectious Diseases

Walter Reed Army Institute of Research

Armed Forces Medical Examiners

U.S. Army Dental and Trauma Research Detachment

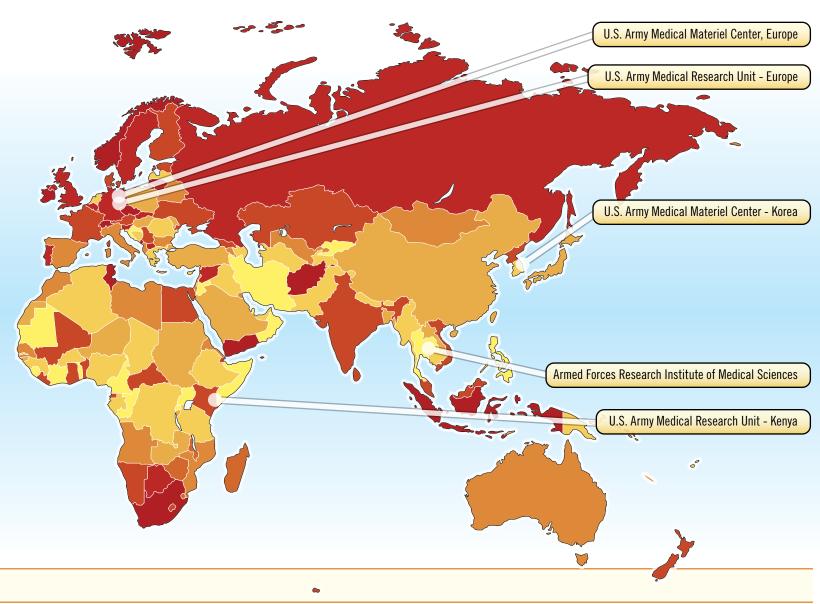
U.S. Army Institute of Surgical Research

U.S. Army Medical Research Detachment

U.S. Army Aeromedical Research Laboratory

National Museum of Health and Medicine

USAMRMC WORLDWIDE PRESENCE



Clinical and Rehabilitative Medicine Medical Chemical and Biological

Advanced Technologies

WORK WITH US

Research Opportunities

USAMRMC funds a broad range of extramural research programs.

Submit a Proposal

Awards are usually contracts, grants, or cooperative agreements. Research proposals can be submitted to the Command through the USAMRMC Broad Agency Announcement (BAA), which is continuously open, or through special USAMRMC BAAs, which are open for limited time frames.

BAAs and additional information can be viewed at www.usamraa.army.mil by selecting the "BAA" button.

USAMRMC currently has the following research funding opportunities:

- The Army SBIR program is a contract program for small businesses supporting defense and commercial applications.
- The Small Business Technology Transfer Research program is a companion program to the SBIR program. It differs only in the requirement that work must be performed by small businesses in collaboration with nonprofit research organizations.
- The Office of the Secretary of Defense SBIR program is a contract program for small businesses supporting defense and commercial applications.
- The Chemical–Biological SBIR program is limited to chemical and biological defense topics.
- The Defense Experimental Program to Stimulate Competitive Research promotes defense-related research and development in states not traditionally receiving significant amounts of federal support for science and engineering.
- The Soldier Enhancement Program identifies and evaluates commercially available items to increase the effectiveness of individual Warfighters.

For questions about these funding programs, call the USAMRMC Plans and Programs Office at 301-619-3354 or visit https://mrmc.amedd.army.mil.

Business Opportunities

Businesses have several ways of pitching products to USAMRMC.

New Products and Ideas Web Site

The Command recognizes that unsolicited proposals with unique and innovative products or ideas that have been developed outside of the government can help it accomplish its mission. To submit a new product or idea for consideration, visit www.usamraa.army.mil and click the "New Products and Ideas Submission" button.

Small Business Programs

The Command makes a concerted effort to forge strategic alliances with various small businesses that offer innovative products, quality services, and dynamic business solutions in support of many Department of Defense initiatives.

Visit the Office of Small Business Programs at www.mrmc.smallbusopps.army.mil to learn more about how small businesses can work with the Command.

Vendor Days

The U.S. Army Medical Materiel Agency, along with other medical professionals at Fort Detrick, Maryland, routinely schedules Vendor Days for medical equipment and supply vendors to display products to multiple organizations at one time. For more information on Vendor Days, visit http://www.detrick.army.mil/services/vendorday.cfm.

Technology Transfer

The Command's Technology Transfer Office coordinates all intellectual property licensing from the federal sector to nonfederal parties on behalf of all the Command's subordinate laboratories.

Visit https://technologytransfer.amedd.army.mil to discover technology available for licensing through issued patents and published pending patents.



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OVERVIEW

Infectious diseases debilitate service members and can influence battle outcome. Infectious diseases in the military cause lost duty time; increase the medical logistical burden for diagnosis, treatment, and evacuation; and decrease combat effectiveness.

Many hospital admissions among U.S. service members in Vietnam were attributed to infectious diseases, including malaria, dengue, scrub typhus, and Japanese encephalitis. Dengue and malaria caused hospitalizations in Somalia, and dengue and diarrhea afflicted troops in Haiti. Diarrhea remains a major cause of illness among deployed service members supporting Operation Enduring Freedom in Afghanistan and Operation Iraqi Freedom in the Persian Gulf. Additional infectious disease threats to service members include hepatitis, leishmaniasis, meningococcal disease, human immunodeficiency virus (HIV), hantavirus infections, and other hemorrhagic fever viruses. Many environments to which service members deploy harbor specific infectious disease hazards. The Military Infectious Diseases Research Program (MIDRP) focuses on prevention, diagnosis, and treatment of naturally occurring disease-causing microorganisms with major impact on mission effectiveness. Research emphasis includes the following:

- Developing vaccines against infectious diseases important to the U.S. military
- Discovering and developing drugs to prevent and treat militarily relevant infections
- Creating techniques to identify disease-causing microorganisms and diagnose infections rapidly
- Collecting and analyzing epidemiological data to optimize infectious disease control strategy
- Evaluating methods to control vectors (insects and arthropods that carry disease-producing microorganisms) of relevant infectious diseases

The program is enhanced by numerous facilities, including eight infectious disease research laboratories around the world, accredited animal and biosafety level 4 containment laboratories, a pilot vaccine facility, and clinical trials units. Most of the associated 330 scientists employed by the military, civil service, or contracting companies have advanced degrees. The program maximizes research dollars by collaborating with industry and universities through more than 100 cooperative research and development agreements.

Vaccines

The discovery and development of vaccines to protect the Warfighter are priorities for the MIDRP. Vaccines can be administered prior to deployment and provide long-term protection thereby reducing disease incidence and the associated medical logistics burden (which includes transportation of preventive countermeasures to prevent illnesses for which no vaccines are available as well as medical equipment for ill Warfighters). The U.S. military's infectious diseases program has played a significant role in the development of 11 licensed vaccines:

- Rubella (1969)
- Adenovirus 4 and 7 vaccines (1980, 2011)
- Tetravalent meningococcal vaccine (1981)
- Hepatitis B vaccine (1981)
- Oral typhoid vaccine (1989)
- Japanese encephalitis vaccine (1992, 2009)
- Hepatitis A vaccine (1995)

More than half of the vaccines routinely given to service members were codeveloped by the military. Development of other vaccines was supervised by investigators who began their careers at military research centers (e.g., yellow fever vaccine by former Army Surgeon General William Gorgas; mumps, measles, and varicella vaccines by Maurice Hilleman; and oral polio vaccine by Albert Sabin). Vaccines currently in advanced development stages include new adenovirus vaccines as well as vaccines for dengue and hepatitis E.



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Drugs

The MIDRP has contributed to the development of most of the synthetic drugs licensed in the United States for the prevention and treatment of malaria, including:

- Chloroquine (1949)
- Primaquine (1952)
- Chloroquine-primaquine (combined drug, 1969)
- Sulfadoxine-pyrimethamine (1983)
- Mefloquine (1989)
- Doxycycline (1992)
- Halofantrine (1992)
- Atovaquone-proguanil (2000)
- Intravenous artesunate (U.S. Food and Drug Administration [FDA] approved investigational new drug protocol #76,725 in 2010)

MIDRP researchers also developed the current dosing regimen for treating cutaneous leishmaniasis with the drug pentostam. Other antileishmanial drugs discovered and developed by MIDRP scientists are WR6026 (sitamaquine) for the treatment of visceral leishmaniasis and a third-generation topical formulation of two aminoglycosides (paromomycin and gentamicin) in a hydrophilic carrier (WR279,396) for the treatment of cutaneous leishmaniasis. WR279,396 is presently in Phase 3 studies. Equally important is the use of WR6026 as prophylaxis against transfusion-transmitted American trypanosomiasis also called Chagas disease.

Diagnostics and Vector Control

MIDRP products include fieldworthy devices to diagnose human infections rapidly (such as leishmaniasis and malaria) and to determine if insects are carrying infectious agents transmissible to humans (such as malaria parasites and dengue virus). Nucleic acid-based, polymerase chain reaction assays developed on multiple platforms allow infectious agents carried by ticks, sandflies, and mosquitoes to be detected at a deployed area medical laboratory. Additional products include insect repellents, a camouflage face paint/insect repellent, and computer-based systems to identify insects capable of transmitting human diseases.

Other Contributions

Licensed products reflect only a small portion of the contributions of the U.S. military to infectious diseases research. Contributions range from the demonstration that yellow fever was transmitted by a virus by Major Walter Reed in 1900 to the treatment of cholera by Captain R.A. Phillips in the 1940s (which led to the development of oral rehydration solution) to the publication of the complete malaria genome in 2000. U.S. military physicians have authored and coauthored thousands of research publications elucidating the etiology, ecology, epidemiology, and pathophysiology of many infectious diseases, leading to effective treatment and control measures. Additionally, long-term deployment of military scientists to Department of Defense (DoD) laboratories in the tropics over the past 100 years has accelerated scientific discoveries and product development and assisted technology transfer of research techniques and tropical disease control measures to developing countries.

Diarrheal Diseases

Diarrhea afflicts up to 50 percent of troops deployed to high-risk areas. Currently, no guaranteed protective measures exist, and the global problem of antimicrobial-resistant, diarrhea-causing microor-ganisms may limit treatment options. Candidate vaccines for major causes of bacterial diarrhea, including enterotoxigenic *Escherichia coli* (ETEC), *Shigella*, and *Campylobacter*, are being developed and evaluated by the MIDRP.

Drugs to Prevent and Treat Malaria

Malaria is rated the most important infectious disease threat facing U.S. troops worldwide. Malaria may cause severe illness and death among U.S. service members sent to tropical and some subtropical regions. The malaria threat is exemplified by the experience of 225 Marines briefly deployed to Liberia in 2003. *Falciparum* malaria was identified in 80 Marines, and 5 persons were noted to have severe and complicated infections. The MIDRP is developing new drugs to prevent infection and accelerate recovery from severe and multidrug-resistant infections. Because malaria parasites eventually develop mechanisms to resist the effect of antimalarial drugs, each drug is only useful for approximately 10–15 years, necessitating continuous replacement drug development efforts.

Malaria Vaccines

The MIDRP is developing vaccines to protect against *Plasmodium falciparum* and *P. vivax* as a long-term solution for the most significant infectious disease threat to U.S. forces. A vaccine with approximately 80 percent efficacy will improve operational capabilities by minimizing malaria casualties and potentially decreas-



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Appendice

ing the need to use malaria drugs thus avoiding drug-associated side effects and compliance issues. The most advanced malaria vaccine, RTS,S/AS01, undergoing licensure trials in pediatric populations in sub-Saharan Africa today, was codeveloped by GlaxoSmithKline (GSK) and Walter Reed Army Institute of Research (WRAIR) scientists. Extensive efforts are under way to improve the efficacy of this vaccine from 50 percent to a target goal of 80 percent. The medical logistic burden associated with the need for administration of drug prophylaxis and medical diagnosis, evacuation, hospitalization, and intensive treatment will be reduced.

Dengue Fever Vaccine

Dengue fever is a painful viral disease caused by a bite from an infected mosquito. Dengue is a leading cause of hospital admission in units operating in the tropics. There is currently no vaccine or drug to prevent or treat the disease. The MIDRP manages a program focusing on pathogenesis studies, diagnostics, and vaccine development to protect against the four types of dengue virus.

Leishmaniasis

Leishmaniasis is a disease caused by protozoan parasites of the genus *Leishmania* transmitted by phlebotomine sandflies that has afflicted more than 1,500 U.S. service members stationed in Iraq. Leishmaniasis includes a wide spectrum of illnesses ranging from the self-healing cutaneous form to a life-threatening visceral disease. This program is focused on diagnostic assays to detect active *Leishmania* infection in theater, diagnostic assays to detect latent *Leishmania* infection in troops deployed in the endemic area (with concern for blood supply), and licensing an FDA-approved, systemic, nonparenteral treatment for cutaneous leishmaniasis.

Scrub Typhus Vaccine

Scrub typhus is caused by a bite from an infected mite or chigger and can cause fever and rash with a long convalescence or death. The disease is prevalent in Asia, Australia, and many Pacific Islands. Outbreaks occurred in the U.S. military in 2001. The MIDRP is developing diagnostic tools to detect infections in humans and a vaccine that can protect individuals from multiple strains of scrub typhus.

Meningococcus Type B Vaccine

Meningitis is a bacterial disease transmitted by human aerosol and is potentially life threatening or permanently debilitating. The threat to service members primarily occurs during basic training but is also prevalent in sub-Saharan Africa, South America, and Asia. Even a single case can be disruptive to troops. The DoD successfully developed meningococcal vaccines for types A, C, Y, and W-135. The MIDRP effort is now focused on type B.

Lethal Virus Countermeasures

Hantaviruses are usually transmitted to humans via aerosols created by infected rodent excreta. The four distinct hantaviruses that cause hemorrhagic fever with renal syndrome (HFRS) are endemic throughout Asia and Europe. There have been thousands of occurrences of HFRS causing illness (often necessitating evacuation and extensive long-term care) and death in U.S. troops. The MIDRP is pursuing DNA vaccines to prevent HFRS.

Diagnostic Systems

There is an urgent demand for fieldworthy methods to rapidly diagnose infectious diseases. This is particularly relevant given concerns about biological warfare. Timely and accurate diagnosis will permit appropriate medical treatments and other protective measures. MIDRP scientists are developing scientific assay sets suitable for a variety of assay platforms.

Identification and Control of Insect Vectors

Seventy percent of deployed military personnel experience problems related to biting insects. The current military repellent is a greasy compound that dissolves plastic, is removed by abrasion or wetting, and is not popular with U.S. service members. The MIDRP is developing a new standard military insect repellent that is effective and has improved acceptability.

Military HIV Research Program

Military personnel can become infected by HIV via blood transfusions, accidental blood exposure while providing humanitarian assistance, or sexual exposure. HIV impacts troop strength of U.S. and allied forces and the political and economic stability of developing nations. Research focuses on the development of a global HIV-1 vaccine. Field sites have been established in Uganda, Kenya, Tanzania, and Thailand. Research management is shared by the MIDRP, advanced development programs of the U.S. Army Medical Research and Materiel Command (USAMRMC), and the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID).



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Adenovirus Vaccine, Types 4 and 7

Description

Adenovirus Vaccine is an orally administered, enteric-coated tablet containing live adenovirus serotypes 4 or 7 and is used almost exclusively by the military. It will prevent acute respiratory disease (ARD) caused by adenovirus (types 4 and 7) that frequently occurs in Soldiers, Sailors, Airmen, and Marines living in barrack-type environments during basic training. Prevention of adenovirus-related ARD will result in decreased recycling of recruits, due to missed training or hospitalization, and considerable cost savings.

The symptoms of ARD are pharyngitis, rhinitis, and pneumonia, and the illness often leads to lost training time. In the absence of vaccine, about 60 percent of ARD cases are due to adenovirus infection. Scientists at the National Institutes of Health and WRAIR developed an Adenovirus Vaccine, oral tablets containing live virus types 4 and 7, which were used for more than two decades. Millions of recruits received the vaccine, and it was shown to be both safe and effective. Failure to upgrade the production facility led to the termination of vaccine production in the 1996. A project to restore the vaccine is currently under way. A new facility has been built to produce types 4 and 7 vaccine in compliance with current FDA standards. Test and evaluation of the new vaccine was completed at Army and Navy basic training commands. The Biological License Agreement was approved by the FDA in March 2011.

Partners

- WRAIR
- USAMMDA
- NHRC
- Teva Women's Health, Inc. USA (A subsidiary of Teva Pharmaceuticals)



Aerosol Generator, Ultra-Low Volume, Electric

Description

The Aerosol Generator, Ultra-Low Volume, Electric (AGULVE) is used for dispensing pesticides in the form of fog. It is a lightweight unit for pesticide fogging operations composed of a spray head and pump that is powered from a vehicle's electric power supply. Completed in 1993, AGULVE improves the sustainability of U.S. forces in regions of the world where disease-carrying insects reside.

- USAMMDA
- Beecomist

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Camouflaged Bednet Shelter

Description

The Camouflaged Bednet Shelter is used to protect service members from insects. It is a self-supporting, low-profile shelter that contains a collapsible support structure and is impregnated with a quick-acting insecticide for knock-down effect. Completed in 2004, it provides improved protection against biting insects and improves service member survivability and sustainability in regions of the world with insect-transmitted diseases.

Partners

WRAIR



Combined Camouflage Face Paint

Description

Combined Camouflage Face Paint (CCFP) with DEET insect repellent improves U.S. troop survivability and sustainability in regions of the world where diseases are transmitted by biting insects. Inclusion of insect repellent protection reduces nuisance factors by repelling insects near the face, helping to reduce diseases (e.g., malaria and dengue fever) transmitted by biting insects. CCFP blends face paint with DEET to provide a minimum of 8 hours of protection against biting insects.

CCFP was completed in 2003 and is packaged in a compact container with a mirror on top and compartments on the bottom providing 20 applications of the loam, green, and sand colors and 10 applications of the black and white colors. A product improvement effort to reformulate and package CCFP in stick-type dispensers is projected to be complete in 2011. All CCFP formulations will be used by individual service members for protection against biting insects. In addition, the face paint reduces a service member's near-infrared signature providing protection against detection by night vision goggles and allowing for assimilation into the military theater environment.

- WRAIR
- USAMMDA
- NSRDEC
- Iguana LLC

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Doxycycline (Vibramycin)

Description

Doxycycline (Vibramycin) is a drug used to treat malaria. It was developed originally as an antibacterial agent with useful antimalarial properties against tissue malaria parasite forms. It is effective against chloroquineresistant malaria parasite strains with fewer adverse effects than mefloquine; however, it requires daily administration, is slow-acting, and is associated with adverse effects that may impact daily compliance. This drug should not be administered to pregnant women or children. A new indication was completed in 1992.

Partners

• WRAIR



Electronic Surveillance System for the Early Notification of Community-Based Epidemics

Description

The Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) is a system proposed for the early detection of infectious disease outbreaks at military treatment facilities. Data from patient symptoms are instantaneously recorded at a patient's visit and uploaded into ESSENCE, which also contains Ambulatory Data System diagnoses from 104 primary care and emergency clinics within a 50-mile radius of Washington, DC. Diagnostic codes are grouped into "syndromic clusters" consistent with emerging infections, including bioterrorism. Once an outbreak is suspected, the system dispatches an epidemic control team that may include epidemiologists, statisticians, and laboratory personnel.

Partners

- WRAIR
- DoD GEIS



Global Emerging Infections System

Description

The Global Emerging Infections System (GEIS) is a communications system supporting medical surveillance activities. In the United States, GEIS units are located in California, Texas, Virginia, and Washington, DC. Overseas they are located in Peru, Egypt, Thailand, Indonesia, and Kenya. Together, these assets represent a global health care system, connected by a worldwide, state-of-the-art communication system using a relatively standardized information technology infrastructure for supporting medical surveillance activities. GEIS facilitates early recognition and control of new disease problems that threaten national security.

Partners

WRAIR

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Hepatitis A Vaccine (Havrix®)

Description

The Hepatitis A Vaccine (Havrix) is an inactivated viral vaccine for the prevention of hepatitis A infection. It prevents epidemics during deployments to endemic regions and areas with suboptimal sanitation, water, and waste systems, as well as at military posts. Havrix replaced the use of immune serum globulin that required repeated injections, was not readily available, and was impractical to distribute during large deployments. Havrix was completed in 1995.

Partners

- WRAIR
- USAMMDA
- GSK



Hepatitis B Vaccine

Description

The Hepatitis B Vaccine (Heptavax B) is used to prevent hepatitis B infection. It was previously produced by using plasma from infected individuals and is now produced by recombinant methods in yeast cells. It prevents hepatitis B infection transmitted by blood and body fluid exposure. Completed in 1981, the Army contributed to the epidemiology and hepatitis B vaccine subtyping efforts.

The use of Heptavax was discontinued in 1990, and currently two recombinant hepatitis B vaccines are available for use (Engerix-B[®] [GSK] and Recombivax HB[®] [Merck].

Partners

• WRAIR



Influenza Virus Vaccine

Description

The Influenza Virus Vaccine is used to prevent influenza infection. The U.S. military helped develop one of the first FDA-licensed vaccines for the prevention of influenza infection composed of inactivated whole influenza virus. The vaccine prevents influenza infection and its rapid epidemic spread in close guarters and contact that otherwise can significantly impact military readiness and civilian productivity and potentially lead to death in the very young and old. It was completed in 1945. The U.S. military does not currently manufacture influenza vaccines, but GEIS contributes pertinent epidemiologic data regarding current influenza vaccine preparation.

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Japanese Encephalitis Vaccine (IXIARO^R)

Description

Japanese Encephalitis Vaccine is used to protect against Japanese encephalitis. It affords U.S. forces the ability to deploy to Asia without the risk of contracting the severe Japanese encephalitis disease. Japanese encephalitis is a potential threat to U.S. forces throughout Asia. Mosquitoes that breed in rice fields transmit the virus to susceptible people. The virus can cause brain infection (encephalitis), which requires intensive medical treatment and evacuation. Outbreaks occur in Asia, the Pacific Islands, northern Australia, and Russia. Japanese Encephalitis Vaccine was licensed in 1992 and is used to immunize approximately 80,000 troops each year. In 2005, the U.S. distributor of the vaccine notified the DoD that manufacturing of the vaccine in Japan would stop while a new vaccine was developed.

Korean and Army scientists working at WRAIR succeeded in inventing and patenting a new Japanese Encephalitis Vaccine made from virus grown in cell culture, purified, and inactivated with formalin. The vaccine eventually was developed by Intercell and Vienna, Austria. Clinical trials were conducted in many locations, including WRAIR. In 2009, the new vaccine was licensed by the FDA. The Defense Supply Center awarded Intercell a contract to supply the DoD with the new Japanese Encephalitis Vaccine. The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices published guidelines for vaccine use.

Partners

- WRAIR
- USAMMDA
- Intercell Biomedical



Meningococcal Vaccine (Menomune)

Description

The Meningococcal Vaccine, Menomune, is used to prevent meningococcal infection. It is a tetravalent vaccine, composed of purified components from the polysaccharide coating (A, C, Y, and W-135 but not B), used against the *Neisseria meningitidis* bacteria that is transmitted by respiratory droplets under close person-to-person contact. The vaccine prevents meningococcal infections that, if invasive, can lead to meningitis and sepsis with a 10–30 percent fatality rate. In addition, it reduces the risk of meningococcal disease outbreaks among military recruits and service members. Menomune was completed in 1981.

- WRAIR
- Sanofi Pasteur

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Oral Live Typhoid Vaccine (Vivotif)

Description

Oral Live Typhoid Vaccine (Vivotif) is a live, attenuated oral vaccine used to protect against Salmonella typhi bacterium infection that is caused by the ingestion of contaminated food or contact with contaminated feces and can be spread by a healthy carrier of the bacterium. This vaccine prevents typhoid fever, an acute generalized illness with fever, headache, abdominal pain, mild rash, and bowel movement and mental changes. In combination with hygiene control, the vaccine reduces the likelihood of epidemic spread of the disease, particularly in areas that lack clean water and effective sanitation systems. Vivotif was completed in 1989.

Partners

- NMRC
- Berna Biotech Ltd.



Pesticide Dispersal Unit, Multicapability, Helicopter Slung

Description

The Pesticide Dispersal Unit, Multicapability, Helicopter Slung is a multimode (solid/liquid) pesticide sprayer used for insect control that is powered by a hydraulic motor and attached beneath a helicopter via a sling with a cargo hook and controlled within the helicopter. This unit will improve the sustainability of U.S. forces in disease-carrying, insect-infested regions of the world. Completed in 1993, it was used successfully after Hurricane Andrew hit southern Florida in 1992.

Partners

• USAMMDA



Rubella Vaccine (Meruvax, now Meruvax II)

Description

Rubella Vaccine (Meruvax II) is a live, attenuated viral vaccine for the prevention of rubella (German measles), which spreads person-toperson via respiratory droplets, causes fever and rash, and can lead to serious fetal malformations in pregnant women. Completed in 1969, the introduction of the vaccine to the United States during the same year resulted in a drop from 47,745 cases (for the 3 years prior) to 345 cases in 1998. As of 2005, rubella virus infection has been eliminated in the United States.

- WRAIR
- Merck

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Chloroquine (Aralen)

Description

Chloroquine (Aralen) is an antimalarial drug for both the treatment and prevention of *P. falciparum* and *P. vivax* malaria. It has rapidly controlled the clinical symptoms of susceptible malarias and is useful in prevention when taken once a week. Completed in 1949, the emergence of chloroquine-resistant malaria parasites has limited the use of this drug.

Partners

- WRAIR
- Abbott
- Eli Lilly and Company
- E.R. Squibb and Sons
- Sanofi-Synthelabo
- Sharp and Dohme, Inc.
- Winthrop



Primaquine

Description

Primaquine is an antimalarial drug used for the treatment and prevention of relapsing malaria following *P. vivax* and *P. ovale* infections. It attacks the liver stage of malaria parasites and reduces recurrent malaria caused by latent forms of the malaria parasites present in the liver after cessation of a prior preventive such as chloroquine. It also prevents malaria infection. Primaquine was completed in 1952.

Partners

- WRAIR
- University of Chicago
- Winthrop-Stearns, Inc.



Sulfadoxine-Pyrimethamine (Fansidar)

Description

Sulfadoxine-Pyrimethamine (Fansidar) is a drug used for the treatment and prevention of malaria, particularly chloroquine-primaquineresistant types, which acts by blocking folic acid to prevent replication of the malaria parasites. The occurrence of infrequent, but serious, adverse allergic reactions limits its use except in countries where chloroquineresistant malaria is widespread and other drugs are not available. Sulfadoxine-Pyrimethamine (Fansidar) was completed in 1983.

- WRAIR
- Hoffmann LaRoche, Inc.

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Malaria Rapid Diagnostic Device

Description

Malaria constitutes a serious infectious disease threat to U.S. forces in times of war and peace in most tropical and some subtropical regions of the world. The Malaria Rapid Diagnostic Device (MRDD) permits field diagnosis of malaria infection and early intervention. Malaria is a potentially fatal illness with the ability to quickly incapacitate large numbers of personnel. Diagnosis must be rapid to initiate proper therapy in infected persons and prevent infection in others.

The MRDD is a field-deployable, handheld, disposable, point-of-care test to detect the presence of malaria parasites in blood samples of persons with symptoms compatible with malaria. The MRDD test follows a simple procedure where a whole blood finger-stick sample is added to a sample pad. After 15 minutes, the results are displayed in a small window on the device. The speed and simplicity allow diagnosis and targeted treatment to occur in the same patient visit, allowing for improved patient outcomes. The MRDD kits were completed and FDA cleared in September 2009. The MRDD kits are marketed worldwide.

- WRAIR
- USAMMDA
- Binax, Inc.



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Atovaquone-Proguanil (Malarone)

Description

Atovaquone-Proguanil (Malarone) is a combination of two existing drugs for the treatment of *P. falciparum* malaria that acts on the malaria parasite by inhibiting essential synthesis pathways. The combination of drugs has an enhanced effectiveness over singledrug treatments for malaria and reduced side effects compared to other antimalarial drugs. Atovaquone-Proguanil (Malarone) was completed in 2000.

Partners

- WRAIR
- USAMRU-K
- GSK



Chloroquine-Primaquine

Description

Chloroquine-Primaquine is a combination of two antimalarial drugs used in the treatment of *P. vivax* infection (see also Chloroquine and Primaquine). Combining the two drugs into a single treatment yields improved compliance with the two-drug treatment for relapsing . Chloroquine-Primaquine was completed in 1969.

- WRAIR
- Sanofi-Synthelabo

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Diarrheal Disease Supplement

Description

Rehydration and antimicrobial treatment are the cornerstones of disease management, but even with early institution of appropriate therapy, diarrheal diseases exact a cost in terms of lost duty and effectiveness. An effective supplement that will aid in the treatment of diarrheal disease will enhance the sustainability of troops in regions of the world where diarrheal illnesses and dysentery are endemic.

There is no licensed drug or biologic that provides a safe, effective mode of prevention against diarrheal diseases, leaving an important deficiency in military and travel medicine. This project is developing bovine milk immunoglobulins as a supplement with activity against ETEC, the predominant cause of traveler's diarrhea. The first of two clinical trials was completed in 2006. The trial showed that anti-adhesin BIgG antibodies afford significant protection against ETEC. Three additional clinical trials to be conducted during 2007–2008 are expected to solidify the foundation for future development of a product suitable for field testing.

- CDMRP
- NMRC



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Intravenous Artesunate for Treatment of Severe Malaria

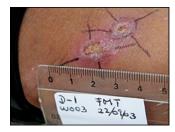
Description

Malaria constitutes a serious infectious disease threat to U.S. forces in times of war and peace in most tropical and some subtropical regions of the world. Even with the most sophisticated preventive drugs and strategies, there will still be cases of malaria. Because of this, our troops will be at risk of dying from severe malaria when a patient is comatose or cannot take oral drugs.

Quinidine gluconate has been the only parenteral drug available in the United States to treat U.S. military and civilian personnel who may get severe malaria. Unfortunately, quinidine has significant cardiotoxic activity and can induce heart failure. Therefore, the use of quinidine requires constant monitoring in an intensive care setting. A safer treatment for severe malaria is needed.

Intravenous Artesunate will be used to treat severe malaria. Artesunate in an intravenous form is being developed as a replacement for quinidine. Artesunate is a derivation of the compound artemisinin, an antimalarial drug extracted from the Chinese herb *Artemisia annua*. The safety profile of artesunate is well established because it is used as a non-GMP (good manufacturing practice) drug in many parts of the world. The MIDRP is developing an FDA, GMP version of the drug for use in the United States and by U.S. troops.

- WRAIR
- USAMMDA
- Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.



Topical Antileishmanial Treatment Drug (Paromomycin)

Description

The topical antileishmanial cream will enhance the survivability and sustainability of U.S. forces in endemic regions by allowing for local early lesion treatment. Additionally, it will prevent morale and personnel problems in a unit due to the loss of affected personnel for treatment. Currently, affected personnel are evacuated out of the theater of operations for daily intravenous injections with highly toxic investigational pentavalent antimony drugs.

Cutaneous leishmaniasis is a potentially disfiguring and serious parasitic disease. Leishmaniasis is one of several names for various tropical diseases that are caused by protozoa of the genus *Leishmania*. The parasites are transmitted by sandflies in tropical and subtropical zones. The manifestations of this disease may be visceral, mucocutaneous, or cutaneous. This illness is predominantly found in tropical and subtropical areas in the Middle East, southwest Asia, the Mediterranean coast, sub-Saharan Africa, Mexico, and Central and South America. In addition, there have been confirmed reports of canine leishmaniasis cases in 21 states across the United States. Current therapy for cutaneous leishmaniasis requires intravenous administration of toxic, metal-based drugs (antimonials) that have undesirable side effects and toxicities including vomiting, diarrhea, pancreatitis, elevated liver enzymes, and at higher doses, pulmonary edema.

Paromomycin, a topical cream made from two aminoglycoside antibiotics (15 percent paromomycin, kills the *Leishmania* parasite, and .5 percent gentamicin, to prevent or limit secondary bacterial infections) formulated in an aquaphilic base, will allow for local early lesion treatment of simple and uncomplicated cutaneous leishmaniasis.

- WRAIR
- USAMMDA
- Pasteur Institute (Tunisia)
- Teva Pharmaceuticals USA

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Leishmania PCR Diagnostic Device

Description

The *Leishmania* PCR Diagnostic Device is a SmartCycler-based qualitative detection of leishmaniasis spp. 16S rDNA and for the differentiation of *L. major* DNA from skin lesion scrapings and punch biopsies in individuals suspected of having cutaneous leishmaniasis. The device will take approximately 45 minutes to run and is highly specific and sensitive to both leishmaniasis genus and *L. major.* It is intended to be deployed worldwide at medical centers and at the WRAIR *Leishmania* Diagnostics Laboratory.

Partners

- WRAIR
- USAMMDA
- Cepheid



Leishmania Rapid Diagnostic Device

Description

The *Leishmania* Rapid Diagnostic Device (LRDD) is a disposable, point-of-care test that will rapidly detect the presence of *Leishmania* parasites in samples taken directly from skin lesions. It will take approximately 15 minutes to run and requires no special training to use. There are five sampling methods under evaluation to detect *L. major* and *L. tropica.* The LRDD will be able to be deployed as far forward as combat support hospitals, the threshold, and battalion aid stations, the objective location.

Partners

- WRAIR
- USAMMDA
- InBios International Inc.



Leishmania Skin Test

Description

The *Leishmania* Skin Test (LST) will be an FDA-approved intradermal test to screen U.S. service members who have been exposed to *L. tropica* parasites during deployment to leishmaniasis-endemic areas. The current diagnosis of leishmaniasis requires a microscopic exam of stained lesion smears or culture of parasites, capabilities not available to medical units.

The LST screening tool will take 48 hours and does not require an expert to read smears or culturing and indentifying parasites. The LST is currently in clinical trials with the industry partner sponsoring the Investigational New Drug and filing the ensuing license application with the FDA.

- WRAIR
- USAMMDA
- Allermed Laboratories, Inc.



Rapid Human Diagnostic Assays

Description

Arthropod-borne pathogens constitute a serious infectious disease threat to U.S. forces in times of war and peace in most tropical and some subtropical regions of the world. Rapid Human Diagnostic (RHD) and Rapid Vector Diagnostic (RVD) tests permit field diagnosis of many different disease infections and increase the chances for early intervention.

Many arthropod-borne pathogens cause serious illness with the ability to quickly incapacitate large numbers of personnel. Diagnosis must be rapid to initiate proper therapy in infected persons and prevent infection in others.

RHDs and RVDs are field-deployable, handheld, disposable, rapid tests to detect the presence of medically important pathogens (Rift Valley fever virus, Chikungunya, Japanese encephalitis, and others) in blood samples of persons with fevers of unknown origin compatible with the diseases. The RVDs detect the presence of medically important pathogens from the vector itself (e.g., mosquitoes, ticks, and sandflies). The RHD tests follow a simple procedure where a whole blood finger-stick sample is added to a sample pad. After just 15 minutes, the result can be read. This speed and simplicity allows diagnosis and targeted treatment to occur in the same patient visit, allowing for improved patient outcomes. The RVD tests follow a simple procedure where insects are ground in solution and a "dipstick" is added to the solution. Results are seen as bands on the sample pad. RHD kits are to be FDA approved whereas the RVD kits do not have the same requirements.

- WRAIR
- USAMRIID
- InBIOS
- Panbio
- VecTOR Systems

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Alternate Insect Repellent

Description

This new repellent will offer the greatest tactical flexibility of any arthropod-borne disease prevention strategy. Repellents can be applied effectively to prevent most arthropod-borne disease even if surveillance has not identified the pathogen. Repellents are often the only means of protection from arthropod-borne diseases in combat environments when vector control measures are not possible, when no vaccines exist for diseases in the deployment area of operations, or when the speed of military developments prevents the use of chemoprophylaxis or vaccines.

The current military insect repellent is ineffective against some disease vectors and has a very low service member acceptance rate. Because no commercially available repellents meet Army requirements, new effective repellent compounds and leading-edge formulation technologies are being explored and prioritized. A new military insect repellent that is completely acceptable to the user and maintains effectiveness under combat conditions is desired.

Partners

• WRAIR



Dengue Fever Vaccine

Description

Dengue Tetravalent Vaccine will prevent mission-degrading, potentially lethal occurrences of dengue fever and dengue hemorrhagic fever in service members who are deployed to tropical and subtropical regions of the world, increasing the survivability and sustainability of U.S. forces.

There are four serotypes of dengue virus. Each serotype causes an acute, incapacitating illness characterized by severe head, muscle, joint, and eye pain with fever lasting 4 to 7 days. Subsequent infection with a different dengue virus can occur and may result in the more severe often fatal hemorrhagic form of the disease. Because of this, a dengue vaccine must be protective against all four dengue virus serotypes (provide "tetravalent immunity"). Dengue fever is a leading cause of hospital admissions in units operating in the tropics. There are currently no licensed vaccines or drugs to prevent or treat dengue fever or the often fatal dengue hemorrhagic fever.

Numerous approaches are being considered to develop a dengue vaccine. The WRAIR/GSK Biologicals dengue vaccine is a tetravalent, classically attenuated live virus vaccine that currently is being evaluated in clinical studies. WRAIR and GSK also are collaborating on the early phase development of a purified inactivated virus (PIV) dengue vaccine; the PIV is in preclinical development. The NMRC is developing a DNA-based vaccine. Numerous variations on the DNA theme are being attempted but, to date, only one monovalent candidate has been tested in a Phase 1 clinical trial. Both WRAIR and NMRC have collaborated with Hawaii Biotech in evaluations of their recombinant protein vaccine candidates; Hawaii Biotech has completed a Phase 1 monovalent study and is positioning to execute a tetravalent Phase 1 study. Several of those above under development are candidates for "prime-boost" strategies of immunization. Preliminary results suggest that prime-boost immunization strategies may provide tetravalent immunity. Priming with DNA or live, attenuated followed by boosting with purified inactivated or subunit vaccines are promising candidates.

Dengue Tetravalent Vaccine ChimeriVax[™] is a candidate chimeric vaccine constructed using the dengue virus components inserted into a yellow fever virus backbone. The ChimeriVax proprietary process was developed by Acambis, Inc. USAMRMC currently is assisting Sanofi Pasteur, owner of Acambis Inc., in the clinical development of this vaccine.

- WRAIR
- USAMMDA
- NMRC

- USAMC-AFRIMS
- GSK Biologicals
- Hawaii Biotech Inc.

- Sanofi Pasteur (vaccines division of sanofiaventis Group)
- Vical Inc.

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Diarrheal Disease Vaccines

- Campylobacter Vaccine
- ETEC Vaccine
- Shigella Vaccine

Description

Vaccines against *Campylobacter*, ETEC, and *Shigella* will enhance the sustainability of U.S. forces. Diarrheal diseases affect up to 50 percent of U.S. service members early and continuously in deployments to disease-endemic areas. Currently, there are no totally effective preventive medicine measures or vaccines to protect troops against these threats.

Campylobacter Vaccine: Campylobacter infections are sometimes complicated by a usually temporary but potentially serious inflammatory neurological disorder called Guillain-Barre Syndrome. The association of an oral whole-cell-killed Campylobacter vaccine approach with Guillain-Barre Syndrome has precluded any additional whole-cell-killed or attenuated vaccine efforts. A second-generation, potentially improved, recombinant protein-based vaccine is nearing the clinical testing phase. Results of a new vaccine approach using capsule conjugates will be compared with the protein subunit results.

ETEC Vaccine: ETEC is a common etiologic agent of diarrhea in the Middle East irrespective of combat phase or operational tempo. Current research is focused on developing a purified protein subunit vaccine against ETEC. The target antigens in this vaccine strategy are the major ETEC colonization factor antigens and nontoxic derivatives of heat-labile enterotoxin.

Shigella Vaccine: Shigella is the most common pathogen during combat phases in U.S. operations in the Middle East. Vaccines against Shigella flexneri, S. sonnei, and S. dysenteriae are under development. Two promising approaches are being evaluated: Invaplex extracts of Shigella bacteria that induce immunity when sprayed into the nose and live Shigella vaccines that are genetically modified and safely induce immunity following ingestion.

- WRAIR
- NMRC



Drug for Malaria Prophylaxis

Description

New drug prophylactics and therapies used for the treatment of malaria will increase the survivability and sustainability of U.S. forces deployed in highly endemic areas.

The malaria parasite, transmitted by infected mosquitoes, is developing resistance to current antimalarial prophylactic drugs, and resistance is now widespread in Africa and Asia. Symptoms can be fever and flu-like including shaking, chills, headache, muscle aches, and tiredness. If not treated promptly, one type of malaria, *P. falciparum*, may cause kidney failure, seizures, mental confusion, coma, and death. Two other types, *P. vivax* and *P. ovale*, concentrate in the liver cells, eventually emerging into the blood and causing disease. The most dangerous species, *P. falciparum*, moves out of the liver and into the blood in just a few days.

Studies suggest that Tafenoquine suppresses both the liver and blood stages of the malaria parasite and their effects and also may block transmission from already infected individuals. Currently, Tafenoquine is under development as a radical cure and potential postexposure prophylaxis against *P. vivax* malaria as a replacement for Primaquine. Future studies will focus on Tafenoquine for prophylaxis against *P. falciparum*.

- WRAIR
- USAMMDA
- GSK

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Malaria Vaccines

- Recombinant Vaccine (RTS,S + Adjuvant)
- P. falciparum RTS,S + MSP-1
- Malaria DNA Vaccine and Prime-Boost Approaches
- Adenovirus Vaccine Against P. falciparum

Description

A safe, well-tolerated malaria vaccine will provide protection against disease and prevent blood-stage infection. *P. falciparum* is the most immediately lifethreatening type of malaria, causing massive destruction of the body's red blood cells. Currently, there are no licensed vaccines, and the malaria parasite continues to develop resistance to new drugs used for treatment or prevention. Initially, *P. falciparum* malaria vaccines were being developed, but a combined vaccine to protect against all types of malaria is the long-term goal.

Recombinant Vaccine (RTS,S + Adjuvant): One *P. falciparum* malaria vaccine candidate consists of the RTS,S recombinant malaria protein antigen combined with a proprietary adjuvant from industry partner GSK.

P. falciparum RTS,S + MSP-1: This vaccine consists of the RTS,S recombinant protein antigen combined with an additional malaria antigen component.

Malaria DNA Vaccine and Prime-Boost Approaches: Investigators have demonstrated substantial protection using a combination of malaria DNA and pox virus. Another approach has been to combine RTS,S with adenovirus 35 (an uncommon adenovirus serotype against which little natural immunity exists). The prime-boost combination will consist of RTS,S/Adjuvant + Adeno35CS vaccines.

Adenovirus Vaccine Against *P. falciparum*: A multicomponent adenovirus vaccine containing five promising antigens of *P. falciparum* will be used as a boost in combination with a DNA priming vaccine.

- WRAIR
- USAMRIID (Lethal Viruses)
- CDMRP (Adenovirus)

- USAMMDA (Prime-Boost: RTS,S/ Adjuvant + Adeno35CS)
- Army and Navy OCONUS Laboratories
- NMRC (Technology Base R&D)
- GSK (RTS,S + Adjuvant)



Meningococcal Type B Vaccine

Description

Meningococcal meningitis is fortunately uncommon but causes a devastating illness, and a single case of meningitis can result in major disruptions of military operations and training because of the need for preventive and assessment measures. Five types of meningococcus (A, C, Y, W-135, and B) cause 80 percent of meningococcal meningitis. DoD researchers have contributed to the development of a licensed tetravalent vaccine protecting against types A, C, Y, and W-135. Development of a vaccine protective against type B meningococcus is under way; the ultimate goal is a pentavalent vaccine. Candidate monovalent meningococcal Group B vaccines have been shown to provide protection against strains of the same subtype in 50 to 80 percent of vaccinated subjects, and work is continuing to develop a polyvalent vaccine to provide wider protection against Group B meningococcus.

Meningococcal meningitis is an acute bacterial disease that occurs commonly in young adults, in males more than females, and particularly in newly aggregated adults under crowded living conditions such as barracks. It is a threat to service members in basic and advanced training, especially during major military mobilizations. The disease is prevalent in sub-Saharan Africa and South America and is potentially life threatening or permanently debilitating. New, virulent Group B clones have caused prolonged epidemics in at least five countries during the past 20 years.

Monovalent Group B vaccines are effective in protecting against disease only if they are made from the specific strain of the organism causing the outbreak. A polyvalent vaccine derived from three different strains is being developed to provide broad coverage against Group B organisms. Both intranasal and intramuscular routes of administration are being examined.

Partners

• WRAIR

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Military HIV Research Program

- HIV Vaccine
- HIV Research Program

Description

An HIV vaccine will enhance survivability and sustainability of U.S. forces worldwide. Furthermore, an HIV vaccine will promote political, social, and economic stability, thereby deterring conflict and the need for U.S. intervention in areas where HIV is causing significant morbidity and mortality.

HIV poses a threat to U.S. military forces and is a national and global security issue. The magnitude of this disease is so great that it could destabilize foreign governments and slow economic growth worldwide. About 300 new cases of HIV occur annually among U.S. Army personnel, and it is estimated that 30 percent of these HIV infections are acquired during overseas deployments, predominantly from the less developed countries of sub-Saharan Africa, Asia, and South America. According to the Central Intelligence Agency, HIV/AIDS will probably cause more deaths than any other single infectious disease and account for at least half of infectious disease deaths worldwide by 2020.

HIV Vaccine: Currently, there is no effective vaccine to prevent HIV infections. A potential HIV vaccine candidate was evaluated in HIV-naïve volunteers using a prime-boost strategy. The HIV prime-boost vaccine consists of a prime with a recombinant canarypox virus expressing the products of three HIV-1 genes and a boost with a recombinant vaccine containing the envelope proteins for HIV types E and B. The prime-boost vaccine approach is being used to induce both cellular and humoral immunity to HIV. A clinical trial conducted by WRAIR in collaboration with NIAID/Thai Ministry of Public Health using this candidate demonstrated the first-ever success in preventing HIV infection. While this vaccine gave modest protection, the Military HIV Research Program (MHRP) is evaluating novel vaccination strategies using modified vaccinia Ankara as a delivery vehicle. Initial Phase 1 clinical trials conducted in the United States and overseas showed that these vaccines are safe and immunogenic.

HIV Research Program: The HIV Research Program is mandated to develop a safe and effective HIV-1 vaccine against all HIV-1 subtypes (A, B, C, D, and E). Regional overseas laboratories, along with additional research sites, play a key role in this effort to test candidate vaccines for global protection. The MHRP collaborates with many U.S. and international agencies and research institutes, including close collaboration with NIAID. Its successful partnerships with host country governments, universities, and community organizations help leverage research dollars and expertise, accelerating the progress toward a globally effective vaccine.



Vaccines to Prevent Hemorrhagic Fever with Renal Syndrome

Description

Vaccine products are designed to provide protection against all four hantaviruses and enhance the sustainability of U.S. forces in regions of the world where hantaviruses are endemic.

HFRS is a problem throughout Asia and Europe that has caused life-threatening illness in thousands of service members. The virus is usually transmitted to humans via exposure to aerosols created when infected rodents' urine, feces, or saliva is released onto environmental surfaces. After an incubation period of approximately 1–4 weeks, a patient may develop fever, kidney dysfunction, alterations of blood pressure, accumulation of fluid in the lungs, and blood-clotting problems.

Two vaccine approaches are under evaluation. The first is a DNA vaccine expressing Hantaan virus M segment expected to protect humans from HFRS caused by Hantaan virus, Seoul virus, and Dobrava virus but not Puumala virus. The second is a Puumala virus DNA vaccine expected to protect humans from HFRS caused by Puumala virus.

Partners

• USAMRIID

- WRAIR
- USAMMDA
- AFRIMS
- NIAID (prime-boost)
- Sanofi Pasteur
- VaxGen

Clinical and Rehabilitation

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Antimalarial Drugs

Description

Development of a new drug for the chemoprophylaxis of malaria will increase the survivability and sustainability of U.S. forces deployed in highly endemic areas. A safe, effective, and well-tolerated drug that will prevent malaria infection is required to replace current antimalarial drugs in use for which compliance is poor and parasite resistance is increasing.

The malaria parasite, transmitted by infected mosquitoes, is developing resistance to current antimalarial prophylactic drugs, and resistance is now widespread in Africa and Asia. Symptoms can be fever and flu like, including shaking, chills, headache, muscle aches, and tiredness. If not treated promptly, one type of malaria, *P. falciparum,* may cause kidney failure, seizures, mental confusion, coma, and death. Two other types, *P. vivax* and *P. ovale,* concentrate in the liver cells, eventually emerging into the blood and causing disease. The most dangerous species, *P. falciparum,* moves out of the liver and into the blood in just a few days.

No effective malaria vaccine yet exists, and currently employed personal protective measures are ineffective in the prevention of malaria. There are compliance issues, side effects, and potential resistance problems with currently used antimalarial drugs.

Efforts are now focusing on the development of a drug that will be administered orally with no more than a weekly dosing. Several candidates have been identified and are in early clinical trials for safety, efficacy, and proof-of-concept testing.

- WRAIR
- USAMMDA
- AFRIMS
- World Health Organization Medicines for Malaria Venture



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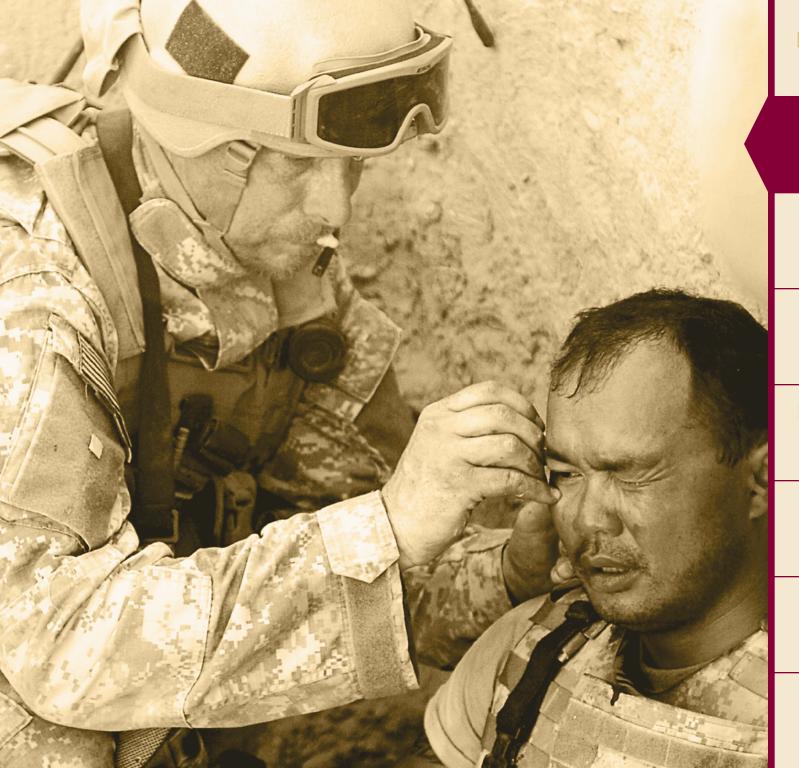
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OVERVIEW

Combat Casualty Care

Caring for combat casualties is constrained by logistics, manpower, and the hostile operational environment. Eighty-six percent of all battlefield deaths occur within the first 30 minutes after wounding, making the ability to rapidly locate, diagnose, and treat injuries vital to reversing the historical outcomes of battlefield injuries. The Combat Casualty Care Research Program's goals are to reduce the killed-in-action rate of American troops by 25 percent, reduce the morbidity of combat injuries, and reduce the medical footprint on the battlefield.

Several factors complicate providing combat casualty care. Military casualties may wait for hours before definitive health care can be provided. Initial treatment and subsequent evacuation occur in austere environments characterized by limited supplies and limited diagnostic and life-support equipment. Further, providing acute and critical care is labor intensive and must frequently be provided by non-physician medical personnel. The primary challenge for combat casualty care research is overcoming these limitations by providing biologics, pharmaceuticals, and devices that enhance the capability of first responders to effectively treat casualties as close as possible to the location and time of injury.

Minimizing Blood Loss and Optimizing Fluid Resuscitation

Since mid-World War II, nearly 50 percent of combat deaths have been due to exsanguinating hemorrhage. Of those, about half could have been saved if timely, appropriate care had been available. Postmortem study of casualties in Operation Iraqi Freedom suggests that up to 18 percent of all battlefield deaths can be prevented with improved measures to stop and treat severe hemorrhage associated with combat injury. The Army and Department of Defense (DoD) seek new technologies and products that can reduce morbidity and mortality of severe battlefield hemorrhage. The Army's research and product development efforts focus on discovery and development of technologies and products that enhance far-forward capabilities for control, resuscitation, and stabilization of casualties with severe hemorrhage and technologies that enhance capabilities for the preservation of vital tissues and reduction of morbidity and mortality as a consequence of severe hemorrhage.

Current technologies and products under investigation or in development include:

- Lyophilized plasma and platelets
- Cryopreserved (frozen) platelets
- Extended shelf-life (8 weeks) red blood cells
- Recombinant, activated factor VII and other blood clotting factors for treatment of clotting abnormalities associated with severe hemorrhage
- New bandages and other agents that may be applied to stop external bleeding
- Simple fluid warming and administration devices

- Treatments to enhance blood flow and oxygen delivery to vital tissues that can:
 - » Prevent cell death or organ failure
 - » Reduce or eliminate oxygen starvation and tissue injury associated with resupply of fluids during resuscitation
 - » Prevent secondary brain or spinal cord injury
 - » Prevent reduction of immune system protection and serious infection associated with shock and resuscitation
 - » Reduce injury to vital tissues by reducing demand for oxygen and other vital nutrients during shock
 - » Prevent bacteria from crossing the bowel wall into the blood stream as a consequence of shock
- Fieldable rapid test kits for testing walking blood donors for blood-borne pathogens and for blood typing
- Fundamental investigations of vascular and tissue responses to fluid resuscitation

Treatments for Battle and Non-Battle Injuries

This science and technology effort includes:

- Refining of closed-loop control algorithms for automated delivery of oxygen, ventilation, and fluids
- Development of noninvasive sensors to determine tissue viability and perfusion
- Identification and testing of techniques, drugs, and treatments to enhance vascular repair
- Techniques and assessments for commercial materiel developments applicable to surgical management of primary ballistics and thermal burn injuries

- Techniques for management of primary blast, crush, and chemical burn injuries
- Defining predictive vital signs for use in tools that assist in deciding to implement life-saving interventions
- Development of simulators for use in training caregivers on trauma treatment techniques

Examples of specific products or efforts that may be addressed include materiel for the pharmacological or surgical management of high-velocity ballistics, fragment, and blast injuries. Materiel of interest also includes agents, including autologous stem cells, which promote neuronal regeneration, bone repair and regeneration, and vascular healing and regeneration; treatment of chemical burns; and equipment and procedures for emergency airway management and mechanical ventilation of severely injured casualties.



