

**US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC)  
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)  
COMBAT READINESS – MEDICAL RESEARCH PROGRAM (CRRP)  
STAKEHOLDERS MEETING  
COMMUNITY ACTIVITIES CENTER, FORT DETRICK, MARYLAND  
25 MARCH 2019**

**Summary of Stakeholder-Defined Research Gaps and Areas of Focus**

A CRRP Stakeholders meeting for the fiscal year 2019 (FY19) was held on 25 March 2019 at the Community Activities Center at Fort Detrick in Frederick, Maryland. The Stakeholders meeting provided a forum for an open dialogue among experts to (1) identify critical issues facing the immediate medical needs of the Warfighter on the battlefield following life-threatening injury or environmental exposure, (2) identify areas of synergy in civilian medical care, and (3) acknowledge the underfunded areas of research and patient care. During the meeting, Stakeholders participated in a breakout session exercise and plenary group discussions to identify gaps in research and areas of focus within topic areas that aligned with the Congressional language used to establish the CRRP:

- Future battlefield priorities to address injury and lethality closer to the point of injury.
- Medical readiness and health surveillance for the future battlefield: sensors, chemical and environmental exposures (toxic industrial chemicals [TICs] and toxic industrial materials [TIMs]), readiness tools, and related advanced computing approaches.
- Challenges relating to infectious disease (e.g., sepsis) and biological exposures in the combat environment.
- Considerations for moving technologies into the hands of providers and patients.

The identified research gaps and high-priority focus areas address challenges of multi-domain operations, including the potential for reduced medical provider capacity compounded by large numbers of casualties, limited resources over longer periods of time, and a highly mobile and lethal battlefield with little-to-no technology availability for communication. A summary of Stakeholder responses and rationale is provided below. *These are not the official gaps of the program for the FY19 cycle. The Stakeholder-defined gaps will be used by the CRRP Programmatic Panel in the determination of the program strategy for funding opportunities. Please refer to future funding opportunities for any final gaps and focus areas associated with a specific application receipt cycle.*

*A. Future Battlefield Priorities to Address Injury and Lethality Closer to the Point of Injury*

The overarching themes within this topic area that were identified by Stakeholders addressed the need for high-fidelity data acquisition, training and decision-support tools for improving triage that would enable non-trained users to provide self- or buddy-aid, multi-use integrated products, management of combined injuries, advancements in exoskeleton technologies, point of care imaging, universal blood products and medications, and improved transitions for evacuation. Regarding high-fidelity data acquisition, Stakeholders noted that access to data acquired from the

point of injury through the spectrum of care would improve triage and expedite medical support of potentially fatal battlefield injuries (hemorrhage, airway and respiration complications, circulation, hypothermia), improve treatment and patient outcomes, and inform research and development efforts. Because the 2009 Congressional mandate that defined the “golden hour” doctrine was based on a battlefield that had numerous forward surgical teams, combat support hospitals, and medevac assets from all three Services, most currently available data sources that document military casualties are based on support provided within Role of Care 2 or Role of Care 3. There is a significant gap in data for triage and injury supported through Role of Care 1, which is necessary for improving sustainment capabilities in prolonged field care settings.

Stakeholders also discussed the need for advancements in training to facilitate long-term retention of knowledge and skill sets by trained medical personnel. Discussions on training centered on incorporation of simulation and virtual or augmented reality to facilitate long-term retention of knowledge and skill sets. A significant consideration for medical personnel transitions, both when entering an operational area and returning to the civilian theater, is characterized by the need to rapidly reacquire skills that are essential but have decayed through disuse or infrequent use. Therefore, improved efficiency in reacquiring skills, or prolonging skill set retention, is critical for circumventing errors that may result in mortality and morbidity.

Greater self-sufficiency and autonomy of embedded providers and non-medical personnel would be beneficial in battlefield scenarios that have reduced or limited medical support. Stakeholders identified three high priority items that are needed to facilitate self- or semiautonomous care: (1) automated monitoring of physiological health parameters; (2) decision-support tools; and (3) automated, integrated, and multi-use products. Through addressing these high priority technology gaps, it would be possible to simplify triage for non-medical personnel and prolong survival until medical care or evacuation is available. The Stakeholders identified bio-sensors for monitoring clinical parameters to optimize self-regulation, workload distribution, and enhance situational awareness. Bio-sensors that integrate clinical monitoring with decision-support that accurately reproduces clinical judgement would be useful for the detection of impending soldier failure from stress load (physical, psychological, and environmental), as well as casualty detection, triage, and early clinical management of potentially life-threatening injuries, such as vascular abscess, hemorrhage, wound contamination, and resuscitative care. Automated, integrated, and multi-use products are needed to support self- or buddy-care, as well as enable trained medics to rapidly and successively attend to and monitor multiple injured Service members at one time. The Stakeholders highlighted manual tourniquet application, vascular access, chest decompression, and imaging (traumatic brain injury, fractures, organ reperfusion) as complex manual procedures that have the potential for automation for use by unskilled providers. Integrated and multi-use products that address two or more injuries would be useful for managing combined injuries (i.e., trauma, burn, chemical, biological, radiological, nuclear, and high-yield explosives [CBRNE]), while also considering the space limitations of the medical pack.

Stakeholders also noted a need for improved exoskeleton technologies for wound, fracture, and amputation stabilization, as well as universal blood products for transfusion support in prehospital resuscitation. Lastly, there were discussions on improving transitions for patient handoff to expedite loading and/or autonomous evacuation, including technology to identify and locate casualties, as well as interventions for patient stabilization during transport. Because high mobility

is an anticipated component of the future battlefield, there is a need for technologies to improve tracking of injured Service members.

### *B. Medical Readiness and Health Surveillance for the Future Battlefield*

Stakeholder discussions in the medical readiness and health surveillance topic area focused on sensors, chemical and environmental exposures, readiness tools, and related advanced computing approaches. The Stakeholders suggested various interventions to improve medical readiness and health surveillance, with the ultimate goals of extending the golden hour and maximizing force availability. The high priority gaps that were identified included wearable sensors for the earliest possible detection of threat agent exposures, field-able lab capabilities (i.e., lab-on-a-chip), and point of care logistics for triage and psychological health resilience.

Sensors or field-able lab capabilities are needed for the detection of chemicals (including opiates), infectious diseases, pollution, ozone, and environmental particles, as well as closed loop sensors for physiological monitoring beyond vital signs (low-complexity blood work, intracranial pressure monitoring) to support prolonged care. Sensors or chip-based platforms that can detect CBRNE threats early and at minute doses would expedite medical care following an insult and enable long term health risk-associated exposure monitoring and dosimetry. Physiological data obtained via wearable sensors would be useful for assessing Soldier performance, far-forward diagnosis, and triage improvement. Ideally, integration of multivariate physiological data by machine learning algorithms or artificial intelligence computing is needed for decision support and triage at the point of injury. However, medical data from one injured individual may not directly translate to another individual with the same or similar injury, and there are also logistical considerations regarding long-term data collection and interpretation to leverage the most clinically relevant information. For example, the sensors should communicate with external devices in real-time. Even without a real-time requirement, data from the sensor needs to be communicated back to the data analytics platform in a time-sensitive manner. Therefore, wireless communication, which may not be readily available in austere environments, is an essential component to the success of wearable sensors. In addition, Stakeholders noted the potential for Soldier non-compliance as a significant consideration, since Soldiers are unlikely to wear a device that is bulky, inconvenient, or uncomfortable.

The Stakeholders also indicated the need for countermeasures to CBRNE exposures, as well as new approaches to pain management in trauma. The Stakeholders indicated that radiological exposure countermeasures are currently available. There were discussions about applying existing knowledge used to develop radiological countermeasures to other types of exposures. Pain control in trauma is an integral part of treatment in combat casualty care. It has been shown that early treatment of pain improves outcomes after traumatic injury, whereas inadequate pain management at the time of injury leads to higher rates of long-term psychological complications. However, the currently available pain control options are not conducive to prolonged care settings due to frequent administration schedules and/or the potential for dependency and addiction.

Similar to Stakeholder-identified need for automated technology solutions for self- or semiautonomous care to address injury and lethality closer to the point of injury (Section A), Stakeholders indicated a need for technology automation for medical readiness and health surveillance applications. Automated, portable, and multi-purpose technologies with low-energy

requirements would minimize training needs and provide an opportunity for untrained personnel to provide immediate and damage control resuscitative care.

### *C. Challenges Relating to Infectious Disease and Biological Exposures in the Combat Environment*

The Stakeholders identified the need for preventing infectious disease, as well as post-exposure interventions in the event of infectious disease exposure. Prevention strategies were indicated as the highest-priority area, since reducing the potential for acquiring an infectious disease or becoming septic would have the greatest impact on maximizing force readiness. Infectious disease prevention strategies included novel and improved delivery systems, prophylactics, vaccines, pathogenically-agnostic products, and insect repellents. The Stakeholders noted that the cytokine interferon-gamma (IFN- $\gamma$ ) has been indicated as a useful prophylactic for infection. IFN- $\gamma$  orchestrates numerous protective functions to heighten the immune response to infection, including enhancing antigen processing and presentation, increasing leukocyte trafficking, inducing an anti-viral state, boosting anti-microbial functions, and affecting cellular proliferation and apoptosis. Bacteriophages were also discussed as a possible prophylactic strategy. Bacteriophages degrade bacterial cell walls, resulting in hypotonic bursting of the inner membrane and leaking of intracellular components, which causes cell death. While bacteriophages effectively kill pathogenic bacteria with minimal to no adverse consequences, there are several limitations to current phage therapy strategies. For example, bacteriophages are unstable in the high acidity environment of the upper gastrointestinal tract, which precludes oral administration. In addition, bacteriophages are highly specific to a given bacterial strain, which limits generalized and broad-spectrum approaches. Therefore, additional research is needed before phage therapy could be applied as a preventive approach to infectious disease. The use of antibodies to provide passive immunity to infections was also discussed by Stakeholders. Prophylactic immunization with antibodies is useful for protection against viral infections, since neutralization of virion particles requires antibody binding. For immunization against bacteria, antibody prophylaxis approaches aim to prevent host-cell entry, enhance phagocytosis, or recruit immune cells, and would be useful for prevention of infection caused by multi-drug resistant organisms. Lastly, an implantable prophylactic was mentioned for prevention of infections caused by parasitic organisms.

Stakeholders also discussed vaccination strategies, topical antimicrobials, and novel insect repellents as infectious disease prevention approaches. Regarding vaccination strategies, Stakeholders noted that many immunization schedules take weeks and up to months to complete, which can delay deployment or may leave some Service members unprotected. In addition, development of multivalent vaccines that provide protection against two or more microorganisms would be useful. Topical antimicrobials, in the form of foams or gels, would be useful for prohibiting contamination, especially when immediate wound debridement is not possible. Insect repellents are useful for prevention of insect-borne diseases that are endemic in areas of military engagement, such as malaria, dengue fever, Zika virus, Lyme disease, etc. Insect-repelling combat uniforms are currently available but not widely used across the Services.

Post-exposure interventions and countermeasures to infection were also a high priority area discussed by Stakeholders. They indicated the need for decision-support tools, risk assessment tools, and universal or novel therapeutics. Decision-support and risk assessment tools are needed to better identify early indicators of sepsis, when infectious agents are still at undetectable levels

within the blood. For identification of infection from bodily fluids (blood, serum, urine, saliva), Stakeholders discussed portable multiplex platforms to identify host or pathogen-specific biomarkers of infection. Finally, Stakeholders indicated the need for novel broad spectrum antibiotics that can be used to treat infections caused by multi-drug resistant pathogens.

#### *D. Moving Technologies into the Hands of Providers and Patients*

Stakeholders were asked to discuss three questions related to moving technologies into the hands of providers and patients:

1. What training should be implemented to advance products?
2. What emerging technology should we leverage?
3. What infrastructure do we need in order to deploy products faster?

A non-prioritized list of responses to each question is provided below.

##### What training should be implemented to advance products?

- Facilitate training in triage for buddy- or self-care to prolong survival and lessen the burden of care for a limited number of combat medics, who will be heavily relied upon in multi-domain battlefield settings to provide care to large numbers of casualties in the absence of medivac capabilities.
- Just-in-Time training for non-medical Service members, as well as medical personnel that are months-to-years removed from formal training and need to quickly reacquire skillsets that have decayed with time, in order to promote and advance the use of novel or currently available products in the multi-domain battlefield environment.
- Training or decision-support algorithms that encourage long-term habitual adoption of practices for better skill retention.
- Engaging the end-user in the development process to encourage an understanding of product feasibility in multi-domain operations.
- Training that encourages broad-user adoption, which is a measure of success from the military standpoint (instead of US Food and Drug Administration [FDA]-approval or commercialization).
- Consideration of artificial intelligence solutions when applied to training protocols, although this may be complicated by trainee distrust of machine-demonstrated intelligence.
- Considerations of military doctrinal standpoints and limitations.

### What existing or emerging technology should we leverage?

- Implementation of wearable sensors to improve triage through acquisition and monitoring of Soldier-specific normative data, which would provide a baseline for comparison to illness or injury.
- Trajectory modeling via machine learning algorithms or artificial intelligence for triage categories, including life-saving interventions and simplistic interpretation.
- Field-able applications (simple, durable, stable) of simple technologies, such as vacuum-assisted closure for wound care management.
- Regenerative medicine applications to prevent injury or accelerate recovery.
- Drug repurposing technologies, as well as commercialized off-the-shelf technologies and consumer produced goods.
- Early engagement of industry partners.
- Clinical research and clinical trials, instead of animal studies or models, for clinical success and sustainment of technologies.
- Alternatives to electricity, such as solar power, for powering electronic devices.
- Algorithms for analysis, interpretation, and sharing of large data sets.

### What infrastructure do we need in order to deploy products faster?

- Involvement of the acquisition community for input regarding modernization considerations.
- Broad spectrum approaches that are long lasting (24 to 72 hours).
- Improved collaboration and data sharing with industry (specifically start-up companies), to facilitate the identification of existing and needed technology.
- Business model alignment, improved resources, and faster timelines for small startup companies that aim to address the needs of the military.
- High-risk financial considerations of industry partners that are marketing products for which the military is the only customer.
- Investment in regulatory affairs to expedite product deployment, since FDA review is required by the military for adoption of new technologies.
- Civilian networks (e.g., Strategies to Innovate Emergency Care Clinical Trials Network [SIREN]) for clinical research.
- Early adoption of products, and continued use to maintain familiarity.

## **Meeting Presentations**

**Enclosure 1**  
**CDMRP Overview**

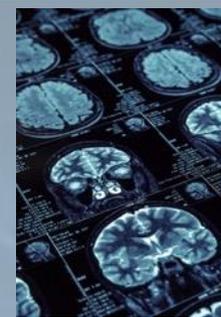
# The Congressionally Directed Medical Research Programs

CUTTING EDGE RESEARCH

**B. Christie Vu, Ph.D.**

CDMRP Program Manager

Combat Readiness—Medical Research Program



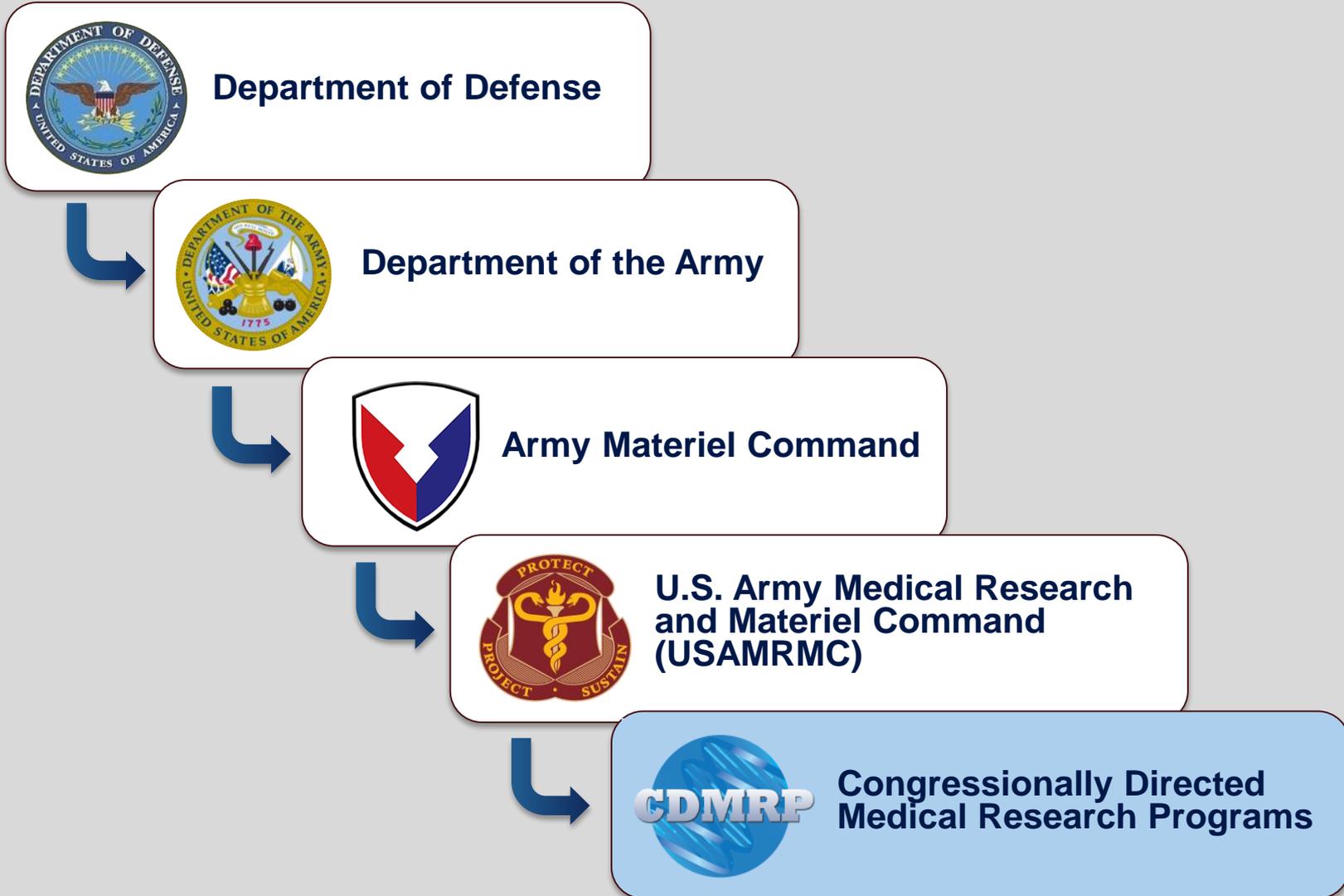
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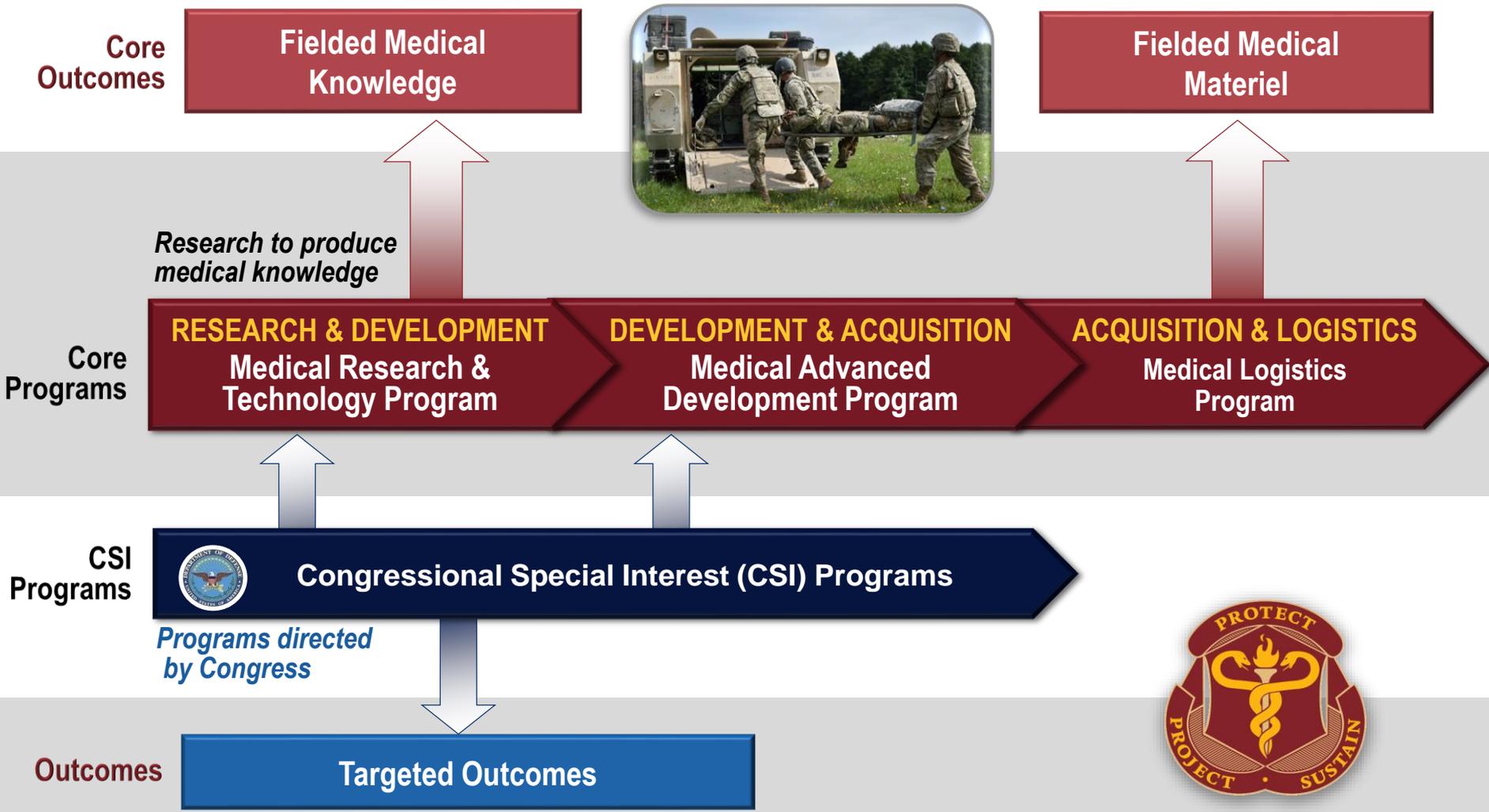
# Outline

