National Defense Authorization Act for Fiscal Year 2018 Section 734

Interim Recommendation for Blast Overpressure Exposure Safety for Brain Health

On Behalf Of:

The Section 734 Workgroup

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Executive Summary

BLUF: An interim blast overpressure exposure safety guidance of 4 pounds per square inch (psi) is recommended to prevent performance degradation and adverse brain health outcomes.

Key Findings

Evidence on the cumulative health effects of repetitive occupational blast overpressure (BOP) suggests an increased likelihood of unfavorable outcomes and warrants implementation of brain health-specific safety measures to mitigate these outcomes. Existing Department of Defense (DOD) guidelines and standards provide safety thresholds for occupational BOP exposure; however, these thresholds do not exist specific to the protection of brain health, due to a lack of evidence with sufficient granularity to quantify the relationships between BOP exposure (e.g., intensity, duration, dose) and brain health. At present, the Services recognize a 4 pounds per square inch (psi) threshold as the limit identified by the auditory community to safeguard against eardrum rupture.

To elucidate the relationship between repetitive BOP exposures and brain health and performance (H&P) outcomes, published literature must present quantified BOP exposure alongside H&P data to permit direct comparison. Currently, published studies presenting data in this manner are limited, but several trends can be observed from the findings. Symptomology (e.g., headache) and reaction time, a metric for neurocognitive performance, alterations were commonly reported associated with exposures above 4 psi. Alternatively, biomarkers and other biological correlates have not yet yielded any reliable associations with BOP exposure.

Recommendation

An interim blast exposure safety guidance of 4 psi is recommended to assist in preventing performance degradation and adverse brain health outcomes. This guidance is in alignment with the safety threshold utilized by the auditory community. As an interim guidance, a binary approach with a threshold to delineate between acceptable and unacceptable exposure is required. Future policy will require continued and targeted data collection and synthesis and may support the use of a performance-risk curve. This curve would allow evaluation along a continuum to account for the influence of multiple blast characteristics related to acute exposures and ultimately better inform leaders' actions to protect the brain health of Service Members (SMs).

Future Research

Future research should support the establishment of evidence-based safety guidance(s) and/or performance-risk curve(s). Specifically, ongoing and future work should: 1) characterize BOP generated by multiple prioritized heavy weapons systems beyond explosive breaching; 2) optimize blast sensor data collection and analysis; 3) identify the most salient H&P outcomes associated with BOP exposure; 4) specify the relationship between exposure dosage and H&P outcome; and 5) integrate the findings from 1-4 to contribute to the establishment of safety policies and procedures that are specific to brain H&P. These goals are in alignment with the output of the Warfighter Brain Health capabilities-based assessment.

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1 Introduction

While exposure to occupational blast overpressure ([BOP], defined as exposure resulting from the intended use of weapon systems in training and/or combat) is common for many Service Members (SMs), certain military occupational specialties are at increased risk of exposure throughout a military career. There is some evidence that suggests that repetitive BOP exposure may negatively impact Warfighter brain health (Belanger, Bowling, & Yao, 2020; Jennifer N. Belding et al., 2021), which has been 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” (Source: WBH DCR and ICD, 2021). Of note, while this definition of Warfighter brain health incorporates injury status, emphasis is placed on performance optimization (i.e., physical, psychological, cognitive) and measures to enhance Warfighter readiness. The impact of repetitive BOP on brain health, as well as the underlying mechanisms, are not fully understood and are not consistent across studies. While the specific relationship(s) between repetitive BOP and brain health continues to be informed by research (DoD Blast Injury Research Program Coordinating Office, 2014; Engel, Hoch, & Simmons, 2018; Simmons et al., 2020), prevention programs targeting performance degradation related to adverse brain health outcomes do not yet exist (Engel et al., 2018).

Previous reviews of the brain health effects of repeated exposure to occupational BOP have acknowledged that there is limited literature in this field and a lack of consensus across existing studies. In 2014, on behalf of the DOD Executive Agent for Medical Research for prevention mitigation and treatment of blast injuries, DOD Blast Injury Research Coordinating Office (BIRCO) hosted the “International State of the Science Meeting on the Biomedical Basis for mTBI Environmental Sensor Threshold Values” and convened an Expert Panel. The panel concluded that sensor thresholds measuring blast events associated with mTBI did not yet exist despite the rapidly-growing literature base on blast-related TBI; furthermore, limited research had examined the health impact of repetitive low-level BOP exposure. The panel recommended that, to work toward identifying safety thresholds for both mTBI and any adverse health and performance (H&P) effects related to low-level BOP, correlations between existing environmental sensor data and medical outcomes need to be established (DoD Blast Injury Research Program Coordinating Office, 2014).

In 2018, the Seventh Annual DOD State-of-the-Science Meeting on “The Neurological Effects of Repeated Exposure to Military Occupational Blast: Implications for Prevention and Health”, sponsored by BIRCO, identified several obstacles hindering the establishment of a comprehensive protective threshold for occupational BOP. First, there is no operationalized, consensus definition for “low-level” exposures (Jennifer N. Belding et al., 2021; Engel et al., 2018). Second, while literature on relevant military populations exists, published studies with blast sensor data related to health effects of exposure were unsuccessfully identified. (Engel et al., 2018). In support of this meeting RAND published “Neurological Effects of Repeated Exposure to Military Occupational Levels of Blast: A Review of Scientific Literature” and reported findings consistent with both the 2014 BIRCO (DoD Blast Injury Research Program Coordinating Office, 2014) and 2018 DOD State-of-the-Science (Engel et al., 2018) recommendations. Collectively, all three reports concluded that little published evidence conclusively links repetitive low-level occupational BOP to neurological injury and related sequelae. These reports called for focused research to augment the current body of literature examining BOP measured through blast sensors in conjunction with effects on SM brain health in order to support safety limits for occupational BOP.

