Warfighter Protection and Acute Care Project Management Office

May 2021 - Volume 1

WPAC NEWSLETTER

& Product Portfolio

Mission: Develop, deliver, and field U.S. FDA-approved preventions, diagnostics, and treatments for infectious diseases and combat wound infections; blood products and blood components; and drugs for battlefield pain management to protect and sustain the Warfighter during far-forward deployments.

U.S. Army Medical Materiel Development Activity

USAMMDA

WPAC PROGRAM OVERVIEW

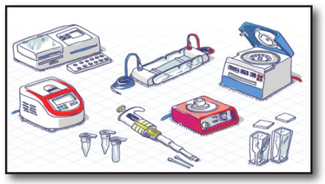
The Warfighter Prevention and Acute Care (WPAC) Project Management Office (PMO) team, led by Dr. Lawrence Lightner, project manager, and Dr. Kendra Lawrence, deputy project manager, is comprised of Defense acquisition-certified professionals, product managers, U.S. Food and Drug Administration (FDA)-regulatory professionals, pharmaceutical manufacturing experts, logisticians and financial analysts. The WPAC PMO accomplishes its mission by leveraging partnerships with industry, academia, and other government agencies to develop materiel solutions to satisfy medical requirements generated through Capability Developers and the user community. The group serves to protect and treat our nation's Warfighters at the point-of-injury and beyond, while reducing the logistical burden when having to carry and use critical medical materiel on the battlefield.

Infectious Disease

We develop vaccines and prophylaxis for infectious disease. Vaccines and other preventive measures are critical for protecting deployed Service Members against existing and emerging diseases that degrade unit readiness.

Treatment

Malarial, viral, bacterial and fungal infections can all deplete troop strength. The WPAC PMO develops safe and effective therapeutics for all relevant threats. Broad-spectrum capabilities to mitigate infections reduce morbidity, improve recovery and enable the Warfighter's return to the fight.



Diagnostics and Assays

Diagnostics quickly identify and diagnose infectious diseases in the field. Deployable diagnostics enable rapid pathogen detection and specified treatment, enhancing far-forward medical response where evacuation times may be extended.

Battlefield Pain Management

Battlefield pain management focuses on safely and effectively treating pain at, or very close to the point-of-injury. Pain treatments must work quickly, be safe, easy-to-use and lightweight to allow medics to carry sufficient doses for the planned operation. Our new products meet these requirements and add to the pain-treatment options available to care providers.

Blood Products

Blood products are essential to effective combat casualty care, and early transfusions improve casualty survival rates. Development efforts focus on blood products that can be deployed in austere environments where mobility is required, including cold platelets, freeze-dried plasma and safe whole blood.

Military Working Dogs

Military Working Dogs (MWD) are critical to saving lives on the battlefield, and they are at risk for traumatic injuries and hemorrhage. Whole blood is preferred to treat MWDs with severe blood loss, but this is not always available at the point-of-injury. Canine freeze-dried platelets and canine freeze-dried plasma can bridge this gap.

COVID-19 RESPONSE: PREVENT - DETECT - TREAT

In 2020, the COVID-19 pandemic ushered medical product development into the national spotlight, from headline news to casual conversation. The details of how to develop and deliver a product to treat, detect or prevent an infectious disease are garnering public attention like never before, and the requirement to act quickly has never been more urgent. The WPAC PMO is lending its expertise to a multi-pronged approach to the COVID-19 response, both in Department of Defense (DOD) programs and the whole-of-government response.

The WPAC team's manufacturing subject matter expert and product manager, Ryan Adams, and Walter Reed Army Institute of Research (WRAIR) director of the Center for Infectious Diseases Research, Dr. Nelson Michael, co-chair the U.S. Army Medical Research and Development Command's (USAMRDC) COVID-19 Product-Focused and Manufacturing Working Groups (WG). The WGs are comprised of representatives across USAMRDC and across the product development spectrum. The product-focused WG is developing a vaccine and therapeutic, and the Manufacturing WG ensures that manufacturing development is compliant with FDA regulations and transferable to an industry partner. The WGs provide guidance on schedules, regulatory strategy, reliable manufacturing, clinical testing and non-clinical studies.

