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Military Medical/CBRN Technology

Special Section:
JPEO-CBD Project Management Update

Committed Defender
Brig. Gen. Jess Scarbrough

Joint Program Executive Officer for Chemical and Biological Defense

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March 2012
Volume 16, Issue 2

Mental Health Roundtable ☆ Biodefense ☆ SAFMLS
Infectious Diseases ☆ Post Traumatic Stress Disorder

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Features

Infectious Diseases

Despite the advances in military medical capability over the last 100 years, and even with the lethality of modern combat weapons, infectious diseases have consistently been the greatest source of morbidity and mortality throughout the history of warfare.
By Colonel Peter J. Benson and Lieutenant Colonel Jennifer Caci

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Joint Program Executive Officer for Chemical and Biological Defense is the Department of Defense's single focal point for research, development, acquisition, fielding and life cycle support of chemical, biological, radiological and nuclear (CBRN) defense equipment and medical countermeasures. Eight joint project managers within the JPEO-CBD lead, manage and direct the acquisition and fielding of CBRN detection and reconnaissance systems, individual and collective protection systems, decontamination systems, information management systems, medical devices, drugs and vaccines, and installation and force protection systems.

Post-Traumatic Stress Disorder

This article suggests that veterans living with post-traumatic stress disorder (PTSD) qualify as "disabled" under the Americans with Disabilities Act, and therefore, their employers must provide them with reasonable accommodations in order to assist them in performing their jobs.
By W. Thomas Smith, Pharm.D., J.D.

USAMRIID

Since 1969, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Md., has been the Department of Defense's lead laboratory for medical biological defense research. While their core mission is to protect the warfighter from biological threats, they also stand ready to help investigate disease outbreaks or emerging threats to public health.
By Leonard A. Smith, Ph.D.

Mental Health Roundtable

A live roundtable wrap up from the Military Health Systems Conference with participants Lt. Col. William E. Geesey, product manager Medical Communications for Combat Casualty Care; Capt. Robert Koffman, chief of clinical operations, National Intrepid Center of Excellence; Dr. Joseph Bleiberg, acting deputy of research, The National Intrepid Center of Excellence; Katherine Helmick, R.N., deputy director, Traumatic Brain Injury, Defense Centers of Excellence; Alison Cernich, Ph.D., ABPP acting VA senior liaison, Defense Centers of Excellence for Psychological Health and TBI; Dr. Anita Brown, senior subject matter expert, Health Services Group, General Dynamics Information Technology; and Dr. Don Workman, chief of Innovative Applications Division, National Center for Telehealth and Technology.

Society of Armed Forces Medical Laboratory Scientists

The 2012 annual meeting theme is "Lead, Collaborate and Educate." As laboratory professionals, we must continuously strive to educate ourselves and revolutionize our current processes. Learning does not stop with ourselves.
By Major Marybeth E. Luna, USAF

Cover / Q&A

Brig. Gen. Jess A. Scarbrough
Joint Program Executive Officer for Chemical and Biological Defense

Departments

Industry Interview

Dr. David Cullin
Chief Technology Officer
FLIR Systems

MILITARY MEDICAL/CBRN TECHNOLOGY

VOLUME 16, ISSUE 2 MARCH 2012

Dedicated to the Military Medical & VA Community

SUBSCRIPTION INFORMATION

Military Medical/CBRN Technology
ISSN 1097-1033
is published eight times a year by KMI Media Group.

Military Medical/CBRN Technology is free to qualified members of the U.S. military, employees of the U.S. government and non-U.S. foreign service based in the U.S.
All others: $65 per year.
Foreign: $149 per year.

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EDITOR'S PERSPECTIVE

Brian O'Shea
EDITOR

President Barack Obama recently unveiled the 2013 military budget and the results may hit veterans' pocketbooks. The $48.7 billion in medical spending in the 2013 defense budget includes proposals to increase pharmacy co-pays, TRICARE Prime enrollment fees and deductibles for most retirees and raise retail and mail-order pharmacy co-pays in an effort to save costs.

However, the request will not increase fees for active duty servicemembers, survivors of military members who died in active duty, or medically retired servicemembers, said Dr. Jonathan Woodson, Assistant Secretary of Defense (Health Affairs) and Director of TRICARE Management Activity.

Proposed changes include:

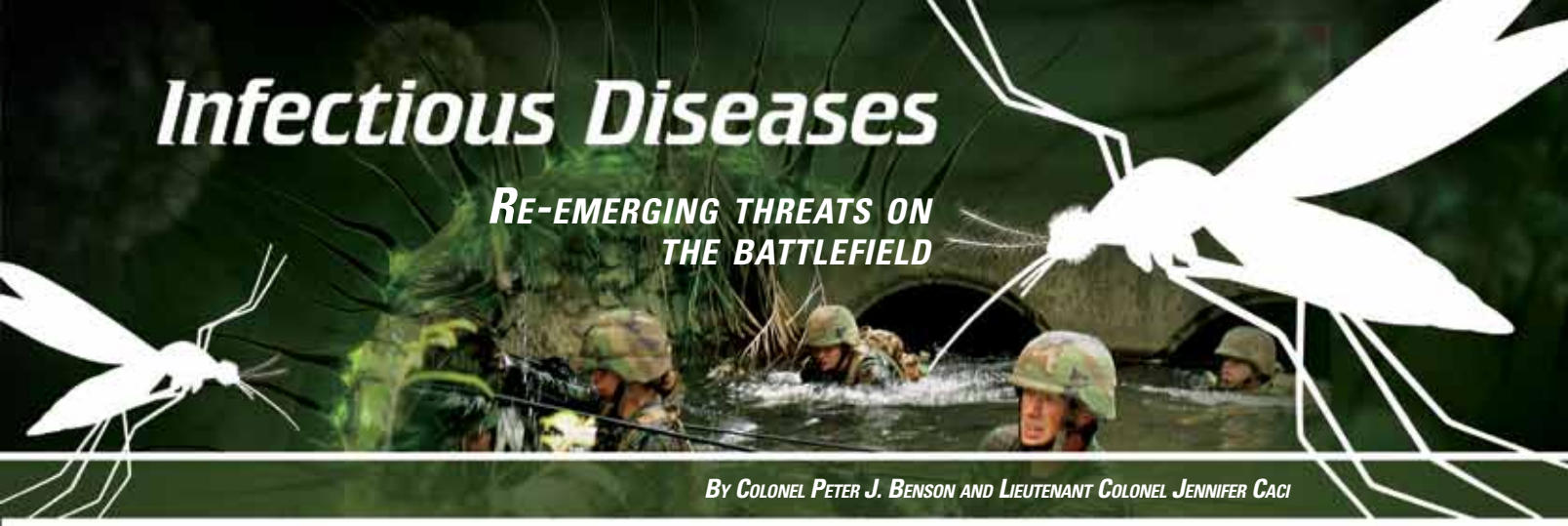
- Increasing enrollment fees for retirees under age 65 in the TRICARE Prime health plan, using a tiered approach based on retired pay that requires senior-grade retirees with higher retired pay to pay more and junior-grade retirees less;
- Establishing a new enrollment fee and increasing deductibles for the TRICARE Standard and TRICARE Extra plans;
- Establishing a new, tiered enrollment fee for the TRICARE-for-Life program for retirees 65 and older;
- Increasing pharmacy co-pays while offering incentive costs for use of mail order delivery and generic medicines;
- Indexing fees, deductibles, pharmacy co-pays, and catastrophic caps to reflect the growth in national health care costs.

In financially difficult times, there are restrictions and limitations on all of us, and the Military Health System is no different in that regard. Whether or not the budget passes has yet to be determined by Congress.

If you have any questions about *Military Medical/CBRN Technology*, feel free to contact me at any time.

Infectious Diseases

Re-emerging threats on the battlefield



By Colonel Peter J. Benson and Lieutenant Colonel Jennifer Caci

Col. Peter Benson

Despite the tremendous advances in military medical capability over the last 100 years, and even with the lethality of modern combat weapons, infectious diseases have consistently been the greatest source of morbidity and mortality throughout the history of warfare. Since 2001, U.S. military personnel have been exposed to a myriad of "Old World" diseases that are not often seen by medical personnel in modern western nations.

Military personnel deployed in underdeveloped areas of the Middle East, Central Asia and Africa are exposed to a host of infectious and vector-borne diseases not usually encountered in routine medical practice. Respiratory and diarrheal diseases are well known as "camp diseases" among operational military populations. Effective vaccination, sanitation and the advent of modern antibiotics have largely prevented these from being significant problems. Some diseases endemic to Afghanistan, Iraq or the Horn of Africa are novel to western providers. Often medical personnel and preventive medicine specialists are unfamiliar with these diseases because they are non-native in their home countries or have long since been controlled or eradicated by public health and vector control programs. Three "old" yet recurring diseases with potential operational impacts are malaria, leishmaniasis and rabies.

Malaria is a known risk to exposed military personnel and remains a constant cause for concern. Eradicated from the U.S. in 1956, malaria is still a threat to forces deployed in Asia, Africa, and Central and South America. Disease estimates range from 100-300 million cases a year with an associated 700,000 to 1 million deaths. The disease is transmitted by the bite of a female *Anopheles* mosquito and the passage of *Plasmodium* parasites into the blood of the human host. The parasites multiply, causing symptoms that typically include fever and headache, in severe cases progressing to coma or death. Mosquitoes capable of transmitting malaria are generally present at altitudes below 2,000 meters and can be found worldwide. It is recently accepted that five species of malaria parasites infect humans, of which *Plasmodium falciparum* causes the most severe disease. Other species generally cause milder symptoms and although rarely fatal are severely debilitating.

Malaria is diagnosed by the combination of symptoms along with laboratory identification of the parasites inside the red blood cells on a thick blood smear. Polymerase chain reaction (PCR) is now used in the laboratory to speciate the parasite and identify its origin. Newer agglutination technology permits effective rapid tests that can be used in the operational field environment. These have simplified the diagnosis in the combat theater with simple blood assay cards that yield a result in 15 minutes with a high degree of sensitivity. This is a tremendous advantage to military providers at forward locations, as it allows for confident malarial diagnosis and treatment without the need for a laboratory.

The malaria risk to deployed personnel is widespread and well documented. In Afghanistan and in the northeastern border region of Iraq, military personnel are at risk of malaria transmission from April through December. In both countries, the disease can appear at any time of year based on the behavior of the parasite and non-compliance with protective medications. The battlefield environment, population dislocations and absent or disrupted public health measures continue to make malaria an ongoing risk to deployed service personnel. The U.S. military reported 959 cases from January 2002 through December 2011, but this number includes only reported cases or those resulting in hospitalizations. It is likely that many more cases occurred and were treated without reporting.

Malarial outbreaks occur when Force Health Protection measures are not strictly enforced. Preserving the combat power of any exposed military force is paramount. Malaria transmission can be reduced primarily by the use of bed nets and insect repellent, augmented with vector control measures such as area spraying of insecticides. Because *Anopheles* mosquitoes are "night-biters" and typically reproduce in larger bodies of water, some frequently-used control measures are not effective. Strict adherence to prophylactic medications regimes with doxycycline, atovaquone-progauanil or mefloquine is paramount. Terminal prophylaxis with primaquine is necessary for deployment to *P. vivax* areas in order to eradicate the latent liver stage of the parasite. The command must clearly highlight the importance of proper wear of permethrin impregnated uniforms and the use of insect repellent and vector control when appropriate.

Leishmaniasis is another disease largely unknown in the U.S. but recently seen among military personnel serving in Iraq and Afghanistan. Over 2,000 cases of leishmaniasis have been diagnosed in military personnel since 2002. The disease is caused by parasites transmitted by the bite of infected sand flies. Leshmaniasis occurs in three forms: the cutaneous form manifests as skin lesions that ulcerate and are often covered with a scab and surrounded by a raised edge; the visceral form spreads to the internal organs and is characterized by fever, weight loss, anemia and enlargement of the liver and spleen; and the mucocutaneous form results in faster growing lesions and deterioration of the soft tissue surrounding the mucous membranes and soft palate. Although cutaneous leishmaniasis

is less systemically disabling, the lesions can be disfiguring.

Until recently, leishmaniasis could only be diagnosed in the laboratory by direct visualization of the parasites from prepared blood samples or aspirates from marrow, spleen, lymph nodes or skin lesions. However, in 2004, the rK39 rapid assay achieved FDA approval for the diagnosis of visceral disease.

There are two medications approved to treat leishmaniasis in U.S. military personnel: amphotericin B (Ambisome) and sodium stibogluconate (Pentostam). In some parts of the world, parasite resistance to these drugs appears to be developing. The need for an effective topical drug for the treatment of cutaneous leishmaniasis resulted in an ongoing U.S. trial of paromomycin, which is so far achieving excellent results. Treatment with paromomycin is relatively inexpensive and fairly easy to administer, meaning there is potential to eventually treat servicemembers in the field or local civilians in military humanitarian missions.

The key in preventing leishmaniasis is protecting the military population from the biting vectors. Education of all personnel to the risk of sand fly bites and the dangers of leishmaniasis is vital. Enforcing good personal protective measures including bed netting, repellent use and treated uniforms is the key to disease prevention.

Rabies is a deadly disease that is often overlooked as a significant military risk. Western nations have longstanding animal control and vaccination programs that limit the exposure of pets and livestock to rabies, but in the developing world, it kills approximately 55,000 people a year. This viral disease is transmitted in the saliva of an infected animal, most commonly by a bite. It travels to the brain via the peripheral nerves, ultimately infecting in the brain and causing death. The incubation period depends on the distance the virus must travel to reach the central nervous system. Symptoms are often delayed for several weeks to months after the animal bite. Early symptoms are malaise, headache, fever and tingling around the bite site; progressing to acute pain, spastic movements, altered mental status, autonomic instability, coma and death. After the virus reaches the central nervous system and symptoms begin, the infection is essentially untreatable and usually rapidly fatal. In humans, rabies is almost invariably fatal if post-exposure prophylaxis is not administered before the onset of symptoms. The Milwaukee Protocol is attributed with saving five lives worldwide, yet the mortality rate due to rabies infection remains over 99 percent.

Rabies can be diagnosed by PCR or viral culture on brain, skin or fluid samples from the infected animal. Brain cell viral inclusion bodies called Negri bodies are 100 percent diagnostic for rabies infection, but are seen in only 80 percent of cases. If possible, the animal from which the bite or exposure was received should be quarantined and observed or sacrificed for tissue examination.

In military personnel in deployed areas, exposure to rabies is overwhelmingly from dog bites. Command policy invariably prohibits the keeping of pets and mascots, vaccinated or quarantined. The key to preventing rabies is command emphasis to ensure that no local pets are kept, or if they are, the animals must be immunized and/or quarantined. If service personnel are bitten by any mammalian animal while deployed, they must be assessed and treated with appropriate post-exposure status based on their vaccination history. Cleansing the wound for 15 minutes with soap and water coupled with immunoglobulin treatment and vaccination before symptom onset is 100 percent effective in preventing clinical rabies. Currently, pre-exposure immunization has been instituted for high-risk groups such as veterinary and special operations personnel.

