CDMRP
Department of Defense

Congressionally Directed Medical Research Programs

Combat Readiness – Medical Research Program

Stakeholders Meeting – March 25, 2019
Fiscal Year 2019




The views and opinions of the authors may not reflect the official policy or position of the Department of the Army, Department of Defense, or the US Government.

Table of Contents

Fiscal Year 2019 (FY19) Combat Readiness Research Program (CRRP) Stakeholders

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Dr. Howard Champion	SimQuest Solutions, Inc.
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Mr. Thomas Dunn	Naval Medical Research Center
Dr. Emily English	Gemstone Biotherapeutics, LLC
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CPT Franz Frye	US Army Medical Research Institute of Chemical Defense
Dr. Ana Gamero	USAMRMC
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Dr. Janice Gilsdorf	Walter Reed Army Institute of Research
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Dr. Patricia Henry	Congressionally Directed Medical Research Programs
Dr. Gregory Hiemenz	InnoVital Systems, Inc.
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Name	Affiliation
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Dr. Therese West	Combat Casualty Care Research Program, USAMRMC
LTC Scott Willens	US Army Medical Research Institute of Chemical Defense
Mr. John Winston	American Defense International
Dr. Erik Wolf	Clinical and Rehabilitative Medicine Research Program, USAMRMC

Agenda

7:30 a.m. – 8:30 a.m.	Registration	All Participants
8:30 a.m. – 8:40 a.m.	Welcome, Introductions, and Overview	Mr. Scott Wheeler, Strategy Arts Dr. Christie Vu, CDMRP
8:40 a.m. – 8:45 a.m.	Moment of Silence	Mr. Matthew Anderson, US Army (CPT, Retired)
8:45 a.m. – 8:50 a.m.	Administrative Remarks Meeting Overview and Objectives	Dr. Sarah Keasey, Leidos Mr. Wheeler
8:50 a.m. – 9:20 a.m.	Overview of CDMRP Science Management Model and the Role of the Stakeholders	Dr. Vu
9:20 a.m. – 10:00 a.m.	Presentation of the CRRP, Survey Results, and Broad Focus for the Program.	Dr. Vu
10:00 a.m. – 10:15 a.m.	***Break***	
10:15 a.m. – 10:45 a.m.	Presentation 1: The Future Battlefield and Priorities for Combat Casualty Care	Col Michael Davis, Combat Casualty Care Research Program
10:45 a.m. – 11:15 a.m.	Presentation 2: Medical Readiness Priorities for the Future Battlefield	CDR Christopher Steele, Military Operational Medicine Research Program
11:15 a.m. – 11:30 a.m.	Presentation 3: Infectious Disease Priorities and Considerations for the Future Battlefield	COL Wendy Sammons-Jackson, Military Infectious Diseases Research Program
11:30 a.m. – 11:45 a.m.	Presentation 4: Infectious Disease Considerations in Austere Environments	Dr. Danielle Clark, Austere Environments Consortium for Enhanced Sepsis Outcomes
11:45 a.m. – 12:05 p.m.	Presentation 5: Overview of Considerations for Fielding Products in the Military	Ms. Leigh Anne Alexander, US Army Medical Materiel Development Activity
12:10 p.m. – 1:30 p.m.	***Lunch***	
1:30 p.m. – 3:00 pm	Breakout Session	All Participants
3:00 p.m. – 3:15 p.m.	***Break***	
3:15p.m. – 3:45 p.m.	Presentation of Breakout Discussions	Breakout Session Participants
3:45 p.m. – 4:15 pm	Discussion: Moving Technologies into the Hands of Providers and Patients	All Participants
4:15 p.m. – 4:45 p.m.	Discussion of Consolidated Priorities, Future Steps, and Additional Questions	Mr. Wheeler and Dr. Vu
5:00 p.m.	Adjourn for the Day	

Overview: CDMRP History

The US Army Medical Research and Materiel Command (USAMRMC) is a major subordinate Command of the US Army Material Command. The Congressionally Directed Medical Research Programs (CDMRP), a subordinate organization within the USAMRMC, is responsible for management and execution of medical research funding programs. The CDMRP's flexible execution and management cycle includes the receipt of annual Congressional appropriations; inaugural Stakeholders meetings for new programs; vision setting; release of full applications; full application receipt and review; recommendation of grants for funding; and oversight of research grants.

During a program's Vision Setting meeting, the state of the science is evaluated; the current program's portfolio is compared to the state of the science; and knowledge gaps are identified. The outcomes of the Vision Setting meeting set up the program cycle for the fiscal year (FY). Products of the Vision Setting meeting include the vision and mission statements, the Focus Areas, and the investment strategy that will be translated into funding opportunities or Program Announcements. Following the Vision Setting meeting and the release of the Program Announcements, the program cycle moves into high gear.