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Meeting Program Goals

Combat Casualty Care

Battlefield conditions impose severe constraints on available manpower, equipment, and medical supplies for casualty care. A premium is placed on medical interventions that can be used on the battlefield or as close to it as possible, before or during medical evacuation, preferably by medical corpsmen. Medical materiel must be easily transportable (i.e., small, lightweight, and durable); devices must be easy to use, low maintenance, with self-contained power sources as necessary; and drugs and biologics, ideally, should not require refrigeration or other special handling.

More specifically, the program's efforts address:

- Products and methods that reduce the number of battlefield deaths due to hemorrhage
- Pathogen inactivation in blood products to reduce transfusioninduced morbidity and mortality
- Techniques and technologies that improve the acquisition and availability of blood products and reduce the medical and logistical requirements to care for battlefield casualties
- The best fluids and strategies for resuscitation to improve survival when evacuation is delayed and resources are limited
- Advanced, noninvasive physiologic sensors and diagnostics for detecting penetrating or blunt trauma wounding events and remote triage of visible wounds and traumatic brain injury
- Automated critical care life support
- Tissue regeneration
- Prevention and treatment of dental disease

- Neuroprotective treatment strategies that significantly improve the prognosis for a service member's functional recovery from brain and spinal cord injuries
- Technology and training aids to render self-aid and buddy aid

The resulting combat casualty care products listed in this section are divided into the following subcategories:

- Hemorrhage Control/Resuscitation Strategies
- Hard and Soft Tissue Injury
- Neuroprotective Treatment Strategies
- Trauma Management Systems
- Training
- Dental

Training

Two compelling needs underpin the Command's simulation and training technology research portfolio: (1) The DoD's requirement to train 100,000 military health care personnel annually and (2) increasing national interest in reducing medical errors. This spans from point of wounding, to combat casualty care, to surgical care given in fully equipped fixed medical facilities. An integrated research team, convened in February 2000, developed an integrated strategic plan. Research is being conducted in four general categories: (1) Personal Computer (PC)-based Interactive Multimedia, (2) Digitally Enhanced Mannequins, (3) Part-Task Trainers, and (4) Total Immersion Virtual Reality. Several funding sources are being invested: congressionally sponsored, Small Business Innovation Research (SBIR), innovation, and dual-use

funds. More than 150 separate projects—some small, some large—have been conducted with a cumulative investment of more than \$60 million since 1999, making it the DoD's largest investor in science and technology research. The strategy is to identify enabling technologies, mature them into components, integrate those components into simulation-based training systems, and validate them to determine the degree to which they transfer skills learned via simulation to the practice of actual patient care. The future plan is to (1) continue identifying and developing enabling technologies; (2) continue training transfer studies; (3) support open source and architecture standards; (4) facilitate convergences between science and technology research areas and surgical robotics, education and entertainment, and virtual reality applied to behavioral health; and (5) emphasize transition of products to relevant military and private sector end-user communities.



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Combat Casualty Care



Chitosan Hemorrhage Control Dressing (HemCon Bandage)

Description

The Chitosan Hemorrhage Control Dressing adheres to an injury site to form a clot and stop severe bleeding. This dressing is manufactured from chitosan, a natural biomaterial obtained from shellfish. Once applied, the Chitosan Hemorrhage Control Dressing tightly adheres to an injury site forming a durable clot. The dressing will stop severe external arterial and venous bleeding. The U.S. Food and Drug Administration cleared the dressing for external use in November 2002 and later expanded the dressing's indication to include use as an antibacterial barrier in June 2005. Named one of the Army's 10 Greatest Inventions for 2004, the development of a chitosan dressing for internal surgical use is currently under way. While effective, it has been replaced by a more flexible kaolin-treated gauze that performs better.

Partners

- USAISR
- USAMMA
- HemCon, Inc.



Combat Application Tourniquet

Description

The Combat Application Tourniquet (CAT) is a lightweight, easy-to-use tourniquet for hemorrhage control in severely bleeding extremities. The CAT is a strap-type tourniquet with a built-in stick or windlass for tightening. It allows rapid, effective control of extremity hemorrhage for self, buddy, or medic application in far-forward locations and is included as a component of the Improved First Aid Kit. The CAT was named one of the Army's 10 Greatest Inventions for 2005.

- USAISR
- USAMMA
- USAMMDA
- Program Executive Office Soldier
- North American Rescue



Combat Gauze

Description

Combat Gauze is a simple 3 inch x 4 yard sterile strip of gauze impregnated with kaolin. When used with direct pressure, the dressing is intended to stop or greatly reduce severe arterial, venous, or mixed bleeding in less than 4 minutes. Medics, combat lifesavers, and other military personnel will use Combat Gauze as the primary hemostatic dressing on the battlefield to aid in the control of severe hemorrhage in injured service members.

Partners

- USAISR
- USAMMA
- University of California, Santa Barbara
- Z-Medica



Demand Oxygen Controller

Description

The Demand Oxygen Controller senses breathing and oxygen rates and reduces the required amount of oxygen to one-third the usual amount needed for standard ventilation. It was completed in 1989.

Partners

• USAMMDA



Field Medical Oxygen-Generating and Distribution System

Description

The Field Medical Oxygen-Generating and Distribution System (FMOGDS) provides oxygen refill capabilities. The FMOGDS is a lightweight system that provides bedside and cylinder-refill oxygen capabilities. Completed in 1993, it provides greater mobility and flexibility with reduced logistics dependence on medical-grade oxygen resupply.

Partners

• USAMMDA

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Golden Hour Blood Container

Description

The Golden Hour Blood Container can hold red blood cells and needs no power source to maintain its internal temperature. It holds 4 units of red blood cells and uses a combination of vacuum-insulated panels and an internal container that has a liquid phasechange material like reusable freezer packs. At room temperature, units of blood cells can last 121 hours at well below freezing (-9°F) for more than 97 hours, and at 105°F, they are good for more than 78 hours. It extends the amount of time a medic can transport blood products and allows for extended evacuation times necessary for far-forward combat units. The Golden Hour Blood Container was named one of the Army's Greatest Inventions for 2003.

Partners

- WRAIR
- Minnesota Thermal Sciences



Hypothermia Prevention and Management Kit

Description

The Hypothermia Prevention and Management Kit consists of a water-resistant reflective blanket, a heat-reflective skull cap, and a Ready-Heat blanket. The Ready-Heat blanket has built-in chemical heating elements that can achieve 100°F–110°F in about 30 minutes and can sustain this temperature for more than 8 hours. The kit weighs 3 pounds and is disposable.

Partners

- USAISR
- North American Rescue
- Tech-Trade



Impedance Threshold Device

Description

The Impedance Threshold Device (ITD) is a small, lightweight plastic valve that attaches to a standard facemask or mouthpiece and acts as a temporary resuscitation device that requires no power. Use of the ITD results in a vacuum within the thorax during each inspiration to increase central blood volume and cerebral blood flow, reducing the risk of hemorrhagic shock. Completed in 2005, the ITD is used in Operation Iraqi Freedom.

Partners

USAISR



Improved First Aid Kit

Description

The Improved First Aid Kit (IFAK) was developed in response to the Tactical Combat Casualty Care Doctrine. The IFAK increases an individual service member's capabilities to provide self-aid/buddy aid and provides interventions for two leading causes of death on the battlefield—severe hemorrhage and inadequate airway. An IFAK is issued to every deploying service member via the rapid fielding initiative. The IFAK was completed in 2005. A new IFAK resupply kit is now available, and a second CAT will be added to the IFAK.

Partners

- USAMRMC
- USAMMDA
- Directorate of Combat and Doctrine Development
- Program Executive Office Soldier
- U.S. Marine Corps



Individual Chemical Resuscitation Device

Description

The Individual Chemical Resuscitation Device restores normal breathing to a battlefield casualty. This device provides manually operated, positive-pressure respiratory resuscitation to assist in the restoration of normal breathing of a battlefield casualty. It also filters chemical warfare agents from ambient air and can be used with an oropharyngeal mask or cricothyroid cannula. The Individual Chemical Resuscitation Device was completed in 1987.

Partners

• USAMMDA



Low-Power Blood Cooling and Storage Device

Description

The Low-Power Blood Cooling and Storage Device extends the capability of the current blood refrigerator and cools fresh whole blood using very low power requirements. It provides greater flexibility and reduces the logistical strain of storage at all levels of medical care from field hospitals to the battlefield. Completed in 2002, this device is being used in Operation Iraqi Freedom.

- USAMMDA
- Accutemp

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Advanced Technologies

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Optimal Fluid Resuscitation Guidelines

Description

Guidelines for the administration of resuscitative fluids by medics and forward-deployed medical personnel will provide optimal fluid resuscitation for wounded service members. Using current understanding, a set of guidelines was developed regarding optimal fluid resuscitation in injured Warfighters who have experienced substantial blood loss and may experience long delays in evacuation.

The guidelines will reduce or eliminate consequences frequently associated with fluid replacement after severe blood loss.

Partners

- USAISR
- WRAIR

2-10



Rapid Blood Sterilization System

Description

The Rapid Blood Sterilization System allows whole blood collection and use within a short time frame. This purification system allows medics to collect whole blood from a donor, sterilize it, and place it into a recipient in a matter of only a few hours. This system enables the rapid sterilization of blood products for use on the battlefield as well as for blood banks.

Partners

• USAMMDA



Rapid Intravenous Infusion Pump

Description

The Rapid Intravenous Infusion Pump is a portable, electronic infusion pump that delivers intravenous fluids to restore blood pressure and intravascular volume. It is battery operated and about the size of a deck of playing cards. It can be used far forward on the battlefield or in the transport of patients and is being used in the global war on terror.

Partners

WRAIR



Spray-On Protective Bandage

Description

The Spray-On Protective Bandage is an antimicrobial, flexible bandage that will reduce or eliminate blood and fluid loss, reduce or eliminate pain associated with motion, and protect wounds from environmental contamination. The bandage is capable of reducing or stopping blood and fluid losses, including compressible hemorrhage and amputation stumps after minimal tourniquet control. Wound stabilization is provided for 2 or more days after injury. It may be used in conjunction with enzymatic and chemical debridement.

This product is easily applied on the battlefield and allows mobility for the Warfighter with small wounds. Large wounds can be stabilized following initial treatment with compression-style and hemostatic dressings or minimal tourniquet use.

Partners

USAISR



Thermal Infusion System (formerly Cartledge Infuser)

Description

The Thermal Infusion System is a portable, rugged, easy-to-use, state-of-the-art fluid infusion device capable of warming and infusing fluids at rapid rates to treat and sustain hypovolemic trauma patients. It can infuse normothermic blood or fluids at rates as low as 10 milliliters per hour up to 1,200 milliliters per minute. The system weighs 22 pounds. The U.S. Food and Drug Administration cleared this product for marketing in October 2006.

Partners

• USAMMDA



Ventilatory Assist Device for Anesthesia Machine

Description

The Ventilatory Assist Device for Anesthesia Machine is an integrated ventilator and anesthesia machine that ensures proper ventilation of patients during surgery and is compatible with low-pressure oxygen sources such as oxygen generators and concentrators. It provides forward surgical teams with the ability to properly ventilate a wounded service member while replacing the more labor-intensive system of an anesthetist handbagging a patient and reduces equipment load. Completed in 2005, the Ventilatory Assist Device for Anesthesia Machine is being used in Operation Iraqi Freedom.

Partners

USAMMDA

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gistics

Appendice

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Combat Casualty Care





Antimicrobials for Orthopedic Injuries

- Antimicrobial Bone Replacement Material
- Antimicrobial External Fixator Pins

Description

Through the use of Antimicrobial Bone Replacement Material and External Fixator Pins, the risk of infection from bone fractures will be reduced. Treatment of casualties in austere environments necessitates extra precautions be taken to minimize the risk of surgical wound infection. Antimicrobial bone repair and stabilization items are impregnated with antibiotics to reduce or eliminate the occurrence of infection associated with bone fracture injuries.

Antimicrobial Bone Replacement Material. This device will replace lost bone and help stabilize bone fractures.

Antimicrobial External Fixator Pins. Surgical pins and screws will be used to stabilize bone fractures.

Partners

USAISR



Splints, Extremity and Pelvic

- Lightweight Extremity Splint
- Pelvic Fracture Stabilizer

Description

The Lightweight Extremity Splint. Replacing the current board splints, this is a spray-on contractible or pneumatic expandable splint fabricated from new, lightweight material(s) and deployable far forward in the battle area. Service members with immobilized and nondisplaced fractures may be able to continue their missions, and service members with serious open fractures may be stabilized and transportable for several days under battle conditions. The splint will enable a service member with a single upper extremity fracture to remain functional, perhaps even operating a weapon until evacuation. A service member with a lower extremity fracture may be able to evacuate with crutches or one other person instead of needing a stretcher evacuation team.

The Pelvic Fracture Stabilizer. This splint system will stabilize a fractured pelvis to facilitate movement of injured patients without risk of further pelvic organ damage due to pelvic instability. Pelvic fractures are very difficult to immobilize and stabilize especially during evacuation from the battlefield via carried litter or ambulance.

Partners

USAISR



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Advanced Medic Training Technologies

Description

The Advanced Medic Training Technologies effort has successfully developed the first wireless, fieldcapable patient simulator and a game-based simulation with courseware to train life-saving skills to combat medics, combat lifesavers, and Warfighters in realistic environments and while deployed.

The Advanced Medical Training Technologies effort was part of a 3-year Army Technology Objective that yielded two products for combat medics, combat lifesavers, and Warfighters to address these concerns. The first is the Stand Alone Patient Simulator (SAPS), the first completely wireless, physiologically based, deployable, and rugged patient simulator that allows training in a field environment. The second is the TC3 (Tactical Combat Casualty Care) simulation, a low-cost, game-based simulation that was developed to meet Army TC3 learning objectives. SAPS is gaining congressional and high-level Army support to be fielded as a rapid-fielding initiative to speed up the fiscal year 2010 transition to the Medical Simulation Training Center. The onboard bleeding capability developed for SAPS already has been transitioned to the Army's standard patient simulator in the Medical Simulation Training Center. The TC3 simulation transitioned to the Department of Combat Medic Training in May 2007.

Partners

2-14

- USAMRMC
- U.S. Army Research, Development and Engineering Command, Simulation and Training **Technology Center**



Army Medical Department Interim Tent System

Description

The Army Medical Department Interim Tent System provides lighter, brighter, and more environmentally resistant patient areas. Future plans call for air beam technology to reduce the weight by two-thirds and setup time by half; this will become the Future Force Tent System. The Army Medical Department Interim Tent System was completed in 2004.

Partners

USAMMDA



Chemical Warfare Agent Protective Patient Wrap

Description

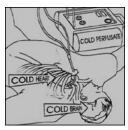
The Chemical Warfare Agent Protective Patient Wrap system is made up of a breathable laminate material for the top layer, a three-layer laminate for the ground cloth, a flexible plastic film for the window, and a coated and laminated chemical and protective cover.

The second-generation Chemical Agent Wrap provides respiration and percutaneous protection for unmasked, uncontaminated patients for at least 6 hours after initial exposure to all known potential chemical warfare agents in vapor, aerosol, liquid, or thickened liquid form.

The wrap is manufactured in one size and is large enough to completely encapsulate military personnel.

Partners

- USAMMDA
- M-C Industries, Inc.
- SafetyTech International, Inc.



Emergency Hypothermia and Smart Aortic Catheter

Description

The Emergency Hypothermia and Smart Aortic Catheter induces hypothermia to slow down metabolism. This device is particularly useful in slowing trauma casualty deterioration during evacuation and surgery. This catheter will help stabilize a casualty's temperature to slow down metabolism during emergency transport to a medical facility.

Partners

- TATRC
- IIRTI



Field Computed Tomography Scanner

Description

The Field Computed Tomography Scanner is a commercial x-ray computed tomography system that is shock mounted and installed in an International Standard Organization (ISO) shelter. This device was completed in 1993.

- USAMMDA
- USAMMA
- Philips

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Field Operating Table Improvement

Description

The Field Operating Table Improvement fixes problems with the rigidity and elevation gearing of the past version. Completed in 2004, the weight and size are significantly reduced from the deployable medical system table that is currently in use.

Partners

2-16

USAMMA



Field Optometry Set

Description

The Field Optometry Set contains field operational optometric equipment, including examining chair, instrument pole, supporting accessories, optometric instrumentation, and field chests. The set was completed in 1988.

Partners

• USAMMDA



Fluid Warming System

Description

The Fluid Warming System is a small, lightweight system for warming blood, lactated Ringer's solution, Hextend, and other fluids to be used in far-forward areas. It extends quality care further in the battle area and allows for extended evacuation times.

- USAMMA
- USAMMDA
- Vital Signs, Inc.



Folding Decontaminable Litter

Description

The Folding Decontaminable Litter consists of aluminum poles and spreader bars, a polypropylene mesh fabric, and retractable nylon handles. Modifications were made to the litter handles to allow the litter to collapse to 78 inches in length. All components are resistant to chemical agents and decontaminating solutions. The litter is a critical component of the M1114/M1151 Casualty Evacuation (CASEVAC) Kit, MRAP CASEVAC Kits, and the MRAP Ambulance Medical Equipment Set.

Partners

- USAMMDA
- North American Rescue



High-Speed Mini-Sterilizer

Description

The High-Speed Mini-Sterilizer is a tabletop device with an inner chamber approximately 10 inches wide by 12 inches deep that sterilizes with bursts of steam on a cycle of approximately 1 minute. Completed in 1986, the High-Speed Mini-Sterilizer was later replaced with a commercial item.

Partners

• USAMMDA



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Life Support for Trauma and Transport System

Description

The Life Support for Trauma and Transport (LSTAT) System is a portable, single-patient, trauma casualty care, surgical support, and evacuation platform. The LSTAT System incorporates a mechanical ventilator with a built-in compressor, vital signs monitor, intravenous infusion pump, suction apparatus, defibrillator, self-contained oxygen supply, and onboard computer for recording patient diagnostic and treatment data. The U.S. Food and Drug Administration cleared the LSTAT for marketing in June 1998, and it has been used in Operations Enduring and Iraqi Freedom. The LSTAT is being modified to meet Critical Care System for Trauma and Transport requirements. In addition, USAMMDA, in collaboration with the Defense Advanced Research Projects Agency, is currently developing the LSTAT-Lite, which will be a lightweight, litter-mountable trauma casualty care system incorporating a ventilator with a built-in compressor, vital signs monitor, intravenous infusion pumps, and integrated display and control with patient data recording.

Partners

• WRAIR

2-18

• USAMMDA



Medical Supply Envelope

Description

The Medical Supply Envelope is a fabric container with pockets for the storage, transportation, and disbursement of medical supplies required at a triage site. It is prepackaged with critical supplies, will fit into a medical chest, and can be retrieved for immediate use. The Medical Supply Envelope was completed in 1992.

Partners

• USAMMDA



Military Transportable Field Radiographic and Fluoroscopic System

Description

The Military Transportable Field Radiographic and Fluoroscopic System provides radiographic and fluoroscopic capabilities. This system incorporates solid-state electronics, composite materials for lightweight construction, and military-specific components for system reliability. Completed in 1987, it also is referred to as the High-Capacity X-ray System.

Partners

- USAMMDA
- USAMMA
- Philips



Mine-Resistant Ambush-Protected Ambulance

Description

The Mine-Resistant Ambush-Protected (MRAP) Ambulance provides up-armored forward support for medical evacuation in theater operations. USAMRMC helped to develop, produce, train, and field MRAP CAT I (Category I) and CAT II ambulances to evacuate patients while protecting forces in theater defending against threats. Before MRAP vehicles, most light tactical vehicles did not have the necessary armor protection for current threats.

With support from BAE and Navistar, the MRAP Ambulance Program Office, the Directorate of Combat and Doctrine Development, and USAMMDA delivered three-litter and two-litter ambulances to Operation Iraqi Freedom and Operation Enduring Freedom.

- USAMMDA
- MRAP JPO
- NAVISTAR
- BAE
- Milton Engineering

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Operating Room Table

Description

The Maquet Table is a manually operated, pedestal-style operating table. It has an articulating top section and adjustable foot and head sections for superior patient positioning with maximum convenience for the surgical team, setting the standard for operating efficiency, ergonomics, and safety. It was designed to accommodate patients weighing up to 300 pounds and includes foot pedal-operated, conductive casters and locks designed to compensate for uneven floor surfaces.

Partners

2-20

- USAMMA
- Getinge USA, Inc.



Pain Control Pump

Description

The AmbIT[®] PCA (patient-controlled analgesia) Infusion Pump is a battery-operated, intravenous pump for administration of medications for pain management. It provides a simple yet sophisticated solution for many types of postoperative local pain management and traditional intravenous delivery of PCA narcotics and regional nerve blocks. The programmable operation delivers technology that is easy to use for clinicians, reduces patient training time, and adds versatility to meet a patient's pain management needs. It is currently being used with great success and is working to relieve patients' pain on long air evacuation flights to Europe and the United States.

Partners

- USAMMA
- Sorenson



Patient Holding and Evacuation Heater Unit

Description

The Patient Holding and Evacuation Heater Unit protects service members from cold conditions during evacuation when used with existing evacuation bags. The unit was completed in 1987.

Partners

• USAMMDA



Portable Field X-Ray Table

Description

The Portable Field X-Ray Table is a lightweight platform for positioning patients for medical imaging in the field. It weighs less than 100 pounds and has a "bucky system" to allow patient imaging in either the horizontal or vertical position. The table was completed in 1999.

Partners

• USAMMDA



Reactive Skin Decontamination Lotion

Description

The Reactive Skin Decontamination Lotion (RSDL) neutralizes chemical agents by rapidly breaking them down to nontoxic or less toxic forms that can then be removed with water. The RSDL can be used on skin or equipment.

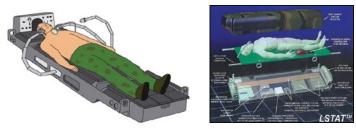
- Chemical-Biological Medical Systems
- USAMMDA



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Robotic Integration of High-Intensity Focused Ultrasound with Life Support and Trauma and Transport

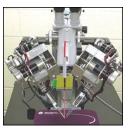
Description

The High-Intensity Focused Ultrasound (HIFU) system is integrated with the LSTAT System. The main advantages of HIFU are its noninvasive nature and that therapy occurs deep within a patient's body without affecting the intervening tissue. The objective of this project is to create a revolutionary teleoperated HIFU system that is robust and at least as effective as a local, non-telerobotic system. To do this, a telerobotic system will be developed that employs a master-slave design, an innovative control system that is stable even in the presence of data latency and bandwidth constraints, a unique series-elastic actuation system for arm flexibility, new methods of detecting and controlling hemorrhaging through HIFU, and an intuitive human interface-all seamlessly integrated with the LSTAT System. This will allow a trauma surgeon or a trained operator to remotely perform noninvasive HIFU surgery on a casualty in the field.

Partners

TATRC

2-22



Robotic Laser Tissue Welding

Description

Incorporating laser tissue welding into a surgical robotic platform provides greater control over some of the parameters that are critical for a successful outcome of the bonds. The synergy between laser tissue welding and robotic surgery has the potential to improve the state of the art of microsurgical procedures and robotic minimally invasive surgery. High precision and lack of tremor of the manipulator, together with the increased uniformity of solder and power delivery, should result in higher quality bonds.

Partners TATRC



Severe Trauma Simulation

Description

The Severe Trauma Simulation (STS) effort developed simulated skin, flesh, blood, and smells to realistically simulate severe trauma for training combat medics, combat lifesavers, and Warfighters. Blast injuries from roadside and car bombs, rocket-propelled grenades, and mortars account for more than half of U.S. combat deaths in Iraq and Afghanistan. The objective of this effort was to research STS technologies to prepare the Army's Warfighters to deal with severe injuries encountered on the battlefield. Medical personnel are not always prepared to treat such injuries and are thus less effective in the use of their medical skills. Additionally, battlefield conditions are vastly different from traditional training in sterile environments. Lessons learned from Iraq and Afghanistan show that traditional techniques and procedures for treating injuries can be improved.

The STS effort was part of a 3-year Army Technology Objective starting in fiscal year 2007 that produced STSs with skin, flesh, blood, and smells that integrate with patient simulators or actors. Research was conducted to identify trade-offs between cost and realism for training efficacy with such simulations. Training scenarios more appropriate for the current operational tempo in the global war on terror also were developed under this effort.

Partners

- USAMRMC
- U.S. Army Research, Development and Engineering Command, Simulation and Training Technology Center



Single-Litter Casualty Evacuation Kit

Description

The Single-Litter CASEVAC Kit allows service members to be evacuated from the theater of operations quickly using an up-armored asset. The M1114, M1151, five MRAP variants, and MRAP All-Terrain Vehicle (M-ATV) transform into CASEVAC vehicles.

USAMMDA and the Directorate of Combat and Doctrine Development developed a safer version of this kit. Kits have been produced and shipped to theater for evaluation by users.

- USAMMDA
- Directorate of Combat and Doctrine
 Development
- MRAP JPO
- Space and Naval Warfare Systems
 Command

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Special Medical Emergency Evacuation Device

Description

The Special Medical Emergency Evacuation Device (SMEED) is a platform used to hold medical monitoring equipment in the evacuation of service members. The platform has modular flexibility and significantly improves the ability to evacuate ventilated patients with multiple IVs and monitors. Completed in 2004, the SMEED has been used in Operation Iraqi Freedom.

Partners

USAISR



Special Operations Forces Medical Handbook

Description

The Special Operations Forces Medical Handbook (SOFMH) provides an up-to-date, portable field medical reference for Special Operations Forces medics and other first responders working in austere environments. The SOFMH was developed through a collaboration between USAMRMC and the Headquarters, U.S. Special Operations Command to make available comprehensive military medical reference materials, including pictures where appropriate, for first responders. The SOFMH is available in printed format or electronic format and has an established online authoring and editing tool to assist in updating and providing the most relevant military medical materials. In the electronic format, the SOFMH is a standard reference provided with Armed Forces Health Longitudinal Technology Application-Mobile (AHLTA-Mobile), a wireless handheld device that is in place throughout the DoD. The SOFMH helps improve military health care by enhancing training and assisting in effective decision making by providing a quick reference tool. Since its publication, the SOFMH has been used extensively in Operation Enduring Freedom and Operation Iraqi Freedom by all levels of U.S. and allied military health care personnel.

Partners

• TATRC



Steam Vacuum Pulse Sterilizer

Description

The Steam Vacuum Pulse Sterilizer is a ruggedized, highly reliable sterilizer for field hospital use with large throughput. It employs a pressure and vacuum pulsing-conditioning principle for air removal and is designed to sterilize instruments, linens, and solutions. This sterilizer was completed in 1991.

Partners

• USAMMDA



Stryker – Medical Evacuation Vehicle

Description

The Stryker – Medical Evacuation Vehicle is the medical evacuation variant of the Stryker Armored Vehicle platform for the Stryker Brigade Combat Team. Capabilities of the Stryker – Medical Evacuation Vehicle include an automated litter lift system, onboard oxygen, suction, storage space for essential medical items and equipment, and the capacity to carry four litter patients or six ambulatory patients and a crew of three. Completed in 2003, this vehicle has been used in Operation Iraqi Freedom.

This vehicle has been fielded with continued product improvement ongoing. A treatment variant is in development.

- USAMMDA
- Stryker Brigade Combat Team
- Directorate of Combat and Doctrine Development



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Surgical Scrub Sink

Description

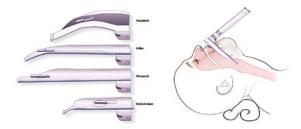
The Surgical Scrub Sink replaced a product that has been used in combat support hospitals for more than 12 years. When it was determined that the fielded model was no longer commercially available, the Army Medical Department required that a new product be procured. USAMMA determined the availability of potential vendors, conducted a market analysis, and identified three manufacturers ready to address military requirements for a field scrub sink meeting both sustainability requirements and current hand hygiene principles. The review and selection process as well as contract award and production was completed in less than a 10-month time period.

Clinical evaluations of all three products were conducted by a panel of tri-service operating room nurses at Fort Detrick, Maryland. Further analysis regarding life cycle logistics and maintenance was conducted as well as altitude, high/low temperature, humidity, dust, shock, and vibration testing. Though multiple products passed environmental and operational testing, USAMMA's source selection board chose the product meeting both clinical and supportability requirements.

Partners

- USAMMA
- Aseptico, Inc.

2-26



Assessment of Learning with the Mobile Telementoring Intubating Video Laryngoscope in Endotracheal Intubation Training

Description

During a mass casualty scenario (whether man made or a natural disaster), health care providers could be overwhelmed by patients, many of whom would need airway support. The study will evaluate the efficacy of the Berci Video Macintosh Intubating Laryngoscope System, which has a camera incorporated into its handle with a short image and light bundle, allowing video projection to a monitor screen. Specific research objectives are to: (1) measure the efficacy of the video laryngoscope for airway training compared to the standard laryngoscope, (2) measure the performance of students using the video laryngoscope compared to the standard laryngoscope, and (3) develop a curriculum for the use of the video laryngoscope in airway training to support anesthesia training programs, advanced cardiac life support airway training, the far-forward battlefield medic, and the conscious sedation training program.

- TATRC
- University of Nebraska Medical Center



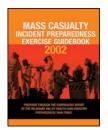
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Emergency Department Self-Assessment Survey and Incident Scenario Exercise Guidebook for Chemical, Biological, Radiological/Nuclear, and Explosive Response Preparedness

Description

This guidebook promotes the development of an effective response by the civilian medical community to chemical, biological, radiological/nuclear, and explosive (CBRNE) terrorist attacks through the use of online tools and advanced distributed learning. A hospital self-assessment survey for emergency department preparedness was developed by the National Bioterrorism Civilian Medical Response Center (CiMeRC) at Drexel University as a deliverable under a government contract funded by congressional appropriation. Based largely on the *Soldier and Biological/Chemical Command Domestic Preparedness Training Manual* and input from an expert consensus panel, the survey was designed to determine emergency department readiness to generate a minimal level of reasonable response to a chemical or biological mass casualty event, regardless of population base or surge capacity. The self-assessment survey contained 14 questions and was accessed online. References and expert opinions were also available. The survey was used to provide a snapshot of regional readiness as well as to support targeted allocation of health care resources. Also developed by CiMeRC is a guidebook entitled *Strategies for Incident Preparedness: A National Model*. The disaster preparedness training handbook contained 20 different CBRNE disaster scenarios. Both the self-assessment survey and guidebook were translated into Spanish and were evaluated in Latin America.

- TATRC
- CiMeRC



Immersive Technologies Approach to Medical Modeling and Simulation

Description

Immersive technologies offer promise to improve medical training in the area of reinforcing cognitive skills for individuals and small units. Forterra Systems, Inc., in collaboration with the Stanford University Medical Media and Information Technologies group, is developing an avatar-based system to train medical first responders for CBRNE events. The avatars can be manipulated in a persistent virtual environment equipped with the features and facilities required to "play the game." CBRNE scenarios can be practiced by multiple players at various locations who are connected over the Internet. Taking a different approach, SIMmersion LLC, in collaboration with the Uniformed Services University of the Health Sciences, is developing a virtual reality (movie-based) training system to teach differential diagnosis skills, such as smallpox versus chicken pox, required by health care providers in response to CBRNE events. This has the potential to augment today's use of standardized patients. Specific to military combat medic training, the Virtual Reality Medical Center is developing a low-cost, interactive virtual reality video game trainer that is hypothesized to improve combat medic skills. The trainer is based on the Army's Combat Medic Advanced Skills Training curriculum. The purpose is to determine the degree to which lower cost, lower fidelity training platforms have a positive "training transfer" from the simulation experience into the delivery of real health care.

- TATRC
- SIMmersion LLC, collaborating with the Uniformed Services University of the Health Sciences
- Forterra Systems, Inc., collaborating with Stanford University Medical Media and Information Technologies
- Virtual Reality Medical Center



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SimSurgery: Development of a Portable Simulator for Training **Robot-Assisted Surgery**

Description

SimSurgery has developed technology for virtual reality simulation with special focus on surgical suturing and soft tissue deformation such as tissue dissection. SimSurgery's vision is to increase clinical performance and reduce health care costs by offering solutions for better training and computer-assisted tools in surgery. This project will produce a portable device that resembles the surgeon console in a surgical robot system as well as surgical simulator software that replaces the need for biological tissue (animals or patients) and equipment. Once this has been accomplished, the performance of surgical robotics versus traditional laparoscopy by use of simulators will be compared.

Partners

- TATRC
- SimSurgery



The Use of Cognitive Task Analysis and Simulators for After-Action Review of Medical Events in Iraq

Description

Researchers are developing an innovative protocol for streamlining expert medical knowledge into simulation development and enhancing learning for hands-on clinical skills. This project attempts to improve medical after-action review with a novel combination of cognitive task analysis conducted while interviewees moulage simulators. Three medical experts who have experienced and solved the same type of important medical problem in Irag will be interviewed separately and together. It is hypothesized that interview protocols employing a novel combination of medical cognitive task analysis combined with the moulage of simulators will more accurately capture the mix of automated and conscious decisions used to solve critical medical problems on the battlefield in Iraq. Each expert will be interviewed separately and, after reviewing the results, the other two experts will be asked to correct and improve on the information gathered from the "other" experts. This process has been found to identify and eliminate errors as well as provide accurate and efficient descriptions of medical decisions and actions that solved battlefield problems.

- TATRC
- University of Southern California



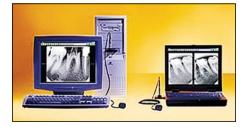
Dental Field Treatment and Operating System

Description

The Dental Field Treatment and Operating System (DEFTOS) is a dental operating system to be used in the field. DEFTOS is a small, lightweight, mobile dental operating system for dental officers in the field that uses the latest electric motor-driven handpiece technology and can be guickly assembled or disassembled and packed into one molded shipping container, reducing the footprint of the field dental operating unit. The system includes both a high-speed and low-speed handpiece, air and water supply, air and water syringe, high-volume evacuator, saliva ejector, variable-speed foot switch, and oil-less air compressor. Completed in 2003, DEFTOS has been used in Operation Iragi Freedom.

Partners

• U.S. Army Dental Research Detachment



Dental Filmless Imaging System

Description

The Dental Filmless Imaging System provides digitized dental images to forwarddeployed service members. The Dental Filmless Imaging System consists of an x-ray detector and image acquisition and storage components to digitize images for storage and viewing. It is compatible with currently fielded x-ray sources. Images are available immediately for the treating dentist. It is used by forward-deployed dental technicians and officers and replaces conventional x-ray film, film processors, and the associated chemicals, eliminating the logistical burden of temperature- and time-sensitive components. Also, volume, weight, and power requirements are reduced. This system was completed in 2002.

- TATRC
- USAMMA
- Dexis



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Field Dental Operating Unit

Description

The Field Dental Operating Unit is a small, lightweight, mobile dental unit used to provide emergency and limited preventive and sustaining dental care in the field. It consists of a light source, suction apparatus, water reservoir, and high- and low-speed drills. The unit was completed in 1990.

Partners

• USAMMDA



Miniature Dental X-Ray System

Description

The Miniature Dental X-Ray System is used to provide dental x-rays in the field. The Miniature Dental X-Ray System is a small, lightweight, handheld dental x-ray system for field use. It is battery operated and suitable for use with self-developing film or a digital imager. The system was completed in 1993.

- USAMMA
- USAMMDA
- Aribex



Blood Refrigerator

Description

A blood refrigerator could store blood and plasma products in the HBCT Treatment Variant Vehicle. A refrigerator for medical treatment vehicles takes blood supplies closer to the point of injury. The refrigerator holds 10 units, opens in the front, has an LCD display, and has communications capabilities. The device has a 72-hour mission to store blood and plasma products, which are the best resuscitative fluids for patients who have lost significant amounts. Funding is being used to modify a commercial off-the-shelf item.

Partners

- USAMMDA
- Thomas EMS



Ceramic Oxygen Generator

Description

The Ceramic Oxygen Generator uses a metal reinforced composite, thin-film ceramic membrane to generate oxygen. Producing 1 liter of oxygen requires 30 watts of electricity. The device will be battery powered and weigh only 10 pounds.

Existing oxygen production technology uses techniques, such as pressure swing adsorption or cryogenics, to separate oxygen from air. The Ceramic Oxygen Generator uses no major moving parts; instead it uses a thin, hot ceramic membrane that has a voltage applied to it. The applied voltage drives atmospheric oxygen and only oxygen through the membrane to a collection chamber. The mechanical simplicity and high efficiency make this a promising technology.

Partners

- USAMMA
- USAMMDA
- IGR Enterprises, Inc.



Clotting Agents

Intravenous Hemostatic Drugs

Description

Clotting agents are drugs or other formulations that act to control bleeding that is not accessible for compression, such as an intra-abdominal hemorrhage. There are no equivalent products currently, and treatment requires immediate surgery. The products will prolong the lives of service members awaiting evacuation.

Intravenous Hemostatic Drugs are administered via intravascular, oral, or other novel routes to enhance natural clot formation. Examples of such drugs are NovoSeven[®] (recombinant human factor VIIa), which is currently in limited clinical use in trauma patients, and fibrinogen, which is used prehospital for trauma in Europe.

Partners

USAISR

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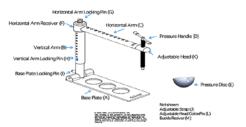
Fibrinogen Bandages

Description

Medics, combat lifesavers, and other medical personnel will use the Fibrinogen Bandage on the battlefield to aid in the control of severe hemorrhage in injured service members. The Fibrinogen Bandage will be composed of human fibrinogen and thrombin. When used with direct pressure, the dressing is intended to stop severe arterial, venous, or mixed bleeding in 2 to 4 minutes.

Partners

- USAISR
- USAMMDA



Junctional Hemostatic Device (Combat Ready Clamp)

Description

This device is a disposable clamp that is designed to control difficult bleeding in the pelvic region, provide compression of large vessels in the inguinal and abdominal regions, and supply additional pressure to a current pressure dressing. It can be fitted with pressure discs of varying sizes to address the bleeding situation. It is easy to assemble and to use.

This device would be used by medics and higher trained medical personnel to provide hemorrhage control at compressible sites not conducive to placement of currently available tourniquets.

Partners

- USAISR
- Combat Medical Systems



Red Blood Cells, Extended Life

Description

Red Blood Cells, Extended Life (RBCXL) consist of a new additive solution that extends the total shelf-life of packed red blood cells from 6 weeks to at least 8 weeks and extends the deployed shelf-life from approximately 3 weeks to at least 5 weeks—an increase of approximately 60 percent. Enhanced shelf-life not only reduces the expiration of packed red blood cells but also improves the quality of red blood cells at every time point of measurement compared to current red blood cells. RBCXL also may mitigate the degradation of packed red blood cells, which may have a negative impact in casualties who receive more than 10 units of packed red blood cells in a single transfusion.

- USAMMDA
- Hemerus Medical, LLC



Rotary Valve Pressure Swing Oxygen Generator

Description

The Rotary Valve Pressure Swing Oxygen Generator (RVPSOG) is a smaller, more efficient product and will reduce the logistical burden of the oxygen generator for forward-deployed medical assets for use in single-patient care and transport. Existing pressure swing adsorption oxygen generator technology is being miniaturized into a portable device. Miniaturization requires the development of a small but reliable compressor. A rotary valve driven directly by a small motor will eliminate complex valve and control systems used in conventional oxygen generators.

The logistical burden of resupply and refill of oxygen cylinders will be eliminated. The RVPSOG replaces the standard "D" cylinder for patient care and transport and yields increased efficiency and reduced size and weight.

- USAMMA
- USAMMDA
- Chart Industries
- SeQual



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Transportable Pathogen Reduction Blood Safety System

Description

The possibility of transmitting disease by the transfusion of blood or blood components to a patient is a longstanding problem in transfusion medicine. Currently, donors are asked about their medical and behavioral history, and samples of their blood are tested for the presence of several viruses. While this approach provides a high level of safety, it has limitations. If an infected person donates blood with virus levels below the detection limit of the screening tests, the test will not detect virus, but the blood could still transmit disease. Another limitation of current practice is that testing is only done for a limited number of viruses; a number of well-known viruses, as well as emerging viruses, will not be detected. Also, testing is not done for parasites and is not routinely done for bacteria.

The proposed approach to pathogen reduction uses light and riboflavin to inactivate pathogens in blood components. This technology is currently in development for application to red blood cells and platelet and plasma products. Treatment of platelet and plasma products is in a later stage of development than that of red blood cells; it has been used in clinical studies in the United States and South Africa with platelet products. The technology requires the addition of a riboflavin solution to plasma or platelets followed by exposure to ultraviolet light. Red blood cells are treated with the addition of a riboflavin solution and exposure to visible light. With the riboflavin-and-light technology, pathogen nucleic acids are damaged, preventing their replication and hence disease transmission in recipients of blood products.

- TATRC
- CDMRP
- USAMMDA
- CaridianBCT



Advanced Regenerative Medicine Technologies to Regenerate Lost Tissues

Description

This effort focuses on developing advanced regenerative medicine technologies to restore functional tissues using the latest advances in stem cell research combined with tissue engineering technologies to produce new cells and tissues to replace damaged cells resulting from combat injuries. Researchers seek to develop novel therapies to regenerate fingertips using extracellular matrix material, to repair and reconstruct injured or missing soft tissues using extracellular matrix as a bioscaffold, and to treat severe skin burns via extraction, expansion, and cell support technologies of autologous skin cells from a healthy area of a patient's skin to enable skin cell tissue engineering in the wound of a patient. Skin regeneration takes place directly in the wound of a patient by using a cell spray device followed by placing a temporary artificial capillary bed to support cell proliferation and cell migration in the wound thereby reducing in vitro culture time (i.e., no in vitro expansion).

- USAISR
- TATRC
- University of Pittsburgh
- Pittsburgh Tissue Engineering Initiative



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Hyperbaric Oxygen Treatment of Post-Concussion Syndrome

Description

USAMMDA is leading a government and academic partnership to determine if hyperbaric oxygen (HBO2) is of benefit in the treatment of chronic symptoms of mild traumatic brain injury (TBI) or post-concussion syndrome (PCS).

HBO2 is defined as the administration of oxygen in a chamber at greater than atmospheric pressure in which oxygen becomes increasingly dissolved in the blood and body tissues. There is anecdotal evidence to suggest that HBO2 may be beneficial in the treatment of acute and chronic symptoms associated with TBI. Better quality evidence, including sham-controlled, randomized trials, must be obtained prior to determining if HBO2 should be used as a standard treatment for TBI or PCS.

Both TBI and PCS adversely impact military operational readiness and effectiveness. Currently there is insufficient evidence to recommend HBO2 to treat PCS; however, the DoD is conducting clinical trials to generate the scientific evidence to guide therapy.

- USAMMDA
- MIRECC 19, Denver Veterans Affairs Medical Center
- Naval Health Research Center
- Intermountain Healthcare
- OxyHeal Health Group
- Henry M. Jackson Foundation



Neuroprotective Drugs

Description

Neuroprotective drugs will improve the outcome following acute brain trauma. A new drug, NNZ-2566, was examined by WRAIR through collaboration with an industry partner for the treatment of brain injury in a penetrating ballistic-like brain injury model. NNZ-2566 demonstrated efficacy in this animal model as well as various other brain injury models. This promising candidate drug treatment currently is being examined for safety and efficacy in a 260-patient Phase 2 clinical trial. NNZ-2256 is an analog of Glypromate[®] (or glycine-proline-glutamate), a naturally occurring small-molecule neuro-protectant derived from IGF-1 (insulin-like growth factor 1), which is produced in the brain but does not bind to IGF-1 receptors.

Neurological trauma is the number one cause of traumatic mortality on the battlefield and often is associated with significant morbidity, disability, and delayed mortality in those who survive the initial injury. A neuroprotective drug used to preserve or protect otherwise uninjured neurological tissue in the face of direct head trauma will reduce residual disability and subsequent long-term care demands. The capability to stimulate or enhance neuronal healing and repair as well as functional recovery will further reduce residual disability.

- WRAIR
- CDMRP
- Neuren Pharmaceuticals Limited



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Appendice

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Neurotriage Diagnostic Tools

Description

A rapid, field-implementable, diagnostic device is in development for the objective assessment of neurological trauma—the number one cause of mortality on the battlefield. A small volume of blood is analyzed to determine the levels of brain-specific biomarkers. Clinical trials are currently being conducted to determine the utility of the biomarkers to diagnose brain injury in severe, moderate, and mild traumatic brain injury (TBI) patients. A 1,200-patient clinical trial is being planned for final U.S. Food and Drug Administration approval of a biomarker diagnostic device for TBI. In the field, the results of this bioassay will be combined with a medical evaluation to provide a diagnosis of injury magnitude, ascertain casualty triage status, and provide treatment recommendations specific to the casualty's condition.

The diagnostic tools being developed will help manage the injury and may reduce subsequent residual disability and associated long-term care demands.

Partners

- WRAIR
- USAMMA
- Banyan Biomarkers, Inc.

2-40



Active Thermal Resuscitation

Description

Active Thermal Resuscitation is a methodology that uses a prototype portable warming system that can heat fluid or blood to prevent the onset of hypothermia. Hypothermia is common and increases mortality in wounded personnel. Forward surgical teams currently use standard civilian fluid warmers and forced-air warming blankets to help prevent the onset of hypothermia. These systems, how-ever, are not portable and do not effectively treat established hypothermia. Also, they require large amounts of generated electrical power and have a sizable transport footprint. Researchers have demonstrated a prototype portable warming system that can address this need while improving the mobility of a forward surgical team. The system uses the most favorable thermodynamic and physiologic methods to achieve rewarming of the hypothermic service member.

Partners

- TATRC
- University of Texas Health Science Center at Houston



Field Sterilizer Improvement Device

Description

This newly improved sterilizer will reduce the water consumption of the device currently used by forward-deployed medical facilities. While the current field sterilizer is a wellproven piece of equipment, one shortcoming has been its high water consumption; it uses 2 ¹/₂ gallons of water every time it sterilizes a load of materials. A water recovery module will be added to the sterilizer to condense the exhaust steam and return it to the sterilizer's boiler. The design of the water recovery module has been updated to use currently available components and improve the access for maintenance and repair. This effort is intended to fully field a water recovery system.

Partners

USAMMDA

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Future Medical Shelter System

Description

The Future Medical Shelter System program uses congressional funding to explore rigid and softwalled shelters for forward-deployed health care providers. The Future Medical Shelter System consists of chemically and biologically hardened ISO containers with quick erect and strike times and integrated electrical, water, and medical packages. Currently, one- and two-sided ISO aluminum rigid wall shelters serve as an interim solution.

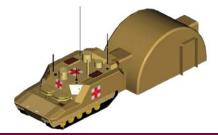
A Request for Proposals has been released seeking commercial off-the-shelf products that will reduce the weight of comparable systems, enhance transportability and deployability, and be stronger and less expensive.

The Army Medical Department is working to transition to Force Provider in fiscal year 2014.

Partners

- USAMMDA
- U.S. Army Natick Soldier Research, Development and Engineering Center
- U.S. Air Force
- U.S. Navy
- Mobile Medical International
- EADS North American

2-42



Ground Combat Vehicles – Medical Variants

Description

Medical variants of the Ground Combat Vehicles (GCV) platform will serve as the ground medical evacuation and treatment assets for heavy brigade combat teams. This program replaces the Future Combat System program and should be ready in fiscal year 2017. Two medical variants of the GCV are planned: Medical Evacuation and Medical Treatment. Medical capabilities will include onboard oxygen generation, suction, storage space for essential medical items and equipment, and automated data management. The Medical Evacuation variant will carry four litter patients on an automated litter lift system or six ambulatory patients and a crew of three. The Medical Treatment variant will provide interior space for treatment (surgery) of one patient and a crew of four.

GCV medical variants will provide the capability for medical response assets to move with the farforward and mobile Units of Action. Additionally, use of the GCV platform yields the same mobility, transportability, and supportability as the supported force.

- USAMMDA Medical
- Program Manager, Future Combat Systems, Brigade Combat Team Vehicle



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Mine-Resistant Ambush-Protected Ambulance

Description

The Mine-Resistant Ambush-Protected Ambulance provides up-armored forward support for medical and area support missions to do evacuation in theater operations. There is a requirement for an MRAP Caiman four-litter ambulance and an M-ATV two-litter ambulance in Operation Enduring Freedom. The AMEDD is helping the MRAP JPO to meet the Joint Urgent Operational Needs Statement for an M-ATV Ambulance. The first unit equipped will be September of fiscal year 2011.

Partners

- USAMMDA
- Directorate of Combat and Doctrine Development
- MRAP JPO



Portable Noninvasive Shock Monitor

Description

The Portable Noninvasive Shock Monitor will assist military medical personnel in preventing mortality and morbidity associated with shock. Trauma and hemorrhage are leading causes of death in the United States and a major concern of the military. Significant loss of blood leads to shock, a condition of inadequate organ perfusion and tissue oxygenation. There is the need for intelligent medical systems to quide corpsmen and combat medics in triage and resuscitation of severely injured combatants. A prototype, portable sensor system based on near infrared spectroscopy to noninvasively measure tissue perfusion has been developed and tested. This system quickly and accurately measures muscle pH, muscle oxygen tension, and hematocrit from light reflected off the palm of the hand and will guide combat medical personnel in resuscitation care and evacuation. The noninvasive, continuous process provides earlier indication of life-threatening medical problems and a means of rapidly triaging casualties; medical information to guide treatment where none currently exists; and advanced medical capability not previously available near the battlefield and during transport. Prototype development was completed in 2005 and capability was demonstrated in 2006. Evaluations are planned at Brooke Army Medical Center's Burn Unit and Beth Israel Deaconess Hospital Emergency Department in 2007.

- USAISR
- CDMRP
- University of Massachusetts Medical School
- Luxtec Corporation



Replacement of the M113 Medical Ambulance/M577 Treatment Variants in the Heavy Brigade Combat Teams

Description

Work is currently under way among the U.S. Army Medical Department Center and School, Project Management Office Heavy Brigade Combat Team (PM HBCT), and the Office of the Surgeon General to determine a replacement ambulance for the aging M113/M577 ambulance. Since the M113 program has been terminated, an interim armored ambulance and treatment variant is needed. Current plans are to replace the M113/M577 in the fiscal year 2018 time frame with 7 BCTs per year, which is 210 evacuation and 56 treatment variants. USAMRMC is working with PM HBCT to ensure that the medical requirements for these vehicles are being met. This includes development of the treatment table, blood refrigerator, and shelter that spiraled from the FCS program. The Army Capabilities Integration Center is now supporting this initiative.

- USAMMDA
- Program Executive Office, Ground Combat and Support Systems
- Directorate of Combat and Doctrine Development
- OTSG



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Stryker – Medical Treatment Vehicle

Description

The Stryker – Medical Treatment Vehicle is the treatment variant of the Stryker Armored Vehicle platform for the Stryker Brigade Combat Team. Capabilities of the Stryker – Medical Treatment Vehicle include a treatment table, onboard oxygen, suction, storage space for essential medical items and equipment, remote weapon station, and the ability to provide forward critical care to the injured. The vehicle variant is in development.

Partners

- USAMMDA
- Stryker Brigade Combat Team
- Directorate of Combat and Doctrine
 Development



Treatment Table

Description

Treatment tables and surgical lights provide required capability to battalion aid stations, and they will transition into Stryker or Bradley variants. Because commercial tables did not meet the requirements, USAMRMC designed and built a prototype table to be tested and then transitioned to the commercial sector.

Partners

- USAMMDA
- Tank and Automotive Research, Development, and Engineering Center Project Management Heavy Brigade Combat Team

2-46



3DiMD: Gaming Environment for Training Team Coordination Skills

Description

A three-dimensional, interactive, networked system assists in training military health care team coordination skills. 3DiMD will provide an effective solution to the problem of expanding the scope of team coordination skill training in military health care environments. In addition, the software platform to be developed will allow for the integration of multiple scenarios and work environments (e.g., training modules) to allow expansion into public health care environments. The main objective is to develop an immersive three-dimensional environment to train and assess military health care team coordination skills. Because this is a development project, there is no formal experimental hypothesis to test. However, the design specification and prototype will be evaluated qualitatively. Ease of use, practicality, scope, and effectiveness of the training system will be assessed through heuristic analysis by experts in team training. Future work will assess the impact of the prototype training environment on the team coordination skills of military health care providers. Future efforts also will evaluate the efficacy of the prototyped interactive team coordination assessment tools.

- TATRC
- Duke University Medical Center



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Center for Advanced Surgical and Interventional Technology

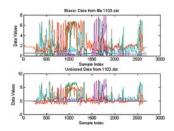
Description

The Center for Advanced Surgical and Interventional Technology (CASIT) of the David Geffen School of Medicine at the University of California, Los Angeles, is working on the TATRC-supported project, "The Application of Novel Technologies in Computer-Mediated Medicine." CASIT uses the resources of the School of Medicine, the Biomedical Engineering Department, the California Nano-Systems Institute, and industry to advance the technology of interventional medicine; to improve telementoring, telesurgery, and telepresence; and to facilitate on-site diagnosis and treatment. The project has seven interrelated subprojects. CASIT is uniquely suited to develop technologies that will enhance the care of the Warfighter as well as provide new and sophisticated simulators for education, training, telementoring, and telesurgery. The close proximity of engineers and scientists to physicians, investigators, surgical robots, and other instruments provides a unique opportunity for interaction resulting in greater potential for innovation, rapid transition of technology into useful medical applications, and effective coordination with TATRC and DoD experts.