- ◆ **Overview of the CDMRP Science Management & the Role of Stakeholders**
- ◆ **Overview of the Combat Readiness—Medical Research Program**
- ◆ **Survey Results and Broad Program Focus**

# WHO is the CDMRP?



# USAMRMC Strategic Process



# About CDMRP

## ◆ CONGRESSIONAL PROGRAMS

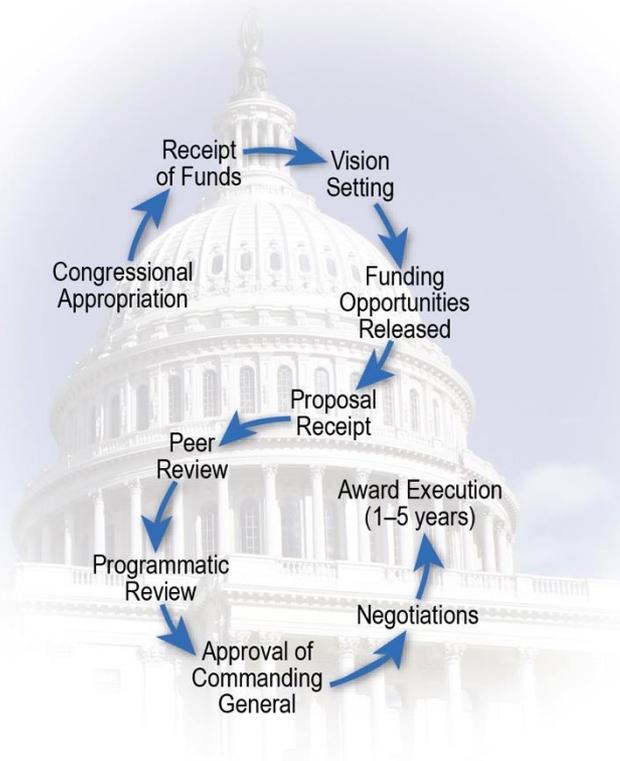
- ❖ Manages extramural research programs directed by Congress
- ❖ Started in 1992 with a focus on breast cancer research; currently includes 30 research programs
- ❖ Congress specifies the focus area; the CDMRP determines research strategy and competitively selects the best projects
- ❖ Unique public/private partnership encompasses the military, scientists, disease survivors, consumers, and policy makers
- ❖ Funds high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected

## ◆ DoD PROGRAMS

- ❖ Provides support to Program Area Directorates (PADs)/Joint Program Committees (JPCs) for managing extramural and intramural research portfolios to advance their missions

## ◆ DIRECTOR

- ❖ COL Stephen Dalal



### CURRENT PROGRAMS:

- Alcohol and Substance Abuse Disorders
- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- Breast Cancer Semipostal
- Duchenne Muscular Dystrophy
- Epilepsy
- Gulf War Illness

- Hearing Restoration
- Joint Warfighter Medical
- Kidney Cancer
- Lung Cancer
- Lupus
- Military Burn
- Multiple Sclerosis
- Neurofibromatosis
- Orthotics and Prosthetics Outcomes
- Ovarian Cancer

- Parkinson's
- Peer Reviewed Alzheimer's
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Peer Reviewed Orthopaedic
- Prostate Cancer
- Reconstructive Transplant
- Spinal Cord Injury
- Tick-Borne Disease
- Tuberous Sclerosis Complex
- Vision

### ADDITIONAL SUPPORTED DOD PROGRAMS:

- Armed Forces Institute of Regenerative Medicine II
- Centers of Excellence
- Defense Medical R&D
- Defense Medical R&D Restoral
- Psychological Health and Traumatic Brain Injury
- Small Business Innovation/Small Business Technology Transfer
- Trauma Clinical

# Vision and Mission

## Vision

**Transform healthcare for Service Members and the American public through innovative and impactful research**

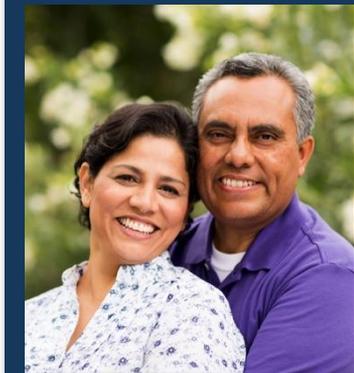
FUNDING GROUNDBREAKING, HIGH-IMPACT RESEARCH

## Mission

**Responsibly manage collaborative research that discovers, develops, and delivers health care solutions for Service Members, Veterans and the American public**

# Hallmarks

- ◆ Targeted research funds are added to the DoD budget by Congress
- ◆ Funds high-impact innovative research
- ◆ Avoids duplication with other funding agencies and targets unfunded/unmet gaps
- ◆ Follows the National Academy of Medicine-recommended model for application review
- ◆ Consumers participate throughout the process
- ◆ Annually adapts each program's vision and investment strategy, allowing rapid response to changing needs
- ◆ Funding flexibility
  - ❖ Funds obligated up-front; limited out-year budget commitments
  - ❖ No continuation funding
  - ❖ No "pay line;" funding recommendations are based on portfolio composition, adherence to intent of mechanism, and relative impact, in addition to technical merit



# Unique Partnerships

## Consumers

- ◆ Demonstrate need
- ◆ Participate at all levels
- ◆ Bring passion and perspective



## Congress

- ◆ Adds funds to budget
- ◆ Provides targeted guidance

## Researchers

- ◆ Focuses on innovation and research gaps
- ◆ Risk/benefit
- ◆ Product-oriented



**IMPROVE  
HEALTH  
OUTCOMES**

## DoD

- ◆ Oversees program management
- ◆ Contracting actions
- ◆ Regulatory requirements

# FY19 Funding

Program	\$M
Alcohol and Substance Abuse Disorders	\$4.0
Amyotrophic Lateral Sclerosis	\$10.0
Autism	\$7.5
Bone Marrow Failure	\$3.0
Breast Cancer	\$130.0
Breast Cancer Research Semipostal	\$0.6
<b>Combat Readiness*</b>	<b>\$15.0</b>
Chronic Pain*	\$10.0
Duchenne Muscular Dystrophy	\$3.2
Epilepsy	\$7.5
Gulf War Illness	\$22.0
Hearing Restoration	\$10.0
Joint Warfighter Medical	\$50.0
Kidney Cancer	\$20.0
Lung Cancer	\$14.0
Lupus	\$5.0
Melanoma*	\$10.0
Military Burn	\$8.0
Multiple Sclerosis	\$6.0
Neurofibromatosis	\$15.0

Program	\$M
Orthotics and Prosthetics Outcomes	\$10.0
Ovarian Cancer	\$20.0
Parkinson's	\$16.0
Peer Reviewed Alzheimer's	\$15.0
Peer Reviewed Cancer (15 Topics)	\$90.0
Peer Reviewed Medical (49 Topics)	\$350.0
Peer Reviewed Orthopaedic	\$30.0
Prostate Cancer	\$100.0
Reconstructive Transplant	\$12.0
Spinal Cord Injury	\$30.0
Tick-Borne Disease	\$5.0
Tuberous Sclerosis Complex	\$6.0
Vision	\$20.0

## Additional Supported DoD Programs/Projects <sup>(1)</sup>

Armed Forces Institute of Regenerative Medicine II	TBD
Defense Medical R&D	\$299.2
Psychological Health and Traumatic Brain Injury	\$125.0
Small Business Innovation Research/Small Business Technology Transfer	TBD
Trauma Clinical	\$10.0

<sup>(\*)</sup> New for FY19 <sup>(1)</sup> Approximate funding of Additional Support DoD Programs/Projects

**TOTAL = \$1.4B**

# FY19 Additional Supported DoD Programs/Projects Program Area Directorates/Joint Program Committees

## Medical Simulation and Information Sciences

- ❖ Health Information Sciences
- ❖ Medical Modeling, Simulation, and Training
- ❖ Health Information Technology and Informatics

## Military Infectious Diseases

- ❖ Bacterial Diseases

## Military Operational Medicine

- ❖ Environmental Health and Protection
- ❖ Injury Prevention and Reduction
- ❖ Physiological Health and Performance
- ❖ Psychological Health and Resilience

## Combat Casualty Care

- ❖ Battlefield Resuscitation for Immediate Stabilization of Combat Casualties
- ❖ En Route Care
- ❖ Prolong Field Care
- ❖ Neurotrauma

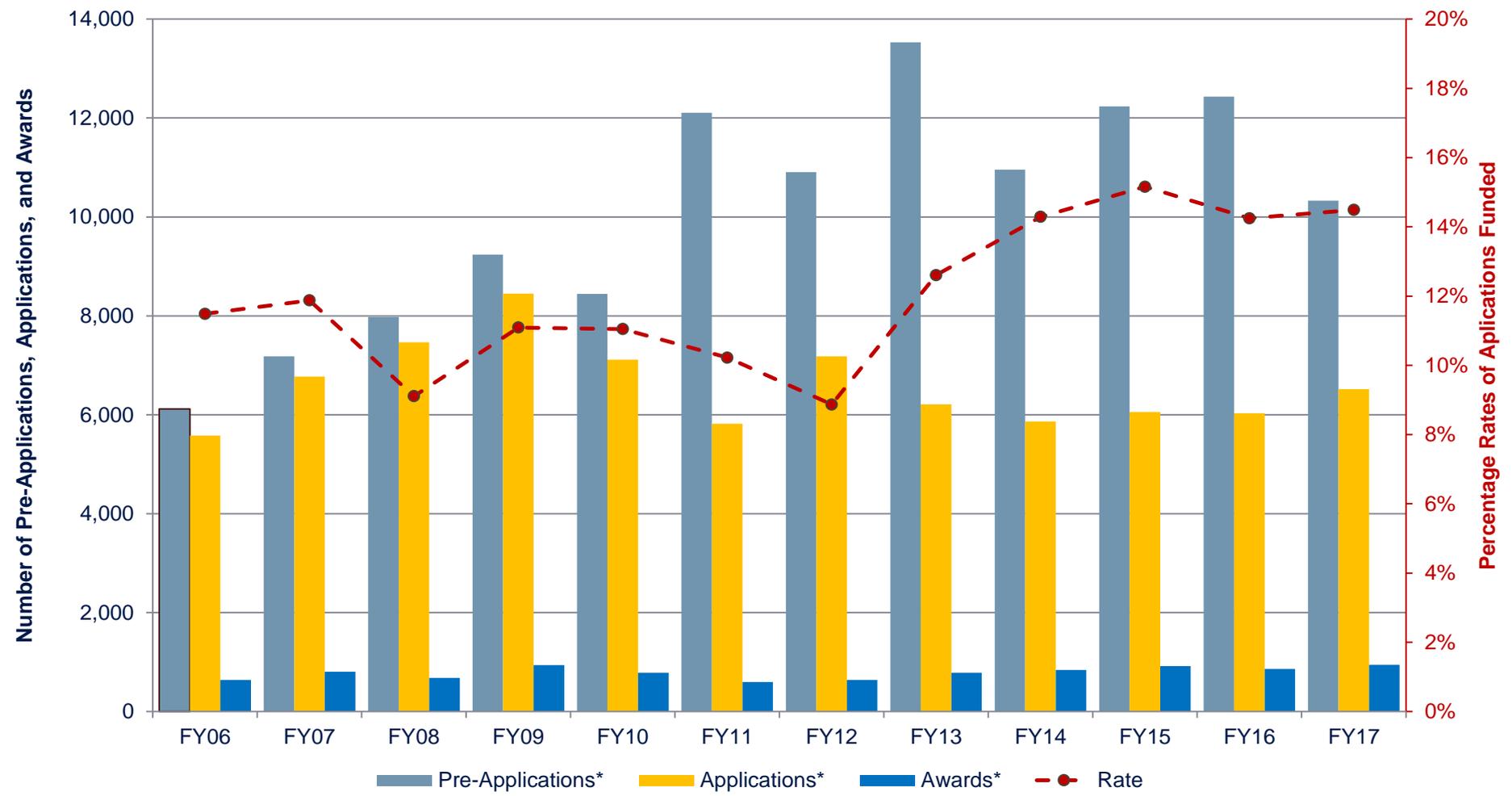
## Radiation Health Effects

- ❖ Biomedical Technology for Radiation Medical Countermeasures

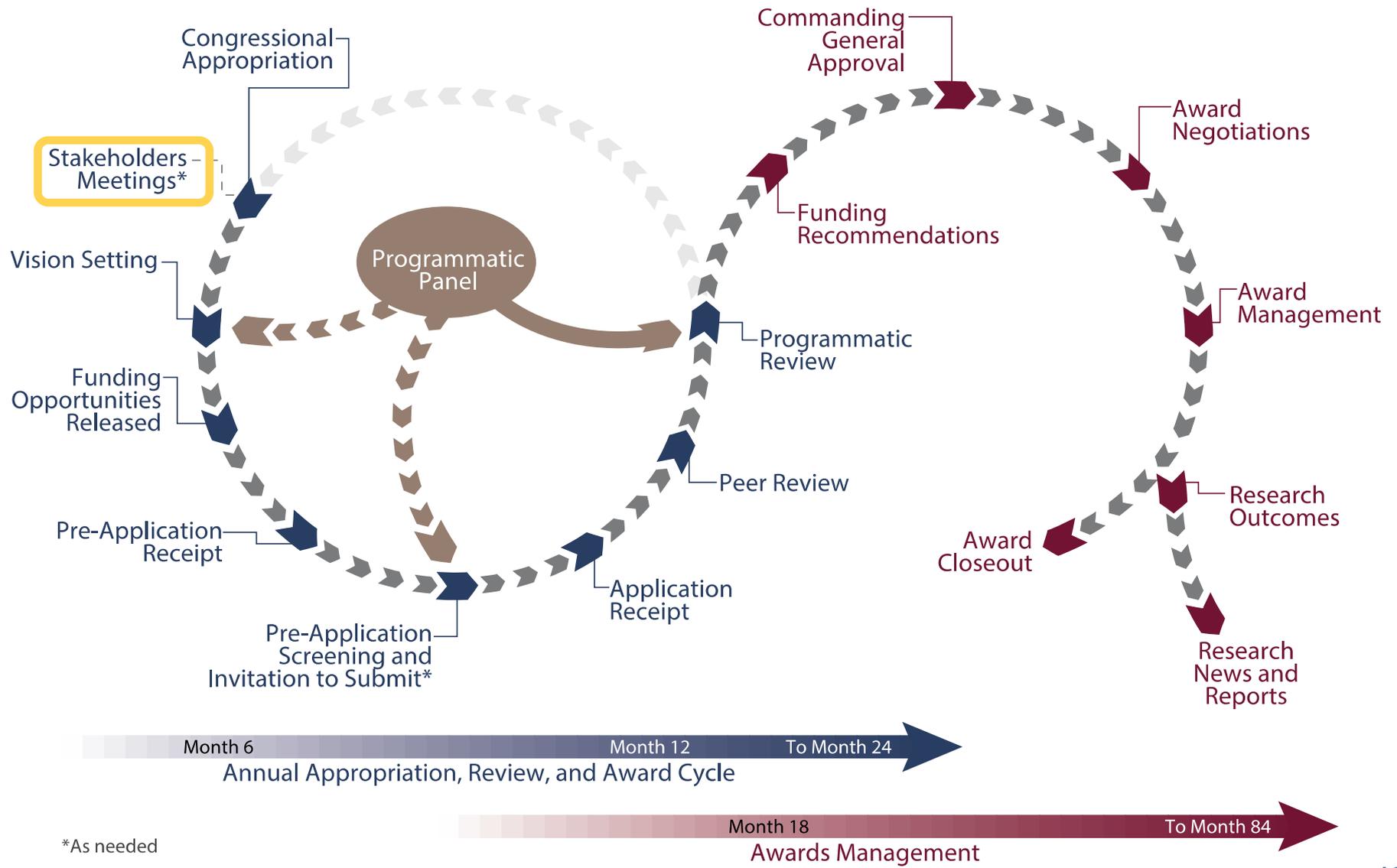
## Clinical and Rehabilitative Medicine

- ❖ Neuromusculoskeletal Injury Rehabilitation
- ❖ Pain Management
- ❖ Regenerative Medicine
- ❖ Sensory System Traumatic Injury (visual, auditory and vestibular dysfunction)

