



PERSONNEL AND
READINESS

OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

The Honorable James M. Inhofe
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

APR 11 2019

Dear Mr. Chairman:

The enclosed interim report is in response to section 734 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Public Law 115-91), which requires the Secretary of Defense to provide an interim report on the study methods and action plan for the required longitudinal medical study on Blast Exposure Pressure of Members of the Armed Forces.

This study will inform safety protocols and Service member health by examining health and performance effects of blast pressure exposure on members of the Armed Forces during combat and training. The Department developed a program structure to facilitate additional detailing of the study methods and action plan. The program structure identifies organizations that will provide oversight, guidance, and coordination, and will promote translation of study findings to the Services. The program structure includes five Lines of Inquiry to support the three reporting Elements of section 734 of the NDAA for FY 2018. These Lines of Inquiry are Surveillance, Weapon Systems, Exposure Environment, Blast Characterization, and Health and Performance.

Offices of primary responsibility for these Lines of Inquiry will identify required efforts and gaps, develop an acquisition/appointment strategy to procure resources/select principal investigators, approve study protocols, leverage and execute research, and analyze and document findings. Relevant information from private industry, academia, and federal agencies including the Department of Defense, is being collected through a series of directive memoranda, requests for information, and other informal means to support these efforts.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the House Armed Services Committee.

Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower
and Reserve Affairs, Performing the Duties of
the Under Secretary of Defense for Personnel
and Readiness

Enclosure:
As stated
cc:
The Honorable Jack Reed
Ranking Member



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OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

APR 11 2019

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower
and Reserve Affairs, Performing the Duties of
the Under Secretary of Defense for Personnel
and Readiness

Enclosure:

As stated

cc:

The Honorable William M. "Mac" Thornberry
Ranking Member

REPORT TO ARMED SERVICES COMMITTEES

Section 734 of the National Defense Authorization Act for Fiscal Year 2018

(Public Law 115-91)

Longitudinal Medical Study on Blast Pressure Exposure of Members of the Armed Forces

Initial Report



The estimated cost of this report or study for the Department of Defense is approximately \$488,000 in Fiscal Years 2018-2019. This includes \$289,000 in expenses and \$199,000 in DoD labor.

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Background

Experiences by Service members in recent conflicts and training environments illuminate concerns related to the possible effects of blast pressure exposure on brain health. Increased knowledge and communication about the physical and cognitive effects of blast pressure exposure resulted in increased Congressional interest of Service member use of heavy weapon systems in training and combat. Additionally, growing evidence of public interest in these exposures was presented in a report released in May 2018 by the Center for a New American Security titled “Protecting Warfighters from Blast Injury,” which described high blast pressure exposures of members of the Armed Forces. Integration of interests from both the public and private sectors resulted in section 734 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Public Law 115–91), which requires that the Secretary of Defense conduct a longitudinal medical study on blast pressure exposure of members of the Armed Forces during combat and training. The law states:

(a) IN GENERAL. The Secretary of Defense shall conduct a longitudinal medical study on blast pressure exposure of members of the Armed Forces during combat and training, including members who train with any high overpressure weapon system, such as anti-tank recoilless rifles or heavy-caliber sniper rifles.

(b) ELEMENTS. The study required under subsection (a) shall—

(1) monitor, record, and analyze data on blast pressure exposure for any member of the Armed Forces who is likely to be exposed to a blast in training or combat;

(2) assess the feasibility and advisability of including blast exposure history as part of the service record of a member, as a blast exposure log, in order to ensure that, if medical issues arise later, the member receives care for any service connected injuries; and

(3) review the safety precautions surrounding heavy weapons training to account for emerging research on blast exposure and the effects of such exposure on cognitive performance of members of the Armed Forces.

(c) REPORTS.-

(1) INTERIM REPORT.-Not later than one year after the date of the enactment of this Act, the Secretary shall submit to the Committees on Armed Services of the Senate and the House of Representatives an interim report on the study methods and action plan for the study under subsection (a).

(2) FINAL REPORT.-Not later than four years after the date the Secretary begins the study under subsection (a), the Secretary shall submit to the Committees on Armed Services of the Senate and the House of Representatives a report on the results of such study.

