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A CASE STUDY ON THE ARMY FIELDING OF HELMET SENSORS AND BLAST GAUGES

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A CASE STUDY ON THE ARMY FIELDING OF HELMET SENSORS AND BLAST GAUGES

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Submitted in partial fulfillment of the
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ABSTRACT

This case study focuses on the U.S. Army's decision to field generation II helmet sensors and Blast Gauges. The intent is to give students within the Department of Defense the ability to evaluate an acquisition program and the decisions made throughout it, and to determine how those decisions are impacted by the views and expectations of stakeholders. Specifically, this case presents a real-life scenario of decision-making that is shaped more so by external stakeholders than by the quality and performance of the product and data themselves.

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LIST OF ACRONYMS AND ABBREVIATIONS

ACH	advanced combat helmet
APM	assistant product manager
BEAST	blast exposure accelerated sensor transition
BG	Blast Gauge
COA	courses of action
COTS	commercial off the shelf
CSA	Chief of Staff of the Army
CTE	chronic traumatic encephalopathy
DARPA	Defense Advanced Research Projects Agency
DHA	Defense Health Agency
DoD	Department of Defense
DoDI	Department of Defense Instruction
DOTmLPF-P	doctrine, organization, training, materiel, leadership and education, personnel, facilities, and policy
DR	directed requirement
DTRA	Defense Threat Reduction Agency
ECH	enhanced combat helmet
eHR	electronic health record
ESiT	environmental sensors in training
FSR	field service representative
FY	fiscal year
Gen I	generation I
Gen II	generation II
GSS	ground soldier systems
HMSS	helmet mounted sensor system
HS	helmet sensor
I-BESS	integrated Soldier sensor system
MRI	magnetic resonance imaging
MRMC	Medical Research and Materiel Command
mTBI	mild traumatic brain injury

NFL	National Football League
NHRC	Naval Health Research Center
NW	Nett Warrior
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
PdM	product manager
PEO Soldier	Program Executive Office Soldier
PM	project manager
PM ICE	Program Manager Infantry Combat Equipment
PM SPE	Product Manager Soldier Protective Equipment
PM SPIE	Project Manager Soldier Protection and Individual Equipment
PTSD	post-traumatic stress disorder
REF	Rapid Equipping Force
RIT	Rochester Institute of Technology
SWATS	soldier wearable acoustic targeting system
T2	National Center for Telehealth & Technology
TBI	traumatic brain injury
TRADOC	Training and Doctrine Command
TTP	tactics, techniques and procedures
USAARL	U.S. Army Aeromedical Research Laboratory
USAMRMC	U.S. Army Medical Research and Materiel Command
USMC	United States Marine Corps
VCSA	Vice Chief of Staff of the Army

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I would like to thank Dr. Robert Mortlock for providing guidance and support throughout this case study. Without his encouragement and feedback throughout every step of the process, this joint applied project would not have been possible. In addition, I would like to express my appreciation to Mr. Brad Naegle, who also provided encouragement and feedback throughout this project. Finally, I would like to thank my family and friends for their support during my time at the Naval Postgraduate School.

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I. INTRODUCTION

This project is presented in the form of a case study, so that it can be used by professors teaching a program management or acquisition–type curriculum. It presents information that can be used as teaching points for cohorts to come. Case studies are effective tools for teaching students critical thinking, and allowing them to build their own knowledge in a contextual, social, and interactive setting. Case studies can also be beneficial in the students' understanding that there could be multiple acceptable paths to follow and decisions to make for various situations (University of Southern California [USC], n.d.). This case study presents a real-world issue that program managers throughout the acquisition community will face, and allows students to think through the problem and come up with a solution.

A. WHY ARE THE HELMET SENSORS AND BLAST GAUGES IMPORTANT?

Helmet sensors (HSs) and Blast Gauges (BGs) are very important because they were originally intended to address a very large problem within our military—traumatic brain injury (TBI). In 2009, there was an incredible amount of interest from the general public, as well as the senior leaders within the Army, to actively pursue the identification and mitigation of TBI. The Army had already fielded 7,000 Gen I HSs known as the helmet mounted sensor system (HMSS), but wanted to develop and field an enhanced version—Gen II. The Gen II HS program was being developed and managed by Program Executive Office (PEO) Soldier. The new Gen II HSs were smaller, weighed less, and had a longer rechargeable battery life. The Gen II HS would be mounted inside on the crown of the advanced combat helmet (ACH) or enhanced combat helmet (ECH), and would measure and record acceleration and pressure.

In addition to the Gen II HS, a BG was being developed by Defense Advanced Research Projects Agency (DARPA) that would measure and record pressure and low acceleration from three different locations on a soldier.

The HSs and the BGs were originally only intended to be used as exposure monitors to record any exposures to acceleration or pressure. There was no known or established link between accelerations and blast overpressure to injuries such as traumatic brain injury (TBI). However, the external view quickly morphed into the HS and BG being fielded and used as a diagnostic tool that would be able to tell medical providers in the field whether a soldier had seen enough pressure and/or acceleration to cause a TBI. This was partly due to the marketing from manufacturers that implied their devices were capable of being used for triage and diagnosis. The new external view of the capabilities of the HS and BG made it very difficult to manage the expectations of stakeholders, forcing the project manager (PM) to make a difficult decision of whether or not to develop, procure and field the products.

B. PROJECT ORGANIZATION

This joint applied project is organized into the literature review and background information, followed by the actual case study. Within the literature review, a timeline of the history of HS and BG is presented. Articles are also summarized on the topic of case studies and sensor programs. The case study presents a situation that the PM faced regarding whether to field the sensors or not. It is based on available information from the PM at the time of the decision to field HSs and BGs. A history of both programs is presented as well as information on the numerous stakeholders involved. Available information on the actual fielding of the products is presented, followed by a discussion on the data that was received back from the sensors that were fielded. Finally, the case study concludes with a section on balancing program decisions with managing expectations of stakeholders. Discussion questions that can be used for teaching are included as well.

II. LITERATURE REVIEW/BACKGROUND

A. THE IMPORTANCE OF CASE STUDIES

There has been significant research done on the most effective styles of teaching, and it seems that case studies have eclipsed lecturing for the lead. By using case studies, educators can get students actively engaged instead of just talking to the students. By getting the student involved, they have a chance to “enhance their decision making skills through real world problem solving” (Brady, 2017, p. 1). As Clyde Herreid put it in his book (2006, p. xiv), “Case studies are stories with an educational message.” Looking at it in this way frees up educators to shape lessons with different formats for different purposes. “What’s the magic of stories? People love stories. Stories put learning into context. Lectures often don’t do this. They are abstract with mountains of facts” (Herreid, 2006, p. xiv).

This project is presented in the form of a case study, so that it could be used by professors teaching a Program Management or acquisition type curriculum. It presents information that can be used as teaching points for cohorts to come. Case studies are effective tools for teaching students critical thinking, and allowing them to build their own knowledge in a contextual, social, and interactive setting. Case studies can also be beneficial in the students’ understanding that there could be multiple, acceptable paths to follow and decisions to make for various situations (USC, n.d.). This case study presents a real-world issue that program managers throughout the acquisition community will face, and allows students to think through the problem and come up with a solution.

B. HOW TO WRITE A CASE STUDY

There are numerous approaches on how to write a case study, but they all have the same overall structure. Case studies generally consist of an introduction, background information, presentation of findings, and a conclusion (Universal Class, n.d.). The introduction should set the stage for the case study and articulate the intention of the study (Universal Class, n.d.). The background section should give the reader the necessary information on the issue and explain the topic (Universal Class, n.d.). Presentation of findings should clearly explain the topic and summarize results from any research conducted (Universal Class, n.d.). The conclusion will offer possible solutions to the situation. (Universal Class, n.d.)

This specific case study follows the above guidelines, but is organized as presented in the following section.

C. HISTORY OF HELMET/BODY SENSORS

From the research completed, it seems that the first time a sensor was fielded to be worn on a Soldier was the generation I (Gen I) helmet sensor (HS), also known as the helmet mounted sensor system (HMSS). Throughout the years, sensors were talked about for integration into numerous platforms to include vehicles, clothing, physiological monitoring, etc. This section will touch briefly on some sensors with a very similar purpose to the HS, and some sensors that are not similar at all. The sensors that are not similar are worth mentioning to show that there has been an interest for years in sensor integration with our Warfighters.

Prior to the HS, there was the Land Warrior, which transformed eventually into Nett Warrior (Figure 1). Nett Warrior is a hand-held or individual equipment mounted device providing Soldiers with battlefield situational awareness.