# FY06–FY17 Funding Rate



# Program Cycle

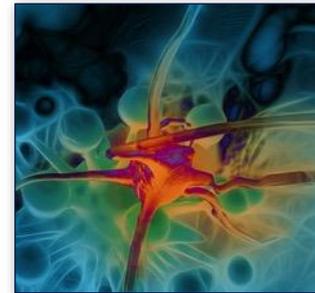


\*As needed

# Vision Setting

At Vision Setting each year, the Programmatic Panel recommends an investment strategy, considering factors such as:

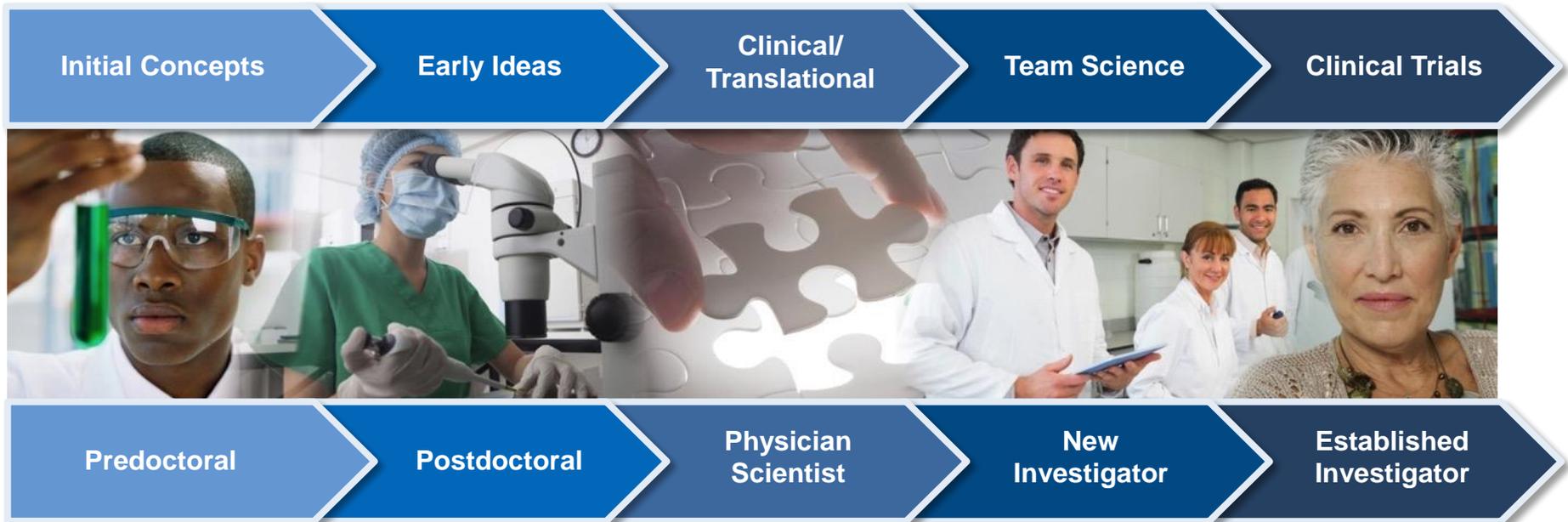
- ◆ Congressional language
- ◆ Current research landscape
- ◆ Emerging technologies
- ◆ Research gaps
- ◆ Impact
- ◆ Portfolio composition



# Award Mechanisms Pipeline

## Research Awards

Closing gaps through innovative and impactful research

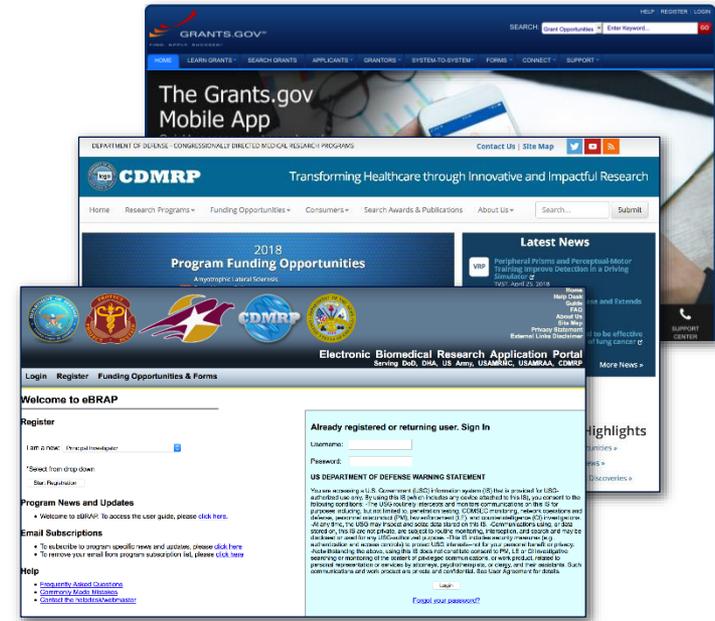


## Researcher Development

Funding for all career stages

# Funding Opportunities

- ◆ **Numerous types of award mechanisms**
  - ❖ Tailored to the goals of each program
  - ❖ May vary from year to year
- ◆ **Each funding opportunity is made available through a Program Announcement (PA) or program-specific Broad Agency Announcement (BAA)**
- ◆ **Pre-announcement release**
  - ❖ CDMRP website and email blast
- ◆ **Funding opportunity postings**
  - ❖ Grants.gov (CFDA 12.420)
  - ❖ electronic Biomedical Research Application Portal (eBRAP) system
  - ❖ CDMRP website
  - ❖ FedBizOps.gov (BAAs)



# Goal of the Two-Tier Review Process

*To develop funding recommendations that balance the most meritorious science across many disciplines and offer the highest promise to fulfill the programmatic goals set forth in the relevant Program Announcement*

## Peer Review

- ◆ Criterion-based evaluation of full proposal
- ◆ Determination of “absolute” scientific merit
- ◆ **Outcome: Summary Statements**
  - ❖ No standing Peer Review panels
  - ❖ No contact between reviewers and applicants

## Partnership



## Programmatic Review

- ◆ Comparison among proposals of high scientific merit
- ◆ Determination of adherence to intent and program relevance
- ◆ **Outcome: Funding Recommendations**
  - ❖ No “pay line” (portfolio balance)
  - ❖ Funds obligated up-front; limited out-year budget commitments (but milestones imposed)
  - ❖ No continuation funding

**Enclosure 2**  
**CRRP Overview**

# The Congressionally Directed Medical Research Programs: Combat Readiness—Medical Research Program

CUTTING EDGE RESEARCH



*The views expressed in this presentation are those of the author and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government*



# Combat Readiness—Medical Research Program

From the FY19 DoD Appropriations Conference Report:

“The conference agreement provides \$15,000,000 for Combat Readiness Medical Research. The conferees direct the Assistant Secretary of Defense (Health Affairs) to competitively award this funding to support the activities described under the heading "Joint Warfighter Medical Research Program" of House Report 115-769.”

*“The Committee...believes priority should be given for research to address the “golden hour” for service members with life-threatening injuries, battlefield diagnostics, and medical threats and treatments for warfighters deployed around the world.”*

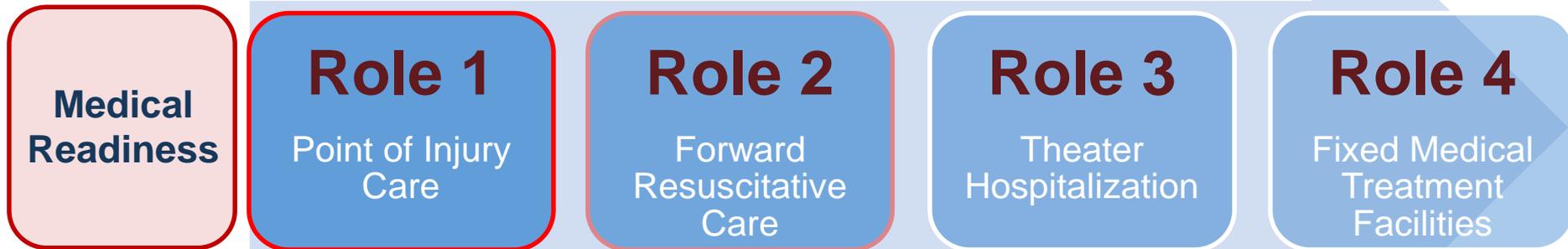
*“...identify current gaps in medical planning and resources, and consider medical capabilities that may mitigate fatalities...”*

\* FY19 Combat Readiness Medical Research reference language from House Report 115-769

The CDMRP’s Combat Readiness—Medical Research Program (CRRP) focuses on research relating to forward-deployable solutions that impact the immediate needs of the Warfighter and promptly address life-threatening injuries and exposure in battlefield settings.

# Topics from Congressional Language

- ◆ Enhancing battlefield diagnostics for neurological injuries and hemorrhage
- ◆ Integrated wound care and tissue regeneration therapies
- ◆ Environmental and wearable sensors, combined with advanced computing, for surveillance and monitoring of chemical and biological threat exposures
- ◆ Telemedicine applications for battlefield medicine
- ◆ Chemical and biological exposure countermeasures and management strategies
- ◆ Solutions for infectious disease management (e.g., sepsis)



# Additional Considerations

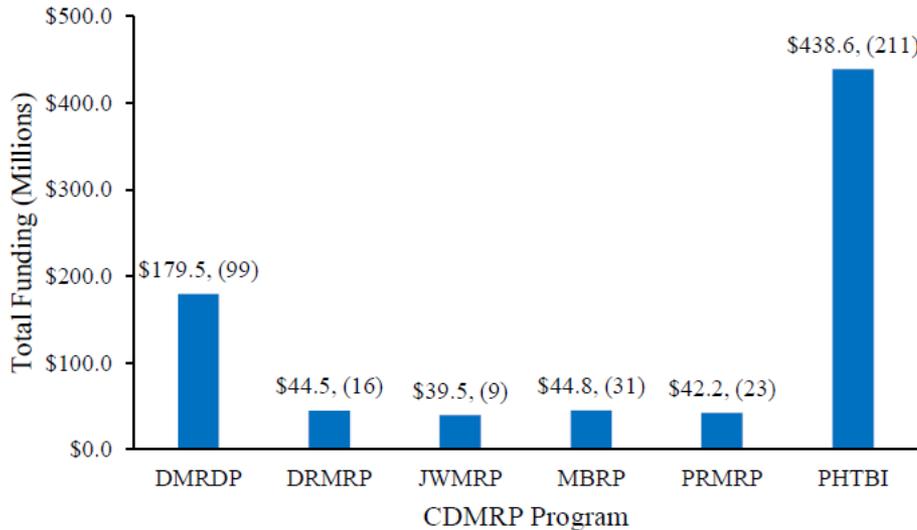


## ◆ Evolution of the battlefield

- ❖ Multi-domain operations
- ❖ Peer and near-peer adversaries
- ❖ Dense urban environments and/or subterranean environments

## ◆ The doctrine of the “Golden Hour”

# Relevant CDMRP-Managed Projects

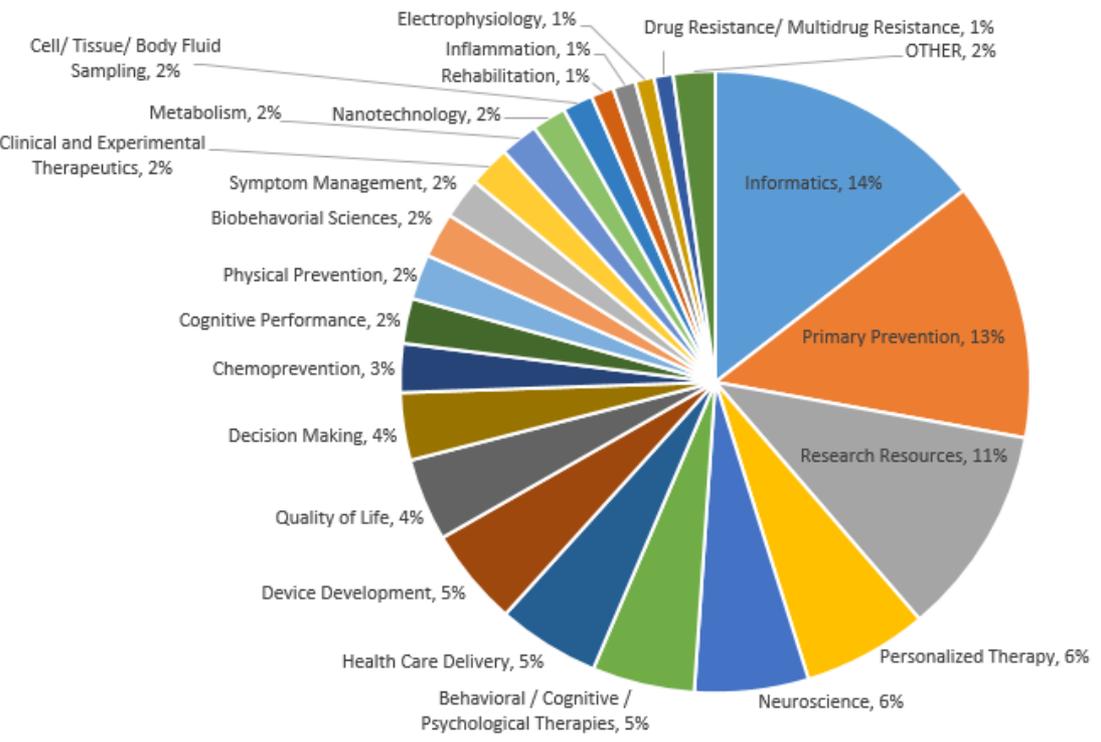


- Clinical management of battlefield injuries
- Traumatic brain injury (TBI)—screening and neuro-physical assessments
- Hemorrhage and resuscitation
- Coagulopathy of trauma
- Tissue injury and regeneration
- Forward surgical and intensive care approaches

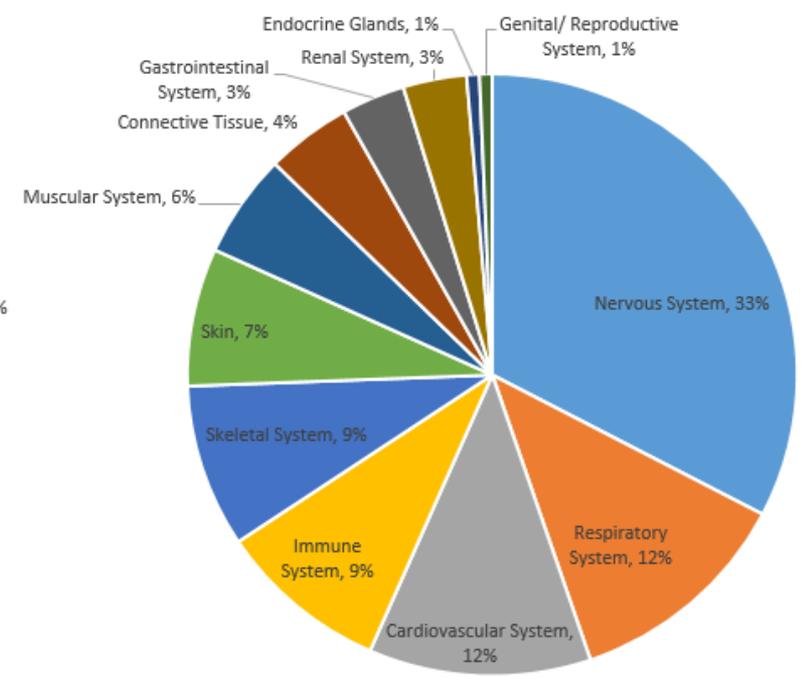
- ◆ ***Partial*** snapshot of projects from six programs with synergistic relevance to the CRRP
  - ❖ Scientific coding
  - ❖ Specific topic focus
- ◆ FY01 through FY18
- ◆ Includes DHP CSI, and DHP Core funded work
- ◆ Includes work with oversight from the JPC/PADs
- ◆ ***Does not represent the full scope of the USAMRMC portfolio***

# Distribution of Relevant CDMRP-Managed Awards\*

**Awards by Scientific Classification**

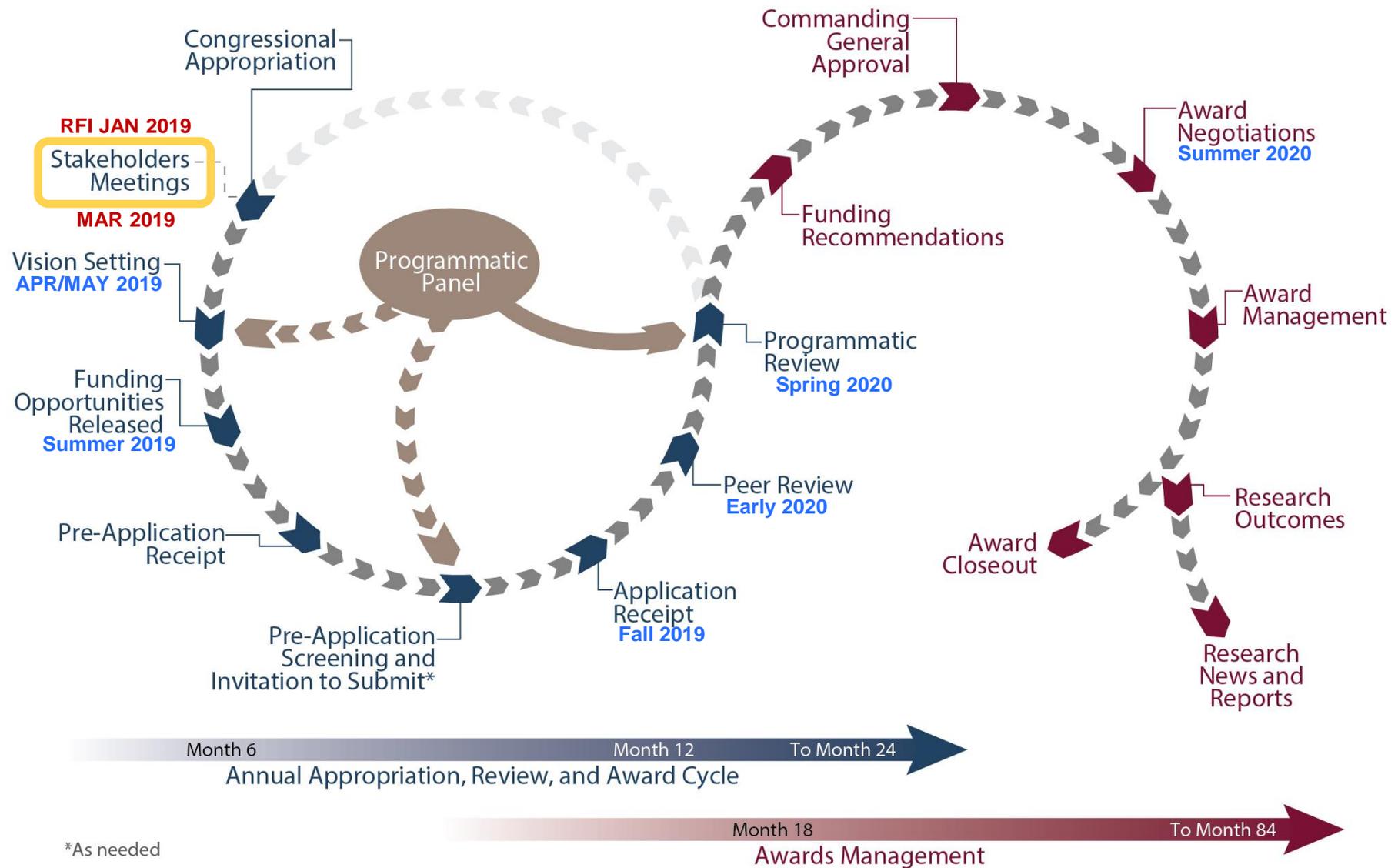


**Physiological Domains**



\* FY13 through FY18 available

# Program Cycle



\*As needed

# Stakeholders Meeting

- ◆ **Discuss key themes, advancements, needs, and gaps aligned to focus areas**
  - ❖ What are the most important challenges to:
    - Reducing morbidity and mortality in battlefield settings?
    - Addressing life-threatening injuries and exposure in battlefield settings?
    - Advancing forward-deployable solutions that impact the immediate needs of the Warfighter?
  - ❖ What needs to be done to support medical readiness for combat situations?
    - Current vs. future battle domains?
    - Materiel vs. knowledge solutions?
- ◆ **Outcomes:**
  - ❖ Identification and potential triage of critical needs, immediate solutions, and long term goals.
  - ❖ Informational materials for DoD Program Offices to *complement existing investments and knowledge base*.
  - ❖ Summary of landscape that will be used to inform on Vision Setting and the CRRP Strategic Plan.
    - *All identified gaps and priorities are pre-decisional and may not necessarily reflect the final focus of FY19 CRRP funding opportunities.*