To better understand the effects of repetitive BOP exposure on performance degradation and adverse brain health outcomes, the National Defense Authorization Act (NDAA) of Fiscal Year 2018 (Section 734), the John S. McCain NDAA for Fiscal Year 2019 (Section 253), and the NDAA for Fiscal Year 2020 (Sections 717 and 742) called for the monitoring, recording, and analyzing of BOP exposure during combat and training to mitigate negative impact to the individual SM and promote force readiness. To identify any associated effects on brain and auditory function, emphasis was placed on assessing high overpressure-generating weapon systems (e.g., anti-tank recoilless rifles or heavy-caliber sniper rifles) and should consider the effects of close succession of multiple types of weapons (Appendix A: Tier 1 Weapons List) and/or days of training, as well as exposure limits both for safe distance and/or feasible annual or lifetime exposures. In response, the Office of the Secretary of Defense for Health Affairs (OSD(HA)) established the Section 734 Program (now inclusive of all NDAA Sections listed above) to address the components of the Congressional requests through five Lines of Inquiry (LOIs) (see Appendix B: Initial Report to Armed Services Committees, 2019 for detailed description). The efforts of the Section 734 Program will augment the body of literature on occupational BOP exposure and associated health effects, and in doing so will inform the establishment of safety guidance that strives to mitigate the risks associated with BOP exposure.

The purpose of this review is to: 1) summarize published findings on the cumulative effects of BOP exposure ("dose") on brain health ("response") to justify investigating key dose-response relationships through research and surveillance efforts; 2) overview the existing DOD blast exposure policy and standards that may inform the development of a safety guidance relevant to brain health; 3) detail findings from acute/sub-acute BOP exposure that will help to elucidate dose-response relationships; and 4) provide a recommendation for an interim BOP exposure safety guidance based on the currently available data.

2 Occupational Blast Exposure Effects and Existing Safety Standards

2.1 Cumulative Effects of Occupational Blast Exposure

Based on existing literature documenting subjective and objective brain health effects of cumulative BOP exposure, the information below highlights evidence for adverse long-term brain health effects associated with *cumulative* BOP exposure, such that the evidence does not include blast sensor data. Nonetheless, the evidence demonstrates the necessity for the establishment of safety measures to mitigate these effects as well as further research to quantify the relationships between blast exposure (e.g., intensity, duration, dose, etc.) and brain health outcomes. Section 3 will describe brain health outcomes following acute and subacute exposure in training.

Neurocognitive

In studies assessing neurocognitive performance associated with cumulative BOP exposure, findings suggest that alterations in cognitive function may arise. Using ANAM, one study querying a subset of archival data (i.e., demographic, neurocognitive assessment data) from Marine Corps units reported statistically significant and clinically meaningful changes in simple reaction time performance from pre-deployment to post-deployment (265 ± 136 days between test administrations) (Haran, Handy, Servatius, Rhea, & Tsao, 2019). International colleagues with Defence Research and Development Canada have also reported on neurocognitive performance among experienced breachers. Compared to an unexposed group, experienced breachers showed impaired cognitive motor integration (measured by the Brain Dysfunction Indicator); however, there were no group differences on a computerized neurocognitive test and the experienced breachers had lower failure rates on memory and comprehension performance tests (measured by Cognistat paper-and-pencil assessment) (Vartanian, Coady, Blackler, Fraser, & Cheung, 2020; Vartanian, Tenn, et al., 2020).

Symptomatology

The most widely reported consequence of cumulative BOP exposure is symptom manifestation. Several studies have found a higher incidence, severity, and/or persistence of common self-reported post-concussive symptoms in individuals exposed to a large number of BOP events (J. N. Belding, Fitzmaurice, et al., 2020; Modica, Egnoto, Statz, Carr, & Ahlers, 2020; Vartanian, Coady, et al., 2020; Vartanian, Tenn, et al., 2020). Of note, greater lifetime exposure to heavy weapons has been associated with increased sensory symptoms, including tinnitus, hearing loss, and changes in taste/smell (Modica et al., 2020). Similarly, ongoing work (unpublished; n=567 as of Mar 2021) from Walter Reed National Military Medical Center (WRNMMC) Audiology in support of Sec 734 has identified the following symptoms to be of greatest concern: tinnitus, hearing, headache, memory, attention, mood, and fatigue. Furthermore, odds of reporting longer duration symptoms and associations with higher blast frequencies were most notable for sensory and mood/fatigue symptoms (WRNMMC Audiology, unpublished).

Medical Diagnoses, Healthcare Utilization, Career Outcomes

Cumulative BOP exposure has been associated with increases in select medical diagnoses, aspects of healthcare utilization, and military career outcomes. Evidence to date supports increased likelihood or risk of diagnoses for tinnitus, most likely to occur 3-4 years into military service, and TBI among those with occupational blast exposure (J. N. Belding, Jackson, et al., 2020; Carr, Kelley, Toolin, & Weber, 2020). Exposed soldiers were more likely to have an ambulatory encounter for tinnitus through 14 years of military service, and had a higher likelihood of being evaluated during years 1-7 of military service for nervous system or sense organ related disability. Among those with the diagnosis of tinnitus, exposed soldiers were more likely than unexposed soldiers to be disability discharged or leave the service (Carr, Kelley, et al., 2020).

Biomarkers

To probe neurophysiological mechanisms of cumulative BOP effects on brain health, several lines of research have focused on emerging biological markers (e.g., blood-based biomarkers, neuroimaging, etc.) of BOP exposure-related health effects. These approaches are in a nascent stage; however, the information generated by these efforts is anticipated to become relevant as work on cumulative effects continues.

Summary

Given the collective evidence of brain health effects associated with cumulative occupational BOP exposure, actions to mitigate these effects are warranted. Findings from research on cumulative BOP exposure cannot directly inform preventative safety measures as they cannot quantify the exposure levels that elicited the observed adverse effect on brain H&P. Therefore, determining how acute exposures (e.g., intensity, duration, dose) may contribute to these observed negative outcomes is integral to establishing a dose-response relationship that will inform future comprehensive safety guidance(s) or performance-risk curves.