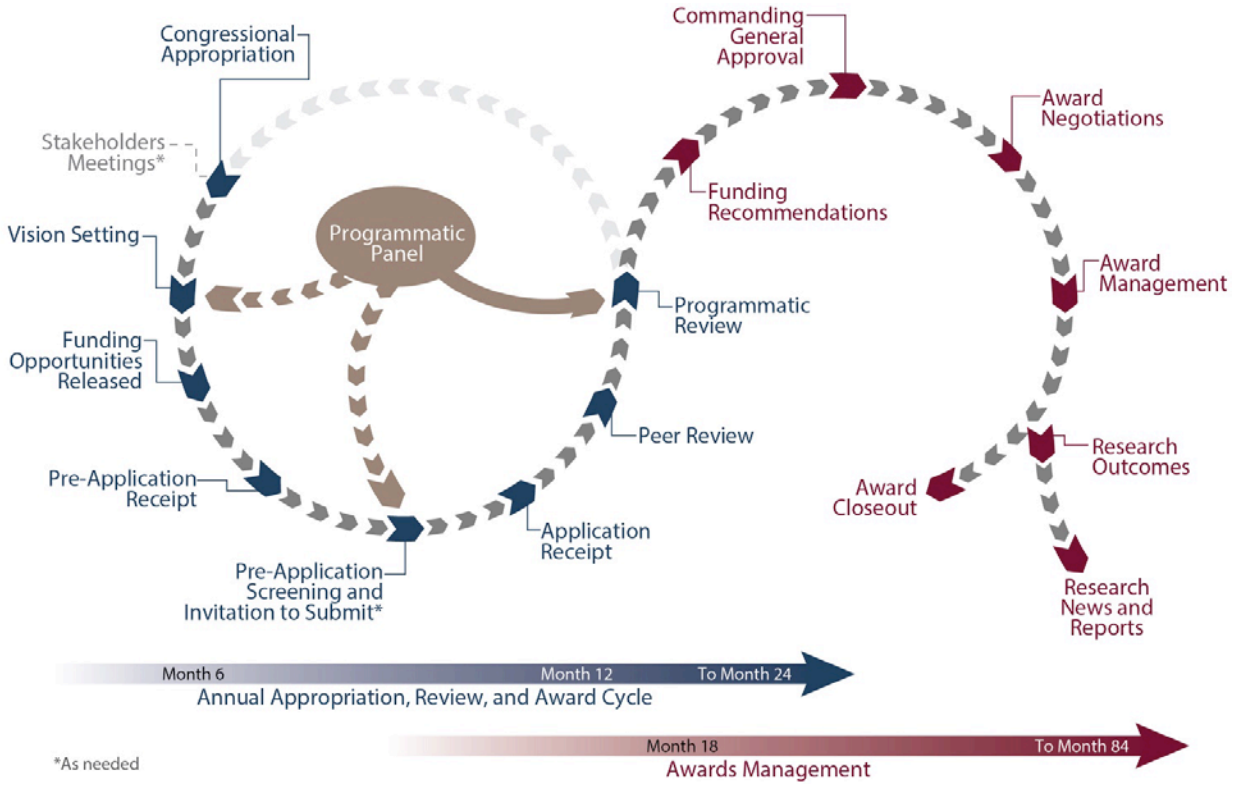

Figure 1. CDMRP Programmatic Cycle.

To ensure that each program's research portfolio reflects not only the most meritorious science, but also the most programmatically relevant research, the CDMRP developed a two-tier model based upon recommendations from a 1993 Institute of Medicine (IOM) report.[1] The IOM recommended a two-step review procedure for research applications that was composed of a scientific peer review and a separate programmatic review. The scientific peer review is conducted by an external panel that is recruited specifically for each peer review session and, therefore, is not a standing panel. Peer review involves the expertise of scientists, clinicians, military members, and consumers. The peer review process includes evaluation of the applications based on the criteria delineated in the Program Announcements. Each application is judged on its own scientific and technical merit with respect to the described criteria. The second tier of review is conducted by a Programmatic Panel and includes discussions by experts in the field. These experts, who include scientists, clinicians, consumers, and Department of Defense (DoD) and other federal representatives, assess the applications based on the scientific peer review ratings and summaries, a balanced portfolio, and programmatic intent. Scientifically sound applications that best meet the program's interests and goals are recommended for funding by the Programmatic Panel. Once approval is received for the funding list, awards are made and CDMRP Science Officers provide full-cycle support of research projects and outcomes.

Overview: CRRP Background

Addressing the Needs of the Warfighter

Treating and returning military personnel to duty, which maintains force strength, has always been a primary mission of the Services. In the wars in Iraq and Afghanistan, the US military achieved the highest rate of survival from battlefield injuries in history. The wounded-to-killed ratio more than doubled, from 4:1 during last century's world wars, to 10:1 today.[2] Substantial credit for this achievement is due to a 2009 Congressional mandate that stated wounded Warfighters should be provided with lifesaving care within 60 minutes of injury, a timespan that is referred to as the "golden hour." At the time, the battlefield had numerous forward surgical teams, combat support hospitals, and medevac assets from all three Services. However, the golden hour is only one aspect of combat casualty care. Future combat scenarios may require Service members to fight conventional wars against peer or near-peer adversaries, and there is a need for deployable and life-saving technologies to address delayed resuscitation, prolonged field care, and longer-distance critical care transport. Moreover, the combat landscape is no longer limited to rural and austere environments, but could also include operations in dense urban or subterranean environments. The possibility of urban warfare presents new challenges and considerations for civilian mass casualty events, such as defining the role of first-responders and emergency room physicians or operating in situations of disrupted communications. This shift requires

[1] Strategies for Managing the Breast Cancer Program: A Report to the U.S. Army Medical Research and Development Command, 1993.
[2] Kotwal et al. JAMA Surg. 2016; 151(1):15-24

a reassessment of existing approaches and innovation of new approaches for extending golden hour care.

Research focused on medical combat readiness has been funded by the DoD Core and other Congressional Special Interest (CSI) programs and managed by the CDMRP since 2001 as part of several research programs: (1) the Defense Medical Research and Development Program (DMRDP); (2) the Deployment Related Medical Research Program (DRMRP); (3) the Joint Warfighter Medical Research Program (JWMRP); (4) the Military Burn Research Program (MBRP); (5) the Peer Reviewed Medical Research Program (PRMRP); and (6) Psychological Health and Traumatic Brain Injury (PH/TBI) research program. From FY01 to FY18, the CDMRP has managed $789.1 million (M) over 389 awards in research related to clinical management of injuries incurred on the battlefield, traumatic brain injury (TBI) screenings and neuro-physical assessments, hemorrhage and resuscitation research and development, coagulopathy of trauma, treatments for tissue injury and regeneration, as well as forward surgical and intensive care approaches (Figure 2). In FY19, the US Congress directed $15M for medical combat readiness research in the DoD appropriation, thus establishing the CRRP.