**For more information, please visit:**  
**[cdmrp.army.mil](http://cdmrp.army.mil)**



# Breakout Session Topic Areas

- ◆ **Future Battlefield priorities addressing injury and lethality closer to the point of injury**
- ◆ **Medical readiness and health surveillance, to include physiological sensors, chemical and environmental exposures, as well as advanced computing.**
- ◆ **Infectious disease, biological exposures, and sepsis.**

# Moving Technology into the Hands of Providers and Patients

## ◆ Questions for Discussion:

- ❖ What training should be implemented to advance products?
- ❖ What emerging technology should we leverage?
- ❖ What infrastructure do we need in order to deploy products faster?

**Enclosure 3**  
**Combat Casualty Care Priorities**



# CCCRP

## Combat Casualty Care Research Program



### Ahead of the Curve: Combat Readiness – Medical Research Program

Col Michael Davis, MD, FACS

US Combat Casualty Care Research Program | JPC-6/JTCG-6

*March 25, 2019*

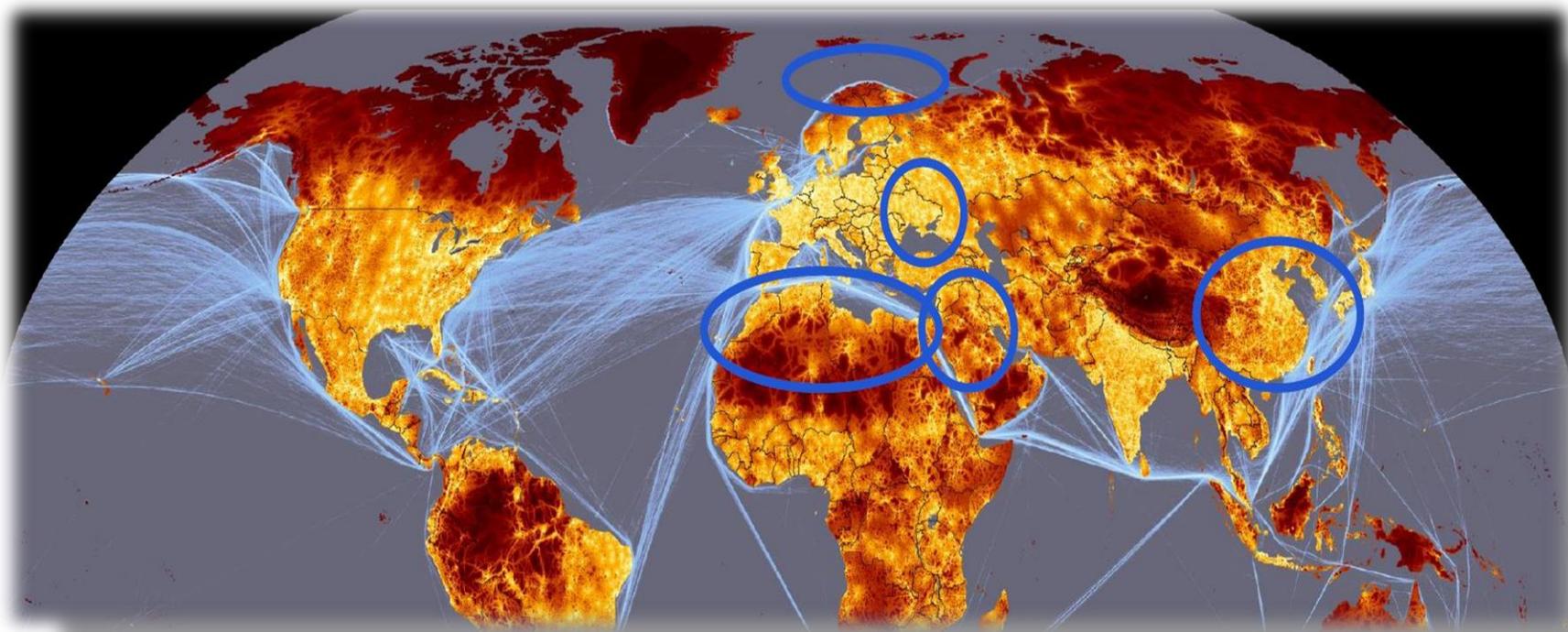


<https://ccc.amedd.army.mil>



**PAST**

**FUTURE**







TRADOC Pamphlet 525-3-1



# The U.S. Army in Multi-Domain Operations 2028



6 December 2018

Distribution Statement A.  
This document is approved for public release; distribution unlimited.



## Foreword

### *From the Chief of Staff of the Army*

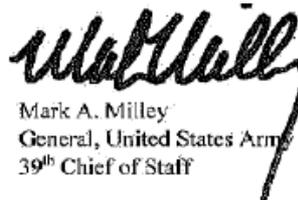
America's adversaries have studied US operations closely during Operations DESERT STORM, IRAQI FREEDOM, and ENDURING FREEDOM. They know the American way of war well and that we excel in a way of war that emphasizes joint and combined operations; technological dominance; global power projection; strategic, operational, and tactical maneuver; effective joint fires; sustainment at scale; and mission command initiative.

Simultaneously, emerging technologies like artificial intelligence, hypersonics, machine learning, nanotechnology, and robotics are driving a fundamental change in the character of war. As these technologies mature and their military applications become more clear, the impacts have the potential to revolutionize battlefields unlike anything since the integration of machine guns, tanks, and aviation which began the era of combined arms warfare.

Strategic competitors like Russia and China are synthesizing emerging technologies with their analysis of military doctrine and operations. They are deploying capabilities to fight the US through multiple layers of stand-off in all domains – space, cyber, air, sea, and land. The military problem we face is defeating multiple layers of stand-off in all domains in order to maintain the coherence of our operations.

Therefore, the American way of war must evolve and adapt. *The U.S. Army in Multi-Domain Operations, 2028* is the first step in our doctrinal evolution. It describes how US Army forces, as part of the Joint Force, will militarily compete, penetrate, dis-integrate, and exploit our adversaries in the future.

This product is not a final destination, but is intended to provide a foundation for continued discussion, analysis, and development. We must examine all aspects of our warfighting methods and understand how we enable the joint force on the future battlefield. We must challenge our underlying assumptions, and we must understand the capabilities and goals of our potential enemies. That is how we change our warfighting techniques and build the fighting forces we need in the future. It is also how we maximize deterrence and, if necessary, win future wars.



Mark A. Milley  
General, United States Army  
39<sup>th</sup> Chief of Staff

# Multi-Domain Battle\*

Future Vertical Lift

Combat Vehicles

Cross Domain Fires

Advanced Protection

Expeditionary  
Mission Command /  
Cyber Electromagnetic

Robotics /  
Autonomous Systems

Soldier and Team Performance and Overmatch

# Multi-Domain Battle\*

Future Vertical Lift

Combat Vehicles

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Soldier and Team Performance and Overmatch

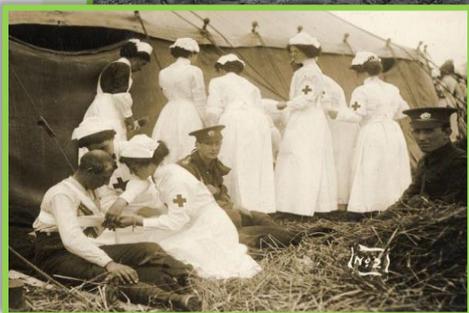
**Medical Support**

## WORLD WAR I



- IN 1917, THE U.S. ARMY DID NOT HAVE AN ESTABLISHED MEDICAL CORPS
- MILITARY MEDICINE HAD CHANGED LITTLE SINCE THE CIVIL WAR
- BATTLEFIELD RESEARCH IN HEMORRHAGE CONTROL WOULD LEAD TO UNDERSTANDING BLOOD GROUPS AND TRANSFUSION
- STRETCHER-BEARERS CARRIED SOLDIERS FROM THE TRENCHES TO AMBULANCES & AID STATIONS

U.S. MILITARY DEATHS: 116,708 | WOUNDED: 204,002  
 MILITARY DEATHS: 8.5 – 10.8M | WOUNDED: 22.1 – 23.7M  
 TOTAL DEATHS: 15.5 – 19.2M | CASUALTIES: >44M



## WORLD WAR II



- THE U.S. MILITARY HAD AN ORGANIZED SYSTEM FOR EVACUATION AND TREATMENT BASED ON MEDICAL CARE ECHELONS
- NEW TECHNIQUES, SUCH AS PENICILLIN USE IN FORWARD SURGERY, WERE TESTED
- THE SMALLER, MORE MOBILE FIELD AND EVACUATION HOSPITALS BECAME THE WORKHORSES OF THE THEATER

U.S. MILITARY DEATHS: 407,300 | WOUNDED: 671,801  
 MILITARY DEATHS: 21 – 25.5M | WOUNDED: 22.1 – 23.7M  
 TOTAL DEATHS: 70-85M | CASUALTIES: >100M



# VIETNAM

- THE VIETNAM WAR GAVE BIRTH TO MODERN PREHOSPITAL EMERGENCY CARE IN BOTH THE COMBAT AND DOMESTIC ARENAS
  - THE USE OF HUEY HELICOPTERS FOR EVACUATION OF THE WOUNDED
  - SOLDIERS RECEIVED ADVANCED, ON-SITE CARE FROM MEDICAL CORPSMEN FOR AIRWAY MANAGEMENT AND RESUSCITATION
- |                       |          |  |             |         |
|-----------------------|----------|--|-------------|---------|
| U.S. MILITARY DEATHS: | 60,036   |  | WOUNDED:    | 153,303 |
| TOTAL DEATHS:         | 1.5-3.6M |  | CASUALTIES: | >5.0M   |

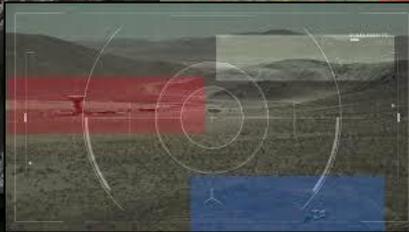


# OEF / OIF

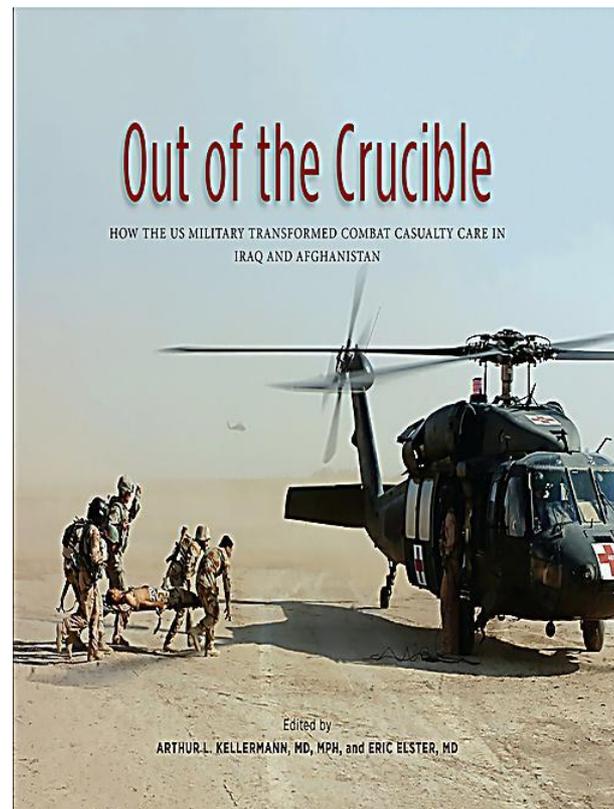
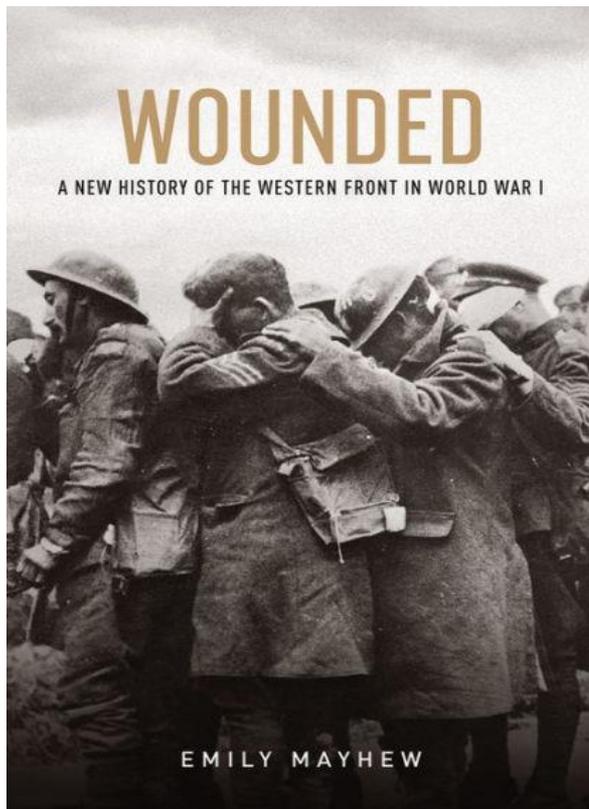


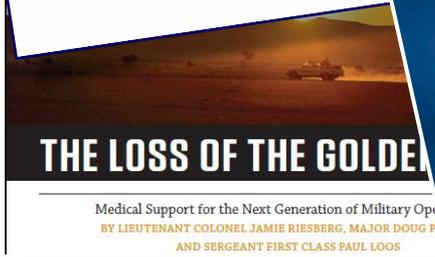
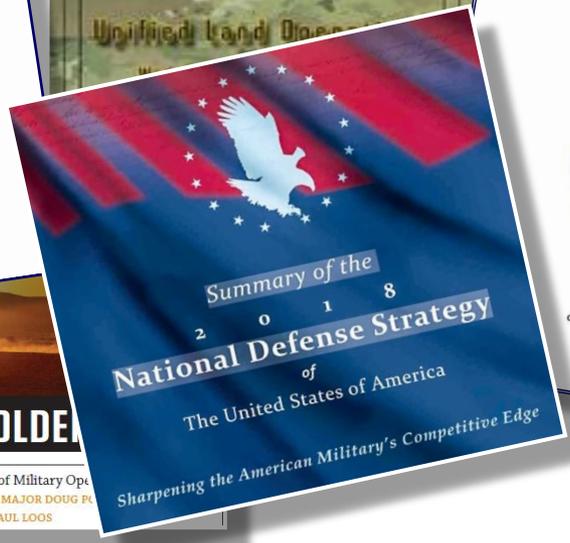
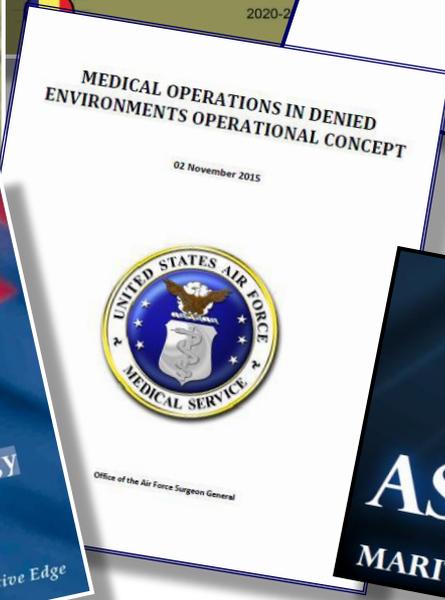
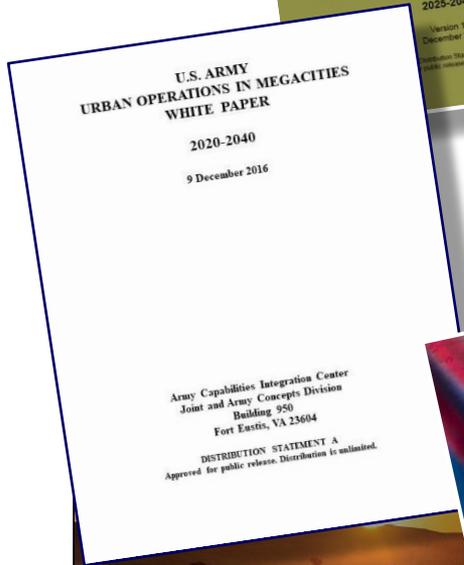
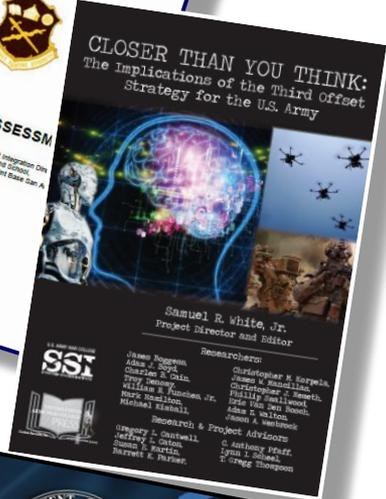
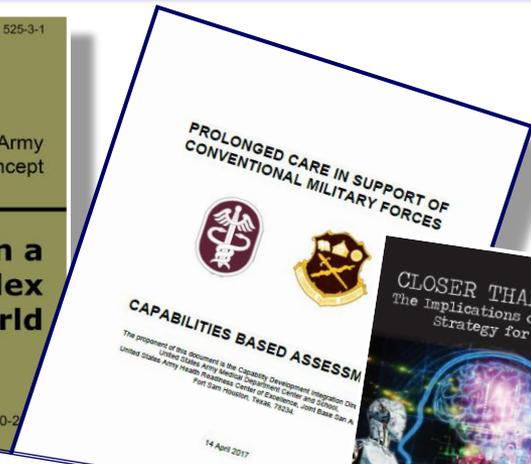
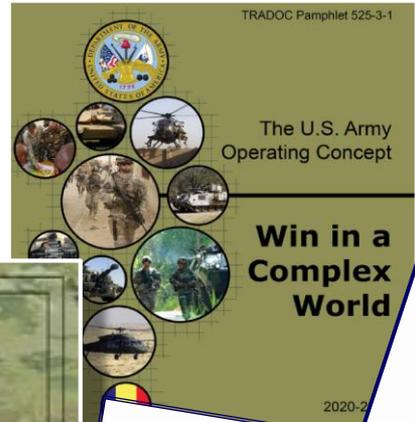
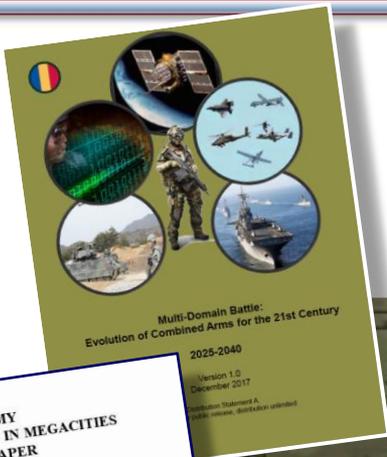
- “DAMAGE CONTROL” SURGERY EMPLOYED TO LIMIT IMMEDIATE POST-INJURY RESUSCITATION VOLUME
  - DOMINANT CAPABILITIES:
    - ROBUST COMMUNICATIONS
    - AIR SUPERIORITY
  - COMMITMENT TO THE “GOLDEN HOUR” CONCEPT OF CARE
- |                             |       |  |          |        |
|-----------------------------|-------|--|----------|--------|
| U.S. MILITARY DEATHS (OIF): | 4,424 |  | WOUNDED: | 31,958 |
| U.S. MILITARY DEATHS (OND): | 73    |  | WOUNDED: | 295    |
| U.S. MILITARY DEATHS (OEF): | 2,350 |  | WOUNDED: | 20,095 |
| U.S. MILITARY DEATHS (OIR): | 62    |  | WOUNDED: | 64     |
| U.S. MILITARY DEATHS (OFS): | 49    |  | WOUNDED: | 268    |
| TOTAL DEATHS:               | 6,958 |  | WOUNDED: | 52,680 |