> Product Manager Ground Soldier Systems (PdM GSS) provides unprecedented situational awareness (SA) and battle command to dismounted Soldiers through the Nett Warrior (NW) system. It allows for faster and more accurate decisions in the tactical fight. With advanced navigation, SA and information-sharing capabilities, fratricide is reduced and lethality and accomplishment of the combat mission is increased. The NW program focuses on the fielding and continual improvements to this SA system, which can graphically display the locations and other information. NW connects through a secure radio to send and receive information from one NW to another and connecting dismounted Soldiers to the network. Connected to higher echelon data and information products assists in decision making, situational understanding, and allows engagement in the method that best suits the user and the particular mission. NW optimizes and integrates future Soldier capabilities while reducing the Soldier’s combat load and logistical footprint by carrying a single device with multiple applications. (Program Executive Office Soldier [PEO Soldier], 2012)

This device was not intended to measure exposures, but to increase soldier and commander awareness.

Figure 1. Nett Warrior system. Source: PEO Soldier (2012).

In 2008, there was the Soldier Wearable Acoustic Targeting System (SWATS) produced by QinetiQ, and also known as EARS (Figure 2).

> The EARS SWATS system is a compact, shoulder-worn acoustic targeting system that instantly detects and locates the origin of hostile gunfire. This system provides situational awareness, protection and enhances survival to those who need to quickly locate and respond to enemy threats.
>
> SWATS empowers soldiers and military police to switch from a defensive to an offensive posture when encountering enemy fire. (QinetiQ North America, n.d.a)

Figure 2. SWATS. Source: QinetiQ North America (n.d.b).

The Gen I HMSS was the first of its kind that was fielded, intended to measure what a soldier is exposed to. Following Gen I, there was generation II (Gen II) HS, the Blast Gauges (BGs), integrated blast effects sensor suite (I-BESS), and integrated soldier sensor system (ISSS) all with very similar purposes. Both the ISSS and I-BESS were sensor suites that integrated blast, acceleration, and physiological monitoring into one system.

I-BESS was a system developed by the Georgia Tech Research Institute (GTRI), and was fielded by the Rapid Equipping Force (REF). I-BESS included a soldier body unit (Figure 3) and blast sensors installed into Army vehicles (Hoffman, 2012).

Figure 3. Components of I-BESS. Source: Becker (2013).

ISSS would fall under the new Soldier Protection System (SPS) program and would integrate the Gen II HS, the BG, and a physiological status monitor. In addition, it would have the capability for automated wireless downloads. BAE and GTRI were working together on the project. ISSS can be seen in Figure 4.

Originally presented in a briefing titled "Environmental Sensors," November 2013. Slide created by Project Manager (PM) Soldier Protective and Individual Equipment (SPIE).

Figure 4. ISSS. Source: R. Mortlock, email to author (August 1, 2017).

In 2012, an article from Live Science talked about "intelligent clothing" that would be able to help save lives:

> The smart uniforms would include medical sensors built into the fabric to monitor the health of U.S. troops, according to a notice issued by the Pentagon's Defense Threat Reduction Agency (DTRA) on May 7. Such clothes would not only detect where wounds occurred and how deep they go, but also report a fallen soldier's location with GPS coordinates and pass along other critical information for battlefield medics.
>
> Smart clothing fibers might even "estimate the depth of penetration" from bullets or shrapnel and how they affect surrounding organs, according to the DTRA solicitation. Sensors could also detect specific "biomarkers" in

> human blood, saliva, sweat or urine that reveal the presence of chemical or biological weapons, radiation from nuclear weapons or even traces of explosives left by a roadside bomb." (Live Science, 2012, para. 2–3)

In 2014, Lt. Gen. Joseph Caravalho Jr., the commander of U.S. Army Medical Research and Materiel Command (MRMC), led a panel called "The Future of Human Performance" at the Association of the United States Army's Medical Hot Topic Forum (Sheftick, 2014).

> The Soldiers of 2025 might have sensors that help them detect and prevent threats such as dehydration, elevated blood pressure and cognitive delays from lack of sleep, he said. Sensors might also detect external threats such as chemical exposure or extreme environment.
>
> The Army is currently working on a number of technologies aimed at optimizing human performance, Caravalho said, with an eye toward providing both physical and cognitive overmatch of any potential enemy.
>
> Soldiers of the future need to perform like elite athletes, Caravalho said. (Sheftick 2014)

At the same panel, other topics of interest included the importance of the Soldier's "mind-body system" by monitoring biomolecular data and psychological stressors. Preventing musculoskeletal injuries by monitoring stress and risk factors such as "heart rate, blood pressure and other biophysical functions" was also a topic of discussion (Sheftick, 2014, para. 14).

When the thought of monitoring physiological factors is brought up, the general population immediately thinks of all of the currently available commercial off the shelf (COTS) solutions. The technology is out there, and people make the assumption that it should be an easy implementation into a military application.

In addition to the COTS solutions, The Defense Department's National Center for Telehealth and Technology (T2) was offering a mobile app called BioZen (McCaney, 2014). The app was capable of providing "biofeedback on heart rate, respiratory rate, skin temperature and other factors, though it requires the user to buy compatible medical sensors separately" (McCaney, 2014, para. 6). Note that T2 is now known as Defense Health Agency (DHA) Connected Health. A screenshot of BioZen is shown in Figure 5.

BioZen was developed as a pilot project to study the feasibility of using smartphones to receive signals from biosensor devices and display the information in a usable graphic. The National Center for Telehealth & Technology (T2) is a Department of Defense organization that evaluates new technologies for telemental health. BioZen represents an approach to mobile monitoring of biosensor devices that may be further developed to support future projects. No further development or enhancements to BioZen are planned. (Defense Health Agency [DHA] Connected Health, n.d.)

Figure 5. Screenshot of BioZen. Source: DHA Connected Health (n.d.).

HSs and BGs were also being looked at by groups other than PEO Soldier who had the Directed Requirement to field the products. In addition to the fielding through PEO Soldier, BGs were being used in various other programs including the Environmental Sensors in Training program (ESiT) program initiated by U.S. Army Training and Doctrine Command (TRADOC), and the blast exposure accelerated sensor transition (BEAST) program, sponsored by DARPA (Department of Defense [DoD] Blast Injury Research Program Coordinating Office [PCO], n.d.d; n.d.e).

The intent of ESiT is to collect data on the exposures that may result in a documented TBI and then take that information and use it to establish dose-response correlations (DoD Blast Injury Research PCO, n.d.d). The purpose is to inform technical requirements for environmental sensors and the methodology for employment of those sensors in select training environments (DoD Blast Injury Research PCO, n.d.e). Using ESiT and leveraging other similar programs provides the opportunity for surveillance measurements of blast exposures in military training, and provides input to current and ongoing research on the association between exposures and neurophysiological effects. ESiT allows the DoD to evaluate and address the risk from chronic exposure to blast, which recent evidence suggests could have negative neurophysiological outcomes (DoD Blast Injury Research PCO, n.d.e).

BEAST was to build on the BG program to enable a better understanding of blast-related injuries. BEAST supports medical studies using BG devices and the program completed development of a web-based tool that stored, organized, analyzed and visualized BG recordings.

As you can see, there were many programs using sensors, and a lot of money being invested in programs that would use the data collected from the various sensors.

D. SUMMARY OF ARTICLES

This section will summarize numerous articles that have been written on the topic of HSs and BGs, going all the way back to 2007 through present day.

In June of 2007, the Vice Chief of Staff of the Army (VCSA) ordered the HS program. Three months later, the Program Executive Office Soldier (PEO Soldier) had developed several potential solutions. Within six months, PEO narrowed the field down to one mounted externally and one mounted internally. These would be known as the generation I (Gen I) HSs, or HMSS. The data collected from these sensors would be used for both short term and long term. “In the short term, data collected through the sensors is expected to help the Army improve the helmets and other protective equipment it provides its soldiers” (Miles, 2008, para. 5). In the long term, although it was emphasized that the medical community was not yet ready for this particular application, it was believed that the impact data could potentially be used to help diagnose TBI (Miles, 2008, para. 6-8).

Gen I HSs were fielded to about 7,000 soldiers in Iraq and Afghanistan (DoD Blast Injury Research PCO, n.d.a) and data was collected from March 2008–2009 (Dawson, 2009). Gen I came in two different variants; an externally mounted sensor, and an internally mounted sensor, both are shown in Figure 6. The reason for the two variants was to “address questions regarding the effect of the sensor’s location on its accuracy and on its ease of access for data downloads” (Dawson, 2009, para. 3). Following the data collection effort of Gen I, PEO Soldier was preparing to send an updated Gen II version into theater (Dawson, 2009).

The external mounted version of the HS was a version from Med-Eng Systems, and the internal mounted system was from BAE Systems and its collaboration with Diversified Technical Services, Inc (Gourley, 2013). Both systems were to measure and collect data on “helmet acceleration and pressure from impacts and explosion” (DoD Blast Injury Research PCO, n.d.a, p. 7-4).