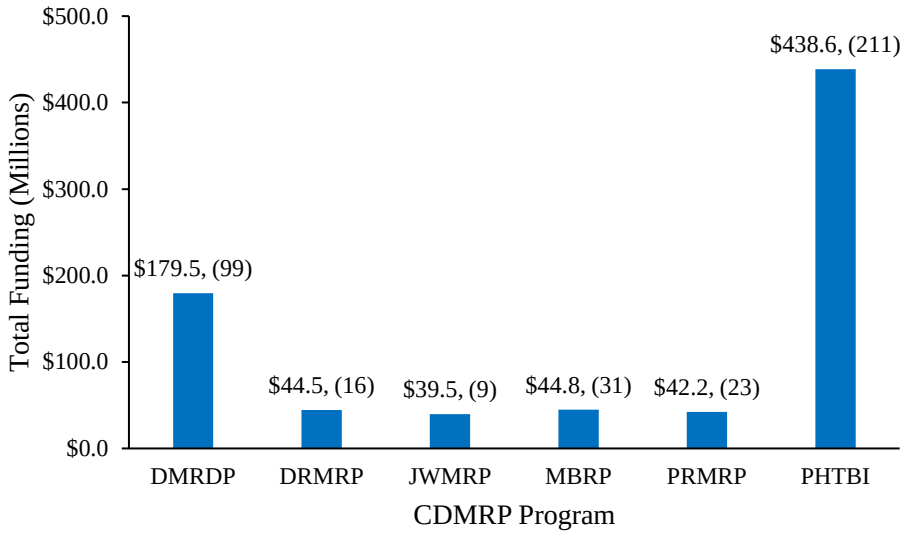

Figure 2. CDMRP Funded Awards Related to Combat Readiness – Medical Research Funded FY01 to FY18, Funding Amount, (Number of Awards).

Meeting Objectives

PURPOSE

- The Stakeholders meeting is 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.

STAKEHOLDER PARTICIPANTS

- Representatives from non-profit organizations, academia, industry, and Government institutions are invited to share broad perspectives on initiatives that have the greatest potential to propel the science forward, break down potential barriers in research and patient outcomes, address key knowledge or scientific gaps, and identify potential approaches for advancing solutions to provide wounded Service members and the American public with lifesaving care.

KEY ACTIVITIES

- Presentations highlighting areas of research related to medical combat readiness.
- Discussion sessions to identify gaps in specific areas of medical combat readiness research, as well as gaps in the immediate care of Service members and civilians.

OUTCOMES

- A summary of relevant gaps, refinement of the state of the science in medical combat readiness, identification of potential challenges, and strategic goals for success.
- Input from the Stakeholders meeting will be used by the CRRP Programmatic Panel to recommend the overall CRRP goals, priorities, focus areas, and investment strategy.
- The final outcomes of the Stakeholders meeting do not represent the final program strategy of the CRRP.

Guidelines for Discussion

- Everyone participate, no one dominate
- Listen to understand
- Use "I" statements
- One speaker at a time
- Disagree without being disagreeable
- Share your unique perspective
- Stay open to new ways of doing things
- All ideas are valid
- Critique ideas, not people
- Respect others' thinking and value their contributions
- Treat everything you hear as an opportunity to learn and grow
- Staying on schedule is everyone's responsibility; honor time limits
- State your "headline" first, then the supporting information as necessary
- Be brief and meaningful when voicing your opinion
- Listen with care instead of "building your story"
- Participate 100%
- Leave the smartphones in pockets, purses, jackets, etc.
- Seek common ground and understanding (not problems and conflict)
- Stay out of the weeds
- Have fun!

Congressional Language

Public Law 115-245, DoD, and Labor, Health, and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 appropriated $15M for research and development of medical combat readiness to be managed by the CDMRP. The FY19 Conference Report 115-952 (Figure 3) established the CRRP, based on reference language from House Report 115-769 for the Joint Warfighter Medical Research Program (Figure 4). The reference language of the Joint Warfighter Medical Research Program specifies the Congressional definition of medical combat readiness and directions for the CRRP, and corresponds to the CRRP in the final appropriations bill[3].

> *Combat Readiness Medical Research* - 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.

Figure 3. Combat Readiness – Medical Research defined by FY19 Conference Report 115-952.

> *Joint Warfighter Medical Research Program* - The Committee recommends $45,000,000 for the Joint Warfighter Medical Research Program. The Committee appreciates the program's focus on the medical needs of the warfighter on the battlefield, and 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.
>
> The "golden hour" policy, which commits to getting wounded Service members lifesaving care within the first hour after an injury occurs, was initially put in place to address battlefield casualties. With reports that the Department may not be able to commit to the "golden hour" for Service members in future conflicts, the Committee expects the Assistant Secretary of Defense (Health Affairs) to identify current gaps in medical planning and resources, and consider medical capabilities that may mitigate fatalities, including enhancing hemorrhage control research and development.

Figure 4. Combat Readiness – Medical Research defined by HAC-D Report 115-769.

[3] The CRRP is distinct program from the Joint Warfighter Medical Research Program listed in the final Congressional Appropriation.

In particular, the Committee encourages research and development of freeze-dried plasma and platelets, in addition to rapidly deployable, all-in-one acute and chronic wound care therapy engineered to address complex trauma and start tissue regeneration. For injuries suffered on the battlefield, the Committee believes that the Department of Defense should make enhancing battlefield diagnostics a priority. The Committee is encouraged by recent technological advances related to traumatic brain injury, including magnetic resonance technology. The Committee is pleased by the development of portable neurological devices in support of mild traumatic brain injury assessment for Service members in the field and supports the continued review of benefits that could be gained from deployment of this diagnostic tool. The Committee also notes that advances in exposure science, including environmental and wearable sensors technology and chemical surveillance, partnered with advanced computing, allow for optimized exposure surveillance and health monitoring through rapid and comprehensive measurement of biosignatures, and believes these efforts should be explored. Additionally, the Committee sees advantages to advancing genomics work to identify and counter evolving chemical and biologic threats, and developing medical countermeasures to chemical or biological weapons of mass destruction.

Further, the Committee believes that additional research of battlefield treatment is necessary and encourages the Assistant Secretary of Defense (Health Affairs) to explore solutions for life-threatening battlefield complications such as sepsis. The Committee also encourages the use of telemedicine and other technologies that would allow for better collection, integration, and transfer of patient data from battlefield medical units through transport and treatment. In preparation for environments military personnel may face while serving, the Committee encourages the Assistant Secretary of Defense (Health Affairs) to establish protocols providing for the training, transport, and treatment for Service members exposed to highly infectious diseases. The Committee also encourages the Assistant Secretary of Defense (Health Affairs) to continue offering competitive grants to applicants from academia, industry, and federal government agencies to expand the chemical control toolbox, and to develop and validate vector management strategies needed to protect deployed military personnel.

