DEFENSE HEALTH AGENCY



7700 ARLINGTON BOULEVARD, SUITE 5101 FALLS CHURCH, VIRGINIA 22042-5101

1. MEMORANDUM FOR DISTRIBUTION ALL

1.1 SUBJECT: Distribution of Approved Defense Health Agency Strategic Research Plan for Traumatic Brain Injury (TBI)

This memorandum provides the approval of the Defense Health Agency (DHA) Strategic Research Plan (SRP) for Traumatic Brain Injury (TBI) (Attachment). The DHA manages the Defense Health Program (DHP) medical research, development, test, and evaluation or RDT&E appropriation. The DHA Research and Engineering (R&E) Directorate provides oversight and management of the DHP Science and Technology (S&T) annual budget to support research across critical investment areas to include TBI.

The DHA Deputy Assistant Director (DAD) for R&E will utilize SRPs to inform the DHP S&T investments. SRPs outline the requirements deemed high priority, identified based on the assessment of current and future medical and operational needs, and existing research gaps of the military medical community. Adherence to SRPs will ensure the Program Objective Memorandum and spend plans are aligned to prioritized Joint and Service requirements. Specific to the TBI SRP, the scope includes not only requirements relating to TBI, but also to medical components of the Department's Warfighter Brain Health Initiative.

My point of contact for the DHA TBI SRP is Dr. Emma Gregory, DHA TBI Portfolio Manager, emma.d.gregory2.civ@health.mil or (571) 835-6497. Thank you for your continued support.

BIGGERSTAFF.S Digitally signed by BIGGERSTAFF.SEAN.11249811 EAN.1124981111 1 Date: 2023.01.25.10:02:42-05:00

Sean Biggerstaff, Ph.D. Acting Deputy Assistant Director, Research and Engineering (R&E)

Attachments:

As stated

cc:

Surgeon General of the Army Surgeon General of the Navy Surgeon General of the Air Force President, Uniformed Services University of the Health Sciences

January 2023

Defense Health Agency Strategic Research Plan: Traumatic Brain Injury



REVISION HISTORY

Revision	Entered by	Reason	Date

This is an abridged version of the Defense Health Agency (DHA) Strategic Research Plan (SRP) for Traumatic Brain Injury (TBI). For access to a version that includes additional supporting information, please contact: dha.ncr.j-9.mbx.stmp@health.mil.

1.2 Contents

			<u>Page</u>
1.	MEN	MORANDUM FOR DISTRIBUTION ALL	1
	1.1	SUBJECT: Distribution of Approved Defense Health Agency Strategic Research Plan for Traumatic Brain Injury (TBI)	1
Re	vision	History	iii
	1.2	Contents	
	1.3	Figures	iv
	1.4	Tables	iv
2.	Over	view and Organization	2–1
3.	Capa	bility Requirements and Associated S&T Paths	3–1
	3.1	Countermeasure Development (T1)	3–2
	3.2	Assessment Tool Development (T2)	3–3
	3.3	Point of Injury Stabilization (T3)	3–4
	3.4	Complex Injury Stabilization (T4)	3–5
	3.5	Treatment Development (T5)	3–6
	3.6	Clinical Practice Guideline Development (T6)	3–7
	3.7	Cognitive Restoration and Enhancement (T7)	
1	Refe	rances	1 1

1.3 Figures

	<u>Page</u>
Figure 2-0 SRP Hierarchy	2–3
Figure 3-0 Capability Requirement Example	3–1
Figure 3-1 Capability Requirement Countermeasure Development (T1)	3–2
Figure 3-2 Capability Requirement Assessment Tool Development (T2)	3–3
Figure 3-3 Capability Requirement POI Stabilization (T3)	3–4
Figure 3-4 Capability Requirement Complex Injury Stabilization (T4)	3–5
Figure 3-5 Capability Requirement for Treatment Development (T5)	3–6
Figure 3-6 Capability Requirement CPG Development (T6)	3–7
Figure 3-7 Capability Requirement Cognitive Restoration and Enhancement (T7)	3-8
1.4 Tables	
	Page
Table 2-0 Canability Requirements Included in this SRP Iteration	2_3

2. OVERVIEW AND ORGANIZATION

The Defense Health Agency (DHA) Research and Engineering (R&E) Directorate leads the discovery of innovative medical solutions responsive to the needs of Combatant Commands, the Military Services, and the Military Health System (MHS). DHA R&E provides oversight and management of a Science and Technology (S&T) annual budget of approximately \$500 to \$800 million to support research across critical investment areas. The cornerstones of the DHA S&T management approach are as follows:

- Portfolio Managers directly accountable for the health and performance of their research portfolios.
- Alignment of research investments to validated and prioritized joint Capability Requirements.
- Identification of the Capabilities needed to work toward fulfilling the highest priority Capability Requirements.
- Balanced portfolios of S&T investments (6.1, 6.2, and 6.3) that focus efforts on areas where the Department of Defense (DoD) can have the most impact, and accelerate the delivery of knowledge and materiel products to end users.
- Focus on multi-year (3 to 5 years) planning and budgeting for research investments while retaining the ability to adapt to emerging (or declining) requirements.