The Secretary of Defense assigned responsibility for fulfilling the longitudinal medical study requirements of section 734 of the NDAA for FY 2018 to the Assistant Secretary of Defense for Health Affairs (ASD(HA)). Additionally, the Deputy Secretary of Defense, in an effort to establish an overarching strategy for brain health and brain injury across the Department, issued the memorandum, “Comprehensive Strategy and Action Plan for Warfighter Brain Health,” on October 1, 2018. The memorandum established a foundation for a cross-agency, multidisciplinary, collaborative effort to tackle this complex issue. The overarching strategic initiative will have six lines of effort; the section 734 study is one of the lines of effort. The longitudinal medical study will involve contributions from blast engineers, munitions testing and operational personnel, safety officers, healthcare providers, and others, to offer a comprehensive approach to interpreting blast exposure data and developing recommendations for enhancing blast exposure safety in the training and operational environments. The Principal Deputy Assistant Secretary of Defense for Health Affairs established the Section 734 Workgroup

(hereafter referred to as the Workgroup) to establish a targeted strategy aimed to: address the three reporting Elements of section 734 of the NDAA for FY 2018, promote collaboration across the Services' line and medical communities, and reduce duplication of effort. The Workgroup comprises members from 54 organizations from the Department, the Armed Services, and the Department of Veterans Affairs. This interim report provides the study methods and action plan as noted in section 734 of the NDAA for FY 2018.

Goal and Scope

The goal of this initiative is to successfully conduct a series of studies (i.e., examination of health and performance effects) of blast pressure exposure of members of the Armed Forces during combat and training, including Service members who train with high overpressure weapon systems, such as anti-tank recoilless rifles or heavy-caliber sniper rifles, and inform training and operational safety doctrine, protocols, and policies to best protect the Warfighter. The scope of the study will include a series of studies and assessments to achieve the goal rather than a single longitudinal study. The multiple study methodology will be used in an effort to capture answers to multiple lines of inquiry that would prove challenging to accomplish with one large and unwieldy study, as well as enable more opportunities for success. The initiative will build on existing work and require a portfolio of studies that will support all reporting Elements in section 734 of the NDAA for FY 2018. The results from the portfolio will inform safety standards and medical policy to protect Service member health. Additionally, the studies will address the feasibility of tracking and documenting blast exposures during a Service member's career lifecycle.

Program Structure: Lines of Inquiry and Responsibilities

The Office of the ASD(HA) (OASD(HA)) and the Workgroup developed a program structure to facilitate additional detailing of the study methods and action plan. The program structure (Figure 1) identifies organizations that will provide oversight, guidance, and coordination, and will promote translation of study findings to the Services. The program structure includes five Lines of Inquiry: Surveillance, Weapon Systems, Exposure Environment, Blast Characterization, and Health and Performance, to support the three reporting Elements of section 734 of the NDAA for FY 2018.