Commanders and military providers must be aware of what the infectious diseases risks are in the deployed environment. Often, endemic "Old World" diseases are significant threats to the health of the force. Emphasis on awareness of the endemic threats and enforcement of personal protective measures and good sanitation and hygiene is paramount. The threat from infectious disease is real and enduring but also preventable. While combat operations are admittedly high risk, the disease threat to the health and lives of deployed servicemembers has been and still is just as deadly. ✯

Col. (Dr.) Peter Benson is Deputy Chief of Staff and Command Surgeon for the United States Army Special Operations Command. Lt. Col. Jennifer Caci is the senior Environmental Science Officer and the sole entomologist for U.S. Army Special Operations Command.

For more information, contact *MMT* Editor Brian O'Shea at briano@kmimediagroup.com or search our online archives for related stories at www.mmt-kmi.com.

JPEO-CBD Project Management Update

The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) is the Department of Defense single focal point for research, development, acquisition, fielding and life cycle support of chemical, biological, radiological and nuclear (CBRN) defense equipment and medical countermeasures. Eight joint project managers within the JPEO-CBD lead, manage and direct the acquisition and fielding of CBRN detection and reconnaissance systems, individual and collective protection systems, decontamination systems, information management systems, medical devices, drugs and vaccines, and installation and force protection systems. joint project management office leverages talent and expertise from across our nation's armed services under a single chain of command, providing the best CBRN defense technology, equipment and medical countermeasures at the right cost, at the right time and at the right place.

JOINT PROJECT MANAGER FOR BIOLOGICAL DEFENSE (JPM-BD)

Mission:

To create and sustain affordable materiel solutions that accurately detect, identify, warn, deter and defeat any biological threats to joint forces.

Vision:

Lead the world in biological defense system acquisition.

Overview:

The Joint Project Manager for Biological Defense is a dedicated team of acquisition professionals who are charged with providing various biological defense capabilities to the joint warfighter. The organization is located on the Edgewood Area of Aberdeen Proving Ground, Md. This joint project office currently manages the development, fielding and sustainment of point detection systems.

The JPM-BD staff consists of business and operations and the following product areas: Joint Product Manager for Point Family of Systems, Joint Product Director for Stand-off Detection, and Joint Product Director for Strategic Initiatives.

Challenges:

The JPM-BD is continuously looking for cutting edge commercial and non-developmental technology to fulfill operational needs in the area of early warning, point bio-detection and environmental biological surveillance. The JPM-BD partners with industry, academia and other government organizations to find the most effective and affordable material solutions to fill capability gaps and lower the operation and sustainment cost of our existing fleet of biological defense equipment for the warfighter.

2012 Outlook:

The JPM-BD will assess the technology feasibility and the readiness level of candidate biological defense technologies. Investigations into early warning system architectures and environmental biological surveillance will be conducted in order to support initiation of new programs of record. Testing of the Joint Biological Tactical Detection System's competitive prototypes will be completed in preparation for engineering and manufacturing development. Production, deployment and technology refresh of the Joint Biological Point Detection System will continue on through the year.

JOINT PROJECT MANAGER FOR CHEMICAL BIOLOGICAL MEDICAL SYSTEMS (JPM-CBMS)

Mission:

To deliver safe, effective and robust medical products that protect U.S. forces against validated CBRN warfare threats. We apply government and industry best practices to develop or acquire FDA-approved products within rigorously managed cost, schedule and performance constraints.

Vision:

A U.S. military force that is fully sustained to fight and win in any CBRN battlespace worldwide.

Overview:

The Joint Project Manager for Chemical Biological Medical Systems is responsible for research, development, acquisition, fielding and life cycle management of U.S. Food and Drug Administration (FDA)-approved/cleared medical systems for protection, treatment and diagnostic capabilities against chemical, biological, radiological and nuclear warfare threat agents. All CBRN medical countermeasures are approved by and regulated through the FDA. The JPM-CBMS aggressively explores opportunities to partner with other government agencies, industry, academia and allied countries for all CBRN medical countermeasure efforts.

The JPM-CBMS product portfolio includes products spanning the entire acquisition life cycle. The JPM-CBMS is composed of a headquarters and three joint product management offices: The Joint Vaccine Acquisition Program (CBMS-JVAP), Biosurveillance (provisional) (CBMS-BSV), and the Medical Identification and Treatment Systems (CBMS-MITS).

The Joint Vaccine Acquisition Program

The CBMS-JVAP product office consolidates DoD's efforts for advanced development, testing, FDA licensing, production and storage of biological defense vaccines.

The CBMS-JVAP's impressive portfolio of fielded products includes: the Anthrax Vaccine Adsorbed Biothrax; the smallpox vaccine ACAM2000; and the Vaccinia Immune Globulin, a treatment for rare adverse reactions to the smallpox vaccine.

The CBMS-JVAP currently has three products in advanced development to protect the warfighter from warfare threats. Recombinant Botulinum Vaccine will protect the warfighter against Botulinum toxin; Plague Vaccine will protect the warfighter against weaponized aerosolized plague; and Trivalent Filovirus Vaccine (FILO) will protect the warfighter against weaponized Ebola and Marburg viruses. Unlike past CBMS-JVAP vaccine efforts, for FILO, the government has chosen to serve as the systems integrator without a prime systems contractor. This approach not only reduces costs but allows for greater harmonization among the key government agencies collaborating on this important vaccine development.

Biosurveillance

The CBMS-BSV product office develops and integrates state-of-the-art CBRN technologies to enable early warning, identification and situational awareness of CBRN threats to U.S. forces.

The CBMS-BSV coordinates the advanced development of products and tools across the JPEO-CBD, providing technologies and solutions to enable effective biosurveillance. This coordination is accomplished, in part, by working directly with JPEO-CBD Joint Project Managers to integrate within DoD, interagency and international partners to guide their respective biosurveillance-related efforts across the JPEO-CBD. These JPMs include Biological Defense, Contamination Avoidance, Guardian, Information Systems, CBMS, and Transformational Medical Technologies.

The CBMS-BSV's portfolio includes the Critical Reagents Program and two diagnostic programs: The Joint Biological Agent Identification and Diagnostics System (JBAIDS) and the Next Generation Diagnostic System (NGDS).

Medical Identification and Treatment Systems

Warfighters need pharmaceuticals, including drugs and biological products, for maximum protection against exposure to CBRN agents. The Medical Identification and Treatment Systems Joint Product Management Office, CBMS-MITS, provides the warfighter with lifesaving drug capabilities by developing, stockpiling, and fielding drugs and devices.

The CBMS-MITS serves as the life cycle manager for the FDA-approved and fielded Convulsant Antidote for Nerve Agents, Antidote Treatment Nerve Agent Autoinjector, and Soman Nerve Agent Pretreatment Pyridostigmine.

Continuously seeking to strengthen the CBMS-MITS portfolio and expand the capabilities currently in the warfighter's arsenal, advanced development efforts within CBMS-MITS include Bioscavenger, Advanced Anticonvulsant System, and Medical Radiation Countermeasures.

Challenges:

Overcoming challenges is part of any program's path to achieving its mission. CBMS looks forward to overcoming its unique challenges in part through continued focus on collaborating and partnering with other organizations, maintaining quality standards, focusing on regulatory compliance, leveraging best practices for program life cycle management and planning for the future.

The CBMS-JVAP challenges include: 1) the timeline to develop and gain FDA licensure is longer than most DoD acquisition programs, 2) challenges of developing biologics with the Animal Rule since post licensure studies are required, 3) the regulatory pathway to ensuring licensure is still evolving, and 4) biodefense vaccines have a limited commercial market because large pharmaceutical company interest is difficult to attract.

A number of national strategy policy documents call for achieving interagency biosurveillance objectives. A common theme in these policies is the need to protect our military and civilian population from traditional, emerging and advanced biological threats. The CBMS-BSV strives to meet this challenge every day by developing aggressive schedules to field products quickly. By bringing communities together, understanding each other's needs, and appreciating the equities that each brings to the national mission, these challenges can be conquered. CBMS-BSV continues to look for ways to contribute wisely to overcoming challenges to best support the warfighter.

In our current fiscally constrained environment, CBMS-MITS challenges include budgetary and other hurdles such as: 1) receiving invoices from industry partners in a timely manner to meet accelerated Office of the Secretary of Defense expenditure goals, 2) overcoming our success, which puts us lower on the priority list than other areas, and 3) maintaining a portfolio mix of relevant fully-funded and stakeholder supported products that satisfy capability needs.

2012 Outlook:

The 2012 outlook for JPM-CBMS includes a passionate commitment to protecting our warfighters and an unrelenting focus on pushing ahead to receive FDA licensure for our products in advanced development.

The CBMS-JVAP recently finished a phase II clinical trial with the botulinum toxoid vaccine and will complete a phase II clinical trial for the RF1V plague vaccine during this fiscal year; both of these products will reach a Milestone C [low rate initial production] decision during fiscal year 2013. The fiscal year 2012 new start CBMS-BSV NGDS effort will provide advanced chemical, biological and radiological warfare threat diagnostic and analytical capabilities to the warfighter. The vision for NGDS is it will have the ability to significantly improve performance over the current JBAIDS platform, enhancing these capabilities across the continuum of threats and operations by 2017, while reducing the logistics burden and sustainment costs. The CBMS-MITS is preparing to transition the Centrally Acting Nerve Agent Treatment System and the Chemical Warfare Agent Prophylaxis and Pretreatment Pharmaceuticals programs from the technology base into advanced development in fiscal year 2014. This will further address capability gaps in our existing treatment regimen to counter nerve agent threats. Additionally, CBMS-MITS expects to have many successes in 2012: Bioscavenger is targeted to reach Milestone B, and Advanced Anticonvulsant System will gear up for new drug application submission to the FDA and Milestone C.

JOINT PROJECT MANAGER FOR GUARDIAN (JPM-G)

Mission:

Provide integrated capability to vigilantly protect our homeland, deployed forces and coalition partners to enable rapid response, mission execution and restore our way of life.

Vision:

Be the Joint Guardian: Always present, never seen; a joint enabler preparing for the worst, poised to save lives and act decisively when the unthinkable occurs.

Overview:

The Joint Project Manager for Guardian's mission is to protect our forces and the American people from threats that pose the greatest risk to national security in the face of a changing, complex and uncertain security landscape. To accomplish this mission, JPM-G employs a "whole-of-government" approach to fielding capabilities as directed in Presidential Policy Directive (PPD-8) while adhering to the guidance provided in the National Defense Strategy, Joint Operating Environment Report, the Quadrennial Defense Review Report, National Response Framework and other Department of Defense guidance. These documents are aimed at strengthening the security and resilience of the United States. They call for systematic preparation for threats that pose the greatest risk to the security of the nation, including acts of terrorism, cyber-attacks, pandemics and catastrophic natural disasters. The JPM-G is dedicated to developing, fielding and sustaining integrated capabilities that prepare and protect our homeland, installation and tactical forces. The JPM-G fields CBRNE defensive, physical security, force protection, emergency management and weapons of mass destruction consequence management capabilities that fuse, automate and integrate data from disparate systems to assist commanders in planning for, responding to and recovering from all-hazard threats and/or incidents. Our capabilities are employed in tactical operations, on forward operating bases, DoD installations (continental United States and outside the continental United States), and in support of domestic and foreign consequence management (CM) operations. The JPM-G is comprised of Product Manager Force Protection Systems, Product Director Emergency Management, Product Director Integrated Base Defense, and Joint Product Manager Consequence Management.

Challenges:

The JPM-G's capabilities include physical security, force protection and consequence management for combat outposts, forward operating bases, DoD installations and homeland security, providing "Fort to Foxhole" enterprise all-of-government solution sets. Force protection and physical security requirements, technology and information exchange is a rapidly changing environment. The JPM-G's main challenges lie in the continued improvement of delivering integrated systems and/or family of systems solutions in order to provide capabilities that can be employed by multiple users in a variety of operational environments that are integrated and governed by one set of information management standards. These challenges require continual and effective collaboration and integration across a complex user community that includes the services, joint staff, combatant commands and interagency partners. In a time of shrinking government budgets and mission space overlap developed during 10 years of war, JPM-G realizes the value and efficiency of developing and providing all-of-government capabilities. These efforts are extremely hard to establish, institutionalize and maintain with other program offices and strategic partners. Requirements and funding are often program specific, and integrating these into a system-of-systems architecture requires project and product managers to understand other systems and their concepts of operation to provide a holistic and more capable system of systems. In order to address these

challenges, JPM-G has employed the concept of trail boss, an innovative management method for integrating and synchronizing efforts with its Integrated Base Defense program. The trail boss concept is to provide an objective integrating and synchronizing management effort, which coordinates programs/products across multiple Program Executive Offices across the Office of the Assistant Secretary of the Army for Acquisition Logistics and Technology portfolios to create enhanced network architecture of capabilities. JPM-G employs the trail boss concept with Integrated Base Defense to fuse product lines for enhanced situational awareness, data fusion, perimeter security, entry control, warning and reporting, response monitoring, and assistance in recovery and restoration into a singular capability that maximizes re-use of current capability (low acquisition cost) and reduced logistical footprint with reduced troop to task.

2012 Outlook:

The JPM-G has an enduring footprint on installations and experience with bio-monitoring and information sharing. Many of the missions supported by JPM-G are by nature, interdependent with civilian organizations and inherently interagency. JPM-G continues to expand its mission in integrating installation/forward operating base defense and response capabilities, force protection and physical security systems, and consequence management and homeland defense. Guardian will continue to expand in integrated base defense, emergency management and modernization, and fielding of rapid response tunneling detection capabilities.

Several new and exciting products and capabilities will be under development in JPM-G during 2012. Product Manager Consequence Management will continue the development of the Common Analytical Laboratory System (CALS). The CALS provides a tailorable, modular, scalable and transportable laboratory capability that provides CBRN-related data and information for processing, exploitation and dissemination in near real time to assist commanders in planning, preparing and executing passive defense, CM, weapons of mass destruction (WMD) interdiction/elimination operations, and force health protection. Other enabling capabilities include interoperability that supports battlespace and operating environment management systems, and the ability to provide responsive network sharing to other DoD components, the intelligence community and CBRN reachback agencies.

The Product Director-Emergency Management and Modernization Program is a new program initiated to develop a single integrated acquisition program for the design, procurement, fielding, new equipment training and life cycle management of emergency management capabilities in support of the Army installations and their assigned soldiers, civilians, contractors and family members. This program will provide a common operating picture (COP) capability for installation emergency operation centers, mass warning and notification to notify all installation personnel within 10 minutes of incident verification, and enhanced 911 to notify dispatcher of caller's location and to broadcast emergency notifications out to designated locations.