Data collected from the fielding of Gen I was analyzed during a three-phased data analysis project led in conjunction by Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC), Product Manager Soldier Protective Equipment (PM SPE) and Program Manager Infantry Combat Equipment (PM ICE) (DoD Blast Injury Research PCO, n.d.a). “The objectives were to (1) assess the reliability and accuracy of HMSS, (2) establish a method for translating HMSS data into meaningful impact or blast ‘doses’ to the head, and (3) correlate the calculated head doses with actual injuries” (DoD Blast Injury Research PCO, n.d.a, p. 7-4). Also included in the JTAPIC analysis team were U.S. Army Aeromedical Research Laboratory (USAARL), L-3 Communications/Jaycor (under contract to U.S. Army Medical Research and Materiel Command (USAMRMC)), and the Naval Health Research Center (NHRC).

Figure 6. Gen I Helmet Mounted Sensor System (HMSS), externally mounted (left), internally mounted (right). Source: PEO Soldier (2009a; 2009b).

The Gen II sensors were being designed to have numerous enhancements including being smaller in size, weighing less, and having a longer rechargeable battery life. In addition to the physical enhancements, there were plans to enhance the data-collection storage, and power management capabilities including adding a wireless capability (Dawson, 2009). Gen II HS is shown in Figure 7. PEO Soldier was planning to "procure enough Gen II helmet sensors, beginning in fiscal year 2010, to equip the equivalent of six brigade combat teams – three to support Operation Iraqi Freedom and three to support Operation Enduring Freedom in Afghanistan" (Dawson, 2009, para. 14). The Gen II sensors also included a way to measure rotational acceleration (DoD Blast Injury Research PCO, n.d.c) instead of just linear, which is what Generation I measured.

The Gen II fielding and data collection plans were improved by lessons learned from the Gen I fielding. The goal of the Gen II effort was to "develop a body of knowledge of kinetic events to support the DoD medical community's research on mild traumatic brain injury (mTBI)" (DoD Blast Injury Research PCO, n.d.c, p. 4-7).

> Approximately 45,000 Gen II HMSS will be fielded to six brigade-sized units deploying to Afghanistan. The PM SPE fielding team will install sensors into new Advanced Combat Helmets and field them to warfighters prior to mission rehearsal exercise. Field service representatives, controlled by PM SPE, will be embedded with each battalion to assist with downloads and provide hands-on technical assistance. The JTAPIC program team will analyze Gen II HMSS data to determine if the Gen II HMSS acceleration

> data can be used to confidently predict head injuries. The JTAPIC program will apply existing data analysis tools and techniques, such as a mathematical helmet-to-head acceleration transfer function developed in Gen I. (DoD Blast Injury Research PCO, n.d.b, p. 4-6)

Originally presented in a briefing titled “Helmet Sensor and Blast Gauge Overview,” September 2014. Slide created by PM SPIE.

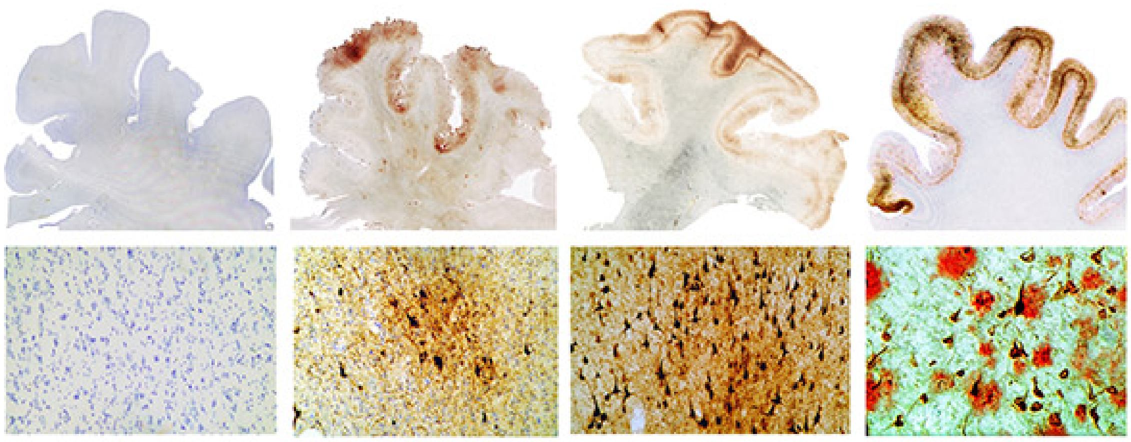
Figure 7. Generation II helmet sensor. Source: R. Mortlock, email to author (August 1, 2017).

It was made very clear that the Army was looking at this effort as a way to collect data that “when properly interpreted” would provide an understanding of the “nature and frequency of head trauma loads facing our deployed warfighters” (Dawson, 2009, para. 18). The actual relationship between physical impact of the head and actual brain injury had not been yet established and it was stated that it “is the subject of considerable active research” (Dawson, 2009, para. 20). “Ultimately, the data gathered on impacts to the helmet may give TBI researchers a clearer picture of what levels and kinds of head trauma should be studied, to gain information with the greatest relevance to the service members on the battlefield” (Dawson, 2009, para. 24).

At this point in 2009, it was never stated that the sensors would be able to measure concussion in theater, or be a diagnostic tool, simply an exposure monitor to collect the data that one day could be used to correlate exposures to actual injuries.

Also in 2009, chronic traumatic encephalopathy (CTE) was gaining attention with the general public and the National Football League (NFL). CTE progression is shown in Figure 8. The definition of CTE from the Concussion Legacy Foundation is:

> CTE is a degenerative brain disease found in athletes, military veterans, and others with a history of repetitive brain trauma. In CTE, a protein called Tau forms clumps that slowly spread throughout the brain, killing brain cells. CTE has been seen in people as young as 17, but symptoms do not generally begin appearing until years after the onset of head impacts. (Concussion Legacy Foundation, n.d., para.1)



"From left, a normal cerebral cortex and a magnification of it; cortexes of two now-deceased N.F.L. players with neurofibrillary tangles; and the cortex from an Alzheimer's patient with both the tangles and beta amyloid plaques."

Figure 8. Progression of CTE. Source: Schwarz (2009).

The debate over whether or not repetitive concussions had a long-term impact continued for years. Many former NFL players were suffering from adverse psychological issues, many of which led to suicide. The NFL had the stance that there was no link between playing in the NFL, and issues encountered a decade later. According to an article by Coates (2013), neuropathologist Bennet Omalu was doing analysis on the brains of these former players and finding CTE, and it was requested by the NFL's MTBI committee that his report to be retracted in 2006. In 2007, a safety pamphlet was given to players stating that "Current research with professional athletes has not shown that having more than one or two concussions leads to permanent problems if each injury is managed properly"

(Coates, 2013, para. 36). In 2009, the NFL began putting up posters in locker rooms that stated, in part, “Concussions and conditions resulting from repeated brain injury can change your life and your family’s life forever” (Coates, 2013, para. 38). Also in 2009, Roger Goodell testified in front of a House Judiciary Committee and made the following statement, “My approach to this concussion issue in football has been simple and direct - medical considerations must always take priority over competitive considerations” (Coates, 2013, para. 40).

In a *New York Times* article titled “A Chance for Clues to Brain Injury in Combat Blast,” it was clear to see that the actual correlation between blast exposures, and even blunt impact, still had not been established. It seemed to be well accepted and intuitive that there was a connection between the exposures and injury, but an official correlation was still lacking.

Research was being done by the Sports Legacy Institute and Boston University Center for the Study of Traumatic Encephalopathy on brain tissue that had been donated from deceased football players. Retired service members were starting to agree to donate their brains upon death as well to add to the research. The research program was planning to compare the findings from the brains of military personnel with the brains from their established athlete program.

> Whether single, non-impact blasts in battle can cause the same damage as the years of repetitive head bashing seen in football is of particular interest to researchers. The damage, primarily toxic protein deposits and tangled brain fibers, cannot be detected through noninvasive procedures like M.R.I.’s and CT scans.
>
> “We don’t know much about the medium- or long-term effects of head trauma experienced by our military,” said Robert Stern, co-director of the Boston University center as well as its Alzheimer’s Disease Clinical and Research Program. “We know that there are some immediate effects in terms of blast injury on cognition and behavior. But we do not yet know whether there are any long-term effects.”
>
> “Does that single blow result in something that doesn’t go away,” he added, “or perhaps sets off a cascade of events that leads to a progressive degenerative brain disease?” (Schwarz, 2009, para. 5-8)

From this brief history of the NFL and brain injury, you can see the years of turbulence that concussions and CTE caused within the NFL. It took years of debate, research, and public interest before the NFL acknowledged that concussions could cause a serious health risk and could be contributing to TBIs. Even once it was acknowledged, there was still a lot of debate to the actual injury mechanism. If suffering a second, third, fourth concussion would exponentially increase risk? How much time between concussions could mitigate that risk? There were a lot of questions to be answered, and plenty of debate over who had those answers. You can see the parallels between what the NFL and the military were going through. A very similar debate continued concurrently on the military side. What exactly causes TBI in the military? Is it blast exposure, blunt impact, the secondary effect of a blast, a combination of all of the above?