Project 1 is a haptic-guided telementoring system that will improve expert surgeon telepresence at remote surgical sites. Project 2 will develop a haptic feedback system for minimally invasive surgery, which also will be applicable to extremity prosthesis. Project 3 is developing a wireless, implantable, catheter-mounted sensor for physiologic monitoring. Project 4 involves a telepresent application using a robotic wireless system that is integrated with a system that delivers relevant and real-time patient information directly to a caregiver's computer. Project 5 is a PC-based multimodal procedure trainer. Project 6 will use flexible, three-dimensional ultrasound technology to enhance diagnosis of injuries and facilitate interoperative guidance. Project 7 takes advantage of the development of thin film nickel titanium for an intravascular prosthesis.

Partners

• TATRC



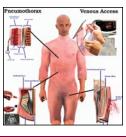
Developing Generalized Algorithms for Objectively Assessing Medical and Surgical Skill with Various Modalities – Data

Description

New simulators being developed will produce large amounts of data that will provide insight into human performance. Inherent difficulties in evaluating clinical competence for physicians have spawned the wide use of various subjective assessment techniques. Inspired by objective methodology, algorithms are based on a mathematical finite-state model. Statistical distances measured between models representing subjects with various skill levels are sensitive enough to provide an objective measure of medical or surgical skill level. The goal of the proposed research project is to develop a generalized methodology based on Markov models independent of the modality being used and to test it using data acquired from three different modalities including: (1) An instrumented surgical tool, (2) a physical simulator (e-pelvis), and (3) a robotic system (DeVinci by Intuitive Surgical). The type and severity of the injuries that military medical personnel will have to cope with in the battlefield may exceed the nature and complexity of the injuries that a civilian clinician has to treat. These circumstances make simulators, along with software for assessing skill level, critical elements for military medical training. The proposed methodology could one day be extended to other nonmedical military simulators.

Partners

- TATRC
- University of Washington



Dynamic Injury Creation Simulator

Description

The Virtual Reality Medical Center is producing a functional, medically and militarily tested prototype of the injury creation simulator to provide a realistic training experience at two levels. For corpsmen embedded with their squads, the goal is rapid initial assessment and stabilization. Medical scenarios will include only wounds that corpsmen address in the field. The medical scenarios for Echelon Il will be selected from a broader choice of procedures while still focusing on the treatment of injuries for which corpsmen have existing equipment. These scenarios will provide medics and corpsmen with the actual experience in the field that they must master. The training exercises take place under live or simulated fire complete with "enemy" actors and combatants, explosions, and other special effects. The investigators will bring all the tools of Hollywood special effects to live training, culminating in a near-real battlefield experience.

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Medical Simulation Training Initiative

Description

Looking into the future, the Medical Simulation Training Initiative (MSTI) is a long-term research effort to identify, develop, and integrate fundamental "enabling technologies" into medical simulation devices and even entire medical training systems. The Center for Integration of Medicine and Innovative Technology (CIMIT) Simulation Group is executing the MSTI program. Examples of enabling technologies are tissue properties measurement, tool-tissue interactions, haptics, virtual reality graphics and visualization, learning, and open systems architecture. Under the auspices of this technology development initiative, concepts have been prototyped into products related to computer-based simulation training systems, for example, VIRGIL and Smallpox Inoculation Training, also called SITU.

TATRC is leading two significant initiatives to pave the way for widespread adoption: validation and open standards development leading to interoperability. TATRC has funded more than a dozen studies to validate the degree to which skills developed via simulation transfer to the delivery of health care. To enhance interoperability among medical simulation systems, TATRC is now facilitating informal discussions to spur the development of "open source standards" for medical modeling and simulation.

Partners

TATRC



Mimic Technologies: Affordable Haptics for Surgical Training

Description

Mimic Technologies will use advanced technologies in haptics and simulation to improve proficiency and safety in surgical training. Wound trauma care is a culmination of many basic skills (regulation of bleeders, wound debridement, suturing, etc.). A basic skills trainer, such as the Wound Trauma Simulator, would not only be appropriate for teaching surgeons but would also be appropriate for training paramedics, emergency medical technicians, and nurses.

Mimic Technologies has developed an affordable two-handed haptic system that can be used for open surgery simulation. The system includes a stereoscopic display that will colocate virtual images with the surgical tools held by the user. To demonstrate this platform, the development of a Wound Trauma Simulator will be initiated, which has the potential to help train medical personnel to treat projectile wounds to the pelvis.

Partners

TATRC



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Part-Task Trainer Approach to Medical Modeling and Simulation

Description

Health care personnel can improve their cognitive and psychomotor skills with "part-task" trainers. Aviation crews simulate portions of missions that are high risk, high consequence rather than an entire mission from start to finish. This has led to the term "part-task trainer." In medical modeling and simulation, many "part-task" efforts are under way to support physician, nursing, and allied health care personnel training. End user input has formed the foundation for current efforts to develop part-task simulators for specific procedures. In addition, platforms are being developed for the purpose of training specific skill sets or hosting different surgical simulators, such as the haptics-optional surgical training system, simulation-based open surgery training system, affordable haptics for surgical training, deployable simulation workstation (Sim-Pod), and portable simulator for training robot-assisted surgery. In addition to training, these simulation platforms have the potential to host the development of new clinical procedures and testing of new medical devices during development.

- TATRC
- Affordable Haptics for Surgical Training Mimic Technologies
- Chest Trauma Training System CIMIT Simulation Group
- Compartment Syndrome Touch of Life
- Cricothyroidotomy National Capital Area Medical Simulation Center
- Exsanguinating Hemorrhage SimQuest LLC
- Fractured Femur Simulution, Touch of Life
- Haptics-Optional Surgical Training System Energid Technologies, SimQuest LLC
- Intracranial Hematoma/Burr Hole and Trauma Flap SimQuest LLC, Verefi Technologies, Inc.
- Portable Simulator for Training Robot-Assisted Surgery SimSurgery
- Regional Anesthesia Energid Technologies, Touch of Life
- Simulation-Based Open Surgery Training System SimQuest LLC, Touch of Life



PC-Based Interactive Multimedia

Description

Simulation Technologies for Advanced Trauma Care (STATCare) by RTI International is a trauma patient simulator that gives sustainment training for emergency medical technicians on a PC-based interactive multimedia "virtual patient." The patient responds physiologically and pharmacokinetically to user diagnosis and treatment. User interaction is recorded for after-action review. With additional funding directed through another agency (the Office of the Secretary of Defense for Health Affairs is expanding STATCare's capabilities into Sim-Patient™, also developed by RTI International), it will have the capability to simulate multiple patients and provide training beyond the emergency medical technician level. TATRC also has begun work to develop PC-based "sim games" for CBRNE training.

Partners

• TATRC



Transurethral Resection of the Prostate

Description

Under SBIR Phase II funding, validation, software, and force feedback research is being conducted to increase training effectiveness. The National Capital Area Medical Simulation Center, together with Emory University, is conducting a comprehensive "virtual reality to operating room" validation study on the URO Mentor[™] simulator. The main components of the software module and also external software and hardware modules. as well as their relations to each other were designed. The haptic device was adapted to laser transurethral resection of the prostate. The interface with the force feedback device was designed at high frequency to maintain a smooth response.

Partners

TATRC



VIRGIL™

Description

The CIMIT Simulation Group is developing this prototype chest trauma training system, which teaches trainees how to diagnose and treat a chest trauma victim in a combat situation. It integrates a hybrid manikin, virtual reality tools, and a computer-based system and offers several levels of difficulty. In April 2004, VIRGIL was selected as one of the Army's 10 Greatest Inventions for 2003. Initial validation studies at the National Capital Area Medical Simulation Center have shown that VIRGIL trains third-year medical students as effectively as pig training.

Partners

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Virtual Reality Demo

Description

Skills degrade over time, may be lost at a moment of need, and are needed for the unexpected. The Virtual Reality Demo psychomotor skills trainer/tester is a portable, flexible, self-contained haptics-based simulator. It allows training to be moved from the laboratory to the workplace or to field conditions for just-in-time training.

Partners

• TATRC



Advanced Resuscitation Fluid

Description

Advanced Resuscitation Fluid will help to maintain critical levels of blood pressure and tissue perfusion to preserve organ integrity and function. The fluid is designed for small-volume resuscitation for trauma and blood loss with delayed evacuation for up to 72 hours.

This product will support the continuing effort to extend the "golden hour" for far-forward treatment to improve survival and minimize morbidity after life-threatening injuries. Specifically, the product will counter vascular injury and immune system activation caused by decreased perfusion and oxygen radical generation during tissue re-oxygenation. The product also will not interfere with the ability of the blood to coagulate or form clots.

Partners

USAISR



Blood Product Shipping and Transport Containers

Description

Researchers are finding ways to deliver viable blood products from blood banks in the United States to hospitals in the combat theater. The shipping and transportation containers for blood products are boxes that need no power source to maintain an internal temperature within the ranges required for blood product shipping (i.e., 4°C, 20°C–24°C, or -20°C). These boxes are the next generation of the "Golden Hour Blood Container," an award-winning, fielded USAMRMC product, which uses a combination of vacuum-insulated panels with an internal container that has a liquid phase-change material similar to that in reusable freezer packs. The internal portion of the container is cooled to below the phase-change temperature (effectively frozen) then returned to the container along with the units of blood product. Different internal containers allow the shipping and transport containers to transport packed red blood cells, fresh frozen plasma, or liquid platelets in their appropriate temperature ranges without the use of wet or dry ice.

Blood products will break down and can significantly harm a recipient if not stored at the right temperature. These containers will replace the Styrofoam[™] and wet or dry ice currently used to ship blood products. They will allow movement of blood products to and storage of blood products at locations much further forward than the current system allows thus getting the much needed product to a combat casualty sooner. The product is not blood specific and could be used for transporting any temperature-sensitive products, such as biologicals, vaccines, or reagents. Future versions of the container may incorporate constant monitoring of the internal temperature.

Partners

• WRAIR

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Cryopreserved Platelets

Description

Cryopreserved Platelets (CPP) will fill the gap so state-of-the-art care can be provided to combat casualties for the control of hemorrhage far forward on the battlefield at combat support hospitals. CPP are human platelets collected, processed, and frozen at -80°C. CPP may be stored for up to 2 years before use. The platelets can be thawed within 5 minutes and reconstituted for administration with normal saline. The functional activity of this blood product is similar to native platelets with regard to the clotting function. Key attributes of this product are battlefield availability and prolonged shelf-life.

Platelets are a key element in normal blood clotting after injury or surgical incision. The current blood-banked platelet product can be stored for only 5 days and is generally not available on the battlefield. Platelets continue to be absent in Operation Enduring Freedom, but fresh whole blood and deployment of platelet apheresis have been used to fill the gap in Operation Iragi Freedom. CPP will fill the current gap in effective medical management of hemorrhage at the combat support hospital.

Partners

WRAIR

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- USAMMDA
- University of Cincinnati
- Dartmouth-Hitchcock Medical Center
- Fast-Track Biologics
- Puget Sound Blood Center



Freeze-Dried Plasma

Description

Freeze-dried plasma is lyophilized human plasma packaged for rapid reconstitution and administration. The functional activity of this blood product is equivalent to fresh frozen plasma including clotting function. Key attributes of freeze-dried plasma include extended shelf-life and temperature stability.

Freeze-dried plasma will reduce the logistical footprint by reducing refrigeration requirements associated with fresh frozen plasma and can be used in far-forward medical treatment facilities for casualty management.

- WRAIR
- USAMMDA
- HemCon Medical Technologies, Inc.



Pathogen Inactivation System

Description

CaridianBCT has developed a way to reduce disease-causing agents and inactivate white blood cells that can contaminate blood products intended for transfusion. The sooner safe blood can be provided and the safer that blood is, the better the chances of survival on the battlefield.

TATRC is working with CaridianBCT to ensure the safety of blood products used in transfusions for military personnel injured in combat. Research has shown that for trauma cases in the field—where the use of fresh whole blood is often put into practice—transfusion of whole blood has a significant positive impact on patient outcomes, including survival.

TATRC is assisting CaridianBCT's development of the Mirasol[®] Pathogen Reduction Technology (PRT) system as a transportable system to treat whole blood thereby reducing the risks associated with blood-borne pathogens and donor white cells. As a lightweight, portable device, the Mirasol PRT system has the potential to introduce safer blood with fewer complications, providing a new way for military and civilian surgeons and transfusion medicine specialists to aid patients with life-threatening blood loss.

- TATRC
- USAMMDA
- CaridianBCT



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Combat Casualty Care



Pharmacological Resuscitation with Complement Inhibitor

Description

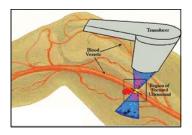
Hemorrhage and the resuscitation fluids used to treat it cause excessive activation of the complement system, a natural body defense mechanism consisting of a system of proteins meant to protect against infection. However, excessive complement activation will cause tissue damage. Complement activation inhibitors greatly reduce tissue and organ injury as well as the requirement for resuscitation fluid in animal models of hemorrhagic shock.

Currently, there are a few complement inhibitors already approved by the U.S. Food and Drug Administration for the treatment of lupus, paroxysmal nocturnal hemoglobinuria, and hereditary angioneurotic edema. These commercially produced complement inhibitors currently are being investigated in military-relevant animal models for efficacy testing for a new indication to treat hyperactivation of the complement system during hemorrhagic shock and trauma.

Partners

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- USAISR/BHT-2
- Harvard Medical School



Remote Acoustic Hemostasis Device

Description

Control of internal hemorrhage by the Remote Acoustic Hemostasis Device will stabilize bleeding. This high-intensity focused ultrasound device functions by focusing ultrasonic waves to cause cauterization of both internal and external bleeding structures without damaging overlying or surrounding tissues. The Remote Acoustic Hemostasis Device will feature a computerized Doppler guidance system designed to locate and focus on hemorrhaging structures.

- USAISR
- Defense Advanced Research Projects
 Agency



Rapid Wound Cleansing System

Description

Rapid wound cleaning is necessary to avoid wound sepsis and achieve optimal healing. This wound cleansing system will replace the current heavier system. Reducing the amount of fluid and the weight a medic carries without compromising care is important for the medic's mobility on the battlefield. The product will be a small-volume wound cleaning device. Replacing the current system will reduce the required volume from 12 liters to less than 2 liters.

Partners

USAISR



Regenerative Medicine for Wound Healing

Description

Wound injury treatments for military personnel are being developed using combinations of products containing hydrogel biomaterials, tunable topical release of antimicrobial/antibiotics, and autologous stem cells for inducing active tissue regeneration. This combination strategy will not only enhance healing through promoting blood vessel growth and granulation but also will limit the onset of opportunistic wound infections. Preventing infection once a wound is inflicted provides the best platform for accelerating wound healing. Developing a fibrin-based scaffold capable of delivering silver sulfadiazine provides the necessary environment for a wound to heal without any further complications. This strategy has advantages over topical delivery by providing release of antibiotic in a controlled fashion. The use of the pegylated fibrin wound dressing provides a convenient delivery format as well as a hydrated, degradable scaffold to manage the wound environment prior to debridement.

- USAISR
- TATRC
- University of Texas at Austin

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Neuroprotective Drug Combination Therapy Strategy

Description

Neuroprotective drugs will improve the outcome following acute brain trauma. TBI is a complex problem not likely to be healed with just one type of treatment. Drugs that show promise in the treatment of one area of TBI sequelae (e.g., antiepileptic drugs) will be examined in combination therapy via isobolic analysis. The goal will be to identify possible combinations of drugs that work together to show efficacy in the treatment of TBI.

Neurological trauma is the number one cause of traumatic mortality on the battlefield and often is associated with significant morbidity, disability, and delayed mortality in those who survive the initial injury. A neuroprotective drug used to preserve or protect otherwise uninjured neurological tissue in the face of direct penetrating head trauma will reduce residual disability and subsequent long-term care demands. The capability to stimulate or enhance neuronal healing and repair as well as functional recovery will further reduce residual disability.

Partners

• WRAIR

2-60



Automated Critical Care Life Support System

Description

The Automated Critical Care Life Support (ACCLS) System will provide automated life support capability up to 72 hours on the battlefield for surgical and postsurgical environments including the en route care transport of patients during recovery and evacuation. The system is a portable, self-contained, lightweight (less than 40 pounds), protected environment for one casualty. Life support functions are automated including computer-driven, closed-loop control of ventilation, fluid, drug, and oxygen administration. It also incorporates data logging and telecommunication capabilities to facilitate record keeping and to enable real-time communication of patient data to the receiving hospital for assistance with monitoring and decision assistance from a remote location.

The ACCLS System automatically optimizes the patient's treatment while freeing the medical staff to care for other casualties once a seriously injured casualty has been stabilized. The system will provide increased and improved holding capability at the forward surgical team as well as extended critical care capability within the ground and air ambulance platforms.

Partners

WRAIR



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Medical Ultrasound, Three-Dimensional, Portable with Advanced Communications

Description

The Medical Ultrasound, Three-Dimensional, Portable with Advanced Communications (MUSTPAC 3) device allows a user to capture ultrasonic information from a conventional ultrasound unit in the form of a three-dimensional databank. The device maps standard two-dimensional volume by coupling the ultrasound machine to a mechanical arm providing six degrees of freedom information. The three-dimensional data are forwarded to a radiologist who then uses the virtual probe to "scan" the imaginary patient in any directional plane and make a diagnosis.

The benefits of the MUSTPAC 3 device are that data are digitized for storage and transmission and reconstructed into three-dimensional images, images are rendered in color, a layperson can operate the ultrasound unit, and distant review and diagnosis can occur.

Partners

• TATRC

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Monitors

- Non-Contact Heart Monitor (Vital Signs Monitor 1)
- Non-Contact Respiration Monitor

Description

These devices allow for the monitoring of casualties enclosed in chemical protective overgarments without exposing either the patient or medical personnel to a contaminated environment. Mass casualty triage and high noise and vibration evacuation environments are situations where these monitors will be useful.

Non-Contact Heart Rate Monitor. This is a handheld diagnostic attachment to the Warrior Medic System or a stand-alone system that will measure life signs in wounded service members. Sensors measure heart rate and possibly cardiac stroke volume to assess the injury status of a patient, and artificial intelligence coding provides treatment suggestions.

Non-Contact Respiration Monitor. This is a small, self-contained monitor that attaches to a gas mask filter canister or is incorporated in the gas mask that will sense the flow of air entering the gas mask and indicate the state of breathing audibly and visually.

- WRAIR
- USAMMDA



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Pneumothorax Detector (Vital Signs Monitor 2)

Description

The Pneumothorax Detector indicates the presence of a collapsed lung in patients with chest wounds. Measurements are made noninvasively using either breath sounds or microwaves.

Penetrating wounds of the chest can result in a collapsed lung that if not readily identified can further complicate treatment. The Pneumothorax Detector replaces radiography for diagnosis and will help guide the rapid, appropriate management of a collapsed lung.

Early detection of a collapsed lung (pneumothorax) will help avoid later complications in treatment. With this device, medics and forward-deployed medical personnel can diagnose a collapsed lung in a patient with a chest wound.

Partners

• WRAIR

2-64



Temporary Implantable Lactate Sensor Biochip

Description

The goal of this project is to develop an implantable lactate-sensing biochip for temporary implantation that is capable of telemetered reporting of local lactate levels that can indicate level of injury and hemorrhage risk. Following injury that results in tissue hypoxia, interstitial lactate levels increase and are the main source of metabolically produced acid responsible for tissue acidosis. Lactate levels also have been found to correlate with the severity of injury, including hemorrhage. In preliminary development studies, these biochips are temporarily implanted into a skeletal muscle bed of animals. Lactate levels are continuously monitored for implantation periods varying from several hours to 3 months and include testing in a model of severe hemorrhagic shock. A hemorrhage rat model has been developed, and lactate- and glucose-specific biosensors have been fabricated, packaged, and implanted into hemorrhaged rats. Preliminary results obtained using an implanted but tethered biochip and portable potentiostats have produced good correlations between blood lactate and tissue lactate levels. Design considerations for the technical performance and the desired "footprint" for an implantable biochip have produced a comprehensive set of technical specifications. A prototype device is pending further in vivo studies on biocompatibility and analysis in another hemorrhage rat model of trauma.

- CDMRP
- Virginia Commonwealth University



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Thirty-Minute Cold Sterilization Solution

Description

The Thirty-Minute Cold Sterilization Solution is produced by reconstituting a dry chemical compound with water. Following mechanical cleaning, instruments are soaked in the solution for 30 minutes to sterilize them.

Medical and dental care requires sterilization of instruments that is typically done with steam, heat, or chemicals, alone or in combination, using relatively large equipment. Field medical and dental personnel carry a limited number of presterilized instrument packs, and once used, the instruments must be resterilized prior to reuse. The Thirty-Minute Cold Sterilization Solution will reduce the logistical burden associated with maintaining a supply of sterilized instruments.

Partners

- WRAIR
- USAMMA



Warfighter Remote Triage

Description

Remote monitoring of wounding and vital signs capability via the Land Warrior Suit will enable a combat medic to attend to the most critically injured first. A minimal set of sensors to detect wounding and monitor vital signs will be embedded in the Future Force Warrior Suit to diagnose and evaluate a casualty's physiological status and triage priority from a remote location to focus and optimally direct the medic's lifesaving skills to the appropriate casualty. Future Force medics will have a small and wearable PC capable of interfacing with physiological sensors and of hosting diagnostic algorithms that will provide medical decision assistance and the capability to send information through the medical alert system.

Warfighter Remote Triage aids in a medic's diagnosis and treatment of casualties thereby enhancing survivability.

Partners

USAISR



Anticaries Components

Description

The Anticaries Components constitute a system of simple, safe, U.S. Food and Drug Administration-approved chemical additives, including antimicrobial peptides, to field rations.

Dental problems cause a significant percentage of lost duty time, and in the austere environment of lengthy deployments and combat, lack of good dental hygiene practice is commonplace. The Anticaries Components will help prevent the occurrence of dental plaquerelated emergencies in deployed forces.

Partners

- WRAIR
- USAISR

2-66



Combat

Care

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OVERVIEW

On the battlefield and at home, service members' physical and mental health, performance, and fitness require state-of-the-science, evidence-based strategies, interventions, and countermeasures.

The mission of the Military Operational Medicine Research Program (MOMRP) is to develop effective countermeasures against stressors and to maximize health, performance, and fitness. Our mission is protecting the whole Soldier from head to toe, inside and out, at home, and on the battlefield. Science to Soldier is indeed our focus.

MOMRP, U.S. Army Medical Research and Materiel Command (USAMRMC), conducts biomedical research to deliver products and solutions to the Warrior that address health and fitness throughout the deployment cycle. MOMRP is centered on cutting-edge scientific research and bringing science to the Soldier on the battlefield in a relevant, timely manner. MOMRP depends on a phenomenal cadre of dedicated scientists and engineers who continuously and tirelessly work to protect the nation's most valuable asset—the Warrior. MOMRP is divided into four research focus areas: Injury Prevention and Reduction, Psychological Health and Resilience, Physiological Health, and Environmental Health and Protection.

Injury Prevention and Reduction

Biomedical basis for countermeasures that prevent and mitigate Warrior injury

Warriors are susceptible to physical, sometimes debilitating injuries. Head and neck injuries, including severe brain trauma, have been reported in one-quarter of evacuated service members. In the past 5 years, the Walter Reed Army Medical Center alone has surgically treated approximately 700 Warriors with moderate to severe visual injuries. Nearly 70,000 combat troops are collecting disability for tinnitus and more than 58,000 for hearing loss. Medical disability discharge rates have increased with 78 percent due to musculoskeletal injury. MOMRP research helps prevent physical injuries through development of injury prediction models, equipment design specifications and guidelines, health hazard assessment criteria, and strategies to reduce musculoskeletal injuries.

MOMRP Injury Prevention and Reduction research develops models to predict the degree of injury from known threats, develops design guidelines and performance specifications for protective equipment, and identifies countermeasures to prevent or mitigate injury to the Warrior. Key threats addressed by this research area include blast overpressure, blunt and penetrating trauma, musculoskeletal and training injuries, and neurosensory injury. This program addresses thoracic and pulmonary injury protection through modeling blast and blunt trauma, protection that prevents or reduces neurosensory injury, validated standards for performance to assess return to duty, and training doctrine based on physiological mechanisms that underlie musculoskeletal injury that identify and mitigate injury risks.

Psychological Health and Resilience

Strategies and interventions that build psychological resilience and optimize psychological health and emotional fitness among Soldiers and families

Psychological health problems are the second leading cause of evacuation during prolonged and/or repeated deployments. Of returning Warriors, 20–40 percent have behavioral health problems post-deployment, mostly related to post-traumatic stress disorder (PTSD), depression, and interpersonal conflict. MOMRP researchers develop strategies and advise policy makers to enhance and sustain mental fitness throughout service members' careers. These include validated prevention and treatment interventions that address psychological health issues, enhanced screening and identification of concussion-related health concerns, and improved clinical guidelines for health care providers.

MOMRP Psychological Health and Resilience research is focused on prevention, treatment, and recovery of Soldiers' and families' behavioral health, which are critical to force health and readiness. Research is necessary to guide policy and ensure optimal delivery of behavioral health training and services across the continuum of care and deployment cycle. Threats addressed by this research component include PTSD, suicide, family separation, and family violence.



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Current Psychological Health research topic areas include:

- Universal and selective behavioral health prevention and resiliency building
- Case identification, treatment, and clinical management of individuals with mental disorders
- Suicide prevention
- Neurocognitive assessment and clinical management of post-concussion-related challenges
- Substance use-related problems
- Ongoing epidemiological and preclinical research to identify vulnerability, protective, and risk factor interactions associated with mental disorders and negative risk-taking behaviors
- Family and community wellness capacity building
- Bereavement interventions
- Prospective epidemiological, intervention, and surveillance research designed to address neurological health, fitness and readiness, longer-term physical and mental health, disease, and performance outcomes over the deployment cycle

Physiological Health

Biomedical countermeasures to sustain Warrior health and operational effectiveness

The rapid pace of operations and the need for repeated deployments have a profound effect on the physiological health and performance of Warriors. MOMRP develops novel nutritional strategies that maintain and sustain optimal health and readiness, a comprehensive sleep and performance management system that predicts Warrior physiological degradation, and a real-time medical status monitoring and situational awareness informational system enabling commanders to ensure mission success.

MOMRP Physiological Health research focuses on developing medical standards, predictive models, and countermeasures to prevent or mitigate the effects of physiological stressors on the performance and fitness of Warriors. These stressors include inappropriate nutrition, poor physical fitness, sleep loss, sleep deprivation, fatigue, and burn out. The focus is on threats and stressors in both the garrison and operational environments. Current research addresses advanced biomedical modeling and networked physiological status monitoring capabilities, a comprehensive sleep and performance management system based on effects of chronic sleep restriction and acute total sleep deprivation, individual physiological differences in sleep loss resilience, nutritional health surveillance and dietary supplement use, and interventions to mitigate threats to operational health.

Environmental Health and Protection

Assess and sustain Warrior health and performance in extreme environments

Warriors train and fight while exposed to a range of harsh environmental conditions, such as extreme heat and cold temperatures and high terrestrial altitude. These harsh environmental conditions, alone or combined with other operational stressors, degrade military physical and cognitive performance. MOMRP provides guidelines to mitigate performance degradation from these environmental extremes. Warriors are also susceptible to exposure to toxic chemicals and materials in the operational environment. MOMRP develops biomarkers to detect toxic exposures and methods to assess their impact on health risk. MOMRP Environmental Health and Protection research develops medical standards, predictive models, and countermeasures to prevent or mitigate the effects of extreme environments and toxic material exposure in the military. Threats addressed by this program include extremes of heat/cold and hydration, high altitude, and toxic industrial chemicals and materials. Current research projects focus on methods that sustain operational performance in extreme heat and cold and at high altitudes to prevent and manage heat, cold, altitude sickness, and hydration-related injuries. This research also includes detecting, monitoring, and assessing the risk of the Warrior's exposure to toxic chemicals and materials during operations.

MOMRP conducts medical research to deliver products and solutions for the Warrior that address health and fitness throughout the deployment cycle. The focus is on life cycle solutions that maximize the effectiveness of taxpayer dollars and minimize the health effects of operational and environmental stressors on the Warrior. MOMRP leverages its Department of the Army funds and congressionally directed funds for research not only at Department of Defense (DoD) laboratories but also at myriad extramural research organizations from small colleges to multinational corporations in the development of cutting-edge technology. The research products are directly applicable to today's battlefield and the anticipated problems of tomorrow's war.



There is nothing more important than the safety of our Soldiers, their confidence in their equipment, and America's confidence in their Army.

> - Former Secretary of the Army Pete Geren

That this nation, in order to continue to field the best, most effective military and Army the world has ever seen, we have to take care of the Soldier and his and her family as well.

- Secretary of the Army John McHugh

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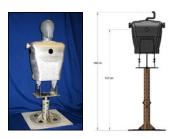
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Advanced Blast Test Device

Description

The Advanced Blast Test Device (ABTD) provides a versatile, biofidelic method to collect blast overpressure and impulse noise data for assessment of blast overpressure hazards to prevent occupational injuries for military personnel during weapon firing exercises. The ABTD is a developmental device to collect blast overpressure and noise data for occupational blast hazard assessment to meet four requirements requested by field testers. First, it is lightweight, approximately 50 pounds, to enable easy handling in tight spaces such as inside a vehicle. Second, it is anthropometrically shaped so that sound data can be measured at the ear location satisfying MIL-STD-1474D specifications with the blast overpressure measured at the correct chest and thorax locations. Third, it is configurable with a suite of accessories provided to allow the user to place the ABTD at standing, sitting, kneeling, and crouching positions. Fourth, it is adaptable with various attachments provided for mounting impulse sound gauges or acoustical headform. Nonauditory hazard is predicted using INJURY 8.3 with the overpressure data as input. Auditory hazard is assessed using MIL-STD-1474D. The ABTD has been field tested for functionality, and a series of field tests is being planned to provide benchmark evaluation data to support the development of a test operational plan for blast testing.

Partners

- MOMRP
- L-3 Communications/Jaycor

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Body Armor Blunt Trauma Performance Testing Method

Description

A biomedically valid body armor blunt trauma performance testing method consisting of two components: (1) a physical model known as the "Anthropomorphic Test Module" that measures the distribution of forces and motions behind body armor systems during a ballistic impact and (2) a biomedically valid, human blunt trauma injury prediction model packaged in a user-friendly, web-based software application known as Behind Armor Blunt Trauma Assessment. The human injury prediction model is the product of carefully controlled animal tests that included advanced medical imaging techniques and the latest mathematical modeling methods. The model's predictions were validated with extensive injury data from the animal tests.

Partners

- MOMRP
- University of California, San Diego
- L-3 Communications/Jaycor



Design Guidelines for Advanced Imaging and Display Technologies

Description

Design criteria and test methods for imaging and display systems based on visual performance capabilities were developed. This includes predictive models of visual performance with sensor and display systems in operational environments. These criteria and methods provide the means for evaluating new system designs and give developers the information necessary to develop effective imaging and display systems for rotary-wing aircraft and other military vehicles.

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Effects of Prolonged Deployment on Physical Performance, Body Composition, and Injury Potential

Description

Anecdotal reports have raised concerns that prolonged deployment to Iraq and Afghanistan may be associated with significant loss of body weight and muscle mass and a reduced capability to carry out physical tasks such as load carriage. If these changes are occurring, there is also the possibility that these service members may be at greater risk for musculoskeletal injury. A series of studies has been conducted involving a complete assessment of body composition, strength, and metabolic aerobic capacity in several hundred service members before and immediately after approximately 1 year of deployment to Iraq and Afghanistan. In addition, information was obtained to determine the relative importance or impact of nutritional factors, energy expenditure related to mission demands, and the ability of service members to continue their physical training on these physiological measures. The results demonstrated that changes in maximal aerobic or endurance capacity were reduced by less than 5 percent, there were minimal changes in body composition in terms of lean body mass or fat, and no significant or consistent changes in strength or power. A key factor impacting changes in body composition and/or physical performance was the fact that Soldiers noted that their ability to physically train was decreased while being deployed.

Partners

- USARIEM
- Public Health Command (Provisional)

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Evaluation of Human Exposure to Whole-Body Vibration: Method for Evaluation of Vibration Containing Multiple Shocks

Description

The Method for Evaluation of Vibration Containing Multiple Shocks is used to predict injuries sustained by service members who ride in Army tactical ground vehicles at high speeds over rough terrain.

This standardized method for health hazard assessment of whole-body vibration and repeated jolt in vehicles is based on laboratory studies of human responses to repeated jolts and a neural network of the lower spine. The method was published as an international standard (ISO 2631-5) and transitioned to the U.S. Army Center for Health Promotion and Preventive Medicine.

Partners

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INJURY-A

Description

INJURY-A is a software tool for material developers to assess the effects of armor materials on blast lung injury so that protection concepts can be developed to mitigate blast overpressure injuries for Warfighters. Based on the normalized work methodology, INJURY-A predicts the risk of lung injury by coupling the material effects with the thorax motion to calculate the total irreversible work done to the lung as a result of a blast insult. Field tests are performed using the Modified Blast Test Device (MBTD) that is instrumented with distributed pressure sensors to measure the under-armor blast load-ing. The MBTD data are used to construct the material model for coupling with the thorax response to calculate normalized work. Predictions have been validated against animal tests with more than 200 subjects involving a range of material concepts. The software is packaged with a GUI (graphical user interface) for managing and analyzing field data, building material models, predicting outcomes, and generating test reports.

Partners

- MOMRP
- U.S. Army Natick Soldier Research, Development and Engineering Center
- L-3 Communications/Jaycor

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INJURY 8.3

Description

Based on INJURY 8.2 and continuing with the normalized work methodology, INJURY 8.3 software has been upgraded to include validation against thermobaric blast data and lethality predictions. Software architecture has been rebuilt on a SimuLink platform to better accommodate future upgrades to include predictions of injury patterns where applications also can be packaged for more seamless linking to support other software applications such as the Toxic Gas Assessment Software. The Blast Test Device is used to collect blast overpressure data as inputs as before. Documentation is being updated in preparation for a verification, validation, and accreditation effort.

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Injury Prevention and Restraint Technologies for Ground Vehicles and Helicopters (Inflatable Restraint Systems)

Description

Inflatable restraint technologies are being developed and integrated into Army aviation platforms. While these technologies have inherent crash protection capabilities, they also introduce novel injury hazards. USAMRMC testing revealed hazards to the upper extremities and ocular regions when the systems are not properly designed or the occupant is not in the design eye position. The prototype lateral bag design was found to present a greater than 90 percent risk of upper extremity injury, prompting a system redesign. The redesign eliminated 99 percent of the hazard. More than 300 UH-60L helicopters have been modified with the air bag system. Surveillance of injury resulting from crashes of these air bag-equipped vehicles is ongoing and will reveal the injury mitigation capabilities and new hazards associated with these protective systems. Expanded research and modeling efforts will provide guidelines to assist in the design of future inflatable restraint systems that reduce the risk of these inherent hazards.

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Laser Exposure Standards to Prevent Laser Eye Injury

Description

Laser exposure standards were developed to prevent laser eye injuries. These standards impact deployment of each military laser system, the design of new military laser systems, and the development of protective eyewear for Soldiers. The understanding of the biomedical thresholds and laser-tissue interaction mechanisms for laser exposure conditions inherent to military laser systems facilitates triage of overexposure to laser radiation. The maximum permissible exposure limits for laser exposure conditions to prevent eye injury during the design, testing, and deployment of advanced military laser systems were updated and incorporated in the Army Radiation Safety Program described in Army Regulation 11-9 for laser radiation. The following key points were determined and published:

- Ocular injury thresholds for wavelengths in the 1–2 micrometer range resulted in the update of exposure guidelines impacting the Airborne Laser, the Airborne Tactical Laser, and other high-energy laser systems.
- Retinal injury thresholds as a function of retinal irradiance diameter were used to assess the hazards of particle cell suspension switches for military optical sites and for the update of exposure guidelines.
- Ocular aversion response (eye movement) impact on retinal injury risk assessments and exposure guidelines for long duration exposures were determined.
- The understanding of the visual effect of visible laser, the ocular aversion response, and the laser-induced retinal injury threshold impacted the safe deployment of laser illuminators (dazzlers). While exposure to safe levels can be perceived as extremely bright, the biomedical data obtained to establish safe exposure limits also facilitated triage of suspected and actual injury from such illuminations.

These standards impact the design of new military laser systems and protective equipment and provide the Army Medical Department with the tools necessary to assess field laser hazard when laser systems are used in testing, training, and operational environments.

Partners

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Ophthalmic Standards for Personal Protective Eyewear

Description

Personal Protective Eyewear design concepts have radically changed over the past few years. These changes have greatly improved the protection of Soldiers but have required the development of new or revised ophthalmic standards for vendor guidance. The wraparound polycarbonate shield design and ophthalmic correction lens carrier approach to Personal Protective Eyewear has required the development of new ophthalmic tests to evaluate face form angle and procedures to adjust ophthalmic prescription to accommodate the effect of large face form angles. These measurements and procedures have been adapted and are currently in use by military ophthalmic fabrication facilities worldwide.

Partners

- USAARL
- Program Executive Office Soldier
- Product Manager Air Warrior



Reference Work on Sensory, Perceptual, and Cognitive Aspects of Helmet-Mounted Display Design

Description

Helmet-Mounted Displays: Sensation, Perception and Cognition Issues provides insights into the effects of helmet-mounted displays (HMDs) for pilots, educators, academics, and the general public who are interested in the field of human factors engineering, military night flight operations, and the visual and auditory science behind improvements in advanced aviation (and other Warfighter) sensor systems.

This is the second in a series of books on HMDs published by USAARL. The first book, *Helmet-Mounted Displays: Design Issues for Rotary-Wing Aircraft,* focused on engineering design issues whereas this book fills the gap identified by the National Research Council related to the relationship between the HMD hardware design and user perception/cognition of visual and auditory displays. From the explanation of the human machine interaction dilemma, through the detailing of visual and auditory display systems, this book provides the reader with a thorough understanding of the issues related to military operations with respect to our senses, how we perceive what is represented, and ultimately how we assimilate and react to this information.

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Total Army Injury Health and Occupational Database

Description

The Total Army Injury Health and Occupational Database (TAIHOD) is used to track and store the demographic, occupational, and health information of Army members over the course of their active duty careers. It is a major research capability used by the Military Performance, Thermal Mountain Medicine, and Nutrition Divisions at USARIEM.

TAIHOD is a database for answering epidemiological questions of injury and health outcomes relevant to the Army. It contains information on individual service member demographic and occupational characteristics, health outcomes, and health behaviors collected over the course of an Army member's active duty career for all Army members who have served on active duty since 1971—approximately 5 million individuals. TAIHOD provides the data necessary for the development of military health and safety policies.

Partners

USARIEM



Military Infectious Diseases

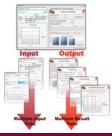
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Toxic Gas Assessment Software – Performance Evaluation

Description

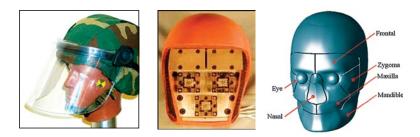
Toxic Gas Assessment Software – Performance Evaluation (TGAS-PE) predicts impairment, incapacitation, and lethality following exposure to toxic gases. TGAS-PE is a tool that predicts probability of total incapacitation, immediate lethality, and delayed lethality from inhalation of a mixture of seven common fire gases (i.e., low O₂, CO, CO₂, NO₂, HCN, HC1, and Acrolein). For exposures to gases that interfere with oxygen delivery, such as hypoxia or altitude or atmospheres with carbon monoxide, the software predicts decrements in physical performance for an arbitrary work profile. The software is based on a comprehensive mathematical model of human physiology, including pulmonary, cardiovascular, humeral, and neural control systems. The model has been validated against physiological and performance data for small and large animal tests and human exposures under normal and altitude conditions. Several forms of the application are available for use in human hazard assessment for occupational exposure at low levels to those for use in survivability and lethality assessment.

Partners

- MOMRP
- L-3 Communications/Jaycor

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Warfighter Face and Eye Injury Protection

Description

Operationally focused face and eye injury research conducted under the USAARL Cockpit Air Bag research program illustrated the need for biomedically relevant facial and ocular injury criteria as well as a timely, low-cost alternative to cadaver-based testing. The primary research thrusts in this program include the development of the Facial and Ocular Countermeasure Safety (FOCUS), a biofidelic test headform capable of measuring blunt impact forces acting on the face and eye and the promulgation of biomedically based facial and ocular injury criteria. Together, these tools will provide Army materiel developers an efficient, cost-effective means of evaluating the efficacy of novel face and eye protection devices. This research effort will lead to improved protective devices, enhancing the survivability and sustainability of the Warfighter.

Partners

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Army Medical Department Suicide Event Report

Description

The Army Medical Department Suicide Event Report (ASER) is a data system that captures information on suicide. ASER is a reporting instrument with both quantitative and qualitative information to better understand and summarize suicides in real time. It uses a web-based electronic data system containing information on all suicides and all hospitalized attempted suicides. Enhanced Army suicide surveillance will allow better targeting of current and future suicide prevention programs.

Partners

- WRAIR
- USAMRU-E
- U.S. Army Europe
- Europe Regional Medical Command

3-16



Pre/Post-Deployment Psychological Screening

Description

Individual and unit functioning are improved through the early identification of service members with potential behavioral health issues using a simple, easily administered, valid, and cost-effective screening procedure. Prior to and returning from deployments, behavioral health providers are tasked with identifying service members who may benefit from behavioral health services. Through the use of survey instruments and brief structured clinical interviews, large groups of service members can be rapidly screened, and those with behavioral health care issues can be identified and referred for follow-up care.

In 2004, two blind-validation screening studies produced a short screen fielded in U.S. Army Europe. The research demonstrated that behavioral health concerns become more evident several months following return from combat. This screening research influenced the development of the DoD's Post-Deployment Health Reassessment program per policy guidance from the Assistant Secretary of Defense for Health Affairs. A third blind-validation study conducted by USAMRU-E in 2005 provided scoring guidelines for the mental health component of the Post-Deployment Health Reassessment (DD Form 2900) and developed a structured interview guide to help triage service members.

By establishing a short and valid screening procedure and determining the optimal time to conduct screening, mental health support can be streamlined and brought forward to meet the needs of a deploying force.

- WRAIR
- USAMRU-E
- U.S. Army Europe
- Europe Regional Medical Command

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Resilience Training System

Description

WRAIR developed and tested Battlemind Training, the Army's first integrated mental health training system, which was mandated Army-wide in 2007. Since that time, the Army initiated Comprehensive Soldier Fitness, a large-scale program designed to increase resilience and enhance performance through unitlevel master resilience trainers, the Army's professional military education system, and mandated deployment cycle training. Battlemind was integrated into this larger effort, and WRAIR has served as the lead in adapting the material as well as creating and piloting a component of the Master Resilience Trainer course. All of the training modules address Soldier and family strengths and include actions Soldiers can take to care for themselves, their buddies, and those they lead.

Throughout this transition period, WRAIR continues to test the efficacy of resilience training. WRAIR has integrated resilience training and programmatic research efforts by incorporating Land Combat Study and Mental Health Advisory Team findings into resilience training modules. In 2010, WRAIR conducted a program evaluation to assess the Training and Doctrine Command's pilot efforts to integrate Master Resilience Trainer course concepts into the Army's Basic Officer Leadership Course. The study resulted in a policy decision to create a 10-hour resilience training course for the Basic Officer Leadership Course. Additional modules are being developed, and follow-on research is assessing methods for increasing resilience training efficacy.

Partners

• WRAIR

3-18

- USAMRU-E
- Training and Doctrine Command
- Comprehensive Soldier Fitness
- Army Center for Enhanced Performance



Enhanced Fluid and Nutrition Delivery System

Description

This research effort exploits new knowledge on water needs and adverse performance consequences from dehydration. New doctrine and sweat prediction software will improve the prediction of water needs while the Enhanced Fluid and Nutrition Delivery System will optimize fluid intakes. Both will reduce hydration-related heat injury incidence while also sustaining performance. The logistical water supply burden will be minimized by reducing water procurement error and increasing potable water consumption due to the presence of a flavoring agent but without water hygiene concerns. Nutritional supplements will minimize adverse performance outcomes of dehydration.

Partners

USARIEM



Guidance on Using Modafinil and Dextroamphetamine as Alertness-Promoting Agents in Aviators Performing Extended Operations

Description

Research was conducted on the use of prescription-only pharmacologic products to enhance performance and alertness during unavoidable sleep loss in aviators. Two stimulants were tested: dextroamphetamine (Dexedrine®) and modafinil (Provigil®). Eighteen pilots each completed 15 heli-copter flights and other evaluations during two 40-hour periods of sustained wakefulness during which they received two of three experimental conditions: 3 doses at 4-hour intervals of modafinil (100 milligrams), dextroamphetamine (5 milligrams), or placebo. Statistical results showed that the stimulants maintained alertness, feelings of well-being, cognitive function, judgment, risk perception, and situation awareness of sleep-deprived aviators consistently better than placebo and without side effects of aeromedical concern. Like previous research, this study strongly suggests that these drugs can maintain acceptable levels of mood and performance during sleep deprivation. The results also confirm that modafinil is well tolerated and appears to be a good alternative to dextroamphetamine for countering the debilitating mood and cognitive effects of sleep loss during sustained operations.

The findings of this study resulted in a change to the Aviation Policy Letter by the U.S. Army Aeromedical Consultant Advisory Panel approving the use of modafinil by U.S. Army aviation forces. The U.S. Navy is using the results to affect an equivalent action.

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Nutritionally Optimized First Strike Ration

Description

The First Strike Ration is a lighter weight, shelf-stable, appealing, and nutritious individual ration that increases mental awareness and stamina for use during high-tempo operations in logistically austere conditions.

Together with the Combat Feeding Directorate, a lightweight, low-volume, 100 percent eat-on-the-move ration was developed and tested. The newly developed ration includes components that have been shown to preserve cognitive and physical performance during demanding mission conditions. The First Strike Ration is now available for procurement.

Partners

- USARIEM
- Combat Feeding Directorate, U.S. Army Natick Soldier Research, Development and Engineering Center, Army Materiel Command



On-the-Move Nutrient Delivery System

Description

The Nutrient Delivery System is a simple add-on to the Personal Hydration System that enables the user to receive nutrition on the move. The patented device enables Soldiers to have on-demand access to a beverage mixed to their current personal taste. It eliminates cumbersome mixing. Moreover, the Nutrient Delivery System is designed to keep the water reservoir free of mold or bacterial contamination over periods of prolonged use.

Product acceptability studies demonstrate that the Nutrient Delivery System is a desired product. Sixty-eight percent of Soldiers rate the device as "moderately" to "extremely valuable" with 83 percent saying they would recommend the system to their peers and 76 percent recommending that the Army invest in the technology.

The Nutrient Delivery System is expected to be available for commercial purchase in 2011.

PartnersUSARIEM

3-20



Probability of Survival Decision Aid

Description

The purpose of this research effort was to develop a Probability of Survival Decision Aid (PSDA) that predicts hypothermia, dehydration, and survival time during prolonged exposure to a wide range of air and water conditions at sea.

Estimates of survival time are required to optimize planning and execution of search and rescue operations and to improve the likelihood of a successful outcome. For accidental immersion, survival times are often represented in tables or curves as a function of water temperature. Such onedimensional representations can be misleading as tables and plots are often over simplified requiring interpolation between discrete values to fit a given set of conditions. Curves provide a continuous analog representation of survival information but require a graphic interpretation. A better alternative is to use a mathematical model of human thermoregulation. The PSDA mathematical model allows the input of more specific information and more complex analysis relative to a given incident and thus predicts survival times that more accurately reflect the physiological state of victims.

This project has been transitioned to the U.S. Coast Guard and integrated into its Search and Rescue Optimal Planning System.

- USARIEM
- U.S. Coast Guard



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Cold Weather Operations: Cold Injury Prevention and Performance Optimization

Description

Cold exposure guidelines were developed to prevent and reduce hypothermia, frostbite, and nonfreezing cold injuries to service members. To alleviate the psychomotor and cognitive deficits associated with cold exposure, nutritional supplements were evaluated for their efficacy in prevention during hypothermia.

Policy memoranda, field manuals, and training aids regarding hypothermia and other cold injuries were produced in conjunction with the U.S. Army Public Health Command and the Office of the Surgeon General. A comprehensive Technical Bulletin guidance document for health care providers entitled "Prevention and Management of Cold Weather Injuries" (TB MED 508) has been published. In addition, NATO STANAG 2539, "Prevention and Management of Cold Weather Injuries," has been adopted. Tyrosine, an amino acid supplement, has been shown to improve marksmanship and cognitive performance in hypothermic Soldiers.

Partners

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Environmental Strain Prediction Models

Description

Environmental Strain Prediction Models are biomedically valid tools for predicting individual and unit-level performance outcomes based on environmental and operational variables. Given particular terrain characteristics, environmental temperature, and clothing requirements, these tools will provide accurate predictions of thermal strain with recommendations for fluid replacement and work/rest schedules. These prediction models provide mission planners and leaders the ability to simulate missions using accurate predictions regarding service member performance in environmental extremes.

Partners



High-Altitude Operations: Management and Performance Optimization

Description

High-altitude (terrestrial) exposure guidelines were developed to prevent and reduce hypobaric hypoxia-related illnesses and performance impairments to service members. Nutritional supplements were evaluated for their efficacy in improving exercise performance at high altitude, and the effect of dehydration on performance at high altitude was guantified.

Policy memoranda, field manuals, and training aids regarding management of high-altitude acclimatization and altitude sickness were produced in conjunction with the U.S. Army Public Health Command and the Office of the Surgeon General. A comprehensive Technical Bulletin guidance document for health care providers entitled "Altitude Acclimatization and Illness Management" (TB MED 505) and a deployment health guide, "A Soldier's Guide to Staying Healthy at High Elevations," have been published and adopted as NATO (North Atlantic Treaty Organization) Standardization Agreements. These state-of-the-art guidelines are used for training and operational planning and serve to prevent and reduce altitude-related injuries to service members.

Carbohydrate supplementation improved exercise performance at high altitude and is a key component of a new Modular Operational Ration Enhancement High-Altitude Pack. Dehydration reduces exercise performance at high altitude and increases severity of acute mountain sickness symptoms.

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Hot Weather Operations: Heat Illness Management and Performance Optimization

Description

Heat exposure guidelines were developed to prevent and reduce heat-related injuries to service members. Nutritional supplements were evaluated for their efficacy in improving exercise performance in the heat, and the effect of dehydration on performance in the heat was quantified.

Policy memoranda, field manuals, and training aids regarding heat injury were produced in conjunction with the U.S. Army Public Health Command and the Training and Doctrine Command Surgeon's Office. Examples include the "Heat Injury Protection Guide," the "Heat Acclimatization Guide," the Technical Bulletin guidance document for health care providers entitled "Heat Stress Control and Heat Casualty Management" (TB MED 507), the NATO STANAG 2981, "Prevention of Heat Injury," and heat injury/heat stroke return-to-duty guidelines for AR 40-501, "Standards of Medical Fitness." In addition, there was a recent update (June 2010) to AR 40-501 for "Heat Illness Medical Evaluation Board and Profile Policy." These state-of-the-art guidelines for training and operational practice serve to prevent and reduce heat-related injuries to service members.

Supplementation with branched chain amino acids, quercetin, and caffeine showed no improvement in exercise performance in the heat. Dehydration reduces exercise performance in the heat with the performance decrement becoming progressively greater as the air temperature increases.

Partners



Intelligent Aquatic Biomonitor System

Description

The Intelligent Aquatic Biomonitor System (iABS) monitors fish behavior as a way to detect toxic chemicals in water. The iABS rapidly detects a wide range of toxic chemicals or chemical mixtures in water sources by measuring changes in fish behavior. Fish are natural integrators of water quality conditions and respond to a wide range of chemicals and mixtures. The system can be used at water treatment plants or other water production facilities, and water can be monitored after it is dechlorinated. The system protects drinking water supplies by continuously monitoring water. The biomonitor responds within an hour to most chemicals at acutely toxic levels and is in use at military facilities and major metropolitan areas. The iABS is available through a commercial partner.

Partners

• USACEHR



Rapid Analysis of Water for Select Chemical Contamination

Description

Rapid Analysis of Water for Select Chemical Contamination is a solid-phase microextraction and gas chromatography-mass spectrometry sampling and analysis method developed for two insecticides, carbaryl and lindane. Minimum levels of detection in environmental water sources are 10 microgram/ liter and 1.0 microgram/liter for carbaryl and lindane, respectively. The total analysis time using field-portable equipment is 30 minutes. This method avoids the use of complex sample preparation steps and enhances analyst safety by the elimination of handling solvents in field environments.

Partners

• USACEHR



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Automated Binocular Vision Tester

Description

This project will develop an Automated Binocular Vision Tester (ABVT) that can rapidly assess oculomotor functions in traumatic brain injury (TBI) patients. An ABVT will serve as an alternative to the time-consuming conventional oculomotor examination that currently must be performed by an optometrist or ophthalmologist.

Even though oculomotor dysfunction is common in military personnel after TBI, the ability to conduct a complete oculomotor evaluation on every deploying/redeploying Warfighter is currently not possible. This limitation can be overcome by employing an easy-to-use ABVT that can rapidly assess a significant number of oculomotor functions. In addition, an ABVT will provide a standardized assessment tool that will reduce the amount of chair time per patient and increase test–retest repeatability.

Partners

- USAARL
- WRAMC



Aviation Tactile Situation Awareness System

Description

The Aviation Tactile Situation Awareness System (TSAS) provides intuitive orientation cues to reduce pilot workload and permits pilots to maintain control of a helicopter under conditions of degraded visual environments. The Aviation TSAS consists of tactile stimulators embedded into a belt, seat, and shoulder straps, which provide information tactually from aircraft sensors concerning drift, velocity, and altitude changes. The information from platform sensors is converted into vibrotactile "taps" applied to the pilot's body intuitively and unobtrusively permitting the pilot to attend to other mission-essential tasks visually. In addition to flight parameters, the Aviation TSAS provides navigation and threat information.