2.2 Existing DOD Blast Exposure Guidelines and Standards

There are several existing DOD blast exposure guidelines and standards that seek to prevent or reduce performance degradation and adverse health effects associated with BOP exposure (see Table 1). Since the consequences of repetitive BOP exposure as they relate to brain H&P remain largely unknown (DoD Blast Injury Research Program Coordinating Office, 2014; Engel et al., 2018; Simmons et al., 2020), existing DOD blast exposure policy and standards are not tailored to the prevention of alterations that may adversely impact Warfighter brain health. The threshold most commonly utilized by operational communities and reported in studies performed by the brain health community is 4 psi, which is directly associated with the prevention of eardrum rupture (U.S. Army Public Health Center, 2017). While this 4 psi threshold is commonly utilized, it has not been adopted by all groups (C. R. LaValle et al., 2019). In the development of an interim BOP safety guidance that is specific to brain health, the existing DOD policies and standards utilized by the TBI and auditory communities are important to consider to promote ease of adaption and integration into standard practice.

Table 1 Current DOD Blast Exposure Policy and Standards

Policy and Standards	Protected System	Safety Recommendation(s)
DODI 6490.11	Brain	Potentially concussive events (including but not limited to blast within 50 m) require mandatory rest periods and medical evaluation. *Note: DODI 6490.11 is only related to the assessment and diagnosis of a mTBI; it does not pertain to the potential acute and/or long-term consequences of subconcussive BOP from use of heavy weapons.
2017 TIP No. 51-070-217	Auditory	U.S. Army Hearing recommends a 4 psi incident pressure threshold limit to safeguard 95% of the exposed population from tympanic membrane rupture.
DESR 6055.09 Edition 1	Auditory	Calculations of tympanic membrane injury probabilities and using the common goal of protecting 95% of the exposed population identify the exposure threshold would be 3 - 3.6 psi.
MIL-STD-1474 (D & E)	Auditory	Provide an Allowable Number of Rounds (ANOR) or noise dose metric for exposures within a 24-hour period for protection of 95% of the population from 25 dB temporary threshold shift that recovers within 24 hours. *Note: USAMEDCOM proposed and is currently using an interim risk criterion for impulsive noise damage as an intermediate step to determining and adopting a medical criterion.
DODI 6055.12	Auditory	Establishes Service-wide guidance for the implementation of a comprehensive Hearing Conservation Program; stipulates acquisition programs must implement noise assessment and engineering control measures to both legacy and new systems with recognized noise exposures ≥ 85 dBA or ≥ 140 dBP sound pressure.
DA PAM 40-501	Auditory	Single hearing protection: impulsive noise exposures between 140 - 165 dBP; double hearing protection: impulsive noise exposures > 165 dBP.
Marine Corps Order 6260.3	Auditory	Single hearing protection: 140 dBP; double hearing protection: 160 dBP
Air Force Instruction 48-127	Auditory	Consultation services are available for the measurement and evaluation of exposures and controls including characterizing impulsive noise > 170 dB. *Note: 2016 U.S. Air Force Hearing Conversation Program heavily centers on continuous noise effects rather than impulsive noise.
APHC HHA Program	Auditory and Lung	The values from the HHA Interim Impulse Noise Damage Risk Criterion and HHA Blast Overpressure- Assessments are used to determine ANORs (number of rounds that may be fired within a 24-hour period for a specific risk level): to protect 95% of the population from auditory injury (Impulse Noise ANOR) and/or to ensure < 1% incidence of any lung injury (BOP ANOR).

Abbreviations: ANOR = Allowable Number of Rounds; APHC = U.S. Army Public Health Center; BOP = blast overpressure; DA PAM = Department of the Army Pamphlet; dB = decibel; dBP = peak decibel; DESR = Defense Explosives Safety Regulation; DODI = Department of Defense Instruction; HHA = health hazard assessment; MIL STD = Military Standard; TIP = Technical Information Paper; USAMEDCOM = U.S. Army Medical Command.

3 Acute and Sub-acute Effects of Training-related Occupational Exposures

To elucidate a dose-response relationship between BOP exposures and H&P outcomes, published literature must present both blast sensor data and H&P data in a manner that supports direct comparison (i.e., in the same publication). To date, few articles (Table 2) present findings in a manner that allows for such comparisons (Belanger et al., 2020). Instead, in most studies, quantification and reporting of BOP was secondary to H&P findings and lacked sufficient analyses between the BOP and H&P data to establish dose-response relationships. Additionally, to understand how occupational BOP exposure can lead to performance degradation, these studies must be performed in humans engaged in relevant training and/or combat environments. Knowledge derived from studies using animal models has been used in the absence of human data to understand the mechanisms and repercussions of more injurious exposures, and to inform the development of health protection criteria, standards, tools and medical research requirements by the HHA Program (APHC AR 40-10, AR 50-5). However, animal studies have limited translatability to the understanding of nuanced alterations in human performance that occur below the level of injury. Given that it is hypothesized that low-level occupational BOP exposure primarily results in performance degradations, findings from animal models will not lend sufficient evidence for determining an interim blast exposure safety guidance to prevent these outcomes.

Key Findings

Table 2 below presents a comprehensive overview of human studies that concurrently present the source of exposure, magnitude of exposure, and the H&P outcome domains evaluated. The subsequent text describes the findings for each H&P outcome domain assessed in greater detail. Figure 1 presents sensor-based mean peak overpressure values (psi) for incident-related exposures (broken down by Tier 1 weapons system categories, Appendix A: Tier 1 Weapons List) reported in published literature.