In 2010, the Defense Advanced Research Projects Agency (DARPA) was working with the Rochester Institute of Technology (RIT) to develop a BG (Figure 9). The BG was "a small device worn by warfighters to measure blast exposure and cue medics for initial response" (Defense Advanced Research Projects Agency [DARPA], n.d., para. 1). In 2011, BlackBox Biometrics Inc. was founded by the RIT researchers and the BG became commercialized. BlackBox Biometrics was founded "with the goal of providing objective data to aid the triage and medical treatment associated with today's signature war wound: traumatic brain injury (TBI)" (The Blast Gauge System, n.d., para.1).

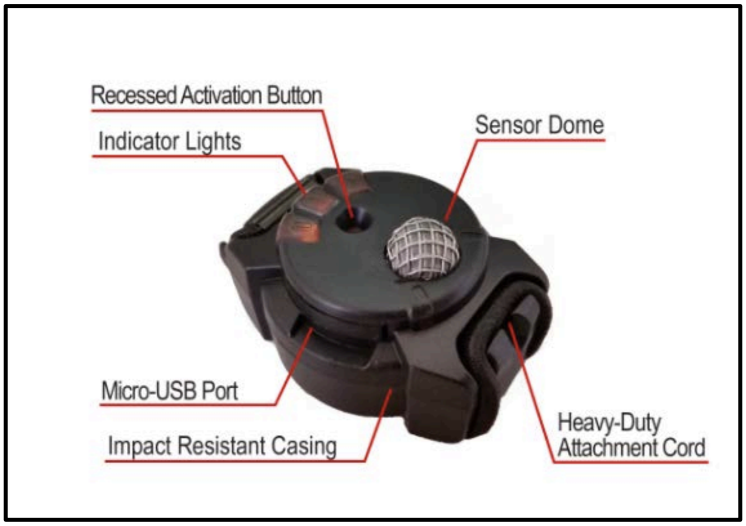


Figure 9. Blast Gauge. Source: The Blast Gauge System (n.d).

Starting around 2011, more and more of the articles and publications began mentioning sensors hand in hand with diagnosing injuries, and the devices measuring “concussive” events and blasts. This is where the misconception that the medical linkage to injury was established began causing a mismanagement of expectations. Every now and then, clarification stating that the sensors were not diagnostic tools could still be found, but the general public started to get the impression that these sensors and gauges would diagnose concussion instantaneously.

In July of 2012, the NFL and Army began collaborating on sensors. The NFL wanted to use the same concept of the Gen II helmet sensor, just altered slightly to measure the severity of the direct blunt impacts to a football players head (Madden, 2012, para. 2). In August of 2012, the NFL and the Army signed a letter (Figures 10 and 11) formalizing their partnership on the initiative of raising awareness about TBI (Nelson, 2012).

“Army Chief of Staff Gen. Ray Odierno and NFL Commissioner Roger Goodell met to sign a letter formalizing the brain injury initiative between the Army and the NFL, photo by Tommy Gilligan / U.S. Military Academy PAO.”

Figure 10. Formalizing the partnership between the Army and NFL.
Source: Basu (2012).

August 30, 2012

Dear Soldiers and NFL Players,

The U.S. Army and the National Football League have begun a long-term initiative to enhance the safety of our Soldiers and Players. Our coordinated efforts aim to inform and educate our respective communities about traumatic brain injuries, empowering you to maintain healthier minds on the playing field and the battlefield.

Our organizations share common traits: pride and passion, dedication and determination, and an enduring belief in the power of team. On a personal level, there is mutual respect, appreciation and admiration between Soldiers and Players. While the execution of our crafts is fundamentally different, these traits make America's Soldiers and NFL Players who they are and the best at what they do.

With this initiative, we are seeking to integrate the uncompromising devotion to win with a need to address traumatic brain injuries with the necessary care, consideration, and commitment to prevention that these injuries require.

With this combined effort, Soldiers and Players are encouraged to discuss issues relating to brain injuries – sharing information, lessons learned and useful tips on how to best recognize, prevent and treat a brain injury. Our objective is to inform the core element of our organizations – our people – with a collective realization that caring for head injuries is a vital part of the mission and game plan. We also hope to instill a realization that it's not just about taking care of the individual. It's also about looking after one's teammates.

We know that this mission cannot be accomplished alone. It is a shared responsibility. A concussion is a brain injury that is not always easily recognizable to the untrained eye. We want to encourage and empower Soldiers and Players to take an active role in the education and prevention process. We all have a crucial role in making sure a brain injury is properly identified and treated.

To support this effort, the NFL is launching today a website dedicated to this initiative– www.NFL.com/military. As an extension of NFL.com, this site provides service members exclusive access to football news and the most up-to-date information on brain injuries.

By coming together in this historic effort, we are combining and strengthening our forces. As we continue to focus our efforts on encouraging safer environments, we will continue to celebrate the spirit of competition and determination that define our two organizations. Working together, we will ensure longer careers and healthier lives. Working together, we all become stronger. And working together, we have the power to make a real difference. We hope you will join us.

Raymond T. Odierno
General, United States Army
Chief of Staff

Roger Goodell
Commissioner
National Football League

Figure 11. Letter formalizing the partnership between the Army and NFL. Source: NFL Communications (2012).

In October of 2012, an article was posted on U.S. Medicine in reference to the joint interest of the NFL and the Army. Within that article was a really good section summarizing where the research on TBI was, as well as the relevance to both the NFL and the Army.

> The partnership comes when the NFL and military increasingly face questions about the long-term impact of head injuries. Concerns have emerged that troops and NFL players are at risk for Chronic Traumatic Encephalopathy (CTE), a progressive neurodegenerative brain disorder, leading to dementia, which some scientists have linked to athletes with multiple concussions and, more recently, war veterans. (Basu, 2012)

It mentioned new research that was emerging about the risk CTE poses for service members.

> In May 2012, Ann McKee MD, a professor of neurology and pathology at VA Boston HealthCare System and Boston University School of Medicine, and her colleagues published a study finding that the brains of four dead veterans who served in Iraq and Afghanistan indicated they had CTE.
>
> Three of the four veterans had been exposed to an IED blast during combat, and two of the three had other head injuries earlier in life. The fourth suffered concussions from sports and military combat and from bicycle accidents.
>
> This research follows a study published in 2011 by researcher Bennett Omalu of a 27-year-old Iraqi war veteran who had developed PTSD and committed suicide after two deployments. He had been exposed to mortar blasts and IED blasts less than 50 meters away. A study of his brain tissue after his death revealed CTE changes. Speaking to reporters at a media roundtable during the four-day Military Health System Research Symposium in August, McKee explained that, in addition to athletes, she has seen CTE in the brains of 21 total veterans. (Basu, 2012)

Unfortunately, at this point in time, there was no way to diagnose CTE in living subjects. The only way to confirm the presence of CTE was by doing post mortem analysis on the brain, and looking for the presence of the Tau protein in brain samples. This fact adds to the already complicated nature of the topic of research. To reiterate what was said earlier, CTE is a degenerative condition found in the brains of people who have had multiple traumatic brain injuries.

> It is a progressive degenerative disease which afflicts the brain of people who have suffered repeated concussions and traumatic brain injuries, such as athletes who take part in contact sports, members of the military and others. (Brain Injury Research Institute [BIRI], n.d.)

Within the same article written on the NFL and Army team up, it was acknowledged that while there is still a lot of work to do regarding the research, enough is known to remove and/or evaluate individuals who have been exposed to a potentially concussive event. The Army already had a policy in place to address that, even if it was not publicly well known.

> While further head injury research is needed to understand brain injury, researchers and policymakers agree that individuals should get off the battlefield or football field if they think they have sustained a mild concussion.
>
> At the signing of the NFL and Army collaboration, Maj. Sarah Goldman, TBI program director for the Office of the Army Surgeon General, spoke about DoD's policy regarding how soldiers should be treated in theater when they may have been involved in a blast or who may be at risk for TBI. The policy is called the Directive-Type Memorandum 09–033.
>
> "If you are within 50 meters of a blast, if you have had a blow to the head or been involved in a vehicle collision or rollover, or if your commander is just concerned about you, there is a command-directed provision [that] there is a mandatory medical evaluation. There is a minimum of 24 hours of downtime. You must have medical clearance before returning to duty," she said. (Basu, 2012)

A Department of Defense Instruction (DoDI) was written based on the Directive Type Memorandum 09–033 mentioned above. It was DoDI 6490.11, dated September 18, 2012, subject of "DoD Policy Guidance for Management of Mild Traumatic Brain Injury/ Concussion in the Deployed Setting." The following is an excerpt of Section 4, Policy. The full DoDI can be found as an appendix to this document.