- USAARL
- Chesapeake Technologies, Inc.
- Defence Research and Development Canada – Toronto



Biomechanical Design Guidelines for Personal Equipment

Description

Biomechanical analyses involving load carriage are made in conjunction with the determination of metabolic rate or energy cost. This includes evaluation of prototype military load carriage systems and footwear to assist in making equipment development and procurement decisions. Physical training programs are being evaluated for improving service member physical performance and quantification of the effects of load carried on the speed of over ground foot travel and the negotiation of obstacles on the battlefield.

Partners

USARIEM



Blast Dosimeter

Description

The Blast Dosimeter is a small (1" diameter, 0.45" thickness), lightweight (0.2 ounce), battery-powered device that contains a thin-film, piezoresistive sensor integrated with a microprocessor-driven electronics board that computes the dose and Work using the INJURY algorithm in real time. The date, time, and Work value are stored in flash memory for later download by two-way radio frequency communications. The INJURY model has been extensively validated against conventional and novel explosives, in free field and enclosure environments, and from blast levels from occupationally safe to lethal.

The Blast Dosimeter is constructed to operate in harsh environments and designed to function as a passive device for up to 2 years of continuous use or 1 year (after 1 year on the shelf-life) of use on a single coin cell battery. The onboard flash memory can store permanent values (Dosimeter Serial No.), temporary values (i.e., calibration data, Battle Roster Number, and Start Date/Time), and replaceable values (Blast Date/Time and Work values). The thin-film, piezoresistive sensor was selected because of low power requirements in standby mode and very rapid response to shock loading.

The Blast Dosimeter can replace the subjective self-reporting by individuals with an objective measure that can distinguish "safe" and potentially injurious exposures, objectively flag a Soldier to a serious or life-threatening exposure, and supplement acceleration-based sensors to understand the pattern of exposure in combat and that could put emerging TBI models into perspective.

- MOMRP
- L-3 Communications/Jaycor

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Customized Functional Hearing Evaluation for Military Occupational Specialties

Description

This program will develop, implement, and demonstrate a Functional Hearing Assessment System (FHAS). Hearing tests and standards will be developed based on the hearing-critical activities necessary to perform Military Occupational Specialty (MOS)-specific duties safely and effectively. The FHAS will evaluate speech intelligibility, sound detection, and localization using the recorded background noise and relevant phrases for MOS-specific, hearing-critical tasks.

Partners

- USAARL
- Creare, Inc.



Design Guidelines for Head-Supported Devices

Description

Developing head-supported devices (HSDs) requires design guidelines and health hazard assessment methods to enhance service member performance and provide protection from neck injury. Biomedically based design guidelines and assessment methods for HSDs, such as protective helmets, weapon sighting, and communication and night vision goggle systems, are being developed. The development process uses epidemiological studies, biomechanical engineering analysis, injury studies with human cadavers and manikins, and advanced biofidelic neck models to develop and validate neck injury criteria. The health risk assessment method includes the neck injury prediction model and algorithms that produce a risk assessment code based on the predicted injury severity and the probability of occurrence.

HSDs are critical components; however, they increase the amount of weight supported by the head and neck and may place service members at risk of degraded performance or neck injury. This project will provide guidelines and assessment methods for the assessment of HSDs used in current operations and the future development of safe and effective helmet-mounted systems, including enhanced combat helmet design.

Partners



Epidemiology and Protection from Injury in Combat

Description

There is an urgent need to assess the performance of personal protective equipment (PPE) in current combat operations. Current trauma databases lack exposure and PPE data necessary for reliable analyses. USAMRMC has a long-standing capability to analyze damaged protective equipment, correlate the analysis with scenario and injury data, and produce recommendations for improved equipment, tactics, procedures, and requirements. In the future, this capability, historically based in aviation, will expand to include mounted Army service members who are injured in combat. This initiative will allow Army decision makers to assess the performance of current combat protective equipment.

A multidisciplinary team of physicians, engineers, safety experts, and operational service members will conduct analyses of damaged protective equipment, correlate those analyses with scenario and injury data, and make recommendations regarding deficiencies, improvements, and future equipment requirements. Specific analyses of protective helmets from aviation and ground service members will allow determination of impact forces and system performance. The result will be a seamless record of a service member's wounding event, risk factors, diagnoses, treatment, and outcome and will lead to enhanced Warfighter survivability through wound pattern detection and optimized PPE.

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Injury Prevention and Restraint Technologies for Ground Vehicles and Helicopters (Conventional Restraint Systems)

Description

Biomedically based injury criteria and test methods for improved helicopter and ground vehicle occupant protection systems will provide system developers with the tools they need to design, develop, and field safer and more survivable air and ground vehicles for service members.

Many injuries that routinely occur in tactical vehicle operations and mishaps are preventable through the use of improved occupant restraint systems. Traditionally, military ground vehicles have not been equipped with state-of-the-art safety equipment, but significant improvement in occupant safety in tracked and wheeled tactical vehicles can be realized through the integration of commercial automotive technology and current military aviation restraint systems. Contact injuries account for more than 80 percent of injuries received in Army vehicle mishaps. Biomedically based performance criteria and flail trajectories are needed during the design and development of occupant restraint systems. New generic test methods are being developed to ease comparative performance assessments among candidate restraint systems. Special considerations in the military platform environment include the need for rapid and unhindered egress following enemy contact and survival in the post-crash (e.g., rollover) environment.

Partners



Physiological and Operational Effects of Extended Mission Duration and Seat Design

Description

Reports from the Center for Army Lessons Learned and operational experience confirm that many deployed service members experience significant back pain due to long mission duration and uncomfortable seating. These symptoms could affect mission accomplishment. In some cases, unauthorized seat cushions have been introduced into the field as a countermeasure; the effects of these cushions on crash survival are largely unknown.

The purpose of this research program is to develop a methodology to quantify seat cushion effects on seated endurance and pain and to develop a cost-effective methodology to assess seat cushion energy attenuation. The product will be a standardized evaluation methodology and performance requirements of seat cushions, increasing service member endurance.

Partners



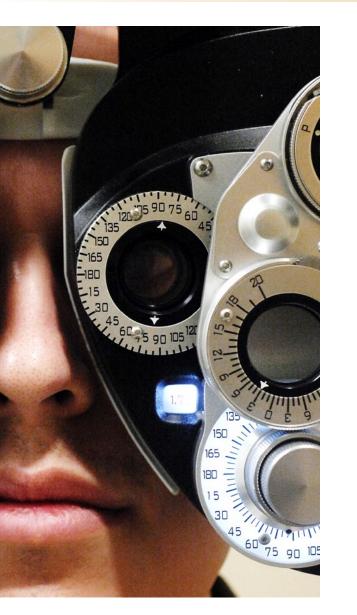
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Return-to-Duty Vision Standards After Traumatic Brain Injury

Description

Determining when a Soldier with a history of TBI is ready to return to duty is problematic. The goal of this project is to provide tests to the clinician that will assist the evaluation of these Soldiers. Visual dysfunctions that can occur with TBI include: visual acuity loss, visual field loss, oculomotor dysfunctions, extra-ocular motility impairment and loss of binocular vision, cranial nerve palsies including lid paralysis, corneal involvement, pupillary involvement, sensory and/or spatial misperceptions, nystagmus, and visual midline shift syndrome. Unfortunately, there is currently no supportive scientific evidence to: (1) establish pre-deployment visual evaluation requirements, (2) develop clinical guide-lines for the diagnosis and future management of TBI-induced visual dysfunctions, and (3) establish fitness-for-duty and return-to-duty ocular/visual standards after TBI. USAARL continues its role of providing testing and guidance to the medical standards community. This project will evaluate the new vision tests and develop recommendations for vision testing after TBI.

- USAARL
- Warrior Resiliency and Recovery Center, Fort Campbell, Kentucky



Strategies to Optimize Bone Health and Eliminate Stress Fractures in New Recruits

Description

Current research, supported in part through special congressional funding, includes nearly 60 major studies centered on physical training and other factors that influence the normal bone remodeling and repair process. In addition to identification of modifiable risk factors for stress fractures that result from changes in physical training load, these studies seek to identify interventions that may improve bone quality through biomechanical forces (including vibration and exercise), nutrition (including protein, vitamin D, and calcium intake), and hormonal influences (including low-dose estrogens, DHEA, and androgens). Combined with the results of additional studies investigating the role of genetics and personal health, dietary, and fitness habits, this bone health research program will lead to innovative approaches to prevent stress fracture injury in new recruits, provide early diagnosis and treatment of stress fractures, and favorably affect disability discharge rates. The ultimate goal of this program is to eliminate stress fracture injuries, improve overall bone health of the Warfighter, and ensure continued quality of life beyond a service member's military career.

Partners

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Tactile Balance Assessment Device

Description

The Tactile Balance Assessment Device (TBAD) provides physiotherapists with a tool to evaluate balance-compromised patients. The TBAD utilizes a balance board to provide center of gravity and stability of stance information to clinical evaluators while subjects are engaged in tasks that challenge the balance system. The center of gravity information from the balance board is provided as a tactile biofeedback cue to a collection of tactile stimulators on the torso-worn belt permitting the patient to correct for any deviations from optimal balance.

- USAARL
- Engineering Acoustics, Inc.
- Balance Sense

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Tinnitus Treatment Strategies

Description

This project will identify active duty Soldiers with uncompensated tinnitus to objectively measure their audiometric function (including tinnitus pitch and loudness matching), to subjectively measure the effect of tinnitus on quality of life, and to determine the best treatment strategies compatible with continued military service and return to duty.

Warfighters' survivability depends on accurate sensory perception of the environment. Despite technological advances in hearing protective devices, the likelihood of exposure to continuous and impulse noise on the modern battlefield remains high. As a result, the prevalence of tinnitus in returning Operation Iraqi Freedom and Operating Enduring Freedom Soldiers is at an all-time high. The goal of this project is to evaluate promising tinnitus treatment programs for active duty Soldiers with debilitating tinnitus.

Partners

- USAARL
- Neuromonics



Traumatic Brain Injury Sensory Assessment Battery

Description

The purpose of the TBI Sensory Assessment Battery is to evaluate and characterize the vestibular, auditory, and oculomotor sequelae in Warfighters diagnosed with TBI.

Sensory deficits secondary to TBI will be measured and compared to normal sensory function to determine which of these tests are sensitive to the sensory effects of TBI in an effort to refine immediate and long-term fitness-for-duty and return-to-duty standards.

- USAARL
- Warrior Resiliency and Recovery Center, Fort Campbell, Kentucky



Mental Health Advisory Teams

Description

The WRAIR Psychological Health and Resilience Program is the lead proponent for Mental Health Advisory Teams (MHATs). Since 2003, WRAIR has led MHATs into Iraq and Afghanistan. The MHATs deliver rapid behavioral health research findings directly to senior leaders within the U.S. Army Central Command, U.S. Army Medical Command, and DoD. MHAT recommendations have informed policy regarding deployment length, dwell time, behavioral health delivery, and other aspects of deployment-related behavioral health. MHATs provide objective data using scientifically validated research and sampling methods to inform policy and best clinical practice for taking care of the Warfighter.

Partners

- USAMRMC
- WRAIR
- DoD-Health Affairs
- Navy Bureau of Medicine and Surgery
- Office of the Army Surgeon General
- U.S. Air Force
- U.S. Army Central Command
- U.S. Marine Corps
- U.S. Navy



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Millennium Cohort and Deployment Health

Description

Launched in 2001 prior to the start of the operations in Iraq and Afghanistan, the Millennium Cohort Study has enrolled more than 150,000 service members from all components (active duty, Reserve, National Guard) and all services (Army, Air Force, Navy, Marine Corps, and Coast Guard). This large population-based study requests cohort members to complete a questionnaire every 3 years regardless of military status at the time of follow-up. These data are linked to other electronic DoD data sources such as electronic medical records, pharmaceuticals, deployment, and occupational exposure data. Findings indicate that combat-related stressors, rather than deployment itself, are associated with increased risk for alcohol misuse, smoking, depression, PTSD, sleep problems, hypertension, respiratory symptoms, and eating disorders in women. Furthermore, certain subpopulations have been shown to be at increased risk for post-deployment health issues, including Reserve/National Guard, those who report low pre-deployment physical or mental health, and individuals who report prior assault. Studies also have highlighted possible ways to mitigate mental health symptoms, such as increasing physical activity levels and avoiding excess weight gain. Finally, immunization research has demonstrated that the anthrax and smallpox vaccinations are not associated with increased symptom reporting or health outcomes.

Current studies are investigating transient symptoms and progression of symptoms to chronic illness, attempting to further understand the relation of possible stress and chronic health conditions, such as hypertension, diabetes, and heart disease. Factors related to common conditions present in the military, such as migraines, hearing loss, and back pain, also are being examined. Ongoing strategic studies are focusing on participants' use of complementary and alternative therapies and factors that may predict wellness. As this study follows service members after separation from the military, strategic research also will be examining separation as it relates to employment, weight change, physical activity, and reasons for leaving military service.

Established at the Marine Corps Recruit Depot in San Diego, California, the Recruit Assessment Program (RAP) was launched in 2001 to collect baseline health data on Marine recruits. Main functions of the RAP include understanding health risks at entrance to the military, understanding how service-related exposures including deployments affect health, and developing early intervention and prevention programs. Strategic studies using RAP data have identified specific risk factors among male Marines for PTSD.

Strategic studies using electronic data from the Military Health System have been conducted to quantify the impact of deployment on post-deployment health care utilization and vaccination status on health care utilization by including inpatient and outpatient encounters. Findings have indicated that deployers are healthier than the regular active duty force prior to deployment and return from deployment with higher hospitalization rates than nondeployed personnel, but these levels regress back to being consistent with the rest of the active duty military. Future studies will aim to assess the spectrum of morbidities related to deployment exposures and injuries.

- MOMRP
- Naval Health Research Center



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Operational and Strategic Studies of Service Member and Spouse Behavioral Health

Description

Since 2003, the Military Psychiatry Branch from WRAIR has collected pre- and post-deployment behavioral health data at U.S. military installations. These studies have included surveys of active duty Soldiers and their spouses as well as National Guard Soldiers. To date, data have been collected on more than 70,000 Soldiers and spouses. Results have informed Army leaders on policy issues related to behavioral health. Products include key publications documenting the effects of combat operations in both Afghanistan and Iraq on service member mental health and the factors that promote access to behavioral health care as well as policy recommendations regarding behavioral health care.

Partners

- WRAIR
- U.S. Army Forces Command
- Clemson University
- Texas Women's University
- University of Maryland
- University of South Carolina



Research on Behavioral Health Practice

Description

In 2010, WRAIR surveyed behavioral health providers in a study designed in collaboration with the American Psychiatric Association. The survey addressed caseload characteristics, the degree to which evidence-based treatments are used for mental health issues such as PTSD and suicidal behavior, and provider job satisfaction. This study is the first time data of this type have been collected in the Army. Results will lead to recommendations for improving behavioral health care delivery for Soldiers.

- WRAIR
- U.S. Army Medical Command
- American Psychiatric Association



Safe and Effective Treatment of Depression and Anxiety Disorders in Warfighters

Description

Research is planned to determine any effects, beneficial or detrimental, of administration of selected serotonin reuptake inhibitor substances on subsequent aviator flight performance and cognition. In the United States, about 10 percent of the population (7 percent women and 3 percent men) meet criteria for major depression, and another 4 or 5 percent undergo a depressive experience that is not sufficient to be officially classified as clinical depression. In the 1998 Department of Defense Survey of Health Related Behaviors Among Military Personnel, 18.9 percent of the surveyed Army members screened positive for depressive symptoms. The aviator community is not immune to these psychiatric problems. One commonly prescribed treatment for mild depression is selective serotonin reuptake inhibitors. The effects of these medications on service member performance and cognition are unknown.

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Design Guidelines for Effective Microclimate Cooling Systems

Description

Improvements in the design and implementation of microclimate cooling (MCC) systems will enhance service member performance and reduce both heat strain and injury. The efficacy of MCC systems will improve through the implementation of physiologically driven designs. Engineering attempts to enhance liquid MCC capabilities include reducing the coolant temperature and increasing flow, both of which increase power requirements. However, over cooling the skin produces skin vasoconstriction, increases thermal resistance, and decreases conductive heat transfer. As the skin-to-MCC garment interface gradient narrows, the amount of cooling per unit of power consumed declines and cooling efficiency decreases. This project examines the use of intermittent MCC to reduce vasoconstriction, maximize heat flux, and conserve battery power requirements.

Future Force operational requirements will accentuate heat strain, increase the incidence of heat casualties, and reduce work performance by demanding sustained work rates and rapid deployment with minimal time for heat acclimatization. Traditional MCC technologies have been successfully used to alleviate heat strain in mounted service members, but cooling limitations and power and weight restrictions do not currently make this technology applicable to dismounted individuals.

This project will maintain performance capabilities of a service member by improving heat flux thus reducing heat strain and water requirements. Intermittent MCC also will decrease cooling power requirements by 45 percent.

Partners

- USARIEM
- U.S. Army Natick Soldier Research, Development and Engineering Center



Effective Army Weight Management Strategies

Description

Biomedical research is being conducted to identify effective strategies for healthy body weight maintenance. Weight loss strategies being evaluated for efficacy among military personnel include meal replacement diets, use of over-the-counter weight loss pharmaceuticals, subsistence on structured energy-restricted meals served in garrison dining facilities, and Internet or personal digital assistant (PDA)-based weight loss and maintenance interventions applicable to Army Reserve and National Guard personnel as well as active duty personnel. Biological factors that influence eating behavior are being examined to identify effective behavioral strategies for modulating food intake. Finally, interactions between nutrients, biology, and eating behavior are being investigated to determine optimal food product formulations for promoting or deterring food intake.

Partners

USARIEM



Model for Fatigue Management

Description

Acute or chronic sleep loss is a common problem encountered by the armed forces, especially during continuous and sustained military operations. The ability to gauge and predict an individual's cognitive performance impairment due to sleep loss can significantly impact the success and safety of a mission. In particular, due to individual physiological differences, this predictive capability needs to be customized to each individual Soldier. Accordingly, the individualized model for fatigue management combines the physiology and neurobiology underlying sleep loss of a Soldier with key concepts in the field of system identification to model and predict performance impairment hours in advance (approximately 24 hours) for an individual subjected to sleep loss. The model uses past performance impairment measurements of the individual to customize the model parameters, predict future performance impairment levels, and provide the corresponding statistically based measures of model reliability for that individual. An important feature of this model is the ability to adapt its parameters to an individual as new performance measurements of that individual become available thereby improving its prediction accuracy with time. The current model for individualized fatigue management can be augmented with physiologically based models of the effects of caffeine in restoring alertness levels to yield an integrated biomathematical model for guantifying the effects of sleep loss and caffeine dosing on performance impairment levels at an individual level.

- WRAIR
- DoD Biotechnology High Performance Computing Software Applications Institute/TATRC



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Motion Sickness Countermeasures in Army Aircraft

Description

This series of studies investigates the use of stroboscopic illumination as a nonpharmacologic countermeasure to motion sickness related to retinal slip. Airsickness remains an important problem for today's Army. Soldiers must be ready to execute missions at any time during or following transportation so minimizing the symptoms of motion sickness is critical. A preliminary assessment of stroboscopic shutter glasses (n = 8) in USAARL's research helicopter indicated that stroboscopic technologies are a promising nonpharmacological motion sickness prevention strategy. A second study examined the idea of applying stroboscopic illumination to the passenger area of moving military vehicles as a countermeasure for motion sickness. This study used a multi-axis ride simulator to reproduce the motion profiles of airborne and amphibious vehicles to examine the effectiveness of a 4 and 8 hertz stroboscopic environment and found evidence of effectiveness in subjects' subjective reports. A third study is in preparation that will utilize 20 subjects and 8 hertz stroboscopic illumination in the cabin area of USAARL's research helicopter. The development of a nonpharmacologic motion sickness remedy would be of great benefit to the operational military community.

- USAARL
- TATRC



Nutritional Products for Digestive Health and Immune Function

Description

Respiratory infections are the leading cause of outpatient illness in U.S. military personnel. Acute gastrointestinal infections are also common. Soldiers appear to be more susceptible to these illnesses during intense physical training particularly when coupled with sleep deprivation, inadequate food intake, and psychological stressors. Thus, there is interest in strategies that can reduce illness rates.

Probiotics are safe, healthy bacteria that live in the human digestive system and can be found in common foods such as yogurt. Daily administration of certain types of probiotics have been shown to positively influence markers of immune function and prevent and/or treat respiratory and gastrointestinal infections in non-military populations. Research is under way to study the impact of a multistrain combination of probiotics on immunocompetence and the incidence, duration, and severity of respiratory and gastrointestinal infections in military personnel. Positive results may lead to improved quality of life for military personnel and potential cost savings due to reduced reliance on the health care system and preserved training/working days.

Micro-mineral elements such as zinc are important for digestive health and immune competence. Research with adult Kenyans frequently afflicted with diarrhea recently was conducted to determine the effectiveness of zinc supplementation for prevention of diarrhea. While environmental conditions prevented general conclusions for the overall population, zinc supplementation was effective for reducing diarrhea incidence and severity in those adults afflicted with HIV and/or malaria.

Partners

- USARIEM
- WRAIR
- The Kenya Medical Research Institute



Operational Ration Sustainment Testing

Description

A systematic chemical analysis of all food components in the Meals, Ready-to-Eat and the First Strike Ration is under way to define the chemical composition of the ration menus. The database produced by this effort will assist the ration developer in producing menus that meet the Nutritional Standards for Operational Rations, enable the Contracting Officer to evaluate whether the contractor is building the desired product, and determine whether standard storage conditions for operational rations affect nutrient quality. Equally important, the database will enable investigators to determine if Warfighters are consuming diets that achieve the Military Dietary Recommended Intakes, and if not, to devise strategies to achieve this desired goal.

- USARIEM
- Combat Feeding Directorate, U.S. Army Natick Soldier Research, Development and Engineering Center, Army Materiel Command

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Prevention and Treatment of Iron Deficiency Anemia in Female Soldiers

Description

USARIEM has tested both iron supplements and iron-containing food products for the maintenance of iron status in female Soldiers during basic combat training. Once daily supplementation with iron in capsule form prevented declines in iron status during basic combat training. Consumption of the iron supplement resulted in improvements in measures of mood following basic combat training and improved running time in Soldiers reporting to basic combat training with iron deficiency anemia. Twice-daily consumption of an iron-fortified food product improved iron status in female Soldiers with iron deficiency anemia.

Current efforts are under way to elucidate rapid, cost-effective methodologies for the screening of Soldiers for iron status at the start of military training such that intervention strategies may be delivered to appropriate target populations.

Partners



Sleep Watch

Description

The Sleep Watch is a wrist-worn, wear-and-forget device that provides real-time quantitative estimates of the wearer's cognitive readiness based on sleep/wake history derived from wrist movements. The Sleep Watch generates online, real-time cognitive readiness estimates using the onboard WRAIR Sleep Performance Model. These estimates are available to the individual service member on the face of the Sleep Watch and can be wirelessly transmitted to a PDA, laptop, etc., allowing commanders to use individual Warfighter cognitive readiness estimates for mission planning via Alertness Management for Military Operations (AMMO) system tools.

An application-specific, integrated circuit for micro-electro-mechanical system activity sensor, the onboard sleep-scoring algorithm, and Sleep Performance Model form an "intelligent sensor" that can be implemented as stand-alone or integrated into other systems such as WPSM (Warfighter Physiological Status Monitoring) and Future Force Warrior.

The Sleep Watch provides remote monitoring capabilities needed to predict service member cognitive readiness and does so at a low cost in terms of power, weight, volume, and computational capacity.

- WRAIR
- Air National Guard
- Defense Safety Oversight Council



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Altitude Sickness, Acclimatization, and Performance Prediction Models

Description

Altitude Sickness, Acclimatization, and Work Performance Prediction Models are being developed to provide mission-specific estimates of the impact of high terrestrial altitude on Warfighter health and performance. The first comprehensive predictive models of altitude sickness risk, performance capabilities, and acclimatization strategies for moderate- to high-altitude operations are being developed. These prediction models will provide mission planners and leaders the ability to evaluate risk mitigation controls, estimate altitude sickness incidence and severity, and accurately predict service member performance in high terrestrial regions. Moreover, this work is developing a prototype Personal Altitude Acclimatization Monitor that will provide automatic assessment of individual altitude acclimatization status and a mountain medicine enhancement to personal physiological status monitoring systems to provide real-time assessment of mountain sickness and performance capabilities. The predictive models are being incorporated into an advanced prototype Altitude Readiness Management System software application that can run on multiple platforms including handheld personal digital devices.

Partners

USARIEM

3-46



Arm Immersion Cooling System

Description

The Arm Immersion Cooling System (AICS) provides an efficient, rapid method of cooling to Soldiers in the training environment, requiring minimal logistical and personnel support to transport, set up, use, and maintain the system. Avoidance of exertional heat injury (EHI) has long been a challenge in the training environment, and a number of heat stress mitigation strategies and methods have been employed over the years. Examples include moving to shady areas, removal or loosening of clothing, providing water misters, and modifying the time of day and order of training events. In spite of these efforts, EHI continues to be a problem. The AICS provides a simple, efficient method for facilitating body core temperature cooling and reducing the risk of EHI. Immersion of the hands and forearms for 10 minutes in cool water decreases the body's core temperature substantially. Phase 2 prototypes are being developed. Phase 1 prototypes have been fielded at Fort Benning and Camp Mackall, been accepted by the Ranger and Special Forces community, and have been successful in mitigating heat stress.

Partners

USARIEM

• U.S. Army Natick Soldier Research, Development and Engineering Center



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Biological Markers of Toxic Exposures and Effects for Deployment Health Surveillance

Description

Biological markers, or biomarkers, are measurable molecular, biochemical, or cellular alterations in biological matrices, such as fluids, cells, or tissues, which occur in response to hazardous chemical exposure. Since individuals may vary in the extent of exposure, uptake, and response to chemicals, biological measures of toxicant exposure and effect—biomarkers—are needed for operational risk management. Since biomarkers can indicate the degree of exposure, biological effects, and susceptibility to disease from hazards that personnel may encounter, they have many potential applications in force health protection and health surveillance of DoD personnel.

This research program is identifying key biomarkers associated with hazardous chemicals encountered by military personnel. Taking advantage of genomic technologies and bioinformatics, experiments are being conducted using genome-sequenced animal models to identify novel biomarkers that are also highly conserved (homologous) in humans. Along with microarrays for gene expression, a proteomics approach (analysis of an organism's proteins or its proteome) also is being used to screen for biomarkers. The products of this effort include validated and measurable sets of biomarkers that can be used to evaluate the toxic exposures encountered by military personnel.

Partners

USACEHR

3-48



Rapid Analysis of Water for Microbial Contamination

Description

The assurance of safe water is paramount to the health and performance of the Warfighter. Any technology to assess the microbial purity of water under field conditions must meet rigorous criteria. It must be readily portable, provide timely results, have adequate sensitivity (1 colony forming unit per 100 milliliters), be compatible with military power sources, and be of a complexity appropriate for operation by a preventive medicine specialist.

Researchers will provide rapid identification and semiquantification of *Escherichia coli* and total coliform bacteria in 8 hours or less instead of the current 18–24 hours. Pacific Technologies developed the "Coliform Analyzer" that combines classical membrane filtration with innovative computer electronics for the selective growth and semiquantification of both total coliform bacteria and *E. coli* in the presence of other water heterotrophic bacteria.

Pacific Technologies has been awarded another contract to continue development and commercialize the "Coliform Analyzer" with the purpose that this detector will replace the coliform tests currently used by the Army.

- USACEHR
- USAMMA
- Pacific Technologies



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Skin Temperature Feedback Microclimate Cooling

Description

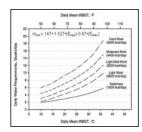
Future Force operational requirements will accentuate heat strain, increase the incidence of heat casualties, and reduce work performance by demanding sustained work rates and rapid deployment with minimal time for heat acclimatization. Improvements in the design and implementation of MCC systems will enhance service member performance and reduce both heat strain and injury.

MCC technologies have been successfully used to alleviate heat strain in mounted service members, but cooling limitations and power and weight restrictions do not currently make this technology applicable to dismounted individuals. Traditional MCC approaches involve constant skin cooling with liquids at low temperatures and high flow rates. As a result, MCC power, size, and weight requirements increase. Because overly cold skin reduces heat flux, the amount of cooling per unit of power is reduced. This project examines the use of skin temperature feedback MCC to maximize heat flux and conserve battery power. The skin temperature feedback MCC methodology has been patented, and prototype systems demonstrate a 45 percent reduction in required power. Skin temperature feedback MCC will decrease the size and weight of MCC systems and make possible effective MCC for dismounted individuals.

Partners

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3-50



Sweat Prediction Models

Description

An improved, comprehensive sweat prediction equation was developed that incorporates a wider range of operational work rates, work durations, and modern clothing/equipment (such as body armor) to better predict modern operational water needs. The improved sweat prediction equation has undergone extensive validity testing (i.e., cross-validity, generalized validity, and extension validity) and demonstrates 65 percent greater accuracy than progenitor equations. The improved sweat prediction equation will provide mission planners the ability to accurately estimate water needs for groups thus improving the efficiency of water procurement. Moreover, it will provide leaders with the ability to predict water needs of individuals in real time thus enhancing the safety and sustainability of service members. Work is ongoing to incorporate the improved sweat prediction equation into a user-friendly software application platform.

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Test System for Evaluating Environmental Endocrine-Disrupting Chemicals and Developing Candidate Biological Markers for Deployment Health Surveillance

Description

Biomarkers (i.e., molecular, biochemical, or cellular alterations) can provide valuable information on exposure of troops to hazardous chemicals. The western clawed frog (*Xenopus tropicalis*) shows promise as a nonmammalian model organism for efficiently identifying candidate human biomarkers. The same frog model is being considered for use by the U.S. Environmental Protection Agency (EPA) to screen for endocrine-disrupting chemicals in the environment. This EPA-funded project will provide EPA with an amphibian growth and reproduction test protocol while refining methods that will facilitate the use of *X. tropicalis* for the development of biomarkers for use in evaluating toxic chemical exposures encountered by military personnel.

Partners

USACEHR

3-52



Thermal Models on a Personal Digital Assistant Format

Description

USARIEM has developed a Heat Strain Decision Aid model that runs on a PDA for predicting the risk of heat casualties. This model is the best available, user-friendly predictor of endurance times in thermally challenging environments within the DoD. It is especially well adapted to military and first responders performing military or paramilitary activities in nuclear, biological, and chemical protective ensembles with or without body armor.

At present, the model requires separate input of clothing, work activity level, and environmental conditions; calculates maximum work time to 300 minutes; recommends work and rest cycles for sustained operations; and estimates water consumption requirements.

Partners

USARIEM



Thermal Warning Algorithm

Description

Heat injury is a serious problem for the armed forces especially during deployments to localities with very hot climates. An early warning of the likelihood of a person's body core temperature rising beyond healthy limits is paramount to alleviating or avoiding different heat-related illnesses. The early warning algorithm combines recent advances in core temperature telemetry with data-driven prediction techniques to forecast an individual's core temperature for up to 20 minutes ahead of current time. The algorithm is based on linear predictive techniques, which make it very stable and easy to implement in real time. Although temperature prediction is based on an individual's recently collected temperature data, the algorithm is robust enough that it is "portable" from person to person. The algorithm requires only modest memory and processing power and can be incorporated into systems that will be used to provide real-time physiological status monitoring of personnel.

Partners

• DoD Biotechnology High Performance Computing Software Applications Institute/TATRC

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Blast Standards for Neurosensory Personal Protective Equipment

Description

Currently, military-authorized PPE is evaluated against the same protective ophthalmic ANSI (American National Standards Institute) standards created for civilian industry but are not evaluated against blast mechanisms to which Warfighters are exposed during combat. USAARL continues its role of providing PPE testing and guidance to project managers and interacting with vendors to facilitate the development and implementation of PPE. This project will develop recommendations that will improve protection against primary neurosensory blast injury.

Partners

- USAARL
- Program Executive Office Soldier
- Alabama National Guard EOD Unit
- Fort Rucker Range Control



Bone Image Analysis

Description

BAMPack is a novel software tool that integrates bone image analysis with database storage of results. Instead of reducing bone density to a single number, BAMPack allows for a detailed regional analysis of images, revealing the subtle changes that otherwise would have gone unnoticed. The changes in the architecture of the cortical bone can have profound implications for bone strength and injury potential. BAMPack can also efficiently handle batch analysis of the many images that are generated by protocols with large cohorts such as those involving military recruits. Its uniform and robust algorithm for segmentation, alignment, and rotation means it can be used to pool data from images collected from various Bone Health and Military Medical Readiness Program-sponsored research protocols. It is the ideal tool for analysis of images, such as those from the tibia bone, and retrieval of results arising from cross-sectional and longitudinal studies involving noninvasive imaging.

- USARIEM
- L-3 Communications/Jaycor



Eye Injury Field Therapy Kit

Description

The Eye Injury Field Therapy Kit will contain comprehensive diagnostic tools and treatment strategies for laser-induced eye injury. Military lasers can produce eye injuries at tactical ranges resulting in immediate visual impairment or blindness. Diagnosis of visual dysfunction from blast or mild TBI in the absence of observable ocular injury (lacerations and fragment injury) often is delayed due to triage of urgent wounds. The Eye Injury Field Therapy Kit will provide the combat medic with the tools to rapidly diagnose and treat laser eye injuries to minimize vision loss.

Current research evaluates enhancements to the high-contrast, achromatic Aidman Vision Screener by utilizing contrast and chromatic targets to characterize visual dysfunction. Research has characterized the relative efficacy of selected steroids and nonsteroidal anti-inflammatory drugs for specific retinal injury taxonomies for both highly localized thermal and thermal-mechanical injury to the retina from laser radiation. Other neuroprotective agents are being investigated to minimize secondary effects of laser-induced retinal trauma. Advanced ocular imaging technologies and assessments of visual function (such as the multifocal electroretinogram and spectral domain ocular coherence tomography) are used to characterize the efficacy of the intervention.

Depending on the taxonomy of the injury (visual dysfunction, laser dose, location within the retina, proximity to other lesions, etc.), primary and secondary effects include retinal burn, retinal and vitreous hemorrhage, retinal hole formation, inter-retinal scar formation, choroidal neovascularization, retinal nerve fiber degeneration remote from the lesion site, retinal traction, and proliferative vitreoretinopathy. Treatment strategies based on the injury taxonomy provided by the Eye Injury Field Therapy Kit will minimize visual impairment from battlefield eye injury.

PartnersUSAISR



Physical Activity Data Logger

Description

An alpha-version of PATracker, which is a smartphone application running on Android OS, has been developed to allow researchers to log physical and other activities performed by recruits during basic combat training. It can track the type, intensity, and other parameters associated with all resting and exercise-related activities over the course of an entire day. The desktop application allows the user to store, view, and analyze data. The alpha-version has been field tested and will be used in prospective studies to collect quality training data. Future versions of the software will improve software functions per user feedback and explore the integration with ambulatory sensor systems to record high-resolution activity data.

- USARIEM
- L-3 Communications/Jaycor

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Repeated Shock and Vibration Limits for Trauma Patients

Description

This project will characterize shock and vibration in common medical transport vehicles using simulated patients, determine doseresponse relationships, develop transmissivity functions in healthy humans, and then develop shock and vibration standards for trauma patients. These outcomes will provide combat medical system designers with necessary criteria to ensure safe transport for wounded Warfighters.

Partners

USAARL

3-56



Training, Overuse Injury, and Performance Modeling

Description

The physical demands of basic training, while designed to enable recruits to pass the Army fitness and body composition standards, are associated with a high prevalence of musculoskeletal injury. These injuries result in lost duty time, medical costs, loss of manpower, and even separation from the service. A large number of empirical studies have been conducted to evaluate the effects of various physical training programs, as well as other factors, on the development of fitness and the occurrence of musculoskeletal injury. The goal is to develop a statistical mathematical "computational" model that can be used to predict the physical performance capabilities and the potential for musculoskeletal injury for a given individual based on medical history and the physical training program being applied.

The first version of Training, Overuse Injury, and Performance (TOP) computational models have been developed based on statistical and biomechanical analysis of performance and injury data from standardized Army training programs. The TOP models have the potential to identify individuals who either are at extreme risk for musculoskeletal injury or unlikely to pass the Army fitness standards. The models also can allow elements of the physical training program, such as running mileage, to be varied to minimize injury while at the same time enable an individual to attain the required performance standards. The models are implemented in both a web-based application and a client application to help Soldiers succeed in finishing by providing software solutions during the recruitment phase and at the beginning of and during basic combat training. The models also are being improved by further data collection and analysis and will be validated by prospective studies.

Partners

USARIEM



Warrior Injury Assessment Manikin

Description

This product will develop a new Anthropomorphic Test Device (ATD) that will assess injury probability in the current military-unique combat environment. ATDs currently used in military vehicle tests were designed for civilian automotive crash tests and are not specific or relevant to the common injuryproducing mechanisms encountered in current combat operations. Automotive ATDs were designed for frontal, rearward, and side impacts not to provide valid biomechanical responses to the primarily vertical loading events found in current threat scenarios. This effort will develop operationally specific vertical impact response corridors, mathematical models, and mechanical surrogates suitable for performing injury risk assessment in military environments.

- USAARL
- Army Research Laboratory
- Tank and Automotive Command
- Denton ATD



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Determinants of Soldier Risky Behavior Post-Deployment

Description

Anecdotally reported cases have suggested an increase in risky behaviors exhibited by Soldiers following deployment. It is unknown if these changes are real or if the changes are due to factors such as combat experiences, demographic variables, cognitive abilities, or experiencing mild TBI or PTSD during deployment.

Operation Iraqi Freedom and Operation Enduring Freedom have been supported by more than 1 million deployed U.S. Soldiers in recent years. Often, the conditions under which these Soldiers carry out their missions are of high stress both physically and psychologically. Soldiers will be surveyed both before and after deployment to determine if any of the previously discussed factors influence increases in risk propensity following deployment. Results may suggest better post-deployment training for Soldiers to decrease risk-taking behavior.

Partners

• USAARL

3-58



Genetic, Proteomic, and Neurobehavioral Determinants of Deployment-Related Psychological Health Disorders and Traumatic Brain Injury

Description

With the increase of reported TBI and PTSD cases found in Soldiers following deployment, it is important to determine a neurobiological basis for these conditions. To this end, it is necessary to identify biomarkers that predict neurocognitive deficits as a result of combat experience.

Changes in plasma proteomic profiles in Soldiers will be compared to cognitive control and mood scores at both pre- and post-deployment stages. In addition, pre-deployment cognitive control will be correlated with post-deployment psychological health outcomes. Finally, variability at genetic loci will be associated with both the development of PTSD and post-concussive syndrome symptom severity following mild TBI.

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Assessment of Mild Traumatic Brain Injury Through Modeling of Central Nervous System Indices

Description

The goal of this project is to develop models to predict the occurrence and persistence of mild TBI using data collected with field-expedient methodologies. Models will be developed to predict the occurrence and persistence of mild TBI from data using relatively simple methods that can be used in the field. Event-related potentials of electroencephalogram and functional near-infrared spectros-copy will be used to train mild TBI diagnostic models. The research will initially determine subclinical consequences of head trauma experienced during military duty under controlled laboratory conditions. Models will be developed and validated using laboratory data. Training of the model will be done using the data collected during the initial study phases. The final model will consist of the fully trained classification algorithm. The intention will be to produce a streamlined product that enables the individual and test administrator to quickly make a diagnosis while minimizing error.

- USARIEM
- WRAIR



Cognitive Readiness/Fatigue Modeling

Description

The Walter Reed Sleep Performance Model (WRAIR SPM) predicts cognitive effectiveness based on the two factors exerting the greatest impact on cognitive effectiveness: sleep/wake history and time of day. Refinements are currently under development to (1) individualize model predictions based on obtained sleep/wake amounts (measured using the Sleep Watch) and actual cognitive readiness (measured using the PDA Psychomotor Vigilance Task) and (2) optimize predictions to account for use of psychoactive compounds (e.g., caffeine). The WRAIR SPM is integrated into the Sleep Watch for online, real-time cognitive effectiveness estimation and is being integrated into the Defense Safety Oversight Council-sponsored AMMO system for mission planning and fatigue risk management.

The AMMO system is a flexible, laptop-based software program that allows the user to (1) prospectively forecast cognitive readiness based on a given mission schedule (from which sleep/wake is then estimated), (2) generate real-time optimizations of personnel work/sleep scheduling to support a given mission, and (3) retrospectively reconstruct cognitive effectiveness level based on a known or estimated sleep/wake schedule associated with an event (e.g., accident reconstruction).

Partners

- WRAIR
- TATRC
- Air National Guard
- Defense Safety Oversight Council



Dietary Supplement Research

Description

More than one-half of military personnel regularly use dietary supplements. The safety and efficacy of dietary supplements are not adequately assessed by any government agency. No DoD process exists to identify potential adverse health events associated with dietary supplement use by military personnel and to evaluate health risks and benefits of dietary supplements. This new program will develop standardized, evidence-based processes for evaluating health risk and safety of dietary supplements and for rapidly evaluating efficacy of dietary supplements for enhancing operational readiness.

- USARIEM
- Office of the Secretary of Defense for Health Affairs
- Uniformed Services University of the Health Sciences

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Finite Element Thermoregulatory Model

Description

The Finite Element Thermoregulatory Model (FETM) will serve as a foundation to inform future development of textiles, clothing ensemble, and architectures for individual protection as well as enabling other complex analyses. Magnetic resonance imaging and computed tomography data of the human body, obtained from the National Library of Medicine's Visible Human Project, will be coupled with three-dimensional body surface scans to create a general model. This general model will be morphed to individual anthropometrics and imbued with thermoregulatory characteristics, such as metabolic heat production, circulation, and sweating. The final model will be a tool to analyze and predict individual thermoregulatory responses to novel protective clothing designs, physical activity, and harsh and asymmetric environmental conditions, such as those found in extreme mountainous terrain or in hot military vehicles. This FETM will improve the ability to predict individual responses to military missions and support the development of clothing and individual protective equipment that has a minimal thermal impact on Warfighters.

PartnersUSARIEM



Guidance on Using Stimulant and Sleep-Inducing Agents Under Operational Conditions

Description

Guidance is needed regarding the "what/when/how much/how long" for safe and appropriate use of (1) prescription (modafinil – Provigil[®]) and over-the-counter (caffeine – Stay-Alert[®] gum) stimulants to sustain cognitive readiness during unavoidable sleep loss associated with continuous and sustained operations and (2) prescription sleep-inducing agents (zolpidem – Ambien[®]; zaleplon – Sonata[®]) to induce restorative sleep under operational conditions—requirements unique to the military.

Stimulants. Results of research indicate no advantage to dextroamphetamine (a Schedule II compound) over modafinil (a Schedule IV compound) and suggest that modafinil should replace dextroamphetamine as the prescription stimulant of choice for operational use. Ongoing research is focused on determining whether modafinil possesses any advantage over nonprescription caffeine. Of specific interest is the extent to which modafinil and caffeine restore sleep loss-induced impairments in judgment, decision making, appropriate risk taking, planning, and other operationally relevant cognitive capabilities. Other issues addressed include potential development of tolerance and operationally relevant side effects (to include impairment of subsequent sleep).

Sleep-inducing agents. Research results indicate that, with the exception of possessing shorter half-lives, there is no advantage of non-benzodiazepine compounds, such as zolpidem, zaleplon, and eszopiclone, over traditional benzodiazepines, such as temazepam, in terms of risk of operationally relevant impairment upon abrupt awakening from drug-induced sleep. Ongoing and future research will address whether newly available compounds possessing novel mechanisms of action (e.g., hypocretin/orexin antagonist, 5-HT2A receptor antagonists, and GABAergic agonists) possess advantages over currently available benzodiazepine receptor agonists (i.e., zolpidem, zaleplon, eszopiclone, and temazepam).

- WRAIR
- University of California, San Francisco
- SRI International

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PDA-Based Psychomotor Vigilance Task

Description

The PDA-Based Psychomotor Vigilance Task (PVT) is a fieldable implementation of the gold standard 10-minute PVT, a simple one-choice reaction time task that is easily administered and sensitive to even small amounts of sleep restriction. The PDA PVT allows for noninvasive, rapid, and relatively unobtrusive assessment of cognitive readiness. The results of this rapid assessment of each individual service member's extant cognitive readiness level can be used by commanders to gauge the extent of cognitive restoration following short sleep opportunities or stimulant administration. Results show that the PVT is the most sensitive and reliable metric for detecting and quantifying impairments due to even mild amounts of sleep restriction—and in advance of frank errors and accidents. PVT output can be input to the WRAIR SPM to individualize the model thus yielding highly accurate, real-time estimates of individual cognitive readiness status. Ongoing work links PVT metrics to the capacity for rapid, correct decision making and other mental operations that enable a service member to recognize and capitalize on emergent battlefield opportunities.

• WRAIR



Remote Physiological Status Monitor

Description

The Remote Physiological Status Monitor (RPSM) is a Soldier-worn device that integrates physiological status monitoring with situational awareness to enable remote monitoring of enabled Soldiers. Product fielding is managed and funded by PEO Soldier with assistance from PM, Medical Support Systems. RPSM is a Nett Warrior additional attribute, which is planned to be fielded with Nett Warrior Increment 2 requirements in 2017. It communicates occurrence, location, activity, and limited physiologic data. The RPSM improves commander/medic response time and helps limit medics' exposure time to reach Soldiers who demonstrate absence of life signs. Immediate detection of injuries with the initiation of first aid measures will improve the likelihood of Soldier survival after injury.

Partners

- USARIEM
- Welch Allyn
- QinetiQ
- Zephyr



SPARNET – Spartan Network

Description

The purpose of the SPARNET system is to increase medical awareness and situational awareness during training. USARIEM, in partnership with MOMRP and TATRC, is guiding the development of personal and squad-area data network technologies to improve remote medical and situational awareness during higher risk training activities. To meet this objective, integrated systems are being developed that will capture, analyze, communicate, display, and archive geo-location and physiological sensor data. The main system elements are a Warfighter-worn Spartan Network (SPARNET), which includes a squad-area network radio for student-to-instructor data communication, and a Personal Area Network (PAN) for on-body data communication. The PAN radio is inductively linked, minimalist, and modular with processing capabilities for use with sensor systems such as the Physiological Status Monitor. The use of inductive data transmission minimizes cross-talk and detectability due to the rapid attenuation of the modulated magnetic field that carries data. SPARNET enables continuous monitoring of a Warfighter trainee's geo-location and health status during field training to improve force health protection.

- MOMRP
- TATRC
- USARIEM

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Diagnosing and Preventing Non-Freezing Cold Injury

Description

Medical diagnostic tests, biomarkers for susceptibility, and focused microclimate heating will be developed to identify cases of non-freezing cold injury (NFCI), prevent NFCI, and maintain manual dexterity during cold weather operations.

The Afghanistan theater is the first U.S. military extreme cold weather operation since World War II and Korea, and it is anticipated that NFCIs again will become a significant U.S. military medical problem. Current medical diagnosis of NFCI is based on medical history with no validated, guantitative clinical test available. Even with sophisticated cold weather clothing systems, susceptible Soldiers still suffer from debilitating NFCIs. Identifying those Soldiers most at risk of NFCI before training and deployment will decrease the number of injuries sustained. Finally, with Soldiers fighting on a digital battlefield, sustainment of manual dexterity will be critical to maintaining combat effectiveness. The deployability, readiness, and sustainability of operations under cold weather conditions will increase with the products from this effort. These research products will include a quantitative medical test for differentially diagnosing NFCI, identification of sensitive biomarkers that predict those Soldier's most susceptible to NFCI, and development of focused microclimate heating strategies to improve manual dexterity and protect Soldiers from NFCI.

Partners

- USARIEM
- Massachusetts Institute of Technology
- United Kingdom Ministry of Defence

3-66



Environmental Sentinel Biomonitor System

Description

Providing drinking water to deployed troops can use a large fraction of available transportation assets. Although decentralized water production could reduce the transportation burden, it will be difficult to ensure that water produced in many diverse locations is safe to drink in view of the many toxic industrial contaminants that may be present in water and the limited number of such chemicals that can be rapidly detected in the field.

Evaluating the overall toxicity of a water sample provides an alternative to identifying a large number of individual chemicals. The Environmental Sentinel Biomonitor (ESB) system uses biologically based sensors to rapidly identify the toxicity associated with many different classes of chemicals thus providing a warning of potential harm that can trigger appropriate risk management actions.

Potential ESB system applications include in rear areas and at garrison facilities, such as water treatment plants, at field water production facilities that use equipment including the Tactical Water Purification System, in Future Combat Systems manned ground vehicles to evaluate water produced by onboard water generation equipment, and by individual service members in the field (e.g., Special Forces).

A prototype ESB system for use in rear areas and at garrison facilities was delivered in 2008. Increment 2 of the ESB reached Milestone A in March 2009 and is scheduled for completion in 2014.

- USACEHR
- USAMMDA
- Directorate of Combat and Doctrine Development
- Edgewood Chemical Biological Center

- USACHPPM
- OTSG
- Agaue Biosystems
- ANP Technologies



Military

Medicine

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Heat Injury/Stroke Treatment and Return to Duty

Description

Heat injury/stroke (HIS) is a significant challenge for the U.S. Armed Forces. There are currently no validated pharmacologic treatments to mitigate the adverse consequences of HIS and ensure recovery. Criteria for return-to-duty guidelines lack sound scientific evidence.

Using rodent models of HIS, alternative therapies and pharmacological treatments will be studied to address these gaps in knowledge. The rodent models to be used accurately simulate human HIS responses and allow for determination of the efficacy of current over-the-counter medications as well as novel drugs in clinical trials. Determining the effectiveness of these HIS therapeutics will help mitigate the acute and long-term effects from HIS, including disturbances in thermoregulatory, cardiovascular, and immune system physiology. In-depth, molecular-level analyses of HIS tissues will allow for the identification of characteristic gene expression patterns that provide insight into molecular-level markers that can be tested for their ability to monitor HIS recovery. Collectively, advances in the field of HIS will improve Warfighter performance, long-term health, and provide sound scientific data for establishing return-to-duty criteria.

Partners

USARIEM

3-68



Hydration Status Monitoring

Description

This research effort began with definitive laboratory work to understand biological variation in hydration assessment measures and to establish a gold standard marker against which future technologies could be evaluated. USARIEM is now in the process of developing, testing, and comparing three prototype noninvasive human hydration sensors designed to be simple, field portable, use little power, and provide a valid measure of body hydration levels when compared to the gold standard. The technology will allow hydration status assessment across all roles of military care and will distinguish between fluid and fluid-electrolyte losses. The prevention and proper treatment of hydration problems would be improved in many medical military scenarios. The insertion of a noninvasive hydration sensor into existing medical equipment sets would improve hydration management by squad leaders during pre-combat checks (prevention), by medics in theater (point of care), and by medical personnel in the rear roles of care (treatment and return to duty).

Partners

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Pathology of Heat and Cold Injury

Description

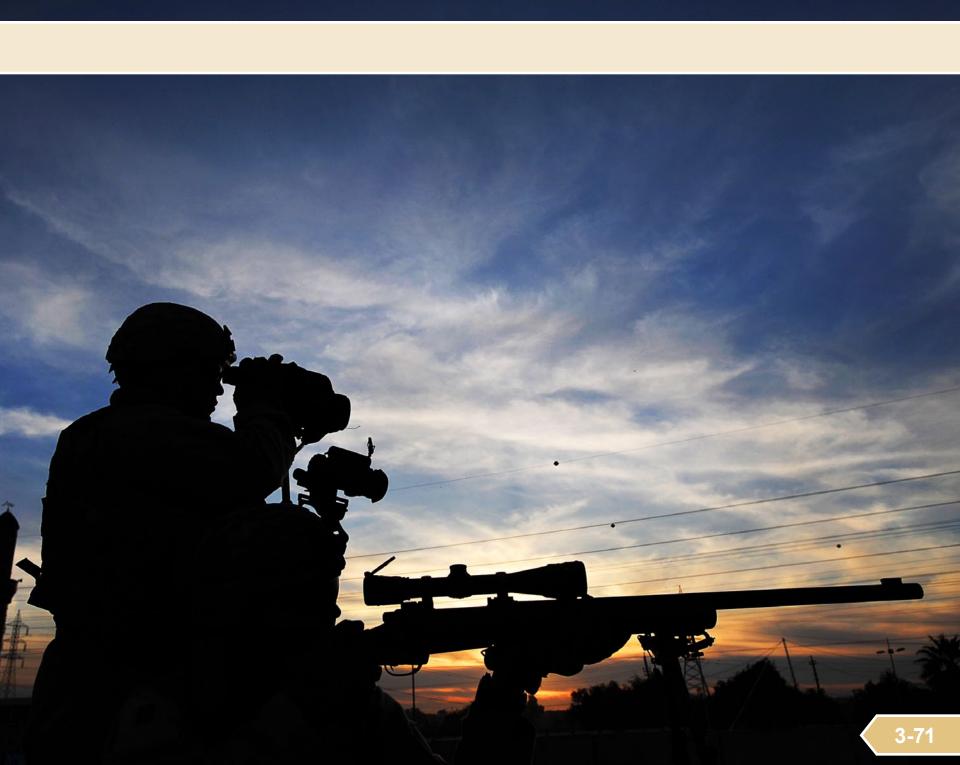
Rapid deployment and sustained operations of the Warfighter at thermal extremes can compromise performance, prevent mission goals, and increase non-combat casualties. Prevention of non-combat casualties only can be realized with knowledge-based enhancement of the complex mechanisms that mediate thermal injury. During the past 20 years, the U.S. Army has seen an eightfold increase in heat stroke hospitalization rates while the hospitalization rate for heat illness has decreased markedly.