3.1 Key Findings

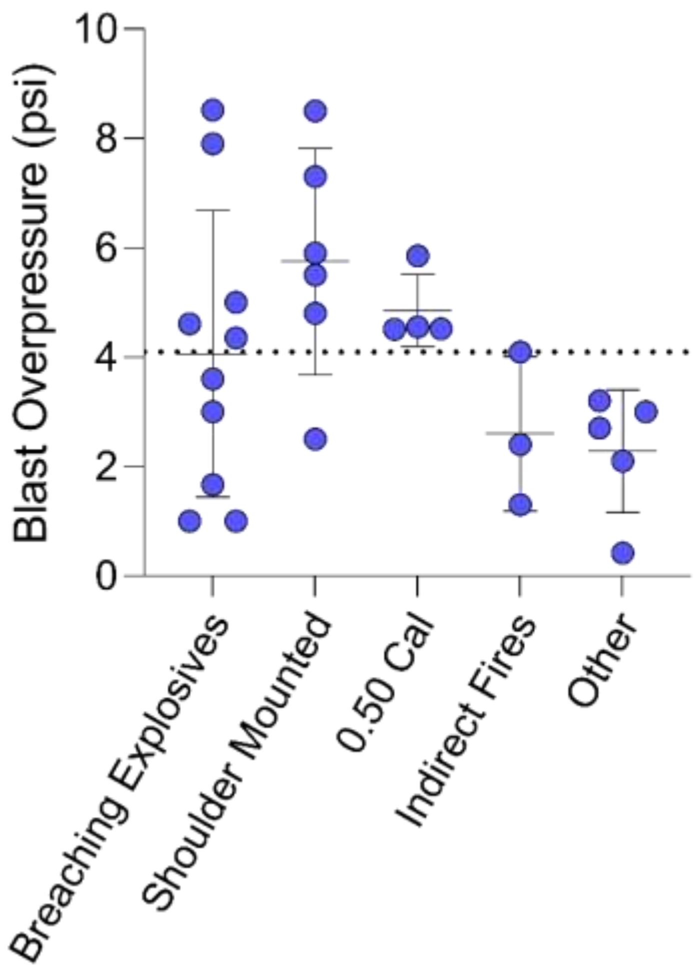
Table 2 Comprehensive Overview of Published Data Presenting BOP and H&P Outcome Domains

Publication	N=	Exposure Source	Exposure Magnitude*	H&P Outcome Domains Evaluated**
Baker et al., 2011‡	14	1-day Breaching	Maximal overpressure per blast: 3 psi	Neurocognitive Sensory
Blennow et al., 2011‡	Experiment 1: 21 Experiment 2: 32 Experiment 3: 7	Experiment 1: FH77B howitzer (3 shells) or a P-skott bazooka (6 shots) Experiment 2: Carl Gustav (10 shots) Experiment 3: detonating explosives, indoor and outdoor (100 total charges)	Experiment 1: maximum 184 dB, B-duration 38 ms (howitzer); maximum 182 dB, B-duration 13 ms (bazooka) Experiment 2: maximum 184 dB, B-duration 13 ms Experiment 3: 18-25 kPa (179–182 dB), B-durations of 20 ms for 50% of detonations and >200 ms for 50% of detonations	Fluid Biomarkers
Boutte et al., 2019	29	1-day Breaching: two overpressure events (back-to-back heavy wall breaches to defeat concrete walls)	Peak pressure: mean 4.35 psi/incident Cumulative peak pressure: mean 8.71 psi/session Impulse: mean 11.7 psi*ms/incident Cumulative impulse: mean 23.5 psi*ms/session	Neurocognitive Symptomology Fluid Biomarkers
Carr , Stone, et al., 2016	40	2-week Breaching	Peak incident pressures: 61% < 1 psi; 4% > 4 psi Highest peak incident pressure: 13.0 psi; minimum peak incident pressure: 0.1 psi	Neurocognitive Neuroimaging Sensory
Carr, Yarnell, et al., 2015	108	2-week Breaching	Single day peak pressures: 5.0-11.7 psi Nearly all peak pressures across all training sessions were < 2 psi.	Neurocognitive Symptomology Fluid Biomarkers Sensory
Eonta et al., 2019	1 (case study)	2-week Breaching, Moderate blast	Multiple pressure events greater than 4 psi; highest peak overpressure: 8.2 psi	Symptomology Neuroimaging Fluid Biomarkers
Gill, Cashion, et al., 2017	69	Breaching, Moderate blast (Day 7)	Peak pressure (Day 7): mean 7.9 psi	Symptomology Fluid Biomarkers
Gill, Motamedi, et al., 2017	62	Breaching, Moderate blast	Day 7 moderate blast peak overpressure: mean 8.52 psi Day 7 no/low blast peak overpressure: mean 0.52 psi Moderate blast average peak overpressure: 5.06–11.73 psi	Symptomology Fluid Biomarkers
LaValle et al., 2019	202	1-day Breaching: 2-4 blast events, concrete wall charges (NEW: 10 lbs) and fence charges (NEW: 15 lbs).	Peak overpressure: 2.57-9.17 psi, Average peak overpressure: of 4.61 psi *authorized to use 5 psi as the safety level for this course	Neurocognitive
LaValle et al., 2020 (abstract)	20	6-week Close Quarter Tactics training	Frequent daily acoustic exposures above 120 dB and 140 dB Number of blast gauge overpressure triggers was comparatively low	Neurocognitive
Rhea et al., 2017	59	21-day heavy weapons training (Carl Gustav, LAW, RPG): median 4 (Range 2-9) blasts	Maximum peak pressure: 5.5 (anterior head), 7.3 (posterior head), 5.9 (shoulder), 4.8 (chest), and 8.5 (back) psi Total impulse: 7.5 (anterior head), 19.4 (posterior head), 15.7 (shoulder), 7.8 (chest), and 15.6 (back) psi*ms	Sensory

