

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

The Honorable Mike D. Rogers Ranking Member Committee on Armed Services U.S. House of Representatives Washington, DC 20515 JAN 1 9 2021

Dear Representative Rogers:

The Department's response to section 742(a)(2) of the National Defense Authorization Act for Fiscal Year 2020 (Public Law 116-92), "Modification of Requirements for Longitudinal Medical Study on Blast Pressure Exposure of Members of the Armed Forces," which requires an annual status report on the longitudinal medical study on blast pressure exposure, is enclosed.

The goal of section 734, also referred to as the Blast Overpressure Study (BOS), is to improve the Department's understanding of the impact of blast pressure exposure from weapon systems on the Service members' brain health and better inform policy for risk mitigation, unit readiness, and health care decisions. Section 734/BOS continues to leverage existing work and expertise across the various lines of inquiry. Results from these efforts will inform safety standards and medical policy to protect Service members' health.

Thank you for your continued strong support for the health and well-being of our Service members, veterans, and families. I am sending an identical letter to the Senate Armed Services Committee.

Sincerely,

//SIGNED//

Matthew P. Donovan



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

Dear Mr. Chairman:

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The Honorable Jack Reed Ranking Member Committee on Armed Services United States Senate Washington, DC 20510

JAN 19 2021

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

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Report to Congress



Section 742(a)(2) of the National Defense Authorization Act for Fiscal Year 2020 (Public Law 116-92): "Modification of Requirements for Longitudinal Medical Study on Blast Pressure Exposure of Members of the Armed Forces"

Annual Status Update January 2021

The estimated cost of this report or study for the Department (DoD) of Defense is approximately \$661,000 for the 2020 Fiscal Year. This includes \$621,000 in expenses and \$41,000 in DoD labor.

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INTRODUCTION

Section 742(a)(2) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 (Public Law 116-92), "Modification of Requirements for Longitudinal Medical Study on Blast Pressure Exposure of Members of the Armed Forces and Collection of Exposure Information," requires an annual status report on the longitudinal medical study on blast pressure exposure (section 734 of the NDAA for FY 2018 (Public Law 115-91)). The first annual status update (section 742) was submitted in April 2020.

The goal of section 734, also referred to as the Blast Overpressure Study (BOS), is to improve the Department's understanding of the impact of blast pressure exposure from weapon systems on the Service member's brain health and better inform policy for risk mitigation, unit readiness, and health care decisions. The scope of section 734 includes 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 several lines of inquiry (LOIs) that would prove challenging to accomplish with one large and unwieldy study, as well as to enable more opportunities for success.

Section 734/BOS has an established Program Structure, which includes the following five LOIs: Surveillance (LOI 1), Weapons Systems (LOI 2), Exposure Environment (LOI 3), Blast Characterization (LOI 4), and Health and Performance (LOI 5), to address the congressional requirements. An In-Process Review for the entire section 734/BOS performers was conducted in October 2020 to include updates by each of the LOIs. For the purposes of this annual status update, progress across each of the LOIs is reported.

SECTION 734/BOS LOIS

Surveillance (LOI 1)

The Surveillance LOI (LOI 1) is focused on designing, planning, and executing the Blast Overpressure Studies Pilot or BOS-P to assess the feasibility of collecting blast overpressure and decibel levels, and capturing these exposures in a Service record. BOS-P will be conducted as a three-phase approach, which includes BOS-D (de-identified), BOS-S (surveillance), and BOS-L (longitudinal) (Figure 1). These phases will lead to additional information and help formulate a knowledge basis to inform a blast surveillance program of record.

Figure 1. BOS-Pilot Phase Approach

BOS-Pilot (BOS-P)

The Blast Overpressure Studies Pilot (BOS-P) is a combination of Blast Overpressure Studies De-Identified (BOS-D), Blast Overpressure Studies Surveillance (BOS-S), and Blast Overpressure Studies Longitudinal (BOS-L) designed to increase capability to support the development of a DoD Blast Surveillance Program.

BOS-D De-Identified	BOS-S Surveillance	BOS-L Longitudinal
Single coded limited data set per performer Utilize data previously collected by performers Data not used for, or to support, research or surveillance	Unit level surveillance, moving personally identified data Leverages newly collected data for inclusion in a service member's record for feasibility purposes Includes access to view cognitive assessments Data used for surveillance and feasibility to integrate into service member record Train staff and develop SOPs to be leveraged during BOS-L	Units selected in the predeployment training window involving live fire training exercises and are on the Road to War Data used for surveillance for longitudinal study Build SOPs and information necessary to inform Services' requirements and impacts to implement as a program of record
Started FY 2020 2nd Quarter	Not Earlier Than FY 2021 1st Quarter	Not Earlier Than FY 2021 3rd Quarter