> POLICY. It is DoD policy that:
>
> a. DoD shall identify, track, and ensure the appropriate evaluation and treatment of Service members exposed to potentially concussive events, to include blast events.
>
> b. Service members exposed to a potentially concussive event shall be medically assessed as close to the time of injury as possible.

> c. Medically documented mTBI/concussion in Service members shall be clinically evaluated, treated, and managed according to the most current DoD clinical practice guidance for the deployed environment found at the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injuries (DCoE) website (Reference (c)).
>
> d. Recurrent concussion shall be managed according to the most current DoD clinical practice guidance for the deployed setting found at Reference (c).
>
> e. Potentially concussive events, results of concussion screening, and diagnosed concussions shall be appropriately documented, to the maximum extent possible in the Service member's electronic health record.
>
> f. All individually identifiable information will be protected in accordance with DoDD 5400.11, DoD 5400.11-R, and DoD 6025.18-R (References (d), (e), and (f)).
>
> g. DoD civilian employees will be treated and managed the same as military Service members to the extent practical and consistent with DoDD 1404.10 (Reference (g)). (DoD, 2012, sec. "Policy")

The Army obviously was taking notice of the magnitude of the situation and had written policies to address them. But when people start to connect that blasts could be contributing to traumatic brain injury, which then could contribute to the eventual development of CTE, the public as well as senior leaders and Congress get even more invested in the topic, and want to know the plan of addressing the serious issue.

There was shift around 2014 to start using the sensors in training environments, to measure the exposures that soldiers were getting from the normal training and firing of artillery weapons (Sherman, 2014). At the same time, there was some publicity coming out saying that the Army stopped all efforts as seen in the NPR article called "Pentagon Shelves Blast Gauges Meant to Detect Battlefield Brain Injuries."

In 2016, an article from NPR came out with the title of "Pentagon Shelves Blast Gauges Meant to Detect Battlefield Brain Injuries." Within that article, it was stated that NPR had learned "the monitoring was discontinued because the gauges failed to reliably show whether service members had been close enough to an explosion to have sustained a concussion, or mild traumatic brain injury" (Hamilton, 2016, para. 2). The article states that even though the gauges could not show what was just stated, they did provide a "trove of data on blast exposure that could have eventually helped researchers understand the links between bomb blasts, concussions and brain diseases" (Hamilton, 2016, para. 3). Eric Fanning, then secretary of the Army, discussed the decision to stop fielding the gauges in a decision letter to Representative Louise Slaughter. Within the letter, Fanning wrote that "one problem was that the gauges failed to show how much blast exposure is too much," adding that "The DoD's current inventory of blast gauges does not provide consistent and reliable data in the training or combat environment" (Hamilton, 2016, para. 7). One thing that was taken from the fielding of the gauges, was the discovery that "The majority of exposures were not from improvised explosive devices, as you might expect," says David Borkholder (Hamilton, 2016, para. 17). David Borkholder is the "founder of BlackBox Biometrics, the company which makes the blast gauges" (Hamilton, 2016, para. 17). Borkholder stated that "the culprit was usually 'blast-intensive weapons systems' like recoilless rifles, shoulder-fired rockets, artillery and mortars," an example of which can be seen in Figure 12 (Hamilton, 2016, para. 17). The article ended with the following statement, "The Department of Defense says it's committed to determining the risks from overpressure exposure, both in combat and in training. It is also testing a new generation of Blast Gauges that are more sensitive and easier to maintain" (Hamilton, 2016, para. 30).

"A soldier fires a Carl Gustav recoilless rifle system during weapons practice in Helmand province, Afghanistan. Heavy weapons like these generate a shock wave that may cause brain injuries. Sgt. Benjamin Tuck/CJSOTF-A/DVIDS."

Figure 12. Soldier firing a recoilless rifle. Source: Hamilton (2016).

On December 13, 2017, Dr. David W. Dodick, who is the sports neurology and concussion program director at the Mayo Clinic, spoke to the Senate Armed Services Subcommittee on Personnel (Maucione, 2017). He stated that "blast exposure was the leading cause of concussion. Blast injury is the result of the rapid transition of an acoustic wave through the brain tissue. Over the last 16 years an estimated 320,000 U.S. troops, about one in five, returning from active theater have sustained a concussion and among those almost half experienced symptoms consistent with Post-Traumatic Stress or Post-Concussion Syndrome" (Maucione, 2017, para. 5). Within this article, it is clear the Department of Defense began looking into the effects of cumulative sub concussive events, which could be introduced by repeatedly firing certain weapons systems, as was referenced previously.

In 2018, there have been numerous articles pushing the widespread use of BGs. Paul Scharre, from the Center for a New American Security says "every service member who is in a position where he or she might be exposed to blast waves should be wearing these devices. And we need to be recording that data, putting it in their record and then putting it in a database for medical studies" (Hamilton, 2018b, para. 13). There has also been a lot of talk on the effects of "blast from some weapons" and the effect it has on service members in the recent months (Hamilton, 2018b). The main weapon that gets referred to is the Carl Gustav recoilless rifle, a shoulder fired weapon.

In May of 2018, the Director of the Army's TBI program spoke with NPR to discuss what the military is doing to address blast exposure (Hamilton, 2018a). Tracie Lattimore described the current ongoing effort that "includes scientific research on troops' exposure to blast during weapons training, enforcing limits on the firing of certain weapons" (Hamilton, 2018a, para. 6). Lattimore says, "We were totally concerned about the enemy weapon and the impact of the enemy weapon on our soldiers" (Hamilton, 2018a, para. 10). Recently though, everyone has focused in the effect of firing our own weapons, specifically referring to weapons that produce a blast upon firing. In "studies by the military show that service members who fire these weapons a lot can experience headaches, temporary memory loss, and other symptoms like those of a concussion" (Hamilton, 2018a, para.13). "Dr. David Brody, a neurologist at the Uniformed Services University" performed a study in 2011 that used a "special type of MRI to look at the brains of" service members who had been exposed to bomb blasts (Hamilton, 2018a, para. 15). This is where BGs come into play in the training environment. Even though the Army stopped fielding gauges to deployed troops in a very fluid and uncontrolled environment, it is recognized that the training environment has a lot to offer due to the controlled setting. Brody mentions that "the scientific program going forward is to get blast gauges on these service members and measure their lifetime history of blast exposures" (Hamilton, 2018a, para. 29). The article ends with a statement from Lattimore on how you can see the difference of how the military views the risk of blast from any source, compared to five or 10 years ago (Hamilton, 2018a).

Overall, as you can see from the available literature on the topic of HSs and BGs, the perception and priorities of stakeholders were very fluid throughout the years. Originally the sensors started out as an exposure monitor, it morphed into something that could diagnose TBI, and then back to being exposure monitors. There was a lot of managing of expectations that needed to occur, which is no easy task with such a high visibility and emotionally charged issue. It took years and even today, some people still have the perception that these sensors will solve the TBI issue.

This was all exacerbated by the questions that arose from new research:

> Many questions abound, and the research is new. Not everyone who has had a head injury develops CTE, so who is at risk? Does the number of head injuries, the type of exposure to the head, the genetic makeup or age of an individual make a difference? (Basu, 2012)

It finally got to the point around 2012 where everyone agreed that concussions were bad and linked somehow to CTE. If you got a concussion, you should try to avoid a second concussion and be monitored. But the actual mechanism of what causes TBI was, and still is unknown.

III. CASE STUDY

A. SITUATION SETUP

You are the Project Manager (PM) from Program Executive Office (PEO) Soldier, specifically within PM Soldier Protective and Individual Equipment (SPIE). You are very familiar with the generation I (Gen I) helmet mounted sensor system (HMSS) that your predecessor fielded and you know that there were many issues with the sensor technology and capabilities, as well as the data that came back from the fielding. A contract for the new Gen II sensor was awarded in response to a Vice Chief of Staff of the Army (VCSA) directed requirement (DR) from 2008 to procure a sensor to measure blast induced head motion. The pressure is on to have a good news story with the generation II (Gen II) helmet sensor (HS) fielding, but the data that is coming back from the original sensors that have been fielded does not look promising. A new DR has come out for additional Gen II HSs, and for Blast Gauges (BGs). Why would more sensors and a new gauge be purchased and fielded, if the data from the first round of Gen II sensors were not showing good results?