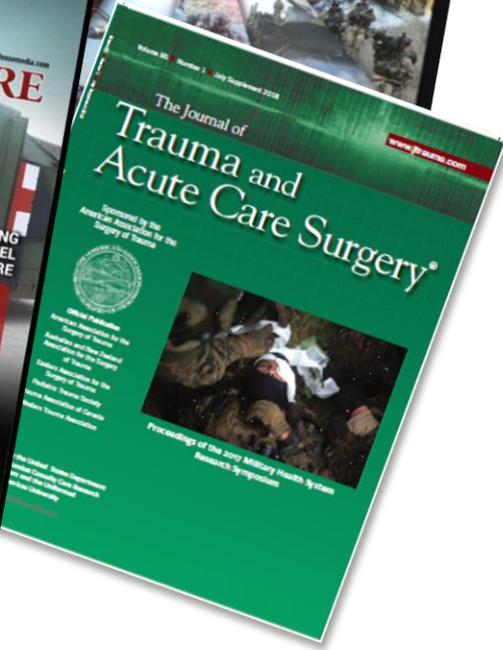
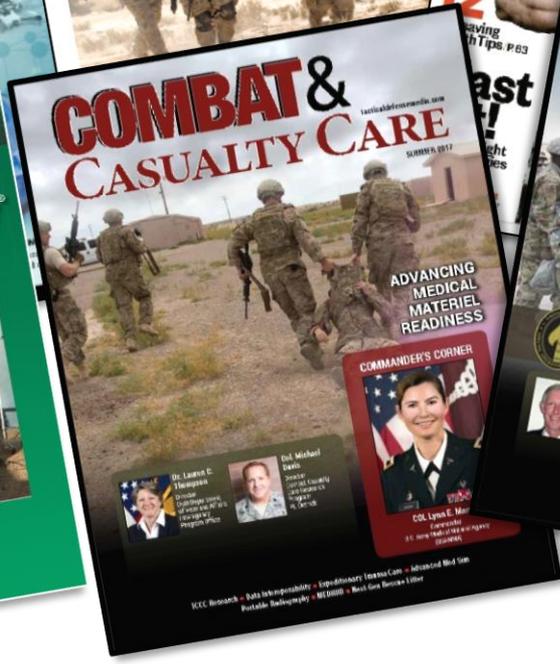
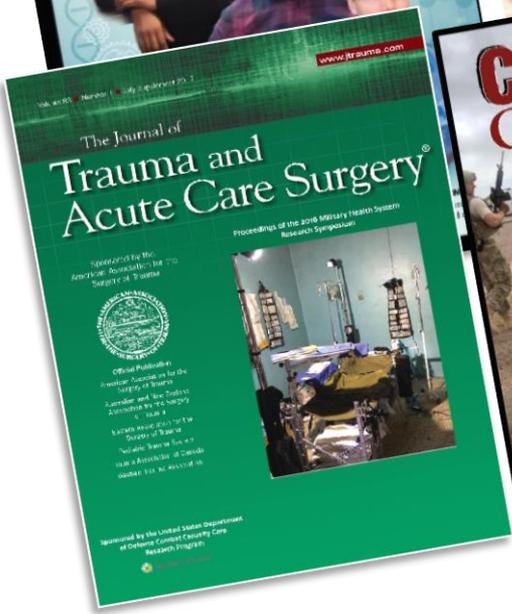
## MULTI-DOMAIN OPERATIONS



- LACK OF AIR SUPERIORITY/ ON DEMAND EVACUATION **X 72H**
- CONTESTED COMMUNICATIONS
- HIGHLY MOBILE BATTLEFIELD
- LARGE CASUALTY VOLUMES (>10,000/ 60 DAYS)
- MORE LETHAL BATTLEFIELD
- HIGHLY CHALLENGING LOGISTICS
- **DOCTRINE OF "GOLDEN HOUR" NOT ATTAINABLE**





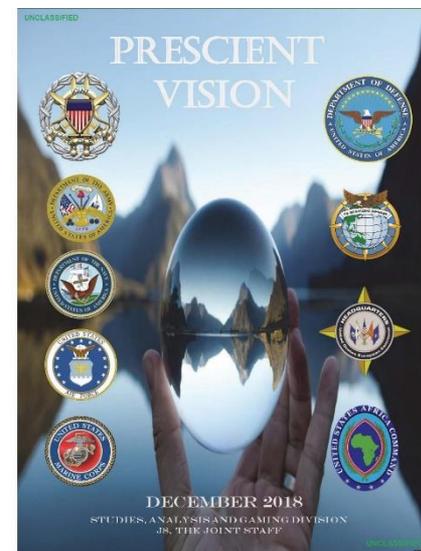


**DENSE URBAN ENVIRONMENT  
(DUE) WARGAMING REPORT:  
COMBAT CASUALTY CARE DEEP DIVE**

US ARMY INSTITUTE FOR SURGICAL  
RESEARCH (USAISR)

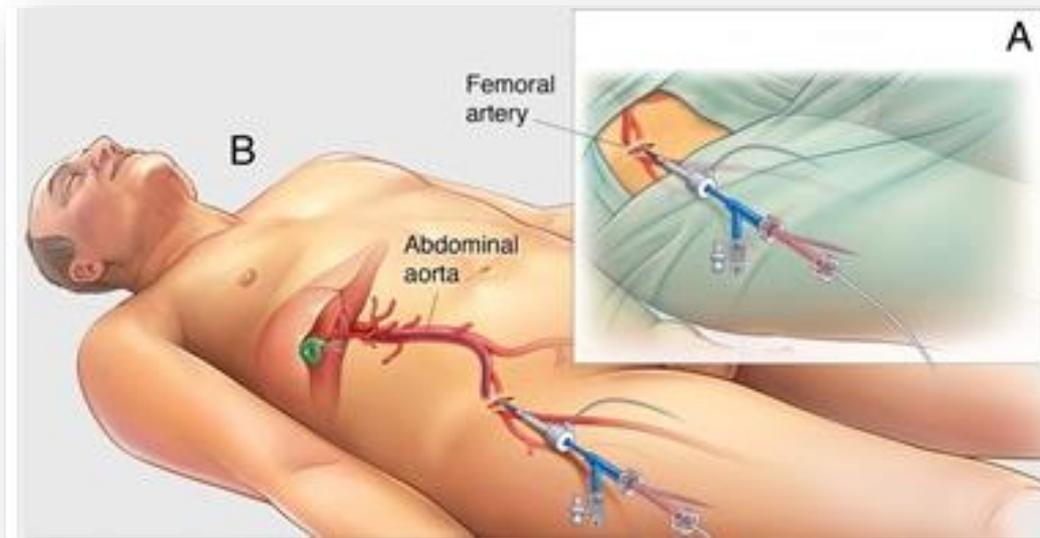
FORT SAM HOUSTON, SAN ANTONIO, TX

JANUARY 30 - FEBRUARY 1, 2018



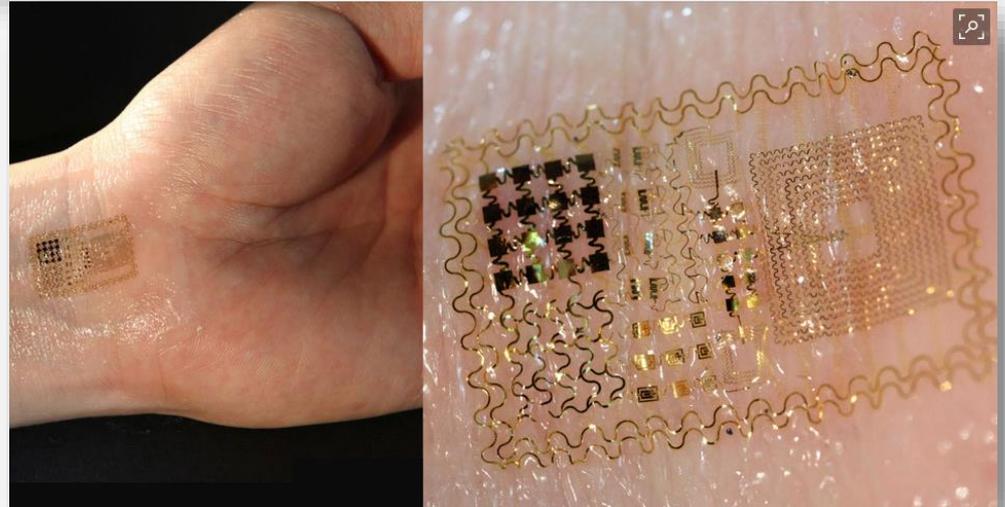


# Automated Resuscitation

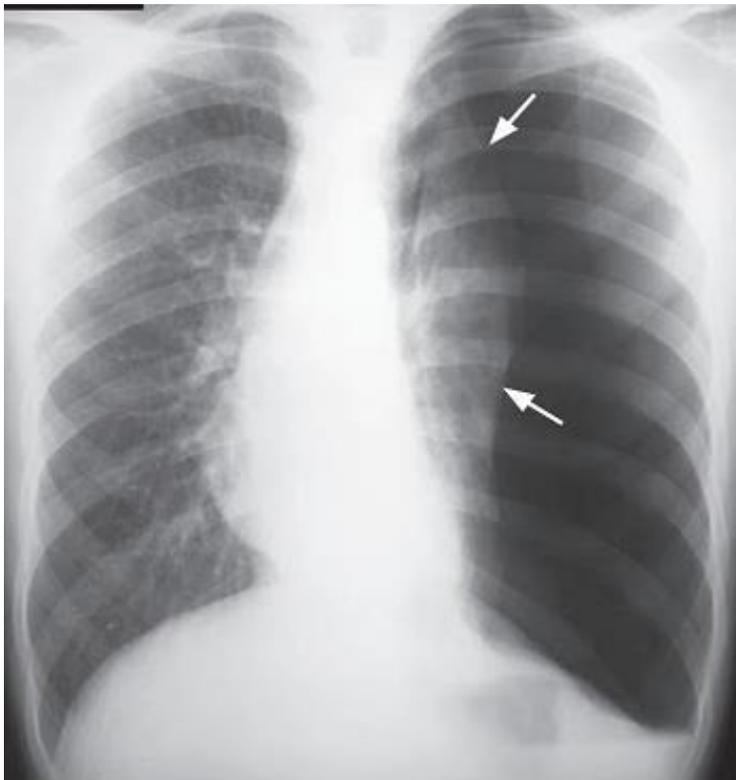




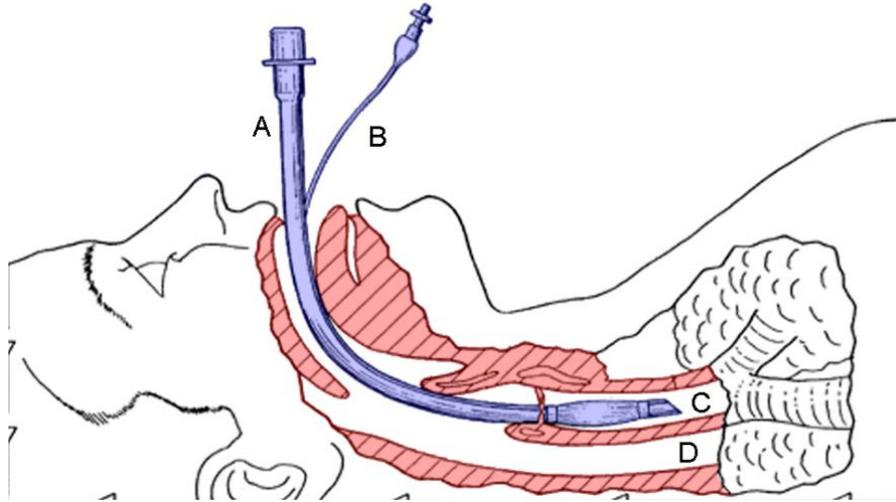
# Advanced Biosensors



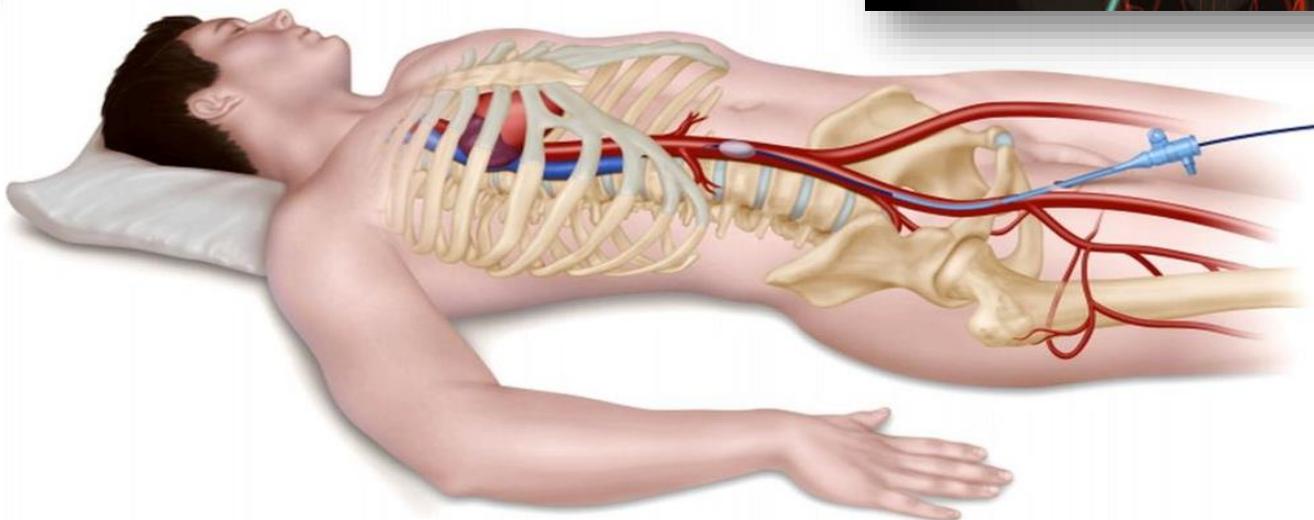
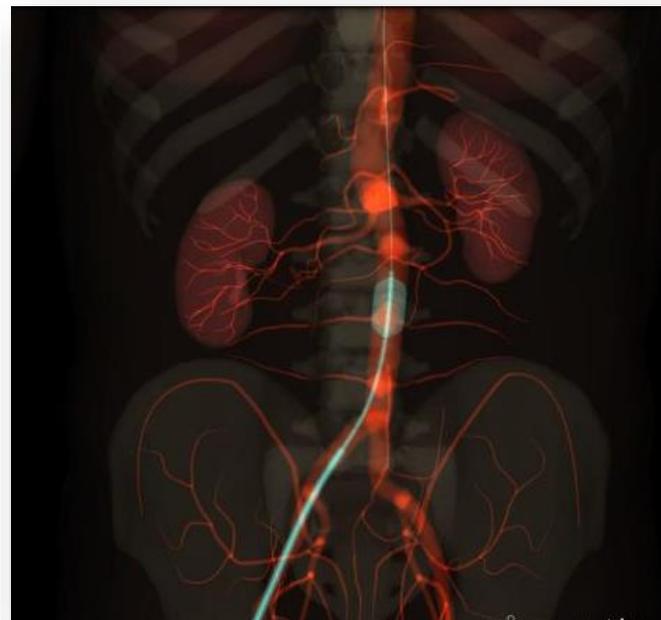
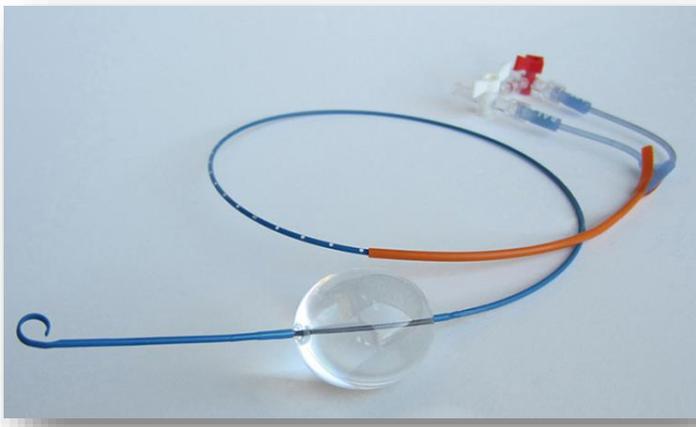
# Automated Thoracostomy