The DHA Deputy Assistant Director (DAD) for R&E employs Strategic Research Plans (SRPs) to inform and describe how MHS capabilities will be developed over time.

SRPs are organized into four levels:

- Capability Areas, which reflect the highest structural element that encompasses broad areas of medical research within a Portfolio.
- Capability Requirements, which are derived from key source documents, and outline Capabilities (knowledge or materiel) required to meet current or future military medical needs.
- **S&T Paths**, which describe the high-level research activities needed to support the transition of Capabilities to Advanced Development or other end users.
- Capabilities, which describe the S&T knowledge and/or material products to be transitioned to Advanced Development or other end users.

SRPs outline only the Capability Requirements deemed high priority, identified based on assessment of the current and future medical and operational needs, and existing research gaps of the military medical community.

SRPs include information that will enable the Portfolio Manager to perform the following activities:

- Develop, on an annual basis, the Future Years Defense Program (FYDP) plans in alignment with Capability Requirements, and to anticipate the resources that will be required for the respective Program Objective Memorandum (POM) cycle.
- Provide the oversight and approval of Year of Execution (YOE) spend plans for which Program Managers (PMs) will be responsible for developing as a recommendation to the Portfolio Manager.
- Facilitate discussion with leadership and stakeholders regarding the research activities required to address Capability Requirements.

Adherence to the SRP will ensure the POM and spend plans are aligned to prioritized Joint Capabilities Integration and Development System (JCIDS)-validated requirements.

Specific to the Traumatic Brain Injury (TBI) SRP, the scope includes not only Capability Requirements relating to TBI, but also to medical components of Warfighter Brain Health (WBH). WBH is defined as the physical, psychological, and cognitive status that affect a warfighter's capacity to function adaptively in any environment and impacts readiness, operational capability, mission effectiveness, and the goal to achieve overmatch or superior lethality [1]. High-priority TBI Capability Requirements are organized into the following major Capability Areas, as shown in Figure 2-0 and described next:

- **Protect:** Decrease incidence of brain injuries in warfighters.
- Recognize and Surveil: Develop validated, objective tools that record, monitor, and recognize changes in a warfighter's brain health in relevant environments.
- Assess and Diagnose: Develop objective diagnostic tools and technologies that can be used in any environment to objectively diagnose brain injury with high sensitivity.
- **Stabilize:** Sufficiently stabilize combat casualties at the point of injury (POI) and as they are prepared for evacuation to a field health care facility.
- **Treat and Rehabilitate:** Provide effective medical countermeasures (MCM) for treating brain injuries.
- **Improve:** Develop validated, approved, and acceptable mechanisms of neuroprotection and cognitive enhancement that are available for use in military-relevant settings.

Figure 2-0 shows the hierarchical relationship as described, with the associated reference schema:

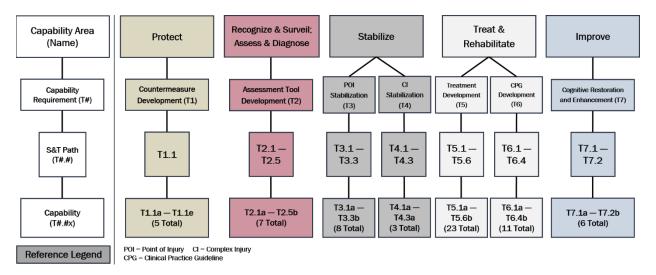


Figure 2-0 SRP Hierarchy

The high-priority TBI Capability Requirements are listed in <u>Table 2-0</u>, with each Capability Requirement noted via a T number (e.g., T1; T2). <u>Section 3</u> describes for each Capability Requirement the S&T Paths leading to defined Capabilities.