Publication	N=	Exposure Source	Exposure Magnitude*	H&P Outcome Domains Evaluated**
Sajja et al., 2019	6	1-day grenade training: 130 detonations	Pencil probe pressure: 0.14-0.42 psi (range 1), 0.22–0.30 psi (range 2) Pressure exposures did not trigger the B3 blast sensors.	Symptomology
Skotak et al., 2019	20	3-day .50 caliber weapons training (20" and 29" barrels): 24-50 exposures per SM	Peak overpressures: 5.85 psi (20") and 4.55 psi (29") (average across all four sensors) Impulse greater for 20"	Neurocognitive
Thangavelu et al., 2020	15	3-day .50 caliber rifle training (20-29" barrels, generally unsuppressed)	Peak overpressures: D1, 3.86 ± 1.04 psi; D2, 3.82 ± 0.42 psi; D3, 4.52 ± 1.59 psi Cumulative impulse: D1, 42.2 ± 18.7 psi*ms; D2, 19.3 ±7.37 psi*ms; D3, 34.1 ± 13.4 psi*ms	Neurocognitive Symptomology Fluid Biomarkers
Tschiffely et al., 2019	50	2-week Breaching, Moderate	Day 7, moderate blast peak overpressure ≥ 5 psi No/low blast control group never experienced blast exposure ≥ 3 psi	Fluid Biomarkers
Wang et al., 2019	34	10-day Breaching (analyzed as average of Days 1-6 vs Days 7-10)	Day 7 average exposure: ~12 psi	Symptomology Fluid Biomarkers

Abbreviations: D = day; dB = decibel; kPa = kilopascals; LAW = light anti-armor weapon; NEW = net explosive weight; psi = pounds per square inch; psi*ms = pounds per square inch times millisecond; RPG = rocket propelled grenade; SM = service member
‡International publication; data do not involve U.S. DOD
*Note 1: BOP exposure parameters of interest varies across studies such that cross-study comparison is not possible.
**Note 2: H&P Outcome Domains Evaluated presents the category of measures that were assessed within the study; inclusion of the domain in the table does not necessarily reflect statistically significant findings within that domain. Operational definitions of the terms for H&P Outcome Domains Evaluated are listed below:
Neurocognitive: Refers to objective assessments of cognitive performance.
Symptomology: Refers to subjective self-reports on common symptom inventories (e.g., Neurobehavioral Symptom Inventory, Rivermead Postconcussive Questionnaire).
Fluid Biomarkers: Refers to objective quantification of molecular biomarkers in cerebrospinal fluid and/or peripheral blood.
Neuroimaging: Refers to structural, microstructural, and/or functional imaging modalities.
Sensory: Refers to objective assessments of sensory (e.g., vestibular, auditory) function.

Figure 1 Blast Sensor-derived BOP Values for Tier 1 Weapons Systems Categories Reported in Published Studies



Blue dots each represent individual mean peak overpressure values (psi) for entire training exercises reported in published literature. Data related to other blast metrics (i.e., impulse) were not consistently reported in the literature for all weapon systems displayed, and as such were not included here. Thangavelu et al., 2020 uniquely reported a mean peak overpressure per day of the exercise (3 days total); therefore, a single value from the three days was selected for the graph to maintain consistency in reporting. Mean (M) and standard deviation (SD) for each weapons system category shown.

“Other” category includes weapons systems such as rifles, shotguns, and grenades.

Broken line indicates the overall mean blast overpressure exposure value (psi) calculated across all weapon system categories (M = 4.01, SD = 2.23).

References: (Baker et al., 2011; Blennow et al., 2011; Boutte et al., 2019; Carr et al., 2016; Carr et al., 2015; Eonta et al., 2019; Gill, Cashion, et al., 2017; Gill, Motamedi, et al., 2017; Kamimori, Reilly, LaValle, & Olaghere Da Silva, 2017; Lang et al., 2018; C. R. LaValle et al., 2019; Rhea et al., 2017; Sajja et al., 2019; Skotak et al., 2019; Thangavelu et al., 2020; Tschiffely et al., 2019; Wang et al., 2019; Wiri, Ritter, Bailie, Needham, & Duckworth, 2017; Yuan et al., 2019).

Note: The graph is taken from the limited published literature displaying mean peak overpressure for the weapons systems of interest. As more comprehensive data (generated by ongoing efforts) begin to be published, this graph and the mean peak overpressures for each weapons system category may be subject to change.

The above Table 2 and Figure 1 present an overview of current published findings that can support development of a dose-response relationship. Similar to previous State-of-the-Science reports which cited inconsistent or null findings (Engel et al., 2018; Simmons et al., 2020), there is limited consistency and/or statistically significant findings for each H&P domain noted. However, some appreciable trends can be observed in the current literature. These key findings are discussed below.

Neurocognitive

For neurocognitive effects, current evidence suggests a possible effect on reaction time performance associated with mean peak overpressure exposures above 4 psi (range: 4.35-5.85 psi), with several studies reporting statistically significant effects on Defense Automated Neurobehavioral Assessment reaction time subtests (Boutte et al., 2019; C. R. LaValle et al., 2019; Skotak et al., 2019). This finding is not universally consistent, as other studies have reported no change with similar exposures (Thangavelu et al., 2020). Another study (5% peak incident pressures > 4 psi) reported no clear evidence of performance decrements on neurocognitive tests; however, in a small group of individuals (n=5), descriptive evidence suggests that following sustained exposure to repetitive blast (breaching instructors), acute (incident) exposure appears to elicit alterations in specific domains of cognition (Carr et al., 2016).

Symptomatology

Multiple studies report symptomology following repetitive BOP exposures > 4.35 psi with weapons training, most commonly headache (Boutte et al., 2019; Gill, Cashion, et al., 2017), concentration problems (Boutte et al., 2019; Gill, Cashion, et al., 2017), taking longer to think (Boutte et al., 2019), dizziness (Boutte et al., 2019), and slowed thinking (Boutte et al., 2019). Even a single day of exposure to > 10 psi (Day 7 mean exposure; Days 1-6, 8-10 mean: 1 psi) is sufficient to elicit a broad range of symptoms, to include the aforementioned symptoms as well as ringing in the ears, sleep disturbance, fatigue, irritability, and frustration (Wang et al., 2019). Similar but more transient symptoms may be elicited by exposures < 4 psi: on Day 1 of a 3-day 0.50 cal rifle training (mean: 3.86 psi), headaches and feeling frustrated or impatient were reported yet resolved on training Days 2 and 3 (Thangavelu et al., 2020). The frequency of cumulative exposure, particularly repetitive exposure to a high number of blasts in a short time frame, may influence symptom manifestation. One study reported that although grenade range instructors were only exposed to 0.1-0.45 psi per detonation, a 1-day training exposure of up to 130 grenade detonations was associated with restlessness, frustration, irritability, headache, light headedness, ringing of the ears, and impeded information processing (“long think”) (Sajja et al., 2019).