In addition to the DR, you are constantly getting pressure from the media and various Congress members to address the problem of traumatic brain injury (TBI) in the military. Questions get asked on a regular basis as to why you are not doing anything to protect the soldier and prevent TBI. The public is also beginning to become aware and sensitive to chronic traumatic encephalopathy (CTE), and the long term effects of concussion on the lives of football players from the National Football League (NFL). Everyone wants to know what causes TBI and what is being done to prevent it, both in the military and the NFL. The Army and the NFL came out with a big public announcement of officially teaming up against TBI. There was a letter signed by both the Chief of Staff of the Army, General Odierno, and the NFL Commissioner, Roger Goodell that formalized the partnership between the two organizations.

You have the external interest of stakeholders (vendors, Congress, etc.), and the public perception that you are doing nothing to address a very serious issue that could have impacts on soldiers for years to come. There is a policy in place (DoD, 2012) but it seems that senior leaders are looking for a device that would enforce the policy. “Former Army Vice Chief of Staff Gen. Peter Chiarelli used to hold up the first blast gauges the Army developed at each one of his speaking events in 2011 to stress their importance. He listed them as his top priority in 2010” (Hoffman, 2012, para. 7).

You have the DR, the funding is available and to add a layer of complication, will be expiring. Can you justify making the call to field the sensors knowing that the data could potentially be useless, and in the end be ok with a waste of the taxpayer’s dollars? Why keep going down a path that you already know you will not obtain the expected results?

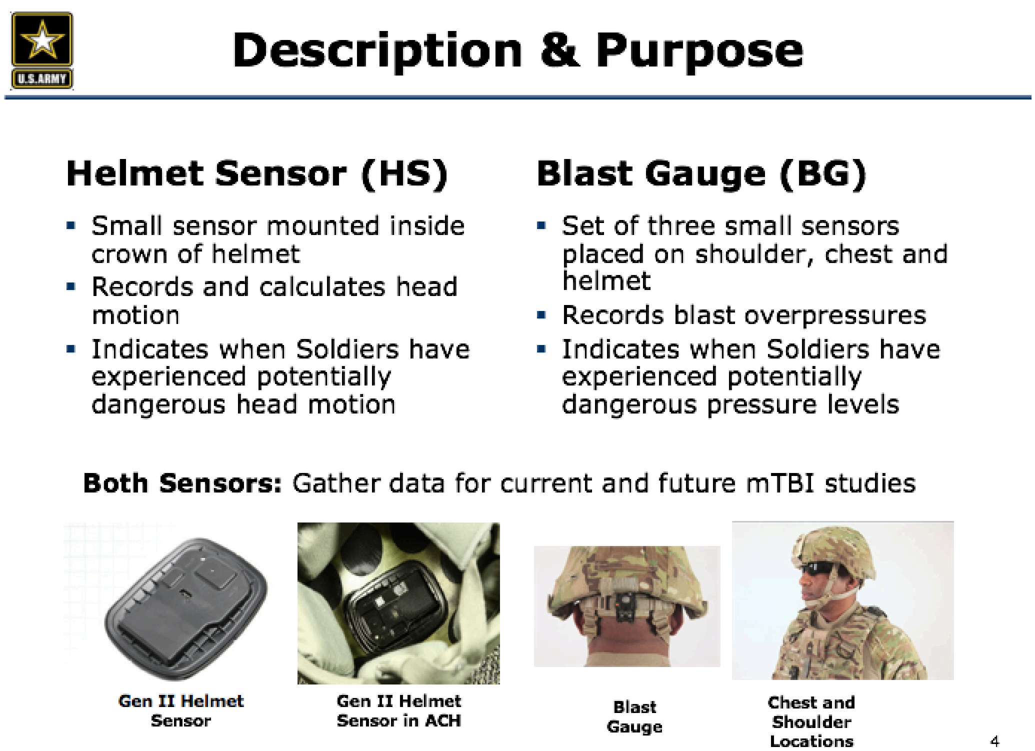
You call a meeting with all of your assistant product managers (APM), your Chief Scientist, and your Deputy. A plan for path forward must be discussed and decided upon very quickly, as you are scheduled to brief your courses of action (COAs) at the Pentagon in two weeks. The information that will be presented and the best way to present it must be decided on. The question that needs answered is whether you will proceed with the fielding of the additional Gen II HSs, and the BGs.

B. HISTORY OF THE HS AND BG PROGRAMS

In 2009, there was an incredible amount of interest from the general public, as well as the senior leaders within the Army to actively pursue the identification and mitigation of TBI. The Army had already fielded 7,000 Gen I HMSS (Figure 6), but wanted to develop and field an enhanced version—Gen II. The Gen II HS program was being developed and managed by PEO Soldier. The new Gen II HSs were smaller, weighed less, and had a longer rechargeable battery life. The Gen II HS would be mounted inside on the crown of the advanced combat helmet (ACH) or enhanced combat helmet (ECH), and would measure and record acceleration and pressure, essentially providing a way to measure head motion (Figure 7).

In addition to the Gen II HS, a BG (Figure 9) was being developed by Defense Advanced Research Projects Agency (DARPA) that would measure and record pressure and low acceleration from three different locations on a soldier.

The HSs and the BGs were originally only intended to be used as exposure monitors to record any exposures to acceleration or pressure. The description and purpose that was presented by PM SPIE can be seen in Figure 13. There was no known or established link between accelerations and blast overpressure to injuries such as TBI. However, the external view quickly morphed into the HS and BG being fielded and used as a diagnostic tool that would be able to tell medical providers in the field whether a soldier had seen enough pressure and/or acceleration to trigger a TBI. This was partly due to the marketing from manufacturers that implied their devices were capable of being used for triage and diagnosis. The new external view and perception of the capabilities of the HS and BG made it very hard to manage the expectations of stakeholders, forcing the PM to make a difficult decision of whether or not to develop, procure and field the products.



Originally presented in a briefing titled “Helmet Sensor and Blast Gauge Overview,” September 2014. Slide created by PM SPIE.

Figure 13. Description and purpose of both HS and BG. Source: R. Mortlock, email to author (August 1, 2017).

Concurrently to the push of documenting exposures within the Army, the NFL became very interested in documenting exposures to potentially concussive events as well. The NFL was hoping to leverage the work the Army was doing and start to install sensors in NFL helmets to gather data on concussions that could benefit both the NFL and the Army (Robson, 2012). An NFL spokesperson said that the league was testing helmet sensors in the hopes of installing them in the players' helmets to gather data on the causes of concussions (Robson, 2012).

C. INTRODUCTION TO THE STAKEHOLDERS

PEO Soldier has the mission of "Develop, acquire, field and sustain affordable integrated state of the art equipment to improve soldier dominance in Army operations today and in the future" (PEO Soldier, n.d.a). Within PEO Soldier is PM SPIE, the mission of PM SPIE is "Develop and provide superior and sustainable integrated clothing and equipment in a rapidly changing global environment as well as provide Soldiers with the state-of-the-art protection to defeat and reduce threats associated with Ballistics, Blast Overpressure, Fragmentation and Heat" (PEO Soldier, n.d.c).

Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) is an organization that falls under the U.S. Army Medical Research and Materiel Command (USAMRMC). "The Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) program facilitates the joint collection, integration, and analysis of data and information to improve our understanding of vulnerabilities to threats and enable the development of improved tactics, techniques, and procedures (TTPs), requirements, material solutions, models, etc., in order to prevent and mitigate injuries" (DoD Blast Injury Research PCO, n.d.b, p. 2-2).

"BAE Systems is a global defence, aerospace and security company employing around 83,100 people worldwide. Our wide-ranging products and services cover air, land and naval forces, as well as advanced electronics, security, information technology, and support services" (BAE Systems, n.d.). BAE systems had developed and fielded the internally mounted variant of the Gen I HMSS, and was involved in the Gen II program as well (Gourley, 2013).

BlackBox Biometrics was founded in 2011 by the RIT researchers who had worked with DARPA to develop BG. BlackBox Biometrics was founded "with the goal of providing objective data to aid the triage and medical treatment associated with today's signature war wound: traumatic brain injury (TBI)" (The Blast Gauge System, n.d.).

In addition to these stakeholders, there is the general public, other vendors, congressmen and women fighting for vendors in their districts, senior leaders within the Army—to include, but not limited to, PEO Soldier's chain of command—the VCSA, and the Chief of Staff of the Army (CSA), and, of course, the warfighter.