Product Director–Integrated Base Defense utilizes the successful trail boss management concept to provide overarching force protection encompassing an enterprise architecture that is scalable between fixed site, semi-fixed/expeditionary and mobile (deployable force protection), leading to improved information management, fusion, automation and integration. This is a broad effort spanning multiple program executive offices, joint services and coalition forces. Also, PD-IBD is currently fielding the Command Outpost Surveillance Force Protection System, also known as Kraken. The Kraken provides critical surveillance and force protection enhancement to small units operating at remote COPs, Ops, and strong points. It allows for detection, identification, targeting and engagement of enemy forces prior to their ability to engage these small elements.

The use of tunnels represents a growing threat to U.S. security and defense interests at home and abroad. Adversaries have demonstrated evolving capabilities to use tunnels to gain access to and transport illegal drugs, people and potentially, weapons and WMDs into the homeland and our overseas installations. The JPM-G's Product Manager for Consequence Management, along with the U.S. Army Corps of Engineers-Engineer Research and Development Center, are teamed to counter this threat with the Rapid Response Tunneling Detection System joint capability technical demonstration (JCTD). This system uses the Border Tunnel Activity Detection System, seismic acoustic point sensors, seismic linear sensors (fiber optics), active seismic imaging system, electromagnetic imaging systems, robotic platforms and infrared cameras, and integrates these technologies into a user-friendly COP.

JPM-G, with our research and development partners, is working several other JCTDs to transition and provide additional capability to the warfighter. In conjunction with DoD's Defense Threat Reduction Agency, we are working the National Technical Nuclear Forensics JCTD, which will increase accuracy and reduce time to reach technical nuclear forensics conclusions after a nuclear or radiological attack to enhance national command authority and military commanders' strategic execution of attribution activities, response options and first responder safety. Along with JPM-NBC CA, JPM-G is working to transition the rapid area sensitive-site reconnaissance, a capability which will rapidly survey large areas and assess and identify contamination with chemical warfare agents, toxic industrial chemicals, or non-traditional agents. Emerging efforts for JPM-G with JCTDs include the Integrated Installation Robotics Surveillance Security System to deliver a robotic system capable of performing manned guard force tasks and functions, such as monitoring secured areas and gates, patrolling performing intruder detection and physical security tasks. Lastly, in conjunction with DTRA and DoD's Joint Science and Technology Office, JPM-G will develop and demonstrate a capability for resilience in countering a wide area biological incident that impacts U.S. and partner nation civilian and military personnel and key infrastructure with the Transatlantic Collaborative Biological Resiliency Demonstration.

The JPM-Guardian remains ever vigilant and our people deeply committed and ready to support the warfighter and the nation … to always be present, but never seen. We are prepared for the worst, but are poised to save lives and act decisively when the unthinkable happens. We are JPM-Guardian.

JOINT PROJECT MANAGER FOR INFORMATION SYSTEMS (JPM-IS)

Mission:

Provide the information architecture and applications required to shape the battlespace against the chemical, biological, radiological and nuclear threat.

Vision:

Provide the warfighter with integrated, early warning capability, an accredited hazard prediction model, and state-of-the-art consequence management and course of action analysis tools.

Overview:

The JPM-IS manages the acquisition of chemical biological defense program (CBDP) information systems, with first increments of two programs of record (Joint Effects Model and Joint Warning and Reporting Network) currently fielded and second increments in the advanced development process. In addition to fulfilling this traditional acquisition program office role within the JPEO-CBD, JPM-IS uniquely functions as the primary focal point for all information management/information technologies (IM/IT) issues and requirements that impact CBDP programs and their development. Recognizing the need to address the complex and often conflicting demands of integrating legacy and disparate information systems across the enterprise, remaining current with host system requirements, keeping abreast of ever-changing commercial technologies, and using cutting edge standards and industry best practices, the JPEO-CBD assigned the JPM-IS additional duties as the IM/IT trail boss (leader) and the director, Software Support Activity (SSA). To this end, JPM-IS assists other JPEO project offices and various external agencies with technical expertise and guidance regarding their IM/IT-related program requirements by providing subject matter expertise and assistance in meeting demanding requirements such as information assurance certifications. The SSA continues to refine the CBRN common sensor interface standard so all CBRN sensors and detectors can seamlessly integrate with JWARN. In addition, the SSA provides IM/IT liaison personnel to other joint project management offices within the JPEO-CBD, including JPM-NBC CA, JPM-BD, JPM-CBMS, JPM-P and JPM-G offices. This holistic approach to meeting IM/IT requirements across the JPEO-CBD enables an enterprise-wide approach to program development, resulting in reduced development costs, greater efficiencies and better buying power.

Joint Warning and Reporting Network (JWARN)

The Joint Warning and Reporting Network enables an immediate and integrated response to threats of contamination by WMD through rapid warning and dissemination of CBRN information. JWARN provides a single, validated and accredited implementation of Allied Tactical Publication 45 (ATP-45) with the capability to predict and display the hazard associated with CBRN/toxic industrial chemical/material events.

The JWARN is a computer-based application that integrates CBRN data and facilitates sensor information into joint and service command and control systems for battlespace situational awareness. The JWARN generates a plot of the hazard area, displays it on the common operational picture and generates the warning message to units within the hazard area. The JWARN operates in near real time and replaces the current manual process of incident reporting, hazard plot generation, and warning of affected forces. It reduces the time from incident observation to warning to less than two minutes, enhances situational awareness throughout the area of operations, and supports warfighter battle management tasks.

The JWARN Increment 2 will provide increased targeted capabilities, and JPM-IS anticipates a successful materiel development decision and Milestone A in fiscal year 2012. The JWARN contracting strategy calls for a prototyping contract followed by a production contract in fiscal year 2013.

Joint Effects Model (JEM)

The JEM is a web-based, software-only application that supplies DoD with the single accredited and operationally-tested high fidelity, physics-based tool to effectively model and simulate the effects of CBRN weapon strikes and incidents. JEM combines the best components from previously existing CBRN science and technology models. It provides rapid estimates of hazards and effects that can be integrated into the COP and supports planning to mitigate the effects of WMD.

JEM Increment 1 is currently in the production and deployment/operations and support phase. A GCCS-M full development decision is anticipated in the fourth quarter of fiscal year 2012. A modernization effort is planned for Increment 1 that includes upgrades to existing fielded capabilities, operating system upgrades, information assurance updates, Web browser upgrades and command and control system architecture changes.

JEM Increment 2 will continue to design and build sustainability into the JEM architecture and software by further decoupling its individual components from each other in order to decrease the costs in maintenance, new development and integration, making it easier and faster to integrate capabilities.

Information Management/Information Technology Trail Boss Initiatives

As the JPEO-designated IM/IT trail boss, JPM-IS leads the effort to build the JPEO-CBD enterprise framework that will enable interoperability and horizontal integration of all CBD

programs with information systems content. A robust JPEO-CBD enterprise framework will result in reduced costs, shorter development cycles and more efficient acquisition of IM/IT capabilities. In addition, critical DoD priorities such as biosurveillance and the Global Conventional Weapons of Mass Destruction Awareness System (GCAS) effort are being supported by JPM-IS IM/IT subject matter experts.

The JPEO-CBD Software Support Activity, managed by the JPM-IS, provides core capabilities associated with implementing standards and policy, architectures, information assurance, and modeling and simulation. These capabilities are critical to achieving systems engineering consistency across the entire CBDP enterprise. Several SSA products, notably the CBRN common sensor interface standard, were created to provide commonality within sensor and detector standards, protocols and data streams.

2012 Outlook:

The JPM-IS will press forward on several fronts in 2012. First, JPM-IS will continue to develop and field follow-on increments of JEM and JWARN capabilities to the warfighter at an affordable cost enabled by better buying power initiatives. Second, JPM-IS will continue to address the JPEO-CBD IM/IT enterprise-wide, net-centric requirements needed to achieve seamless levels of interoperability across the entire CBDP portfolio of programs, projects and efforts. Third, JPM- IS will continue to provide support for DoD high priority efforts such as biosurveillance and GCAS.

As in the past, JPM-IS will rely upon industry's help in identifying and leveraging the most promising and cost-effective information technologies available to meet IM/IT requirements. JPM-IS looks forward to working with industry partners to achieve success as we move forward in this extremely challenging and dynamic environment.

JOINT PROJECT MANAGER FOR MEDICAL COUNTERMEASURES ADVANCED DEVELOPMENT AND MANUFACTURING (JPM-MCM ADM)

Mission:

To develop a national capability and capacity to produce medical countermeasures rapidly to counter known and unknown chemical, biological, radiological and nuclear threats, including novel and previously unrecognized, naturally-occurring emerging infectious diseases.

Vision:

A dedicated, cost-effective and domestic capability that provides a flexible, adaptive and scalable advanced development and transformational manufacturing center of excellence.

Overview:

The Medical Countermeasures Initiative (MCMI) began in response to a December 2010 White House Memorandum to the Secretary of Defense. The MCMI has been established to develop a national capability that will allow the U.S. government to counter known and unknown chemical, biological and radiological attacks or naturally-occurring emerging infectious diseases. This initiative stemmed from the 2009 H1N1 flu pandemic and the inability to rapidly produce a vaccine in a timely manner. A naturally occurring disease or a terrorist attack using CBR agents may seem like a public health issue, however, the effects of disease outbreaks and biological warfare could devastate U.S. military readiness and operations. The military force health protection is a DoD responsibility and priority. As a result, the Joint Chemical, Biological Defense Program is working closely with the Department of Health and Human Services to establish this national capability. Additionally, the MCMI team will also work with other departments to reduce cost, synchronize activities and eliminate overlap. While MCMI is a national capability, the MCM ADM will be an enduring and dedicated capability for DoD. The DoD component complements efforts by Health and Human Services, but differs significantly in focus area and scale.

The White House memorandum calls on DoD to establish three components: science and technology, advanced development and manufacturing, and test and evaluation (T&E). The deputy assistant to the Secretary of Defense for Chemical and Biological directed that the JPEO-CBD, through the Army Executive Agent, manage the advanced development and manufacturing component. The ADM will be a DoD-dedicated capability that provides DoD MCM developers with a set of core services; contract manufacturing organization (CMO), contract/clinical research organization (CRO), T&E, and fill and finish (F&F). Additionally, the ADM and its core services will have the ability to be tailored to the needs of each contractor as well as provide valuable lessons learned from previous development, which will be passed on to the next MCM contractor. These services will increase DoD's efficiency through the application of lessons learned to future MCM developments while lowering cost and schedule.

2012 Outlook:

JPM-MCM ADM released a request for proposal in August 2011, and contract award is planned for the third quarter of fiscal year 2012. Establishment of the ADM CMO component will occur within the base period, while the other core service components of CRO, T&E and F&F will be available shortly after contract award.

A key feature of the JPM-MCM ADM is its ability to be a flexible, tailorable and multi-facility. Unlike traditional facilities that use fixed stainless steel bioreactors and produce one product, the ADM will use modular and disposable single-use equipment to allow for flexibility in manufacturing multiple MCM products within one facility. The contractor will complete facility commissioning within 24 months following contract award. The contractor will also provide the expertise necessary to maintain the facility's readiness to support the development and manufacture of MCMs and conduct training. The ADM capability will also support the transition and integration of enabling science and technology, including novel platform and expression systems, and advancements in regulatory science. Once this capability is established, DoD will issue future separate contracts for specific MCM products, thus creating an MCM pipeline.

Working with the JPEO-CBD medical enterprise, JPM-MCM ADM will support the rapid advanced development of medical countermeasures to FDA licensure. With its flexible and modular manufacturing, JPM-MCM ADM will be able to manufacture multiple FDA-approved products within 30 days of receipt of order and respond to surge requirements. The JPM-MCM ADM, in concert with JPM-CBMS and JPM-TMT, represent the JPEO-CBD's dedication to protecting the warfighter. The JPM-MCM ADM's goal is to evolve

processes to develop and improve capabilities countering the effects of chemical, biological and radiological threats, including novel and previously unrecognized, naturally-occurring emerging infectious diseases.

JOINT PROJECT MANAGER FOR NUCLEAR, BIOLOGICAL, AND CHEMICAL CONTAMINATION AVOIDANCE (JPM-NBC CA)

Mission:

The JPM-NBC CA develops, produces, integrates, tests, fields and sustains NBC detection, obscuration and reconnaissance systems. We ensure our system development efforts integrate materiel solutions and services that focus on joint warfighters' needs within cost, schedule and performance.

Vision:

The JPM-NBC CA vision is to equip and sustain the world's most capable, powerful and respected joint forces with world-class chemical, biological and radiological contamination avoidance products, capabilities and services.

Overview:

The JPM-NBC CA is a team of dedicated acquisition professionals responsible for efficiently providing effective operational capability to the joint warfighter. The organization is located on the Edgewood Area of Aberdeen Proving Ground, Md. This joint project office currently manages the development, fielding and sustainment of obscuration and NBC contamination avoidance programs.

Organization:

The JPM-NBC CA staff consists of business and operations, logistics, fielding, new equipment training, test/evaluation management and the following product areas: 1) Product Director Sensors, 2) Product Director Cross-Commodity Advanced Threats and Test Infrastructure, and 3) Joint Product Manager Reconnaissance and Platform Integration.

Challenges:

The JPM-NBC CA is continuously challenged to do more with less. Technical challenges include identifying cutting-edge commercial and non-developmental technology to fulfill urgent operational needs; providing cost-effective sustainment solutions for highly complex, low-density NBC systems deployed worldwide; and developing reliable detection/identification capabilities for nontraditional and toxic industrial threats.

2012 Outlook:

The JPM-NBC CA will assess technology feasibilities and readiness levels for next generation chemical point detectors. Developmental chemical and biological capabilities will be verified and validated for program of record insertion. Dismounted reconnaissance sets kits and outfits developmental and operational testing will be conducted to support the Milestone C decision. Traditional and nontraditional agent rapid initiative capabilities will continue to be developed, tested and fielded. Stryker-NBC Reconnaissance Vehicle full-rate production projects will initiate for JPM-NBC CA provided mission packages. Test and evaluation capabilities for traditional and nontraditional chemical agents; current and future biological detectors; reliable simulant release referee instrumentation packages; and individual protective ensemble mannequin systems will continue to be designed, validated and delivered to the DoD test and evaluation community.

JOINT PROJECT MANAGER FOR PROTECTION (JPM-P)

Mission:

Develop, field and sustain CBRN protection and hazard mitigation capabilities for the nation.

Vision:

Promote a creative and innovative workforce focused on acquiring capability to defend the nation against CBRN threats.

Overview:

The Joint Project Manager for Protection provides both direct and indirect support to the nation's CBRN defense. As the DoD total life cycle manager for individual and collective protection as well as hazard mitigation equipment, JPM-P develops, fields and sustains CBRN protection and hazard mitigation capabilities.

Primarily, these capabilities include equipment such as protective garments and respirators, equipment and personnel decontamination, and collective protection shelters and systems. The JPM-P also provides subject matter expertise as required or upon request.