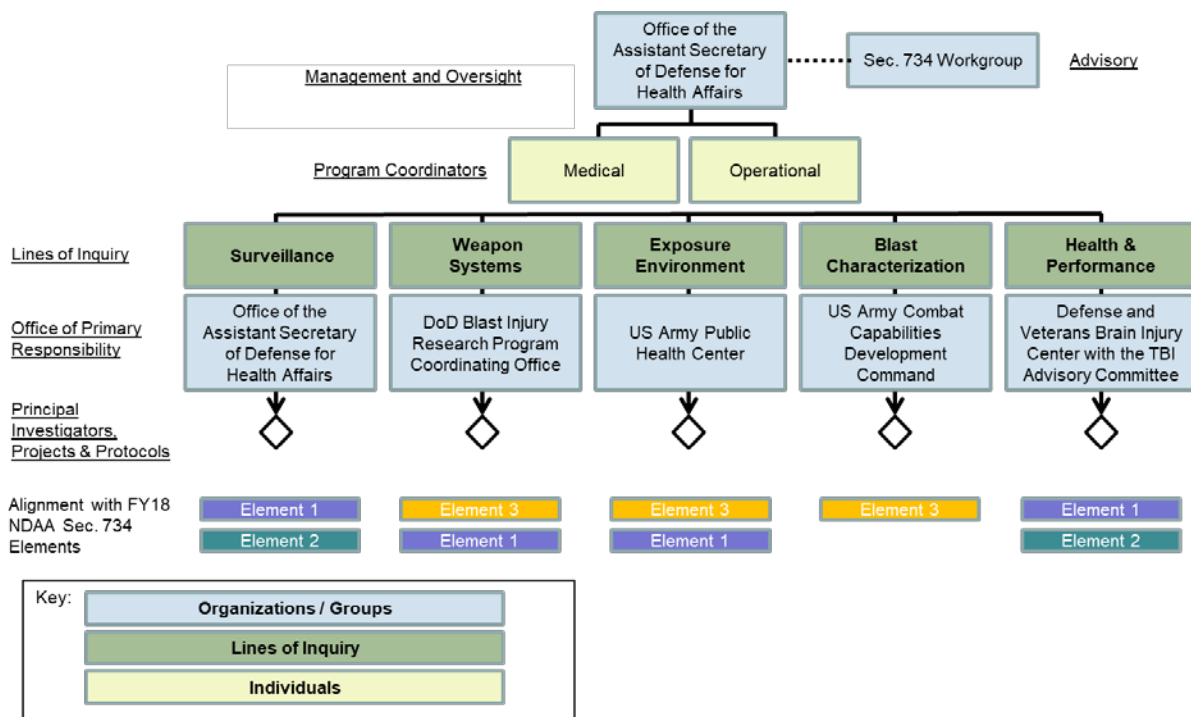


Figure 1. Program Structure Developed to Support Section 734

OASD(HA) provides oversight of section 734 of the NDAA for FY 2018 progress, exercises tasking authority, and coordinates with Congress. The roles and responsibilities of the Workgroup are identified in the Workgroup Charter. They include providing access to information and points of contact to assist in data gathering efforts; providing technical guidance for monitoring, recording, and analyzing data on blast pressure exposure; recommending and evaluating study methodologies and action plans for implementation of the longitudinal study; and coordinating and informing their respective organizations about Workgroup activities.

The Workgroup Co-Chairs identified Program Coordinators to oversee the Lines of Inquiry, providing direction to Line of Inquiry Offices of Primary Responsibility (OPRs). The OPRs will provide operational management of Line of Inquiry performers. The OPRs will chair any sub-Workgroups developed in support of section 734. The Principal Investigators (PIs) will develop and execute study protocols and provide regular reports to the OPRs.

To support further development and execution of study methods by OPRs and PIs, the Workgroup and OPRs defined the scope and approach for each Line of Inquiry as illustrated in Figure 2 and as follows:

The Surveillance Line of Inquiry will assess the feasibility and advisability of including blast pressure exposure history in the service and/or medical record of members of the Armed Forces, pilot implementation of a personnel monitoring surveillance program, and analyze data to improve understanding of blast pressure exposures of members of the Armed Forces.

The Weapon Systems Line of Inquiry will coordinate, collate, and analyze information on blast pressure resulting from heavy weapons and blast events, and will inform strategies to account for emerging research on the effects of blast pressure exposure on health and performance of members of the Armed Forces.

The Exposure Environment Line of Inquiry will review safety precautions for heavy weapons and blast events in different blast environments, features of the environment that may contribute to blast exposure-related changes in health and performance of members of the Armed Forces, and compliance with existing safety precautions and Standing Operating Procedures.

The Blast Characterization Line of Inquiry will review modeling of blast and blast effects relevant to Warfighter brain health in training and combat, and will identify technical challenges, knowledge gaps, and considerations for future efforts to monitor, record, and analyze blast pressure exposure.

The Health and Performance Line of Inquiry will evaluate health and performance outcomes of blast pressure exposure focused on Warfighter brain health; this will include leveraging human performance optimization programs and existing clinical and research data.