Three WPAC-managed programs were selected for CARES Act funding, managed by the Defense Health Agency. Program highlights include:

COVID-19-related Acute Respiratory Distress Syndrome (ARDS) Treatment
Product Manager: Dr. Lindsey Garver
ARDS complications occur in approximately 48 percent of patients hospitalized due to COVID-19 and caused nearly 28 percent of the deaths in the early months of the pandemic. Secreted phospholipase A2 (sPLA2) is produced in excess during the body's response to SARS-CoV2 infection, which leads to immune dysfunction, oxygen depletion, organ failure and death. Varespladib is a small molecule PLA2 inhibitor originally under development as a broad-spectrum snakebite antidote in partnership with Ophirex and is now currently under a repurposing development effort for COVID-19 associated- ARDS treatment. As with BSSA, varespladib can be given orally (tablet) or IV to patients developing or experiencing ARDS. A clinical trial in COVID-19 patients is scheduled to begin in April 2021.

A Next-Generation Diagnostic Test
Product Manager: Dr. Clifford Snyder
The BioFire Defense COVID-19 test is a FDA-cleared laboratory diagnostic used with BioFire FilmArray® for detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs. This test provides a "detected" or "not detected" answer within 50 minutes and supports initiation of appropriate isolation, quarantine measures and treatment. BioFire Defense has collected more than 500 nasopharyngeal swab specimens needed for clinical validation. The BioFire Defense COVID-19 test will be used by deployed Army, Navy and Air Force medical teams and in fixed facilities.

A Lateral Flow Assay for SARS-CoV2 Detection
Product Manager: Ms. Calli Rooney
SCOV-2 Rapid Diagnostic Lateral Flow Tests are rapid diagnostic assays for diagnosis of SARS-CoV-2 in symptomatic and asymptomatic patients from a nasopharyngeal swab for direct antigen (SCoV-2 Ag DetectTM) detection and whole blood serology (SCoV-2 Ab DetectTM) detection. The SCoV-2 Ag DetectTM test can be used to diagnose current SARS-CoV-2 infection in individuals who are suspected of COVID-19 by their healthcare provider. The SCoV-2 Ab DetectTM test can be used to aid healthcare providers with identifying individuals with an adaptive immune response indicating recent or prior COVID-19 infection. Both assays are FDA-authorized for use under an Emergency Use Authorization (EUA), and provide rapid diagnostic assay for diagnosis of SARS-CoV-2 in symptomatic and asymptomatic patients. These assays will be used by deployed medical teams of all Services to enable early detection and support evacuation and treatment decisions to decrease impacts on troop performance.

SPOTLIGHT ON 2020 DEVELOPMENT EFFORTS:

Malaria Treatment Drug-Intravenous Artesunate (MTD-IVAS):

Malaria, a disease caused by a mosquito-transmitted parasite, can be mild, chronic or severe in its symptoms. Risk of developing severe malaria increases in Service Members who have not generally been exposed to malaria parasites and are therefore non-immune. Severe and complicated malaria can result in a rapid decline in condition (24-48 hours) and is fatal if not treated immediately. It causes seizures and coma if parasites enter the brain, as well as kidney and/or liver failure, spleen rupture and difficulty breathing. Severe hemolytic anemia is secondary to ruptured red blood cells, which is caused by the malaria parasite replication inside infected red cells. MTD-IVAS is the only available FDA-licensed treatment for severe malaria, particularly in cases where all other malaria treatments have failed. It is infused every 12 hours for the first day, then daily for up to seven days. The rapid effect of MTD-IVAS can result in miraculous recoveries, reversing malaria-induced coma and seizures, and breathing difficulties. MTD-IVAS was licensed by FDA on May 26, 2020.

Commercialization is anticipated in the 3rd Quarter of FY2021. It is currently available from the Centers for Disease Control (CDC) upon request for treatment of severe malaria, until manufacturing ramps up and general distribution begins.

Sufentanil NanoTabs (DSUVIA™):

DSUVIA™ was FDA-approved on November 18, 2020, for the management of acute moderate to severe pain in adults. DSUVIA™ has a wider safety margin than that of morphine and in a noninvasive sublingual tablet form, and it is rapidly absorbed without the need for intravenous access. DSUVIA's non-invasive medication circumvents the risks associated with intramuscular injection of morphine in casualties with poor circulation due to shock. Its rapid absorption allows medical personnel to easily titrate the correct dose of DSUVIA™ to control the casualty's pain.