The JPM-P not only provides equipment to DoD but also supports federal agencies such as the Department of Homeland Security and Federal Bureau of Investigation and provides products for foreign military sales. This equipment provides all customers with the protection required to effectively conduct active combat, consequence management and homeland defense operations in CBRN threat environments.

Subject matter expertise in the area of CBRN defense is another product JPM-P provides. A recent example is the support provided during the Fukushima Daiichi nuclear disaster. Requests for information as to potential threats posed by the reactor, as well as recommended protection and hazard mitigation actions, were answered for both DoD and international customers.

In addition to total life cycle management responsibilities for CBRN equipment, JPM-P is also tasked with the mission of serving as the Major Defense Acquisition Program (MDAP) CBRN survivability trail boss. The MDAP trail boss facilitates the research, development, testing, procurement, operations and sustainment, and delivery of CBRN survivability requirements and force protection systems and subsystems. This support is provided for both DoD programs designated as CBRN mission-critical and those that are not in an effort to meet the CBRN requirements of these programs.

In order to successfully accomplish its mission, the MDAP trail boss develops, demonstrates and provides CBRN survivability and force protection solutions that are integrated into DoD acquisition program architectures and schedules in order to provide capabilities that allow missions to be performed in CBRN threat environments. Specific tasks or responsibilities of the MDAP trail boss include:

- Being the "Go-To" resource for assisting CBRN mission-critical programs in meeting their CBRN requirements
- Maximizing DoD return on investment by leveraging JPEO-CBD expertise and product portfolio to provide programs with CBRN survivability capabilities
- Providing a full range of acquisition support and engaging early in the acquisition life cycle
- Providing to MDAPs a system engineering team designed to specifically address CBRN requirements, regardless of platform

Challenges:

The JPM-P faces increased pressure to maintain delivery schedule, equipment performance and perform total life cycle management of CBRN protection and hazard mitigation programs as a result of budget reductions in fiscal year 2012. In order to maintain its portfolio, JPM-P will employ creative acquisition approaches and efficiencies to maximize utilization of shrinking resources. Additionally, JPM-P works with its stakeholders to look for ways to garner efficiencies across the entire life cycle of programs. This comprehensive approach provides cost savings to the warfighter as well. Improved efficiencies will be pursued to synergize JPM-P needs and priorities with other government agencies. Leveraging these synergies is key to "doing more without more" during these times of fiscal austerity.

2012 Outlook:

Fiscal year 2012 is proving to be a pivotal period for JPM-P. Fiscal challenges have resulted in a reduction in structure. Despite the challenges, JPM-P will continue to comprehensively procure and manage support for fielded CBRN protection and hazard mitigation systems as well as develop and mature increased capabilities through the technology development and engineering and manufacturing development phases.

Specific acquisition programs vital to meeting warfighter requirements in the future include the Uniform Integrated Protection Ensemble, Joint Expeditionary Collective Protection, and the Decontamination Family of Systems. The introduction of these items into the DoD inventory will increase warfighter capability and safety while decreasing cost, environmental impacts, and the logistical and physical burdens associated with CBRN protection and hazard mitigation.

In the role of MDAP trail boss, JPM-P will also continue to promote the early development of CBRN survivability requirements across DoD and provide the subject matter expertise required to facilitate research and implementation.

The JPM-P will continue to improve alignment of science and technology efforts with recognized warfighter capability gaps to leverage scarce resources. Additionally, proactive collaboration and effective partnerships with interagency organizations, government and international labs, academic institutions and industry will be pursued. All of these strategies will ensure that JPM-P continues to develop materiel solutions to deliver the right operational capability, at the right time, to our customers worldwide.

JOINT PROJECT MANAGER FOR TRANSFORMATIONAL MEDICAL TECHNOLOGIES (JPM-TMT)

Mission:

JPM-TMT expedites development and delivery of innovative medical solutions to prepare and protect warfighters and the nation against biological warfare agents and emerging infectious diseases.

Vision:

To protect the warfighter and the nation from biothreats.

Overview:

JPM-TMT facilitates the advanced development and acquisition of broad-spectrum medical countermeasures (MCM) and systems to enhance our nation's biodefense response capability.

Challenges:

Aligning the "Possible" with the "Requirement"

In addition to the routinely recognized drug development challenges of cost, schedule and performance, JPM-TMT must also address the warfighter requirements, which may not always align with the many technical challenges associated with MCM product attributes, and the FDA's drug approval process. The challenge for JPM-TMT is to strike a balance between fielding critical MCM against

threats for which no countermeasure exists and providing capabilities that meet warfighter requirements.

Navigating the Interagency Investment in MCM for Biodefense

Securing, preserving and justifying funds for development of MCM that meet DoD needs while significant investments are being made for MCM development for the civilian population—often for the same threats—presents a challenge for JPM-TMT. To remain relevant, JPM-TMT strives to leverage existing investments and identify specific gaps to ensure unique DoD requirements are met.

Going Above and Beyond the National Response to Biothreats

Embracing the "transformational" aspect of its undertaking, JPM-TMT invests in the advanced development of innovative MCM against biothreats that otherwise would not be undertaken by the private sector due to risk and cost considerations. To enhance the national response to preparedness and rapidly develop MCM and systems against biothreats, JPM-TMT must continue to collaborate with interservice, interagency and industry partners and ensure that the DoD's stringent acquisition process is aligned with the safety and efficacy criteria of the FDA.

2012 Outlook:

Hemorrhagic Fever Virus (HFV) Class MCM

JPM-TMT's HFV Class MCM acquisition program will continue to develop broad-spectrum and/or platform-based MCM to mitigate the effects of HFV exposure. The initial design concept is to develop an FDA-approved MCM against members of the HFV Filoviridae family (Ebola and Marburg viruses) based on highly adaptable technologies. There are no vaccines or therapeutics available against the highly deadly Ebola and Marburg viruses.

One of JPM-TMT's contractors, AVI BioPharma, is developing drugs based on its technology platform, phosphorodiamidate morpholino oligomers (PMOplus). Recently, their lead HFV therapeutic candidates for Ebola (AVI-6002) and Marburg (AVI-6003) have each successfully completed the single-ascending dose (SAD) studies as part of the Phase 1 human clinical trials. A "fast track" designation was granted by the FDA to AVI-6002. By granting this designation, the FDA recognizes that AVI BioPharma's Ebola drug candidate, AVI-6002, has the potential to fill an unmet medical need and their development plan has the ability to gain the data necessary to evaluate whether the drug will fulfill that need. This designation also gives AVI BioPharma priority in scheduling meetings and reviews with the FDA in discussing the development of AVI-6002. AVI-6002 and AVI-6003 are both set to begin the multiple ascending dose (MAD) studies in June 2012.

The FDA also has granted another JPM-TMT contractor, Tekmira Pharmaceuticals, approval to proceed with clinical trials for its Stable Nucleic Acid Lipid Particle platform-based Ebola drug candidate, TKM-Ebola. The dosing of the first volunteers to test the safety of TKM-Ebola began in January 2012 and the complete reports from the SAD and MAD studies are expected before January 2013.

Emerging Infectious Diseases-Influenza (EID-Flu) MCM

The EID-Flu MCM acquisition program will continue supporting the development of a broad-spectrum and/or platform-based MCM that targets multiple influenza virus strains, including the H1N1 virus. The focus will be on therapeutics that interfere with the infection process to prevent or reduce symptoms of an influenza infection. Drug candidates are intended for post-exposure prophylaxis and/or post-exposure, post-symptomatic treatment. JPM-TMT anticipates awarding a contract in spring 2012. Pending successful contract award, FDA clinical trials could begin as early as October 2012.

Response Systems and Predictive Systems

JPM-TMT's proposed response systems and predictive systems capabilities would seek to field solutions to enhance CBRN military operations and improve mission planning effectiveness.

Two requests for information (RFI) were released in January 2012 and closed in February 2012. To address the interest for a response system capability, one RFI sought solutions that can put biological identification capability in the hands of dismounted warfighters. JPM-TMT envisions a lightweight handheld device (less than 3 pounds), interoperable with existing military batteries, cost less than $10 per test, and capable of rapidly identifying hundreds of different biological agents—including emerging or genetically modified pathogens—at the point of discovery/ infection. JPM-TMT is collaborating with the JPEO-CBD biosurveillance trail boss, JPM Biological Defense, and JPM Chemical-Biological Medical Systems to support the JPEO-CBD's current and future biosurveillance efforts and enhance CBRN early warning and military medical operations. Several acquisition strategies are being considered for this effort.

The second RFI sought predictive systems solutions that will aggregate and relate relevant data to build a prediction engine for selected regions and diseases. Advance knowledge of future pathogenic theater conditions will enable military planners and decision-makers to make accurate and timely medical and operational decisions that will protect the warfighter, improve medical logistics planning and mitigate health risks. JPM-TMT is collaborating with the JPEO-CBD biosurveillance trail boss, JPM Information Systems and other supporting JPMs within JPEO-CBD to integrate this predictive capability within the Joint Effects Model.

Animal Models and Enabling Technologies

Developing animal models of infection is a critical part of JPM-TMT's process of developing medical countermeasures. Data from animal models are required by the FDA before testing of a medical countermeasure can occur when testing in humans is too dangerous or unethical. JPM-TMT is advancing small and large animal models for evaluation of medical countermeasures intended to mitigate the effects of exposure to aerosolized biological pathogens. JPM-TMT and partners from the U.S. Army Medical Research Institute for Infectious Diseases and the U.S. Army Medical Materiel Development Activity have submitted a Letter of Intent to the FDA requesting qualification of the only animal model for the aerosolized Ebola virus infection—the first ever to go through the FDA's new process for qualification of animal models. In FY12, JPM-TMT convened strategy and planning sessions with representatives from across the biodefense community to collaboratively chart the path forward for addressing the FDA's input. The full briefing package for the FDA will be submitted in spring 2012. JPM-TMT's unique efforts and collaboration with the biodefense community and the FDA will benefit the DoD, other government agencies, and the medical community at large. Specifically, its involvement with the Filovirus Animal Nonclinical Group—a working group of government agencies collaborating on projects to ensure that dollars spent by one group ultimately benefit many other groups—increases the chances of success for model systems and MCM developers. ✯

For more information, contact *MMT* Editor Brian O'Shea at briano@kmimediagroup.com or search our online archives for related stories at www.mmt-kmi.com.

FDA Clears Single-Use Negative Pressure Wound Therapy System

Smith & Nephew plc, a global medical technology business, announced the FDA clearance of the pocket-sized Pico system, a single-use negative pressure wound therapy (NPWT) system. Pico is cleared for use both in a hospital and homecare setting and expands the use of NPWT from the traditional wound care population to include a wider range of patients undergoing orthopaedic surgery, plastic surgery and general surgical procedures. This FDA clearance follows the recent successful launch of Pico in Europe, Canada and Australia.

The Pico system is indicated for chronic, acute and traumatic wounds, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts and closed surgical incisions. The Pico system is as easy to apply as a conventional wound dressing, reducing the need for the staff time, intensive training and administrative paperwork associated with traditional NPWT. The simple application technique can be viewed online via an MS Tag included on the packaging.

The Pico system's one-button pump is easy-to-use and its small size and silent operation provide a discreet, unobtrusive way to carry on daily life with NPWT. The disposable device works with a revolutionary dressing technology that manages fluids, eliminating the need for bulky canisters. The system can be worn on a wound up to a week, depending on the level of exudates. Its gentle silicone wound contact layer helps minimize pain at a dressing change.

The Pico system is more affordable than traditional NPWT, and can significantly reduce therapy costs associated with traditional NPWT. The Pico system is available off-the-shelf and therefore may reduce the occurrence of delayed hospital discharges.

Adapting Sonar Technology for Multiple Applications

ITT Exelis and Altapure LLC are introducing an advanced disinfection system to decontaminate medical, military and other critical equipment and facilities. The two companies have worked jointly for the past seven years to develop a portable nebulizer that eradicates viruses, bacteria, spores and fungi in less than 10 minutes.

Exelis adapted its piezoelectric ceramic-based technology—developed initially so underwater sensors could be the eyes and ears of submarines—to enable the nebulizer to disinfect areas, equipment and electronics effectively and efficiently. The system has been successfully piloted in targeted hospitals, and Exelis and Altapure now plan to offer the technology for additional commercial and defense applications.

"After seeing the nebulizer's impact in select hospitals across the country, we realized the system could make a real difference in many areas," said Chris Bernhardt, Exelis executive vice president and president of the Electronic Systems division. "From treating contaminated public buildings and military aircraft that have been subjected to biological agents, to disinfecting tainted food and keeping food processing facilities clean, we see many ways our piezoelectric ceramic technology can provide safer environments through the Altapure nebulizer."

The Exelis technology enables the ultrasonic subsystem of Altapure's nebulizer to deliver a robust, dense cloud of sub-micron droplets, providing high-level disinfection or decontamination of large areas. This approach results in the destruction of a wide range of pathogens at a reduced time and expense and at greater efficacy when compared to existing methods. This automated operation reduces the need for manual cleaning and decreases the risk of human exposure. The Altapure solution is non-corrosive, leaves no residue and is approved by the Environmental Protection Agency. Rooms treated by the nebulizer can be reoccupied within 30 minutes.

This is the second significant commercial application of the Exelis sonar technology within the past year. In 2011, Exelis signed an agreement with the oncology company, NovoCure, to provide its piezoelectric ceramic technology to help treat brain cancer.

Automated Education and Training-Plan Management

Siemens Healthcare Diagnostics launched PEP [Personalized Education Plan] Administrator, an innovative web-based software solution giving clinical laboratory managers a way to simplify and streamline administration of education and training programs for their staff. PEP Administrator is an extension of Siemens' recently-launched PEP—the industry's first virtual competency-based clinical laboratory education model that can be personalized for each staff member. Designed with an intuitive interface, PEP Administrator enables education managers to guide, plan and monitor the progress of every learner according to her/his specific competency needs, seamlessly consolidating continuing education from any source and automatically summarizing the progress of every staff member.

Beyond serving as a single source for consolidated training program management, PEP Administrator also automates the time-consuming administrative tasks required to achieve compliance. As such, organization-wide training invitations, status reports, certifications of completion and compliance verification are now all accessible in real time and are as simple as a keystroke.

PEP is available exclusively to Siemens Healthcare Diagnostics customers as part of the company's Customer Care portfolio, which includes services and support, education and training and workflow management. PEP is currently available in multiple languages.

PEP Administrator reflects Siemens' continuing innovation leadership, which is a goal of the recently launched Siemens Agenda 2013 program: an initiative to further strengthen the health care sector's innovative power and competitiveness.

New Technology for Ultrasound Probe Disinfection

Commonly used ultrasound transducer liquid disinfection systems use hazardous chemicals that were introduced nearly 30 years ago. These disinfection systems may expose users to toxic chemicals, introduce extensive work flow requirements and can require substantial time. DoD hospitals and VA medical centers across the U.S. are updating disinfection protocols to include the latest in disinfection technology. Most recently this includes the implementation of a new system, the Trophon EPR.