Figure 4 (cont). Combat Readiness – Medical Research defined by HAC-D Report 115-769.

Request for Information Survey

The CRRP released a Request for Information (RFI) in January 2019 as part of initial market research to establish a State of the Science ahead of the Stakeholders meeting.

Combat Readiness – Medical Research Program
Fiscal Year 2019 State of the Science

A Combat Readiness – Medical Research Program (CRRP) for FY2019 has been included in the United States FY19 Department of Defense appropriation at $15M. The CRRP will be established as a program of the CDMRP to research forward-deployable solutions that can promptly address life-threatening injuries and medical diagnostics, threats, and treatments, and medical threats and treatments for Service members in battlefield settings.

To efficiently manage CRRP, the CDMRP will utilize its two-tier review process (http://cdmrp.army.mil/about/2tierRevProcess). Traditionally for new programs, the CDMRP holds an inaugural Stakeholders meeting where experts from different subject areas are brought together to identify knowledge gaps, outcome and product needs for the state of the science and patient care, etc. After the Stakeholders Meeting, a Vision Setting meeting is held to recommend an investment strategy to answer some of the unmet medical needs, knowledge gaps, and consumer concerns. In order to expedite the process, the CDMRP is currently soliciting information on the identification of current research efforts and knowledge gaps in medical planning and resources for providing wounded Service members lifesaving care within the golden hour after an injury occurs, as well as medical capabilities that may mitigate fatalities.

Medical combat readiness focuses on the immediate medical needs of the warfighter on the battlefield following life-threatening injury or environmental exposure. Injuries or exposures include, but are not limited to, neurological injuries, hemorrhage, and exposures to chemical and biological threats. In order to address the diagnosis and treatment of battlefield injuries, there is urgent need for forward- and rapidly deployable diagnostics, therapeutics, telemedicine (to include monitoring and data transfer technologies), and countermeasures to chemical and infectious disease exposures.

Please take the time to answer the following survey on medical combat readiness research, the state of the science, and medical care. Consider in your answers the program's Congressional direction to support military-relevant advanced technology and therapeutic research related to the following focus areas:

(1) Enhancing battlefield diagnostics for neurological injuries and hemorrhage;

(2) Integrated wound care and tissue regeneration therapies;

(3) Environmental and wearable sensors, combined with advanced computing, for surveillance and monitoring of chemical and biological threat exposures;

(4) Telemedicine applications for battlefield medicine, to allow for better collection, integration, and transfer of patient data from battlefield medical units through transport and treatment;

(5) Chemical and biological exposure, countermeasures, and management strategies; and

(6) Solutions for infectious disease management, including sepsis.

Provide answers within your area(s) of expertise and aligned with these topics identified by the CRRP. All answers should be submitted by 31 January 2019.

Do not include classified or sensitive information in your answers.

If the above hyperlink does not redirect you, please copy and paste the following URL: https://www.surveymonkey.com/r/ZQMRSMM

Questions about this survey and the CRRP should be directed to the CDMRP public affairs mailbox at usarmy.detrick.medcom-cdmrp.mbx.cdmrp-public-affairs@mail.mil.

Sincerely,

Combat Readiness – Medical Research Program, CDMRP

SURVEY QUESTIONS:

1. What cutting edge and forward-looking research could make a significant impact on addressing the medical needs of the warfighter on the battlefield?
2. What existing technology solutions currently exist? What technology needs to be developed?
3. What basic research is primed to move towards development of technology solutions?
4. What are the needs and considerations for deploying solutions in a civilian (e.g., first responders, rural environments, etc.) versus military environment?

Results of Request for Information Survey

A total of 346 survey responses were obtained. Responses were manually binned into five Topic Areas that aligned with the six Focus Areas described in the RFI:

- Early Diagnostics: Focus Area (1) "Enhancing battlefield diagnostics of neurological injuries and hemorrhage;"
- Wound Care: Focus Area (2) "Integrated wound care and tissue regeneration therapies;"
- Environmental Exposures: Focus Areas (3) "Environmental and wearable sensors, combined with advanced computing, for surveillance and monitoring of chemical and biological threat exposures," and (4) "Chemical and biological exposure, countermeasures, and management strategies;"
- Telemedicine: Focus Area (5) "Telemedicine applications for battlefield medicine, to allow for better collection, integration, and transfer of patient data from battlefield medical units through transport and treatment;" and
- Sepsis: Focus Area (6) "Solutions for infectious disease management, including sepsis."

The frequency of prevalent keywords for each Topic Area was tabulated for Questions 1–4. A summary of results is provided below.

Question 1: What cutting edge and forward-looking research could make a significant impact on addressing the medical needs of the warfighter on the battlefield?

Summary of data: The overall breakdown of responses per topic area is shown in Figure 5A, while a word map of high-frequency keywords within each topic area is shown in Figure 5B. In Figure 5B, the keyword color corresponds to the topic area color in Figure 5A, and the font size correlates with the keyword frequency over all survey responses. The majority of responses (43%) identified the need for early diagnostics in order to promptly address life-threatening injuries of Service members in battlefield settings. An additional 43% of responses fell within the topic areas Environmental Exposures (16%), Telemedicine (14%), Wound Care (7%), and Sepsis (6%). Approximately 14% of responses did not align with any of the five topic areas, and were binned within the category "Other."