The development of cellular and animal models of heat injury and exertional hypothermia permits the study of militarily relevant issues associated with environmental extremes under thermal conditions that are too dangerous to study in human volunteers. Elucidation of the mechanisms of thermal injury will lead to novel strategies to enhance and sustain Warfighter performance and health in hot and cold environments.

Partners

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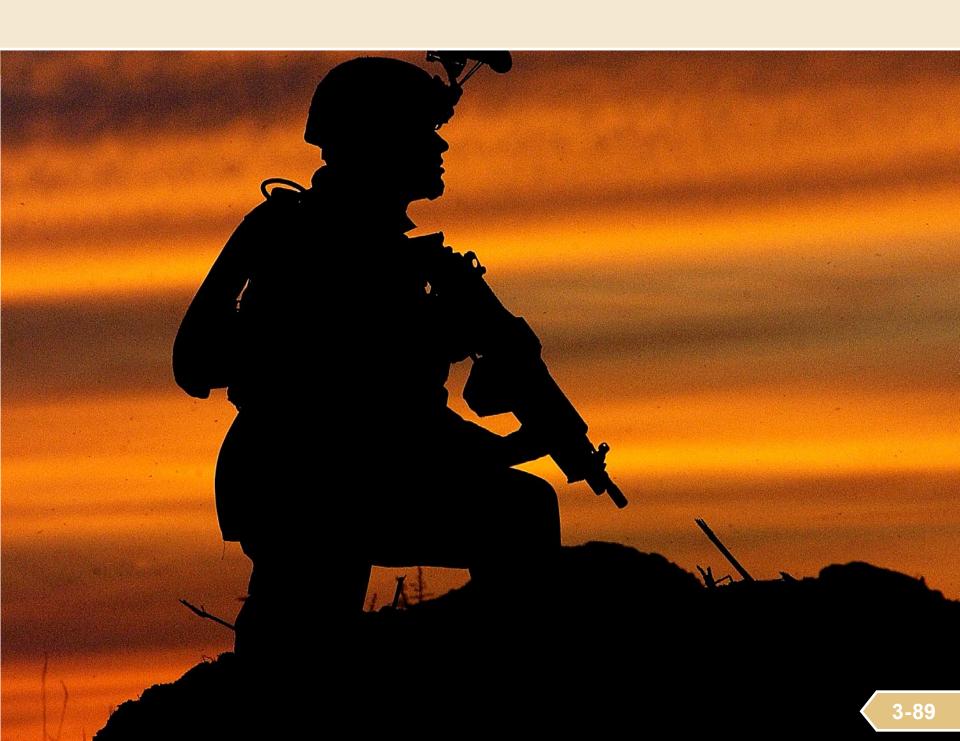
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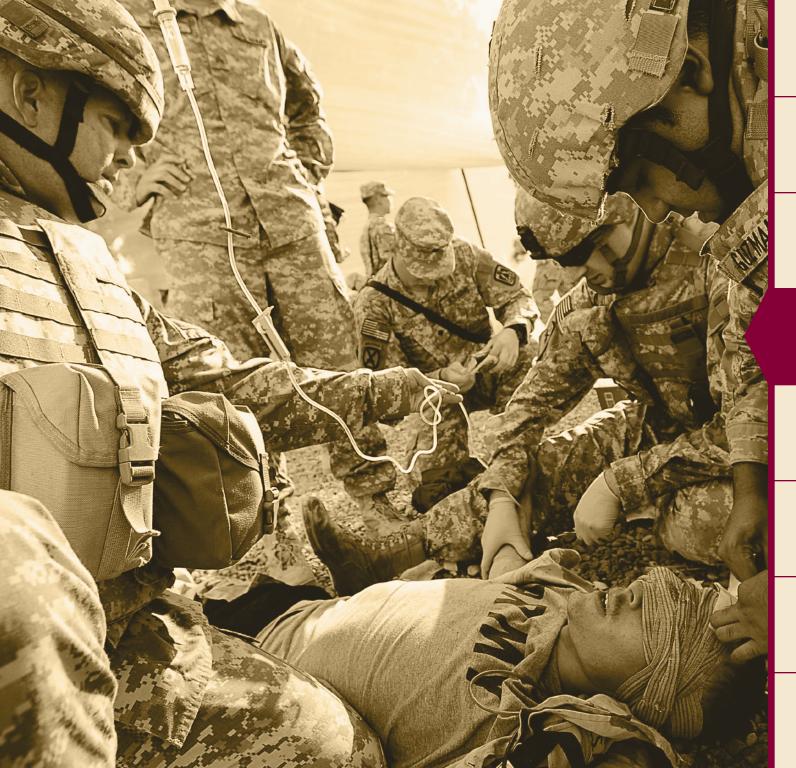
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Combat Casualty Care

Military Operational Medicine

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Appendices

Infectious Diseases Clinical and Rehabilitative Medicine

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OVERVIEW

The injuries of Operations Enduring and Iraqi Freedom are shaped by the widespread use of improvised explosive devices (IEDs). IEDs increase the likelihood that active-duty service members will be exposed to incidents such as blasts that can cause traumatic brain injuries (TBIs) and other debilitating injuries. Since 2001, there have been more than 30,000 battlefield injuries with most receiving more than 1 injury. Current war casualties are driving changes in health care needs and, therefore, changes in research and development.

The U.S. Army Medical Research and Materiel Command's establishment of the Clinical and Rehabilitative Medicine Research Program (CRMRP) will enable active planning and coordination of an area of military research that has grown in importance during the current conflicts. The CRMRP focuses on definitive and rehabilitative care innovations required to reset our wounded Warriors in terms of duty, performance, and quality of life.

The CRMRP has six primary focus areas of research:

- Regenerative Medicine includes the Armed Forces Institute of Regenerative Medicine (AFIRM)
- Rehabilitation of Neuromusculoskeletal Injuries
- Advanced Prosthetics/Amputee Care
- Vision Restoration and Rehabilitation
- Pain Management
- Hearing and Balance

The portfolios for each of the CRMRP's six primary research focus areas are defined as follows:

The Regenerative Medicine portfolio exploits stem cell and biomaterials research to:

- Improve the speed of healing and decrease scarring
- Regenerate missing tissue, such as bone, cartilage, nerve, and muscle
- Improve functionality and appearance following craniofacial reconstruction
- Develop scaffolds to integrate created tissue
- Reduce the need for tissue rejection therapy
- Improve surgical approaches and limb/tissue function

The Rehabilitation of Neuromusculoskeletal Injuries portfolio includes research that focuses on the following aims:

- Neuromuscular:
 - » Improve rehabilitation
 - » Strategies for limb salvage patients and limb health
- » Fitness in amputees
- » Spine rehabilitation and research strategies
- » Minimize deleterious effects of contracture on function
- » Bone loss and heterotopic ossification

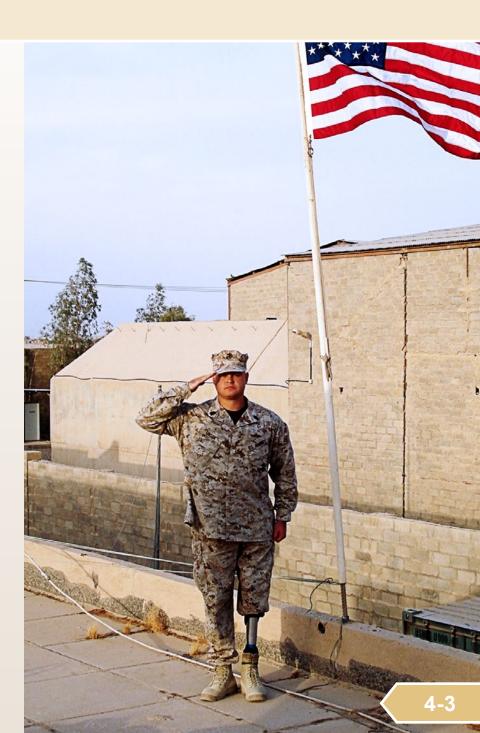
- » Psychosocial aspects
- » Strategies that consider complicating factors
- Identify upper extremity kinematics and kinetic variables following injury that negatively influence locomotor and dynamic stability tasks

The Advanced Prosthetics/Amputee Care portfolio focuses on research to:

- Address psychosocial recovery aspects
- Improve rehabilitation for limb salvage and spinal injury patients
- Exercise and fitness systems and strategies (amputees)
- Improved orthotics, prosthetics, and robotics to improve extremity function
- Incorporate neural interface/feedback

The Vision Restoration and Rehabilitation portfolio includes research for:

- Acute treatment of ocular injury
- Restoration and rehabilitation of ocular injury, including artificial vision
- Ocular drug delivery



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The Pain Management portfolio (including acute, chronic, and battlefield pain) supports both product development and knowledge research with aims to:

- Improve management of chronic and acute pain
- Establish safety margins for individual prescriptions
- Identify and treat pain generators
- Develop strategies to empower patients in managing pain

The Hearing and Balance portfolio focuses on the development of products and strategies for the restoration and rehabilitation of hearing and balance including:

- Restorative treatments and rehabilitation of hearing loss and auditory function due to traumatic injury (including TBI) and noise exposure
- Treatment and rehabilitation of auditory processing disorders and tinnitus
- Restorative treatments and rehabilitation of vestibular dysfunction and balance disorders due to traumatic injury (including TBI)
- Capabilities supporting assessments and evaluations conducted during diagnosis, treatment, and rehabilitation

Regenerative Medicine Overview

The burgeoning field of regenerative medicine provides hope for restoring the structure and function of damaged tissues and organs and curing previously untreatable injuries and diseases. The concept of regenerative medicine—in its simplest form—is to replace or regenerate human cells, tissues, or organs to restore or establish normal function. Advanced technologies, such as tissue regeneration, bone scaffolding, and stem cell-enabled treatments, are needed to revolutionize the clinical rehabilitation of severely injured service members.

The Department of Defense established the AFIRM in 2008 with the mission of developing new products and therapies to treat severe injuries suffered by U.S. service members. This multi-institutional, interdisciplinary network of scientists has been designed to accelerate the delivery of regenerative medicine therapies for severely injured service members. Centered around well-established, proven research investigators, the AFIRM has been able to expand the rehabilitative medicine knowledge base, develop models of injury, and test advanced technology products.



Clinical and Rehabilitative Medicine

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C-Leg[®] (Second Generation) Microprocessor Knee Prosthesis

Description

The prosthesis is based on the Otto Bock C-Leg design but has additional enhanced properties and functionality that make it suitable for use by military personnel who wish to remain on active duty subsequent to undergoing transfemoral amputation. It provides improved gait support, the ability for the user to walk backward and ascend stairs, an enhanced battery life between charging, and the ability to be charged while in use.

Partners

- USAISR
- TATRC
- Military Amputee Research Program
- BAMC
- Center for the Intrepid
- MATC

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• Otto Bock Healthcare Products



iWalk Microprocessor-Controlled Prosthetic Ankle System

Description

The new microprocessor-controlled prosthetic ankle system, which is the first to provide powered plantarflexion, is clinically feasible in terms of hardware and software difficulties, patient and prosthetist satisfaction, and yields significant functional improvement in service members who have sustained transtibial amputation.

As the first commercially available device that provides active plantarflexion push-off, the PowerFoot prosthetic device manufactured by iWalk holds great potential to significantly reduce detrimental compensations, functional limitations, and long-term morbidity association with lower extremity amputation. It is expected to provide the greatest benefit during performance of challenging and militarily relevant tasks, such as walking over rocky terrain and on stairs and slopes where the demand for push-off power is significantly increased.

- USAISR
- TATRC
- Military Amputee Research Program
- WRAMC
- BAMC
- MIT
- iWalk



Allogeneic Engineered Skin/ StrataGraft[®]

Description

The goal of this project is to develop a universal skin graft as a "ready to use" alternative to cadaveric skin for a period of time until an injured patient's own skin can be used for grafting.

StrataGraft skin tissue is provided as a suturable circular patch of stratified epithelial tissue composed of a living dermal matrix (containing dermal fibroblasts) overlaid with human epidermal cells (NIKS[™] cells).

Partners

- AFIRM Wake Forest-Pittsburgh Consortium
- DHP
- University of Wisconsin–Madison
- Stratatech Corporation



Autologous Engineered Skin/Lonza Permaderm

Description

The goal of this project is to reduce the requirement for harvested skin autographs for the treatment of burn injuries by developing an engineered skin substitute (ESS) product. This technology uses a small sample of the patient's healthy skin as the basis for growing a larger sheet of engineered skin over a 30-day period. ESS products may be used to close burn wounds of greater than 40 percent at a single operation using autologous skin, and they heal in place.

Partners

- USAISR
- AFIRM Rutgers-Cleveland Clinic Consortium
- JIEDDO
- Lonza Walkersville, Inc.



Autologous Skin Expander Device

Description

The goal of this program is the development of a device that enables the expansion of skin area by two- to fourfold to cover a greater surface area when treating burn patients. The Autologous Skin Expander Device enables covering burn injuries involving greater than 40 percent total body surface area. A small sample of a patient's healthy skin is subjected to a process that stretches it in a bioreactor over several days. The expanded skin then is reimplanted over the burn injury.

Partners

 AFIRM – Wake Forest-Pittsburgh Consortium

Clinical and Rehabilitative Medicine

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ReCell®/Partial Thickness Burn

Description

This technology is utilized for the treatment of partial thickness burns, resulting in less scarring. It also is under investigation for scarless healing of resected hypertrophic scars. ReCell is a stand-alone, rapid, autologous cell-harvesting, processing, and delivery technology that enables surgeons and clinicians to treat skin defects using the patient's own cells in a regenerative process, accelerating healing, minimizing scar formation, eliminating tissue rejection, and reintroducing pigmentation to the skin. ReCell has been designed for use in a wide variety of wound, plastic, reconstructive, burn, and cosmetic procedures. This product has point of care capability with an approximate 30-minute preparation time.

Partners

- USAISR
- AFIRM Wake Forest-Pittsburgh Consortium
- DHP

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Avita Medical Limited



Autologous Fat Transfer Procedure

Description

The goal of this project is to develop autologous, cell-based therapies and constructs that repair, replace, regenerate, or supplement missing, damaged, or inadequate soft tissue and/or that reduce the aesthetic and functional deficits associated with soft tissue scarring and contracture.

There are few if any technologies at present that are known to positively impact the remodeling of established scar tissue. Essentially, all battlefield wounds involve some component of skin and/or soft-tissue injury, and in many cases the tissue loss/damage can be quite extensive. Autologous, adipose, and adipose-derived stem cells offer potential advantages over existing treatment options for remodeling existing scar tissue to improve functionality and esthetics of facial skin.

Partners

- USAISR
- AFIRM Rutgers-Cleveland Clinic Consortium

REGENERATIVE MEDICINE – CRANIOFACIAL



Neodyne Mechanical Scar Reduction Device

Description

The goal of this project is to reduce scarring following trauma by addressing the mechanical stress state of the healing wound through the use of region-specific devices capable of stress-shielding the healing wound.

Scar formation following trauma can lead to severe functional disability and disfigurement. Mechanical force has been recognized to influence cellular behavior and wound healing. Currently there are no commercially available wound care products that can specifically address the mechanical stress state of healing wounds to reduce scarring. The Neodyne Mechanical Scar Reduction Device is intended to stress-shield wounds by off-loading mechanical forces thereby reducing fibrosis (scar formation). The device would be applied following surgical closure of cutaneous wounds.

- AFIRM Wake Forest-Pittsburgh Consortium
- NeoDyne Biosciences, Inc.



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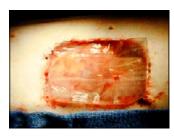
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Biologic Extracellular Matrix Scaffold for Functional Muscle Replacement

Description

The goal of this project is to develop an off-the-shelf biologic extracellular matrix scaffold capable of promoting clinically relevant muscle regeneration and function for the repair and reconstruction of complex extremity injuries suffered by Warfighters.

The current management of tissue coverage and augmentation for extremity reconstruction is minimal, allowing the body to heal by fibrosis (scarring). In many instances, this approach delays the rehabilitation process and rarely regains normal tissue function. The approach taken in this project is to produce an off-the-shelf scaffold implant to address missing soft tissue. The scaffold implant would initiate a stem/progenitor cell recruitment process and facilitate site-appropriate functional tissue restoration.

- USAISR
- AFIRM Wake Forest-Pittsburgh Consortium
- JIEDDO
- DePuy, Inc.



C-Leg (Third Generation) Microprocessor Knee Prosthesis

Description

The prosthesis is based on the Otto Bock C-Leg design but has additional enhanced properties and functionality that make it suitable for use by military personnel who wish to remain on active duty subsequent to undergoing transfemoral amputation. This version of the Otto Bock C-Leg microprocessor knee prosthesis is salt water resistant and watertight, and has increased static and cyclic strength and durability, a nonreflective coating, and a concept for hydraulic unit cooling.

Partners

- USAISR
- TATRC
- Military Amputee Research Program
- BAMC
- Center for the Intrepid
- MATC
- Otto Bock Healthcare Products



DEKA/APL Arms

Description

The overall objective is to develop a neurally controlled arm and hand prosthesis that will perform, look, and feel like a natural limb.

The DEKA arm is a strap-and-go technology. Inertial measurement units, in lieu of the prosthetic's footpad myo-switch on the shoulder, allows the amputee to move from gross arm movements to hand movements. Additionally, the switch is adaptable so the system leads the amputee through a pressure system and myo-sites even if the amputee is a lower amputee as well. The APL arm intends to provide improved functionality through neural control (i.e., targeted neural motor reinnervation).

- USAMRMC
- USAISR
- DARPA
- Department of Veterans Affairs
- CFI
- DEKA
- APL

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Powered Knee-Ankle-Foot System

Description

This is a prosthetic knee-ankle-foot system that improves mobility with computer-controlled components that have minimal energy requirements but are able to provide greater assistance than existing devices.

The prosthetic knee is being developed to generate its own electricity and uses it to control braking and swinging of the knee and leg. The prosthetic ankle uses active control to capture the user's energy in a spring and release at the appropriate time to push off. Sensing technology is being developed to detect motion and muscle activity and to record daily living activities. The long-term objective of this project is to develop a prosthetic knee-ankle-foot system that actively coordinates the joints using multimodal biomechantronic sensory data for detection of user intent and control as well as for data logging as a functional outcome measure.

- USAISR
- CDMRP
- VA Medical Center
- MIT
- Seattle Institute for Biomedical and Clinical Research



Socket Technologies

Description

These socket technologies were designed to maintain an appropriate prosthetic fit and residual limb volume. They measure shear and normal pressures, can be adjusted in real time as limb volume changes, improve coupling between the limb and the socket, and increase comfort during daily activity.

Partners

- USAMRMC
- USAISR
- WRAMC
- · Center for the Intrepid
- Department of Veterans Affairs
- VA Puget Sound Healthcare System
- Providence VA
- Henry Jackson Foundation
- Texas Scottish Rite Hospital
- Liberating Technologies, Inc.
- Foster Miller, Inc.
- Next Step Orthotics and Prosthetics
- D.E. Hokanson, Inc.
- Buster Greene and Associates
- Spencer Technologies
- Infoscitex Corporation
- Physical Optics Corporation



Spring Ankle with Regenerative Kinetics

Description

The Spring Ankle with Regenerative Kinetics (SPARKy) seeks to develop a new generation of powered prosthetic devices based on the robotic tendon actuator. The robotic tendon is a lightweight actuator that has kinetic advantages and stores and releases energy to provide users with 100 percent of required push-off power and ankle range of motion comparable to able-bodied ankle motion while maintaining a form factor that is portable to the wearer. Additionally, this prosthesis will support continuous unstructured walking for up to 2.8 hours.

- TATRC
- Military Amputee Research Program
- United States Military Academy
- Arizona State University

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Fraxelated Carbon Dioxide Laser for Treatment of Scar Contracture

Description

The Fraxelated Carbon Dioxide Laser will improve range of motion, scar compliance, and aesthetics of erythema and pigmentation while decreasing scar thickness and minimizing side effects and the potential complications of treatment.

The laser will be assessed on its ability to improve range of motion, thickness, compliance, and aesthetics in patients with burn scar contractures in the perioral and axillary regions.

Partners

- USAMRMC
- U.S. Air Force



Riluzole Spinal Cord Injury Treatment

Description

The North American Clinical Trials Network will carry out an acute safety and pharmacokinetic clinical trial of riluzole, a benzothiazole anticonvulsant NA+ channel-blocking agent with anti-glutamatergic activity that exerts a neuroprotective effect in patients who have sustained an acute spinal cord injury.

- USAISR
- TATRC
- The University of Toronto
- The University of Texas Medical School
- The University of Texas School of Public Health
- The University of Virginia Hospital
- The Methodist Hospital, Houston
- The Rehab Institute of Chicago
- Christopher Reeves Foundation



Treatment of Tinnitus

Description

Tinnitus is the perception of sound by the auditory system in the absence of an actual external sound; typically, a ringing or buzzing is heard. In many individuals this is merely an occasional annoyance, but for others this can be significant enough to interfere with hearing, sleep, and/or cause emotional distress. Tinnitus has been reported in noise and blast-exposed patients and in patients with TBI. Tinnitus and hearing loss are the top service-connected disabilities for compensation by the Department of Veterans Affairs. Existing therapies include noise-masking devices, counseling, and brain/auditory system retraining tools and techniques, but effectiveness varies. Efforts are under way to evaluate the Neuromonics Tinnitus Treatment Program (NTTP), a commercially available tool for retraining the brain's perception of tinnitus. Studies are being done using military patients to evaluate the effectiveness of the NTTP for tinnitus resulting from military-relevant exposures to noise and blast. Additionally, the device and treatment program are being enhanced to enable telemedicine capabilities and optimize the hardware and software. As opposed to strategies that provide masking noise or coping skills, the NTTP has the advantage of potentially treating tinnitus.

Partners

Neuromonics, Inc.



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Formable, Nanostructured Ca PO4 (NanoCaPS) Scaffolds

Description

The goal of this project is to develop novel bioactive bone cements and scaffolds based on natural polymers that incorporate nanostructured calcium phosphate to address craniofacial reconstruction.

This project focuses on developing novel bone regeneration strategies for craniofacial reconstruction by exploiting the combined attributes of nanoscale inorganic bioactive cements and naturally derived polymer hybrid materials that possess excellent bioreactivity, biocompatibility, safety, and regenerative capability. This combination of materials would result in the development of structurally and functionally normal bone for injured military personnel. The proposed technologies also will be investigated for regenerating large osseous defects in the extremities where bone fracture is a major clinical problem contributing to nearly 50 percent of all armed forces personnel injuries.

Partners

- AFIRM Wake Forest-Pittsburgh Consortium
- JIEDDO

4-16



Peripheral Nerve Scaffolds

Description

This represents two projects with the goal to develop nerve conduits that have the capacity to repair the type of large defects in mixed nerves that will be needed for limb salvage procedures or for repair of small motor nerves.

The contemporary standards of care for treatment of peripheral nerve lacerations or segmental defects include primary repair or nerve grafting. When direct repair is not possible, currently the most effective method to reestablish functional nerve continuity is the use of an autologous nerve graft. However, autologous nerve grafts have several drawbacks, including loss of function at the donor site, size mismatch, and limited availability. An alternative to nerve autografts would enhance the current standard of care and lead to better outcomes and capabilities. NeuraLum is a surgically implanted polycaprolactone fumarate scaffold, and KeraGen is a surgically implanted keratin-derived polymer scaffold. These materials are absorbed by the body over time and may be delivered with adipose- or mesenchymal-derived stem cells or growth factors.

Partners

- TATRC
- AFIRM Rutgers-Cleveland Clinic Consortium



PlexurLV Injectable Allograft Bone-Composite Scaffold

Description

This goal of this project is to develop an injectable bone void filler for use in extremity long bone defects and craniofacial surgical repair that would alleviate the need for autografts as a bone grafting material.

Extremity injuries are common battle injuries with current treatment options incorporating the use of bone allo- or autografts. Due to the size and geometry of many of these injuries, surgery involving the harvest of bone allo- or autografts has limited application. An injectable nanoporous bone void filler composed of an allograft bone-biodegradable polyurethane composite may provide significant advantages over current treatment options. The material is designed to promote faster cellular infiltration and remodeling leading to better outcomes.

Partners

 AFIRM – Rutgers-Cleveland Clinic Consortium

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Protocol for Immunomodulation for Composite Tissue Allotransplantation – Hand and Face Transplants

Description

The goal of this project is to develop a novel immunosuppressive/immunomodulative protocol for composite tissue allotransplantation (CTA) to mitigate the inherent risks associated with current immunosuppressive protocols.

Composite tissue allografts (e.g., hand and face transplants) are now a clinical reality. Apart from excellent and highly encouraging functional results, CTA has not reached widespread clinical use because recipients currently require lifelong, high-dose, multidrug immunosuppression to prevent graft rejection. These regimes carry a high risk for serious side effects. Using a minimization strategy, various protocols consisting of recipient conditioning, donor bone marrow infusion, and monotherapy maintenance immunosuppression have been defined and currently are being tested in a clinical setting.

Partners

- TATRC
- AFIRM Wake Forest-Pittsburgh Consortium
- AFIRM Rutgers-Cleveland Clinic Consortium

4-18



Molecular Signatures of Chronic Pain Subtypes

Description

Knowledge of why different chronic pain syndromes develop after a seemingly identical injury would enhance the understanding of pain biology in general; allow military and civilian physicians to provide earlier, more targeted interventions; and permit a more sophisticated approach to novel analgesic discovery and development.

The project will collect data and specimens from approximately 350 existing and 100 prospective subjects who will represent discovery and validation populations, respectively. From the discovery population, mechanistically relevant biomarkers capable of discerning subtypes of chronic pain will be identified, the validity of which will be confirmed in the prospective population as they receive treatment at WRAMC, BAMC, and the Durham VAMC.

- DVPMI
- WRNMMC
- BAMC
- Durham VAMC



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Pain Center of Excellence and Chronic Pain Impact Network

Description

Established in 2003, the Defense & Veterans Pain Management Initiative (DVPMI), also known as the DoD Pain Center of Excellence located at WRNMMC, seeks to improve the management of pain in military and civilian medicine. Through clinical research efforts, it has become a model for effective integration of acute and chronic pain medicine.

Currently, there is a large number of Soldiers in the Army's Warrior Transition Units (WTUs) with chronic pain. Physicians have been reluctant to prescribe opioids for the treatment of chronic non-cancer-related pain, which has resulted in pervasive undertreatment of this disabling condition. Although the importance of the role of opioids in the treatment of chronic non-cancer-related pain was finally recognized in the 1990s, a lack of confidence persists among health care providers in their ability to manage chronic pain patients, in particular among primary care physicians.

To address these and other concerns, the Army Surgeon General chartered the Pain Management Task Force in August 2009. In its Final Report of May 2010 was a recommendation to implement a comprehensive electronic patient assessment screening tool and outcomes registry that could be standardized across DoD and VHA clinics.

The Chronic Pain Impact Network (CPAIN) will be an electronic assessment screening tool and outcomes registry. A similar tool has been built previously and validated at a leading academic pain treatment center (University of Washington). The research will evaluate the use of the CPAIN tool to assist in the clinical management of Soldiers with chronic pain at two different WTUs. The research is expected to determine whether using CPAIN will help decrease the average daily dose of opioids, number of patients on large doses of opioids, and/or the duration of opioid use for patients in the WTU; decrease the number of unscheduled visits for opioid medication refills; facilitate the identification of patients at risk for opioid misuse and for linking therapeutic outcomes to medication dosage; and increase the level of physician confidence in managing opioid therapy in WTU pain patients.

- WRNMMC
- Madigan Army Medical Center
- Department of Veterans Affairs

- DVPMI
- University of Washington
- Conemaugh Health System



Wearable Visual Aid as Treatment for TBI-Associated Visual Dysfunction

Description

To develop and refine the BrainPort vision device to enable blinded veteran testing and evaluation in normal operational settings, at home, occupationally, and in other activities of daily living. To implement and test hardware and software device enhancements through an iterative process using feedback and performance measures from users who are blind. This work will lead directly to a proven assistive technology ready for rapid deployment to wounded Warriors, veterans, and civilians who are blind.

The BrainPort visual prosthetic enables perception of visual information using the tongue and camera system as a paired substitute for the eye. Visual information is collected from a video camera and translated into gentle electrical stimulation patterns on the surface of the tongue. With training, users perceive shape, size, location, and motion of objects in their environment. It is a functional, nonsurgical device developed as an aid to the visually impaired.

- TATRC
- University of Southern California



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Rehabilitation of Balance

Description

Dizziness and balance are common outcomes of head injury and blast-related TBI. Optimized balance rehabilitation devices and treatment protocols are needed to retrain the brain and balance-sensing systems of the body. These devices and protocols are expected to provide more rapid and/or complete recovery with good retention and reduced patient workload for therapists. Various technol-ogy approaches are being employed. Generally, balance instability (sway) is detected by having the patient stand on a motion-sensing platform with feedback provided to the patient visually (video screen) or tactually (e.g., vibration). Treatment involves having the patient practice with the device; thus, portable, low-cost solutions are being developed. Studies are under way to evaluate existing commercial-off-the-shelf and research and development phase technologies along with treatment protocols to assess the approach with the best effectiveness and stability over time. The technologies being researched also may support the development of tools for the diagnosis of balance disorders and evaluations/guidelines for return to duty including in the forward deployed setting.

- USAARL
- Naval Medical Center, San Diego
- Office of the Secretary of Defense, SBIR Program
- Headley Court (UK)



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> > Logistics

Appendices

Infectious Diseases Clinical and Rehabilitative Medicine Medical Chemical and Biological Defense

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Appendice

OVERVIEW

Future battlefields are expected to be at least as dangerous as any of the past or any that were anticipated during the Cold War. Although treaties and agreements forbidding the use of chemical and biological weapons were milestones in arms control, such weapons remain significant threats to U.S. and allied forces. Stockpiles of chemical weapons found in Iraq after the 1990–1991 Gulf War, the use of these weapons in the Iran–Iraq War, the 1995 nerve gas attack in the Tokyo subway, and the anthrax letter attacks of 2001 are vivid reminders of the potential risk and threat to both service members and civilians from these weapons.

Medical Chemical Defense Research

The mission of the Medical Chemical Defense Research Program is to preserve combat effectiveness by timely provision of medical countermeasures in response to joint chemical warfare (CW) defense requirements. This program executes Department of Defense (DoD) medical chemical defense science and technology research programs assigned to U.S. Army Medical Research and Materiel Command (USAMRMC) laboratories by the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense.

Nerve agents can be fatal to the unprotected Warfighter. Survivors may have recurring seizures and long-term brain damage. Through joint research and development, the nerve agent threat has been substantially reduced by the fielding of numerous products:

 Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP), a pretreatment drug, can be administered orally to troops under risk of CW attack without degrading their performance.

- Mark I Nerve Agent Antidote Kit (NAAK) provides a service member with the nerve agent antidote atropine and an oxime, 2-pralidoxime chloride (2-PAM).
- Antidote Treatment Nerve Agent Autoinjector (ATNAA) is an improvement over the Mark I NAAK.
- Convulsant Antidote for Nerve Agent (CANA), diazepam in an autoinjector, is used as an adjunct therapy for nerve agent poisoning to protect against seizure-induced brain injury and to enhance survival.
- Medical Aerosolized Nerve Agent Antidote (MANAA) is an aerosolized atropine that can be rapidly administered far-forward to casualties for the control of respiratory effects of nerve agents.
- Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) is a topical pretreatment that forms a film barrier on the skin and augments Mission-Oriented Protective Posture gear by preventing or delaying the penetration of a wide variety of CW agents including the blistering agent sulfur mustard.

Reactive Skin Decontamination Lotion (RSDL) is a U.S. Food and Drug Administration (FDA)-cleared, individually carried skin decontamination kit. RSDL provides the Warfighter with the ability to decontaminate the skin after exposure to CW and biological warfare (BW) agents in support of immediate and thorough personnel decontamination operations. RSDL also provides the Warfighter with improved capability over the existing M291 Skin Decontamination Kit to reduce lethal and performance-degrading effects of CW agents. RSDL neutralizes, as opposed to removing, the agent. Additionally, it can be used to decontaminate individual equipment, weapons, and casualties (unbroken skin only). Research and product development supporting pretreatment, treatment, diagnostics, and clinical management of the chemical casualty are the keys to continuing discovery and fielding of medical countermeasures to CW agents. Successful technology base programs that have transitioned to advanced development and that have received acquisition program status include the Advanced Anticonvulsant System Program, the Improved Nerve Agent Treatment System (INATS) Program, and the Bioscavenger Program. Bioscavenger Increment II is a recombinant protein that is produced from an engineered expression system, giving it a significant manufacturing advantage over Bioscavenger I, which was a plasma-derived human butyrylcholinesterase.

Active programs in the USAMRMC technology base include research to develop medical countermeasures against vesicants and nontraditional chemical agents, research to identify and develop neurological therapeutics (i.e., neuroprotection), research to develop a catalytic nerve agent bioscavenger pretreatment (Bioscavenger III) that enhances efficacy by degrading multiple molecules of nerve agents in vivo, and research to identify and develop therapeutics to treat the respiratory and systemic effects of CW agents.

The Medical Chemical Defense Research Program also provides education and training to officers and enlisted persons from all of the services who will be the doctors, nurses, and medics who will treat a Warfighter exposed to CW agents. Depending on the availability of funding, the capability exists to broadcast this information around the world via satellite to first responders who would likely be tending to casualties exposed to CW agents in the event of a terrorist action.



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Medical Biological Defense Research

The mission of the Medical Biological Defense Research Program is to ensure the sustained effectiveness of U.S. forces in a BW environment and to deter the use of these weapons by maintaining a strong medical defensive posture. This USAMRMC program executes DoD medical biological defense science and technology research programs assigned to USAMRMC laboratories by the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense.

Vaccines and drugs for biological threat agents and toxins are designed to prevent casualties in a BW attack. Diagnostic tests and reagents are developed to diagnose disease in the event of actual exposure to biological agents. Antitoxins and drugs are designed to treat casualties, prevent deaths, and expedite return to duty after exposure.

Technologies that have transitioned to Medical Chemical and Biological Defense Program advanced development include a recombinant plague vaccine (Plague Vaccine Program), a vaccine against botulinum toxin subtypes A and B (Recombinant Botulinum A/B Vaccine Program), and a vaccine against Venezuelan equine encephalitis (VEE) virus (VEE Vaccine Program). The VEE Vaccine Program has been put on hold after adverse reactogenicity was observed in a Phase 1 clinical trial. An improved anthrax vaccine (recombinant protective antigen vaccine), the outcome of research at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), was being developed by the U.S. Department of Health and Human Services (HHS) under Project BioShield; however, the contract with the performer was terminated when problems with the vaccine's stability caused the company to miss a deadline for starting a clinical trial. HHS, through the Biomedical Advanced Research and Development Authority, has established a contract with PharmAthene for

advanced development of its second-generation recombinant protective antigen vaccine targeted for future procurement in the U.S. Strategic National Stockpile. Diagnostic assays developed in the technology base that meet requirements for application to the currently fielded Joint Biological Agent Identification and Diagnostic System (JBAIDS) have also transitioned to Medical Chemical and Biological Defense Program advanced development. In addition, recombinant human monoclonal antibodies for therapeutic treatment of exposure to staphylococcal enterotoxins A and B were transitioned to advanced development supported by the National Institute of Allergy and Infectious Diseases (NIAID).

Technologies in the technology base that are maturing to eventually transition to advanced development include diagnostic assays and protocols for incorporation into the fielded JBAIDS, a combined VEE, eastern equine encephalitis (EEE), and western equine encephalitis vaccine (WEE), and vaccines against staphylococcal enterotoxin and ricin toxin exposure.

Research efforts supported by the Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) at USAMRMC laboratories continue to focus on the development of multiagent vaccines against viral, bacterial, and toxin agents that will afford recipients protection against unique combinations of biological threat agents. JSTO-CBD-directed research efforts in biological therapeutics leverage cutting-edge technologies, such as nanotechnology and small-molecule application, which will intervene in post-exposure effects of biological threat agents.

The most likely route of dissemination of a BW agent on the battlefield is through small-particle aerosols; therefore, researchers continue to develop, refine, and validate experimental models used to study airborne infection and disease prevention. If exposure and illness occur, rapid diagnosis is essential for proper treatment and medical management. Field-deployable, rapid assays are being developed for diagnosis of BW agent exposure. In addition to research and development, training military and civilian health care professionals in the diagnosis and treatment of BW agent exposure is a Command priority. USAMRMC experts also provide technical support to law enforcement agencies and counterterrorism initiatives.

The products in this section are divided into medical chemical defense products and medical biological defense products, and then subcategorized appropriately.



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Skin Exposure Reduction Paste Against Chemical Warfare Agents

Description

SERPACWA is an FDA-approved paste containing chemically inert perfluorinated polymers that delay or prevent penetration of nerve agents and sulfur mustard. Completed in 2003, it is used as a pretreatment in conjunction with Mission-Oriented Protective Posture gear to prevent or reduce the toxicity resulting from CW agents on the skin.

Partners

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- USAMRICD
- USAMMDA



Soman Nerve Agent Pretreatment Pyridostigmine

Description

SNAPP is a drug that was previously used to treat a chronic neuromuscular disease known as myasthenia gravis. It is now FDA approved as a prophylaxis against the lethal effects of the nerve agent soman. It is the first such drug to be approved under the FDA's Animal Efficacy Rule. Completed in 2003, SNAPP is used in conjunction with current antidotes.

Partners

- USAMRICD
- USAMMDA



Antidote Treatment Nerve Agent Autoinjector

Description

ATNAA provides treatment for nerve agent exposure of U.S. forces. The FDA-approved ATNAA is a two-chambered autoinjector used for the intramuscular injection of the nerve agent antidotes atropine and 2-PAM through the same needle. The ATNAA is administered after onset of symptoms to treat nerve agent toxicity. The ATNAA is a replacement for the currently fielded Mark I NAAK that delivers the same two drugs but requires two separate autoinjectors.

Partners

- USAMRICD
- USAMMDA

Medical Chemical Defense: **THERAPEUTICS**



Convulsant Antidote for Nerve Agents

Description

CANA offers U.S. forces additional protection from nerve agent poisoning. CANA is a diazepam 10 milligram autoinjector used for the prevention or abatement of convulsions and the prevention or reduction of brain injury associated with nerve agent poisoning. Completed in 1991, CANA is an FDAapproved, service member-carried item used with the Mark I NAAK.

Partners

- USAMRICD
- USAMMDA



M291 Skin Decontamination Kit

Description

Emergency decontamination products are intended to remove and neutralize potentially lethal CW and BW agents following agent exposure. The M291 Skin Decontamination Kit is a superior, safe, and effective system for use against multiple percutaneous CW agents. The wallet-like, flexible pouch contains six individually sealed foil packets and is carried in the pocket of protective suits. This kit was completed in 1990.

- USAMRICD
- USAMMDA



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Mark I Nerve Agent Antidote Kit

Description

The Mark I NAAK is administered when personnel are exposed to nerve agents, such as sarin, soman, tabun, and VX, and have signs and symptoms of exposure. The kit contains two multichamber autoinjectors containing 2 milligrams of atropine and 600 milligrams of 2-PAM each. The Mark I NAAK was completed in 1983 and replaced by the ATNAA.

Partners

- USAMRICD
- USAMMDA



Medical Aerosolized Nerve Agent Antidote

Description

MANAA increases the survival and sustainability of U.S. forces by supplying treatment for nerve agent exposure. MANAA is packaged as a pressurized inhaler device containing aerosolized atropine to counteract the effects of nerve agents, such as tabun, sarin, soman, cyclosarin, and VX. This antidote was completed in 1994.

Partners

- USAMRICD
- USAMMDA



Test-Mate Cholinesterase Kit

Description

The Test-Mate Cholinesterase Kit measures blood enzyme erythrocyte AChE and plasma cholinesterase, providing detection of nerve agent exposure in less than 4 minutes. The kit contains a battery-operated colorimeter, a photometric analyzer, and all equipment and reagents necessary for performing up to 96 tests. Blood for each test is easily obtained from a finger stick. This kit was completed in 1997.

Partners

- USAMRICD
- USAMMDA



Anthrax Vaccine Adsorbed (Biothrax™)

Description

Anthrax Vaccine Adsorbed (Biothrax) protects U.S. forces against all forms of anthrax, decreases the threat of a biological attack, and enhances strategic mobility. Anthrax Vaccine Adsorbed (Biothrax) is a sterile, cell-free filtrate containing proteins made from an avirulent strain of *Bacillus anthracis*. This FDA-licensed vaccine meets requirements for safety, efficacy, purity, and potency.

The Anthrax Vaccine Program provides the DoD with the Biothrax used to vaccinate and protect the Warfighter from potential exposure to *B. anthracis.* Biothrax is produced by Emergent BioSolutions and is FDA approved. The vaccine is administered in a 5-dose regimen over an 18-month period with an annual booster dose.

- Joint Program Executive Office for Chemical and Biological Defense
- Emergent BioSolutions



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Smallpox Vaccine System

Description

Smallpox is a viral disease that was declared eradicated by the World Health Organization. Consequently, the general public is no longer routinely vaccinated. This leaves a highly vulnerable population, especially when smallpox is considered to be a prime candidate for use as a biological weapon. The case fatality rate of smallpox disease among unvaccinated individuals is between 15 percent and 40 percent. The disease can be transmitted through casual contact.

An improved vaccine to protect against this BW threat is highly desirable. Only limited doses of the currently licensed smallpox vaccine (DryVax) are available, and there are significant reservations about mass inoculation due to its known side effects. The Joint Vaccine Acquisition Program (JVAP) Prime Systems Contractor, DynPort Vaccine Company, obtained FDA licensure in February 2005 for a new Vaccine Immune Globulin (VIG) product for intravenous administration instead of intramuscular (i.e., Vaccine Immune Globulin Intravenous [VIGIV]).

The Smallpox Vaccine System Program provides both the ACAM2000[™] smallpox vaccine and the VIGIV to vaccinate and protect the Warfighter from potential exposure to smallpox. Both products are FDA approved. The DoD's ACAM2000 requirement is being met through an Inter-agency Agreement with HHS under which the DoD draws upon supplies held within the U.S. Strategic National Stockpile. VIGIV is used to treat rare but serious adverse reactions associated with vaccination with ACAM2000, and the DoD maintains its own supply of VIGIV through a direct contract with the manufacturer, Cangene Corporation.

Partners

- HHS
- CBMS JVAP
- Cangene Corporation



Comprehensive Educational Tools and Resources

Description

Comprehensive educational tools and resources provide additional learning materials to service members to enrich the overall learning experience of managing chemical agent casualties.

An example of a comprehensive educational tool is the Medical Management of Chemical Casualties Supplemental Training Materials V. 4.00 CD-ROM. In addition, the Chemical Casualty Care Division web site at https://ccc.apgea.army.mil provides access to educational videos, an article database, a student tracking database, and a chemical agent symptoms and treatments bookmark.

Partners

USAMRICD



Computer-Based Training

Description

Computer-Based Training (CBT) offers service members a variety of interactive, multimedia learning courses both online and in compact disk format. Many of the CBT modules listed below are accredited for continuing medical education and continuing education unit credits for physicians, nurses, and paramedics.

- Medical Management of Nerve Agent Casualties
- Medical Management of Chemical Casualties Course
- Triage of Chemical Agent Casualties Course
- Virtual Field Training Exercise Course
- Patient Decontamination Station Small Group Exercise
- M40A1 Chemical-Biological Mask Function and Operation
- Nerve Agent Virtual Casualty Assessment

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Field Identification of Biological Warfare Agents Course

Description

The Field Identification of Biological Warfare Agents (FIBWA) course was designed to allow students to set up, maintain, and operate a deployable laboratory under field conditions. The 4-week FIBWA course includes classroom instruction, extensive hands-on laboratory training in diagnostic techniques, and a field exercise that integrates course material with real-world scenarios. Concepts of operations and diagnostic materials, equipment, and technology are continually evaluated and transitioned into the field to ensure that training is cutting edge. Six student courses and three manager courses for laboratory officers and commanders are offered each year. While FIBWA is designed for organizations within the DoD, course material can be tailored to meet the specific needs of other government agencies.

Partners

• USAMRICD



Field Management of Chemical and Biological Casualties Course

Description

The Field Management of Chemical and Biological Casualties course is designed for medical and chemical noncommissioned officers, Chemical and Medical Service Corps officers, and civilian first responders. Course instruction focuses on emergency treatment, triage, decontamination, and evacuation of casualties. Pre- and postcourse tests are administered to each class to evaluate student learning progress.

Partners

- USAMRICD
- USAMRIIID



Hospital Management of Chemical, Biological, Radiological/Nuclear, and Explosive Incident Course

Description

The Hospital Management of Chemical, Biological, Radiological/Nuclear, and Explosive (CBRNE) Incident course is designed to equip military and civilian hospital-based medical and management professionals with skills, knowledge, and information resources to carry out the full spectrum of health care facility responsibilities required by a CBRNE incident or mass casualty event.

Classroom and practical application instruction focuses on diagnosis, treatment, and incident management in response to mass casualty events of all types, including incidents involving weapons of mass destruction. The course also is offered as a modified, exportable 2- to 5-day course to meet specific audience needs. Pre- and postcourse tests are administered to evaluate student progress.

Partners

- USAMRICD
- USAMRIID



Medical Management of Chemical and Biological Casualties Course

Description

The Medical Management of Chemical and Biological Casualties course is designed for medical professionals. Instruction focuses on pathophysiology, diagnosis, and treatment of chemical and biological casualties. The course also is offered as an exportable 2-day course to meet specific audience needs. The exportable 2-day version does not include laboratory and field instruction.

- USAMRICD
- USAMRIID

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Nerve Agent Bioscavenger

Description

Nerve agents (e.g., soman, sarin, and VX) are fast acting and lethal at low doses. The DoD is developing a bioscavenger medical countermeasure, a prophylactic regimen intended to prevent incapacitation and death from exposure to a broad spectrum of nerve agents. Bioscavenger is a recombinant form of human butyrylcholinesterase produced in the milk of transgenic goats. FDA approval for the recombinant bioscavenger product (Bioscavenger Increment II) is planned for 2017. The DoD also is exploring more efficient and cost-effective alternative technologies for production of bioscavenger. The technology base is performing research to develop a catalytic bioscavenger (Bioscavenger Increment III) that will actively degrade nerve agents without losing its own activity. The technology is immature, and a candidate will not be ready for transition to advanced development until late 2020.

Partners

- USAMRICD
- WRAIR
- CBMS MITS



Advanced Anticonvulsant System

Description

Nerve agent exposure can cause seizures and convulsions in Warfighters. The use of an anticonvulsant provides an effective treatment for service members against nerve agent-induced seizures and subsequent brain damage caused by nerve agent exposure.

The Advanced Anticonvulsant System (AAS) will treat seizures and prevent subsequent neurological damage caused by exposure to nerve agents. The AAS, injected intramuscularly, will consist of the drug midazolam in an autoinjector. Midazolam will replace diazepam in the fielded CANA. Midazolam is more water soluble than diazepam and terminates nerve agent-induced seizures more quickly than diazepam. AAS will not eliminate the need for other protective and therapeutic systems. FDA approval is planned for 2012.

Partners

- USAMRICD
- CBMS MITS



Improved Nerve Agent Treatment System

Description

Provide protection against nerve agentinduced symptoms of toxicity, such as breathing difficulties, hypersecretions, and muscle tremors. The INATS is an enhanced treatment regimen designed to provide protection against a broad spectrum of nerve agents. The components of INATS include (1) replacing the currently fielded oxime (2-PAM) with a new oxime and (2) obtaining FDA approval for use of pyridostigmine bromide, the component of SNAPP, for use against additional nerve agents. The current pretreatment indication for SNAPP is limited to soman. The new oxime is intended to replace 2-PAM in the currently fielded ATNAA or similar device. The INATS will not eliminate the need for other protective and therapeutic systems. The INATS is intended for self-administration. FDA approval is planned for 2017.

- USAMRICD
- CBMS MITS



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Next-Generation Anthrax Vaccine

Description

Anthrax is caused by spores and most commonly occurs in wild and domestic mammals, although it has been manufactured as a BW agent. Symptoms vary depending on the route of exposure; however, sore throat, mild fever, and muscle aches usually begin within 7 days of exposure. Severe breathing difficulty, shock, and meningitis follow, and as the bacteria multiply in the lymph nodes, toxemia progresses and the potential for widespread tissue destruction and organ failure increases. Up to 90 percent of untreated cases result in death. Currently, ciprofloxacin is the only antibiotic approved by the FDA to treat anthrax exposure.

Obtaining an alternative for the currently licensed anthrax vaccine would provide the DoD with additional options in protecting the force against this serious BW threat. HHS, through the Biomedical Advanced Research and Development Authority, has established a contract with PharmAthene for advanced development of its second-generation recombinant protective antigen vaccine targeted for future procurement in the U.S. Strategic National Stockpile.

Partners

- USAMRIID
- HHS
- PharmAthene



Plague Vaccine (Recombinant Plague Vaccine)

Description

An effective FDA-licensed vaccine against aerosolized plague will enhance force protection and strategic mobility. Infection induced by inhalation of *Yersinia pestis* represents a serious BW threat. The resultant disease, pneumonic plague, has an incubation period of 2 to 5 days and an untreated mortality rate of nearly 100 percent within 1 to 3 days after the onset of illness. The disease can be transmitted through flea bites and is characterized by high fever, chills, headache, malaise, myalgias, cough with blood-tinged sputum, and tender, swollen lymph nodes. The disease progresses rapidly, resulting in epigastric discomfort, noisy respiration, and a bluish discoloration of the skin followed rapidly by respiratory failure, circulatory collapse, and bleeding tendencies if left untreated.

CBMS JVAP is developing a new vaccine intended to protect Warfighters against pneumonic plague as a result of aerosolized exposure to Y. *pestis*. The Recombinant Plague Vaccine (rF1V) candidate is composed of the F1V fusion protein formulated with an aluminum hydroxide adjuvant and delivered intramuscularly as a 3-dose series prior to potential aerosol exposure to Y. *pestis*. Initial development of this vaccine candidate was pioneered at USAMRIID. FDA approval is planned for 2015.

- USAMRIID
- CBMS JVAP



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Project Argus: A National Biosurveillance Priming System

Description

For the United States to meet present and future biothreats that span agricultural, animal, and human considerations, an integrative strategy for information discovery, exploitation, and effective proactive use by the response community is critical. Indications and Warnings (I&Ws) provide a key component for integration within the U.S. biosurveillance portfolio, enabling earlier warning potential. Project Argus is the first attempt to integrate I&Ws in an effort to detect catastrophic bioevents on an international scale.

I&Ws alert U.S. responders of an imminent bioevent weeks to months in advance. I&Ws are markers occurring globally, outside of U.S. borders, before an outbreak can affect U.S. interests, forces, citizens, or territory, thus allowing the United States time to respond. In effect, I&Ws can prime the national response infrastructure by alerting agencies of an evolving threat that could ultimately be catastrophic. Retrospective analyses of major bioevents have demonstrated the presence of multiple I&Ws present in multiple data sources weeks to months in advance, which were not recognized and used properly by the national response community. In addition to funding provided by USAMRMC's Telemedicine and Advanced Technology Research Center, the project also has benefited from financial support from the Intelligence Technology Innovation Center and the Department of Homeland Security National Biodefense Analysis and Countermeasures Center.

Partners

- TATRC
- Imaging Science and Information Systems Center-Georgetown University in partnership with the MITRE Corporation



Recombinant Botulinum Toxin A/B Vaccine

Description

An effective FDA-licensed vaccine against aerosolized botulinum toxins A and B will enhance force protection and strategic mobility. The paralytic neurotoxins elaborated by *Clostridium botulinum* are the most potent, naturally occurring toxins known. Botulism is acquired naturally by oral ingestion of the organism or infection of a preexisting wound. Direct intoxication of humans can be accomplished by aerosolizing the toxin, leading to intoxication by inhalation. Botulism symptoms appear within hours to days following exposure to botulinum toxin. All symptoms are the result of irreversible binding of the toxin to neurons. Typical symptoms include nausea, vomiting, headache, dry mouth, urinary retention, intestinal obstruction, and general neurologic disorder characterized by weakness and dizziness. Eventually, the illness results in weakness in descending extremities and respiratory muscles. Respiratory paralysis is most often the immediate cause of death.

CBMS JVAP is developing a new vaccine intended to protect Warfighters against aerosolized exposure to botulinum toxins. The Recombinant Botulinum Toxin A/B Vaccine (rBV A/B) candidate is composed of nontoxic but immunogenic fragments of the botulinum toxin heavy chains of serotypes A and B. Initial development of this vaccine candidate was pioneered at USAMRIID. FDA approval is planned for 2016. The vaccine is intended for use in an active vaccination program and will be administered intramuscularly as a 3-dose primary series prior to deployment of Warfighters into possible threat areas.

Partners

- USAMRIID
- CBMS JVAP



Medical Chemical and Biological Defense

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Trivalent Filovirus Vaccine

Description

USAMRIID scientists have made and patented several potential vaccines against Ebola and Marburg viruses using different vaccine strategies, including gene based (DNA), replication-defective viral vectors (alphavirus replicons), and virus-like particles using two filovirus proteins. These have all been tested successfully in rodents, and some have demonstrated efficacy in nonhuman primates. In addition, USAMRIID investigators are collaborating with scientists in other government agencies, industry, and academia to test experimental adenovirus-vectored and rhabdovirus-vectored vaccines for Ebola and Marburg viruses. At least one of these candidate vaccines successfully protected nonhuman primates from Ebola virus.

CBMS JVAP is developing a new trivalent vaccine for the DoD intended to protect against aerosolized exposure to filoviruses. The CBMS JVAP will develop a trivalent vaccine system to protect against Ebola Sudan, Ebola Zaire, and Marburg viruses. The objective end product would contain all three vaccine components in a single vaccine formulation. CBMS JVAP will serve as the integrator for the technology development phase by managing and coordinating the various vaccine development contracts and intergovernmental efforts from Milestone A to B. Anticipated fielding is fiscal year 2024.