D. DEVELOPMENT AND FIELDING OF HS

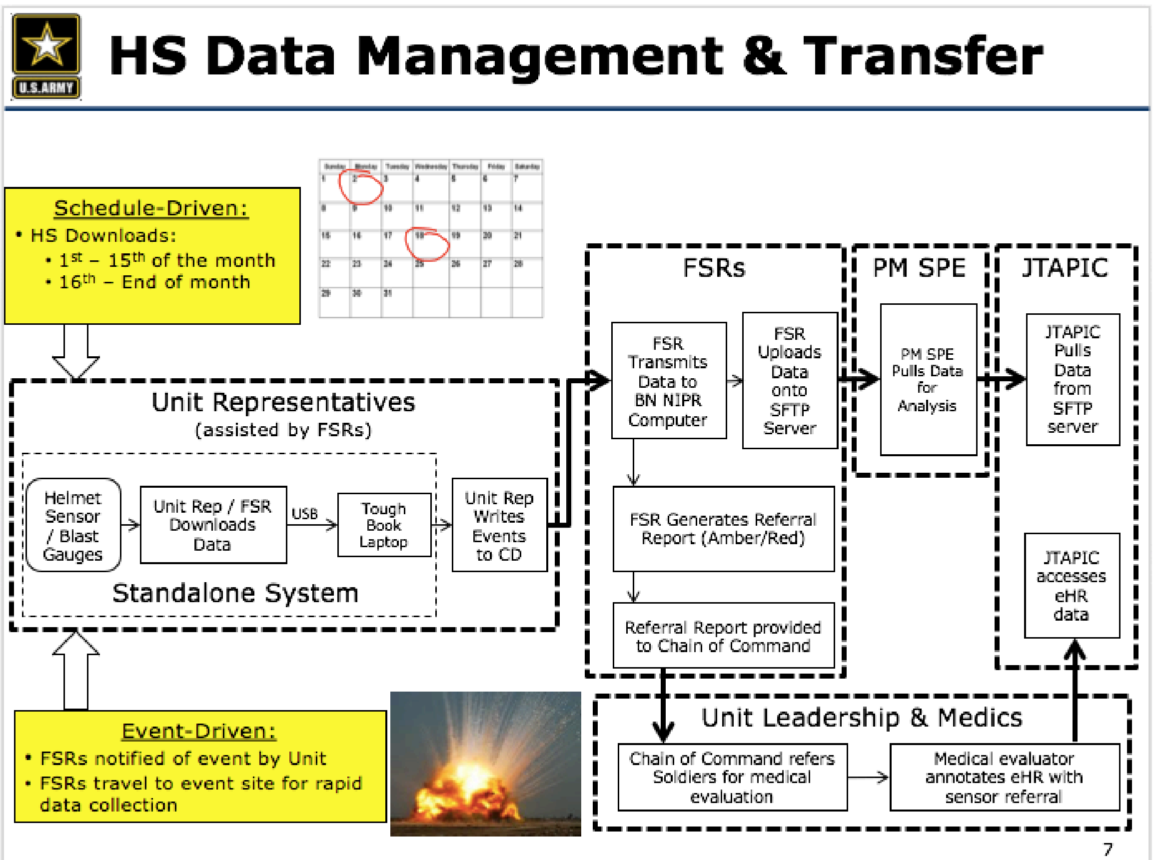
In August of 2007, the DR from the VCSA for a HS was approved. In September of 2007, two Gen I contracts were awarded for a total of 10,000 sensors (R. Mortlock, email to author, August 1, 2017). The vendors participating in Gen I were BAE Systems and Med-Eng (Gourley, 2013). PEO Soldier fielded 6,979 Gen I HSs to the 1st Brigade Combat team, 4th Infantry Division (Operation Iraqi Freedom [OIF]) and 4th Brigade Combat Team, 101st Airborne Division (Operation Enduring Freedom [OEF]) between December 2007 and February 2008. In addition to the numbers that the Army fielded, USMC's Program Manager, Infantry Combat Equipment (PM ICE) fielding 1,952 Gen I HSs to 2 deployed Marine Battalions (DoD Blast Injury Research PCO, n.d.b). The Gen I HS came in two variants, an internally mounted version and an externally mounted version (Figure 6), and was known as the Helmet Mounted Sensor System (HMSS).

JTAPIC, in partnership with Product Manager Soldier Protective Equipment (PM SPE) and Program Manager Infantry Combat Equipment (PM ICE), led a three-phased Helmet Sensor data analysis project. "The objectives were to (1) assess the reliability and accuracy of HMSS, (2) establish a method for translating HMSS data into meaningful impact or blast 'doses' to the head, and (3) correlate the calculated head doses with actual injuries" (DoD Blast Injury Research PCO, n.d.a, p. 7-4). There were many valuable things revealed during the analysis project including performance problems, data artifacts, a screening tool to quickly distinguish between good and bad data, and a mathematical model that uses the raw HMSS data to estimate concussion "doses." Unfortunately, when it came to Phase III, there was not enough data to draw conclusions on the correlation of HMSS data with acute head injuries. Sixty-one individuals were identified among the population of deployed Soldiers and Marines wearing the HMSS. Of those, only two had HMSS data recorded within one day of the reported injury. There were multiple factors identified that played a part in the low percentage of usable data. HMSS performance problems included problems and errors with entering battle roster numbers and inaccurate timestamps, making it very difficult to match HMSS data with the Soldier or Marine who wore it as well as matching the data with injury dates. There were also problems with Unit compliance with the downloading requirements. In the early stages of deployment, there was good compliance; however, later in the deployment the number of downloads decreased. Following the project, “the research teams recommended to the VCSA to field the Generation II HMSS only if all lessons learned from the first-generation HMSS are applied” (DoD Blast Injury Research PCO, n.d.a, p. 7-5).

Following the data collection effort of Gen I, PEO Soldier was preparing to send an updated Gen II version into theater (Dawson, 2009). The Gen II sensors (Figure 7) were being designed to have numerous enhancements including being smaller in size, weighing less, and having a longer rechargeable battery life. In addition to the physical enhancements, there were plans to enhance the data-collection storage, and power management capabilities including adding a wireless capability (Dawson, 2009). The Gen II sensors also included a way to measure rotational acceleration (DoD Blast Injury Research PCO, n.d.c) instead of just linear, which is what Gen I measured. PEO Soldier was planning to “procure enough Generation II helmet sensors, beginning in fiscal year 2010, to equip the equivalent of six brigade combat teams—three to support Operation Iraqi Freedom and three to support Operation Enduring Freedom in Afghanistan” (Dawson, 2009, para. 14). The Gen II HS would be able to record linear and rotational acceleration, as well as blast overpressure.

The Gen II fielding and data collection plans were improved by lessons learned from the Gen I fielding. The goal of the Gen II effort was to “develop a body of knowledge of kinetic events to support the DoD medical community’s research on mTBI” (DoD Blast Injury Research PCO, n.d.b, p. 4-7).

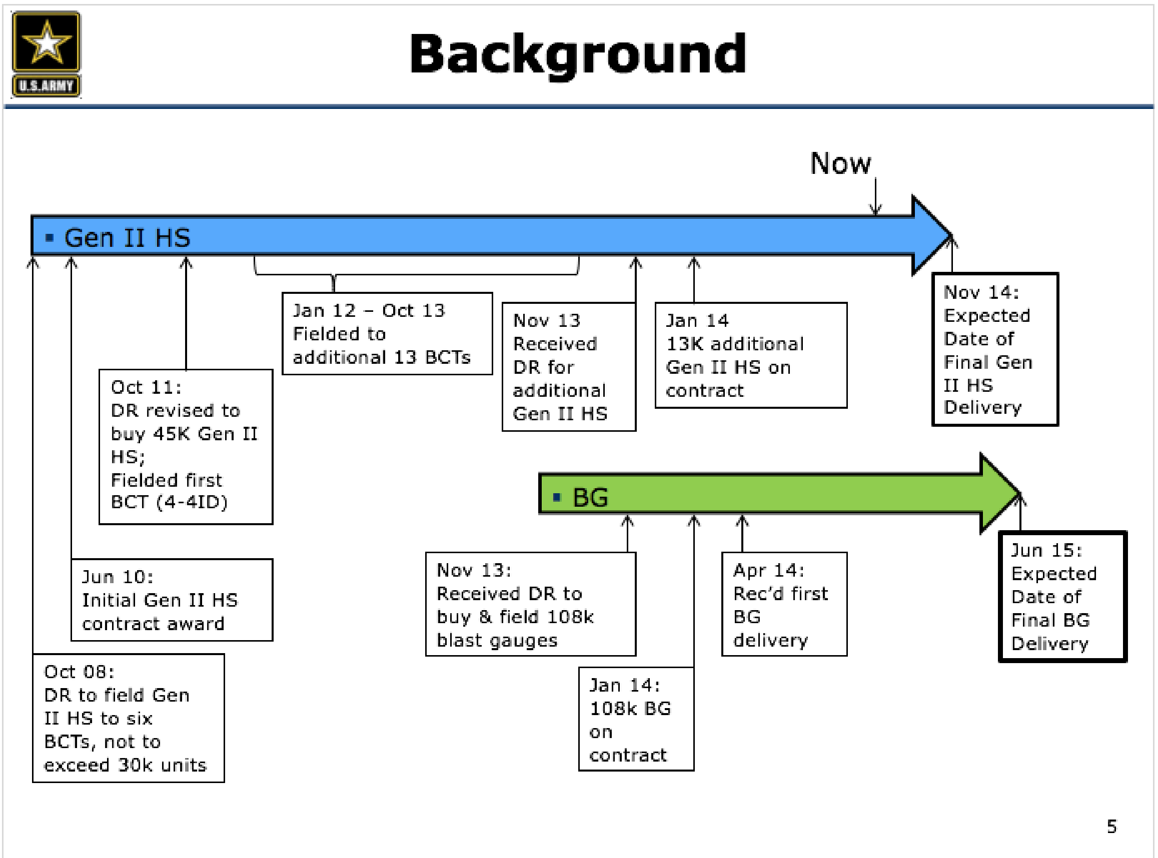
For Gen II HS, PM SPE was planning to install the sensors in the ACHs, and field them to warfighters prior to mission rehearsal exercise (DoD Blast Injury Research PCO, n.d.b). Field service representatives (FSRs) were to be embedded in each battalion to actually perform and assist with downloads and provide technical assistance where needed (DoD Blast Injury Research PCO, n.d.b). As shown in Figure 14, the FSRs would work with unit representatives to do both event and schedule driven downloads. If there was an event, a download would occur. Otherwise there would be a bi-monthly download. The flow of data is also shown, and goes from the FSRs, to PM SPE, and then to JTAPIC for analysis (R. Mortlock, email to author, August 1, 2017).