Trophon EPR (Environmental Probe Reprocessing System) is a software-controlled ultrasound transducer disinfection device that provides several advantages. First, the system helps eliminates toxic chemical exposure to the patient, technician and to the probe. It uses a unique platform technology to effectively disinfect the transducer, including the shaft and handle. A hydrogen peroxide-based proprietary solution is nebulized within a closed system into a highly concentrated hydrogen peroxide vapor, which is distributed through the chamber. The high-level disinfection vapor spreads like a gas but retains liquid properties, completely immersing the pre-cleaned transducer. Solution cartridge replacement is accessible through a side door on the system, allowing the user to avoid contact with the solution. With the Trophon EPR, operators are exposed to less risk both because the system is closed (eliminating chemical exposure) and because the by-products are environmentally friendly—water vapor and oxygen. The environmentally friendly properties of the solution and improved workflow process help keep equipment functioning with reduced risk of image quality issues.

Second, the Trophon EPR provides an opportunity for workflow improvements and provides a convenient disinfection system. Measuring only 19.3 inches tall and 13.6 inches wide, the Trophon takes up a small amount of space and requires no drainage system. It can be used at point-of-care, so time used to take probes to central supply or other designated disinfecting areas could be eliminated. In addition to a wall-mount option, a mobile cart is available for the Trophon EPR, allowing the 38-pound system to be moved easily. It only requires a standard power outlet. The replacement solution comes in a convenient lightweight 80ml sealed cartridge that can be used for up to 40 cycles.

Lastly, the Trophon EPR may provide users substantial time savings related to their high-level transducer disinfection process. The amount of time required to reach high-level disinfection in the Trophon system is precisely seven minutes, while other processes may require up to 45 minutes. The disinfected transducer can be used immediately after a cycle is complete, once the probe has been wiped, reducing wait times. After approximately 40 cycles, the Trophon cartridge replacement door will automatically open and cartridge replacement takes approximately 1 minute or less without any mixing or measuring. In addition, Trophon EPR's software constantly monitors time, temperature and dose

parameters. When the cycle is complete a chemical indicator changes color to verify that the minimum effective concentration of disinfectant was delivered.

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Vaccine Candidate Under Development as Counter Measure

CSC announced recently that DynPort Vaccine Company LLC (DVC), a CSC company, has completed a Phase 2 clinical trial for its recombinant botulinum vaccine candidate, rBV A/B. The vaccine was safe and well-tolerated, and elicited a strong immune response.

The rBV A/B is being developed for the protection of adults 18 to 55 years of age from fatal botulism caused by inhalational intoxication with two serotypes of botulinum neurotoxin.

This Phase 2 clinical trial evaluated rBV A/B or placebo in 440 healthy adults, comparing two dosing schedules administered intramuscularly at 0, 28 and 182 days or 0, 56 and 182 days. The primary safety objective was to assess the safety of rBV A/B compared to placebo. The primary immunogenicity objective was to evaluate the neutralizing antibody rate in volunteers given rBV A/B or placebo.

The rBV A/B was immunogenic in healthy volunteers at the dosage and schedules used in this clinical trial. The maximum immune responses to both BoNT serotypes were observed 28 days after the third dose. More than 94 percent of the volunteers maintained detectable neutralizing antibody concentrations for at least one year after the third dose, indicating that rBV A/B elicited a strong immune response.

Committed Defender

Q&A

Achieving an Integrated Medical and Non-Medical Joint CBRN Program

Brigadier General Jess A. Scarbrough
Joint Program Executive Officer
JPEO-CBD

Brigadier General Jess A. Scarbrough is the Joint Program Executive Officer for Chemical and Biological Defense. His responsibilities include the research, development and acquisition of all chemical and biological defense equipment and medical countermeasures for the United States armed services.

Scarbrough was commissioned a Second Lieutenant in Air Defense Artillery (AD) aftergraduating from the University of Arizona with a Bachelor of Arts degree in political science. Upon graduation, he was assigned to the United States Army – Europe (USAREUR) and Seventh Army as a Unit Commander responsible for Nuclear Surety on a NATO Nike Hercules AD Missile Site. In 1985, Scarbrough was reassigned to III Corps and Fort Hood, Texas, where he served in multiple operational assignments as a Battalion S4 and Battery Commander in a Division AD Chaparral/Vulcan Battalion. In 1988, he was reassigned to the 31st Air Defense Artillery Brigade, III Corps and served as the chief of the Air Defense Element.

In 1989, Scarbrough entered into his functional area; research, development and acquisition and has served in numerous acquisition management and staff positions to include: project manager for the Army's Tactical Exploitation of National Capabilities Program and director, Army Space Program Office; Program Executive Office (PEO) for Intelligence, Electronic Warfare and Sensors (IEW&S); and product manager for the Army's Information Warfare Program, PM Signals Warfare, PEO IEW&S.

Scarbrough's other assignments include program director, Special Operations and Conventional Special Programs, Office of the Under Secretary of Defense for Acquisition and Technology; director, International Cooperative Programs Activity, United States Army Research, Development and Engineering Command; chief of Staff to the Army Acquisition Executive, and assistant deputy, Acquisition and Systems Management, Office of the Assistant Secretary of the Army for Acquisition, Logistics and Technology.

Scarbrough has earned two Master of Business Administration degrees from the University of Oklahoma and in Strategic Studies from the United States Army War College. Other professional schooling includes the AD Officer Basic and Advanced Courses, the Army's Command and General Staff College, the Air Force Air Command and Staff College, the Department of Defense Systems Management College, and the National Defense University's Capstone General and Flag Officer Course.

His decorations and awards include the Legion of Merit with one oak leaf cluster, the Defense Meritorious Service Medal, the Army Meritorious Service Medal with six oak leaf clusters, the Army Commendation Medal with one oak leaf cluster and the Army's Achievement Medal with one oak leaf cluster. He is also authorized to wear the Office of the Secretary of Defense Identification Badge, the Army Staff Identification Badge, the Army Air Assault Badge and the German Air Force Air Defense Badge in Bronze.

Q: What is on the horizon as far as JPEO-CBD's involvement with drug discovery and development?

A: The JPEO-CBD supports drug discovery and development by advancing specific products and, more importantly, by creating innovative processes and tools to generate new medications, enable regulatory approval and enhance mass production.

Part of our strategy is to seek broad-spectrum therapeutics that are effective against a wide range of pathogens. This will simplify medical care and logistics in the battlefield. An example of an innovative approach we are pursuing is the rapid modification of an adaptable platform technology to generate therapeutics for new pathogens. The JPEO-CBD sponsors the advancement of broad-spectrum medical countermeasures [MCMs] by investing in synthetic RNA or RNA analogues that can be rapidly tailored to "silence" disease-causing genes. Already, JPEO-CBD-sponsored scientists produced MCM candidates to show treatment effects in influenza and dengue. Three candidates—two for Ebola virus, one for Marburg virus—protected non-human primates during pilot studies and are in Phase I clinical trials for safety in humans. When fully FDA-approved, these will be the first medications to treat Ebola and Marburg infections. Preliminary research suggests that this approach will be effective against a wide range of viruses and bacteria.

Another key focus is the development of animal models. The MCMs we deliver must be proven effective to obtain regulatory approval from the U.S. Food and Drug Administration [FDA]. Data from animal

models are required by the FDA to assess efficacy of an MCM when testing in humans is too dangerous or unethical. Our partners have requested FDA review of the first non-human primate model of aerosolized Ebola infection—the first submitted into the FDA's new process of animal model qualification.

In fiscal year 2012, DoD established a new effort, known as the Medical Countermeasures Initiative for Advanced Development and Manufacturing. In support of this initiative, the JPEO-CBD created the Joint Project Manager for Medical Countermeasures Advanced Development and Manufacturing [JPM-MCM ADM]. We know that the agile development and manufacturing of MCMs in quantities to treat affected populations rapidly is vital. To this end, we are working hand-in-hand with HHS to create a national biodefense rapid manufacturing capability. DoD is looking to address the needs of military personnel while HHS is focusing on large scale production to address the needs of the U.S. population. Additionally, the JPM-MCM ADM team will forge partnerships with other federal departments and international allies to reduce cost, synchronize activities and eliminate overlap.

Q: What is the top challenge of chemical/biological threats in today's operational environment, and how have they evolved over the past year?

A: The strategic environment has undergone a significant shift in recent years. The chemical/biological threat is expanding from traditional chemical and biological warfare agents to emerging and nontraditional agents. The threat is also changing from Cold War state military tactics to terrorist employment of these agents. Controlling the biological threat is likely to become the critical challenge because of the rapid proliferation of biological knowledge and the inherent dual-use nature of the biological warfare enabling technologies. Biological agents are relatively easier and cheaper to develop than nuclear weapons. As such, biological agents have the potential to be far more destructive than chemical agents and may be viewed by some as a valuable asymmetric weapon.

Biosurveillance is becoming a very important mission across the various departments of the federal government. The JPEO-CBD is concerned with data-gathering and analysis of biosphere data related to disease activity and threats to human or animal health—whether infectious, toxic, metabolic, or otherwise—to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity.

In response to this challenge, the JPEO-CBD is working with other agencies and international allies to counter the challenge of emerging threats. Biosurveillance at JPEO-CBD is focused on developing systems that integrate information from sensors and sharing information with multiple agencies to respond faster and more effectively to bioterrorism or an infectious disease. The JPEO-CBD is also working on a Next Generation Diagnostic System to field a more comprehensive and certified diagnostic tool. Additionally, we are developing MCMs to rapidly and safely respond to emerging infectious diseases with pre- and post-symptomatic treatments.

Q: How does JPEO-CBD work with industry to acquire and develop the most up-to-date technological advancements while maintaining a balance between effectiveness and cost savings?

A: The JPEO-CBD regularly engages with industry to understand technological advancements and convey warfighter requirements that lack a technological solution. One avenue most familiar to our industry partners is the annual Advanced Planning Briefing to Industry, or APBI, hosted by the JPEO-CBD. The APBI is one of the best forums for us to make those key contacts and build relationships with industry leaders and technology developers who may design a next-generation device or a therapeutic the nation's warfighters can utilize. Our 2012 APBI will be held September 19-21 in Baltimore, Md. We will devote two days of the APBI to one-on-one discussion opportunities between industry representatives and our joint project managers. We encourage industry to utilize these sessions to convey their latest technological breakthroughs to us. I believe our APBI events achieve a level of openness and access that is much appreciated by industry. [Their website: www.jpeocbd.osd has additional information regarding the 2012 JPEO-CBD APBI].

We are always seeking technical innovation. The JPEO CBD engages in the major industry conferences and co-hosts government science and technology conferences and seminars. My joint project managers, contracting officers and other personnel within the organization continually engage in market research ventures. These ventures include hosting technical briefings by industry representatives on new capabilities and products and making frequent visits to industry labs to survey technologies.

We ensure a close relationship with the Defense Threat Reduction Agency's Joint Science and Technology Office. They execute the science and technology portion of the DoD's Chemical Biological Defense Program and transition technologies through research and development, experiments and demonstrations. We share the responsibility for maintaining a robust technology industrial base with that office by informing their investments in basic research so that it can support our research and development efforts.

Achieving the right balance between cost and effectiveness is very important to us. In support of this, we have implemented competitive prototyping into our advanced development programs. Competing designs and technologies are compared not only for procurement and total life cycle cost, but also for achievement of Key Performance Parameters and other key attributes. This allows us to perform rigorous trade space analyses and make informed, best value decisions for the DoD and the taxpayer.

All of our programs actively pursue 'Should-Cost' management in support of DoD's Better Buying Power initiatives. Teams scrutinize every element of program cost to identify how those elements can be conducted more efficiently, thus reducing overall program cost. Our early success in implementing the Better Buying Power initiatives demonstrates our commitment to providing warfighting capability at the absolute best value to the taxpayer.

Q: What challenges would the JPEO-CBD like industry to address?

A: We realize that concepts of threat response to address emerging chemical and biological agents require more rapid detection, assay response and analysis. Fielded biological detection and medical diagnostic equipment and information systems must be quick, versatile and adaptable. The capability to support surveillance missions, tactical early warning and post-event monitoring must be provided. Ideally, systems will have to monitor many indicators and provide near real-time detection and confirmatory analysis. Utilization of the large amount of new data from these tools will rely on the creation of predictive modeling and analysis tools. These tools will map and interpret health activity in likely vectors [animals, humans and

plants], provide early indications and warnings and provide decision-makers with accurate situational awareness.

Effective support of the military will rely on lightweight, versatile, point-of-care diagnostics as well as the acceleration of the development of broad-spectrum medical countermeasures—pretreatments, prophylaxes and therapeutics for protection against CBRN exposure. All of our fielded MCMs require FDA licensure. These products must also be compatible with the medical logistics, medical information systems and sustainment capabilities of diverse military operations. Additionally, features such as ruggedized packaging along with reduced size, weight, power usage and logistical burden are often factors when acquiring and developing our products.

The JPEO-CBD depends on the innovation and products of our supporting industrial base. We will continue to communicate our needs and interact with industry through our annual APBI, open data calls such as requests for information on www.fbo.gov and by Small Business Innovative Research opportunities. In addition, industry partners are encouraged to learn about our needs through our website www.jpeocbd.gov, a phone call, or even an office visit.

Q: What are the greatest challenges when coordinating interaction with civilian emergency response agencies, and what does JPEO-CBD do to mitigate those challenges?

A: Establishing and maintaining collaborative relationships is challenging when coordinating with emergency response agencies. Our dynamic and diverse portfolio requires an approach that exemplifies fielding whole-of-government solutions in addressing national security and homeland defense. To meet the challenge, we've established Memoranda of Understanding [MOUs] with various federal partners to facilitate information sharing and technologies and to leverage existing information sources such as concept of operations and capabilities. The MOUs established with other agencies are the administrative mechanisms by which we link our stakeholders to the solutions needed to credibly operate in the all-hazards community and beyond. These agreements enable the JPEO-CBD to provide holistic solutions to warfighters, the DoD CBRN Response Enterprise and DoD Installation emergency responders to integrate among other federal, state and local partners and their respective programs. It is always more efficient and effective for all CBRN or all-hazards capabilities to be developed in-house as a standalone solution.

Training is critical to success. When our capabilities are fielded to provide emergency management, consequence management and/or provide defense support to civil authorities' operations, the new equipment training and exercise packages are developed and conducted in concert with the National Incident Management System, the National Response Framework and the Homeland Security Exercise and Evaluation Program. We strongly encourage state and local police, fire, emergency medical services, public health and medical provider participation during these fielding operations. The JPEO-CBD fully understands that all incidents are local and, as a result, develops and fields systems that integrate domestic prevention, preparedness, response, and recovery activities into a single, all-hazard discipline.