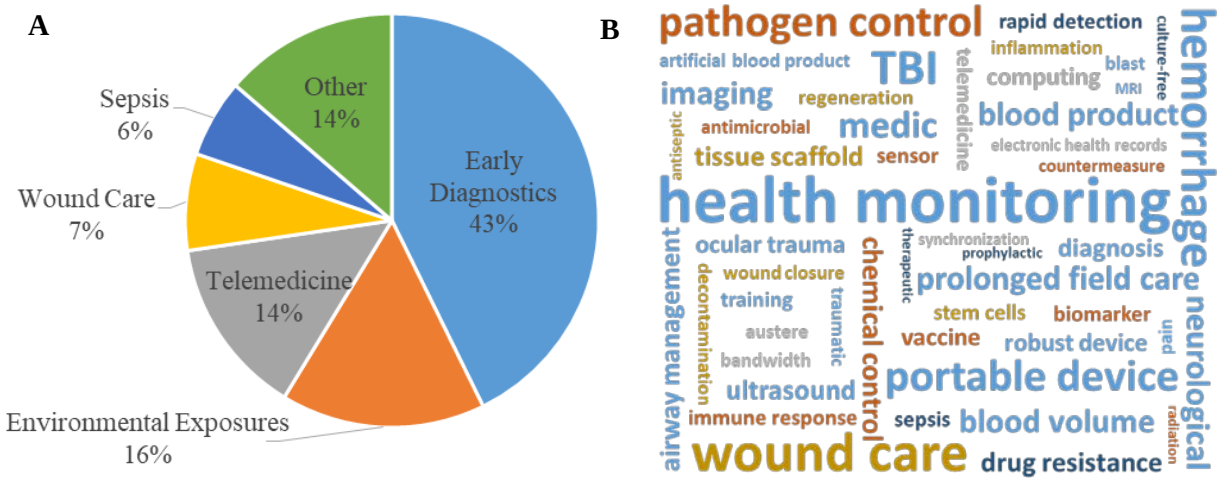

Figure 5. Survey Responses to Question 1 by Topic Area (A) and Keyword Frequency (B)

The Early Diagnostics topic area comprises research related to neurological injuries, TBI, hemorrhage, and addressing immediate medical needs following traumatic injury, such as stabilization, respiratory distress, fluid replacement, and medical training. Environmental Exposures comprised responses related to chemical, biological, radiological, and nuclear exposures (CBRNE)[4] countermeasures, surveillance, detection devices, and treatment of battlefield complications that result from exposures. Telemedicine responses addressed the need for improved tracking of health data and remote medical care, which can be complicated by deployment to austere environments. Responses within the Wound Care category revolved around the need for advanced wound healing and tissue repair, scar-less healing, and wound decontamination. Finally, responses within the topic area Sepsis emphasized the need for rapid detection of infection to mitigate long-term complications, as well as the need for novel drugs to combat multi-drug resistant organisms.

[4] Survey responses included the spectrum of CBRNE, but nuclear exposures are not a specific focus of the CRRP under the Congressional language.

Question 2: What existing technology solution currently exist? What technology needs to be developed?

Summary of data: A comparison of existing and needed technology within the five topic areas was performed. Each topic area is addressed separately below.

Early Diagnostics

Survey responses within the Early Diagnostics topic area comprised TBI, hemorrhage, medical imaging, monitoring of clinical health parameters, airway management, blood products and blood substitutes, and medical training (Figure 6). The majority of responses were related to TBI (25%), hemorrhage (24%), and medical imaging (19%). Specific research gaps that were identified included guided placement of endotracheal tubes or cricothyrotomy for management of respiratory trauma, artificial blood products or donor-free production of blood products for hemorrhage, ideal resuscitation fluids, field-able imaging for TBI assessment, non-invasive quantitation of intracranial pressure, extra-corporeal life support/extra-corporeal membrane oxygenation (ECLS/ECMO), and training of complex equipment for use by non-expert medical responders. Specific technology highlights are listed in Table 1.

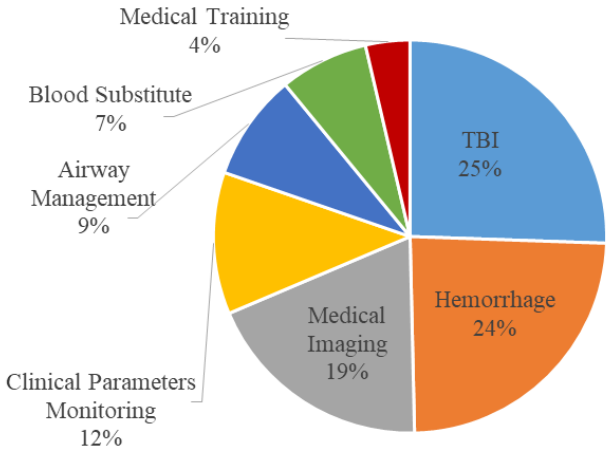

Figure 6. Survey Responses of Existing and Needed Technology Related to Early Diagnostics

Table 1. Early Diagnostics: Existing and Needed Technology

Diagnostics Category	Existing Technology	Needed Technology
Airway management		
	Endotracheal intubation	Expandable endotracheal tube with guided placement
	Ventilator	Portable ventilator
	Microbubbles for acute respiratory distress syndrome	Further development needed
Clinical parameters		
	Pulse oximeter	Pulse oximeter for hemorrhagic shock
	Blood pressure cuff	Cuff for remote conditioning
	Bio-impedance vector analysis	Wearable metabolic health monitor
	Micro electrocardiogram patch	Further development needed
Hemorrhage		
	Resuscitative endovascular balloon occlusion of the aorta (REBOA)	Distal perfusion avoidance
	Trans arterial embolization	Embolic agents
	Gravity infusion devices	Auto-transfusion devices
	Vascular shunts	Vascular shunts in trauma
	Level 2 surgical care	Level 1 surgical care
	Ultrasound	Ultrasound for internal bleeding
	Blood substitutes (freeze-dried plasma/platelets)	Artificial hemoglobin, FDA-approval of existing products, non-donor platelets
	Animal models	Clinical testing
	Colloidal plasma expanders	Plasma expander with oxygen carrier
	Resuscitation fluids	Optimization needed
	Topical absorbable hemostats	Further development needed
	ECLS/ECMO	Further development needed
TBI		
	Helmets/body armor	Coup-countrecoup protection
	Animal models	Neuroprotective therapeutic
	Invasive intracranial pressure measurement	Non-invasive
	Electroencephalogram (EEG), ultrasound	Diagnosis of axonal injury
Training		
		Augmented/mixed/virtual simulation of response to injury
		REBOA

Wound Care

Survey responses within the Wound Care topic area comprised wound regeneration, closure, and decontamination, as well as tissue scaffolding and genomics approaches to assess inflammation and response to healing (Figure 7). The majority of responses were related to regeneration (38%) and tissue scaffolding (31%). Wound closure and wound decontamination represented 17% and 10% of responses, respectively, and focused on technology applications to prevent wound infection. Only a small proportion of responses (4%) indicated the need for genomics approaches to study wound healing. Specific technology highlights are listed in Table 2.