DSUVIA™ is a synthetic opioid that is orally administered using a single-dose delivery applicator. This new pain management option was co-developed with AcelRx Pharmaceuticals, Inc. It can be administered by properly trained medics and used at all Roles of Care. DSUVIA™ was added to the Joint Deployment formulary and recommended for inclusion in the medical assemblages.

What's New With:

(See Additional WPAC Product Highlights on the following pages.)

Battlefield Pain Management
- Sufentanil (DSUVIA™)
- Ketamine

Blood Products and Components
- Canine Blood Products (CBP)
- Cold-Stored Platelets (CSP)
- Cryopreserved Platelets (CPP)
- Freeze-Dried Plasma (FDP)

Diagnostics and Assays
- BioFire Defense COVID-19 Test
- Global Fever Assays
- Rapid Diagnostics
- SARS CoV2 Assay

Infectious Disease Products
- Adenovirus Vaccine
- Broad Spectrum Snakebite Antidote (BSSA)
- Covid Treatment
- Dengue Tetravalent Vaccine (DTV)
- Enterotoxic E. Coli Vaccine (ETEC)
- Human Immunodeficiency Virus Vaccine (HIVV)
- Malaria Treatment Drug-Intravenous Artesunate (MTD-IVAS)
- Malaria Prophylaxis Drug-Tafenoquine (MPD-TQ)

WPAC PRODUCT PORTFOLIO

The WPAC PMO serves to protect our Nation's Warfighters against life-threatening illnesses, injuries and emerging diseases. The team collaborates with worldwide partners to develop, implement and field innovative solutions. The group works within the laws and regulations of the DOD and the FDA to develop medical capabilities identified as a priority to Service medical providers.

Battlefield Pain Management

Program	Product Information	Key Events
Sufentanil (DSUVIA™)	Sufentanil NanoTabs are a rapid-acting opioid to relieve acute pain with without the risks associated with autoinjected morphine.	FDA was approval as 1QFY19 (November 2018). MS C was 3QFY20 (April 2020).
Ketamine	Ketamine is a rapid-acting non-opioid for treatment of acute pain. It is designed to treat pain close to the point of injury with minimal side-effects.	FDA IND update pending

Blood Products & Components

Program	Product Information	Key Events
Canine Blood Products	Freeze-dried canine plasma is being developed to enable emergency fluid resuscitation in austere environments for injured MWD	Veterinary study execution planned January 2021 to May 2022
Cold-Stored Platelets (CSP)	Platelets stored at 2—6ºC to extend the shelf life from 5-7 days to 14 days or longer. Enables supply of platelets to Role 2 medical teams.	Phase 3 study will initiate June 2021
Cryopreserved Platelets (CPP)	CPP are human platelets frozen at –80ºC in 6% dimethylsulfoxide (DMSO), and stored at –65ºC or lower to extend the shelf life to 2 years.	A Phase 2/3 study started in 2020
Freeze Dried Plasma (FDP)	Single-donor, pathogen tested FDP made from Fresh Frozen Plasma (FFP). Reconstituted with sterile water for injection.	Phase 2 study planned 3QFY21. Final submission of initial rolling BLA was submitted to FDA 1QFY21

WPAC PRODUCT PORTFOLIO
CONTINUED

Diagnostic and Assays

Program	Product Information	Key Events
BioFire Defense COVID-19 Test With Sample Type Expansion Option	A laboratory diagnostic for detection of nucleic acids from the SARS-CoV-2 virus.	Sample study underway; FDA clearance anticipated June 2021
Global Fever Assays	Test expansion for the BioFire®FilmArray device. Detects malaria, Dengue, Chikungunya and Leptospirosis infections.	Cleared by FDA; Product launch July 2021
Rapid Diagnostics	Rapid diagnostic panels for detection of military-relevant infectious diseases. Devices include the Rapid Human Diagnostic Device-Dengue (RHDD), Next Generation Diagnostic System (NGDS) Portable Diagnostic Tropical Fever Panel, and NGDS Portable Diagnostic Fluvid	Product Available 4Q FY21
SARS CoV2 Assay	SARS CoV-2 Rapid Diagnostic Lateral Flow tests using serum and direct antigen detection. Nasopharyngeal swabs (SCoV-2 Ag Detect™) and serum (SCOV-2 Ab Detect™) can be used to detect infection in symptomatic and asymptomatic individuals.	SCOV-2 Ab Detect™ clinical and analytical studies initiated January 2021