# Automated/ Semi-automated Airway Access



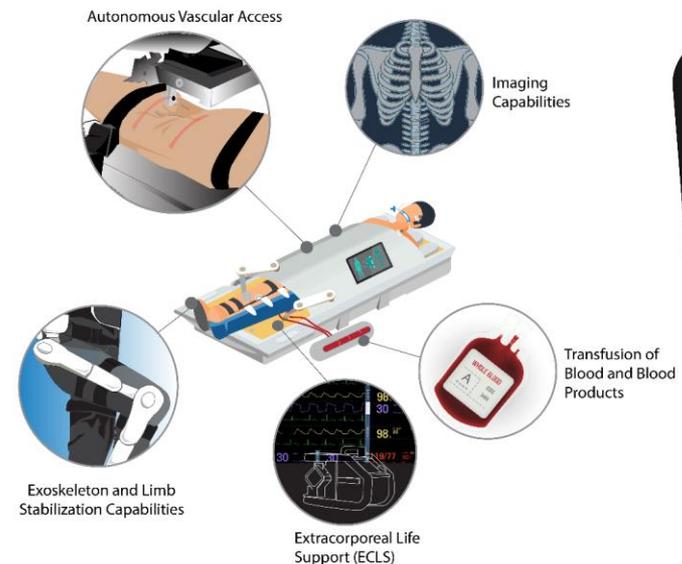
## REBOA (Next Generation)



# Extracorporeal Life Support (ECLS)



- Miniaturized medical mini-tools
- Sustained O<sub>2</sub>/ventilation
- **Automated detection/ decompression of tension pneumothorax**
- Drugs to control airway secretions/inflammation
- Large animal platforms for in-vivo training for PFC conditions
- **Organ preservation drugs**
- **Automated tourniquet/smart tourniquets**
- Walking blood banks
- Drugs to support hemostasis
- Improved junctional bleeding control
- **Field expedient vascular clamps**
- Ability to visualize hemorrhage source
- Non-compressible torso hemorrhage control
- Manufacturing/production of medical materials on-site
- Unmanned extraction
- **Algorithms and decision support for triage**
- **Field expedient pelvic fixation**



- Better body armor/suits to protect abdomen
- Robotic support
- MEDEVAC re-configuration for MDO
- **Field device to determine anatomic location of hemorrhage**
- **Device to non-invasively measure cerebral perfusion/ detect EDH, SDH, ICH**
- **Automated cranial decompression**
- Non-neuro-invasive neuro-assessment devices to determine RTD decisions in the battlefield
- Non-opioid analgesia solutions with limited side effects
- Optimal analgesia solutions for TBI patients
- **Rapid pain management solutions that do not compromise cognition or affect hemodynamics**
- Automated anesthetic capabilities that can be implemented at Role 1/PFC
- Tool to enable regional nerve blocks at Role 1 with limited training
- **New long-lasting (>2 hr.) analgesics for prolonged care**
- High fidelity cricothyrotomy/airway model



- **Tactical cricothyrotomy kit with functional field suction**

- Tactical medical light
- High fidelity hearing protection
- Improved hemostatic pressure bandages

- **Hemorrhage control drugs**

- Ligation/surgical repair capabilities at POI
- AI/Decision support tools for effective tourniquet conversion

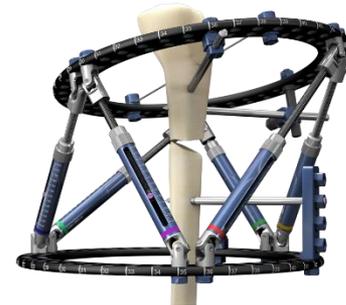
- **Advanced external skeletal fixation/ exoskeleton**

- **Diagnostics and therapeutics for compartment syndrome**

- Field amputation

- **Autonomous critical care support systems for unmanned evacuation platforms**

- Gas mask with airway access for trauma care
- MOPP-4 with fluid resuscitation capability



# CCCRP

Combat Casualty Care  
Research Program

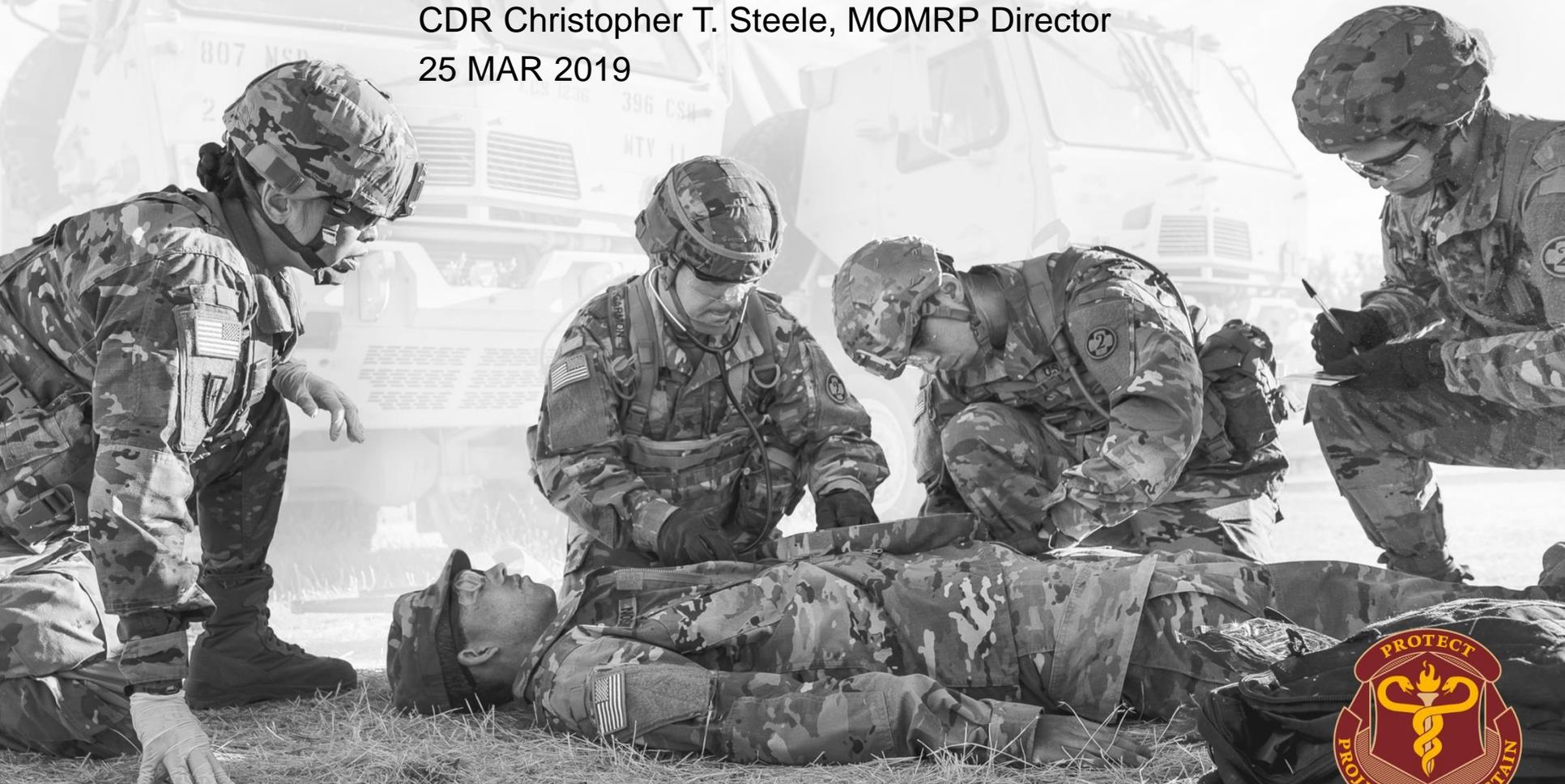


**Enclosure 4**  
**Medical Readiness Priorities**



# Military Operational Medicine Medical Research Priorities: Combat Readiness - Medical Research Program

CDR Christopher T. Steele, MOMRP Director  
25 MAR 2019





# MOMRP Overview

MOMRP portfolio serves to ensure Service members are **responsive** to the challenges of training and **resilient** to the rigors of combat

- Develops capabilities to prepare for the fight and stay in the fight
- Gaps are to monitor medical readiness and develop countermeasures to maintain it
- Enables Service members to overcome external and internal stressors
  - External factors include heat, blast and repeated impacts (operating weapons, physical injury)
  - Internal factors are both physiological and psychological





# MOMRP Overview

This portfolio develops solutions to **prevent** injury or performance degradation, **improve or enhance** performance in complex operating environments and **treat** detrimental conditions (psych) to rapidly reset/return Service members to combat.

- **Medical Readiness** efforts impact the potential of Warfighters through Preparation/Prevention/Sustainment
- **Biomedical Performance** drives lethality of the individual and small unit through Optimization/Enhancement





# Molding the Scope of the Combat Readiness Research Program

What is the scope of investments in this space?

Should efforts focus on:

- preventing adverse events?
- performance/effectiveness?
- care providers or others (or both)?

What is the ***temporal nature*** of Combat Readiness for this program?

e.g., is this line of effort to advance treatment/return to duty in the:

- Near-term (minutes to hours)
- Mid-term (days to weeks)
- Long-term (months to years)

After an intervention, are they back in the fight?



# Maintaining Medical Readiness Across Broad Exposures

Develop effective biomedical countermeasures against operational stressors and to prevent physical and psychological injuries during training and operations in order to maximize the health, readiness and performance of Service members and their Families, in support of the Army Human Performance Optimization and Enhancement (HPOE), Human Dimension (HD), Multi-Domain Operations (MDO), Army Modernization Priorities, DoD Total Force Fitness (TFF) concepts and DoD Lethality initiatives. ***JROC approved Joint Military Operational Medicine ICD NOV***

2018

## Science

### ENVIRO

Environmental Health and Protection

THREATS

- Heat/Humidity Stress
- Dehydration
- Cold Stress
- Dust/Air Pollution
- Toxic Industrial Chemicals/Materials
- Water Contaminants
- Altitude & Undersea Hypoxia

### INJURY

Injury Prevention and Reduction

THREATS

- Musculoskeletal Injury
- Blast Overpressure
- Blunt Head/Body Trauma
- Face/Eye/Spinal Injury
- Acoustic Trauma
- Directed Energy Injury
- Degraded Visual Environment

### PHYSIO

Physiological Health and Performance

THREATS

- Disaggregated/Continuous Operations
- Sleep Deficit and Circadian Desynchrony
- Sustained Fatiguing Work (Physical/Mental)
- Malnutrition
- Dietary Supplements Misuse

### PSYCH

Psychological Health (PH) and Resilience

THREATS

- Resilience
- PTSD/Other PH Disorders
- Suicide Behavior
- Alcohol/Other Drug Use
- Access/Retention in Behavioral Health Care
- Family Transitions and Well-being

Biomedical Performance Enhancement  
Wearables for Health, Readiness and Performance  
Medical Aspects of Manned/Unmanned Teaming

## Service Member

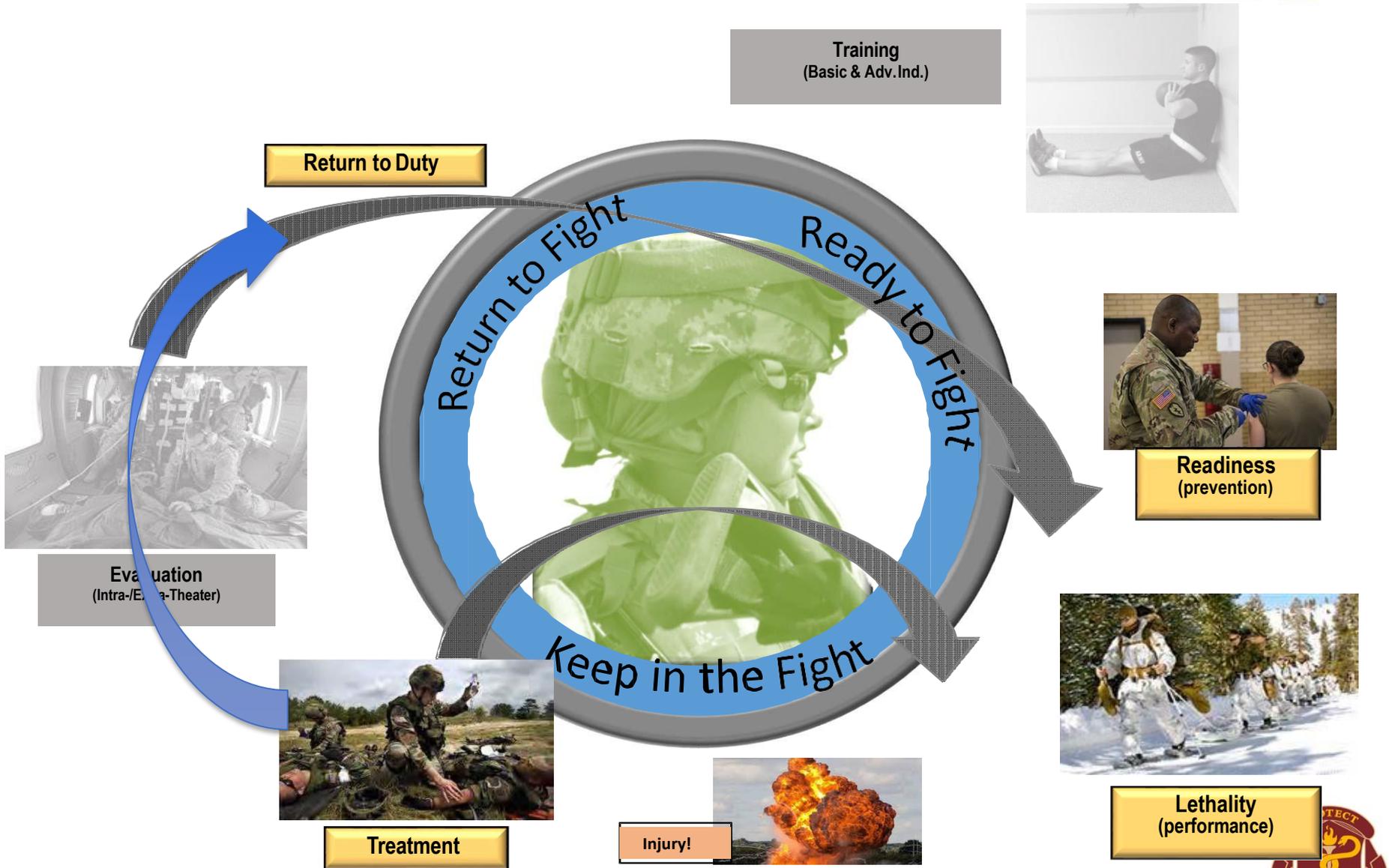


# Medical Capabilities support the Joint Force in several ways...





# 'Combat Readiness' should likely focus on maintaining combat power





# Multi-Domain Operations - Impacts on Combat Readiness

## Will Challenge Sustained Lethality of Warfighter/Unit

- Increased cognitive and physical stressors on Warfighter
- Must Maximize cognitive & physical performance, return to the fight quickly
- Prevent/mitigate disease non-battle injury (DNBI)

## High Casualty (~30%) & DNBI Volume

- High demand on medical assets; requires greater efficiencies

## Medical assets must be highly mobile & more dispersed

- Rely on smaller, more modular medical units

## Medical Capabilities Far-Forward will have limited medical support

- Requires greater self-sufficiency & autonomy of embedded providers and non-medical personnel





# MOMRP and Medical RDT&E Efforts:

## Prevent Warfighter Illness and Injuries

- Through selection, training and Medical Preparation, MED S&T enables “Ready Service members” for the fight in varied environments and complex operating conditions
  - Pre-deployment focused to ensure the Force is ready and available for the fight
- Improve Readiness of the force- ‘fight tonight’
- Maximize Combat Power by ensuring Availability

## Maintain and optimize Warfighter performance in all operating conditions

- Focus on toxic, extreme environmental (heat, cold, altitude) and extreme physical and cognitive stressors
- Rapidly reset cognitive and physiological state (e.g., nutritional recovery, sleep optimization)
- Improve combat power by maintaining Individual and Unit performance in Multi-Domain Operations
- Develop and maintain Psychological Health under complex challenges
- Develop far-forward (acute stress) psych health treatments





# MOMRP and Medical RDT&E Efforts:

## Biomedical Performance Enhancement

- Ethical Strategies that capitalize on biomedical advances

## Treat Warfighter Illness, Injuries and Casualties

- Focus on Training, Combat and Evacuation
  - Multi-Domain Operations (MDO) constrain the provision of care, and restrict logistical support creating the need for modified COTS, new technologies and DoD-unique Clinical Practice Guidelines (CPGs, e.g., TTPs)
  - MDO limits casualty evacuation and degrade patient management capabilities, forcing prolonged care of casualties at all roles of care
    - **Disease and Non-Battle Injuries**
    - **Psychological Impacts**
- Return Warfighters to the fight and improve Combat Power & availability
- Maintain Unit morale
- Reduce medical footprint and export medical expertise wherever and whenever needed (embedded providers and non-clinicians need support of some type)

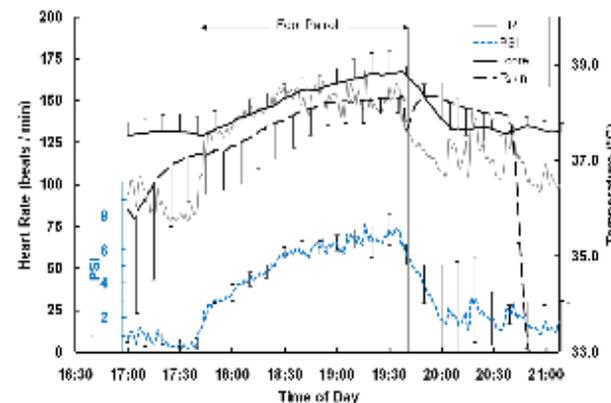
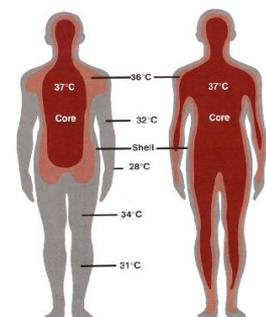




# Precision Operational Medicine

## Physiological monitoring provides real-time feedback on Health, Readiness and Performance State of Warfighter

- Thermal work strain prediction
- Permits Warfighter to work within physiological limits & moderate intensity to sustain performance
- To make a difference, need to greatly expand and share data. Lots of it
- Environmental/Occupational exposure monitoring can prevent many adverse events
- Scope of “what to monitor” can be immense





# Cross-Domain Integration of Wearables: From Performance to Patient

Actionable Alerts	Sense	Model	Decide	Limitations
Heat stress				Needs compensable/uncompensable modeling, use-specific alerting
Cold stress				Confounded core temperature sensing
Musculoskeletal injury				Limited predictive models
Agility				Limited predictive models
Hypoxia				Challenges in collecting meaningful data
Dehydration				Lacking sensing modality; limited predictive models
Exhaustion / metabolic				Metabolic cost models limited; alert states not well defined
Training recovery				Proprietary commercial products not validated
Diminished cognition / judgment				Alert states not well defined
Alertness				Current metrics require intervention; limited predictive models
Emotional instability				Lacking sensing modalities, alert states not well defined
Infection / bioagent				Primate model data only; alert states not well defined
Stopped activity				Simple 'Are you OK?' based on location / movement
Chemical exposure				Primate model data only; alert states not well defined

Sufficiently validated for routine use

Further development needed

Further research needed





# Performance Nutrition and Combat Readiness

- Long history of building DoD field rations with Combat Feeding Directorate
- Efforts have produced First Strike Ration and environmentally specific meals
- Calcium / Vitamin D bar composition fed to augment nutritional requirements of recruits with intense musculoskeletal remodeling demands
- Numerous DoD efforts in microbiome characterization
- Metabolic monitoring and field measurements will enable improvements in this space
- **Future will be in personalized performance and recovery nutrition**





# Environmental Performance Sustainment

Need a plan for supporting Lethality that includes **sustained performance under environmental stressors...**

Arctic/Extreme Cold – Protective gear and physiological mechanisms

- Microclimate warming
- Dietary supplement that increases vasodilation
- Biofeedback training of hand warming
- Use of physiological reflexes (face warming)

Dense Urban and Subterranean Environments –

- Understanding the physiological limitations and psychological impacts.
- Stress on the force will be very unfamiliar

Altitude

- Moving from group to individualized models for greater predictions and focused interventions
- Still have issues at altitude (aviation and ground) that need advanced countermeasures





# Sleep and Circadian Disruption

- Numerous tools developed for sleep manipulation, none validated for field reliability
- Efforts to improve understanding, monitoring and TRANSLATION of what predictive sleep models really mean
- **Rapid Reset is a Combat Readiness Goal**





# Biomedical Performance Enhancement

- **Scalable and ethical modalities and interventions to ensure overmatch**
- Warfighter as weapon – augmented hardiness, accelerated training, faster decisions
- Medical integration with exoskeleton technologies
- Human genetics of extreme performance (selection, manipulation)
- Pharmaceutical interventions enhancing physical, cognitive or psychological performance





# Performance Pharmacology

**TABLE 1.** Substances prohibited in international sports competition (source: <http://list.wada-ama.org/prohibited-in-competition/prohibited-substances/>).