Table 2-0 Capability Requirements Included in this SRP Iteration

T No.	Capability Requirement Name	Capability Requirement Description
T1	Countermeasure Development	Develop countermeasures for adverse brain health outcomes that mitigate brain exposures and injuries [1].
T2	Assessment Tool Development	Develop and validate objective assessment, diagnostic clinical decision support tools, technologies, and models for brain exposures and injuries, and develop tools that help frontline responders recognize changes in a warfighter's brain health [1] [2] [6].
Т3	Point of Injury (POI) Stabilization	Develop technologies, knowledge, skills, and tools to sufficiently stabilize combat casualties at the POI and as they are prepared for evacuation to a field health care facility [2] [3] [6].
T4	Complex Injury Stabilization	Develop technologies that prevent the progression of TBI following complex combat injuries that involve TBI and an associated trauma (i.e., neuromusculoskeletal injury, sensory dysfunction, infection or other polymorbidities) [2] [4] [5].
T5	Treatment Development	Develop MCM knowledge products to treat brain injury [1] [3].
Т6	Clinical Practice Guideline (CPG) Development	Develop standard CPGs and outcome measures for TBIs and brain exposures [1] [2].
T7	Cognitive Restoration and Enhancement	Develop neuroprotection and cognitive enhancement knowledge products [1] [6].

3. CAPABILITY REQUIREMENTS AND ASSOCIATED S&T PATHS

This section outlines the TBI Capability Requirements, detailed S&T Paths that describe the research activities associated with the requirement, and Capabilities expected to transition to Advanced Development or other end users (e.g., members of the clinical or operational community) to aid in fulfillment of the requirement. The Capabilities represented will transition to Advanced Development or other end users when they reach the appropriate technology or knowledge readiness level (TRL or KRL). Advanced Development will then perform, as appropriate, additional development activities required to mature these Capabilities to the extent to which they can be delivered for full clinical or operational use by the intended end user. Each Capability Requirement in the sections that follow is depicted as a figure in the format shown in Figure 3-0.



Figure 3-0 Capability Requirement Example

3.1 Countermeasure Development (T1)

The development of countermeasures to protect warfighters from the effects of exposures or injury to the brain is a critical facet in the overall mission of maintaining a capable and ready fighting force. Protecting the brain health of warfighters across multiple environments will require a spectrum of countermeasures and applied knowledge. Figure 3-1 outlines the S&T Paths for this Capability Requirement and the planned Capabilities that will transition to Advanced Development or other intended end users. Appendix B.3 provides an expanded description of the Capability Requirement for Countermeasure Development (referenced in Appendix B.3 as 2.2).

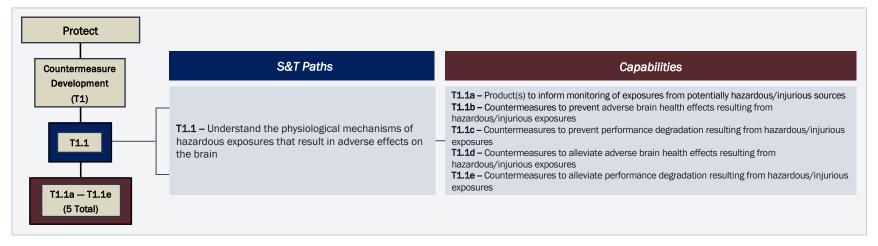


Figure 3-1 Capability Requirement Countermeasure Development (T1)

3.2 Assessment Tool Development (T2)

Recognizing, assessing, and diagnosing TBI in warfighters is critical for ensuring the continued readiness and health of the force in garrison, training, and deployed environments. Medical tools and knowledge are needed to support accurate and reliable assessment and diagnosis of TBI, and surveillance of warfighter brain health. Subsequently, diagnostic and clinical decision-support tools will help ensure that the appropriate management and treatment approaches can be used. Figure 3-2 outlines the S&T Paths for this Capability Requirement and the planned Capabilities that will transition to Advanced Development or other intended end users. Appendix B.3 provides an expanded description of the Capability Requirements for Assessment Tool Development (referenced in Appendix B.3 as 3.4 and 4.2).

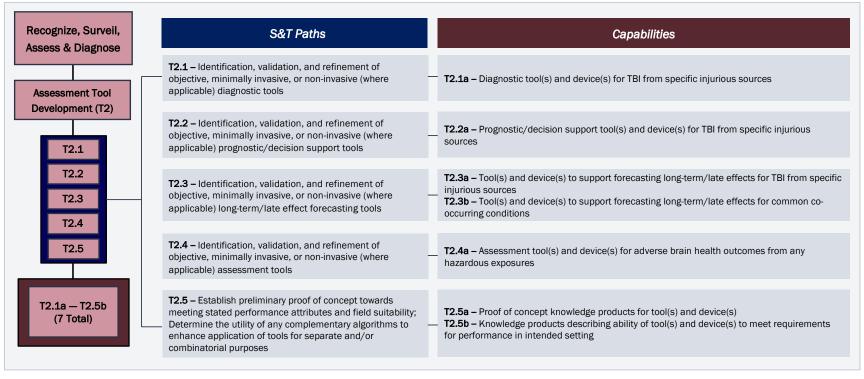


Figure 3-2 Capability Requirement Assessment Tool Development (T2)