Partners

- USAMRIID
- CBMS JVAP



Tularemia Vaccine

Description

Tularemia is an incapacitating and occasionally fatal infection transmitted to humans by fly and tick bites. Clinical symptoms are often confused with those of plague; therefore, tularemia can be very difficult to diagnose. Infection induced by inhalation or ingestion of Francisella tularensis organisms represents a serious BW threat because only a small amount is necessary to cause infection. Antibiotics may not be a viable option in the theater of operations, and there is no U.S.licensed tularemia vaccine.

The DoD's advanced development program for a tularemia vaccine was terminated due to removal of funding; however, HHS continues tularemia vaccine development through submission of an Investigational New Drug application to the FDA.

- USAMRIID
- HHS/NIAID



Venezuelan Equine Encephalitis Infectious Clone Vaccine

Description

The VEE virus is a highly infectious agent that is easily manufactured in large quantities, stable in storage, and efficiently transmitted by aerosol. The alpha viruses are amenable to genetic manipulations, thereby increasing their potential as BW weapons.

Clinical manifestations include a sudden onset of a nonspecific febrile illness that consists of malaise, fever, chills, headache, retro-orbital pain, nausea, vomiting, and sore throat. The acute phase of the illness lasts 4–6 days with total recovery taking 2–3 weeks. There is no antiviral with recognized efficacy against VEE infection, and medical intervention remains limited to supportive care.

The VEE Infectious Clone Vaccine, designated V3526, is a genetically engineered, live, attenuated virus that will be administered subcutaneously. Because this is a live viral product, only one vaccination will be required. The vaccine will elicit an immune response within 30 days, provide 80 percent protection for 1 year, and have a shelf-life of at least 3 years. The advanced development program for VEE vaccine was terminated in 2006 due to reallocation of program funding to the DoD's Transformational Medical Technologies Initiative program.

- USAMRIID
- CBMS JVAP



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Continuous Product Improvement to the Joint Biological Agent Identification and Diagnostic System

Description

The JBAIDS is a reusable, portable, modifiable biological agent identification and diagnostic system capable of rapid, reliable, and simultaneous identification of multiple biological agents and other pathogens of operational concern. The JBAIDS Anthrax, Tularemia, and Plague Detection Systems are FDA cleared for diagnostic use. On 24 August 2009, the FDA granted an Emergency Use Authorization for the swine influenza (2009H1N1) diagnostic capability on JBAIDS. CBMS through the Office of the Surgeon General, submitted the JBAIDS H5 avian influenza in vitro diagnostic kit to the FDA on 29 January 2009; the FDA approved the H5 in vitro diagnostic kit 510(k) submission on 6 July 2010. In addition to these two influenza detection assays, the Office of the Assistant Secretary of Defense for Health Affairs has released funding for expanded infectious disease detection capability on the JBAIDS; this additional infectious disease detection capability is projected to be available to deployed military forces in 18 to 24 months. CBMS will submit the Q-Fever in vitro diagnostic kit to the FDA for clearance by the fourth quarter of fiscal year 2010.

USAMRIID develops state-of-the-art technologies, critical diagnostic reagents, and protocols to support rapid and confirmatory identification of biological threat agents. Diagnostic assays developed at USAMRIID are standardized, optimized, and transitioned to the advanced developer for application with the JBAIDS.

- USAMRIID
- CBMS MITS



Field-Deployable Ultra-Sensitive Assay System for Biological Toxins

Description

The early and rapid detection of biological toxins is critically important to the protection of military personnel deployed in combat situations. However, current methods for detecting biotoxins are not well suited to the development of highly specific assay systems for detecting biotoxins down to the level of 1 attomolar (10–18 M) in combat deployment situations. Investigators have developed assays to detect cholera toxin B subunit in deionized water, human urine, and farm run-off water. The detection limits achieved with this immunoassay were all well below 1 attomolar. Assays also have been developed for botulinum neurotoxin serotype A and tetanus toxoid using trisialoganglioside GT1b-labeled immunoliposomes. The detection limits of these assays were also well below 1 attomolar. A prototype field-deployable version of the assays has been developed based on the Roche LightCycler[®]. These efforts have resulted in the development of a simple immunoassay system that is easily field deployable but is also more sensitive than any previous technology for the detection of biological toxins. Efforts are under way to develop a more portable "lab-chip" format for the assay and assays for the detection of human diseases, such as HIV, amyloid disorders (prion disease), and cancer. A patent covering this technology is pending.

- CDMRP
- AFIP



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Chemical Diagnostics

Description

The Chemical Diagnostics area seeks to develop screening procedures and definitive analytical methods for testing biomedical samples for individual exposure to CW agents.

Chemical Diagnostics research focuses on developing state-of-the-art laboratory/fieldable methods that detect exposure to CW agents (e.g., nerve agents and vesicants) in clinical samples. It also targets identifying biomolecular targets that can be leveraged as analytical methodologies as well as in vitro and in vivo studies characterizing the time course and longevity of a particular analyte/ biomarker.

Partners

USAMRICD



Cyanide Medical Countermeasures

Description

Medical countermeasures against cyanide intoxication and the development of more accurate and reliable methodologies to assay for cyanide from biological samples will provide additional protection to service members on the battlefield. Cyanide is a fast-acting inhibitor of cellular respiration. No pre-treatment against cyanide is presently available, and modern cyanide treatments accessible to DoD personnel have serious limitations. Pharmaceutical countermeasures against cyanide (i.e., pretreatments and treatments) must act rapidly, have relatively long half- and shelf-lives, and present no or minimal side effects. Efforts are ongoing to identify pretreatment compounds that will protect service members from cyanide. In addition, scavengers for cyanide are being evaluated as treatments and pretreatments.

Research toward medical countermeasures against cyanide is funded through the National Institutes of Health (NIH) Countermeasures Against Chemical Threats (CounterACT) Research Network program. This program seeks to enhance the current medical response capabilities of the nation in preparation for a chemical event emergency. To achieve this goal, NIH has developed a comprehensive cooperative research network composed of research centers of excellence, individual research projects, small business innovation research projects, and contracts and inter-agency agreements with other federal entities.

Partners

- USAMRICD
- NIH CounterACT Research Network

Medical Chemical Defense: **PREVENTION**



Cutaneous and Ocular Therapeutics

Description

This research area focuses on the development of therapeutic strategies to effectively minimize injuries to dermal and ocular tissues resulting from exposure to vesicant CW agents. Vesicant chemical agents such as sulfur mustard are a significant threat to U.S. forces, and there is currently no vesicant agent treatment available. This work will yield a vesicant agent countermeasure that will substantially reduce the number of casualties or degree of injury, reduce the medical logistical burden, deter use of sulfur mustard, and enhance the ability of U.S. forces to sustain operational tempo.

Research efforts validated countermeasure approaches using anti-inflammatories and chemical scavengers. Research efforts also are exploring the use of debridement techniques combined with treatment adjuncts, to include dressings, growth factors, and skin substitutes, to facilitate the healing of vesicant-induced skin injuries. In addition, the technologies of an injectable, FDA-approved fluorescence dye and a wearable, portable diagnostic instrument that uses night vision technology were combined to create a method for evaluating the depth of burn injuries caused by exposure to sulfur mustard.

Partners

USAMRICD



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Skin and Wound Decontamination

Description

A method for skin and wound decontamination will enhance survival and sustainability of U.S. forces in need of emergency decontamination products following nerve agent exposure. Current techniques of decontamination include activated charcoal that is rubbed over the body to absorb the chemical agent. One technology being explored is a cotton sponge impregnated with enzymes, including acetylcholinesterase, which bind organophosphorus compounds or nerve agents and inactivate them before they can do harm. The additives in the sponge remove, contain, and destroy organophosphorus compounds and vesicants, preventing further contamination. The decontamination product also is being evaluated for decontamination and detoxification of biological agents and removal of radiologicals from skin.

The sponge reacts to a nerve agent by changing color. Because it is made of polyurethane, it is inexpensive and sturdy and should not require any special training for its use. It already has been shown to be stable when stored at 45°C. Decontamination currently is being tested in animals.

The FDA approved the RSDL as a medical device on 25 March 2003. Testing indicates that the lotion is superior to the currently fielded activated charcoal decontaminant, the M291 Skin Decontamination Kit, in the removal and neutralization of chemical agents. The RSDL is a component of the Joint Service Personnel/Skin Decontamination System (JSPDS), an FDA-cleared individually carried skin decontamination kit. The JSPDS provides the Warfighter with the ability to decontaminate the skin, after exposure to CW and BW agents, in support of immediate and thorough personnel decontamination operations. The M291 Kit will be replaced by the JSPDS.

- USAMRICD
- WRAIR
- Joint Program Executive Office for Chemical and Biological Defense Decontamination Program Manager



Recombinant Ricin Vaccine Candidate

Description

A ricin vaccine will decrease the threat of a biological attack and enhance strategic mobility of U.S. forces. Ricin is a toxin derived from the castor plant, which is grown throughout the world for commercial purposes. Approximately 1 million pounds of castor beans are used each year in the process of manufacturing castor oil. Given its ready availability and its high level of toxicity—particularly when delivered as an aerosol—ricin is a significant potential agent of BW or terrorism. Currently, there is no vaccine or therapy available for human use.

The new vaccine candidate, called RTA 1-33/44-198, is a fragment of the ricin toxin A-chain that has been modified to eliminate the toxic enzymatic property of RTA, increase protein stability, and maintain its ability to elicit a protective immune response. The vaccine fully protected mice from a whole-body aerosol challenge with lethal doses of ricin.

Next steps include testing in nonhuman primates and refinement of a scaled-up production method that is robust and reproducible.

Partners

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Staphylococcal Enterotoxin A/B Multivalent Vaccine Candidate

Description

Recombinant staphylococcal enterotoxin serotypes A and B (SEA/B) multivalent vaccines will decrease the threat of a biological attack and enhance strategic mobility of U.S. forces. *Staphylococcus aureus* produces a number of toxic proteins, including SEA/B. These are part of a larger group of superantigen toxins capable of directly stimulating a large population of immune cells and inducing an intense inflammatory response that injures host tissues. Symptoms begin approximately 3 to 12 hours after aerosol infection and include flu-like and respiratory signs, which may persist for weeks. Severe exposures can result in acute pulmonary edema and respiratory failure. These toxins are easily manufactured and very stable. There are currently no FDA-licensed vaccines or therapeutics for protection from SEA/B.

The recombinant SEA and SEB vaccine components are expressed in *Escherichia coli*. Preclinical safety, efficacy, and long-term immunity have been demonstrated in rodents and nonhuman primates. Furthermore, scalable manufacturing and purification processes, formulation studies, and lot release criteria have been developed. These accomplishments serve as a basis for considering the SEA/SEB vaccine candidates of sufficient maturity to transition out of the technology base.

Partners

• USAMRIID



Vaccine Constructs for a Combined Equine Encephalitis Vaccine

Description

A multivalent vaccine that protects against VEE, EEE, and WEE would decrease the threat of a biological attack and enhance strategic mobility of U.S. forces. In addition to developing a new candidate vaccine for VEE, USAMRIID research is focused on developing safe and efficacious vaccines for EEE and WEE. Like VEE, these viruses are highly infectious and easily transmitted by the aerosol route. Current vaccines for EEE and WEE are available for Investigational New Drug use only and have been found to be relatively ineffective in a significant portion of the recipients. Three approaches are being pursued: naked DNA vaccines; replicon-vectored vaccines; and live, attenuated vaccines derived by genetic engineering.

USAMRIID scientists also are working to confirm cross-protection among various strains of VEE, EEE, and WEE with the ultimate goal of developing a multivalent vaccine that would protect against all three viruses.

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Virus-Like Particles

Description

The goal of this research effort is to develop a safe and efficacious subunit, vector-free filovirus vaccine consisting of multiple virus-like particles (VLPs) each expressing three antigens, glycoprotein (GP), VP40, and nucleoprotein (NP), of a filovirus strain. The VLPs are spontaneously produced in cells when the three genes are expressed ectopically. These VLPs have a morphology that is strikingly similar to the authentic filovirus with the GP expressed on the surface, traversing the envelope, a layer of matrix protein (VP40) underneath the envelope, as well as encapsidated NP. It is anticipated that the final product will be a trivalent vaccine consisting of VLPs for Ebola virus Zaire, Ebola virus Sudan, and Marburg Musoke, each produced separately in mammalian cells. This trivalent vaccine will provide immunity against multiple Ebola and Marburg viruses. To date, mono- and multivalent efficacy in nonhuman primates and a high degree of efficacy following 2 doses of the vaccine have been demonstrated.

Partners

USAMRIID



Therapeutic Strategies for Botulinum Neurotoxins

Description

Botulinum neurotoxins are the most toxic biological substances known. These toxins bind to peripheral cholinergic nerve cells, rendering them inactive and causing neuromuscular paralysis, respiratory failure, and death. Current treatment for botulinum intoxication involves weeks of intensive care.

USAMRIID has worked closely with the University of California, San Francisco, to develop monoclonal antibodies to treat all seven serotypes of botulinum neurotoxin. These efforts resulted in a combination of three human-compatible monoclonal antibodies that bind to the toxin, rendering it harmless.

NIAID has awarded a contract to XOMA Ltd. and SRI International to produce three human monoclonal antibodies against botulinum neurotoxin A.

- USAMRIID
- University of California, San Francisco



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Therapeutic Strategies for Treating Filovirus Infection

Description

Drugs to treat infection with the filoviruses Ebola and Marburg would reduce Warfighter morbidity and mortality and also decrease the associated hazard to medical and laboratory personnel. USAMRIID scientists are identifying viral targets as well as strategies for the treatment of clinical symptoms and are evaluating an extensive array of drugs and antibodies for their potential in therapeutic and prophylactic treatments of filovirus infections. USAMRIID has identified new targets as well as lead compounds and small molecules for further exploration. One drug, recombinant nematode anticoagulant protein c2 (rNAPC2), successfully protected some monkeys from challenge with Ebola virus, apparently by blocking the abnormal blood clotting that is characteristic of Ebola infection.

Monoclonal antibodies to Ebola virus isolated from vaccinated mice by USAMRIID protected mice from challenge when administered as late as 2 days after infection, and other monoclonal antibodies have protected guinea pigs from lethal Marburg virus infection. USAMRIID researchers are collaborating with Arizona State University, Biovation, and The Dow Chemical Company in evaluating these antibodies as potential treatments.

- USAMRIID
- Arizona Sate University
- The Dow Chemical Company
- Biovation



Therapeutics for Smallpox and Other Orthopoxviruses

Description

Smallpox was eradicated in 1979 through the efforts of the World Health Organization. Currently, the virus is known to exist only in two World Health Organization-sanctioned repositories. However, there is concern that undisclosed reference stocks may exist, and the U.S. population is no longer routinely immunized against smallpox. Due to the potential for the virus to be used as a BW agent or for bioterrorism, antiviral drugs are urgently needed.

Because smallpox no longer occurs naturally, vaccine and drug candidates cannot be tested for their ability to prevent or treat the disease in humans. Licensing of future medical countermeasures for smallpox will depend on animal studies. The FDA has established an Animal Efficacy Rule to facilitate the approval of vaccines and drugs for biological agents in cases where efficacy data in humans cannot be obtained.

Tecovirimat (ST-246) inhibits orthopoxvirus egress from infected cells and therefore prevents it from causing disease. Research at USAMRIID has established that oral ST-246 is able to stop the spread and disease progression of both smallpox and monkeypox in nonhuman primate models. Additional studies are aimed at refining the therapeutic window and the dose-route schedule.

- USAMRIID
- HHS/NIAID



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OVERVIEW

Advanced Medical Technologies

The U.S. Army Medical Research and Materiel Command's (USAMRMC's) Telemedicine and Advanced Technology Research Center (TATRC) manages congressionally mandated advanced technology projects, including identification, exploration, and demonstration of key technologies that will reduce the medical "footprint" and increase medical mobility while ensuring Warfighters have access to essential medical expertise and support wherever they deploy. Through partnerships with industry and academia, resulting products help make medical care and services more accessible to Warfighters, reduce costs, and enhance the overall quality of health care in wartime and peacetime. Current projects focus on:

- Advanced prosthetics, orthotics, and other orthopedic assistive devices, treatments, and interventions for patients with major limb amputations, fractures, and other orthopedic-related injuries
- Chronic disease management that highlights the use of telemedicine, home care monitoring, evolving biosensor development, and advanced immunologic testing in vulnerable populations
- Computational biology or bioinformatics, which involves the development and application of methods for analysis, interpretation, prediction, and modeling of biological data
- Health information technologies

- Advanced medical imaging technologies, which is divided into four distinct research areas: portable imaging and image-guided therapeutics, advanced high-performance imaging, computational methods and decision support in imaging, and optical/paraoptical imaging techniques
- Medical logistics of state-of-the-art prototype devices
- Robotic technologies to locate, identify, assess, treat, and rescue battlefield casualties
- Mobile computing and remote monitoring that focus on identifying and developing point-of-care medical technologies and support architectures to improve military health care
- Nanotechnology and biomaterials to improve drugs and devices for diagnosis and therapy
- Neuroscience projects that leverage the latest technologies in prevention, diagnosis, treatment, and therapy to prevent injury or improve Warfighter outcomes from traumatic brain, spinal cord, and peripheral nerve injuries as well as the neuropsychologic effects of war
- Regenerative medicine, created in response to the current military medical needs to treat traumatically injured tissues resulting from combat or battlefield wounds





Clinical Looking Glass, "A Revolutionary Clinical Intelligence Tool"

Description

TATRC is working with Emerging Health IT, Inc. (Montefiore Medical Center, New York) to pilot a revolutionary clinical intelligence tool known as the Clinical Looking Glass. The Clinical Looking Glass currently is used by clinicians at Montefiore Medical Center to perform quality assurance studies and health research studies. It is a data warehouse with an easy-to-use front end that allows clinicians to build study and control cohorts at their desktops, using data from the electronic health record, and make comparisons between these groups as to differences in health outcomes. Cohorts can be compared easily with statistical measures and graphical outputs ready for use in quality assurance meeting and publications. All of this is done automatically, in a matter of minutes, with no need for chart abstracts, or statisticians. All cohorts and results can be saved as objects for reuse and sharing with colleagues. By default, all studies are done with de-identified data; however, identified data are available to those with permission to support patient remediation at the point of care.

Between 2006 and 2008, TATRC established the Clinical Looking Glass with de-identified data from the National Capital Area. In 2009, TATRC began establishing a pilot of the Clinical Looking Glass at the U.S. Air Force Population Health Center, Brooks City, Texas. The plan for 2010 is to enhance the Clinical Looking Glass with Military Health System (MHS) data from the Air Force Corporate Health Information Processing Service warehouse and then make the Clinical Looking Glass available for further evaluation by select clinicians at the National Naval Medical Center in Bethesda and Walter Reed over the Internet. Given a successful pilot at Brooks City Base, clinician support, and funding, the plan is to move the Clinical Looking Glass to production as a system of record for the MHS.

Partners

- TATRC
- Emerging Health IT, Inc. (Montefiore Medical Center, New York)





Departments of Combat Medical Training – Technology Enhancement

Description

To reduce the number of persons needed to conduct the All Skills Practical Exam and reduce the amount of time candidates must wait to receive the results of their skills evaluation. This is a significant challenge to both military and civilian training departments. Deloitte Consulting LLP has completed the research, design, and development of a technical solution: to digitize and integrate formsbased testing and training documents into the 68W training program to improve the quality of combat medic training. This includes the digital conversion of paper to electronic forms, processing of radio frequency identification signals using passive tag technology, two-way secure wireless synchronization of the tablet, and central servers managing the data.

- TATRC
- Deloitte Consulting LLP (formally BearingPoint, Inc.)



Digital Imaging Network-Picture Archiving and Communications System

Description

The Digital Imaging Network-Picture Archiving and Communications System (DIN-PACS) provides service members and their families with faster and better images to enhance quality of care. DIN-PACS is made up of several components, including reusable phosphorus plates that work with a normal x-ray machine, a computerized radiography scanner, and a workstation to view captured images. Images can be lightened or darkened, leveled to find the best quality, sent off-site to a radiologist for diagnostic reading, and archived immediately. DIN-PACS was completed in 1991.

Partners

- TATRC
- USAMMA
- Army PACS Program Management Office
- AGFA
- Fuji
- GE
- Philips
- Medweb



Digital Information and Communications System

Description

The Digital Information and Communications System (SMART/MC3T) enables service members to establish communications (e.g., self-sufficient Internet and telephone coverage) in remote areas and provides local authorities with medical situational awareness and telemedicine services. SMART/ MC3T implements commercially available technologies through a modular solution that is heterogenous, multiplatform, open standards based, and upward compatible in both capacity and technology. The system was completed in 2003.

Partners

• TATRC

Milit Opera Clinical and Rehabilitativ Medicine Medical Chemical and Biological Defense

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Teleconsultation/Teledermatology

Description

Facilitates readiness and promotes health protection of the force. Teleconsultation/ teledermatology facilitates delivery of medical treatment through information and telecommunication technologies and was completed in 2001.

Partners

• TATRC



Video Laryngoscope

Description

TATRC has been supporting efforts led by Dr. Ben Boedeker to develop increasingly improved airway management tools for the far-forward battlefield. This effort has been centered on video laryngoscopy. With the advent of video laryngoscopy, a need for novel support devices was created. Two novel support devices, the Intubating Forceps and the suction Video Laryngoscope Blade were developed and fielded for military use.

The Video Laryngoscope Blade was evaluated in a simulated airway model with secretions. The hemorrhagic airway creates difficulty in airway visualization, impeding attempts to successfully perform intubation. Challenges in the development of a suction laryngoscope include insufficient suction rates and complicated methods of attaching catheters, making the device difficult to use. Video laryngoscopy requires optics free from distortion. This work compared a specially designed Video Laryngoscope Blade with an integrated suction capability and its comparison to, and support of, a standard suction system. The new system was comparable to and in many ways superior to older systems. The significant difference between each individual type of suction and the combination of the two indicate that using both during a procedure would increase the amount of blood and debris removed from a severely bleeding airway. The Laryngoscope Blade is present in almost every intubation so integrating suction provides an additional avenue for removal of liquid from the airway while freeing the practitioner's hands for other tasks.

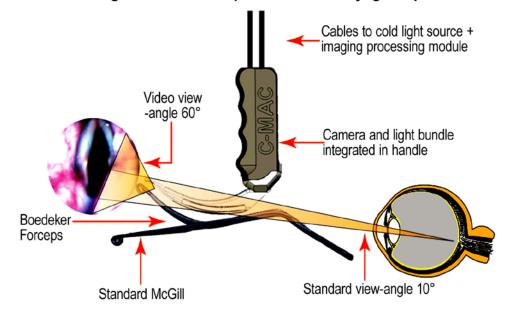
The Boedeker (Curved) Intubating Forceps for Removal of a Foreign Body also have been evaluated in a manikin. Foreign body aspiration is a common clinical problem, especially in children. The foreign body is commonly removed using McGill forceps and direct laryngoscopy. While standard laryngoscopes provide a direct view along the line of sight (10 degree field of view), with video laryngoscopy a much wider (60 degree) field of view may be achieved. Conventional (straight shaft) McGill forceps are designed to operate in direct line of sight. However, when using video laryngoscopy, the working end of this instrument does not pass into the laryngoscopist's field of view. The Boedeker Intubating Forceps were developed to allow the operator to reach into the full field of view offered by video laryngoscopy. In this testing, curved forceps, bent in an arc similar to the MacIntosh blade, were shown to offer advantages for retrieval of foreign objects passed beyond the field of view by straight line of sight. This study demonstrated that the successful removal of foreign bodies using forceps that are curved to match the shape of the MacIntosh laryngoscope blade is significantly more effective than using forceps with a noncurved shaft.

These two instruments, the novel suction blade and the novel laryngeal retrieval forceps, have been licensed and production has begun by medical manufacturers.

Partners

- TATRC
- University of Nebraska Medical Center

Using Intubation Forceps with a Videolaryngoscope

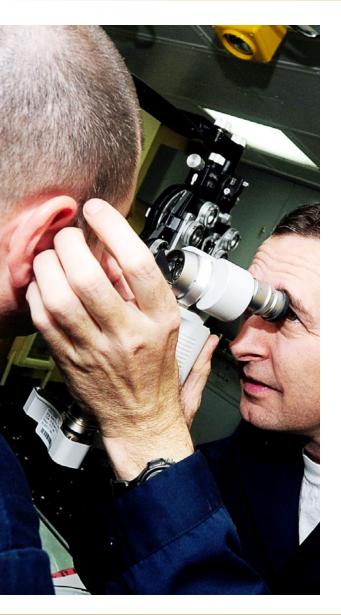


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Web-Enabled Refractive Surgery Information System

Description

Collection and management of refractive surgery information will protect patients, improve care, and reduce costs by providing an electronic medical record that is accessible at any facility a patient visits. The Warfighter Refractive Eye Surgery Program (WRESP) provides service members with refractive eye surgery to increase their mobility in combat.

WRESP was initiated to support service members as well as track the long-term effects and benefits of refractive surgery. It was developed and adopted in cooperation with the ophthalmology consultant for the Surgeon General.

The Web-Enabled Refractive Surgery Information System (WebRSIS) was developed to capture refractive surgery clinical data and to conduct outcome analysis. This program was developed by doctors for doctors to meet the business needs and clinical environment found at regional medical centers.

Current technology provides audit trails, provider tracking, digital signatures, and privilege management; data consolidation, real-time and historical reporting, and a questionnaire; pre-operative exam, treatment plan, operation notes, and post-operative exam; and a deployment questionnaire.

To date, about 4,100 patients have been entered into the existing RSIS program with more than 3,900 patients entered into the new WebRSIS. Next year, about 12,000 new records are anticipated. These numbers will be used in the Standard Refractive-Surgery Data Report, which automatically summarizes outcomes from multiple surgeries. The Standard Refractive-Surgery Data Report benefits the patient, surgeon, and the MHS by reporting data in a concise and meaningful way.

• TATRC



Advanced Surgical Technologies

Description

Advanced Surgical Technologies (AST) will use progressive advanced technologies in communication and patient care to improve the efficiency and safety of military and civilian operating rooms. The operating room is a highly complex environment of startling isolation in real time. Staff teamwork is fragmented and requires an inordinate amount of voice communication resulting in negative unplanned events occurring frequently and in clusters. In addition, valuable time is wasted; quality indicators, including patient safety, are assessed only in retrospect; and too much energy is expended on making the operating room function instead of directing patient care.

AST will integrate existing pockets of research through collaboration to implement advanced medical technologies in both the federal and civilian health care systems and stimulate new research and development focused specifically within the following topical research areas: patient safety, advanced devices, medical informatics, telesurgery, and perioperative systems design.

Partners

TATRC



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AHLTA-Mobile

Description

On the battlefield, it is crucial for first responders to have current medical information at the point of care. AHLTA-Mobile (Armed Forces Health Longitudinal Technology Application-Mobile) is a diagnostic tool that provides useful medical informatics and telemedicine support across the spectrum of the military health care operations and continuum of support levels of care.

AHLTA-Mobile, a wireless handheld device that is used throughout the Department of Defense (DoD) to capture electronic health records for more than 9 million U.S. service members, retirees, and their families, enables first responders and other health care staff to quickly and accurately capture, integrate, transmit, and display data from medical histories and physical examinations, medical reference libraries, diagnostic and treatment decision aids, medical sustainment training, and medical mission planning. The personal digital assistant (PDA) can be used by military health care providers at all levels of care from the foxhole to the medical center. AHLTA-Mobile, also called BMIST-J (Battlefield Medical Information System Tactical-Joint), supports a user interface that includes help windows and decision rationale. The system is easily adaptable to evolving medical procedures and protocols in addition to new medical databases and mission requirements. Under adequate conditions, AHLTA-Mobile is capable of supporting real-time "teleconsultation" between the first responder and expert medical staff in different locations. AHLTA-Mobile was named as one of the Army's 10 Greatest Inventions for 2003 and 2004.

Partners

TATRC

6-10



Center for Military Biomaterials Research

Description

The Center for Military Biomaterials Research (CeMBR), located at Rutgers University in Piscataway, New Jersey, will become the military's scientific resource in the field of biomaterials science and engineering. CeMBR will facilitate the research and development of new biomaterial technologies and improve the control of cell-material interactions with applications for improving both preventive and combat casualty care.

CeMBR was specifically designed to address the shortcomings and needs of the military as outlined in a 2001 Board on Army Science and Technology Report, "Opportunities in Biotechnology for Future Army Applications." CeMBR has implemented a roadmap process in which the military's requirements for new biomaterials are delineated and targeted. Specifically, the center will address the process by which the military incorporates biotechnology developments and specific applications of biomaterials for improving both preventive and combat casualty care.

CeMBR will create a unique industrial/academic/government network with a core faculty and a panel of nationally renowned scientific advisors for project selection and outcomes evaluation. The major focus of the center is to help the military negotiate an environment of rapidly changing science and assist in the translation of science from the bench to the field and bedside using the most efficient technology translation mechanisms available. Some of the scientific investigations supported at the center include sprayable wound dressings, scaffolds for bone regeneration, a model for a human skin equivalent, and stem cell technologies for tissue regeneration. New technologies are added to the center's portfolio of projects as determined by a scientific advisory panel.

Partners

TATRC



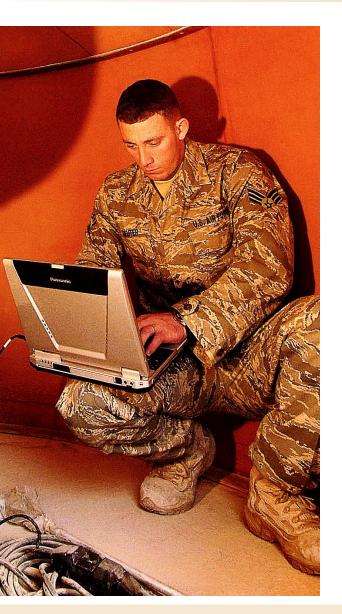
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Common Development Environment Initiative

Description

The Common Development Environment (CDE) Initiative will organize and facilitate local and regional innovations in health informatics and technology, as well as steer the IM/IT research agenda toward the rapid enhancement of the Enterprise-Wide Electronic Health Record solution, AHLTA.

Promising health information technologies are being developed in military research settings and at local MTFs across the MHS. However, these efforts are not well coordinated and yield few benefits to mainstream military health information systems. The lack of an agile process or methodology for the coordinated development, testing, and hand off of health IT products to the enterprise has resulted in a failure to capitalize on emerging technology innovations and financial investments in information management/information technology (IM/IT).

The CDE Initiative seeks to align IM/IT research and prototyping activities with mainstream IM/IT acquisition strategies and business processes to improve the quality and availability of candidate solutions for AHLTA. To achieve this goal, the CDE Initiative will design and test a management model that coordinates research and business practice, sets standards and guidelines, and offers a representative AHLTA development environment for government, academia, and industry partners to use when designing, developing, or testing IM/IT solutions.

Partners

• TATRC

6-12





Copper Antimicrobial Program

Description

The Copper Antimicrobial Program will determine the efficacy of copper touch surfaces to mitigate cross-contamination of infectious diseases. This project is conducting a multiyear study to determine the impact of copper touch surfaces on three organisms: methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant Enterococci, and *Acinetobacter baumannii*. This study includes multicenter clinical trials that focus on three different patient populations. The first trial was conducted in an intensive care unit at three hospital sites, the second clinical trial examined the effect of copper touch surfaces in cancer care units at two hospital sites, and the final trial examined whether the intervention also is efficacious for "routine" patients (i.e., those hospitalized on a gastrointestinal care unit [regular] medical ward at a single hospital site).

Fabrication of the copper components and the installation of the objects in the intensive care units were completed. Preliminary results are encouraging. The microbial burden associated with the copper surfaces was substantially lower than the non-copper counterparts in the rooms studied. Sixty-seven percent of the copper objects were found to have fewer than 100 cfu/100 cm² while an almost inverse relationship was observed for the non-copper objects where greater than 63 percent of the objects evaluated were found to have a microbial burden greater than 100 cfu/100 cm².

Partners

- TATRC
- Medical University of South Carolina
- Charleston Research Institute at the Ralph H. Johnson Veterans Affairs (VA) Medical Center
- Memorial Sloan-Kettering Cancer Center



Development of an Over-Ground, Pneumatically Actuated Body-Weight Support System

Description

Developed and patented, the ZeroG is a revolutionary over-ground gait training system that will enhance therapeutic outcomes in individuals following neurological injuries, such as stroke, spinal cord injury, and traumatic brain injury, as well as individuals with amputations of the lower extremities.

- TATRC
- ZeroG

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I.D. Badge Receiver

Protection Zone Transmitters

Handwashing Compliance Reminder and Documentation System

Description

To reduce the number of hospital-acquired infections by developing a "zone of protection" for the patient through a reminder system that emits a quiet beep to providers in the event they have not washed their hands prior to engagement with the patient.

The Center for Integration of Medicine and Innovative Technology's (CIMIT's) system can be incorporated into a clinician's or other caregiver's badge to remind them, in real time, if proper hand cleansing has not occurred according to room-specific protocols. The unique features in this system are expected to minimize disruption of clinical efficiency and to facilitate compliance in a nonthreatening way yet still allow data logging to document compliance for quality assurance purposes. The system will be smart enough to "know" when proper cleansing has or has not occurred and to do so in a context-sensitive manner. Thus, it will be flexible enough to conform to different care practices in different units, be subtle enough to not embarrass the clinician in front of the patient, and finally be inexpensive enough to be used by every clinician. It will be designed for quick and easy installation at the local unit level, yet will be totally scalable, and hence does not require expensive or invasive infrastructure modification or installation.

To date, a prototype device has been developed, and preliminary testing has proven successful. The project was selected for funding from the DoD and VA Joint Incentive Fund to demonstrate how this system will work in a ward of the Boston VA Hospital and in a ward at the U.S. Army Institute of Surgical Research.

Partners

- TATRC
- CIMIT

6-14



High-Altitude Platforms Mobile Robotic Telesurgery

Description

The use of an unmanned aerial vehicle (UAV) containing communication platforms has the capability to address communication deficiencies for successful telesurgery.

A surgeon from the University of Cincinnati operated the telerobotic surgical arm from the University of Washington by manipulating the master unit several miles from the simulated patient. Communication signals were provided to and from a master unit and a surgical arm by the Programmable Universal Manipulation Arm (PUMA) UAV on a wireless 802.11g system. The PUMA also was employed to establish a link between Simi Valley, California, and Seattle, Washington. This research demonstrated the potential of using UAVs for scalable wireless communication with reduced latency. Additional research is planned.

Partners

• TATRC

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Joslin Comprehensive Diabetes Management Project

Description

Providing state-of-the-art diabetes and endocrine medical care within a team setting, Joslin uses a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, centralizes patients in the care process, empowers patients to better manage their disease, can be performed in a costeffective manner, and maintains the high standard of care required for the appropriate management of diabetic patients.

The Comprehensive Diabetes Management Project is a web-based diabetes health care delivery system that provides connected care for patients and providers based on clinical guideline decision support and alerting. It was developed to provide an optimal design for needed comprehensive care. This is a patient-entered, care manager-driven, customizable program that interacts with the electronic medical record and other diverse clinical data sources, such as laboratory systems, to aggregate data and present them in a medically appropriate manner to increase the efficiency of the physician–patient encounter. The system is built on available technologies and tools, uses open source tools when appropriate, and has a Health Insurance Portability and Accountability Act-compliant, secure Internet patient portal component for patients to access their results, participate in educational modules, and observe trends in their own illnesses. In addition, the system facilitates more continuous communication between patients and their care teams. This diabetes-specific patient information system stratifies patients into risk categories that include systemic and comorbid risks as well as behavioral risks, tracks outcomes, and stimulates physicians to improve care.

Partners

TATRC

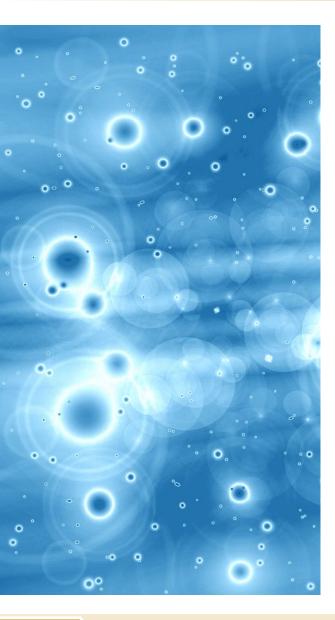


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Medical Surveillance Network

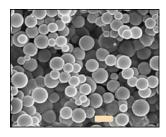
Description

The Medical Surveillance Network will facilitate data exchange and support all levels of care with an integrated joint medical information system thereby linking system communications and promoting situational awareness.

The Medical Communications for Combat Casualty Care (MC4)/Theater Medical Information Program (TMIP) is a defense medical surveillance system. The MC4/ TMIP conducts medical trend analyses based on data from multiple sources (i.e., environmental survey data; nuclear, biological, and chemical data; patient encounter data; and medical sensor data). This system links to worldwide surveillance resources to include the command and control system for Warfighter situational understanding updates.

Partners

- TATRC
- MC4
- TMIP



Microencapsulation and Vaccine Delivery

Description

The goal of this effort is to produce a more effective vaccine delivery method. More effective and easily stored vaccines are a critical tool in the military's defense against possible viral warfare or terrorist attacks. Investigators at Texas A&M University are engaged in promising research in microencapsulation of vaccines, entrapping them within micro- or nanoparticles, as a way to enhance their effectiveness. These encapsulated vaccines could have the capability to be shipped at room temperature and taken orally in a single dose.

TATRC is supporting the group's efforts to develop prototype controlled-release vaccines for animal testing with the ultimate goal of improving the delivery of a number of vital vaccines.

Partners

- TATRC
- Texas A&M University

6-16



Nanofabricated Bioartificial Kidney

Description

Many combat casualties result in substantial blood loss and shock along with traumatic organ injury. When service members with such injuries are successfully resuscitated and transported to medical treatment facilities (MTFs), acute renal failure can develop secondary to shock and traumatic injury. In Operation Iragi Freedom, in-hospital mortality from acute renal failure approaches 40 percent.

Advances in the treatment of renal failure will involve the tissue engineering of kidney nephronal units. For this technology to be generally applicable, devices must be compact, inexpensive, and self-monitoring. The advent of microelectromechanical systems technology has produced practical surface and bulk micromachining techniques with the ability to manufacture mechanical devices (pores, valves, gears, etc.) with feature sizes on the same order of magnitude as subcellular organelles in combination with on-chip electronics and sensors. This combination allows the development of microelectromechanical devices that can be engineered to interact intelligently with their environment.

The current project will result in the development of a bioartificial kidney consisting of synthetic membranes and living cells that can be deployed quickly to the bedside of a wounded service member to treat acute renal failure and improve the unacceptably high mortality rates associated with it.

- TATRC
- University of Michigan
- Cleveland Clinic Foundation
- Innovative BioTherapies, Inc.



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New Clinical Data Mart Prototype and Research Data Cube Initiatives

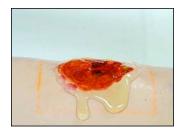
Description

The New Clinical Data Mart (CDM) Prototype and Research Data Cube will exploit cutting-edge data warehousing technologies to support improved clinical decision making, impacting the lives of 9.2 million military beneficiaries.

New CDM Prototype: This is a new data warehousing model that will receive feeds from the AHLTA Clinical Data Repository. The Clinical Data Repository contains detailed clinical encounter information that can be used to improve clinical decision making. Execution is through a Cooperative Research and Development Agreement (CRADA) that requires TATRC to collect metrics on the performance of the prototype and compare it to the existing CDM. The prototype will be designed to support queries by up to 50,000 users.

Research Data Cube: This project will build a set of de-identified clinical encounters and other data that can be used to support Small Business Innovation Research and congressional initiatives aimed at improving access to care, health care delivery, and population health. The ultimate concept is to provide Health Insurance Portability and Accountability Act-compliant, public-use files containing large, longitudinal patient data sets to support random clinical trials and observational data studies. These data also can support a variety of specialized studies, such as post-marketing surveillance of the safety of drugs or cohort studies involving chronic disease conditions. The Research Data Cube also will support true data mining to discover relationships in clinical data through pattern recognition and clustering techniques. These techniques can help researchers and health care personnel better understand the disease causation process and can influence patient interventions.

- CDM: Microsoft Corporation; Hewlett Packard, Inc.; Intel, Inc.; and Solid Quality Learning, Inc.
- Research Data Cube: Will leverage past work of KBSI, Inc.; Windber Research Institute; Emerging Health, Inc.; Montefiore Medical Center; and Lincoln Technologies. May be supported by a new CRADA with Oracle.



New Sprayable Liquid Wound Dressing

Description

Researchers are developing a New, Sprayable Liquid Wound Dressing technology that an injured Warrior could apply onehanded in a combat setting. The GelSpray™ Liquid Bandage forms a tough hydrogel in seconds that conforms directly to a wound without sticking to it when removed.

The GelSpray Liquid Bandage was approved by the U.S. Food and Drug Administration (FDA) for minor cuts and irritations in 2008. With TATRC's assistance, its developers are preparing for a human clinical study required to extend the technology to battlefield care. The technology shows promise for quicker wound healing with less care needed.

- TATRC
- Rutgers University



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Next-Generation Portable X-Ray System

Description

Engineers at GE Global Research, collaborating with research scientists at Emory University and TATRC, are working to incorporate the advanced diagnostic image quality of GE flat panel digital detector technology in portable x-ray systems. GE researchers, along with TATRC personnel, spent several days at Fort Lewis working with military stakeholders to carry out the critical "customer input" phase of this process. Military participants included active and retired military personnel, the majority of whom had deployed and recently returned from the theater of operations on the battlefield. Included in this group are radiologists, staff sergeants, specialists, and physicists. All were willing and eager to frame requirements for a forward-deployed portable x-ray system. The key high-level system characteristics gathered in this exercise were classified in seven major categories: availability, transportability, durability, reliability, portability, flexibility, and simplicity.

These high-level customer requirements were transformed into concrete specifications and further characterized by the GE team into specific subsystem capabilities. It was clear from the resulting detector subsystem requirements that the digital detector with its glass panel and sensitive hardware required a significant development effort. Modeling of mechanical packaging options gives a design that will meet the rugged requirements, the addition of the wireless and battery operation will free the detector of its tether, and a custom positioned design will provide the flexibility required for tube positioning and imaging applications without the weight and space necessary for systems found in brick and mortar facilities.

Currently a prototype is being developed to demonstrate the design presented to and accepted by the military stakeholders. Key areas of focus of prototype development are the detector ruggedization, wireless integration, and development of a system that can be easily transported to combat support hospitals in theater and survive the environment there.

- TATRC
- USAMMA
- Emory University
- GE Global Research



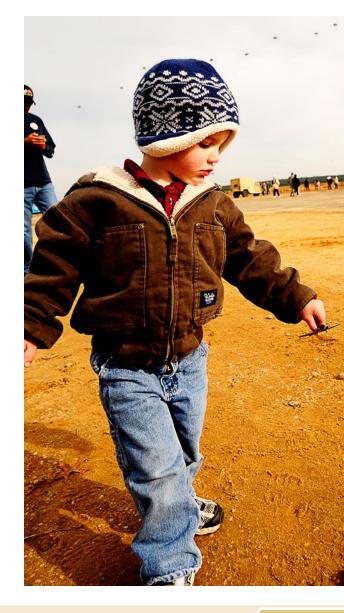
Novel, Noninvasive, Patient-Specific Electrographic Seizure Warning System

Description

CIMIT is building and evaluating a noninvasive, patient-specific system that accurately detects electrographic seizure onset sufficiently in advance of the onset of clinical symptoms to warn the patient of an impending seizure or to automatically trigger potentially abortive therapy.

This detection system is capable of learning to recognize seizure onset patterns with high sensitivity and specificity. CIMIT aims to integrate this automated seizure detection system with an audible alarm and the Vagus Nerve Stimulatory (VNS) to trigger acute VNS stimulation as an abortive therapy upon seizure detection. The audible alarm could potentially ameliorate the consequences of seizures by giving patients and caregivers time to seek a safe position or to administer an acute pharmacological therapy. Results to date include the development and integration of the system with VNS as well as the successful demonstration in five patients in a clinical setting (VA hospital).

- TATRC
- CIMIT



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OASIS

Description

OASIS provides an IM/IT environment for the developmental test and evaluation of patient health care hardware and software architectures thus replicating the flow of information from levels I–IV. The platform also serves to integrate emerging and innovative technologies that have yet to interface with MC4 equipment to ensure interoperability.

OASIS, formerly known as the Forward Deployable Digital Medical Treatment Facility, was developed as a research, development, and testing platform. It provides a rapidly deployable MTF used for showcasing, evaluating, and training advanced medical technologies and information systems developed through collaborations with government, industry, and academia. OASIS also emphasizes modular configurations composed of lightweight and rugged equipment packages engineered to reduce weight, cube, and airframe requirements while providing essential care in theater and reach-back capabilities from any deployed location. Successful products that have transitioned through this platform include the BMIST-J (Battlefield Medical Information System Tactical-Joint) and the Alaska Structure shelter system.

Follow-on actions include the integration of medical programs of record into the architecture, such as the Joint Medical Workstation, Theater Medical Database System, and the Joint Patient Tracking System, and the formulation of a Joint Developmental Test Plan along with the associated program offices and service representatives outlining the acceleration of the test, evaluation, and acquisition of emerging technologies. To determine form, fit, and functionality, OASIS may be deployed in support of the Army Medical Department Board and its operational test and evaluation functions, the Stryker Brigade National Training Center rotations, the Uniformed Services University of the Health Sciences, Bushmaster field training exercise, or to support the Regional Training Site-Medical.

Partners

TATRC



Periscopic Spine: Georgetown University

Description

Georgetown University's Periscopic Spine project is aimed at improving the state of the art of imageguided and minimally invasive spine procedures by developing new clinical techniques along with the computer-based hardware and software needed for their use. The focus of the project is the development of new techniques for precision, minimally invasive procedures. While techniques for the spine will continue to be investigated, the focus has broadened into other anatomical regimes, in particular thoraco-abdominal procedures. On the scientific side, the characterization of respiratory motion and compensation for this motion has become one of the focal points of the work, including the use of electromagnetic tracking for this purpose. New initiatives in precision radiosurgery have been developed with Radiation Medicine, and there are two new collaborations, one with the University of Maryland in exoskeleton robotics and another with the Department of Physics at Georgetown University in nanotechnology. A new phase of the project, to develop an integrated interventional suite of the 21st century based on rotational angiography and electromagnetic tracking, is anticipated.

Partners

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Proton Beam Therapy – Loma Linda University Medical Center

Description

The goal is to develop the next generation of technologies that will ensure the availability of high-quality, noninvasive cancer therapy. The Loma Linda University Medical Center is the country's first proton treatment center. The history of this center dates back as far as the 1960s; Dr. James Slater first conceived of a plan to develop the core technologies needed for such a clinic. The facility went online in the early 1990s. To revolutionize the current standard of care for proton beam therapy, Dr. Slater and his team partnered with TATRC to manage the resources needed to develop innovations in active beam scanning technologies. Previous efforts funded by TATRC completed the accelerator and beam transport system's enhanced control system. This provided the foundation for delivering active beam scanning to the treatment rooms, increased dose monitoring sampling and accelerator cycle delivery, and decreased fluence variation. These are critical factors for targeting irregularly shaped volumes common in cancers and other diseases.

Partners

- TATRC
- Loma Linda University Medical Center



Proton Beam Therapy – The Hospital of the University of Pennsylvania

Description

The goal is to develop the next generation of technologies that will ensure the availability of high-quality, noninvasive cancer therapy. The Hospital of the University of Pennsylvania has developed a comprehensive program to develop tools that will precisely modulate proton beams, control patient movement, monitor treatment in real time, and develop advances in three-dimensional treatment planning for proton beam therapy. The Principal Investigator, Dr. James McDonough, has engaged experts at the Walter Reed Army Medical Center for additional expertise in radiation oncology and treatment planning.

- TATRC
- Walter Reed Army Medical Center
- Hospital of the University of Pennsylvania



Rugged Mobile Logistics System

Description

The Rugged Mobile Logistics System (RMLS) consists of a number of intelligent, rugged, portable hardware items, integrated by VerdaSee, to provide critical information at the local, regional, and global levels. The hardware components are a mixture of commercial off-the-shelf (COTS) and COTS products that have been modified and enhanced by VerdaSee to meet the project needs, and some of the hardware/software components are custom designed by VerdaSee specifically for the RMLS. RMLS nodes can support large and small, fixed and mobile warehouses, depots, and terminals.

The RMLS is an economical, innovative, and unique combination of COTS hardware and software elements. An example of the uniqueness is the ability to track supplies carried within containers down to a single item, such as a pill bottle. The GPS-enabled system provides near real-time data and information with graphic displays linked to standard enterprise systems to provide local, regional, and global visibility of assets at a granularity and in a presentation model needed by specific users accessing the system.

This design protects the end-user community from the issue of obsolescence that otherwise burdens the traditional approach to logistics management that is software or product driven.

- TATRC
- VerdaSee



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Troop Recruitment Improvement

Description

The goal of Troop Recruitment Improvement (TRIM) is to provide definitive information on the factors that underlie the development of obesity in young persons. This knowledge will help ensure the availability of a large pool of youth who are fit and ready for military service. The proposed TRIM design is using state-of-the-art measures to characterize the range of factors influencing obesity in children and adolescents from early childhood to recruitment age in a comprehensive and coordinated manner. This project is to pilot test those measures and methods.

Partners

- TATRC
- Clemson University
- Medical University of South Carolina
- University of Iowa
- University of South Carolina (including South Carolina State University)
- The Cooper Institute
- Pennington Biomedical Research Center
- South Carolina Research Authority

6-26



Wear-and-Forget Physiological Sensing System for Combat Casualty Care

Description

Physiological monitoring of individual Warfighters would provide the Army with an unprecedented capability to assess the health state of Warfighters and rapidly identify and respond to critical cases. A uniquely qualified team from Foster-Miller and Malden Mills Industries, in continuing collaboration with USAMRMC and TATRC, proposes to apply electronic textile technologies to develop robust and reliable wear-and-forget physiological sensing platforms. These intelligent textile technologies would allow sensing systems to be manufactured as minimally constrictive garments. Furthermore, these systems must tolerate physical activity, minimize motion artifacts, and generate clinical quality data.

The ultimate objective of the program is a wearable physiological sensor platform that is comfortable enough to ensure the compliance of a service member while producing and reporting highly reliable vital sign data, including heart rate, respiration rate, and skin temperature, as well as the wearer's activity level and body posture. These data will then be tied to algorithms that generate valuable information about the health status of a Warfighter to either a medic or a commander. A medic would use this information to assess and triage an injured person. Such information could allow for immediate notification of an injury or warn a medic not to risk his or her own life because the person is already dead. A commander who has knowledge about the physical state of multiple Warfighters or squads could choose those most fit for a mission.

- TATRC
- Combat Casualty Care Research Program
- Foster-Miller
- Malden Mills Industries

Combat Casualty Operational

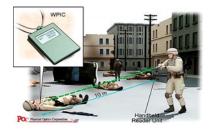
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Wireless Electronic Information Carrier/Personal Information Carrier

Description

The Electronic Information Carrier (EIC) is integral to "patient-centered" medical data flow on the battlefield. It is intended for issue to each service member prior to deployment and is preloaded with each individual's medical history, master problem list, immunizations, etc. It will then serve as a personal medical data storage device for any care provided to the patient from point of injury to CONUS (continental United States)-based medical centers and beyond.

The EIC is a wireless data storage device the size of a dog tag that is capable of storing up to 4 gigabytes of data; however, the real power of the EIC is its ability to securely and wirelessly read and write data within a range of 10 meters of a medical device such as the BMIST and the Composite Health Care System II-T. It also has a universal physical interface that ensures compatibility with any commercial or government off-the-shelf IT products and can be used when wireless communications are not available.

The Personal Information Carrier is an earlier nonwireless version with storage capacities up to 1 gigabyte. Like the EIC, it is a rugged, low-power consumption, flash memory device that is hardware and operating system independent.

The EIC allows individual medical data to be accessed and updated by medical personnel when realtime connectivity to a database is unavailable. The EIC was chosen as one of the Army's 10 Greatest Inventions for 2004.

Partners

• TATRC

6-28



Alliance for NanoHealth

Description

The Alliance for NanoHealth (ANH) is collectively bridging the disciplines to develop nanotechnologybased solutions to unresolved problems in medicine. The principal goal is to provide new clinical approaches to saving lives through better diagnosis, treatment, and prevention.

The ANH is a highly interdisciplinary consortium of several institutions. It was established to advance nanotechnology for a broad range of applications, including cancer therapy and drug delivery. The ANH is currently conducting research for imaging and hyperthermia treatment of inflamed endo-thelium, nanotechnology applications in vascular grafts, and targeted delivery of nanoparticles for antitumor therapies.

In addition, the ANH is supporting 10 seed projects to evaluate application of nanotechnology for clinical proteomics, molecular imaging of neurological diseases, targeted RNA therapies for drug-resistant cancers including lung cancer, studying biological dynamics of solid cancers, prosthetic sensors for improved rehabilitation, central nervous system therapeutics and axon regenerative scaffolds, threedimensional sensors for neural recording, and multiplexing magnetic resonance imaging diagnostics.

- TATRC
- University of Houston



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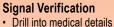
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Process of Pharmacovigilance Formulary: Safe, Effective, and Favorable Risk/Benefit Ratio

Signal Generation

- Clinical Trials: Premarket
- Passive Surveillance: AERS (FDA) and needed military reporting systems
- Active Surveillance: Pharmacovigilance Defense Application System
- Directed Surveillance: Monitor signal and risk/benefit ratio



- Develop case definitions
- for case series

 Comparative cohort

 analysis
- · Verify among database



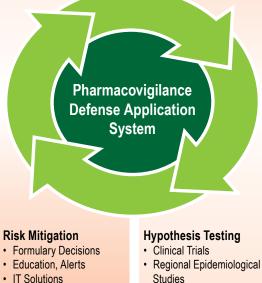


A Standards-Based Tool for Pharmacovigilance

The overall purpose of the U.S. Army Medical Department-FDA collaboration is to evaluate the safety of drugs. The focus is research into and development of enhancements to existing software in support of the FDA Sentinel Initiative using data derived from DoD medical records and medical insurance claims related to its population of active service personnel, dependents, and retirees, as well as the support of supplementary staff at the Office of the Surgeon General (OTSG) Pharmacovigilance Center (PVC) to carry out medical product safety research of interest to the collaborating parties. Initially the PVC succeeded in enhancing its signal detection software and in deploying that software in a server facility to support interactive use by staff at the PVC.