Another challenge is providing integrated and interoperable solutions that offer real-time warning, a common operating picture and enable timely information sharing when preparing for, responding to and recovering from an all-hazard threat or incident. The days of providing our commanders with single-use, standalone capabilities are long past. This causes an unacceptable level of risk for emergency response forces as well as unaffordable costs associated with operating and maintaining these different systems. Whenever possible, the JPEO-CBD ensures its information management systems are integrated and interoperable to meet the needs of multiple users like warfighters, CBRN response forces and installation emergency responders. Our Emergency Management Modernization Program has a network-based Decision Support System that bridges communication gaps by providing near real-time data to DoD officials and has the ability to share non-sensitive data with local responders.

Q: What major initiatives does the JPEO-CBD plan to implement in 2012?

A: Our portfolio has shifted a bit but still consists of a balanced mix of medical countermeasures that include prophylaxes, therapeutics, biosurveillance and diagnostics as well as non-medical equipment, such as CBRN individual protection, detection, force protection, decontamination and information technology/information management.

In particular, we always seek ways to expedite the drug approval process while ensuring the rigid acquisition regulations within DoD and the safety and efficacy criteria of the FDA are fulfilled. The creation of the Joint Project Manager for Medical Countermeasures Advanced Development and Manufacturing will assist in this effort.

Q: How has the FDA's decision to "fast track" a drug candidate to fight the highly lethal hemorrhagic fever virus (HFV), Ebola, improve your Joint Project Manager for Transformational Medical Technologies' effort to battle this threat?

A: The FDA's decision to Fast Track AVI-6002, Joint Project Manager-Transformational Medical Technologies' [JPM-TMT] drug candidate for Ebola, is another significant milestone for the JPEO-CBD. Currently, no other government-sponsored drug candidates for Ebola have been granted a Fast Track designation. The FDA has acknowledged that Ebola is a serious disease for which there is no treatment. The development of AVI-6002 [by AVI BioPharma], fulfills an "unmet medical need." AVI-6002 is anticipated to have a positive impact on the outcome of Ebola infection, in this case, improved survival. A Fast Track designation will permit AVI BioPharma to have more frequent meetings and other communications with the FDA to ensure that, among other things, the design of and data collected in planned studies will support their drug's approval. The Fast Track designation will also make AVI-6002 eligible for Accelerated Approval and Rolling Review. An Accelerated Approval will allow AVI BioPharma to use substitute endpoints that are reasonably likely to predict clinical benefit. A Rolling Review will allow the company to submit sections of its final drug approval application as they are completed rather than waiting until all work is completed, thus speeding up the approval process. Finally, most drugs that achieve the Fast Track designation are considered appropriate to receive a Priority Review, which means that, whenever possible, the FDA will preferentially direct overall attention and resources to process the application for drug approval. While Priority Review does not guarantee approval, it can shorten the length of time needed for the regulatory process by 4 months or more. ★

Post-Traumatic Stress Disorder

REASONABLE ACCOMMODATIONS FOR VETS WITH PTSD UNDER THE AMERICANS WITH DISABILITIES ACT.

By W. Thomas Smith, Pharm.D., J.D.

A growing number of military personnel, both active and retired, suffer from post-traumatic stress disorder (PTSD). A 2009 Congressional hearing revealed that more than 300,000 veterans of Operation Iraqi Freedom and Operation Enduring Freedom were believed to be suffering from PTSD or major depression. Moreover, a report from 2007 indicated that there were about the same number of soldiers currently deployed who suffer from PTSD or depression.

The U.S. Department of Veterans Affairs diagnoses PTSD using the American Psychiatric Association's diagnostic criterion set forth in the fourth edition of its Diagnostic and Statistical Manual of Mental Disorders. There are six criteria: a stressor; intrusive recollection; avoidant/numbing; hyper-arousal; duration of the symptoms lasts more than one month; and a functional significance, causing significant distress or impairment in social, occupational, or other important areas of functioning.

Manifestations of PTSD, such as feelings of extreme fear, helplessness, or horror occur after someone witnesses a traumatic event involving severe injury and/or death. Persons suffering from PTSD oftentimes experience difficulty falling or staying asleep, have nightmares or daytime memories of the traumatic event, become exaggeratedly startled, and feel emotionally numb and detached from others. Consequently, many of these individuals become addicted to drugs and alcohol, lose their jobs (if they have them in the first place), become homeless, engage in acts of domestic violence, perpetrate violent crimes, and/or commit suicide.

With regard to employment, many newly-discharged veterans are finding it difficult to find and maintain employment in the civilian sector. Veterans living with PTSD are struggling, especially because many of them do not self-identify as having a condition that may affect their ability to do their jobs effectively. Additionally, employers struggle because they simply do not understand how to accommodate for conditions that are unseen. It is much easier, for example, for an employer to construct a ramp for an employee in a wheelchair as opposed to accommodating symptoms of PTSD such as panic attacks, lapses in memory and poor concentration. However, just because it is more challenging for employers to provide such accommodations certainly does not mean that they can get away with not providing them.

When it was enacted a little more than 20 years ago, the Americans with Disabilities Act (ADA) intended to protect individuals who were discriminated against due to physical and/or cognitive characteristics beyond their control. Title I of the ADA provides statutory recourse to acts of employment discrimination. Congress' intent with this particular section of the law was to stop employers from making decisions based on disability. At the time, employers typically did not hire individuals with physical and/or cognitive challenges, and if they did employ such individuals, they likely would not adequately accommodate them. Because these employees were not provided with the accommodations that would essentially allow them to be on a level playing field with all other employees, they were unable to optimally perform; as such, this provided employers with the ammunition needed to discharge them. If ever challenged, employers simply (and successfully) argued that these individuals just could not perform the job for which they were hired.

As stated above, the ADA was poised to dispose of such discriminatory practices in the workplace. Unfortunately, this law did not have the transformative effect it was expected to have. Over the years, as a result of decisions handed down by federal courts, it became increasingly difficult for individuals with a wide array of limiting conditions to prove that they had disabilities that would qualify them for protection under the ADA. Disability under the ADA is defined as (1) a physical or

mental impairment that substantially limits one or more major life activity of such individual (referred to as the "actual" disability), (2) a record of such an impairment, or (3) being regarded as having such an impairment. Under the actual definition of disability, a plaintiff was considered disabled if he/she suffered from a physical (including sensory) or mental impairment that essentially prohibited him/her from engaging in an activity that constitutes a major life activity (such as caring for oneself, performing manual tasks, walking, seeing, speaking, breathing, learning or working). In lawsuits brought by employee plaintiffs claiming disability discrimination, defendant employers generally argued that such plaintiffs were not sufficiently impaired to qualify for protection because their impairments did not "substantially limit" them from performing any one or more major life activities, thus disqualifying plaintiffs from requested relief under the ADA. Because it was much more difficult to prove that the accommodations provided were reasonable (or that it was reasonable not to provide them in the first place), employers found it much easier to go on the offensive and claim that their employees just were not "disabled enough."

In 2008, the ADA was amended in order to restore its intent, as well as the scope of protections for people with disabilities under the law. According to the amendments, the question of whether an individual's impairment is a disability under the ADA should not require extensive analysis; rather, the analysis should focus instead upon whether entities covered under the ADA (like employers) have complied with their obligations. Additionally, the amendments require that the term "substantially limits" in the actual prong of the definition of disability must no longer be interpreted so strictly that it creates too demanding a standard for qualifying as disabled under the law. In passing the amendments, Congress intended that the definition of disability be construed by courts in favor of broad coverage of individuals under the law.

With the enactment of the amendments to ADA, in a disability discrimination lawsuit, a plaintiff with a physical and/or mental condition who is unable to perform any one or more major life activity is going to be much more likely today to demonstrate that he/she is a person qualified to receive the protections of the ADA. Such protections include employers providing reasonable accommodations to their legally disabled employees. It is important to note that employers are not required to provide extravagant or unnecessary accommodations; the law simply requires that they provide accommodations that are reasonable. And the reasonableness of accommodations is a question of fact for juries. Today, plaintiffs are much less likely to be dismissed at the steps of the courthouse because they are not "disabled enough"; instead, they will get inside where juries will hear the facts of the case and decide whether the accommodations provided (or not provided) were reasonable.

Because today's courts are expected to be much more welcoming to employee plaintiffs with disabilities, the time is ripe for veterans with PTSD to assert that they have conditions that qualify them as disabled under the ADA. Accordingly, their employers are mandated to provide them with reasonable workplace accommodations. If employers fail to provide such accommodations, then these veterans should seek justice in courts of law. Plaintiffs' lawyers should have much less difficulty demonstrating that their clients with PTSD are substantially limited in performing major life activities under the amended ADA. Major life activities that those with PTSD may have trouble performing may include thinking, concentrating, and learning. And, because substantially limited no longer means significantly restricted or completely prohibited, plaintiffs with PTSD should be able to show that, while at some times they are perfectly capable of performing these major life activities, at other times they cannot perform them due to their condition. This change in the ADA has the propensity to benefit the millions of veterans living with this hidden condition. It is now time for these veterans to come forward and demand what is rightfully owed to them. ✭

W. Thomas Smith is on faculty at the University of Florida College of Pharmacy in the Department of Pharmaceutical Outcomes & Policy. Smith teaches courses involving pharmacy law and ethics, as well as drug regulation and policy. Smith's scholarship focuses primarily on disability education in pharmacy and other health professions, and on legal and ethical issues related to disability and health care. Smith holds leadership positions in the American Bar Association Health Law Section and in the American Society for Pharmacy Law.

For more information, contact *MMT* Editor Brian O'Shea at briano@kmimediagroup.com or search our online archives for related stories at www.mmt-kmi.com.

USAMRIID

Developing biodefense solutions to protect the nation.

By Leonard A. Smith, Ph.D.

Since 1969, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Md., has been the Department of Defense's lead laboratory for medical biological defense research. While our core mission is to protect the war fighter from biological threats, we also investigate disease outbreaks and threats to public health. Research conducted at USAMRIID leads to medical solutions—therapeutics, vaccines, diagnostics, and information—that benefit both military personnel and civilians.

We support all phases of medical product development, from basic science to research/discovery, development, test and evaluation (RDT&E) of medical countermeasures, and we develop and refine diagnostic assays for biological agent identification. We also provide specialized education and training for military medical providers, laboratory personnel, first responders and the CBRN community.

As the only DoD laboratory equipped to safely study highly hazardous pathogens requiring maximum containment at Biosafety Level 4, USAMRIID is uniquely positioned to develop and maintain biological safety, security and surety standards to meet multiple levels of regulatory oversight. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command.

Medical Product Development

USAMRIID's RDT&E efforts have resulted in the development of vaccines to protect against anthrax, botulism, plague, the Ebola and Marburg hemorrhagic fever viruses, Hantavirus, ricin, and Staphylococcal enterotoxin B, all of which are in various stages of clinical trials. We are continuing to develop new and improved vaccines, working with the Food and Drug Administration (FDA) to move medical products forward using the "animal rule." Under this rule, specifically designed for biodefense vaccines and drugs, products can be considered for FDA licensure using data from animal studies in cases where human clinical trials cannot ethically be conducted. USAMRIID continues to be a leader in developing animal models for a variety of biothreat agents and validating that these models adequately reproduce critical aspects of human disease.

Our proprietary technology for non-replicating, vector free virus-like particles (VLPs) has been licensed to Integrated Biotherapeutics for continued development of multivalent hemorrhagic fever vaccines to protect against the Ebola and Marburg filoviruses. This technology, initially developed at USAMRIID, has demonstrated high protective efficacy in nonhuman primates (NHPs). Another promising technology pioneered by USAMRIID is based on VEE Replicon Particles (VRPs). In this system, the infectious cDNA gene from Venezuelan equine encephalitis virus is cloned and inserted into a replicon construct so that its structural genes are replaced with a different gene of interest for immunization purposes. Multivalent VRPs are currently in advanced development for protection against filoviruses. The VRPs and VLPs will be compared and the best vaccine candidate will be forwarded for Milestone B development.

Current human vaccines for anthrax are based on the protective antigen (PA) component of the anthrax toxins. However, concerns about reliance on a single antigen and vaccine-resistant anthrax strains have prompted the search for additional vaccine components. USAMRIID is working to develop the anthrax capsule, a naturally occurring component of the bacterium that causes the disease, as a vaccine candidate. We recently reported the first successful use of this capsule vaccine to protect NHPs from disease, and further studies are planned. Addition of the capsule to PA to create a multi-component vaccine may broaden and enhance the protection afforded by PA-based vaccines.

USAMRIID's therapeutics program is focused on the RDT&E of broad-spectrum antiviral and antimicrobial drugs against multiple biothreat agents. We also continue to discover and develop therapeutic interventions for diseases caused by toxins such as botulinum neurotoxin.

In cooperation with the Defense Threat Reduction Agency (DTRA), USAMRIID has developed a state-of-the-art Genomics Center capable of high-speed and high-quality sequencing, comparative genetics and genotyping of diverse microbial pathogens that are considered potential biological warfare or bioterrorism agents. This capability will enable tracking of the emergence of pathogenic or drug-resistant strains and understanding of the molecular basis of virulence and pathogen-host interactions, allowing medical personnel to mount a broad-spectrum response to biological threats to the warfighter.

Rapid Diagnostic Technologies

USAMRIID develops new and improved affinity-based immunodiagnostic reagents using recombinant DNA technologies and molecular assays utilizing polymerase chain reaction (PCR) for identification of biological agents. This work allows for the development of new, faster assays for medical identification to protect the warfighter against biothreat agents.

We continue to evaluate and develop diagnostic instruments and technologies for use in forward field medical laboratories and with the Joint Biological Agent Identification and Detection System (JBAIDS). This includes evaluating the MSD multiplexing immunoassay platform and developing and evaluating the Block III expansion of the JBAIDS to include several new biothreat agents.

Thanks to a partnership with the Centers for Disease Control and Prevention (CDC) and the DoD Global Emerging Infections Surveillance and Response System, USAMRIID transitioned the CDC diagnostic assays for avian influenza and swine flu to the JBAIDS platform, enabling all military organizations with the JBAIDS platform to utilize the CDC assays for rapid detection of these

viruses. In addition, we performed the necessary studies leading to an emergency use authorization (EUA) from the FDA for use of these assays on the JBAIDS platform.

That work has led to a new approach for pre-positioning critical diagnostic assay data packages for rapid EUAs in the event of an emerging biothreat. In collaboration with the FDA, the CBMS-JPO, and the U.S. Army Medical Materiel Development Agency, USAMRIID is developing data packages for pre-EUA of these assays. The packages support JBAIDS and ABI 7500 Fast Dx platforms used by DoD and public health/Laboratory Response Network (LRN) laboratories. Thus far, we have developed and prioritized 73 PCR assay data packages and submitted them to the FDA as candidates for pre-EUA package development.

If USAMRIID is called to assist with a disease outbreak investigation or a threat to public health, our Diagnostic Systems Division and Emergency Operations Center (EOC) will surge to meet the demand. As part of the nation's LRN, USAMRIID would collaborate with CDC to rapidly characterize suspected pathogens. Our EOC can reach into the Institute's RDT&E assets to consult the right subject matter experts for the most challenging cases. Whether the request comes from a Combatant Command or another federal agency, USAMRIID stands ready to assist in any biological contingency.