3.3 Point of Injury Stabilization (T3)

Efficient and effective stabilization from the point of injury to the point of care is crucial in preventing TBI progression; in identifying and implementing treatment; and ultimately in optimizing readiness and outcomes. Figure 3-3 outlines the S&T Paths for this Capability Requirement and the planned Capabilities that will transition to Advanced Development or other intended end users. Appendix B.3 provides an expanded description of the Capability Requirement for Point of Injury Stabilization (referenced in Appendix B.3 as 5.2).

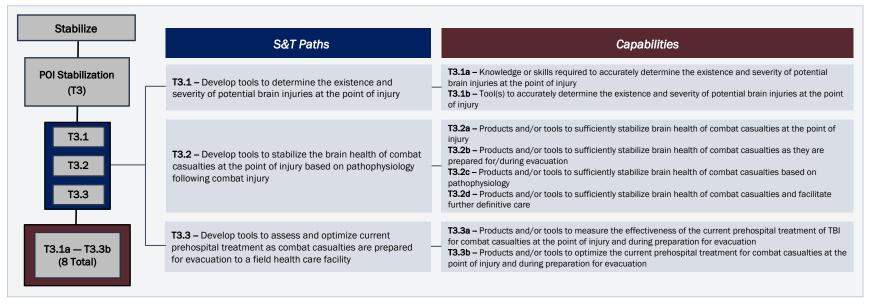


Figure 3-3 Capability Requirement POI Stabilization (T3)

3.4 Complex Injury Stabilization (T4)

TBI is often part of a complex injury profile requiring TBI stabilization alongside treatment of co-occurring injuries. The development of validated products and tools is essential in allowing for both TBI stabilization and prevention of the progression of other polymorbidities, neurosensory dysfunction, and infection. Figure 3-4 outlines the S&T Paths for this Capability Requirement and the planned Capabilities that will transition to Advanced Development or other intended end users. Appendix B.3 provides an expanded description of the Capability Requirement for Complex Injury Stabilization (referenced in Appendix B.3 as 5.3).

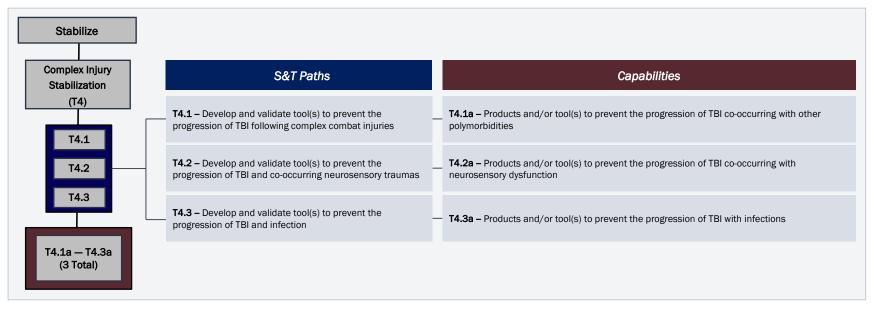


Figure 3-4 Capability Requirement Complex Injury Stabilization (T4)

3.5 Treatment Development (T5)

Effective TBI treatment and rehabilitation methods are essential for maintaining a healthy warfighter population. <u>Figure 3-5</u> outlines the S&T Paths for this Capability Requirement and the planned Capabilities that will transition to Advanced Development or other intended end users. Appendix B.3 provides an expanded description of the Capability Requirement for Treatment Development (referenced in Appendix B.3 as 6.1).

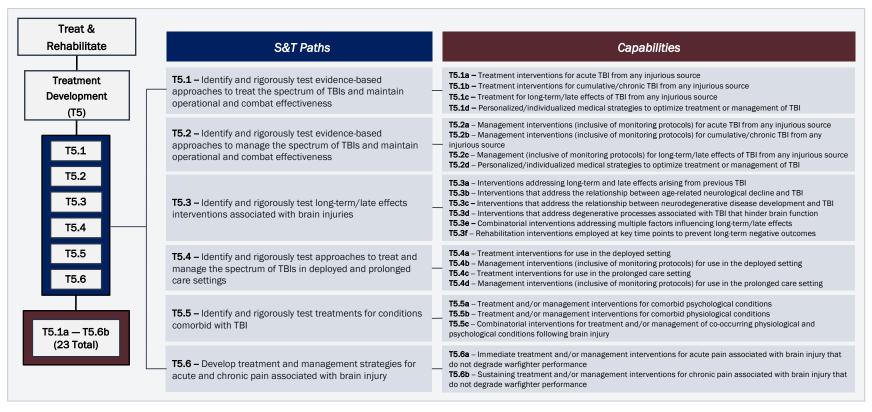


Figure 3-5 Capability Requirement for Treatment Development (T5)