Biomarkers

Biomarkers are commonly evaluated to investigate biological correlates related to brain health outcomes. The most commonly studied candidate biomarkers in occupationally BOP exposed cohorts have been serum GFAP and serum UCH-L1 (4 publications and 3 publications, respectively) (Blennow et al., 2011; Boutte et al., 2019; Carr et al., 2015; Eonta et al., 2019; Thangavelu et al., 2020; Tschiffely et al., 2019). However, the majority of the studies that have examined these proteins have not found statistically significant alterations associated with BOP (Blennow et al., 2011; Boutte et al., 2019; Eonta et al., 2019; Thangavelu et al., 2020). The lack of significant findings could be due to a variety of factors, to include sensitivity of the biomarker to BOP exposure or the quantification method as well as variability across studies with respect to exposure, design, and sample timing relative to exposure. To our knowledge, the statistically significant alterations reported in several other biomarker candidates (e.g., Nf-L, Tau, Aβ40, Aβ42, APP, and several pro-inflammatory markers) have each only been observed in a single publication (Blennow et al., 2011; Boutte et al., 2019; Gill, Cashion, et al., 2017; Gill, Motamedi, et al., 2017; Thangavelu et al., 2020; Wang et al., 2019).

3.2 Synthesis of Key Findings

In reviewing the data related to H&P outcomes presented concurrently with blast sensor data, patterns have emerged suggesting that some changes in specific H&P domains occur at exposures generally above 4 psi. The most consistent results from studies assessing neurocognitive outcomes suggest that exposures above 4 psi are associated with significant changes in reaction time subtests (Boutte et al., 2019; LaValle et al., 2019; Skotak et al., 2019). Collectively, headache is reported as the symptom most commonly associated with heavy weapons use at exposures both above and below 4 psi (Boutte et al., 2019; Gill, Cashion, et al., 2017; Sajja et al., 2019; Thangavelu et al., 2020; Wang et al., 2019). However, headache presentation irrespective of 4 psi underlies that peak overpressure alone may not always be the most appropriate blast metric to consider, but rather the interaction of magnitude and number of exposures (e.g., low BOP, high number of exposures; high BOP, low number of exposures) may drive symptom manifestation. Above 4 psi, common symptoms also included: concentration problems (Boutte et al., 2019; Gill, Cashion, et al., 2017), taking longer to think (Boutte et al., 2019), dizziness (Boutte et al., 2019), and slowed thinking (Boutte et al., 2019). Evidence of biological correlates that can be used to reflect physiological alterations, as measured by candidate biomarkers leveraged from the TBI community, have not demonstrated significant and/or consistent associations with occupational low-level BOP exposure (Blennow et al., 2011; Boutte et al., 2019; Carr et al., 2015; Eonta et al., 2019; Gill, Cashion, et al., 2017; Gill, Motamedi, et al., 2017; Thangavelu et al., 2020; Tschiffely et al., 2019; Wang et al., 2019). These findings are unsurprising given the discrepancies across the state-of-the-science in candidate biomarker expression and detection for clinically diagnosed TBI; a more thorough understanding in this clinical population is most likely required to subsequently inform accurate candidates for subclinical exposure. Current patterns in H&P domain changes are focused on neurocognitive, symptom, and biomarker-related findings, but further research is required in these areas as well as areas of psychological, sensory, and neuroimaging to provide a more comprehensive understanding of the dose-relationship between BOP exposure and H&P outcomes.

4 Discussion

4.1 Interim Blast Exposure Safety Guidance Recommendation and Way Forward for Future Safety Guidance

Interim Blast Exposure Safety Guidance

Based on the patterns derived from currently published literature and evidence presented in Section 3, an interim blast exposure safety guidance of 4 psi is recommended to assist in preventing performance degradation and adverse brain health outcomes. This interim guidance is in concurrence with the safety threshold utilized by the auditory community to safeguard against eardrum rupture, and will inform the development of interim health protection criteria for brain health by the APHC.

Future Comprehensive Safety Guidance(s) or Performance-Risk Curves

Although this interim blast exposure safety guidance can be helpful as a first step in informing safety guidance to mitigate exposure risks, a single, discrete value (4 psi) may not be sufficiently comprehensive to capture the inherent complexities of exposure. More accurately, a threshold indicates the probability of injury in a binary manner (i.e., injured or not injured), but this approach fails to consider the number of variables and differences in exposure conditions, sensor measurements, blast metrics, and individual SM variation and exposure history (DoD Blast Injury Research Program Coordinating Office, 2014). As an interim solution, this threshold approach is an improvement over the current lack of a DOD-wide, brain health-specific guidance. As a long-term solution, a dichotomous threshold of 4 psi (or best evidence-based single value) may be subject to higher than desirable false negatives (i.e., failing to identify adversely affected performance in SMs) and false positives (i.e., over identifying SMs with adversely affected performance), with implications for training and/or medical intervention for exposed SMs. Conversely, a risk curve may prove to be a more comprehensive solution. Rather than a dichotomous evaluation, a risk curve indicates a decision threshold for action (e.g., medical evaluation, modification of training) based on risk tolerance (DoD Blast Injury Research Program Coordinating Office, 2014). Since repetitive low-level occupational BOP exposure does not commonly result in injury, but rather performance degradations, a non-interim comprehensive safety guidance would benefit from the establishment of a performance-risk curve. A performance-risk curve, similar to the preliminary BLAST Algorithm (a predictive algorithm for humans provides guidance to interpret sensor-measured exposure in terms of individual risk of injury and allow for operationally-relevant decisions) developed by the Office of Naval Research, may also account for a greater number and relative contribution of exposure variables (e.g., incident pressure [psi], number of exposures, number of days of exposures) (Bentley, 2020). The volume of data required to develop and train such an algorithm to account for the vast number of variables may be accomplished by the Section 734 Program as well as subsequent blast surveillance programs and cognitive surveillance programs as described by the Warfighter Brain Health initiative. As further data is collected to elucidate the dose-response relationship between repetitive occupational BOP exposure and adverse brain H&P outcomes, the development of a curve(s) that comprehensively characterizes a continuum (ranging from uninjured through appreciable performance degradation to injured) may be the most informative approach.