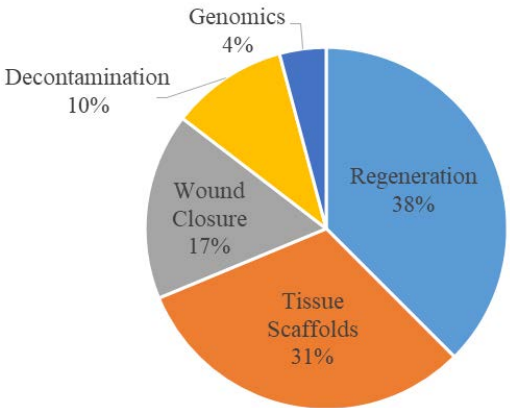

Figure 7. Survey Responses of Existing and Needed Technology in Wound Care.

Table 2. Wound Care: Existing and Needed Technology

Wound Category	Existing Technology	Needed Technology
Decontamination		
	Topical antimicrobial	Topical exogenous growth factors
	Broad spectrum therapeutics	Pathogen-specific therapeutics
		Stem cells and/or autologous tissue transplantation
Regeneration		
	Exosomes	Exosomes for wound healing
Tissue scaffolds		
	Skin substitutes (placenta-derived, fish-derived)	Further development needed
	Scaffolds (nanofiber, lithography, tissue bridge)	Further development needed
	Organotypic models of adult tissues	Further development needed
Wound closure		
	Biotape, sutures, Zipstitch, etc.	Incorporation of prophylactics
	Tourniquets	Addition of therapeutic agents
	Self-pressuring wound care	Further development needed
Genomics		
	Single cell analysis	Single cells analysis to predict healing

Environmental Exposures

Survey responses within the Environmental Exposure topic area were analyzed by agent (Figure 8A) and technology type (Figure 8B). Regarding responses categorized by agent type, the majority (63%) of Environmental Exposures survey responses addressed technology related to exposures of naturally occurring biological pathogens. Compared to biological agent exposures, the percentage of responses that addressed exposures to chemical (12%) and radiological (11%) agents were approximately four-fold less. In addition, 14% of responses addressed technology that could be broadly applied to any exposure (General CBRNE), such as sensors for detection, diagnostics with improved sensitivity and specificity, and drug-delivery methods. There were four types of technology types identified in survey responses within the Environmental Exposures topic area: (1) therapeutics; (2) detection strategies; (3) diagnostics; and (4) vaccines. The largest number of responses were related to therapeutic technologies (40%), followed by detection strategies (26%), diagnostics (20%), and vaccines (14%), respectively. Specific technology highlights are listed in Table 3.

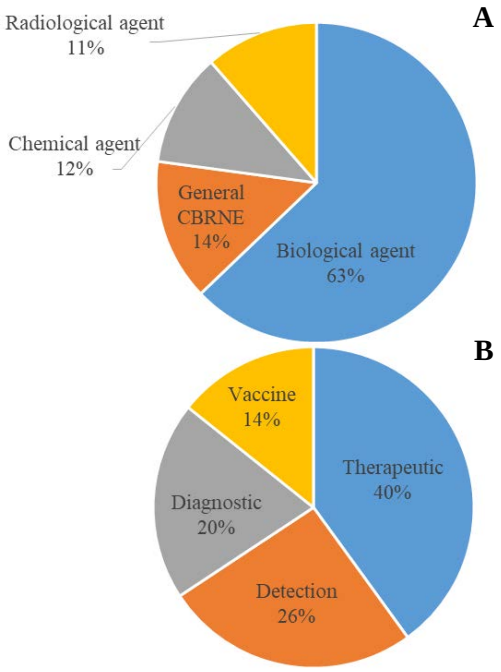

Figure 8. Survey Responses of Existing and Needed Technology Related to Environmental Exposure by Agent (A) and Technology (B)

Table 3. Environmental Exposures: Existing and New Technologies

Exposures Category	Existing Technology	Needed Technology
General CBRNE		
	Single-agent sensors	Small multiplex sensor
	Lateral flow assays	Simplification
	Intravenous countermeasures	Auto injectors
Biological agent		
	Malaria rapid test	Rapid test for other infectious disease
	Strategies for pathogen control	Implementation
	Antibiotics	New antimicrobial drugs
	Drug repurposing	Drug repurposing for infectious disease
	Aminoquinolines	Non-aminoquinoline candidates
	Traditional vaccines (including gamma-inactivated vaccines)	Monoclonal antibodies as vaccines
	Vaccines against emerging pathogens	Vaccines against small molecule bio-threats
	Humanized monoclonal antibodies (HuMabs)	HuMabs discovery platform
	Traditional adjuvants	Novel adjuvants
Radiological agent		
	Exposure detection by urine screening	Exposure detection using breath tests
	Complex treatments	Prophylactics

Telemedicine

Responses that addressed the Telemedicine topic area stated that, while telemedicine technology exists, it is not yet sufficiently developed for applications in deployed environments. Significant limitations that were noted included low/no bandwidth availability in austere environments, as well as medics who require additional training for use of complex equipment and devices used in trauma care. Furthermore, there are significant challenges to forward access to health records (e.g., electronic health records). Knowledge of pre-existing conditions or previous clinical data could significantly expedite treatment of Service members in the battlefield, thereby mitigating downstream complications.

Sepsis

Survey responses within the Sepsis topic area addressed the need for rapid detection of infection in order to mitigate long-term complications, as well as the need for novel drugs to combat multi-drug resistant organisms. A significant technology gap identified in this area was rapid diagnostics. Existing diagnostic technologies require many hours (polymerase chain reaction, PCR) and up to several days (culture methods) for definitive identification of the infecting pathogen. In addition, these tests are difficult to perform in field settings, and deployable technologies are urgently needed. Another significant concern of survey respondents was related to the use of broad-spectrum antimicrobials, which may potentiate the spread of antimicrobial resistance. Instead, respondents identified a need for cell- or microbe-specific therapeutics in order to treat infections, as well as reduce the potential for acquisition of genetic resistance determinants. Specific Sepsis-related technology is highlighted in Table 4.