Progress to Date:

LOI 1 has made progress across all phases of the pilot study to include the following:

- Established data management and transfer processes from blast gauge to surveillance system
- Developed standardized data dictionary and data fields in Defense Occupational and Environmental Health Readiness System Industrial Hygiene (DOEHRS-IH).
- DOEHRS-IH has completed system change request to accommodate specified blast data elements.
- Established standardized procedural guidance for contextual data capture in support of Blast Overpressure Study –Pilot (BOS-P) consisting of three phases: de-identified data (BOS-D), surveillance (BOS-S), and longitudinal (BOS-L).
- Completed Phase 1 BOS-D on October 31, 2020.
- Developed a Concept of Operations, which outlines planning requirements to include data collection and data management in the field.
- Published an Execute Order with the Deputy Assistant Secretary of the Army for Military Personnel and Quality of Life, Headquarters, Department of the Army, to have designated training venues participate in the BOS-S portion of LOI 1.

Weapons System (LOI 2)

Weapons System LOI 2 is focused on assessing and reviewing the safety precautions surrounding heavy weapons used in training to account for emerging research on blast exposure and the effects of such exposure on cognitive performance of members of the Armed Forces. The resultant effect is to gain insights and develop an understanding of the exposures that result

from weapons firing or detonating systems by collecting and analyzing weapon system safety guidance, conducting analyses, and identifying knowledge gaps and policy implications to inform recommendations to senior leaders. LOI 2 divided the Service-identified list of weapons and weapon systems into tiers for a phased approach to data collection and analysis. The initial series or "Tier 1" set of weapon systems is outlined at Figure 2.

50 CALIBER WEAPONS SHOULDER MOUNTED • M107 sniper rifle • M3, MAAWS • M136, AT 4 • M2A1 machine gun • M72, LAW • MK 15 • GAU 21 INDIRECT FIRE SYSTEMS BREACHING CHARGES Howitzer (all • Door: NEW of .23 lbs platforms) TNT (slider) - .30lbs TNT (fruit roll up) • Mortars (all platforms), 120mm, · Wall: NEW of 10.0 lbs 81mm and 60mm - 14.0 lbs

Figure 2. Tier 1 Weapons

Progress to Date:

LOI 2 accomplished the following:

- Drafted "Blast Injury Threshold Review," a collaborative effort between LOIs 3 and 5 summarizing current information on repeated low-level exposure threshold for brain injury, limitations, and ongoing efforts to potentially close critical knowledge gaps.
- Finalized draft Tier 1 Weapon System informational executive summaries for submission to the Section 734 working group
- Established prototype database(s) in coordination with LOI 3 to support collection, coordination, analysis, and sharing of Tier 1 Weapon System information for Section 734/BOS LOIs. Information within the database includes:
 - Allowable Number of Rounds by pose, type of rounds; updated as Health Hazard Assessment is performed
 - Safety precautions utilized (hearing protection, standoff distances)
 - Detailed testing methodologies
 - o Training information
 - o Tier 1 Weapon System information (most commonly fired round, round of most concern)

Exposure Environment (LOI 3)

The Exposure Environment (LOI 3) is focused on determining the factors that contribute to how Service members are exposed to blast overpressure through reviewing safety precautions for weapons in different blast environments, as well as reviewing compliance with existing safety protocols and environmental features which may contribute to the blast overpressure exposure. Additionally, LOI 3 is identifying, assessing, mitigating, quantifying, and cataloguing postmateriel, fielding-related health hazard exposures (e.g., blast overpressure, impulse, noise) on Service members. These will be accomplished through the development of an interim Brain Injury Risk Criteria, conducting Service member Occupational Health Assessments and archiving exposure data in Service record (e.g., DOEHRS-IH).

Progress to Date:

LOI 3 has collaborated with key groups/organizations to move forward specifically with Training Commands, Division Surgeons, the Joint Weapons Safety Working Group, military operators and instructors, and others in the Military Departments. Other accomplishments include:

- Published Technical Guide 351A: "Health Hazard Assessor's Guide: Steady-state Noise, Impulse Noise, Blast Overpressure" (April 30, 2020).
- Submitted a proposal to add a "Primary Blast Injury to Brain" code to the ICD-10-CM Tabular List. Defense of this proposal is scheduled for March 2021.
- Conducted two Safety and Occupational Health Assessments: Breaching Charges at Ft. Leonard Wood (September 2020) and M107 Long Range Sniper Rifle at Quantico, MCB (October 2020).

Blast Characterization (LOI 4)

The Blast Characterization (LOI 4) is focused on modeling blast and blast effects relevant to warfighter brain health in training and combat, and identifying technical challenges, knowledge gaps, and considerations for future efforts to monitor, record, and analyze blast pressure exposure. LOI 4 focused on three areas: 1) Repository Development and Toolset Integration; 2) Computational Modeling; and 3) Automation and Analysis.