The combined efforts across the Section 734 Program works to collect and move blast sensor data into the medical record, and continues to identify H&P domains most sensitive to exposure effects and the relevant measures to assess those outcomes. These efforts will be necessary in combination to inform risk curve algorithms that predict performance degradation and potential injury, and to aid in the development of comprehensive health protection criteria that are specific to brain health.

4.2 Gaps, Limitations, and Recommendations

The recommended interim blast exposure safety guidance of 4 psi was derived from findings reported in the available literature. Across these studies, methodological variations (e.g., magnitude of blast exposure, use of personal protective equipment, use of sensors [standardized use and analysis], sample size, inclusion criteria, assessment method/measures, evaluation periodicity, follow-up time periods, statistical analysis strategies, etc.) pose a challenge from a meta-analysis perspective (Belanger et al., 2020; Jennifer N. Belding et al., 2021; Simmons et al., 2020). Beyond the methodological variations, gaps in the understanding of physiological alterations resulting from BOP exposure exist. Therefore, to establish more comprehensive safety guidance, these gaps must be addressed.

- To optimize preventative measures against adverse occupational BOP exposure, a thorough examination of correlations between quantified blast metrics from sensors and relevant H&P outcomes must be conducted (DoD Blast Injury Research Program Coordinating Office, 2014; Engel et al., 2018; Simmons et al., 2020). This will allow for the identification of the H&P domains most sensitive to exposure effects, the time course of these domain alterations, and the standardization and implementation of relevant measures to assess these outcomes. Section 734 LOI5 is working to identify relevant effects on H&P, with the expectation that one or more salient outcomes may be identified.

4.3 Per Key Findings

- Table 2, the majority of the identified studies have focused on explosive breaching, potentially limiting the generalizability of H&P findings to other weapon systems. Figure 1 provides some evidence of variable exposures across categories of weapons, with higher BOP recorded with shoulder-mounted and 0.50 caliber weapons systems, demonstrating the need to investigate BOP exposures and associated risk beyond breaching. Section 734 LOI5 performers from Walter Reed Army Institute of Research and Naval Medical Research Center have both initiated research to capture a broader range of weapons systems.
- Currently, it is unclear if a specific, single variable of blast waves (e.g., peak overpressure, peak impulse) will be most highly correlated with H&P outcomes, or whether an index score or other alternative metric that encompasses multiple variables of the blast wave provides a more comprehensive indication of harmful BOP exposures (Engel et al., 2018). Notably, recent findings suggest that auditory pressure and BOP might contribute independently or synergistically to dysfunction, but the particular impact of each or their combinatorial effects should be included in the discussions of relevant blast metrics (Carr, LaValle, et al., 2020; C. LaValle, Lohmann, Salib, Carr, & Kamimori, 2020). Key findings to support such an initiative may be derived from the work of Section 734, which focus on weapons systems, exposure environments (i.e., SM occupational health hazards assessments), and blast characterization (e.g., modeling efforts), respectively.

The Section 734 Program, as well as other research programs in multiple Services are actively engaged in activities to address these gaps and integrate findings across LOIs to inform meaningful BOP exposure mitigation strategies to enhance Warfighter brain health and operational readiness. Notably focused research will augment the current body of literature examining blast sensor data and the H&P effects to support the discovery of more comprehensive dose-response relationships and subsequent safety recommendations for occupational BOP.

5 Conclusions

While research continues to explore solutions to inform a dose-response relationship between repetitive occupational BOP exposure and brain H&P effects, at this time, the available data can provide an interim blast exposure safety guidance of 4 psi. Targeted studies related to acute and sub-acute training-related effects of BOP exposure that evaluate sensor data and H&P outcomes will be critical for establishing a dose-response relationship, as cumulative effects do not lend themselves to this kind of analysis. Such studies, combined with establishment and access to data of a blast surveillance program will feed a more comprehensive performance-risk curve to preserve the brain health of SMs, prevent performance degradation, and promote operational readiness.

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Appendix A: Tier 1 Weapons List

Category of Weapons System	OSD(HA) Tier 1 Weapons
Breaching explosives	Door: NEW of .23lbs TNT (slider) - .30lbs TNT (fruit roll up)
	Wall: NEW of 10.0lbs – 14.0lbs
Shoulder Mounted	M3, MAAWS
	M136, AT4
	M72, LAW
0.50 Cal	M107 sniper rifle
	M2A1 machine gun
	MK 15
	GAU 21
Indirect Fires	Howitzers (all platforms)
	Mortars (all platforms), 120mm, 81mm, 60mm

Appendix B: Initial Report to Armed Services Committees, 2019

See next page

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REPORT TO ARMED SERVICES COMMITTEE

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.-

(l) 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.