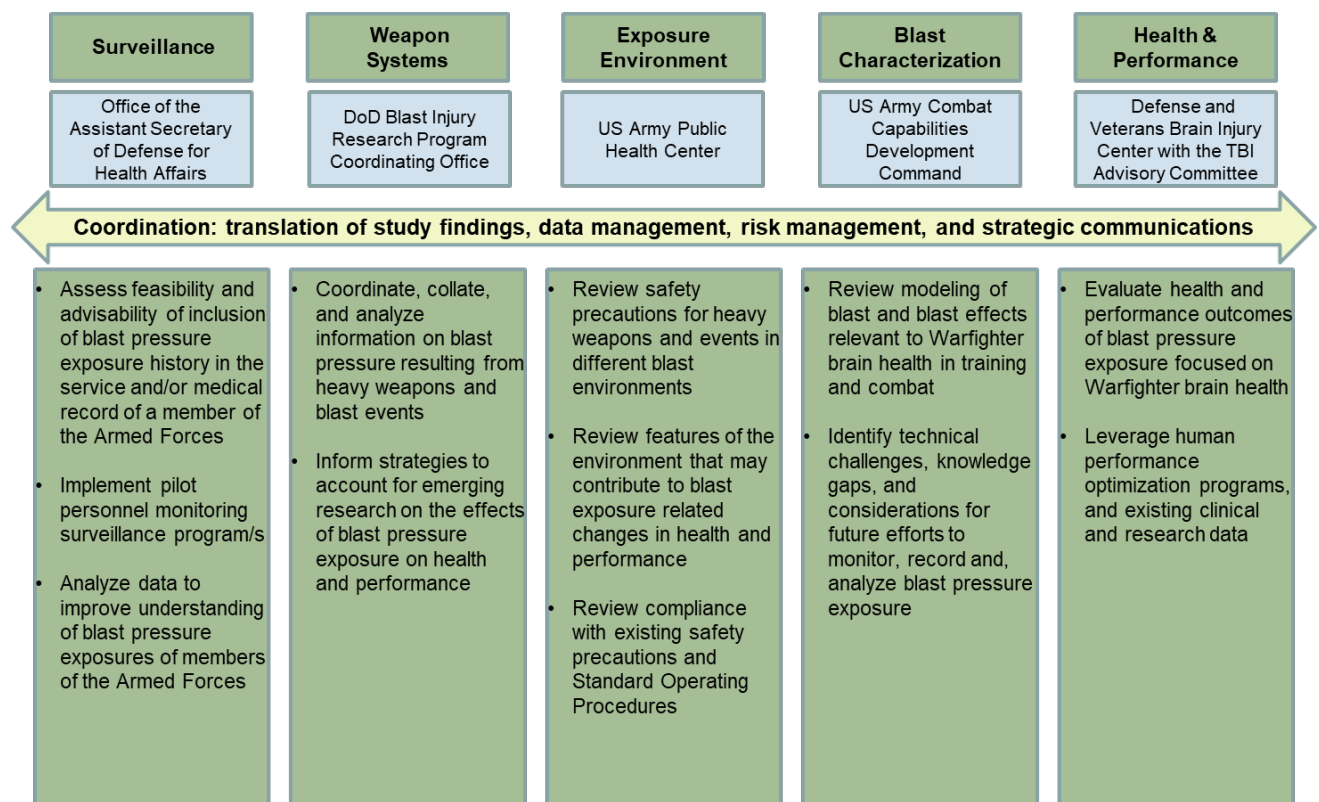


Figure 2. Lines of Inquiry

Action Plan

The Workgroup identified four key focus areas for implementation of the study described in section 734 of the NDAA for FY 2018:

- Communication
- Data management
- Risk mitigation
- Research translation

The OPRs will be responsible for the following actions:

- Identify efforts and gaps
- Develop acquisition/appointment strategy
- Approve study protocols
- Leverage and execute research
- Analyze, summarize and document findings: final report as requested in section 734 of the NDAA for FY 2018

Study Methods

Information from private industry, academia, and federal agencies including the Department of Defense (DoD), is being collected through memorandums, Requests for Information, and informal means. For example:

- Deputy Secretary of Defense memorandum, “Comprehensive Strategy and Action Plan for Warfighter Brain Health,” dated October 1, 2018
- OASD(HA) memorandum, “Request for Information in Support of Longitudinal Medical Study on Blast Pressure Exposure,” dated October 22, 2018
- Office of the Under Secretary of Defense for Personnel and Readiness memorandum, “Request for Information in Support of Longitudinal Medical Study on Blast Pressure Exposure: Identification of High Overpressure Weapon Systems and Associated Military Occupational Specialties and Training Events,” dated February 4, 2019

The information collected has informed the study methods. Details of the study protocols will be finalized in collaboration with the PIs following the acquisition/appointment process, site approvals from the Services, and Institutional Review Board approvals. Additionally, the Workgroup reviewed confounding factors, blast sensor technologies, and brain injury assessments, and contributed to the following initial recommendations:

- Study protocols will seek to include a wide sample of Service members who are in different stages of their careers (entry, mid and late) where possible, with a focus on high risk military occupational specialties operating weapon systems identified by the Services as priority and units at greater risk of exposure (e.g., explosive ordnance disposal, heavy weapons, and special operations forces);
- Study protocols will include the weapon systems identified by the Services such as (1) Carl Gustaf, (2) AT4 (Anti-tank recoilless weapon), (3) LAW light anti-armor weapon;
- PIs of protocols with health and performance assessments will select assessments that are operationally feasible, reflect hypothesized domains of vulnerability (e.g., memory, emotional dysregulation, balance), and demonstrate strong test psychometrics (e.g., sensitivity, specificity, and test-retest reliability);

- OPRs will encourage standardization of assessment methods to facilitate meta-analysis across studies;
- PIs of protocols requiring blast data collection, within operational and technological constraints, will use inclusive (all-hazards) high-resolution measurement approaches for quantifying blast exposure; and
- OPRs will encourage PIs of protocols to leverage findings of previous blast measurement.

Challenges

There are challenges to successful implementation of this study such as, conducting research in austere environments and confounding factors (e.g., history of head injury, recreational use of firearms) based on self-report. OASD(HA) and the Workgroup have carefully considered these potential barriers while collaboratively developing the action plan and study methods described in this interim report to capture as much information as possible.

Timeline

The following timeline is subject to change depending on selected acquisition strategies and DoD and vendor approval processes.

- Plans of Action and Milestones developed by 31 May 2019.
- Existing complimentary efforts identified by 31 May 2019 to leverage for immediate incorporation.
- Gaps identified and requirements developed for new study protocols by 30 September 2019.
- Costing, acquisition and procurement strategies developed for Lines of Inquiry by 30 September 2019.
- In progress review briefings to unit commanders and senior leaders of the appropriate governance body on Brain Health at quarterly intervals.

The Department will also provide updates on the continued progress of the implementation of the study methods and action plan, as requested by Congress.

Finally, as stated previously, the intent of these studies is to inform training and operational safety doctrine, protocols, and policies to best protect the Warfighter.