Table 4. Sepsis: New and Existing Technology

Category	Existing Technology	Needed Technology
Sepsis		
	Chlorine dioxide for pathogens	Efficient delivery
	Oxygen reduction for sepsis	Oxygen reduction in trauma
	Catheters (that frequently result in urinary tract infections)	Improved urine collection systems
	PCR or culture	Rapid diagnostics
	Broad-spectrum drugs	Cell-specific delivery systems

Question 3: What basic research is primed to move toward development of technology solutions?

Summary of data: Research or products primed to move towards development of technology solutions were identified from survey responses to Question 3. A word map of primed research within the five topic areas (Early Diagnostics, Environmental Exposures, Telemedicine, Wound Care, and Sepsis) is used to illustrate technologies that were frequently noted in responses to Question 3 (Figure 9). The keywords of primed research and products are colored by topic area (indicated in the key to the right of the word map), and the font size correlates with the keyword frequency over all survey responses. Primed research and products are highlighted in Table 5).

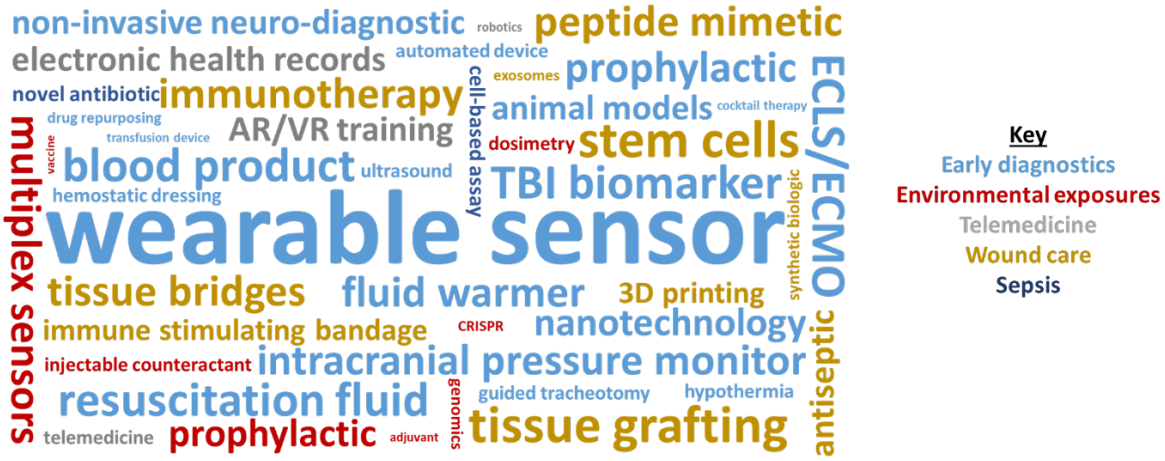

Figure 9. Word Map Representation of Research and Products Primed Towards Development of Technology Solutions.

Table 5. Existing research primed toward the development of technology solutions.

Category	Technology for Further Development
Airway management	Cricothyrotomy
	Prophylactic antibiotics
	Time-controlled ventilation
Hemorrhage	Hemostatic dressings
	Blood and fluid warmer
	Resuscitation fluids
	Topical absorbable hemostats
	Self-propelling hemostatic agents
	ECLS/ECMO
	Non-donor platelet production
	Freeze dried plasma/platelets (FDA-approval)
TBI	Intracranial pressure monitoring
	Micro electrocardiogram patch
	Non-invasive neuro-diagnostic devices (EEG, cerebral blood flow, ultrasound, near infrared spectroscopy)
	Bio-fluid biomarker assays (and validation)
	Virtual reality model of skull and optical orbit
Training	Technology for simulated response to injury
	Virtual/augmented/mixed reality
Wound care	Small peptides for treatment of burns
	Wound matrices comprised of omega-3 fatty acids
	Force modulating tissue bridges
Biological exposure	Point-of-care blood-testing platform for diagnosis of infection
	Multiplex real-time PCR diagnostics
	Antivirals for lethal virus exposure
	Polarization anisotropy diagnostics for detection

Question 4: What are the needs and consideration for deploying solutions in a civilian (e.g., first responders, rural environments, etc.) versus military environment?

Summary of data: Considerations for deploying solutions in a civilian versus military environment were identified from survey responses to Question 4 (Figure 10). Approximately 57% of respondents identified at least one difference between civilian and military environments. The top considerations for deploying solutions in a military environment included the need for prolonged field care, more severe and abundant injuries, technology limitations (low/no bandwidth), portability and robustness of medical devices, and FDA-approval of deployed technology solutions. Considerations in the civilian environment included the possibility for mass destruction of large populations (urban warfare), population diversity (children, elderly), health insurance dictation of medical care, and complex technology that limits the ability for self-care. However, respondents also indicated that civilian environments offer more infrastructure availability and access to care and are better able to leverage telemedicine applications through bandwidth access. For respondents that felt the considerations were the same in both environments, the overarching similarities were related to the treatment of traumatic injuries and sepsis, the need for rapid diagnostics for TBI and infection, and the potential for novel therapeutics and countermeasures to mitigate fatalities and the spread of antimicrobial resistance.