Training and Education Initiatives

Research performed at USAMRIID is translated into state-of-the-art information for medical providers, laboratory personnel and first responders through our training and education programs. USAMRIID and the U.S. Army Medical Research Institute of Chemical Defense jointly conduct the Medical Management of Chemical and Biological Casualties (MCBC) course to prepare military and civilian health care professionals to effectively manage casualties of chemical and biological agent exposure. Utilizing a mix of classroom instruction, laboratory work and field exercises, it is the only training of its kind. MCBC is offered as a six-day resident course each quarter and as an abbreviated "road course" for CONUS and OCONUS audiences several times per year. Materials are also available via several distance-learning and web-based training methods. Since its inception, over 110,000 health care providers have been trained through MCBC course offerings.

USAMRIID also sponsors the Field Identification of Biological Warfare Agents (FIBWA) course to train medical laboratory personnel in a realistic field setting, duplicating the austere conditions that might exist in war fighting theaters. Coursework is designed to certify technicians on fielded diagnostic systems, giving them hands-on training that culminates in a situational training exercise at the conclusion of the course. Materials and modules are tailored to student and unit requirements. In addition to the standard 4-week FIBWA course, training options are available for Civil Support Team (CST) personnel and laboratory managers/decision-makers. Since 1999, FIBWA has reached 645 personnel from the Army, Navy, Air Force, Marine Corps, National Guard, Federal Bureau of Investigation, Department of Health and Human Services/CDC and other countries.

Our newest offering, the Biological Agent Identification and Counterterrorism Training (BAIT) course, provides realistic training scenarios, facilities and subject matter experts to increase the ability of first responders to handle a biological threat event. Training can be customized based on the organizations involved and projected threats. Since 2009, the BAIT course, held at our field training site at Fort Detrick, has reached 24 combined teams (156 personnel) from local, state and federal HAZMAT, CST and law enforcement agencies.

Setting the Standard for Biological Surety

Biological surety, or biosurety, is comprised of systems and procedures to properly safeguard Biological Select Agents and Toxins (BSAT) against theft, loss, diversion, or unauthorized access or use, and to ensure that operations are conducted in a safe, secure and reliable manner. USAMRIID's biosurety program is governed by a broad set of federal, DoD, U.S. Army and U.S. Army Medical Command regulations and policies, which have been either newly published or modified since 2001. Our program consists of four key areas: safety, physical security, personnel reliability and agent accountability.

The first priority is maintaining a safe and secure environment for our workforce and the surrounding community. USAMRIID's comprehensive safety program emphasizes safety training, risk management, environmental surveillance and occupational health screening. Our physical security program uses layered security measures to allow only authorized individuals access to the areas in which BSAT are stored or used. These individuals must satisfactorily complete laboratory safety training, physical examination screening and a security background investigation. Our personnel reliability program requires that all individuals who have completed the requirements for BSAT access also undergo a personnel records review, a medical evaluation, and an interview with the certifying official highlighting individual responsibilities, reliability standards and reporting requirements. Agent accountability involves inventory control, shipping, transfer and destruction records, and observation of laboratory procedures.

USAMRIID has led the nation in development and implementation of its biosurety program, setting the benchmark for other laboratories engaged in the national biodefense effort.

A Unique National Asset

For over 40 years, USAMRIID has responded to epidemics and developed protective medical countermeasures against the world's deadliest diseases. It provides DoD and the biodefense community with unique facilities and expertise to safely conduct critical research, testing and evaluation in regulated, high-level biocontainment laboratories. USAMRIID innovations continue to yield vaccines, drugs, diagnostics and information that protect military personnel and civilians from biological threats. In short, USAMRIID is a key national asset to the global war on terrorism—a cornerstone for medical biological defense. ★

Dr. Leonard Smith

Dr. Smith is acting science director, USAMRIID.

For more information, contact *MMT* Editor Brian O'Shea at briano@kmimediagroup.com or search our online archives for related stories at www.mmt-kmi.com.

Mental Health Roundtable

Utilizing technology to provide better care for the warfighter.

By Brian O'Shea
MT2 Editor

I recently moderated a *Military Medical/CBRN Technology* live roundtable held during the 2012 Military Health System (MHS) Conference. The topic was "How clinical information technology (IT) solutions are improving the collection and dissemination of patients' behavioral health information to provide better quality of care for our Wounded Warriors." Below are excerpts of the discussion; I have posted the entire roundtable dialogue at www.mmt-kmi.com.

Lt. Col. William E. Geesey

Product Manager, Medical Communications for Combat Casualty Care (MC4)

Lieutenant Colonel William E. Geesey

Medical Communications for Combat Casualty Care (MC4) Product Manager

How do you feel the U.S. military will leverage technology to support behavioral health services for soldiers deployed in the future?

"MC4's responsibility is to take a joint suite of software applications developed by the Military Health System and to integrate them onto a variety of different hardware platforms ranging from handhelds, laptops and up through large servers in combat support hospitals, and field, train and sustain that system," Geesey said.

He added that a problem facing the medical community today is treating warfighters in remote or forward operating locations.

"In late 2010, we went to Afghanistan and stood up a pilot program to leverage existing technologies to extend the reach of mental health providers there. Basically, we enabled providers to have a video teleconference capability where the soldier at a remote forward operating base would be able to go into a private area with either an enlisted mental health specialist, provider or medic and they would be able to then collaborate with a mental health provider on the other end who could document that encounter electronically into that system," Geesey said.

He added that a survey done by the Army Public Health Command (APHC) found that younger soldiers were comfortable discussing intimate personal stressors over a video teleconference medium.

"We have gone out to the Army's network integration evaluations out at Fort Bliss and White Sands Missile Range and demonstrated a commercial solution that will enable us to field a telehealth capability that will be an enduring capability to all brigade combat teams and all combat operational stress control units," he said. "We are in final evaluation of that now. We will begin fielding that in Kuwait in March, go through a formal testing evaluation and hope to field it to the rest of the Army later this year. I think in the future our responsibilities are to Army operational forces, so we are talking with the tactical front line folks; we will probably be able to better utilize tactical networks, as they become more mature. There's an opportunity right now to bridge the gap from a tactical network into a satellite network and then back into the Army Medical Department's telemedicine network, where users can conduct teleconsultations and the like."

Capt. Robert Koffman

Chief of Clinical Operations, National Intrepid Center of Excellence (NICoE)

Captain Robert Koffman

Chief of Clinical Operations, National Intrepid Center of Excellence (NICoE)

With the vast array of technologies available at the National Intrepid Center of Excellence, what additional technologies are needed, or could be utilized, to enhance the current capabilities within programs and initiatives for the treatment of TBI and psychological health?

"The technology that we have at NICOE is really geared to trying to understand the interplay between TBI and psychological health," said Koffman. "For instance, clinical practice guidelines that actually guide direct providers to manage traumatic brain injury are not well understood in individuals with psychological health and vice versa. In fact, the evidence-based treatment for various psychological health conditions like PTSD may not even be possible with TBI. Similarly, treatments may even be contraindicated with TBI. Our technology really exists to help us understand the interplay between brain injury and the dysfunction that arises from different psychological

Dr. Katherine Helmick

Deputy Director, Traumatic Brain Injury, Defense Centers of Excellence (DCoE)

Alison Cernich, Ph.D., ABPP

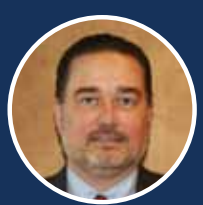
Acting VA Senior Liaison, Defense Centers of Excellence for Psychological Health and TBI

Dr. Joseph Bleiberg

Acting Deputy of Research, National Intrepid Center of Excellence (NICoE)

Dr. Anita Brown

Senior Subject Matter Expert, Health Services Group at General Dynamics Information Technology



Dr. Don Workman

Chief of Innovative Technology Applications Division, National Center for Telehealth and Technology (T2)

health conditions. That said, our technology really gives us the best idea of an assessment."

He added that there is room for improvement.

"What's really needed is the ability to do what we would consider to be ambulatory physiologic monitoring when they leave," said Koffman. "Patients arrive and the first thing they do is they are given actigraphs and they're studied both in the sleep lab as well as back in their Fisher House for the next several days. Being able to, via some technology like Bluetooth, and I know that is a mature technology, to be able to continue monitoring sleep architecture when people leave. Similarly we spend a lot of time with autonomic regulation, and teaching, training and working with individuals—if you will, teaching them how to fish—so when they leave NICOE they will have skill sets and they will not be dependent upon somebody giving them something as opposed to a skill set that they have mastered. We're able to monitor and watch their mastery of various practices, whether it be diaphragmatic breathing, progressive muscle relaxation, any of the Eastern practices, Chi gong, yoga. But the ability to, if you will, monitor the autonomic status of the individual to include perhaps what may ultimately be the most important assessment, and that's heart rate variability monitoring in an ambulatory environment when they leave, is not yet there."

Katherine Helmick, CRNP

Deputy Director, Traumatic Brain Injury, Defense Centers of Excellence (DCoE)

What improvements can DoD implement to the process of data exchange from theater back to MTFs and other medical facilities relating to TBI?

Helmick said it was necessary to look at treatment of TBI as a full continuum from a mild concussion to severe TBI patient.

"We're really looking at 'how do we exchange data with providers?'" Helmick said. "So that people are aware what happened downrange and are able to follow that path all the way through. For severe, moderate and penetrating brain injury we really don't have a lot of challenges, that data is readily available. The injuries are quite obvious. We have a trauma system of care that more than adequately takes care of that transfer out of the theater environment—lots of documentation, copious documentation from multiple parameters. There are lots of machines, bells and whistles that can help us with data exchange for the more severe brain injured patient. With people that sustain a mild TBI or a concussion, we have a greater challenge. Because many times those wounds are invisible and until you talk or gather more information, you're not so sure the person even sustained a concussion. Our VA colleagues are challenged by this predicament as well, because as patients move from the Defense Department into the VA (Department of Veterans Affairs) and you're going back to an injury event years ago, it's pretty difficult to try and piece it together in the absence of that data. So one of our primary stakeholders in this discussion about theater data is the VA. So that many years later both the rule-in for concussion, and the rule-out, is important. As Captain Koffman mentioned, it gets to be very blurry and very complex; the longer that the injuries happened and clinical conditions ensue, and the patient has more time, the clinical picture can get much more complex. And through time and struggling with those initial injuries and initial clinical conditions, even more conditions can become apparent like depression, substance abuse or other things. So it is really important to try and keep that data exchange and record all the way through that system."

Alison Cernich, Ph.D, ABPP

Ph.D., ABPP Acting VA Senior Liaison, Defense Centers of Excellence for Psychological Health and TBI

Can you discuss future initiatives within Veterans Affairs that relate to Wounded Warrior care using telehealth, technology and robotics in rehabilitation?

Telehealth

"There have been major expansions in our video teleconference capability that center not only on care provision. We are developing home video teleconferencing protocols using things like the Movi sort of platform, independent web-based teleconferencing," said Cernich. "It's mobile so you can follow the patient if they are transfers. We even have a basic protocol where the patient can be tracked and trained doing transfers in their own home using the Movi protocol."

She added that there have also been advancements in telehealth reaching rural areas through mobile satellite clinics.

Technology

VA has the VA I2 program, which encourages private corporations to come up with innovative ideas of how to use technology solutions for health care problems the VA is currently facing.

"But one of the other huge initiatives that we have is MyHealtheVet. MyHealtheVet is a way for the veteran to access their medical record from home, via a secure protocol. They can secure message to their primary care provider over our networks, they can check lab results, they can check their appointment schedule, they can look at and refill their medications, so it is a way for the patient to interact with the record. They can request changes to the record if they see an inaccuracy and they can access some of their DoD records, and it is the same record that I as a clinician would see on the other end."

Robotics

The VA has a number of programs utilizing robotics, including the Center for Restoration and Regenerative Medicine (CRRM) that created Brain Gate, a nanotechnology that uses a microchip in the primary cortex, using Bluetooth and other technology to activate a robotic arm.

Other projects CRRM has developed include the DEKA arm using muscle enervation to control a robotic arm, bio hybrid limbs that use a combination of human tissue and technology to create limb function, and the use of virtual reality and motion analysis to see at what point motor difficulties are breaking down so they can fine-tune the rehabilitation intervention.

Dr. Joseph Bleiberg

Acting Deputy of Research, The National Intrepid Center of Excellence

How can the development of ecologically valid neuropsychological tests be improved using virtual reality and other advanced technologies?

"Using CAREN [Computer Assisted Rehabilitation Environment] computer assisted environment, which is 180-degree immersive reality, a platform that is totally synchronized to the screen so if you are in a boat with waves, the platform is waves. It also has a split treadmill in it so you can move. And we have created a dismounted warrior model within the CAREN. The notion being that warriors may have slight impairment, or be near normal, or just be on the other side of normal," said Bleiberg.

He added that the key was to combine auditory, visual and vestibular functions together.

"Now putting those three functions together is different than having them one at a time and then using those functions to do cognitive tasks, especially when you are moving. It sounds complicated, but that is what everybody does every day. So we have created a model where you are looking at things with the 64 speakers behind the screen, so you can localize auditorily, you are dismounted and you are moving, you can have various amounts of gear on; we can stress that in whatever ways that are necessary to make the paradigm as stressful as we want it to be, using vestibular function. The retinal trackers have gotten so good they look like a large pair of eyeglasses, and we have the cameras that can tell where the head movement is. So we can look at the ocular vestibular reflexes in terms of movement and are you keeping what you are looking at in sight and target. So essentially what we are doing is creating a complex environment in which you can look at cognitive function. You can then add to that environment what happens in the real world: things come in on the radio, you are told to do things, you see things change, you have to hear things and then look at them."

Dr. Anita Brown

Senior Subject Matter Expert, Health Services Group, General Dynamics Information Technology

What recommendations do you have, or improvements would you like to see, in how telehealth and telepresence are being utilized within military medicine?

Dr. Brown believes that the integration of systems, technology and people, as well as training to ensure utilization and acceptance of the technology, is a key element in the future success of telehealth and telepresence across military medicine.

"The real issue is how we talk between technological systems and find a sort of a ubiquitous language," said. "Clearly the technology outstrips the policies, the existing policies, the adjustments to policies. How do we credential or privilege someone to do telehealth when they are credentialed over here, but the telehealth is being done over there? How do you license people across state lines to do telehealth? With the privacy act, how do you make these networks secure for transmitting information? … These are all issues that are sort of human issues that the technology has outstripped but can stop a telehealth program dead-cold in its tracks. So I would like to see telehealth and the platform that it provides more ubiquitous for taking in and using all kinds of tools and techniques on these platforms."

She added that the richness of data collected through telehealth and telepresence gives us the opportunity to analyze and predict behavior in a unique and enhanced way.