Infectious Disease Products

Program	Product Information	Key Events
Adenovirus Vaccine	FDA approved for military use. Protects against Febrile Respiratory Illness (FRI) caused by the adenovirus Types 4 and 7	10-year full rate production contract signed through 2029
Broad Spectrum Snakebite Antidote (BSSA)	Varespladib is an oral treatment for snakebite envenomation. Supplied as an oral medication, it is easily used in austere conditions; effective against wide range of poisonous snake species.	Received DHA MDA approval to enter the Acquisition Lifecycle

WPAC PRODUCT PORTFOLIO
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Infectious Disease Products

Program	Product Information	Key Events
COVID-19 Treatment	Varespladib is a PLA2 inhibitor, a molecule that is associated with Acute Respiratory Distress Syndrome that develops in many COVID-19 patients.	Clinical Trial planned for 3QFY2021
Dengue Tetravalent Vaccine (DTV)	Dengue vaccine to protect Service Members against disease caused by any of the four dengue virus serotypes.	1QFY21 Expert panel assessed vaccine candidate for military utility.
Enterotoxic E. Coli Vaccine (ETEC)	Multivalent vaccine designed to prevent bacterial diarrhea caused by ETEC.	Received DHA MDA approval to enter the Acquisition Lifecycle 3QFY20
Human Immunodeficiency Virus Vaccine (HIVV)	A globally effective vaccine to prevent HIVV-1 infection in Service Members, healthcare workers, and allied forces.	Final Phase 3 efficacy study initiated in 1QFY20
Malaria Treatment Drug-Intravenous Artesunate (MTD-IVAS)	Intravenous Artesunate is a drug to treat severe malaria in Service Members, civilians and contractors deployed to malaria endemic regions.	FDA approval received 3QFY20
Malaria Prophylaxis Drug-Tafenoquine (MPD-TQ)	MPD-TQ is an FDA-approved weekly prophylactic drug for the prevention of malaria in nonimmune adults with normal enzymatic activity (G6PD).	FDA-approved in 2018, included on both the Uniform and Joint Deployment Formularies

WPAC Team Member Highlights

Operation Warp Speed

Lola Ajayi, product manager, spent the last seven months detailed to Operation Warp Speed (OWS) to provide program management support to the COVID-19 Convalescent Plasma (CCP) and Hyperimmune globulin (HIg) efforts. Ajayi managed both the $1 billion plasma budget with the Department of Health and Human Services, and the contracting actions to expand collection facilities around the U.S. She also led the donor-awareness and activation campaign in order to inspire recovered COVID patients to donate their plasma, engaging with stakeholders such as Quest Diagnostics and LabCorp, to send outreach to recovered COVID individuals in order to increase donations. In addition, Ajayi collates all the plasma efforts into a weekly report presented to OWS leadership, the White House Coronavirus Task Force, and the Assistant Secretary of Preparedness and Response (ASPR).

ASA(ALT) Medical Systems 90 Day Development Assignment

Calli Rooney, product manager, was detailed to Medical Systems in the Office of the Assistant Secretary of the Army for Acquisition, Logistics and Technology (ASA[ALT]) for a 90-day developmental assignment. During this assignment, Rooney was able to gain a better understanding of the relationship and role that Medical Systems has in supporting USAMRDC, as well as the processes for engaging with ASA(ALT).

Awards and Other Achievements

Army Maj. Christopher Morgan and Ryan Adams, product managers, achieved Defense Acquisition Workforce Improvement Act Program Management (DAWIA) Level II Certification

Andy Atkinson, product manager, was awarded the Civilian Service Commendation Medal in June 2020 for successfully managing the Battlefield Pain Management-Sufentanil (BPM-SUF) program to a successful Milestone C/Full-Rate Production Decision.

Mark Seymour and Carmen Sanders each were awarded the Civilian Service Commendation Medal in March 2020 for their efforts in developing the Program Objective Memorandum (POM) 22-26.

Carmen Sanders was accepted for membership in the Army Acquisition Corps in August 2020.

U.S. Army Medical Materiel Development Activity
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