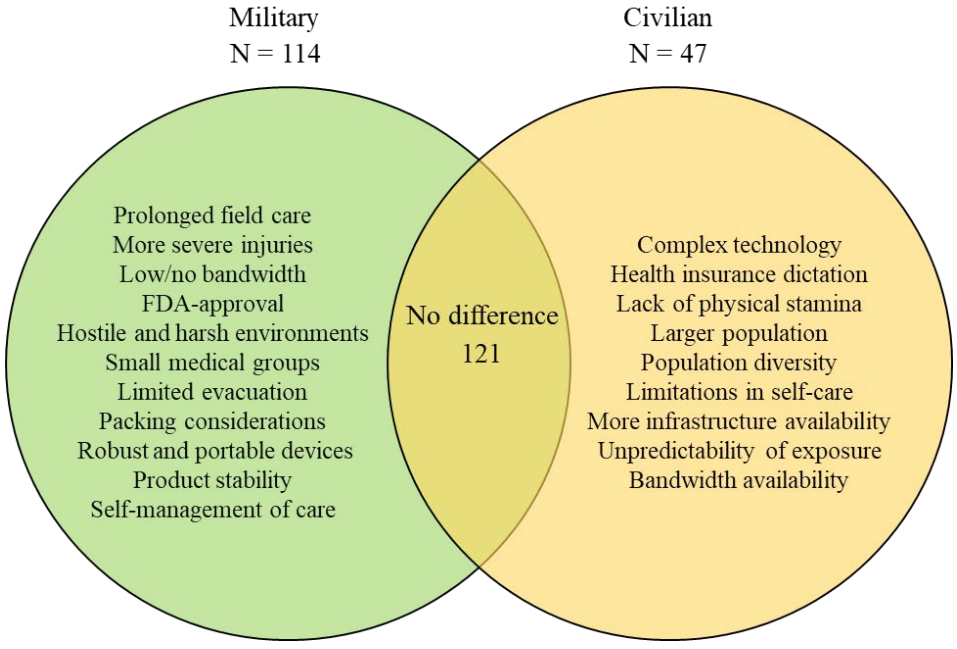

Figure 10. Venn-diagram Comparison of Considerations for Deploying Solutions in a Civilian versus Military Environment.

Considerations for Battlefield Care

The following considerations for medical care in battlefield settings are derived from current published research, white papers, and resource guides, including the 2018 Tactical Combat Casualty Care Guidelines for Medical Personnel, a Position Paper of the Prolonged Field Care Working Group, and the Joint Special Operations University Report 17-10, *The Death of the Golden Hour and the Return of the Future Guerrilla Hospital*. Identified gaps were generated from the results of the Request for Information Survey.

- Up to 28% of combat deaths are potentially preventable.
- Medical personnel on the battlefield are routinely saving soldiers who would have died in previous wars.
- The Special Operations Command (SOCOM) Prolonged Field Care Working Group recently identified ten capabilities necessary to provide prolonged field care:
  1. Monitor the patient
  2. Resuscitate the patient
  3. Ventilate/Oxygenate the patient
  4. Gain definitive control of the patient's airway
  5. Use sedation and pain control effectively
  6. Use physical exam and diagnostic measures to gain awareness of potential problems
  7. Provide nursing/hygiene/comfort measures
  8. Perform advanced medic-level surgical interventions
  9. Perform teleconsultation
  10. Prepare the patient for flight
- SOCOM medics are trained to manage trauma patients for up to 72 hours.
- Minimizing the time between critical injury and definitive care maximizes survival following a traumatic injury.
- The golden hour is only one component of combat casualty care.
- There is an identified need for technologies that address battlefield and point-of-care resuscitation, pain control, improved oxygen-carrying intravenous fluids, tourniquets, hemostatic dressings, and prehospital antibiotics.
- Further development of tissue scaffolds that accelerate wound healing, while also preventing infection through incorporation of therapeutic agents, would address the needs of injuries that result in severe wounds.
- Novel therapeutics and countermeasures, specifically to address exposures to naturally occurring biological pathogens, are needed to prevent infection in a far-forward manner.
- Advancements in telemedicine technologies are needed to facilitate improved health monitoring.
- Identification of pre-sepsis determinants at the earliest stages of infection would enable accelerated treatment to minimize systemic infection.

Web Page Resources

- Congressionally Directed Medical Research Programs (CDMRP); https://cdmrp.army.mil/
- CDMRP Combat Readiness – Medical Research Program (CRRP); https://cdmrp.army.mil/crrp/default
- Defense Health Agency (DHA) Component Acquisition Executive (J4); https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Component-Acquisition-Executive
- DHA Research and Development (J9); https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Development
- DHA Joint Program Committees (JPCs); https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Development/Joint-Program-Committees
- eBRAP; https://ebrap.org/eBRAP/public/index.htm
- Grants.gov; https://www.grants.gov/
- US Army Medical Materiel Development Activity (USAMMDA); https://www.usammda.army.mil/
- US Army Medial Materiel Agency (USAMMA); https://www.usamma.amedd.army.mil/Pages/Main01.aspx
- USAMRMC; https://mrmc.amedd.army.mil/
- USAMRMC Research and Development; https://mrmc.amedd.army.mil/index.cfm?pageid=medical_r_and_d.overview
- US Army Medical Research Acquisition Activity (USAMRAA); https://www.usamraa.army.mil/Pages/Main01.aspx

Abbreviations

CBRNE	Chemical, Biological, Radiological, and Nuclear Exposures
CDMRP	Congressionally Directed Medical Research Programs
CRRP	Combat Readiness – Medical Research Program
CSI	Congressional Special Interest
DHA	Defense Health Agency
DMRDP	Defense Medical Research and Development Program
DoD	Department of Defense
DRMRP	Deployment Related Medical Research Program
eBRAP	Electronic Biomedical Research Application Portal
ECLS	Extra-Corporeal Life Support
ECMO	Extra-Corporeal Membrane Oxygenation
EEG	Electroencephalogram
FDA	US Food and Drug Administration
FY	Fiscal Year
HuMabs	Humanized Monoclonal Antibodies
JPC	Joint Program Committee
JWMRP	Joint Warfighter Medical Research Program
IOM	Institute of Medicine
MBRP	Military Burn Research Program
M	Million
PCR	Polymerase Chain Reaction
PHTBI	Psychological Health and Traumatic Brain Injury
PRMRP	Peer Reviewed Medical Research Program
RDT&E	Research, Development, Test, and Evaluation
REBOA	Resuscitative Endovascular Balloon Occlusion of the Aorta
RFI	Request for Information
TBI	Traumatic Brain Injury
SOCOM	Special Operations Command
USAMMDA	US Army Medical Materiel Development Activity
USAMRAA	US Army Medical Research Acquisition Activity
USAMMA	US Army Medical Materiel Agency
USAMRMC	US Army Medical Research and Material Command

Notes