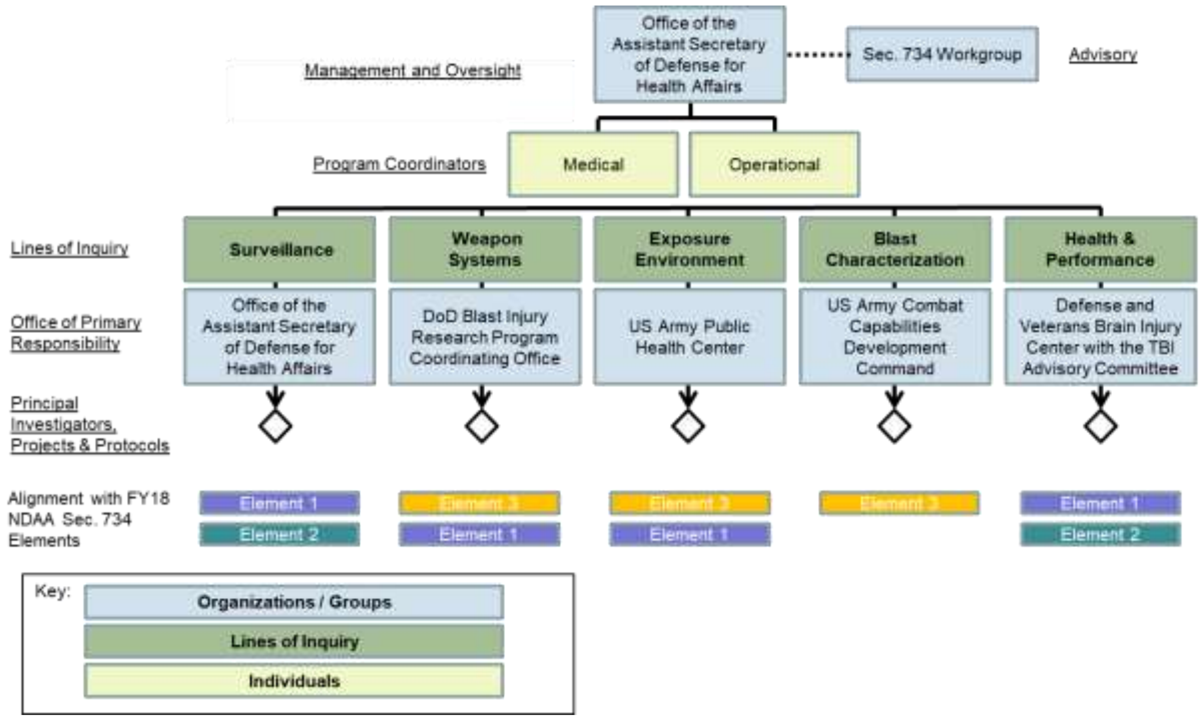

Figure 1. Program Structure Developed to Support Section 734

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.

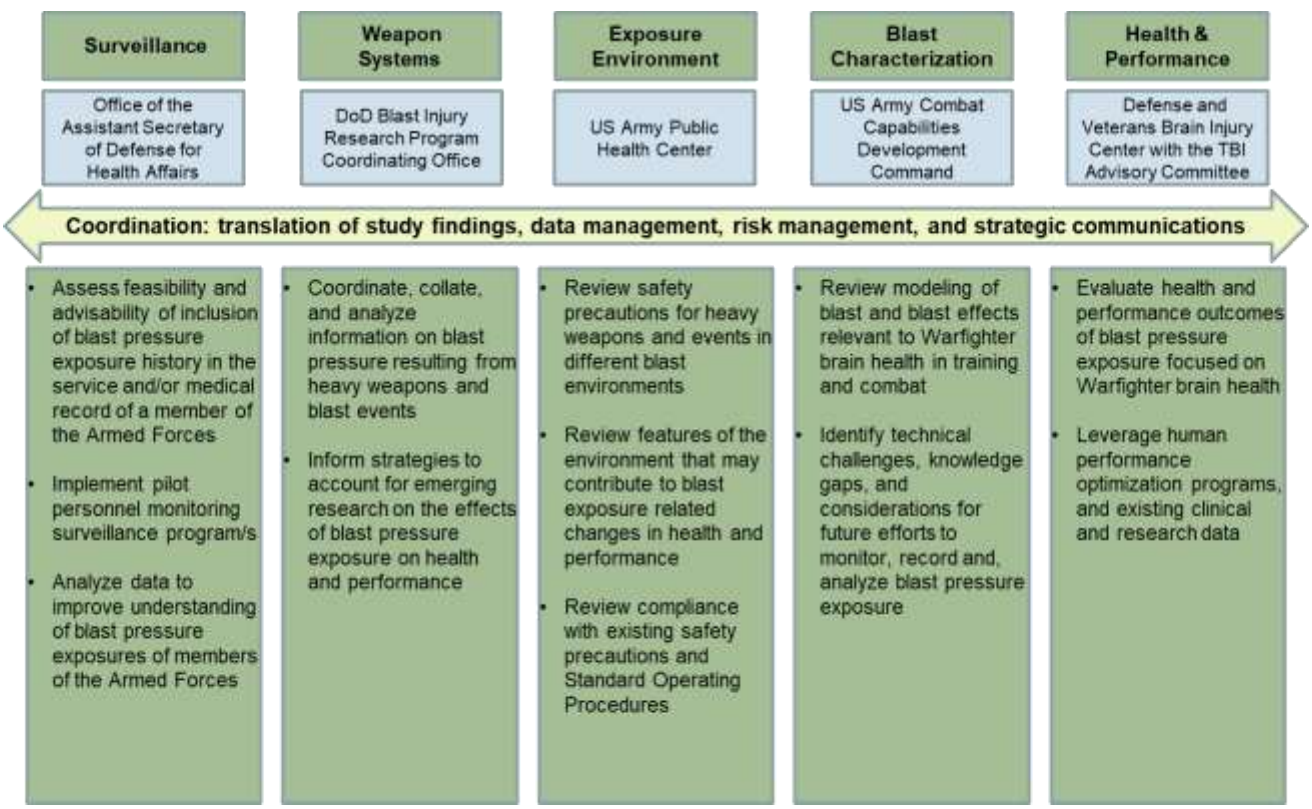

Figure 2. Lines of Inquiry

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 May 31, 2019.
- Existing complimentary efforts identified by May 31, 2019 to leverage for immediate incorporation.
- Gaps identified and requirements developed for new study protocols by September 30, 2019.
- Costing, acquisition and procurement strategies developed for Lines of Inquiry by September 30, 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.