Progress to Date:

LOI 4 has identified gaps across each of its three focus areas to include the following: 1) there is a lack of standardized validation and verification processes as well as lack of data quality screening; 2) Test and Evaluation (T&E) storage of data varies and is challenging to locate; 3) current blast models are isolated and lack comparability and are not fully automated; and 4) no validated protocols or common data elements are used. Additional key accomplishments are:

• Developing plans and processes for modeling communities to better inform weapons T&E procedures.

- Working on strategy plans for reviewing T&E data of Tier 1 weapon systems and existing modeling efforts to identify gaps and forward strategies necessary to support a large surveillance effort. Modeling efforts include environmental blast, armoring systems, biomechanics, and biosystems models.
- Adapting automation techniques to provide solutions for better scalability and translatability of blast modeling and analysis work.
- Exploring Artificial Intelligence methods for comparing exposures to health and performance outcomes to develop processes for risk prediction

Health and Performance (LOI 5)

The Health and Performance (LOI 5) is focused on evaluating the acute, sub-acute, and chronic health and performance outcomes for warfighters exposed to repetitive, low-level, sub-concussive blast pressure with an emphasis on wearable sensor data. LOI 5 leveraged existing efforts and identified 26 relevant studies/performers it currently tracks ("tracked studies"). These studies/efforts align with LOI 5 objectives related to performance, health and biological correlates and will increase the understanding of blast pressure effects on brain health (Table 1).

Study Characterization	Studies N (%)
Study Type	
Retrospective	6 (23.1)
Prospective	20 (76.9)
Study Status	
Data collection/extraction complete, Data analysis/Manuscript preparation	7 (26.9)
Pending Institutional Review Board (IRB) approval or Initiation of enrollment	3 (11.5)
Ongoing data extraction or enrollment and data collection	16 (61.5)
Blast Quantification	
Gauges	11 (42.3)
Shot Count	2 (7.7)
Detailed self-report questionnaire/interview	8 (30.8)
MOS used as proxy	5 (19.2)

Note: Study counts are tracked by unique studies with distinct lines of effort as originally reported by performers; however, some studies have merged reporting due to overlapping hypotheses and funding streams.

Table 1. Section 734 Studies (By Type, Status, and Blast Quantification)

Progress to Date:

Below are accomplishments by LOE 5 and the tracked studies and research performers to date:

- Identified gaps on blast exposure effects on brain health to include:
 - o Specific dose-response relationship is currently unknown.
 - O To date there is insufficient data to support establishing a single blast pressure threshold for brain injury.

- o Implications or persistence of health effects is unknown and requires more study.
- Most published findings are on effects of blast exposure specific to breaching rather than specific weapons.
- Captured both blast gauge data and health and performance data on approximately 975 Service members.
- Generated 49 scientific papers in various stages of publication in peer-reviewed journals.
- Hosted "Blast Effects on Warfighter Brain Health (Section 734): Virtual Breakout Session from MHS Research Symposium Abstracts;" a total of 126 attendees/stakeholders participated.

NEW BLAST PRESSURE EXPOSURE REQUIREMENTS IN THE NDAA FOR FY 2020

The Under Secretary of Defense for Personnel and Readiness has developed a DoD-wide comprehensive strategy and action plan for warfighter brain health as a Departmental initiative developed to address the health effects, including brain health, from blast pressure exposure from the use of kinetic weapons in training and operations. The strategy also addresses promoting and maintaining brain health in support of individual Service member combat lethality. Leveraging efforts already in progress in response to section 734 of the NDAA for FY 2018, work is underway to assess the feasibility and advisability of uploading personnel exposure data into the existing DOEHRS-IH, as required by section 742 of the NDAA for FY 2020. Section 717 of the NDAA for FY 2020 directs documentation of blast exposures into the medical record with a set of minimum elements for inclusion. Further efforts under review include an examination of elements beyond the minimum listed for a more robust surveillance capability.

CONCLUSION

Section 734/BOS continues to leverage existing work and expertise across the various LOIs. The LOI efforts are interconnected resulting in close coordination and collaboration. The results from these efforts will inform safety standards and medical policy to protect Service members' health. Additionally, this work will address tracking and documenting blast exposures. Due to the nature of some of the efforts underway for Section 734/BOS, specifically field research activities, the current COVID-19 pandemic has delayed some progress (due to travel arrangements requiring longer lead time or being curtailed; additional documentation and virus testing requirements; quarantine periods after travel; research sites that have not resumed inperson human subject testing; and reduced DoD training tempo). Despite these challenges, the Department continues to make the adjustments necessary to continue moving the study forward.