Drug category	Definition or examples	Tested with soldiers
Nonapproved substances	Substances with no current approval for human therapeutic use	
Anabolic agents	Androgens, androgen metabolites, and anabolic steroids	Testosterone enanthate, methyltestosterone, and nandrolone decanoate
Peptide hormones, growth factors, related substances, and mimetics	Erythropoietins, growth hormones, and hypoxia-inducible factor activators (e.g., argon, xenon)	Autologous blood transfusion*
Beta-2 agonists	Clenbuterol, isoprenaline, and salbutamol†	Salbutamol
Hormone and metabolic modulators	Myostatin inhibitors, estrogen inhibitors, and insulins	Testolactone
Diuretics and masking agents	Probenecid, acetazolamide, and furosemide	Acetazolamide (for prevention of acute mountain sickness)
Stimulants	Amphetamine, modafinil, cocaine, ephedrine, epinephrine, and caffeine‡	Amphetamine, modafinil, and caffeine
Narcotics	Buprenorphine, morphine, and oxycodone	
Cannabinoids	Cannabis and delta 9-tetrahydrocannabinol	
Glucocorticoids	Cortisone, prednisone, and dexamethasone	Compound "E" (cortisone)

\*Manipulation of blood or blood components is a "prohibited method."

†Permitted in competition below a maximum dose.

‡No longer banned but monitored in competition for "patterns of misuse."





# Protection in support of Combat Readiness and Lethality

## Medical Criteria for Helmets and Body Armor

- Behind Helmet Blunt/Ballistic Trauma to support development, test and evaluation, and acquisition of future head protection systems for the DoD



The Joint Force lacks sufficient capabilities to mitigate or eliminate the effects of blast, ballistic, blunt ... threats to the operational health, readiness, and performance of SMs in all environments - Joint Initial Capabilities document for Military Operational Medicine, dated October 2017

**\*\*\*Currently there exists no medical criteria for helmets to stop ballistic threats outside of common small arms**



There could be significant brain injury risk due to back face deformation resulting from defeating round penetration.





# Psychological Health in support of Combat Readiness and Lethality

## Psychological and Behavioral Influences

- Small Unit Team Cohesion
- Post-traumatic Growth
- Resilience and Mindfulness Efforts

## Far-forward Behavioral Health

- Acute Stress reaction focus
- Incorporation of predictive sensory analytics (multimodal)



Improved embedded provider training and interventions from non-PH/medical personnel can be added here...





## Desired Capabilities that support Combat Readiness

- Sensors that can accurately measure Service member status that cross broad medical disciplines and span performance to patient
- Optimal delivery of far-forward psychological health care (improved providers, improved tools for in the field management of PH issues)
- Medical interventions/technologies to manipulate physiological processes for optimization and rapid reset (microbiome, sleep, etc.)
- Decision aids and countermeasures to prevent warfighter performance degradation in extreme environments
- Operational risk planning tools for environmental threats
- Technologies and decision aides to assess far-forward musculoskeletal injuries and manage blasts and head impacts
- Biomedical performance enhancement technologies
- Unit-level psychological interventions to enhance performance
- Improved protective equipment based on the proper biomedical basis



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**Enclosure 5**  
**Infectious Disease Priorities**



# Combat Readiness - Medical Research Program Stakeholders Meeting

COL Wendy Sammons-Jackson  
Director, MIDRP/Chair, Joint Program Committee-2  
25 March 2019





# Future Fight Implications for Infectious Disease Threats

## » Predict and Prepare for Infectious Disease Threats

### » Leverage surveillance and medical intelligence

» Detect, identify

» Predict based on trends and anticipated environmental and operational influences

## » Prevent Warfighter Illness

» Through infectious disease prevention strategies, enable Service Member readiness and availability in varied environments and complex operating conditions

» Pre-deployment focused to ensure Soldiers are ready and available for the fight

» Vaccines, drugs and biologics

## » Treat Warfighter Illness/Injuries

» Multi-Domain Operations limit casualty evacuation and degrade patient management capabilities, forcing prolonged care of casualties at all roles of care

» Prevent, Detect and Treat wound infections and sepsis at point of need





# Military Infectious Diseases Research Program

## Mission

To conduct for the Department of Defense, a focused and responsive world class infectious diseases research and development program leading to fielding of effective, improved means of protection and treatment to maintain maximal global operational capability with minimal morbidity and mortality

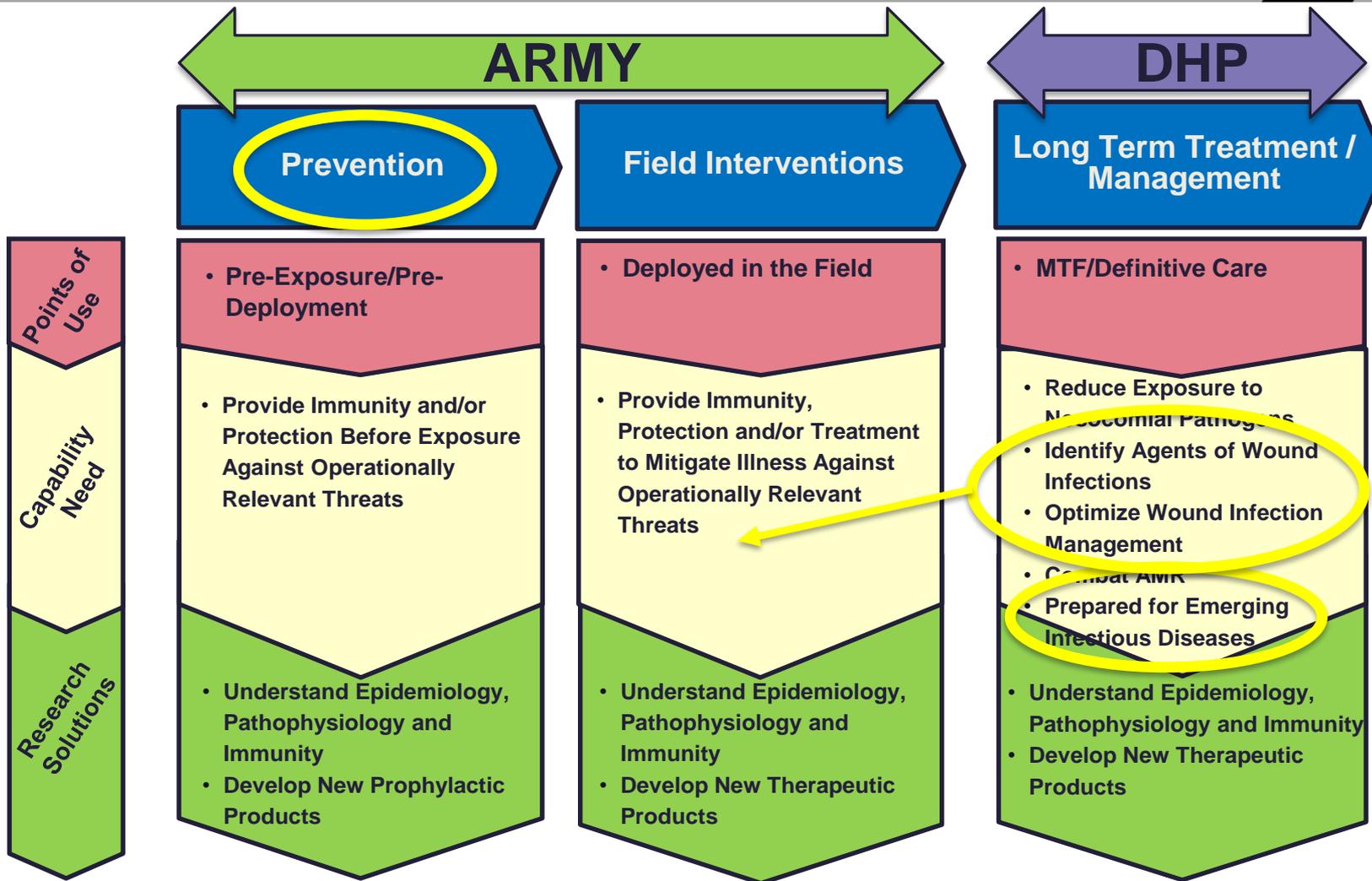
### ➤ CNA Gaps

- Medical Readiness
- Detection, Prevention and Treatment of Disease Threats
- Medical Surveillance





# Infectious Diseases Countermeasure Development Strategy



- Malaria Drug/Vaccine
- Dengue Vaccine
- ETEC Vaccine
- HIV Vaccine

- HFRS Vaccine
- Tafenoquine
- IV Artesunate

- ~~Topical Paromomycin~~
- Leishmania Rapid Diagnostic
- NGDS

- Bacteriophage
- Sentrex Biosponge
- Accelerate Pheno System & Pheno Test BC
- *S. aureus* vaccine





# Investment Strategy

**Tier 1: High user need,  
High operational risk**

**Tier 2: Medium user need,  
Medium operational**

DISEASE
Malaria (all types)
Diarrhea (bacterial)
Dengue Fever
Chikungunya/Onyong-nyong, Ross River Virus
Norovirus
MERS-CoV and other EID
MDR Bacteria
Ebola Hemorrhagic fever, Marburg
Influenza

**Active  
MIDRP  
Effort**

Chem / Bio  
Agents

National and  
Global Effort

Vaccine,  
Prophylactic or  
Therapeutic  
Available

DISEASE
Leptospirosis
HIV/AIDS
Leishmaniasis (cutaneous, mucosal, visceral)
Hantaviruses (HFRS, HPS)
Adenovirus
Crimean-Congo hemorrhagic fever
Q fever
Lassa fever
Rift Valley fever
Melioidosis
Tuberculosis (MDR included)
West Nile fever
Schistosomiasis
Typhoid Fever/Paratyphoid Fever
Meningococcal meningitis
Rabies

Conduct of Chemical And Biological Defense Program

50 U.S.C. § 1522 (d)(2) "Funding requests for the program may not be included in the budget accounts of the military departments."





# Program Areas

## Army RDT&E

- Parasitic Diseases Research
  - Anti-Parasitic Drug Development
  - Malaria Vaccine Research
- Viral Diseases
  - Flavivirus Vaccine Research
  - Lethal Virus Countermeasures
- Bacterial Diseases
  - Prevention of Diarrheal Diseases
  - Rickettsial Diseases
- Vector Identification
  - Identification and Control of Insect Vectors

Portfolio Managed By IIPT  
Intramural (WRAIR, NMRC, USAMRIID) Awards

## DHP RDT&E

- Parasitic Disease Research
  - Defense Malaria Assistance Program
- Viral Diseases
  - **Military HIV Research Program**
  - Emerging Infectious Diseases
- Bacterial Diseases
  - Combat wound Infection Prevention, Management & Treatment
  - **Combatting Antibiotic Resistant Bacteria**
  - Infectious Disease Clinical Research Program (IDCRP)
- Vector Control
  - **Deployed Warfighter Protection Program**
- Bio-preparedness Research Platform Dev
  - Joint West Africa Research Group
- Outside of JPC2 Oversight
  - Center for Global Health Engagement
  - Service Directed Funding for ID Research

**DHP Named Programs under JPC2**



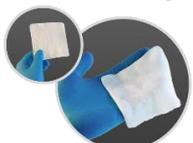


# Military Infectious Diseases Portfolio

	Research Effort	Advanced Development	Fielded Products
Parasitic Diseases	<ul style="list-style-type: none"> <li>Malaria drug (CDD)</li> <li>Malaria vaccine (CDD)</li> <li>Leishmaniasis</li> </ul>	<ul style="list-style-type: none"> <li>Intravenous Artesunate (CPD)</li> <li>Topical Paromomycin drug (CPD)</li> </ul>	<ul style="list-style-type: none"> <li>Tafenoquine (2018)</li> <li>Atovaquone/Proguanil (Malarone®, 2000)</li> <li>Doxycycline (Vibramycin®, 1992)</li> <li>Halofantrine (Halfan®, 1992)</li> <li>Mefloquine (Lariam®, 1989)</li> <li>Sulfadoxine-Pyrimethamine (1983)</li> <li>Chloroquine-Primaquine Tablets (1969)</li> <li>Primaquine (1952)</li> <li>Chloroquine (1949)</li> </ul>  <chem>CNCCCNc1nc2c(nc3c1OC)c4ccc(F)cc4O3</chem>
Viral Diseases	<ul style="list-style-type: none"> <li>Dengue vaccine (CDD)</li> <li>Hemorrhagic fevers-HFRS DNA vaccine</li> <li>HIV Global vaccine (CDD)</li> <li>HIV Regional vaccine (CDD)</li> <li>Acute respiratory disease research</li> <li>Chikungunya vaccine</li> </ul>	<ul style="list-style-type: none"> <li>Dengue Tetravalent vaccine (CDD)</li> <li>HIV Global vaccine (CDD)</li> <li>Modernized Production Adenovirus vaccine (CDD)</li> </ul>	<ul style="list-style-type: none"> <li>Adenovirus 4 &amp; 7 (1980) – (2011)</li> <li>Japanese Encephalitis - cell based (2009)</li> <li>Hepatitis A (1995)</li> <li>Japanese Encephalitis (1992)</li> <li>Hepatitis B (1981)</li> </ul>   
Diagnostics Development	<ul style="list-style-type: none"> <li>Point-of-need devices (CDD)</li> <li>ESKAPE pathogens</li> </ul>	<ul style="list-style-type: none"> <li>Biofire Filmarray Global Fever Panel – Malaria, Dengue, Chikungunya, Leptospirosis</li> <li>Dengue-Rapid Human Diagnostic Device</li> </ul>	<ul style="list-style-type: none"> <li>Malaria Rapid Diagnostic Test (2007)</li> <li>Leishmania Rapid Diagnostic Device (2014)</li> <li>Accelerate Pheno™ System and PhenoTest™ BC Kit – Feb 2017</li> </ul> 



# Military Infectious Diseases Portfolio

	Research Effort	Advanced Development	Fielded Products
<b>Bacterial Diseases</b>	<ul style="list-style-type: none"> <li>• Preclinical studies with novel therapeutic agents for the treatment of wound infections</li> <li>• Broad-spectrum conjugate vaccine               <ul style="list-style-type: none"> <li>• Bacteriophage therapy</li> <li>• Monoclonal antibodies against MDR pathogens</li> <li>• Lysin therapy</li> </ul> </li> <li>• Preclinical studies with novel anti-infective delivery systems for the treatment &amp; prevention of wound infections</li> <li>• Rickettsial Disease (Scrub Typhus)</li> <li>• Diarrheal Disease (CDD)               <ul style="list-style-type: none"> <li>• Enterotoxigenic <i>E. coli</i> (ETEC) vaccines</li> <li>• <i>Shigella</i> vaccines</li> <li>• <i>Campylobacter</i> vaccines</li> <li>• Travelan® (bovine Abs for ETEC)</li> <li>• Evaluating nutraceuticals for the prevention and/or treatment of traveler's diarrhea</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Bacteriophage therapy</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical Practice Guidelines (Antimicrobial Prescribing Practices) - Prevention of Infections Associated With Combat-Related Injuries (series of publications. <i>J. Trauma</i> 2011)</li> <li>• Arbekacin (FDA-approved for Single site study at Walter Reed National Military Medical Center)</li> <li>• Recognition and Comprehensive Management of Invasive Fungal Infections in War Wounds - JTTS Clinical Practice Guideline approved 1 Nov 2012</li> <li>• Meningococcus (A, C, Y, W-135) (1981)</li> <li>• Oral Live Typhoid Ty21A (1989)</li> <li>• Sentrex BioSponge™ - added to FSS 1 Apr 2015</li> </ul> 
<b>Vector ID</b>	<ul style="list-style-type: none"> <li>• Repellents/Insect control</li> <li>• Insect identification</li> </ul>	<ul style="list-style-type: none"> <li>• AV-RDD Chikungunya Virus</li> <li>• AV-RDD Pan-alpha/flavi</li> <li>• AV-RDD <i>Borrelia burgdorferi</i></li> </ul>	<ul style="list-style-type: none"> <li>• Combined Camo Face Paint (2013)</li> <li>• Alternate Repellent System (2013)</li> <li>• Arthropod Vector Rapid Detection Device for Dengue (2012)</li> <li>• Rift Valley Fever virus Vector Detection Assay (2011)</li> <li>• West Nile Virus detection Kit (2001)</li> <li>• Amifostine (Ethyol®, 1995)</li> <li>• DEET-based Insect Repellent (1946)</li> <li>• Vector Hazard Reports</li> </ul>



**Enclosure 6**  
**Infectious Disease in Austere Environments**



**aceso**

*Austere environments Consortium  
for Enhanced Sepsis Outcomes*

# Infectious Diseases Considerations in Austere Environments

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Danielle Clark, PhD  
Director, ACESO  
HJF

## OUR MISSION

Improve survival for patients with sepsis  
in austere settings through development of  
host-based diagnostic and prognostic assays  
and evidence-based clinical management.