"My final point would be data mining and data analysis. Can you imagine how many data points you collect using telepresence? I can't see the person in theater shaking their leg constantly throughout my session, but if I'm [virtually] sitting across from this servicemember who has just flown into Landstuhl Regional Medical Center in Germany as a medical evacuee from theater, and they're telling me they're fine but I can see the agitation … Can you imagine the richness of the data we can get using this sort of telehealth recording of sessions? And then we can throw some of that data into the other data pools that we have, use some of the newer techniques of data mining and data analysis to come up with a whole new perspective of what works best for whom, under what circumstances, which is sort of the perennial question."

Dr. Don Workman

Chief of Innovative Applications Division, National Center for Telehealth and Technology

How do you foresee clinical tool platforms such as mobile apps being further developed in the future to support the psychological health of the warfighter?

"Mobile platforms and mobile apps offer an exciting opportunity to support the psychological health of the warfighter. We have already discussed a lot of possible scenarios here; such as providing health-related information, recording thoughts and behaviors in order to understand how they impact emotions, biofeedback and clinical assessment opportunities." said Workman.

"As we think about the future of mobile platforms, they will doubtless become again more functional and more portable than they are now. With 'cloud storage' opportunities, access to information,—photographs, video, etc.,—is almost limitless and in real time. There is also opportunity to give warriors and veterans access to quality care anywhere they can access the Internet. Telehealth is one way of having access, and mobile platforms can provide access to caregivers and to care in terms of health tools and information. We have developed a number of mobile apps at T2 that have functional uses for training people in health-related skills that also have clinical uses. As we think about going 'beyond health care to health,' we can leverage the tools we develop for the clinic to promote health and resilience. If we use the tools from the clinic to also address population health and prevention, we may also reduce some of the stigma related to seeking clinical care. If clinicians used tools that were already familiar to servicemembers and veterans, clinical care might seem like a less stigmatizing environment." ✯

Society Of Armed Forces Medical Laboratory Scientists

By Major Marybeth E. Luna

The Society of Armed Forces Medical Laboratory Scientists (SAFMLS) is a non-profit professional organization consisting of active and reserve members from the Army, Navy, Air Force, U.S. Public Health Service and the Veterans Administration. There are approximately 500 members whose backgrounds in clinical laboratory medicine, research and development, and laboratory administration have greatly improved laboratory policies and technology in support of the health care delivery systems of the armed forces, public health services and Veterans Administration. Our joint conferences have resulted in people crossing service lines, serving equally well in the other services. Many of our members have left the uniformed services to serve in the U.S. Public Health Service and the Veterans Administration.

History

SAFMLS traces its roots back to 1958 when it was called the Air Force Society of Medical Laboratory Scientists. Colonel Frank Townsend, who would later become the consultant to the Air Force Surgeon General and director of the Armed Forces Institute of Pathology (AFIP), set the wheels in motion to establish a recurring professional meeting for laboratory professionals.

The original meetings consisted of a small group of Air Force officers who met annually at an Air Force hospital to discuss clinical and research papers, receive briefings on the USAF laboratory training program and talk about laboratory operations. These meetings first began in 1958 with 12 participants. By 1970, attendance had jumped to 97 participants. It was during this meeting that talks about expanding membership first began.

In 1971, the organization became incorporated in the state of Maryland and formally became known as the Society of Air Force Medical Laboratory Scientists. By 1974, the society's shield was changed to reflect the new name and in the following year, members from the Navy and Army were accepted into the organization.

Over the next 40 years, SAFMLS developed into an organization that focused its efforts on education in its dual roles of peacetime and wartime laboratory medicine. Meeting themes included "War Readiness/ Mobilization and the Military Laboratory" as well as workshop topics on federal regulations, quality assurances and scientific posters.

2012 Annual Meeting Theme: Lead, Collaborate and Educate

Our 2012 annual meeting theme is "Lead, Collaborate and Educate." As laboratory professionals, we must continuously strive to educate ourselves and revolutionize our current processes. Learning does not stop with ourselves, however. We have a responsibility to teach our colleagues and combine our common energies into collaborative efforts. Synergistic relations are pivotal to our success. We must step out of the comfort and safety of our research and clinical labs to lead these changes. If we don't, we leave ourselves vulnerable to the political and fiscal forces that dictate the course of our profession.

As the defense budget continues to tighten and the prospects of a united health care system begin to take shape, it is imperative that our laboratory community be at the forefront of change. Unity of effort and resource sharing are the keys to navigating the uncharted waters of our political environment and the unknown future of budgetary constraints. We must collaborate, educate and lead to ensure the inevitable change is managed in ways that best serve the customers' needs.

SAFMLS' annual meetings and quarterly publications intend to do just that. Our focus is to maintain and enhance professional standards by introducing members to new technologies, procedures and standards of care within the health care complex. Our objective is to educate our leaders so that they may return to their laboratories and share this knowledge. Like internet sensations, we want to see our educational efforts "go viral" and see our society members spread the information to their colleagues. With education comes innovation and with innovation comes change. SAFMLS strives to ignite a constant thirst for learning and modernization among its members. With this intent, it is our hope that SAFMLS provides the conduit for continued innovation, change and leadership for our laboratory profession as it postures itself for the ever-evolving environment we work in.

Conclusion

Throughout its 41 years of existence, SAFMLS has shown its ability to direct an ever-changing laboratory environment. By making itself relevant to our in-garrison mission of quality patient care by revolutionizing combat laboratory medicine and providing top-notch laboratory care to our veterans, SAFMLS has shown that it can and will continue to innovate and educate its laboratory leaders. From humble beginnings as an Air Force-only meeting to expanding membership to the Army, Navy, Public Health Service and Veterans Administration, SAFMLS has proven that collaboration with fellow governmental organizations is, indeed, the key to continued success and survival in a dynamic political and budget-conscious future. ✯

Marybeth Luna

Major Marybeth E. Luna, USAF, is president, SAFMLS. She would like to extend her gratitude to Colonel Danny Deuter, USA; Colonel Bailey H. Mapp, USAF; Captain Cynthia Wilkerson, USN; and Lieutenant Commander Stacie Milavec, USN, for their contributions to this article.

For more information, contact *MMT* Editor Brian O'Shea at briano@kmimediagroup.com or search our online archives for related stories at www.mmt-kmi.com.

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Calendar

March 12-14, 2012
Joint CBRN Conference & Exhibition
Baltimore, Md.
www.ndia.org/meetings/2300

April 1-6, 2012
Society of Armed Forces Medical Laboratory Scientists (SAFMLS) Annual Meeting
Memphis, Tenn.
www.safmls.org/annual_meeting_information.html

April 16-18, 2012
SeaAirSpace
National Harbor, Md.
www.seaairspace.org

Dr. David Cullin
Chief Technology Officer
FLIR Systems

Q: Please tell us about FLIR Systems and the CBRNE Detection business.

A: FLIR is organized into two basic divisions: commercial systems and government systems. CBRNE is part of the government systems division, which came to FLIR as part of the ICX Technologies acquisition last year. Within our CBRNE business, we have the broadest, deepest CBRNE footprint of any company out there. We have more sensors that detect more threats and more smart people who develop those sensors and really understand CBRNE business more than anybody else in the world.

Q: How are FLIR Systems' products specifically designed to meet the needs of the U.S. military?

A: With a fairly deep heritage going back to the ICX Technologies days, a lot of those products were developed through contract research and development (CRAD) as part of ICX's growth. We are slowly moving away from the CRAD model for our CBRNE business. The major initiatives, both from a funding perspective from the Department of Defense and Department of Homeland Security as well as marketplace ideas of what those sensors should detect, came from the challenges that the DoD and DHS faced. Sensors were designed and developed with those requirements in mind. For instance, if you look at the suite of chemical detective sensors that we have, the types of chemical warfare agents—toxic industrial chemicals, explosive, all of those things that we detect—are things that DoD and DHS are interested in detecting. This is also true for biological warfare and radiological material that we detect and identify, especially for soldiers, sailors, airman, Marines, Customs and Border Patrol and various others who would want the capability.

Q: Can you discuss a few of the recent successes by FLIR Systems, related to DoD and DHS?

A: About two years ago, we won a contract to develop and eventually produce the CBRNE, Dismounted Reconnaissance Kits and Outfits Program (DRKO), integrated CBRNE system that is for the dismounted soldier. Dismounted reconnaissance is a capability that is required for the global war on terrorism that we are involved in now. A suite of sensors, personal protective equipment, decontamination equipment and various other things, which allow the soldiers, sailors, airmen and Marines to be able to find an unknown threat, identify what it is, determine if it's dangerous and provide them with protective posture to operate in a dangerous environment. This is one of the largest programs of record that the DoD has in the chemical and biological defense world.

We provide a lot of handheld radiation detection equipment to the Coast Guard, U.S. Navy and various other government entities. We are involved in the next DoD program that is envisioned against biological warfare agents, Joint Biological Tactical Detection Systems (JBTDS). We have hundreds, if not thousands of our handheld explosive detection system, FIDO, fielded in Iraq and Afghanistan. We also have mass spectrometers and enzyme detecting chemical sensors that are currently being procured by DoD and feel that we are very much supporting the current and future warfighter, not developing sensors against Cold War threats anymore.

Q: How has FLIR Systems positioned itself to coincide with HSPD-10?

A: The biggest response from the federal government is in the area of biodefense, which seems to be the threat where the government is focused. The biggest area that we have been working on is critical infrastructure protection. We have taken a lot of the lessons from governmental efforts, like the DARPA immune building program, and transitioned out of it some sensing and mitigation architectures that really should provide containment and mitigation of threats. Not only does this protect people from getting exposed in the event of an attack, it also provides the capabilities to potentially reduce the amount of contamination in critical infrastructure so that places can be habitable very quickly without spending exorbitant amounts of money trying to clean up contamination after an attack, which is sometimes sort of a lost thought. Not only do you worry about protecting peoplein the event of a biological, chemical, radiological or dirty bomb attack, but you also have to deal with the consequences with regards to your infrastructure. Consider the amount of money it took to clean up the Hart Senate office building up in D.C. after the anthrax attacks in the fall of 2001. You will find tens of millions of dollars were spent to clean up that building. If you apply that to airports and train stations, there is a real economic impact. You can think of some of these sensors and mitigation systems as insurance. They are not free; you have to pay something to put them in place and to keep them operating, but you are buying insurance against that kind of attack, a low probability yet high consequences if something happens. We believe, specifically in the area of biodefense, that we have some really solid systems that just need some exercising by the government to prove that they work the way we know that they work.

Q: Is there anything else that you would like to add?

A: FLIR is here to solve tough problems. We reinvest 10 percent of revenue for IR&D to develop new products, which is a commercial investment model in terms of developing new products and capabilities to solve those problems. We take things seriously and we have really smart people to work on those problems every day. ✯

NEXT ISSUE

May 2012
Vol. 16, Issue 3

Dedicated to the Military Medical & VA Community

Military Medical/CBRN Technology

Cover and In-Depth Interview with:

Lt. Gen. Patricia D. Horoho

U.S. Army Surgeon General

Special Feature

Yellow Ribbon School Directory

An update of the Yellow Ribbon Program by Keith Wilson, Director of Education Service for the Department of Veterans Affairs, as well as a directory of schools participating in that program.

Features

Leadership Insight

James B. Poindexter, commanding officer of Naval Medical Logistics Command

Hospital Security

Fred Jackson, director, security and law enforcement at the Department of Veterans Affairs, elaborates on maintaining vigilant security at medical facilities within the VA.

AFMS CATS Contract

In February 2012, the USAF issued a five-year, multiple-award contract worth up to $985 million to support the USAF medical service. Winners will have the chance to bid on delivery orders under the mixed indefinite delivery/indefinite quantity, firm-fixed-price, cost-plus-fixed-fee contract. Services will include management and professional support services, engineering and technical services, and studies, analyses and evaluations over the five-year period.

San Antonio Military Health System

Military health care in San Antonio is evolving to another level and will have a positive effect on patients and medical organizations, both military and civilian. The Air Force and Army have come together to operate an effective and efficient integrated regional healthcare system dedicated to providing high quality, patient-centered care that is convenient and accessible to 230,000 DoD beneficiaries in the San Antonio metropolitan area.

En Route Medical Evacuation

A look at recent mission success from 160th SOAR (A), key equipment needed for en route medical evacuation, current challenges and future programs/initiatives pertaining to care provided in transit.

Who's Who Organization Profile

Who's Who: Q&A with Major General David L. Harris, director, J-3/7, National Guard Bureau, as well as an in-depth look at Chemical, Biological, Radiological, Nuclear and High Yield Explosive Enhanced Response Force Packages (CERFP teams), which consist of approximately 186 soldiers and airmen. Each team has a command and control section, a decontamination element, a medical element, a casualty search and extraction element and a fatalities search and recovery element.

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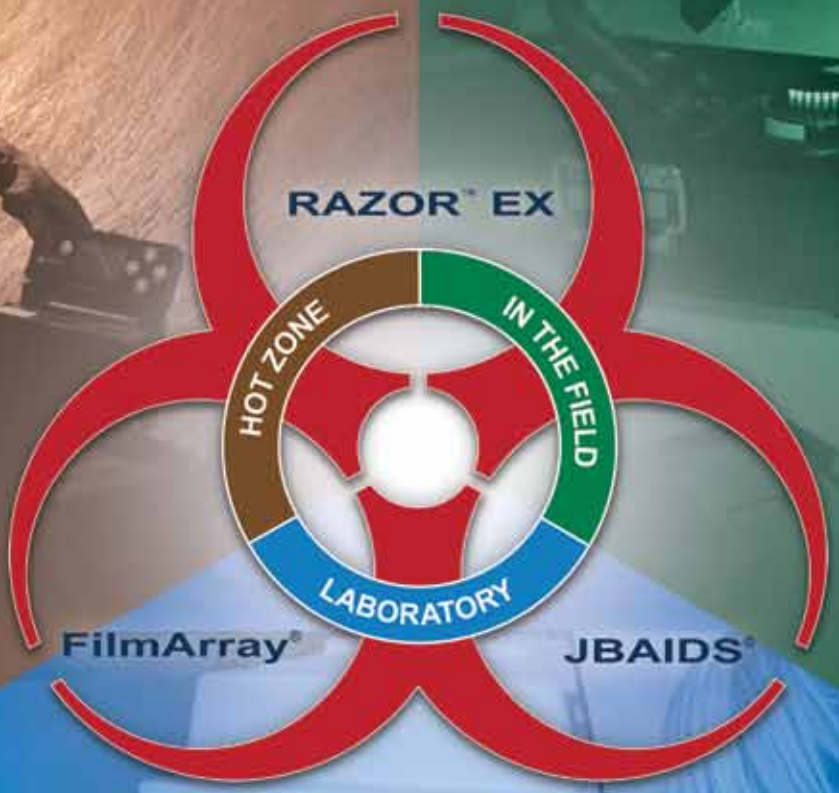

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