3.6 Clinical Practice Guideline Development (T6)

Standardized, research-based CPGs are essential to aid in the monitoring, treatment, and management of warfighters following exposures or injuries to the brain. <u>Figure 3-6</u> outlines the S&T Paths for this Capability Requirement and the planned Capabilities that will transition to Advanced Development or other intended end users. Appendix B.3 provides an expanded description of the Capability Requirement for CPG Development (referenced in Appendix B.3 as 6.2).

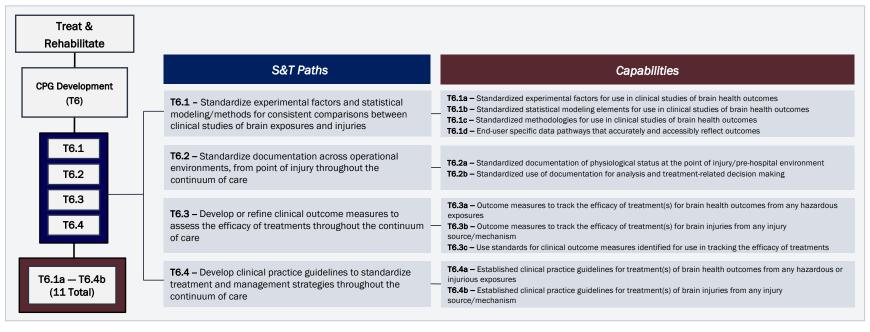


Figure 3-6 Capability Requirement CPG Development (T6)

3.7 Cognitive Restoration and Enhancement (T7)

Research activities focused on developing materiel and knowledge products that support cognitive restoration and enhancement will result in improved warfighter brain heath and performance both pre- and post- exposure or injury. Figure 3-7 outlines the S&T Paths for this Capability Requirement and the planned Capabilities that will transition to Advanced Development or other intended end users. Appendix B.3 provides an expanded description of the Capability Requirement for Cognitive Restoration and Enhancement (referenced in Appendix B.3 as 7.1).

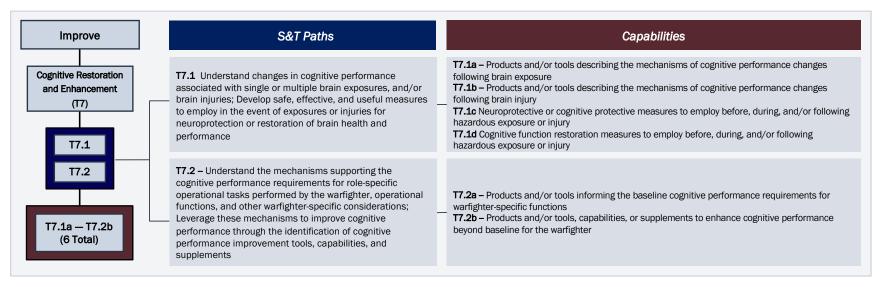


Figure 3-7 Capability Requirement Cognitive Restoration and Enhancement (T7)

4. REFERENCES

- [1] Initial Capabilities Document (ICD) for Warfighter Brain Health, DoD, 2022
- [2] Initial Capabilities Document (ICD) for Combat Casualty Care Devices and Products, DoD, 2014
- [3] Initial Capabilities Document (ICD) for DoD Combat Casualty Care (C3) Training Technologies, DoD, 2015
- [4] Initial Capabilities Document (ICD) for Clinical and Rehabilitative Medicine, DoD, 2017
- [5] Initial Capabilities Document (ICD) for Military Infectious Disease, DoD, 2020
- [6] Initial Capabilities Document (ICD) for C3 Support for Future Operations, DoD, 2021
- [7] Science and Technology Portfolio Management Process (STMP) Concept of Operations (CONOPS), JHU/APL, AOS-L-20-0230, 8 July 2020
- [8] Science and Technology Portfolio Management Process (STMP) Research Roadmapping Methodology, JHU/APL, December 2020
- [9] National Research Action Plan (NRAP): Responding to the Executive Order Improving Access to Mental Health Services for Veterans, Service Members and Military Families, DoD, DVA, DHHS, DOEd, August 2013