**Austere environment = any environment where the resources are not sufficient for the need**



Prolonged field care

Pandemic or mass-casualty

Low and middle income countries



**aceso**  
Austere environments Consortium  
for Enhanced Sepsis Outcomes

# Challenges for Medical Combat Readiness

## Future Military Operations

- Small/mobile footprint
- Long MEDEVAC chains
- Humanitarian/stability ops

## Infectious Disease Threats

- Diverse endemic disease threats
- Increasing rate of emerging infectious diseases
- Decreasing barriers to deliberate biological attack



# Sepsis as a Threat

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Definition: An infection with systemic inflammatory manifestations

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**Common end-point** for a large number of military relevant infectious disease threats

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Common complication of combat trauma

---

One of the leading causes of death across the world



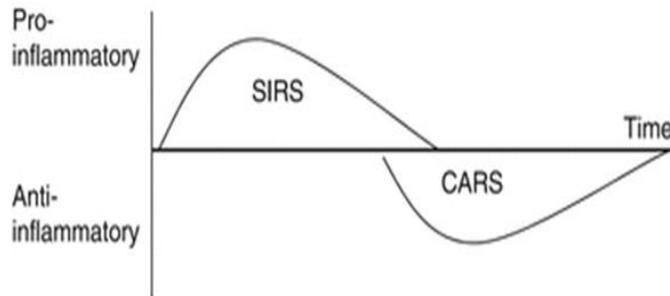
# Sepsis Commonalities

- Severe sepsis has similar presentation regardless of causative agent
  - Usually impossible to differentiate bacterial vs. viral vs. parasitic based upon clinical observation
  - Microbiological diagnosis requires time & resources
- Infectious causes of sepsis may share mechanistic pathways<sup>‡</sup>
- Pathogen-agnostic treatment strategies may improve clinical outcome

<sup>‡</sup>Bray and Mohanty. JID 2003;188: 1613-1617

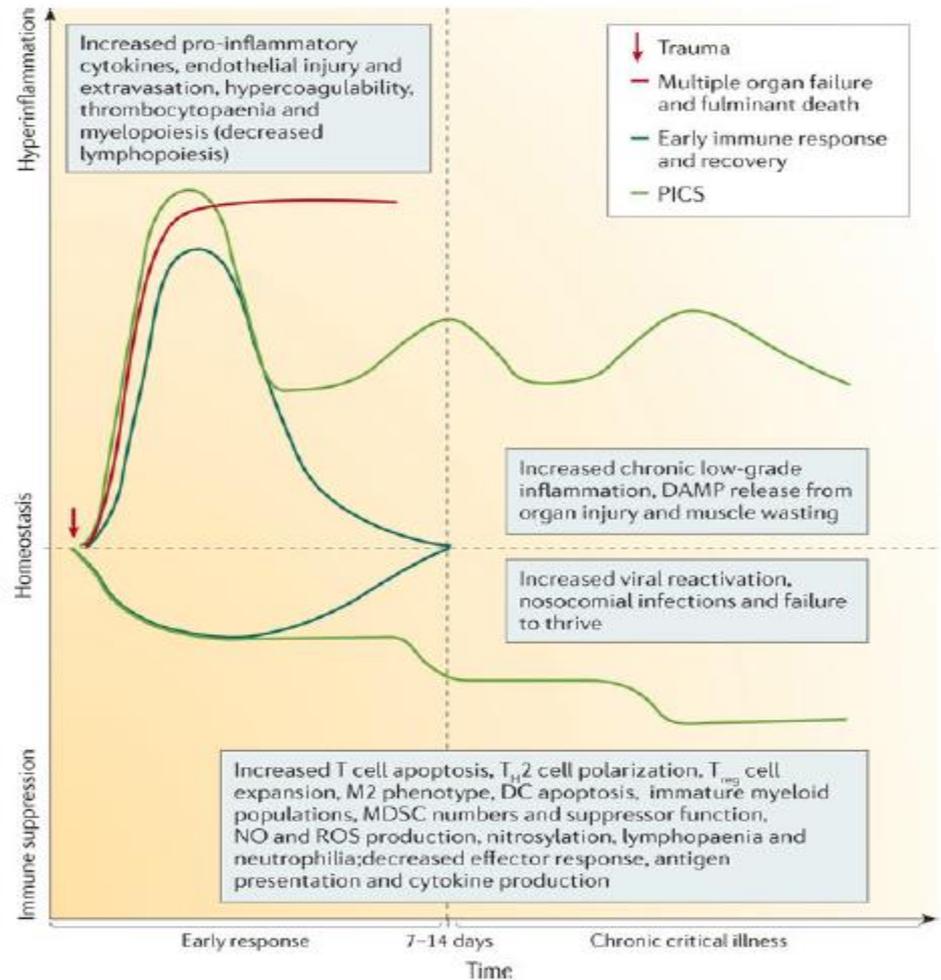


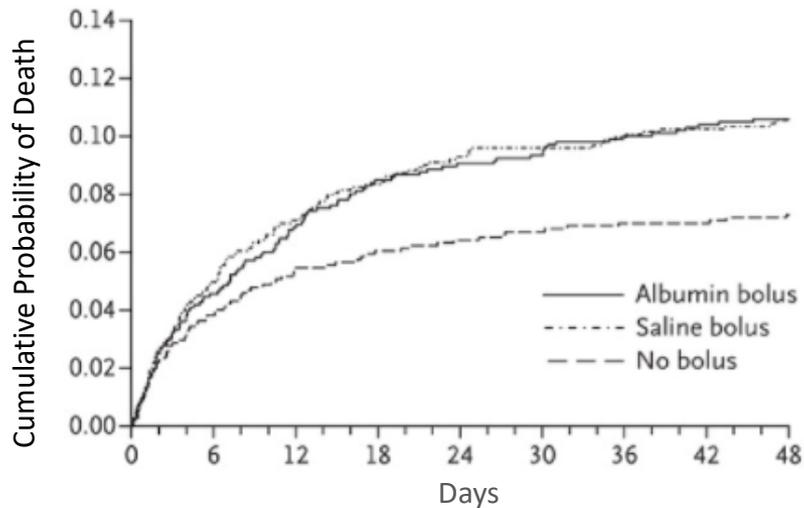
# Sepsis biology: Biomarker-driven paradigm shift



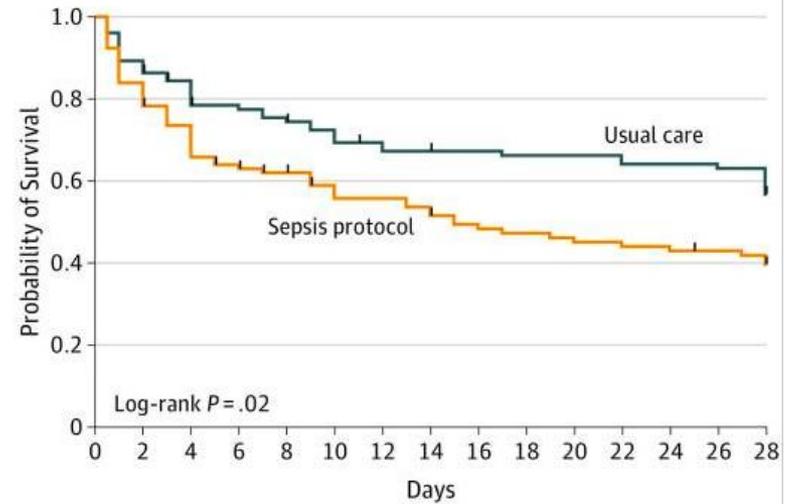
- No cure yet – previous (failed) sepsis therapies only targeted pro-inflammatory stage.
- Shift from sequential model of SIRS and CARS to multiple possible trajectories
- Shift has profound implications for modeling approach, clinical trial design, and treatment

SIRS: systemic inflammatory response syndrome  
 CARS: compensatory anti-inflammatory response syndrome  
 PICS: persistent inflammation, immunosuppression and catabolism syndrome





Maitland. N Engl J Med 2011; 364:2483-2495



Andrews. JAMA 2017 Oct 3;318(13):1233-1240

# Treatment Doesn't Always Translate



# Critical Issues

- We do not have tools to adequately guide decision-making at the point of need
- We do not have evidence-based strategies to manage patients with an infection in prolonged field care settings



# Tools for Decision-making

## Questions/Decisions

- Risk of symptom onset?
- Urgency/MEDEVAC?
- Infection?
- Bacterial?
- Treatment?

## Assessments

- Host-response
  - Physiologic monitoring
  - Biomarkers
- Pathogen identification

**Data Architecture and Algorithms**

**Technology Development**

# Evidence-based Strategies

- Advances in tools/technology should be linked to decision-making
- Research on impact of tool/technology use is critical, and often lacking





# aceso

Austere environments Consortium  
for Enhanced Sepsis Outcomes



**Enclosure 7**  
**Medical Solutions**



# Getting Medical Solutions into the Field

Ms. Christine Parker

Project Manager

US Army Medical Materiel Development Activity

Combat Trauma and Acute Rehabilitation Project Management Office





# USAMMDA

## Vision

USAMMDA is the **PREMIER DEVELOPER** of world-class military medical capabilities.

## Mission

Develop and deliver quality medical capabilities to **PROTECT, TREAT, AND SUSTAIN** the health of our Service Members.

## Ethos

**UNITED** in **SERVICE** to our Nation's Warfighters.





# Army Modernization Priorities

PRESENT	Long Range Precision Fires	FUTURE
	Next Generations Combat Vehicle	
	Future Vertical Lift	
	Network	
	• Assured Position, Navigation, Timing	
	Air and Missile Defense	
	Soldier Lethality	
	• Synthetic Training Environment	

*Preservation of Life is at the Forefront of the Battlefield*





# Product Development

## USAMMDA Translates Research Into Fielded Products = *Medically Ready Force*

RESEARCH → PRODUCT DEVELOPMENT → FIELDED PRODUCT

### USAMMDA's Product Development Pathway

Medical Product Prototyping

Clinical Testing and FDA Regulatory Engagement

Environmental and Operational Testing

Fielding

*Bridging the Valley of Death*



USAMMDA Translates Research Into Fielded Products to Maintain a Medically Ready Force





# Where Our Products Touch the Lives of Warfighters

## Pharmaceutical Systems



## Medical Support Systems and Evacuation



## Neurotrauma and Psychological Health



## Force Health Protection



## Combat Trauma and Acute Rehabilitation



### Prevention



### Diagnose & Treat



### Rehabilitate & Restore

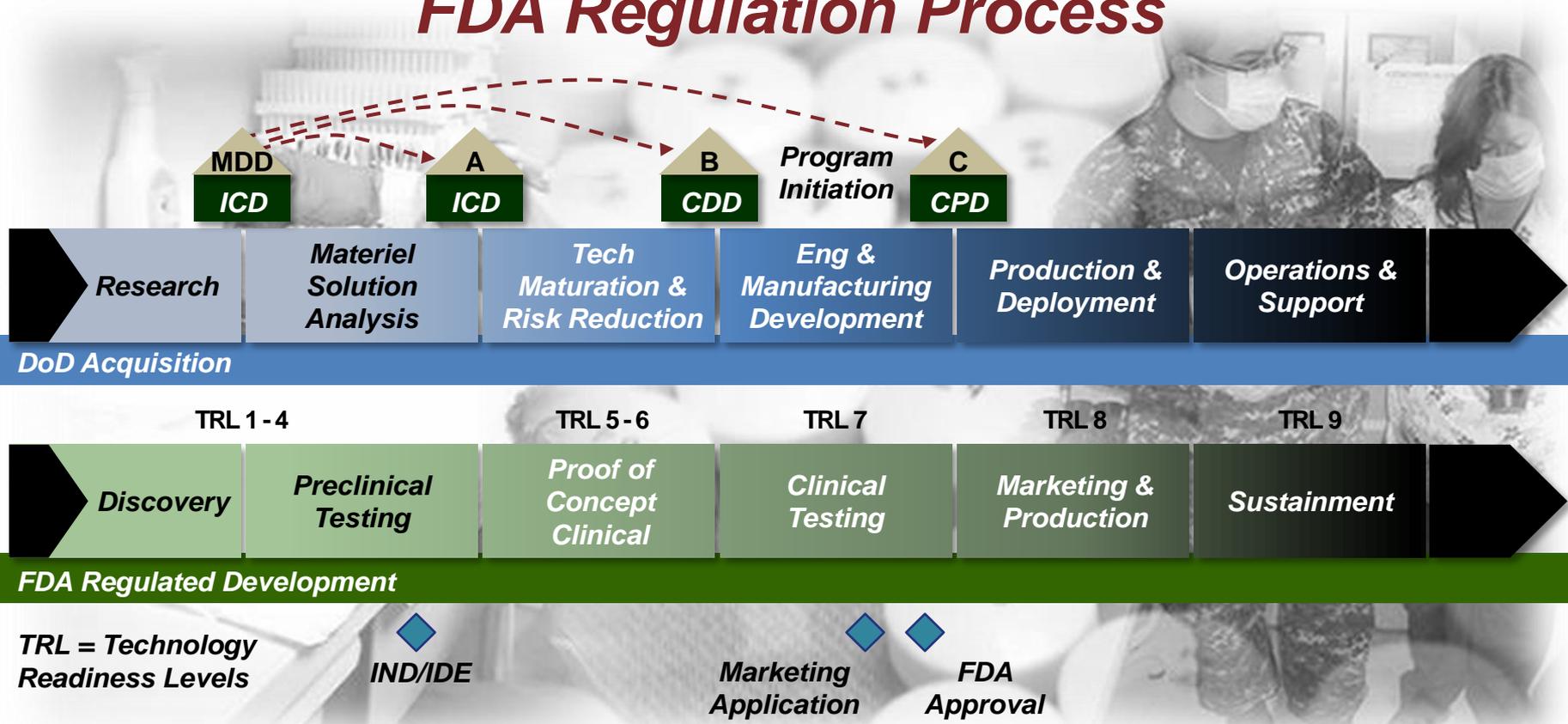


*USAMMDA develops and delivers quality medical capabilities to protect, treat, and sustain the health of Our Service Members*



# Governing Processes

## Integration of DoD 5000 and FDA Regulation Process



**“Translate Research Into Products”**





# Integrated Product Teams

Research Program  
Clinicians  
Scientists  
Pre-clinical Testing

Product Development  
Development  
Logistics  
Manufacturing  
Clinical Testing  
Operational and  
Environmental Testing  
Fielding



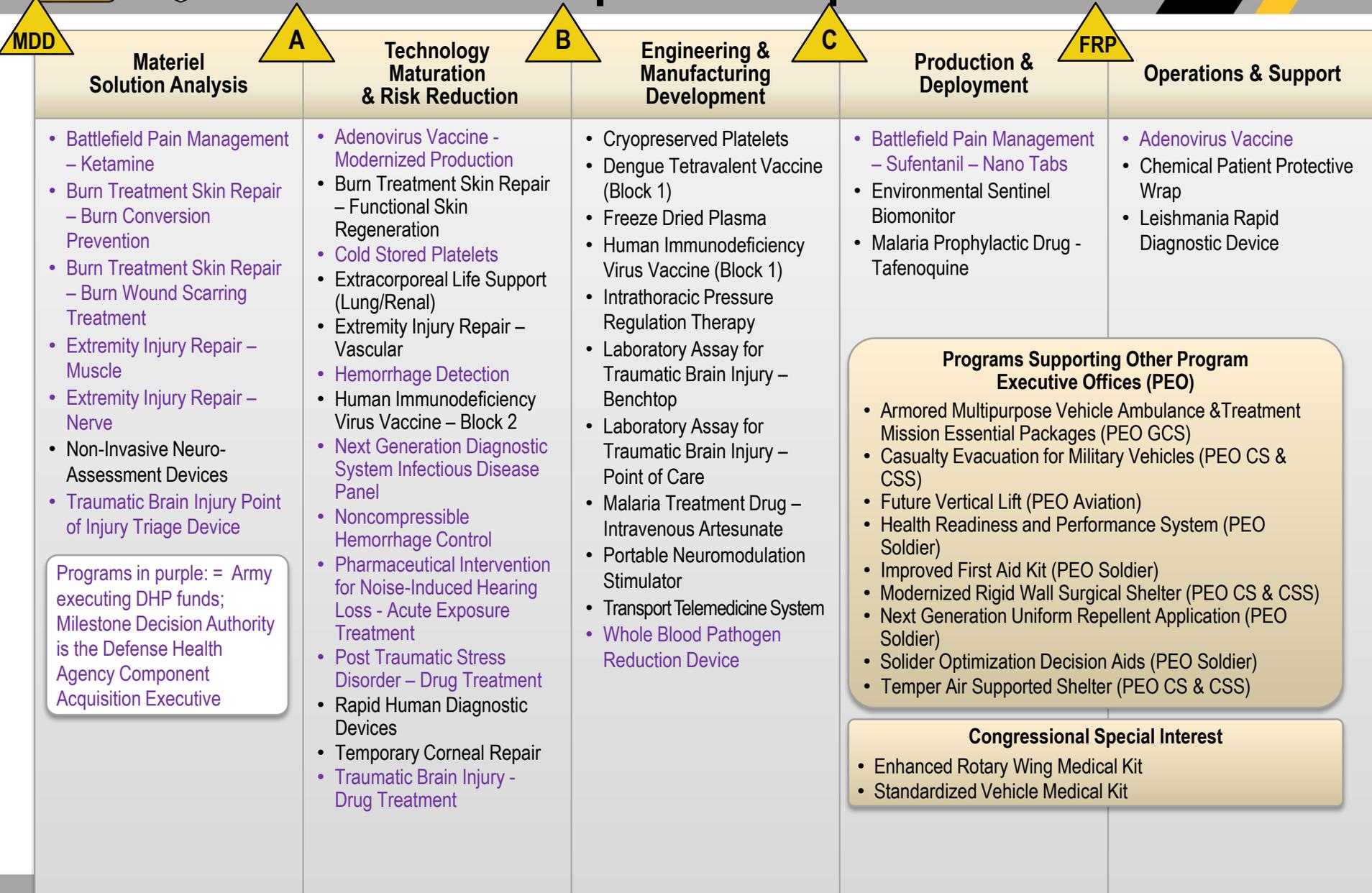
**Integrated  
Product  
Teams**

Requirements • Acquisition • Contracting • Regulatory • Legal •  
Office of Research Protections





# USAMMDA Medical Product Development and Acquisition Pipeline





# Product Management Responsibilities





# Product Support Considerations





# Proactive Considerations for Development

- » Who is the intended user? (e.g. Medic, PA)
- » Where would this solution go?
- » How easy is it to use?
- » Who is the FDA sponsor?
- » Are there companion diagnostic considerations?
- » How does this augment clinical practice?
- » Space considerations (size, weight, cube)
- » Shelf life / expiration
- » Environmental conditions (heat, cold, humidity, etc.)
- » Does the product need to be ruggedized?
- » Training
- » Air worthiness





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