There remain several challenges in the evolution of the signal detection facility to full production status. The complete set of medical data resources useful in signal detection must be assembled from multiple systems within the DoD, and data elements outside the core data available from the Medical Data Repository (MDR) are still being assembled. Also, it has been difficult to provide rapid response times for some analysis tasks generated by the PVC on the large health care database. Further work in these areas, as well as work to improve the ease of use of the software, is continuing in the remainder of the year. Last, there is not enough flexibility in the software to answer the kinds of questions required for rapid analysis of signals.

The PVC staff also found problems with the military's data dictionaries. They noted that their pharmacy data transaction system had inaccurate dispense dates that linked to the claims processing and not the dispensing of the medication. The PVC took these findings and requested the data warehouse (MDR) data dictionary be updated, and it requested the requirements group for the new electronic medical record pull data from the "DRX key" from the Composite Health Care System for all dispensing of drugs, both new and refills. In addition, the PVC requested that the ALLERGY section be linked with the Computerized Physician Order Entry (CPOE) and that the CPOE document



- Policies
- Guidelines

Studies

MHS Epidemiology



Center for Research on Integrative Medicine in the Military

Description

The objective of the Center for Research on Integrative Medicine in the Military (CRIMM) is to identify an integrative biopsychosocial program for the management of stress focused on skills training of combat troops and their families in four key areas: physical, social, mental, and spiritual. The specific aims of the CRIMM are to gather best evidence on the most reputable and scientifically advanced programs of biopsychosocial preset and reset training and rigorously assess the most promising ones for use in military populations; synthesize the evidence for the best programs and make a recommendation for program configuration and implementation; assess the needs of combat-exposed military personnel and their families at key military training sites and readiness of these environments to participate in such programs; develop a valid and reliable toolkit for assessing such programs; launch a pilot program incorporating the biopsychosocial model within an appropriate training and education environment; and evaluate the cost, timing, and outcomes of the training to provide military decision makers with the evidence to determine whether expansion of such training will effectively support the mind-body-spirit of our nation's Warriors.

Partners

- TATRC
- Samueli Institute

reasons why drugs are stopped (e.g., intolerant, ineffective, allergy, complete treatment, or patient reason). In addition, the PVC documented the need for establishing an adverse drug event reporting tool and development of an enterprise database.

In several cases, the scientific research performed by the PVC staff helped identify gaps in the available data and software resources and led to improvements in these resources.

An extension of the collaboration for fiscal year 2010 is presently under discussion between the FDA and DoD.

- TATRC
- OTSG-MEDOM
- FDA Center for Drug Evaluation and Research

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Clinical Breast Care Project at Walter Reed Army Medical Center

Description

This multidisciplinary model integrates prevention, screening, diagnosis, treatment, and continuing care; however, the project is further unique in the incorporation of advances in risk reduction, informatics, tissue banking, and research.

The goal of this project is to decrease the morbidity and mortality of breast cancer among American women, develop a comprehensive breast care center/system to enable health care providers with a multidisciplinary team approach that works toward the common goal, and empowering women with breast cancer and other breast disorders with the decision-making tools and environment to enhance quality of life and to meet psychosocial needs of the patients and their families.

Partners

• TATRC

6 - 32

- Walter Reed Army Medical Center
- Windber Medical Center



Comfortable Socket

Description

This research effort examines both active and passive methods of decreasing discomfort/increasing comfort, eliminating intra-socket moisture, and maintaining intra-socket vacuum. Amputees may use a variety of ways to wrap their residual limb within the socket to make themselves more comfortable. For a suction socket, the most common method is to wrap the residual limb in one or several socks. The limb is then compressed with a gel liner that provides cushioning between the limb and the hard-shell socket and enhances suction between the prosthesis and the residual limb. Once the limb is inside the liner and socket, a polymeric gel sleeve is placed over the socket, extending up onto the limb to secure the vacuum that holds the socket onto the limb. This configuration, even during low-intensity activities, can cause sweating. The sweating will lead to slipping between residual limb and the socket/sleeve. The increased movement in the socket could lead to rashes and blistering as well as loss of vacuum integrity.

There are a variety of ways to make the socket more comfortable. Improved gel liners and more padding within the socket are simple solutions. TATRC is working with several organizations to achieve this goal. Many of the organizations have novel ideas that could completely change the interface between a prosthetic device and the residual limb.

- TATRC
- University of Wisconsin, College of Health Sciences
- Infoscitex Corporation of Waltham, Massachusetts
- Ohio Willow Wood Company
- Physical Optics Corporation in Torrance, California
- Sandia National Laboratories



Digital Emergency Medical Services

Description

Telementoring and telemedicine capabilities will allow earlier interventions in recording patient data and give medics access to medical information. The digital emergency medical services (EMS) system, a component of the Disaster Relief and Emergency Medical Services project, integrates diagnostic medical equipment, medical informatics software systems, and communications systems. The digital EMS system provides a common user interface, integrated medical equipment, and remote video cameras. A unique and vital aspect is the system's capability to provide real-time patient information, such as vital signs, to a remote physician and, in turn, communicate instructions back to personnel on-site. This also allows medics to refer to treatment protocols or refresher training for any situation.

Partners

• TATRC



Facilitating Cell Transplantation Research

Description

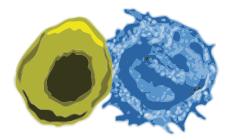
This is a unique transplantation research project that investigates the role of facilitating cells in promoting immune tolerance. This research suggests that modulation of the immune response is possible and can be used to overcome problems of rejection and graft versus host disease that are common in complex tissue transplantations. Studies in patients with sickle cell disease have established that facilitating cell therapy can induce chimerism in these patients. The sickle cell trait is treated using donor bone marrow, which is tolerated by the recipient patient, dramatically treating the sickle cell disease.

The following figure illustrates the conditions and disorders that could benefit or be cured by bone marrow/facilitating cell transplants derived through this research.

Partners

- TATRC
- University of Louisville

Conditions That Will Benefit from or Be Cured by a Bone Marrow/Facilitating Cell Transplant



Autoimmunity • Diabetes • Multiple Sclerosis • Rheumatoid Arthritis • Crohn's Colitis	Rare Childhood Disorders • ADA Deficiency • Aplastic Anemia • SCID		
LupusPsoriasis	Regenerative Repair		
HemoglobinopathiesSickle Cell DiseaseThalassemia	 Macular Degeneration Myocardial Infarction Islet Regeneration 		
Leukemia	Transplants Heart 		
Metabolic Disorders Chronic Granulomatous Hunters Syndrome Leukodystrophy 	 Heart Kidney Liver Pancreatic Islets Hand/Face 		

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Hibernation Genomics: Mechanisms for Metabolic Suppression and Neural Protection

Description

The overall goal of this research program is to understand the fundamental molecular and biological adaptations that create the animals' (i.e., Arctic ground squirrel and black bear) unique capabilities. Understanding such mechanisms can identify unique solutions to the difficult medical problems that are associated with battlefield trauma, both acute survival following traumatic hemorrhage and improved recovery/rehabilitation.

Through basic studies on hibernating mammals, this research seeks novel therapies for use in the treatment of battlefield injuries in field-forward positions where Warfighters would benefit from stabilization before transport to advanced medical facilities. The proposed work will develop natural animal model systems of hibernators as genetic and physiological resources for use in determining the molecular basis of hibernation. The intent is to identify the biochemical pathways that are altered to regulate preparation for, entry into, and recovery from hibernation and to provide candidate pharmaceutical products that can induce and reverse similar states in humans. The results of these studies could translate to novel approaches to improve recovery from traumatic injury to muscle and bone.

Partners

- TATRC
- University of Alaska Fairbanks

6-34



Military Foot

Description

To return to the field on active duty or to an active civilian life, service members need a prosthetic leg that is able to perform during rigorous activities and under extreme conditions, such as swimming, climbing, or running on uneven, wet, or sandy terrain.

The ideal "military foot" is not a simple problem as every patient and his/her circumstances are unique and require what is essentially a custom solution. Lower limb amputations are generally categorized as transfemoral (above the knee) or transtibial (below the knee). Other levels of amputation include ankle, knee, and hip disarticulations. There are a variety of solutions that incorporate passive or active knee and ankle joints that can be controlled by an onboard computer or system of myoelectric devices.

TATRC is fostering a broad range of lower extremity-related projects to support service members as they strive to achieve their highest possible quality of life.

- TATRC
- Arizona State University Human Machine Integration Laboratory
- The Massachusetts Institute of Technology Media Laboratory
- KCF Technologies of State College, Pennsylvania
- Otto Bock
- The Rehabilitation Institute of Chicago



or

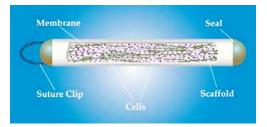
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National Eye Evaluation Research Network for Clinical Trials in Retinal Degenerative Diseases by the National Neurovision Research Institute

Description

The focus of this research effort is to establish a network of five clinical treatment and evaluation centers to study retinal degenerative diseases. Retinal degenerative diseases are a family of inherited pathologies with the ultimate consequence of photoreceptor apoptosis and severe visual impairment usually ending in blindness. The National Eye Evaluation Research Network advances the science of therapeutic and preventive interventions for inherited orphan retinal degenerative diseases and dry age-related macular degeneration through the conduct of clinical trials.

Neurotech's encapsulated cell technology uniquely enables the controlled, continuous delivery of biologics directly to the back of the eye, overcoming a major obstacle in the treatment of retinal disease.

Partners

- TATRC
- University of California, San Diego
- University of Medicine and Dentistry of New Jersey
- University of Utah Moran Eye Center
- Children's Hospital of Philadelphia
- Wilmer Eye Institute at Johns Hopkins University

6-36



National Functional Genomics Center

Description

The status of oncology care in the United States can perhaps best be described as "experimental." Even though there is a wide range of accuracy in the diagnosis of many cancers, reliability in the prediction of prognosis for patients is seriously lacking, resulting in variability of treatments rendered and subjecting patients to tremendous stress during the course of their disease, which can complicate treatment. The National Functional Genomics Center (NFGC) was established to address these issues and to provide cancer patients with accurate diagnosis, prognosis, and treatment.

The NFGC's research focuses on three interconnected areas: microarray, proteomics, and drug discovery. These areas of research are tied together with bioinformatics and support by additional technologies and are used to discover molecular signatures for cancer, identify cancer markers for early detection and unique therapeutic targets, discover putative new drug therapy targets and develop innovative treatments, and ensure each of these areas of research provides solutions to enable "personalized" medicine.

The NFGC also planned and designed new and expanded infrastructure at the Moffitt Cancer Center subsequently to pave the way for state-of-the-art genomics research. Investment in high-quality shared resources staffed with trained technical personnel has been shown to minimize the costs of equipment outlay for individual researchers and maximizes efficiency and reproducibility of research. Early funding efforts also helped to create NFGC's External Advisory Board. This board consists of top, internationally recognized experts in various disciplines of genomics and is designed to oversee the activities of the NFGC and provide recommendations for its future growth.

Once the infrastructure was in place, the NFGC began to establish and maintain collaborations with other centers that have directly produced beneficial research to the military and to homeland security. Today, the collaborations through the NFGC keep expanding, and the NFGC continues its pursuit to study and validate molecular targets of cancer that predict cancer risk, diagnosis, prognosis, and response to treatment.

- TATRC
- Moffitt Cancer Center
- NFGC

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Personal Area Network for Remote Physiological Monitoring

Description

Elintrix has been contracted to develop an integrated system that will capture, analyze, communicate, display, and archive geo-location and physiologic sensor data. The program consists of two projects to include Soldier-worn elements of the Spartan network (SPARNET), which includes a squad area network radio for Soldier-to-Soldier data communication, and a personal area network (known as BIONET) radio for on-body communication. The BIONET radio is a modifiable, integrated, inductively linked, minimalist, modular design with processing capability for use with sensor systems like the Warfighter Physiological Status Monitor. BIONET supports the transmission of data via a modulated magnetic field. Detection of the resulting short-range, bidirectional communications by hostile forces is made problematic due to the frequency and rapid attenuation of the magnetic field. SPARNET enables continuous monitoring of a Warfighter's geo-location and health status in the field to improve force health protection.

Partners

- TATRC
- USARIEM
- Elintrix

6-38



Robotic Medic Assistant, Patient Evacuator

Description

The Robotic Medic Assistant is to be used by combat medics and Warfighter-buddy first responders to assist in combat casualty location, assessment, treatment, extraction, and evacuation.

This robotic device can be used in urban terrain and in hazardous or contaminated environments. The device supports Future Combat Systems concepts of mobility, agility, survivability, and sustainment. A vehicle crew can recover a casualty, either manually or mechanically, without the need to dismount and without driving to the casualty.

This robotic patient recovery technology performs multiple missions in hazardous areas thereby reducing risk to first responders. The greatest benefit of this technology is that it allows providers to focus on patients.

Partners

TATRC



Robotic Telepresence for Subspecialty Care

Description

This research effort will focus on developing a software application for remote wireless access in real time to a comprehensive set of medical data. A wireless, mobile pocket device will allow access to all data. including viewing radiographic imaging connected to the PACS (Picture Archiving and Communications System). The entire medical electronic record can be accessed remotely in real time. New high-speed cell phone networks are employed. This technology will be fused with the InTouch robot for virtual physician presence at the bedside, in the emergency room, or on the battlefield. It will allow for remote expert consultation with the ability to view the patient, interview the patient, and assess a complete set of medical data in real time.

Partners

- TATRC
- Center for Advanced Surgical and Interventional Technology



Serpentine Robotic Manipulator Arm

Description

The Serpentine Robotic Manipulator Arm could be used to perform more complex treatment tasks or could be attached to a small robot for conducting triage during mass casualty situations.

This project is intended to adapt Carnegie Mellon University's serpentine manipulator arm and integrate it with the life support for trauma and transport (LSTAT) system as a remotely controlled casualty examination device that enables medics or surgeons to perform tele-examinations on a patient before or during evacuation. A set of noninvasive physiological monitors, developed by TeleMedic of Canada, has been integrated so that they can be robotically placed by remotely manipulating the serpentine arm and a movable gantry device on the LSTAT.

- TATRC
- Carnegie Mellon University



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Simulation-Based Open Surgery Training System

Description

The goal is to improve training so surgeons can obtain and maintain proficiency in the performance of open surgical procedures. A personal computer-based Simulation of Open Surgery Training System (SOSTS) is a developmental platform to obtain surgical metrics (of devices, instruments, and their use in procedures of surgical technique) and to develop and evaluate new open surgical procedures and advanced medical devices. TATRC envisions an open architecture surgical simulation platform that allows the rendering and use of virtual versions of actual instruments used in trauma surgery. A final goal is to enable novel surgical instruments to be "scanned" and "virtualized" or entered into the simulator before they reach the physical prototype stage and then are evaluated. The SOSTS has potential to reduce surgical errors, improve patient safety, reduce costs, improve access to care in fixed medical treatment facilities, and improve medical educational training programs. This technology also will allow the assessment of novel surgical instruments and techniques in silico, in turn limiting the use of animals and reducing development costs. Two examples are the Fractured Femur Simulator and Compartment Syndrome Simulation System.

Partners

- TATRC
- Energid Technologies

6-40



Soldier Health Promotion to Examine and Reduce Health Disparities

Description

This project examines the root causes of military attrition and many of the factors that contribute to Soldier health issues (e.g., diet, military environment, physical activity patterns, physical readiness, stressors, and anxiety) both pre- and post-deployment. Other key focuses are post-traumatic stress disorder (PTSD) and mental health.

The efforts will provide a framework for understanding the historical and cultural backgrounds of Soldiers and how certain factors (e.g., poverty, educational history, inequities in health care access, diet, and mental health) contribute to health disparities.

Project 1 is focused on obesity and nutrition issues. This will include evaluation of the physical training program, assessment of whether obesity demotivates Soldiers, and drill sergeant knowledge of nutrition/obesity issues. A primary interest will be the "life course perspective" (impact of Soldier entrance into the military environment) to better understand the transition.

Project 2 will assess baseline data for injury rates and examine the training regimen (load and progression) during basic combat training with the recommendation of Fort Jackson personnel. The Certified Athletic Trainer-Forward program collaborates with on-site, certified athletic trainers to analyze data related to lost hours from training, Troop Medical Center visits, heat-related injuries, and Army Physical Fitness Test scores.

Project 3 examines methods for screening recruits for mental health problems (e.g., PTSD) at point of intake, the stigma associated with seeking mental health services, the career paths of Soldiers, the small number of mental health referrals, and the impact of sleep deprivation on mental health (also a factor in Soldier injury).

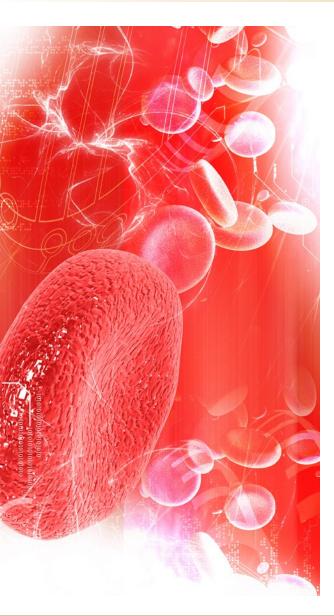
- TATRC
- The University of South Carolina Institute for Partnerships to Eliminate Health Disparities

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Speech-Capable Personal Digital Assistant

Description

The Speech-Capable PDA will allow military health care providers to enter data hands-free, allowing focus to be on the patient.

The PDA is equipped with a directional-array miniature microphone system and speech recognition software. Health care providers can perform hands-on medical and surgical procedures at all echelons of care, ranging from combat medic first responders to physicians in tertiary care medical centers.

Partners

• TATRC



Treatment of Peripheral Vascular Disease by Adipose-Derived Stromal Cell Injection

Description

The focus of this research is to advance regenerative medicine to enhance recovery after battlefield injuries.

This project is investigating whether adiposederived stromal cells can be delivered directly to ischemic tissue by intramuscular injection into ischemic tissues or through in situ vasculature and to increase distal circulation and relieve the symptoms of peripheral vascular disease. Tissue Genesis, Inc. has successfully developed a portable, automated cell separation system and patented process that isolates and sorts human fat tissue into therapeutic cells.

Partners

- TATRC
- Tissue Genesis, Inc.

6-42



Virtual Humans

Description

The program SimCoach proposes to build on advances in "human-centered" computing to create a more personal, reassuring, and ultimately more effective interface for access and dissemination of medically relevant information. The Institute for Creative Technologies is developing an intelligent, interactive program called "SimCoach" to help Warfighters and their families initiate the medical treatment process and to learn about resources for psychological health and traumatic brain injury.

Through SimCoach, Warfighters, spouses, or other family members will be able to initiate a dialogue about their medical concerns with an interactive Virtual Human. This intelligent graphical character will use speech, gesture, and emotion to introduce the capabilities of the system, solicit basic anonymous background questions about the user's history and medical concerns, and direct them to appropriate medical information and medical professionals.

The user will be given access to a variety of general relevant information on psychology, neurology, rehabilitation, the military health care system, and also to other service members. They can also be directed to experts on specific areas such as stress, brain injury, marriage counseling, suicide, rehabilitation, reintegration, and other relevant specialties.

SimCoach is not conceived to deliver treatment or diagnosis or to replace human providers and experts or seen as a replacement for existing services. Instead, SimCoach will aim to start the process of engaging Warfighters and/or their families to become aware of and to seek out treatment programs, to give advice and encouragement, and act as a supplement that will allow individuals who may otherwise be initially uncomfortable talking to a "live" person to initiate treatment.

Partners

- TATRC
- Institute for Creative Technologies, University of Southern California



Virtual Retinal Laser Display

Description

An unobstructed full field of vision of the computer screen for health care providers while performing hands-on medical and surgical procedures is vital for patient treatment.

The Virtual Retinal Laser Display technology provides head-, helmet-, headgear-, or eyeglasses-mounted, hands-free, daylight readable computer color display by directing a laser beam containing a computer image directly onto the retina of the eye. This projects vital medical information on a health care provider's retina while treating a patient.

• TATRC

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Virtual Therapies for Psychological Trauma: Virtual Iraq

Description

The rapidly growing field of clinical virtual reality holds promise for innovative treatments for PTSD. Exposure therapy is a well-researched, evidence-based treatment for PTSD that involves patients being gradually re-exposed to relevant traumatic events in a progressive and repetitive manner directed by a clinician. This often involves re-imagining the trauma through guided visualizations with a therapist. Exposure therapy helps to slowly desensitize the patient to the strong emotional and physiological responses triggered by memories of traumatic events and helps the patient to process these memories in an effort to increase adaptive coping. Using virtual reality exposure may enhance treatment by providing a more controlled method for prompting this re-imagining and may circumvent the patient's natural (albeit counterproductive) tendencies to avoid painful memories during treatment sessions.

This project developed a series of virtual Iraq environments to be used for exposure therapy with Iraq combat veterans with PTSD. The virtual environment was initially designed from an Xbox game and U.S. Army-funded combat simulation trainer. Virtual Iraq consists of multiple combat environments (i.e., city and desert road) that were created to simulate common combat experiences in Iraq, including Humvee patrols, improvised explosive devices, and ground combat. Patients can use either a game controller or replica M4 to navigate the game environment. The virtual reality component uses a virtual reality helmet, three-dimensional audio, and vibrotactile and olfactory stimuli with physiological monitoring. The therapist is able to modify and change the experience in real time. The treatment consists of two weekly, 90–120-minute sessions over 5 weeks and is paced by the patient following parameters of general exposure therapy and includes outside education and homework around PTSD and exposure therapy. There are a number of research and clinical projects under way within the DoD utilizing Virtual Iraq. Preliminary analysis of the first 20 completers has shown significant reduction in pre- and post-PTSD symptoms with high levels of patient and provider acceptance and satisfaction.

Partners

TATRC

6-44

- U.S. Army Research, Development, and Engineering Command
- Defense Centers of Excellence
- Office of Naval Research
- U.S. Air Force
- Institute of Creative Technologies, University of Southern California



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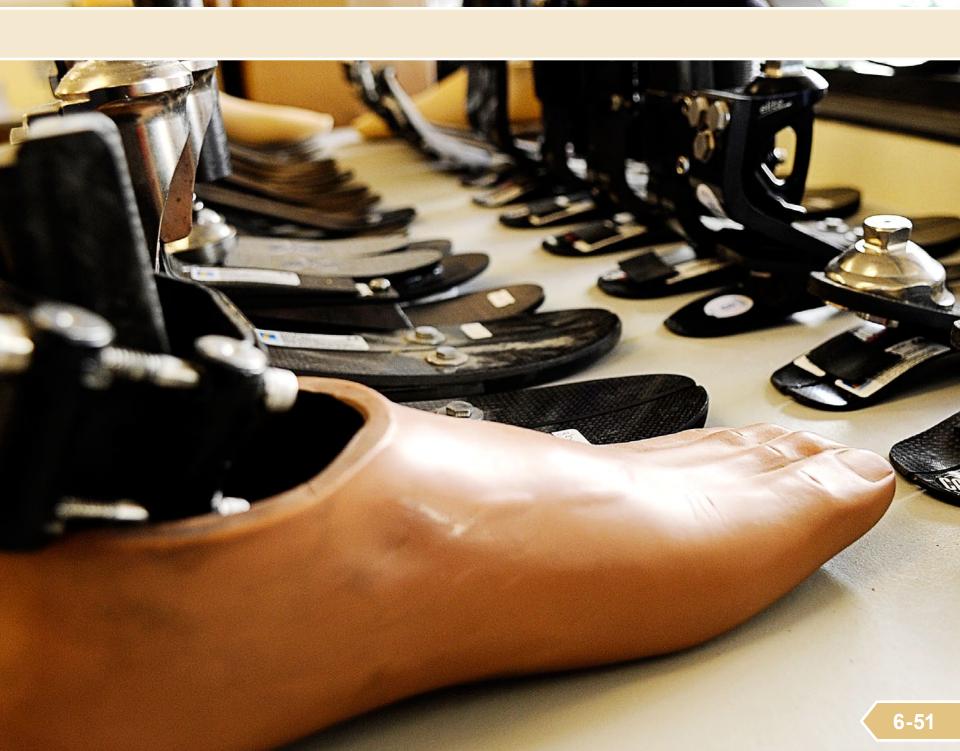
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OVERVIEW

Medical Logistics

The U.S. Army Medical Research and Materiel Command's (USAMRMC's) responsibilities in the medical materiel arena include medical materiel acquisition and logistics functions, strategic medical logistics readiness, and critical health care programs. The U.S. Army Medical Materiel Agency (USAMMA) and the U.S. Army Medical Materiel Center, Europe (USAMMCE), the Command's logistics organizations, provide direction and resources, acquire and manage assets, provide capabilities and distribute materiel, and support the national military strategy of power projection. Key programs include the acquisition, storage, distribution, and transfer of prepositioned stocks located ashore and afloat, medical chemical defense packages, short shelf-life pharmaceuticals, and other materiel. Integral to this support are partnerships with defense organizations and inventory-management contracts with industry. The Command also supports deployable medical logistics support teams.

Both USAMMA and USAMMCE explore and employ innovative methods to bring best business practices and new information technologies to the medical logistics system. Such focused logistics initiatives provide more efficient and accurate ways to deliver and manage precision packages and biomedical maintenance capabilities.





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Apheresis System

Description

The treatment of hemorrhage in battlefield casualties requires the use of large amounts of blood products for transfusion to replace lost blood and to enable successful surgery. Delivery of adequate supplies of platelets, the crucial cellular component for the control of bleeding, poses significant logistical challenges because of their short shelf life, need for constant agitation, and delays that can occur during shipping, leading to a decrease in their viability and functionality.

The Haemonetics MCS 9000 mobile collection system is a multicomponent platform providing a complete portfolio of protocols for the collection of platelets, red cells, plasma, and combinations of these. Its versatility enables blood collection organizations throughout the world to implement a complete and economical solution for the automation of blood donation operations. For forward-deployed locations, the system provides the ability to collect platelets for immediate use or to store them until needed. The system addresses the traditional drawbacks of platelet therapy by automating the platelet collection process, which permits the collection of greater quantities of platelets from a single donor, and enabling on-site platelet collection, which eliminates the need for platelet shipping.

Partners

Haemonetics



Cold Chain Management

Description

Cold Chain Management is a system that is used to distribute medical supplies to firstlevel users. It protects service members by managing and coordinating the distribution of temperature-sensitive medical products in critically short supply from manufacturers to first-level users. Supplies are shipped in validated containers, which include temperaturemonitoring devices, and are moved rapidly to users. Cold Chain Management is ongoing.

Partners

USAMMA



Equipment Maintenance and Repair

Description

The Medical Maintenance Management Directorate (M3D) has principal responsibility for and serves as the Army's lead for Class VIII medical equipment maintenance. M3D manages the Army Medical Department's National Maintenance Program, operates a National Maintenance Sustainment Program for medical materiel, and provides depot-level medical maintenance capability. It provides maintenance policy, initiatives, guidance, and assistance in the development, acquisition, and sustainment of medical equipment. MD3 also performs depot-level maintenance, major overhaul/maintenance, and sustainment maintenance on standard and selected nonstandard medical materiel to Active Army, U.S. Army Reserve, Army National Guard, authorized Department of Defense (DoD) activities, and other federal agencies.

PartnersUSAMMA



Equipment Publications

Description

USAMMA develops and publishes interactive electronic technical manuals, publishes electronic medical equipment operator and service literature, and develops and publishes electronic support and consumables handbooks to support field-deployable medical equipment.

Interactive electronic technical manuals are developed using SGML tagging and display software developed by the Missile Command at Redstone Arsenal. The software is Interactive Authoring and Display System. Tagging is consistent to the definition type document guidelines specified in military specifications. All manuals are published on CDs and mailed when requested.

Electronic medical equipment operator and service literature is groomed and bookmarked then published on the AKO (Army Knowledge Online) web site. All literature is also published on CDs. A table of contents on USAMMA's web site lists available resources. Before operator and service literature was available on AKO, approximately 400 CDs per month were mailed in response to requests from the order form on the Medical Devices Program Management Office web page.

A Support and Consumable Handbook is developed for each unit assemblage set. The handbook contains inserts for each item of equipment within that set. It also lists all other unit assemblages that employ that equipment item. The insert provides detailed descriptions, characteristics, resupply items, start-up lists, and many times repair parts. The handbooks are updated promptly when items change. Handbooks remain available for retired unit assemblages and are labeled as Archived. All are available on USAMMA's web site.

Partners

• USAMMA

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Technology Assessment and Requirements Analysis

Description

The Technology Assessment and Requirements Analysis (TARA), a core capability of USAMMA's Project Management Office for Integrated Clinical Systems, provides information and analyses to ensure that clinical outcomes for service members are optimized. It provides information via database analyses to senior decision makers at Army military treatment facilities and the Medical Command for accomplishing missions and developing acquisition strategies to optimize clinical outcomes. TARA allows 5-year budget requirements to be aggressively managed with front-loading of medical care support equipment and super capital expense equipment program requirements for the routine replacement of diagnostic, imaging, laboratory, and patient-monitoring systems. Resulting process improvements through the generation of requirements and delivery of services have generated a cost avoidance of \$243 million to the AMEDD since 1994. TARA is ongoing.

Partners

- USAMMA
- MEDCOM
- OTSG



USAMMA Revolution in Logistics

Description

The USAMMA Revolution in Logistics (URL) supports the medical mission and enables the optimization of business practices. It improves business practices through employment of an enterprise resource planning system based on the same software product as the Army's Logistics Modernization Program and DoD's Business Systems Modernization Program. This system employs an integrated business information warehouse capability to provide USAMMA and stakeholders with highly detailed reports to support the dynamic changing medical mission. The system optimizes and modernizes medical logistics business practices. Employment of the URL has achieved a \$13 million cost avoidance and reduced customer wait time for medical assemblages from 18 months to an average of 2 months. URL is ongoing.

Partners

USAMMA



Medical Materiel Readiness Program

Description

The Medical Materiel Readiness Program (MMRP) will support medical units transitioning through their operational readiness cycles. This program will allow commanders to easily manage their training and maintenance requirements, which will prove to be a better solution for deployment.

USAMMA has developed the MMRP to support the Army Force Generation (ARFORGEN) model and the Army Campaign Plan, which are designed to improve Joint Force readiness. One tenant of the Army Medical Department's transformation is to develop an equipping solution that supports units once they are designated Deployment, Ready, and Contingency Expeditionary Forces and transitioned to the Reset/Train, Ready, and Available force pools. The equipping solution must encompass the three ARFORGEN equipment sets: (1) Baseline Equipment Set, (2) Training Equipment Set, and (3) Deployment Equipment Set, which are designed to support training and mission requirements of units transitioning between the force pools.

The goal of the program is to ensure that appropriate equipment items are ready for training and deployment to meet the requirements of the Joint Force. The MMRP serves as the umbrella program, encompassing equipment authorized by units and as part of other programs, such as the Reserve Component Hospital Decrement Program, Hospital Optimization Standardization Program, and the Army Pre-Positioned Stocks Program.

Partners

• USAMMA





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Provided in this appendix are two lists regarding USAMRMC-developed technologies. The first is a summary of licensed technologies, and the second is a listing of patents issued to the laboratories. All expired licenses are indicated with an asterisk (*).

Licensed Technologies from USAMRMC Laboratories

The following list highlights technologies developed in USAMRMC laboratories that have been licensed to commercial entities for further development or production.

Title	Patent No.	Issue Date
Flavivirus Detection and Quantification Assay	6,793,488	9/21/04
Force Sensing Treadmill	6,878,100	4/12/05
Method for Interpreting Forces and Torques Exerted by a Left and Right Foot on a Dual-Plate Treadmill	7,455,620	11/25/08
Internal Positive Control for Probe-Based Nucleic Acid Molecule Assays and Methods of Making and Using Thereof	7,005,267	2/28/06
Internal Positive Control for Probe-Based Nucleic Acid Molecule Assays and Methods of Making and Using Thereof	7,052,848	5/30/06
Detoxification with Sponges or Foams Containing Plurality of Enzymes and Encapsulated Indicator	6,541,230	4/1/03
Immobilized Enzymes Biosensors for Chemical Toxins	6,406,876	6/18/02
Preparation of Enzymatically Active Sponges or Foams for Detoxification of Hazardous Compounds	6,642,037	11/4/03
Material Include the DNA Sequences for the Primers and Probes	N/A	N/A
Antibodies Against Type A Botulinum Neurotoxin	6,667,158	12/23/03
System and Method for Predicting Human Cognitive Performance Using Data from an Actigraph	6,241,686	6/5/01
Method for Predicting Human Cognitive Performance	6,419,629	3/4/03
System and Method for Predicting Human Cognitive Performance Using Data from an Actigraph	6,527,715	3/4/03
Method and System for Predicting Human Cognitive Performance	6,530,884	3/11/03
Method and System for Predicting Human Cognitive Performance	6,553,252	4/22/03
Method and System for Predicting Human Cognitive Performance	6,740,032	5/25/04
Method and System for Predicting Human Cognitive Performance Using Data from an Actigraph	6,743,167	6/1/04
Method and System for Predicting Human Cognitive Performance	7,766,827	8/3/10
Supplemented and Unsupplemented Tissue Sealants, Methods and Their Production and Use	6,054,122	4/25/00
Antibodies with Simultaneous Subsite Specificities to Protein and Lipid Epitopes	N/A	N/A
Automated Inhalation Toxicology Exposure System	N/A	N/A
Automated Inhalation Toxicology Exposure System	6,904,912	6/14/05

Title	Patent No.	Issue Date
Automated Inhalation Toxicology Exposure System	N/A	N/A
Prophylactic and Therapeutic Monoclonal Antibodies	6,451,309	2/9/01
Prophylactic and Therapeutic Monoclonal Antibodies	6,620,412	9/16/02
Prophylactic and Therapeutic Monoclonal Antibodies	6,451,309	8/7/10
Prophylactic and Therapeutic Monoclonal Antibodies	6,620,412	9/16/03
Assay for Detecting, Measuring and Monitoring the Activities and Concentrations of Proteins and Methods of Use Thereof	6,746,850	5/4/01
Murine Hybridoma Producing Monoclonal Antibodies Against Neisseria meningitidis, Numbers 14-1-A, 4-2-C, 7-1-W, F-1-Y	N/A	N/A
Topical Skin Protectants	5,607,979	3/4/97
Practical Serological Assay for the Clinical Diagnosis of Leishmaniasis	7,452,721	11/18/08
Internal Positive Control for Probe-Based Nucleic Acid Molecule Assays and Methods of Making and Using Thereof	7,005,267	2/28/06
Leishmania Diagnostic Kit and Background Information Related to This Kit as well as the FDA 510(K) for Leishmania	N/A	N/A
Dengue Virus Monoclonal Antibodies Produced by Several Hybridoma Lines	N/A	N/A
Raman Spectra Database System	N/A	N/A
Attenuated Japanese Encephalitis Virus Adapted to Vero Cell and a Japanese Encephalitis Vaccine	6,309,650	10/30/01
Absorbable Tissue Adhesives	5,350,798	9/27/94
Personal Water and Additive Apparatus	7,533,786	5/19/09
Fish Hatching Method and Apparatus	N/A	N/A
Asporogenic B. anthracis Expression System	6,316,006	11/13/01
Method of Making a Vaccine for Anthrax	6,387,665	5/14/02
System and Method for Evaluating Task Effectiveness Based on Sleep Pattern	6,579,233	6/17/03
Copyrights, Data Architecture, Business Rules and Know How Related to Biosurety Program Management Software	N/A	N/A
Identification of Small Molecule Inhibitors of Filovirus Replication	N/A	N/A
Moes OB/GYN Training System	N/A	N/A
System and Method for Handling Medical Information (BMIST)	N/A	N/A
System and Method for Handling Medical Information (BMIST)	N/A	N/A
Collaborative Development of a Tetravalent Live-Attenuated Vaccine Against Dengue	N/A	N/A
Attenuated Dengue-2 Virus Vaccine	6,511,667	1/28/03
Attenuated Dengue-3 Virus Vaccine	6,528,065	3/4/03
Attenuated Dengue-4 Virus Vaccine	6,537,557	3/25/03

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Title	Patent No.	Issue Date
Multivalent Dengue Virus Vaccine	6,638,514	10/28/03
Adaptation of Virus to Vertebrate Cells	6,613,556	9/2/03
Sitamiquine 4-Methyl 1-5 (unsubstituted and substituted phenoxy) 6-Methoxy-8-(aminoalkylaminio) Quinolines	N/A	N/A
Inactivated Dengue Virus Vaccine	6,254,873	7/3/01
Method and Kit for Detection of Dengue Virus	6,190,859	2/20/01
Apparatus and Method for Automated Biomonitoring of Water Quality	6,058,763	5/9/00
Apparatus and Method for Automated Biomonitoring of Water Quality	6,393,899	5/28/02
Automated Biomonitoring of Water Quality*		
Vaccine Technology		
Vaccine Technology		
Oral or Intranasal Vaccines Using Hydrophobic Complexes Having Proteosomes and Lipopolysaccharides	7,112,332	9/26/06
Immuno-Potentiating Systems for Preparation of Immunogenic Materials		
Immuno-Potentiating Systems for Preparation of Immunogenic Materials	5,726,292	3/10/98
Multi-Purpose Self-Erecting Structure Having Advanced Insect Protection and Storage Characteristics	6,672,323	1/6/04
Critical Care Platform for Litters	6,493,890	12/17/02
Critical Care Platform for Litters*	N/A	N/A
Critical Care Platform for Litters*	N/A	N/A
Critical Care Platform for Litters*	N/A	N/A
Critical Care Platform for Litters*	N/A	N/A
S. flexneria Hybridoma 220-2E8	N/A	N/A
Chikungunya Vaccine-Strain of Live, Attenuated Chikungunya Virus, TSI-GSD-218 (Strain Chik 181/Clone 25)	N/A	N/A
Vaccine Strains: (1) Chikungunya, 181/25, (2) Venezuelan Equine Encelphalitis Tc-83, (3) Junin, Candid #1, and (4) Rift Valley Fever Virus, MP12	N/A	N/A
Bacterial Superantigen Vaccines	6,713,284	3/30/04
Bacterial Superantigen Vaccines	6,399,332	6/4/02
Transdermal Delivery System for Antigen	5,910,306	6/8/99
Hybridoma Cell Line 7H2 Against E Protein of West Nile Virus (WNV)	N/A	N/A
Enhanced Substrates for the Protease Activity of Serotype A Botulinum Neurotoxin*	N/A	N/A
System and Method of Handling Medical Info-BMIST*	N/A	N/A
System and Method of Handling Medical Info-BMIST	N/A	N/A

Title	Patent No.	Issue Date
System and Method of Handling Medical Info-BMIST	N/A	N/A
System and Method of Handling Medical Info-BMIST	N/A	N/A
Monoclonal Antibodies to Ebola Glycoprotein	6,630,144	10/7/03
Monoclonal Antibodies and Complementarity-Determining Regions Binding to Ebola Glycoprotein	7,335,356	2/26/08
Vaccine Against Gram-Negative Bacterial Infections	7,025,963	4/11/06
Vaccine Against Gram-Negative Bacterial Infections	7,235,644	6/26/07
Vaccine Against Gram-Negative Bacterial Infections	7,018,636	3/28/06
Vaccine Against Gram Negative Bacteria	6,558,677	5/6/03
Meningococcal Multivalent Native Outer Membrane Vesicle Vaccine, Methods of Making and Use Thereof	Pct/ Us2009/045818	6/1/09
Convulsant Antidote Nerve Agent (Cana) New Drug Application	N/A	N/A
Identification of Small Molecule Inhibitors of Anthrax Lethal Factor	N/A	N/A
Identification of Small Molecule Inhibitors of Anthrax Lethal Factor	N/A	N/A
Inhibition of Anthrax Lethal Factor Protease	7,781,183	8/24/10
Identification of Small Molecule Inhibitors of Anthrax Lethal Factor	Pct/ Us2004/029112	9/8/04
Small Molecule Inhibitors of Botulinum Neurotoxins*	N/A	N/A
Small Molecule Inhibitors of Botulinum Neurotoxins	7,825,154	11/2/10
Broad Spectrum Antibacterial Compounds*		
Broad Spectrum Antibacterial Compounds	N/A	N/A
Broad Spectrum Antibacterial Compounds		
Broad Spectrum Antibacterial Compounds*		
Multi-Purpose Self-Erecting Structure Having Advanced Insect Protection and Storage Characteristics	6,672,323	1/6/04
System and Method for the Deconvolution of Mixed DNA Profiles Using a Proportionately Shared Allele Approach	N/A	N/A
Master Virus Seed (Designated as RVF Master Seed Pass 1 Zh548-P-1) and Production Seed Used to Make Live Attenuated, MP-12, Rift Valley Fever Virus Vaccine, Designated TSI-GSD-223 Lot 7-2-88	N/A	N/A
System and Method for Predicting Human Cognitive Performance Using Data from an Actigraph	6,241,686	6/5/01
Method for Predicting Human Cognitive Performance	6,419,629	7/16/02
System and Method for Predicting Human Cognitive Performance Using Data from an Actigraph	6,527,715	3/4/03
Method and System for Predicting Human Cognitive Performance	6,530,884	3/11/03
Method and System for Predicting Human Cognitive Performance	6,553,252	4/22/03

Casualty

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Title	Patent No.	Issue Date
Method and System for Predicting Human Cognitive Performance	6,740,032	5/25/04
Method and System for Predicting Human Cognitive Performance Using Data from an Actigraph	6,743,167	6/1/04
Compositions for Treatment of Hemorrhaging with Activated Factor VIIA in Combination with Fibrinogen and Methods of Using Same	6,825,323	11/30/04
Clone BE2 Anti-Soman; Clone ID8.2 Anti-Sarin	N/A	N/A
Human Liver Cell Line	7,015,036	3/21/06
7G8 Isolate of P. falciparum	N/A	N/A
Composition and Method of Treating Hepatitis C	N/A	N/A
Composition and Method of Treating Hepatitis C	5,849,696	12/15/98
Composition and Method of Treating Hepatitis C	N/A	N/A
Screening Methods Using Normal Human Liver Cell Line	7,781,186	8/24/10
Trauma Training Mannequin*	N/A	N/A
Trauma Training Mannequin*	N/A	N/A
Trauma Training System*	N/A	N/A
Trauma Training System	N/A	N/A
Trauma Training Mannequin	N/A	N/A
Lethal Mosquito Breeding Container	5,983,557	11/16/99
Lethal Mosquito Breeding Container	6,185,861	2/13/01
Lethal Mosquito Breeding Container	6,389,740	5/21/02
Lethal Mosquito Breeding Container	N/A	N/A
Antibodies Against Type A Botulinum Neurotoxin	6,667,158	12/23/03
Antibodies Against Type A Botulinum Neurotoxin	7,049,085	5/23/06
Method of Lysing Thrombi	5,399,158	3/21/95
Prolonged Storage of Red Blood Cells and Composition	6,150,085	11/21/00
Prolonged Storage of Red Blood Cells	6,447,987	9/10/02
Method for the Production of Purified Invasin Protein and Use Thereof	N/A	N/A
Automated Neuropsychological Assessment Metrics (ANAM)	N/A	N/A
Automated Neuropsychological Assessment Metrics (ANAM)*	N/A	N/A
Automated Neuropsychological Assessment Metrics (ANAM)	N/A	N/A
Automated Neuropsychological Assessment Metrics (ANAM)*	N/A	N/A

Title	Patent No.	Issue Date
Automated Neuropsychological Assessment Metrics (ANAM)*	N/A	N/A
Automated Neuropsychological Assessment Metrics (ANAM)*	N/A	N/A
Automated Neuropsychological Assessment Metrics (ANAM)*	N/A	N/A
Neurocognitive and Psychomotor Performance Assessment and Rehabilitation System*	7,837,472	11/23/10
Method of Prophylactically Treating Organophosphate Poisoning	N/A	N/A
Method of Prophylactically Treating Organophosphate Poisoning*	N/A	N/A
Method of Prophylactically Treating Organophosphate Poisoning*	N/A	N/A
Vaccine Against Gram-Negative Bacterial Infections	7,018,636	3/28/06
Vaccine Against Gram-Negative Bacterial Infections	7,235,644	6/26/07
Vaccine Against Gram-Negative Bacterial Infections	7,025,963	4/11/06
Alphavirus RNA Replicon System*		
Alphavirus RNA Replicon Systems	5,792,462	8/11/98
Alphavirus RNA Replicon System	6,639,650	6/17/97
Method of Inducing an Immune Response with a Live Venezuelan Equine Encephalitis Virus Expressing a Heterologous Immunogen	5,643,576	7/1/97
Attenuating Mutations in Venezuelan Equine Encephalitis Virus	5,505,947	4/9/96
cDNA Clone Coding for Venezuelan Equine Encephalitis Virus and Attenuating Mutations Thereof	5,185,440	2/9/93
Master Virus Seed (Designated as RVF Master Seed Pass 1 ZH548-P-1) and Production Seed Used to Make Live Attenuated, MP-12, Rift Valley Fever Virus Vaccine, Designated TSI-GSD-223 Lot 7-2-88	N/A	N/A
Burn Patient Resuscitation System and Method	7,857,803	12/28/10
Decision-Assist Method for Resuscitation of Patients	N/A	N/A
Use of Bilosomes for Oral Delivery of Subunit Vaccines for Diarrheal Diseases	N/A	N/A
Monoclonal Antibodies or Assay Test Kits Using Monoclonal Antibodies Derived from the Provided Hybridomas for the Detection of Dengue Virus or Diagnosis of Dengue Virus Infections	N/A	N/A
Battlefield Medical Information System-Telemedicine (BMIST)	N/A	N/A
Battlefield Medical Information System-Telemedicine (BMIST)	N/A	N/A
Battlefield Medical Information System-Telemedicine (BMIST)	N/A	N/A
Shigella flexneri Strain Designated 15G	N/A	N/A

Clinical and Rehabilitative Medicine

Medical Chemical and Biological Defense

Patents Issued to USAMRMC Laboratories

The following list is a summary of the patents issued to USAMRMC laboratories. An asterisk (*) after the patent number indicates that the patent has expired.

Patent No.	Issued	Title	
Armed Forces Institute of Pathology			
7,445,908	11/4/08	Detection of Oxidizing Agents in Urine	
7,582,430	9/1/09	Immunoliposome-Nucleic Acid Amplification (ILNAA) Assay	
7,662,568	2/16/10	Immunoliposome-Nucleic Acid Amplification (ILNAA) Assay	
		Brooke Army Medical Center	
7,552,729	6/30/09	Intubation Device and Method	
		Letterman Army Institute of Research	
4,461,284*	7/24/84	Surgical Retaining Device	
4,473,494*	9/25/84	Preparation of Stroma-Free, Non-Heme Protein-Free Hemoglobin	
4,473,496*	9/25/84	Intramolecularly Crosslinked Hemoglobin	
	Madigan Army Medical Center		
6,876,780	4/5/05	Providing for Automated Note Completion	
7,043,437	5/9/06	Standardized Inpatient-Outpatient Nomenclatures and Accepting Both Outpatient and Inpatient Data to Commonly Accessible Storage	
7,291,016	11/6/07	Opthalmic Surgery Simulation Device	
7,761,463	7/20/10	Self-Serve Patient Check-In and Preventative Services Kiosk	
		Telemedicine and Advanced Technology Research Center	
7,779,025	8/17/10	System and Method for Evaluating Data Sets over a Communication Network	
	Tripler Army Medical Center		
6,754,306	6/22/04	Portable Medical Digital Radiography Assembly	
7,204,171	4/17/07	Apparatus for Fastening and Loosening a Lid from a Container	
7,316,298	1/8/08	Wheelchair Safety Brake Assembly	
7,437,972	10/21/08	Apparatus for Fastening and Loosening a Lid from a Container	

Patent No.	Issued	Title	
	U.S. Army Aeromedical Research Laboratory		
5,022,306*	6/11/91	Method of Ejecting an Interceptor Missile from Its Silo	
6,834,971	12/28/04	Low-Backscatter Aperture Structure	
6,896,377	5/24/05	Interchangeable Low-Backscatter Aperture Structure	
7,096,184	8/22/06	Calibrating Audiometry Stimuli	
7,143,031	11/28/06	Determining Speech Intelligibility	
7,149,684	12/12/06	Determining Speech Reception Threshold	
7,557,734	7/7/09	Airborne Visibility Indicator System and Method	
7,734,101	6/8/10	Apparatus and System for Testing an Image Produced by a Helmet-Mounted Display	
7,779,359	8/17/10	Multifunction Display Design Tool	
		U.S. Army Biomedical Research and Development Laboratory	
4,941,631*	7/17/90	Semi-Micro Manipulators	
4,960,496*	10/2/90	Atmospheric HCL Monitor	
		U.S. Army Center for Environmental Health Research	
4,453,768*	6/12/84	Portable Reclining Examination Chair	
4,788,789*	12/6/88	Collapsible Insect Trap	
5,224,148*	6/29/93	X-Ray Cassette Holder and Positioning Device	
5,375,276*	12/27/94	Portable Surgical Table	
6,058,763	5/9/00	Apparatus and Method for Automated Biomonitoring of Water Quality	
6,393,899	5/28/02	Apparatus and Method for Automated Biomonitoring of Water Quality	
6,988,394	1/24/06	Apparatus and Method of Portable Automated Biomonitoring of Water Quality	
7,094,417	8/22/06	Fish Hatching Method and Apparatus	
7,702,473	4/20/10	Submersible Portable In-Situ Automated Water Quality Biomonitoring Apparatus and Method	
	U.S. Army Center for Health Promotion and Preventive Medicine		
6,875,602	4/5/05	Portable Thermocycler	
6,905,454	6/14/05	Handheld and Hand-Powered Centrifuge Device	
7,069,814	7/4/06	Apparatus for Fastening a Lid to a Container	
7,627,434	12/1/09	Method for Field-Based Ecological Risk Assessment Using Rodent Sperm Analysis	

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Patent No.	Issued	Title	
	U.S. Army Institute of Dental Research		
4,637,931*	1/20/87	Polyactic-Polyglycolic and Co-Polymer Combined with Decalcified Freeze-Dried Bone for Use as a Bone Repair	
		U.S. Army Institute of Surgical Research	
4,391,799*	7/5/83	Protective Gel Composition for Treating White Phosphorus Burn Wounds	
4,393,048*	7/12/83	Protective Gel Composition for Treating White Phosphorus Burn Wounds	
5,200,402*	4/6/93	Anti-Microbial Mafenide-Phosphanilate Compound, Pharmaceutical Compositions and Method of Use Thereof	
6,144,867	11/7/00	Self-Piercing Pulse Oximeter Assembly	
6,253,098*	6/26/01	Disposable Pulse Oximeter Assembly and Protective Cover Therefor	
6,256,524*	7/3/01	Pulse Oximeter Sensor Combined with a Combination Oropharyngeal Airway and Bite Block	
6,263,223*	7/17/01	Method for Monitoring Arterial Oxygen Saturation	
6,266,547*	7/24/01	Nasopharyngeal Airway with Reflectance Pulse Oximeter Sensor	
6,470,200	10/22/02	Pacifer Pulse Oximeter Sensor	
6,493,890	12/17/02	Critical Care Platform for Litters	
6,514,208	2/4/03	Method and Apparatus for Power Doppler Ultrasound Image Analysis	
6,533,761	3/18/03	Catheter Securing Device and Bite Block	
6,565,054	5/20/03	Syringe Holder Attachment for Medication	
6,610,045	8/26/03	Orthogonal Arterial Catheter	
6,708,935	3/23/04	Device for Upper Extremity Elevation	
6,755,191	6/29/04	Securing a Device for an Endotracheal Tube	
6,842,922	1/18/05	Critical Care Platform for Litters	
6,890,322	5/10/05	Catheter Securing Device	
6,981,969	1/3/06	Orthogonal Arterial Catheter	
7,149,562	12/12/06	Needle with Fiberoptic Capability	
7,198,620	4/3/07	One Stage Saline Lock and Intravenous Catheter Set and Method of Use	
7,458,743	12/2/08	Critical Care Platform for Litters	
7,857,803	12/28/10	Burn Patient Resuscitation System and Method	
D439,388	3/20/01	Medical Monitor Chassis	
D443,062	6/5/01	Biomedical Data Recorder Chassis	

Patent No.	Issued	Title		
	U.S. Army Medical Materiel Agency			
6,418,932	7/16/02	Convertible Patient Isolation Pod		
		U.S. Army Medical Materiel Development Activity		
7,169,112	1/30/07	Non-Contact Respiration Monitor		
		U.S. Army Medical Research and Materiel Command		
4,706,676*	11/17/87	Dermal Substance Collection Device		
4,819,645*	4/11/89	Dermal Substance Collection Device		
4,960,467*	10/2/90	Dermal Substance Collection Device		
6,669,481	12/30/03	Neurocognitive Assessment Apparatus and Method		
7,498,331	3/3/09	Arthropod Repellent Pharmacophore Models, Compounds, Identified as Fitting the Pharmacophore Models, and Methods of Making and Using Thereof		
7,837,472	11/23/10	Neurocognitive and Psychomotor Performance Assessment and Rehabilitation System		
		U.S. Army Medical Research Institute of Chemical Defense		
5,607,979	3/4/97	Topical Skin Protectants		
6,001,625	12/14/99	Site-Directed Mutagenesis of Esterases		
6,211,230*	4/3/01	Method of Reducing Brain Damage Resulting from Seizures		
6,403,653	6/11/02	Active Topical Skin Protectants Using Reactive Nanoparticles		
6,410,603	6/25/02	Active Topical Skin Protectants Using Combinations of Reactive Nanoparticles and Polyoxometalates on Metal Salts		
6,410,604	6/25/02	Active Topical Skin Protectants Containing OPAA Enzymes and Clecs		
6,414,039	7/2/02	Active Topical Skin Protectants Containing Polyoxometalates and/or Coinage Metal Complexes		
6,417,236	7/9/02	Active Topical Skin Protectants Using Hybrid Organic Polysilsesquioxane Materials		
6,420,434	7/16/02	Active Topical Skin Protectants Using Polyoxometallates		
6,437,005	8/20/02	Active Topical Skin Protectants Using Polymer Coated Metal Alloys		
6,472,437	10/29/02	Active Topical Skin Protectants		
6,472,438	10/29/02	Active Topical Skin Protectants Containing S-330		
6,555,334	4/29/03	Free Floating Cryostat Sections for Use in Light and Electron Microscopy		
6,637,885	10/28/03	Method for Self-Detection of Pupillary Response		
6,871,147	3/22/05	Automated Method of Identifying and Archiving Nucleic Acid Sequences		

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Military Operational Medicine

Clinical and Rehabilitative Medicine Medical Chemical and Biological Defense

Patent No.	Issued	Title
		U.S. Army Medical Research Institute of Chemical Defense (cont.)
7,303,759	12/4/07	Compositions and Methods for Reducing Blood and Fluid Loss from Open Wounds
7,371,714	5/13/08	Chemical Agent Decontamination Composition Comprising a Perfluorinated Aalkyl Bromide
		U.S. Army Medical Research Institute of Infectious Diseases
4,532,122*	7/30/85	Anti-Trypanosomal Activity Coordination Compounds
5,185,440	2/9/93	cDNA Clone Coding for Venezuelan Equine Encephalitis Virus and Attenuating Mutations Thereof
5,298,423	3/29/94	Nucleotide Sequences Encoding the Expression of a Hantaan Virus Nucleocapsid Protein and G1 and G2 Glycoproteins
5,320,069*	6/14/94	Small Animal Restraint Device
5,453,271	9/26/95	Vaccine Against Ricin Toxin
5,505,947	4/9/96	Attenuating Mutations in Venezuelan Equine Encephalitis Virus
5,614,193	3/25/97	Hantavirus Vaccine
5,626,844*	5/6/97	Monoclonal Antibody Against Ricin A Chain
5,643,576	7/1/97	Method of Inducing an Immune Response with a Live Venezuelan Equine Encephalitis Virus Expressing a Heterologous Immunogen
5,792,462	8/11/98	Alphavirus RNA Replicon Systems
5,807,741*	9/15/98	Protective Monoclonal Antibody Against Botulinum Neurotoxin Serotype F
5,965,699	10/12/99	Assay for the Proteolytic Activity of Serotype A from Clostridium Botulinum
6,008,329*	12/28/99	Method for Purifying Cholera Toxin
6,046,806	4/2/00	Flow-Through Cell Culture Chamber
6,156,558	12/5/00	Alphavirus RNA Replicon Systems
6,200,959	3/13/01	Genetic Induction of Anti-Viral Immune Response and Genetic Vaccine for Filovirus
6,258,788	7/10/01	DNA Vaccines Against Tick-Borne Flaviviruses
6,261,567	7/17/01	Overcoming Interference in Alphavirus Immune Individuals
6,261,570*	7/17/01	Live Attenuated Virus Vaccines for Western Equine Encephalitis Virus, Eastern Equine Encephalitis Virus, and Venezuelan Equine Encephalitis Virus IE and IIIA Variants
6,287,566*	9/11/01	Protective Peptides of Neurotoxin of C. botulinum
6,296,854*	10/2/01	Live Attenuated Venezuelan Equine Encephalitis Vaccine
6,316,006	11/13/01	Asporogenic B. anthracis Expression System
6,387,665	5/14/02	Method of Making a Vaccine for Anthrax

Patent No.	Issued	Title
		U.S. Army Medical Research Institute of Infectious Diseases (cont.)
6,399,332	6/4/02	Bacterial Superantigen Vaccines
6,406,862	6/18/02	Dip-Stick Assay for C-Reactive Protein
6,451,309	9/17/02	Prophylactic and Therapeutic Monoclonal Antibodies
6,495,143	12/17/02	Botulinum Neurotoxin Vaccine
6,517,842	2/11/03	Marburg Virus Vaccines
6,521,235	2/18/03	Alphavirus RNA Replicon Systems
6,531,135	3/11/03	Alphavirus RNA Replicon Systems
6,531,487	3/11/03	Indolo(2,1-b) Quinazole-6, 12-Dione Antimalarial Compounds and Methods of Treating Malaria Therewith
6,541,010	4/1/03	Alphavirus RNA Replicon Systems
6,562,376	5/13/03	DNA Vaccines Against Poxviruses
6,620,412	9/16/03	Prophylactic and Therapeutic Monoclonal Antibodies
6,630,144	10/7/03	Monoclonal Antibodies to Ebola Glycoprotein
6,632,640	10/14/03	Vaccine Against Staphylococcus Intoxication
6,667,158	12/23/03	Antibodies Against Type A Botulinum Neurotoxin
6,713,284	3/30/04	Bacterial Superantigen Vaccines
6,762,280	7/13/04	High Throughput Assays for the Proteolytic Activities of Clostridial Neurotoxins
6,770,479	8/3/04	Anthrax Vaccine
6,824,778	11/30/04	Prophylactic and Therapeutic Monoclonal Antibodies
6,869,787	3/22/05	Ricin Vaccine and Methods of Making and Using Thereof
6,875,433	4/5/05	Monoclonal Antibodies and Complementarity-Determining Regions Binding to Ebola Glycoprotein
6,904,912	6/14/05	Automated Inhalation Toxicology Exposure System
6,919,200	7/19/05	Purification Method and Apparatus
6,984,504	1/10/06	Ebola Virion Protein Expressed from Venezuelan Equine Encephalitis (VEE) Virus Replicons
7,005,267	2/28/06	Internal Positive Control for Probe-Based Nucleic Acid Molecule Assays and Methods of Making and Using Thereof
7,034,107	4/25/06	High-Throughput Assays for the Proteolytic Activities of Clostridial Neurotoxins
7,037,680	5/2/06	Recombinant Light Chains of Botulinum Neurotoxins and Light Chain Fusion Proteins for Use in Research and Clinical Therapy
7,049,085	5/23/06	Antibodies Against Type A Botulinum Neurotoxin

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Patent No.	lssued	Title
		U.S. Army Medical Research Institute of Infectious Diseases (cont.)
7,052,848	5/30/06	Internal Positive Control for Probe-Based Nucleic Acid Molecule Assays and Methods of Making and Using Thereof
7,081,529	7/25/06	Recombinant Vaccine Against Botulinum Neurotoxin
7,087,235	8/8/06	Fusion Protein of Streptococcal Pyrogenic Exotoxins
7,090,852	8/15/06	VEE Virus Replicon Encoding Marburg Proteins
7,157,553	1/2/07	High Throughput Assays for the Proteolytic Activities of Clostridial Neurotoxins
7,175,845	2/13/07	Monoclonal Antibodies Against Ricin Toxin and Methods of Making and Using Thereof
7,214,787	5/8/07	Recombinant Vaccine Against Botulinum Neurotoxin
7,217,812	5/15/07	DNA Vaccines Against Hantavirus Infections
7,227,010	6/5/07	Recombinant Light Chains of Botulinum Neurotoxins and Light Chain Fusion Proteins for Use in Research and Clinical Therapy
7,235,235	6/26/07	Alphavirus RNA Replicon Systems
7,267,823	9/11/07	Ebola Peptides and Immunogenic Compositions Containing Same
7,297,785	11/20/07	Unique Chromosomal Sequence of <i>Bacillus anthracis</i> and Methods of Making and Using Thereof Including Real-Time PCR Assays
7,335,356	2/26/08	Monoclonal Antibodies and Complementarity-Determining Regions Binding to Ebola Glycoprotein
7,351,435	4/1/08	Deglycosylated Ricin Toxin A-Chain Vaccine
7,374,931	5/20/08	Vaccine Against Staphylococcus Intoxication
7,377,276	5/27/08	Automated Inhalation Toxicology Exposure System and Method
7,378,257	5/27/08	Bacterial Superantigen Vaccines
7,407,935	8/5/08	Ricin Toxin A-Chain Fragment for Use as a Vaccine
7,455,994	11/25/08	Methods for Producing Marburg Virus Proteins
7,563,875	7/21/09	Recombinant Chimeric Human Anti-Botulinum Antibodies
7,574,340	8/11/09	Small Molecules and a Pharmacophore Model for Inhibition of Botulinum Toxin and Methods of Making and Using Thereof
7,638,333	12/29/09	Anthrax Vaccine
7,666,404	2/23/10	Glanders/Meliodosis Vaccines
7,682,618	3/23/10	Generation of Virus-Like Particles and Use as Panfilovirus Vaccine
7,718,779	5/18/10	Prophylactic and Therapeutic Monoclonal Antibodies
7,731,975	6/8/10	Chimeric Filovirus Glycoprotein

Patent No.	Issued	Title	
		U.S. Army Medical Research Institute of Infectious Diseases (cont.)	
7,736,656	6/15/10	Immunogenic Compositions and Vaccines for Ebola	
7,750,132	7/6/10	Altered Superantigen Toxins	
7,781,183	8/24/10	Inhibition of Anthrax Lethal Factor Protease	
7,786,285	8/31/10	Recombinant Vaccine Against Botulinum Neurotoxin	
7,790,181	9/7/10	Live Attenuated Virus Vaccines for Eastern Equine Encephalitis Virus	
7,790,182	9/7/10	Protein Vaccine Against Pox Viruses	
7,795,015	9/14/10	Antibodies Expressed in Insect Cells	
7,825,154	11/2/10	Small Molecule Inhibitors of Botulinum Neurotoxins	
		U.S. Army Research Institute of Environmental Medicine	
5,206,652*	4/27/93	Dopler Radar/Ultrasonic Hybrid Height Sensing System	
5,415,379*	5/16/95	Pneumatic Winch	
5,682,882*	11/4/97	Vigilance Monitor System	
5,739,119*	4/14/98	Antisense Oligonucleotides Specific for the Muscarinic Type 2 Acetylcholine Receptor MRNA	
6,104,671*	8/15/00	Apparatus and Method for Measuring the Relative Velocity and True Distance Between Two Objects	
6,488,267	12/3/02	Apparatus for Lifting or Pulling a Load	
6,670,170	12/30/03	Temperature Required Cell Perfusion	
6,878,100	4/12/05	Force Sensing Treadmill	
7,455,620	11/25/08	Method for Interpreting Forces and Torques Exerted by a Left and Right Foot on a Dual-Plate Treadmill	
7,533,786	5/19/09	Personal Water and Additive Apparatus	
7,658,303	2/9/10	Personal Water and Additive Apparatus	
7,837,723	11/23/10	Body Thermoregulation Using Skin Temperature Feedback	
7,851,775	12/14/10	Gear-Type Drink-o-Meter to Monitor Fluid Consumption	
	Walter Reed Army Institute of Research		
3,476,311*	11/4/69	Two Dimensional Structure Encoding Typewriter	
3,595,899*	7/27/71	2-(Phenylalkylamino) Ethanethio-Sulfuric Acids as Antiradiation Agents	
3,597,444*	8/3/71	Method of Synthesizing Selenoureas from Thioureas	

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Patent No.	Issued	Title		
	Walter Reed Army Institute of Research (cont.)			
3,600,396*	8/17/71	Alpha Dilower Alkyl Amind-2,6,-DI-[p-Chlorophenyl]-4-Pyridine Methanols and Derivatives Thereof		
3,629,410*	12/21/71	Alpha-Adrenergic Blocking Agents		
3,636,192*	1/18/72	Meningococcal Polysaccharide Vaccines		
3,655,715*	4/11/72	Synthesis of N-Substituted 2-Amino-Ethanethiosulfuric Acids		
3,667,471*	6/6/72	Surgical Clamp		
3,753,997*	8/21/73	Trifluoromethyl Substituted-2, 6-Diphenyl-4-Pyridyl Carbinolamine Antimalarials		
3,763,148*	10/2/73	2,6-Bis-Tricluoromethyl-Phenyl-4-Pyridinecarbolyic Acid and Derivatives Thereof		
3,764,604*	10/9/73	4-Pyridylcarbinolamine Anti-Malarials		
3,886,167*	5/27/75	2-Aryl-6-Trifluoromethyl-4-Pyridyl-Carbinolamines Antimalarials		
3,940,404*	2/24/76	2-Substituted Phenyl-6-Trifluoromethyl-4-Pyridyl-Carbinolamines		
3,953,463*	4/27/76	2-Aryl-6-Trifluoromethyl-4-Pyridyl-Carbinolamines Antimalarials		
3,961,898*	6/8/76	Comparator Circuit for Automatic Analysis Apparatus		
4,135,131*	1/16/79	Microwave Time Delay Spectroscopic Methods and Apparatus for Remote Interrogation of Biological Threats		
4,148,005*	4/3/79	Thermometric Transducer Device		
4,162,500*	7/24/79	Ridged Waveguide Antenna Submerged in Dielectric Liquid		
4,186,183*	1/29/80	Liposome Carriers in Chemotherapy of Leishmaniasis		
4,187,300*	2/5/80	Use of Phosphonium Salts in Treatment of African Trypanosomiasis		
4,209,519*	6/24/80	Anti-Leishmanial Lepidine Derivatives		
4,240,027*	12/16/80	Electromagnetic Method for the Noninvasive Analysis of Cell Membrane Physiology and Pharmacology		
4,246,534*	1/20/81	Calibration Method for Lumped Capacitance Measurement of Complex Permittivity at HV, VHF and UHF Frequencies		
4,247,815*	1/27/81	Method and Apparatus for Physiologic Facsimile Imaging of Biologic Targets Based on Complex Permittivity Measurements Using Remote Microwave		
4,267,182*	5/15/81	Narcotic Antagonists in the Therapy of Shock		
4,271,389*	6/2/81	Method and Apparatus for Physiologic Facsimile Imaging of Biologic Targets Based on Using Remote Microwave Interrogation		
4,282,253*	8/4/81	Topical Prophylaxis Against Schistosomiasis		
4,285,936*	8/25/81	Method for Producing a Vaccine Against Bacterial Infections Caused by Pseudomonas aeruginosa		
4,299,493*	11/10/81	Auto-Optical Centering Device for Photometers		

Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
4,302,459*	11/24/81	Liposome Carriers in Leishmaniasis Chemotherapy with 8-Aminoquinoline Derivatives
4,317,776*	3/2/82	2-Acetyl- and 2-Propionylpyridine Thiosemicarbazones
4,346,608*	8/31/82	Floating Device for Density Gradient Fractionation
4,368,959*	1/18/83	Apparatus for and Method of Testing Vision
4,384,117*	5/17/83	Silver Metachloridine
4,385,055*	5/24/83	2-Acetyl- and 2-Propionylpyridine Thiosemicarbazones as Antimalarials
4,401,670*	8/30/83	Method of Treating Gonorrhea Infections with 2-Acetyl- and 2-Proprionylpyridine Thiosemicarbazones
4,415,565*	11/15/83	Silver Metachlorodine in Treatment of Infections
4,416,872*	11/22/83	Treatment of Malaria with Liposomes Containing 8-Aminoquinoline Derivatives and Glycoconjugates
4,426,378*	1/17/84	Thyrotropin Releasing Hormone in Therapy of Shock as a Central Nervous System Stimulant
4,431,807*	2/17/84	4-Methyl-5(Unsubstituted phenoxy)-6-Methoxy-8-[Aminoalkylamino]Quinolines(Sitamiquine)
4,434,168*	2/28/84	Narcotic Antagonists in the Therapy of Shock
4,440,771*	4/3/84	2-Acetyl Quinoline Thiosemicarbazones Useful in Treatment of Gonorrhea, Malaria or Bacterial Infections
4,443,431*	4/17/84	Neisseria gonorrhoeae Vaccine
4,447,395*	5/8/84	Sampling Device
4,447,427*	5/8/84	Method for Treating Bacterial Infections with 2-Acetyl- and 2-Propionylpyridine Thiosemicarbazones
4,453,546*	6/12/84	Scleral Depressor
4,488,043*	12/11/84	Topographic Marking Device
4,493,930*	1/15/85	Medical 2-Acetyl-and 2-Propionylpyridine Thiosemimcarbazones and Preparation Thereof
4,554,279*	11/19/85	5-(Straight Chain 3-12 Carbon Alkoly)8-Quinolinames and Their Use for Treatment of Malaria
4,580,567*	4/8/86	Suture Needle Holder
4,591,573*	5/27/86	Sensitive Radioimmunoassay Using Antibody to L-Hyoscyamine
4,596,798*	6/24/86	2-Acetylpyridine Thiosemicarbazones as Antiviral Agents
4,617,394*	10/14/86	4-Methyl-5(Unsubstituted and Substituted) Phenoxy-2, 6-Dimethoxy-8-(Aminoalkylamino)Quinolines (Tafenoquine)
4,632,830*	12/20/86	Oral Vaccine for Immunization Against Enteric Disease
4,657,903*	4/14/87	Transition of Metal Complexes of the Selenium Analogs of 2-Acetyl- and 2-Propionylpyrine Thiosemicarbazones Useful for Treating Malarial Infections and Leukemia

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Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
4,659,708*	4/21/87	Anti-Leishmanial Lepidine Derivatives
4,659,738*	4/21/87	Topical Prophylaxis Against Schistosomal Infections
4,665,173*	5/12/87	2-Acetyl- and 2-Propionylpyridine Selenosemicarbazones
4,707,357*	11/17/87	Immunologically Active Peptides Capable of Inducing Immunization Against Malaria and Genes Encoding Therefor
4,707,543*	11/17/87	Process for the Preparation of Detoxified Polysaccharide-Outer Membrane Protein Complexes, and Their Use as Antibacterial Vaccines
4,713,391*	12/15/87	Azabicyloalkane Phenyl Substituted Alkane Carboxylates, Their Preparation and Use as Anticholinergic Agents
4,717,115*	1/5/88	Adjustable Mold for Fabricating Bone Replacements
4,739,069*	4/19/88	2-Acety1- and 2-Proprionylpyridine Thiosemicarbazones
4,777,166*	10/11/88	2-Acetylpyridine Thiosemicarbazone Compositions as Antiviral Agents
4,791,135*	12/13/88	Novel Antimalarial Dihydroartemisinin Derivatives
4,794,549*	12/27/88	Excito-Repellency Test System
4,808,598*	2/28/89	Method for Producing Protection in an Animal Against Cyanide Poisoning Using 8-Aminoquinolines
4,863,874*	9/5/89	Method for Detecting Phosphatidylinositol Through Binding to Concanavalin A
4,883,890*	11/28/89	Unsymmetrical Organic Disulfide Compounds Useful as Antiradiation Agents
4,885,256*	12/5/89	Monoclonal Antibodies to Cholesterol and Methods
4,897,403*	1/30/90	Antimalarial Compositions and Methods
4,906,564*	3/6/90	Antigenic Determinants Recognized by Antidotes Obtained Using a Pathogenic Agent or Derivative Thereof That Presents a Restricted Set of Antigens
4,909,256*	3/20/90	Transdermal Vapor Collection Method and Apparatus
4,943,657*	7/24/90	Unsymmetrical Organic Disulfide Compounds Useful as Antiradiation Agents
4,944,449*	7/31/90	Oversize Laser Mailer and Return Envelope and Method
4,973,734*	11/27/90	Carbaphens: Aprophen Analogs That Are Binary Antidotes for Organophosphate Poisoning
4,978,782*	12/18/90	Organic Disulfide Compound Useful as Antiradiation Agents
4,992,561*	2/12/91	Simple Conversion of Artemisinic Acid into Artemisinin
4,999,344*	3/12/91	Phospholipid Compositions and Their Effective Use as Anti-Tumor Agents
5,000,732*	3/19/91	Device and Method for Providing Doses of a Liquid Material over Time to a Gut Associated Lymphoid Tissue or a Test Animal

Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
5,011,495*	4/30/91	Unique Bone Regeneration Tricalcium Phosphate
5,026,897*	6/25/91	Carbaphens: Apropen Analogs That Are Binary Antidotes for Organophosphate Poisoning
5,055,394*	10/8/91	Nucleic Acid Probe and Method for the Rapid Detection of Typhoid Fever Bacteria
5,071,759*	12/10/91	Mouse Hybridoma Cell Lines Producing Antibodies Specific for Clostridium difficile Toxins
5,074,247*	12/24/91	Insect Containing Test Apparatus
5,077,570*	12/31/91	Photo Processing Work Station
5,112,607*	5/12/92	Potentiation of Immunotoxin Action by Brefeldin A
5,130,438*	7/14/92	Bis-Methylene Ether Pyridinium Compounds
5,202,320	4/13/93	Method for Treating Leishmaniasis (NIH rights)
5,204,352*	4/20/93	Compounds Exhibiting Antiparasitic Activity and a Method for Their Use
5,206,236	4/27/93	Method for the Treatment of Malaria
5,229,376*	7/20/93	Encapsulated Plant-Derived Phosphatidylinositol (PI) Compositions for the Prevention of Mitrogenicity-Induced Cell Proliferation
5,238,927*	8/24/93	Hydrolytic Stabilizer for Unstable Organic Ions
5,243,540*	9/7/93	Computer-Driven Amino Acid Indexer for Peptide Synthesis
5,258,386*	11/2/93	Synthesis and Use of Novel [+] -3-Substituted-N-Alkylmorphinans as Anticonvulsants and/or Antiischemic Agents
5,281,597*	1/25/94	Heterocyclic and Aromatic Thiosemicarbazones Useful in the Treatment of Filariasis
5,290,553	3/1/94	Alkaloids of Picralima Nitide Used for Treatment of Protozoal Diseases
5,331,010*	7/19/94	1-Phenylakanecarboxylic Acid Derivatives as Anticonvulsant and Neuroprotective Agents
5,350,798	9/27/94	Absorbable Tissue Adhesives
5,399,158	3/21/95	Method of Lysing Thrombi
5,415,532*	5/16/95	High Efficiency Balanced Oscillating Shuttle Pump
5,417,986*	5/23/95	Vaccines Against Diseases Caused by Enteropathogenic Organisms Using Antigens Encapsulated Within Biodegradable- Biocompatible Microspheres
5,470,311*	11/28/95	Microsphere Drug Application Device
5,476,771*	12/19/95	Test for Quantitative Thrombin Time
5,626,151	5/6/97	Transportable Life Support System
5,631,283*	5/20/97	Use of Sialidase Inhibitors in the Prevention and Treatment of Infectious and Inflammatory States

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Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
5,660,854	8/26/97	Drug Releasing Surgical Implant or Dressing Material
5,693,343	12/2/97	Microparticles of Maximal Uptake Capacity by Both M Cells and Non-M Cells
5,695,750*	12/9/97	Compositions for Use to Deactivate Organophosphates
5,698,416	12/16/97	Method for Production of Antigens Under Control of Temperature-Regulated Promotors in Enteric Bacteria
5,705,197*	1/16/98	Extraction Process for Producing PLGA Microspheres
5,711,966	1/27/98	Method of Treating Malaria with Desbutylhalofantane
5,716,637	2/10/98	Solid Fat Nanoemulsions as Vaccine Delivery Vehicles
5,726,292	3/10/98	Immuno-Potentiating Systems for Preparation of Immunogenic Materials
5,736,148*	4/7/98	Infectious Japanese Encephalitis Virus cDNA Clones That Produce Highly Attenuated Recombinant Japanese Encephalitis Virus and Vaccines Therefor
5,762,965	6/9/98	Vaccines Against Intracellular Pathogens Using Antigens Encapsulated Within Biodegradable Biocompatible Microspheres
5,820,880	10/13/98	Liposomal Formulation
5,824,538	10/20/98	Shigella Vector for Delivering DNA to a Mammalian Cell
5,888,519*	3/10/99	Encapsulated High-Concentration Lipid A Compositions as Immunogenic Agents to Produce Human Antibodies to Prevent or Treat Gram-Negative Bacterial Infections
5,910,306	6/8/99	Transdermal Delivery System for Antigen
5,914,114	6/22/99	Method of Raising Antibodies Against E. coli of the Family CS4-CFA/I
5,916,096*	6/29/99	Advanced Surgical Suite for Trauma Casualties
5,916,588	6/29/99	Peptide-Containing Liposomes Immunogenic Liposomes and Methods of Preparation and Use
5,919,129*	7/6/99	Fiber Optic Periodontal Endoscope
5,939,075*	8/17/99	Mutants of Brucella melitensis
5,958,686	9/28/99	Simple PCR Technique for Detecting and Differentiating Bacterial Pathogens
5,961,970	10/5/99	Submicron Emulsions as Vaccine Adjuvants
5,965,572*	10/12/99	Methods for Treating Antibiotic-Resistant Infections
5,972,366*	10/26/99	Drug Releasing Implant or Dressing Material
5,980,898	11/9/99	Adjuvant for Transcutaneous Immunization
5,983,557	11/16/99	Lethal Mosquito Breeding Container

Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
5,985,284	11/16/99	Oral or Intranasal Vaccine Using Hydrophobic Complexes Having Proteosomes and Lipopolysaccharides
6,007,838	12/28/99	Process for Making Liposome Preparation
6,046,200	4/2/00	Compositions Having Neuroprotective and Analgesic Activity
6,066,323	5/23/00	Use of Antibodies to Sialidase as Anti-Infectious Agents and Anti-Inflammatory Agents
6,071,949	6/6/00	Use of Lipoxygenase Inhibitors as Anti-Cancer Therapeutic and Intervention Agents
6,074,865	6/13/00	Recombinant Dengue Virus DNA Fragment
6,090,614*	7/18/00	Method for Production of Plasmodium Causing Relapsing Malaria
6,093,406*	7/25/00	Vaccine for Induction of Immunity to Malaria
6,110,492	8/29/00	Immunogenic Compositions
6,110,671*	8/29/00	Method of Measuring Tumor Suppressor Gene P53
6,117,640	9/12/00	Recombinant Vaccine Made in E. coli Against Dengue Virus
6,124,108*	9/26/00	Protein Biomarker for Mustard Chemical Injury
6,150,085	11/21/00	Prolonged Storage of Red Blood Cells and Composition
6,159,958*	12/12/00	Treatment or Prophylaxis of Retinal Pathology and Spinal Cord Injury
6,185,861	2/13/01	Lethal Mosquito Breeding Container
6,190,859	2/20/01	Method and Kit for Detection of Dengue Virus
6,214,548*	4/10/01	Diagnostic Methods for Cyclospora
6,217,911*	4/17/01	Sustained-Release Non-Steroidal, Anti-Inflammatory and Lidocaine PLGA Microspheres
6,241,686	6/5/01	System and Method for Predicting Human Cognitive Performance Using Data from an Actigraph
6,245,892	6/12/01	Invaplex from Gram Negative Bacteria, Method of Purification and Methods of Use
6,248,574*	6/19/01	Polypeptides Selectively Reactive with Antibodies Against Human Immunodeficiency Virus and Vaccines Comprising the Polypeptides
6,254,873	7/3/01	Inactivated Dengue Virus Vaccine
6,268,383*	7/31/01	Substituted Aromatic Compounds for Treatment of Antibiotic-Resistant Infections
6,274,598*	8/14/01	Methods for Treating Antibiotic-Resistant Infections
6,277,379	8/21/01	Use of Purified Invaplex from Gram Negative Bacteria as a Vaccine
6,284,739	9/4/01	Antileishmanial Composition for Topical Application

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Military Operational Medicine Clinical and Rehabilitative Medicine Medical Chemical and Biological Defense

Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
6,284,772*	9/4/01	Indolo[2,1,B] Quinazole-6,12-Dione Antimalarial Compounds and Methods of Treating Malaria Therewith
6,309,650	10/30/01	Attenuated Japanese Encephalitis Virus Adapted to Vero Cell and a Japanese Encephalitis Vaccine
6,309,669	10/30/01	Therapeutic Treatment and Prevention of Infections with Materials Encapsulated Within a Biodegradable-Biocompatible Polymeric Matrix
6,310,046*	10/30/01	Sequestrin of Plasmodium falciparum
6,316,197	11/13/01	Method of Diagnosing of Exposure to Toxic Agents by Measuring Distinct Pattern in the Levels of Expression of Specific Genes
6,339,102*	1/15/02	Method and Compositions for Treating and Preventing Retinal Damage
6,389,740	5/21/02	Lethal Mosquito Breeding Container
6,403,576	6/11/02	Antifungal and Antiparasitic Compounds
6,406,876	6/18/02	Immobilized Enzymes Biosensors for Chemical Toxins
6,410,012	6/25/02	Antimicrobial Mediated Bacterial DNA Delivery
6,410,056	6/25/02	Chemotherapeutic Treatment of Bacterial Infections with an Antibiotic Encapsulated Within a Biodegradable Polymeric Matrix
6,410,537	6/25/02	Compositions Having Neuroprotective and Analgesic Activity
6,419,629	7/16/02	Method for Predicting Human Cognitive Performance
6,432,434	8/13/02	Treatment of and/or Prophylaxis Against Brain and Spinal Cord Injury
6,433,023	8/13/02	Compositions Having Anti-Leishmanial Activity
6,444,445	9/30/02	Live Vaccine Against Brucellosis
6,447,796	9/10/02	Sustained Release Hydrophobic Bioactive PLGA Microspheres
6,447,987	9/10/02	Prolonged Storage of Red Blood Cells
6,469,049	10/22/02	Method of Treating, Preventing or Inhibiting Central Nervous System Injuries and Diseases
6,476,201	11/5/02	Methods for Production of Non-Covalently Complexed and Multivalent Proteosome Sub-Unit Vaccines
6,511,667	1/28/03	Attenuated Dengue-2 Virus Vaccine
6,514,501	2/4/03	Recombinant Vaccine Against Dengue Virus
6,527,715	3/4/03	System and Method for Predicting Human Cognitive Performance Using Data from an Actigraph
6,528,065	3/4/03	Attenuated Dengue-3 Virus Vaccine
6,528,097	3/4/03	Sustained Release Non-Steroidal, Anti-Inflammatory and Lidocaine PLGA Microspheres
6,530,884	3/11/03	Method and System for Predicting Human Cognitive Performance
6,537,557	3/25/03	Attenuated Dengue-4 Virus Vaccine

Patent No.	Issued	Title	
	Walter Reed Army Institute of Research (cont.)		
6,541,230	4/1/03	Detoxification with Sponges or Foams Containing Plurality of Enzymes and Encapsulated Indicator	
6,553,252	4/22/03	Method and System for Predicting Human Cognitive Performance	
6,558,677	5/6/03	Vaccine Against Gram-Negative Bacteria	
6,573,244	6/3/03	Previns as Specific Inhibitors and Therapeutic Agents for Botulinum Toxin B and Tetanus Neurotoxins	
6,613,556	9/2/03	Adaptation of Virus to Vertebrate Cells	
6,628,751	9/30/03	Digital Radiographic Sensor View Capture	
6,638,514	10/28/03	Multivalent Dengue Virus Vaccine	
6,641,815	11/4/03	Sequestrin of Plasmodium falciparum	
6,642,037	11/4/03	Preparation of Enzymatically Active Sponges or Foams for Detoxification of Hazardous Compounds	
6,654,736	11/25/03	Chemical Information Systems	
6,664,280	12/16/03	Antivesicant Compounds and Methods of Making and Using Thereof	
6,672,323	1/6/04	Multipurpose Self-Erecting Structure Having Advanced Insect Protection and Storage Characteristics	
6,680,374	1/20/04	Invaplex from Gram Negative Bacteria, Method of Purification and Methods of Use	
6,706,754	3/16/04	Reversed Amidines and Methods of Using for Treating, Preventing, or Inhibiting Leishmaniasis	
6,713,444	3/30/04	Buforin I as a Specific Inhibitor and Therapeutic Agent for Botulinum Toxin B and Tetanus Neurotoxins	
6,740,032	5/25/04	Method and System for Predicting Human Cognitive Performance	
6,743,167	6/1/04	Method and System for Predicting Human Cognitive Performance Using Data from an Actigraph	
6,746,850	6/8/04	Assay for Detecting, Measuring and Monitoring the Activities and Concentrations of Proteins and Methods of Use Thereof	
6,753,155	6/22/04	Protein Biomarker for Mustard Chemical Injury	
6,756,399	6/29/04	Use of Lipoxygenase Inhibitors and PPAR Ligands as Anticancer Therapeutic and Intervention Agents	
6,793,488	9/21/04	Flavivirus Detection, and Quantification Assay	
6,797,276	9/28/04	Use of Penetration Enhancers and Barrier Disruption Agents to Enhance the Transcutaneous Immune Response	
6,797,485	10/13/04	Mass Spectrometry of Colonization Factors	
6,800,618	10/5/04	Chemosensitizing Agents Against Chloroquine Resistant P. falciparum and Methods of Making and Using Thereof	
6,803,042	10/12/04	Oral or Intranasal Vaccines Using Hydrophobic Complexes Having Proteosomes and Lipopolysaccharides	
6,815,425	11/9/04	Pharmaceutical Composition Containing pGlu-Glu-Pro-NH2 and Method for Treating Diseases and Injuries to the Brain, Spinal Cord and Retina Using Same	

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Military Operational Medicine

Clinical and Rehabilitative Medicine Medical Chemical and Biological Defense

Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
6,825,323	11/30/04	Compositions for Treatment of Hemorrhaging with Activated Factor VIIA in Combination with Fibrinogen and Methods of Using Same
6,825,382	11/30/04	Trifluoromethylepinephrine Compounds and Methods of Making and Using Thereof
6,844,010	1/18/05	Therapeutic Treatment and Prevention of Infections with a Bioactive Materials Encapsulated Within a Biodegradable- Biocompatible Polymeric Matrix
6,849,050	2/1/05	System and Method for Detecting Visual Alterness
6,855,322	2/15/05	Isolation and Purification of P. falciparum Merozoite Protein-142 Vaccine
6,855,331	2/15/05	Sustained Release Hydrophobic Bioactive PLGA Microspheres
6,869,602	3/22/05	Methods for Treating or Inhibiting Enterotoxigenic Escherichia coli Infections with Bovine Red Blood Cells
6,872,398	3/29/05	A Conjugate Vaccine Against Gram-Negative Bacterial Infection
6,891,077	5/10/05	Fibrinogen Bandages and Arterial Bleeding Models and Methods of Making and Using Thereof
6,900,025	5/31/05	Detection of Antibodies to Squalene in Serum
6,902,743	6/7/05	Therapeutic Treatment and Prevention of Infections with a Bioactive Material(s) Encapsulated Within a Biodegradable Bio- Compatible Polymeric Matrix
6,906,098	6/14/05	Mixed Steroidal 1,2,4,5-Tetraoxane Compounds and Methods of Making and Using Thereof
6,939,546*	9/6/05	Model for Testing Immunogenicity of Peptides
6,951,846	10/4/05	Artemisinins with Improved Stability and Bioavailability for Therapeutic Drug Development and Applications
7,008,774	3/7/06	Practical Serological Assay for the Clinical Diagnosis of Leishmaniasis
7,010,089	3/7/06	Digital Radiographic Sensor View Capture
7,015,036	3/21/06	Human Liver Cell Line
7,018,636	3/28/06	Vaccine Against Gram-Negative Bacterial Infections
7,025,963	4/11/06	Vaccine Against Gram-Negative Bacterial Infections
7,029,685	4/18/06	Plasmodium falciparum AMA-1 Protein and Uses Thereof
7,033,608	4/25/06	Novel "Burst-Free" Sustained Release Poly(Lactide/Glycolide) Microspheres
7,037,499	5/2/06	Adjuvant for Transcutaneous Immunization
7,045,336	5/16/06	Bacterial Delivery System
7,060,276	6/13/06	Plasmodium falciparum AMA-1 Protein and Uses Thereof
7,084,132	8/1/06	Artemisinins with Improved Stability and Bioavailability for Therapeutic Drug Development and Applications

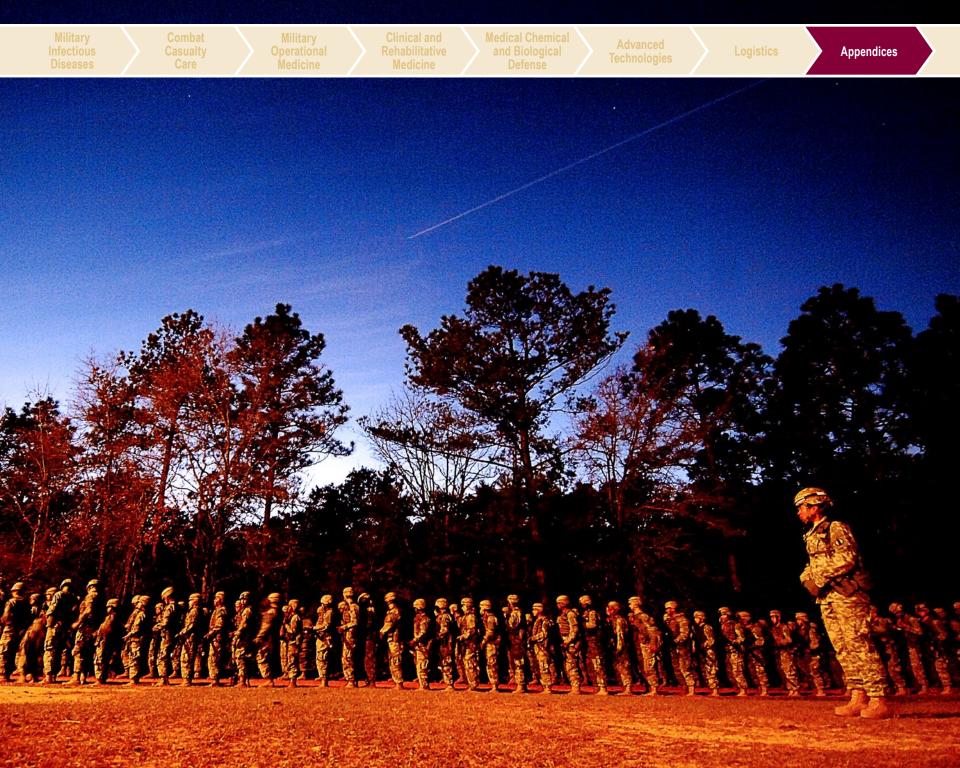
Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
7,094,883	8/22/06	Monoclonal Antibody Which Agglutinates E. coli Having the CS4-CFA/I Family Protein
7,101,902	9/5/06	2-Guanidinylimidazolidine Dione Compounds and Methods of Making and Using Thereof
7,112,332	9/26/06	Oral or Intranasal Vaccines Using Hydrophobic Complexes Having Proteosomes and Lipopolysaccharides
7,118,758	10/10/06	Transformed Bacteria Producing CS6 Antigens as Vaccines
7,150,875	12/19/06	Recombinant P. vivax Merozoite Protein-1 p42 Vaccine
7,175,981	2/13/07	Method of Diagnosing Stage or Aggressiveness of Breast and Prostate Cancer Based on Levels of Fatty Acid Binding Proteins
7,217,418	5/15/07	Multivalent Dengue Virus Vaccine
7,217,541	5/15/07	Method of Making CS6 Antigen Vaccine for Treating, Preventing, or Inhibiting Enterotoxigenic Escherichia coli Infections
7,235,234	6/26/07	Bacterial Delivery System
7,235,521	6/26/07	Previns as Specific Inhibitors and Therapeutic Agents for Botulinum Toxin B and Tetanus Neurotoxins
7,235,644	6/26/07	Vaccine Against Gram-Negative Bacterial Infections
7,253,177	8/7/07	Synthesis and Antimalarial Activity of Pyrrolo[3,2-F]Quinazoline-1,3,-Diamine Derivatives
7,256,281	8/14/07	Recombinant P. falciparum Merozoite Protein-142 Vaccine
7,258,863	8/21/07	Heterologous Protection Induced by Immunization with Invaplex Vaccine
7,259,167	8/21/07	Antimalarial and Antiproliferative Pharmacophore Models, Novel Tryptanthrin Compounds Having Increased Solubility, and Methods of Making and Using Thereof
7,265,215	9/4/07	Recombinant Vaccine Against Dengue Virus
7,270,964	9/18/07	Detection of Antibodies to Squalene in Serum
7,283,962	10/16/07	Methods and Systems for Detecting, Measuring, or Monitoring Stress in Speech
7,306,806	12/11/07	Recombinant P. falciparum Merozoite Protein-142 Vaccine
7,332,172	2/19/08	Transformed Bacteria Producing CS6 Antigens as Vaccines
7,375,079	5/20/08	Previns as Specific Inhibitors and Therapeutic Agents for Botulinum Toxin B and Tetanus Neurotoxins
7,378,097	5/27/08	Use of Penetration Enhancers and Barrier Disruption Agents to Enhance the Transcutaneous Immune Response
7,404,961	7/29/08	Antibodies Against Consensus Peptide of the CS4-CFA/1 Family Proteins
7,416,878	8/26/08	Immunogenic Compositions Including Rough Phenotype Brucella Host Strains and Complementation DNA Fragments
7,419,683	9/2/08	Method of Inhibiting Side Effects of Pharmaceutical Compositions Containing Amphiphilic Vehicles or Drug Carrier Molecules
7,452,721	11/18/08	Practical Serological Assay for the Clinical Diagnosis of Leishmaniasis

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Patent No.	Issued	Title
		Walter Reed Army Institute of Research (cont.)
7,494,980	2/24/09	Antimicrobial Peptide and Methods of Use Thereof
7,527,802	5/5/09	Vaccine for Transcutaneous Immunization
7,550,275	6/23/09	Expression, Purification and Uses of a Plasmodium falciparum Liver Stage Antigen 1 Peptide
7,563,883	7/21/09	Recombinant P. falciparum Merozoite Protein-142 Vaccine
7,566,465	7/28/09	Artemisinins in the Clinical and Veterinary Management of Kinetoplastid Infections
7,566,540	7/28/09	Monoclonal Antibody Which Agglutinates E. coli Having the CS4-CFA/I Family Protein
7,595,191	9/29/09	Isolation and Purification of P. falciparum Merozoite Protein-142 Vaccine
7,604,811	10/20/09	Oral-Intestinal Vaccines Against Diseases Caused by Enteropathic Organisms Using Antigens Encapsulated Within Biodegradable-Biocompatible Microspheres
7,611,896	11/3/09	A Novel and Practical Serological Assay for the Clinical Diagnosis of Leishmaniasis
7,625,571	12/1/09	Transformed Bacteria Producing CS6 Antigens as Vaccines
7,632,659	12/15/09	Use of <i>Shigella</i> Invaplex to Transport Functional Proteins and Transcriptionally Active Nucleic Acids Across Mammalian Cell Membranes In Vitro and In Vivo
7,655,247	2/2/10	Malaria Vaccines
7,660,692	2/9/10	Ballistic Impact Detection System
7,678,828	3/16/10	Methods for the Formulation and Manufacture of Artesunic Acid for Injection
7,722,889	5/25/10	Plasmodium Liver Stage Antigens
7,741,431	6/22/10	Liposomes Containing Target and/or Fusogenic Peptides, Preparations Containing Them, and Therapeutic Use Thereof
7,754,461	7/13/10	Large-Scale Production of Human Serum Butyrylcholinesterase as a Bioscavenger
7,759,106	7/20/10	Construction of Live Attenuated Shigella Vaccine Strains That Express CFA/I Antigens (CfaB and CfaE) and the B Subunit of Heat-Labile Enterotoxin (LTB) from Enterotoxigenic E. coli
7,766,827	8/3/10	Method and System for Predicting Human Cognitive Performance
7,780,966	8/24/10	Artificial Invaplex
7,781,186	8/24/10	Screening Methods Using Normal Human Liver Cell Line
7,790,186	9/7/10	A Plasmodium vivax Hybrid Circumsporozoite Protein and Vaccine
7,799,536	9/21/10	Endothelial Monocyte Activating Polypeptide II, a Biomarker for Use in Diagnosis and Treatment of Brain Injury
7,824,864	11/2/10	Detection of Human Antibodies to Squalene in Serum
D454,140	3/5/02	ICON for a Portion of a Display Screen

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	Walter Reed Army Institute of Research (cont.)		
D454,356	3/12/02	Toolbar for a Portion of a Display Screen	
D463,445	9/24/02	ICON for a Portion of a Display Screen	
D463,446	9/24/02	ICON for a Portion of a Display Screen	
4,824,666*	4/28/89	Method of Large Scale Growth of Toxoplasmic Microorganisms	
5,550,214	8/27/96	Isolated Antigenic Oncogene Peptide Fragments and Uses	
5,916,224*	6/29/99	Tendon Repair Clip Implant	
6,054,122	4/25/00	Supplemented and Unsupplemented Tissue Sealants, Methods of Their Production and Use	
RE39,321	10/3/06	Supplemented and Unsupplemented Tissue Sealants, Methods of Their Production and Use	
7,766,870	8/3/10	Foley Catheter Adaptor (Dabbs Adaptor)	
		Walter Reed Army Medical Center	
4,824,666*	4/28/89	Method of Large Scale Growth of Toxoplasmic Microorganisms	
5,550,214	8/27/96	Isolated Antigenic Oncogene Peptide Fragments and Uses	
5,916,224*	6/29/99	Tendon Repair Clip Implant	
6,054,122	4/25/00	Supplemented and Unsupplemented Tissue Sealants, Methods of Their Production and Use	
RE39,321	10/3/06	Supplemented and Unsupplemented Tissue Sealants, Methods of Their Production and Use	
7,766,870	8/3/10	Foley Catheter Adaptor (Dabbs Adaptor)	



ACRONYM LIST

- 2-PAM 2-Pralidoxime
- AAS Advanced Anticonvulsant System
- ABTD Advanced Blast Test Device
- ABVT Automated Binocular Vision Tester
- ACCLS Automated Critical Care Life Support
- AFIRM Armed Forces Institute of Regenerative Medicine
- AGULVE Aerosol Generator, Ultra-Low Volume, Electric
- AHLTA-Mobile Armed Forces Health Longitudinal Technology Application-Mobile
 - AICS Arm Immersion Cooling System
 - AMMO Alertness Management for Military Operations
 - ANH Alliance for NanoHealth
 - ARD Acute Respiratory Disease
- ARFORGEN Army Force Generation
 - ASER Army Medical Department Suicide Event Report
 - AST Advanced Surgical Technologies

ATD	Anthropomorphic Test Device
ATNAA	Antidote Treatment Nerve Agent Autoinjector
BAA	Broad Agency Announcement
BAMC	Brooke Army Medical Center
BW	Biological Warfare
CANA	Convulsant Antidote for Nerve Agent
CASEVAC	Casualty Evacuation
CASIT	Center for Advanced Surgical and Interventional Technology
CAT	Combat Application Tourniquet
CBMS	Chemical Biological Medical Systems
CBRNE	Chemical, Biological, Radiological/Nuclear, and Explosive
CBT	Computer-Based Training
CDE	Common Development Environment
CDM	Clinical Data Mart
CDMRP	Congressionally Directed Medical Research Programs
CeMBR	Center for Military Biomaterials Research

CiMeRC	Civilian Medical Response Center
CIMIT	Center for Integration of Medicine and Innovative Technology
COTS	Commercial-off-the-Shelf
CounterACT	Countermeasures Against Chemical Threats
CPAIN	Chronic Pain Impact Network
CPOE	Computerized Physician Order Entry
CPP	Cryopreserved Platelets
CRADA	Cooperative Research and Development Agreement
CRIMM	Center for Research on Integrative Medicine in the Military
CRMRP	Clinical and Rehabilitative Medicine Research Program
СТА	Composite Tissue Allotransplantation
CW	Chemical Warfare
DEFTOS	Dental Field Treatment and Operating System
DHP	Defense Health Program

DIN-PACS	Digital Imaging Network- Picture Archiving and
	Communications System
DoD	Department of Defense

- DVPMI Defense & Veterans Pain Management Initiative
- EEE Eastern Equine Encephalitis
- EHI Exertional Heat Injury
- EIC **Electronic Information Carrier**
- **Emergency Medical Services** EMS
- EPA U.S. Environmental Protection Agency
- FSB Environmental Sentinel Biomonitor
- ESS Engineered Skin Substitute
- ESSENCE Electronic Surveillance System for the Early Notification of **Community-Based Epidemics**
 - ETEC Enterotoxigenic Escherichia coli
 - FDA U.S. Food and Drug Administration
 - FETM Finite Element Thermoregulatory Model
 - FHAS Functional Hearing Assessment System
 - FIBWA Field Identification of Biological Warfare Agents
- FMOGDS Field Medical Oxygen-Generating and Distribution System

- FOCUS Facial and Ocular Countermeasure Safety Ground Combat Vehicles GCV
 - GEIS Global Emerging Infections System
 - GP Glycoprotein
 - GlaxoSmithKline GSK
- Heavy Brigade Combat Team HBCT
- HBO2 Hyperbaric Oxygen
- HFRS Hemorrhagic Fever with Renal Syndrome
- HHS U.S. Department of Health and Human Services
- HIFU High-Intensity Focused Ultrasound
- Heat Injury/Stroke HIS
- HIV Human Immunodeficiency Virus
- HMD Helmet-Mounted Display
- HSDs Head-Supported Devices
- iABS Intelligent Aquatic Biomonitor System
- Indications and Warnings I&Ws
- IEDs Improvised Explosive Devices
- IFAK Improved First Aid Kit
- Information Management/ IM/IT Information Technology
- INATS Improved Nerve Agent Treatment System
 - International Standard ISO Organization

Impedance Threshold Device ITD JBAIDS Joint Biological Agent Identification and Diagnostic System JSPDS Joint Service Personnel/Skin **Decontamination System** JSTO-CBD Joint Science and Technology Office for Chemical and **Biological Defense** Joint Vaccine Acquisition JVAP Program LRDD Leishmania Rapid Diagnostic Device LST Leishmania Skin Test LSTAT Life Support for Trauma and Transport M3D Medical Maintenance Management Directorate M-ATV MRAP All-Terrain Vehicle MANAA Medical Aerosolized Nerve Agent Antidote Medical Communications for MC4 Combat Casualty Care MCC Microclimate Cooling MDR Medical Data Repository MHATs Mental Health Advisory Teams Military Health System MHS MIDRP Military Infectious Diseases **Research Program** MMRP Medical Materiel Readiness Program

MOMRP	Military Operational Medicine Research Program
MOS	Military Occupational Specialty
MRAP	Mine-Resistant Ambush-Protected
MRDD	Malaria Rapid Diagnostic Device
MSTI	Medical Simulation Training Initiative
MTFs	Medical Treatment Facilities
MUSTPAC 3	Medical Ultrasound, Three- Dimensional, Portable with Advanced Communications
NAAK	Nerve Agent Antidote Kit
NFCI	Non-Freezing Cold Injury
NFGC	National Functional Genomics Center
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NMRC	Naval Medical Research Center
NP	Nucleoprotein
NTTP	Neuromonics Tinnitus Treatment Program
OTSG	Office of the Surgeon General
PAN	Personal Area Network
PC	Personal Computer
PCS	Post-Concussion Syndrome
PDA	Personal Digital Assistant
PIV	Purified Inactivated Virus

PPE	Personal Protective Equipment
PRT	Pathogen Reduction Technology
PSDA	Probability of Survival Decision Aid
PTSD	Post-Traumatic Stress Disorder
PUMA	Programmable Universal Manipulation Arm
PVC	Pharmacovigilance Center
PVT	Psychomotor Vigilance Task
RAP	Recruit Assessment Program
RBCXL	Red Blood Cells, Extended Life
RHD	Rapid Human Diagnostic
RMLS	Rugged Mobile Logistics System
RPSM	Remote Physiological Status Monitor
RSDL	Reactive Skin Decontamination Lotion
RVD	Rapid Vector Diagnostic
RVPSOG	Rotary Valve Pressure Swing Oxygen Generator
SAPS	Stand Alone Patient Simulator
SBIR	Small Business Innovation Research
SEA	Staphylococcal Enterotoxin A
SEB	Staphylococcal Enterotoxin B
SERPACWA	Skin Exposure Reduction Paste Against Chemical Warfare Agents
SMEED	Special Medical Emergency Evacuation Device

SNAPP	Soman Nerve Agent Pretreatment Pyridostigmine
SOFMH	Special Operations Forces Medical Handbook
SOSTS	Simulation of Open Surgery Training System
SPARKy	Spring Ankle with Regenerative Kinetics
SPARNET	Spartan Network
STATCare	Simulation Technologies for Advanced Trauma Care
STS	Severe Trauma Simulation
TAIHOD	Total Army Injury Health and Occupational Database
TARA	Technology Assessment and Requirements Analysis
TATRC	Telemedicine and Advanced Technology Research Center
TBAD	Tactile Balance Assessment Device
TBI	Traumatic Brain Injury
TGAS-PE	Toxic Gas Assessment Software – Performance Evaluation
TMIP	Theater Medical Information Program
TOP	Training, Overuse Injury, and Performance
TRIM	Troop Recruitment Improvement
TSAS	Tactile Situation Awareness System
UAV	Unmanned Aerial Vehicle

Casualty

Military Operational Medicine Clinical and Rehabilitative Medicine Medical Chemical and Biological Defense

Appendices

URL	USAMMA Revolution in Logistics
USAISR	U.S. Army Institute of Surgical Research
USAMMA	U.S. Army Medical Materiel Agency
USAMMCE	U.S. Army Medical Materiel Center, Europe
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRICD	U.S. Army Medical Research Institute of Chemical Defense
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
VA	U.S. Department of Veterans Affairs
VAMC	Veterans Affairs Medical Center
VEE	Venezuelan Equine Encephalitis
VIG	Vaccine Immune Globulin
VIGIV	Vaccine Immune Globulin Intravenous
VLPs	Virus-Like Particles
VNS	Vagus Nerve Stimulatory
WebRSIS	Web-Enabled Refractive Surgery Information System
WEE	Western Equine Encephalitis

WPSM	Warfighter Physiological Status Monitoring
WRAIR	Walter Reed Army Institute of Research
WRAIR SPM	Walter Reed Army Institute of Research Sleep Performance Model
WRESP	Warfighter Refractive Eye Surgery Program
WRNMMC	Walter Reed National Military Medical Center
WTUs	Warrior Transition Units

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