Originally presented in a briefing titled "Helmet Sensor and Blast Gauge Overview," September 2014. Slide created by PM SPIE.

Figure 14. HS data management and transfer schematic. Source: R. Mortlock, email to author (August 1, 2017).

In October of 2008, the Assistant Secretary of the Army (Acquisition, Logistics and Technology) (ASA(ALT)) received the DR to field Gen II HS to six BCTs, the total not to exceed 30K units (R. Mortlock, email to author, August 1, 2017). An overall timeline is shown in Figure 15.



Originally presented in a briefing titled "Helmet Sensor and Blast Gauge Overview," September 2014. Slide created by PM SPIE.

Figure 15. Timeline. Source: R. Mortlock, email to author (August 1, 2017).

As of when the DoD Blast Injury Research Program Coordinating Office FY12 report was published, there were more than 17,000 sensors fielded to 6 brigade combat teams. There was a screening software developed by the JTAPIC Program that extracted and processed the HS data as it was downloaded to a computer. The output on the computer would have a Red/Amber/Green designation for each recorded event. Service members that had either an amber or red event would receive a command directed evaluation. At this time, PEO Soldier also organized an Integrated Product Team that consisted of representatives from the medical community, Army Rapid Equipping Force (REF), and DARPA to try and synchronize sensor development efforts, both current and future (DoD Blast Injury Research PCO, n.d.c).

In November of 2013, a new DR was approved for additional HSs, and by January of 2014, an additional 13,000 were put on contract (see Figure 13) (R. Mortlock, email to author, August 1, 2017).

E. FIELDING OF BG

In 2010, the Defense Advanced Research Projects Agency (DARPA) was working with the Rochester Institute of Technology (RIT) to develop a BG (Figure 9). The BG was "a small device worn by warfighters to measure blast exposure and cue medics for initial response" (Defense Advanced Research Projects Agency [DARPA], n.d.). In 2011, BlackBox Biometrics Inc. was founded by the RIT researchers and the BG became commercialized. BlackBox Biometrics was founded "with the goal of providing objective data to aid the triage and medical treatment associated with today's signature war wound: traumatic brain injury (TBI)" (The Blast Gauge System, n.d.).

The BG was meant to be fielded as a set of 3 individual gauges (Figure 16) that would record blast overpressure as well as linear acceleration. The gauges were to be worn on the chest, shoulder, and nape pad of the soldier.

Figure 16. Blast Gauge placement on soldier: chest, shoulder, and head (nape pad). Source: The Blast Gauge System (n.d.).

In 2011, the VCSA approved a pilot fielding of the Blast Gauge to a brigade deployed in Afghanistan. JTAPIC was to analyze the data from this sensor and provide the common link among sensor development efforts (DoD Blast Injury Research PCO, n.d.b).

In November of 2013, a new DR was approved for the procurement and fielding of 108,000 sets of BGs, as can be seen in the timeline above (Figure 15) (R. Mortlock, email to author, August 1, 2017).

F. PRESENTATION OF PMS INFORMATION

Gen I HMSS results were less than satisfying, Gen II was supposed to address the lessons learned. Unfortunately, even the Gen II data from the initial fielding is coming back less than impressive, with very small numbers matching up with events or health records. With that knowledge, you need to decide whether you are going to proceed with fielding the additional HSs from the newest DR. You decide to call a meeting with the JTAPIC Director to discuss the data collected. JTAPIC is the organization responsible for the data analysis, linking medical records to helmet sensor data and developing the screening software (R. Mortlock, email to author, August 1, 2017).

Looking at HS data from theater, of all events only 52.9% (108,764) were analyzable. Of those, 98,2000 were considered empty helmet events, meaning that the helmet registered an event on an impact but when it was not being worn, which could happen if a helmet is dropped, amongst other scenarios. The remaining 10, 564 analyzable events that registered a red-amber-green exposure accounted for a total of 6,004 exposed Service Members (SMs), only 26 exposed SMs had an electronic Health Record (eHR) entry that matched. Of those 26, there were only 7 who were referred to medical attention that resulted in a concussion or mTBI diagnosis that was documented in their eHR. Adaptations of the original slides can be seen in Figures 17 and 18, with a summary in Table 1. In addition, there were known events that were not part of the routine download (refer to Figure 14). The FSRs would track known events, and then would download the data from any service member wearing a sensor who was involved in the known event. Unfortunately, from the data in Figures 17 and 18 and Table 1, it is not known if any of the events downloaded from known events triggered a red-amber-green reading from the sensors.

	Data Collected as of 10/28/2013	Theater Cumulative to Date	
		Number	%
	Number of events analyzed	205,436	100%
	Number of non-analyzable events (anomalies / errors)	96,672	47.1%
Non-Analyzable Events	False Trigger Anomalies	71,206	34.7%
	Pressure Trigger Anomalies	11,751	5.7%
	Non-Events	13,715	6.7%
	Number of analyzable events	108,764	52.9%
Analyzable Events	Empty Helmets	98,200	47.8%
	R-A-G Exposures	10,564	5.1%

Originally presented in a briefing titled "Helmet Sensor Slides for BRP," November 2013. Slide created by PM SPIE.

Figure 17. Helmet sensor theater data. Adapted from R. Mortlock, email to author (2017).

Data Collected as of 10/31/2013	Cumulative Theater
Total Number R-A-G Exposures	10,564
Total # of SMs Exposed	6356
Total # of SMs w/Matching e-HR Entry	238
Total # of SMs w/Matching e-HR Entry & Concussed	74
Red Exposures	222
# of SMs Exposed	207
# of SMs Exposed w/matching e-HR entry	6
# of SMs Exposed w/matching e-HR entry and diagnosed concussed/mTBI	1
Amber Exposures	1,529
# of SMs Exposed	1,248
# of SMs Exposed w/matching e-HR entry	11
# of SMs Exposed w/matching e-HR entry and diagnosed concussed/mTBI	3
Green Exposures	8,813
# of SMs Exposed	4,549
# of SMs Exposed w/matching e-HR entry	9
# of SMs Exposed w/matching e-HR entry and diagnosed concussed/mTBI	3
Known Events	532
# of SMs Exposed	352
# of SMs Exposed w/matching e-HR entry	212
# of SMs Exposed w/matching e-HR entry and diagnosed concussed/mTBI	67

Originally presented in a briefing titled "Helmet Sensor Slides for BRP," November 2013. Slide created by PM SPIE.

Figure 18. Linkage to medical records. Adapted from R. Mortlock, email to author (2017).

Table 1. Correlation of HS red-amber-green data to SMs exposed. Adapted from R. Mortlock, email to author (August 1, 2017).

Total exposures recorded on HSs (as of 10/31/2013)	10,564
# SMs exposed	6,004
# SMs exposed with matching eHR	26
# SMs exposed with matching eHR and diagnosed with concussion/TBI	7

All numbers listed are from helmet sensor data that flagged as red-green-amber during a routine download. Numbers here exclude the known events.

The information in Figures 18 and 19 and Table 1 were taken from the JTAPIC meeting. The information in Figure 20 tells a similar story, but is based off of a slightly different dataset from the DoD Blast Injury Research PCO. It shows the total number of exposures that registered as red, amber or green, and then in the table shown within the figure, it breaks down how many of those exposures had SMs with matching eHRs.

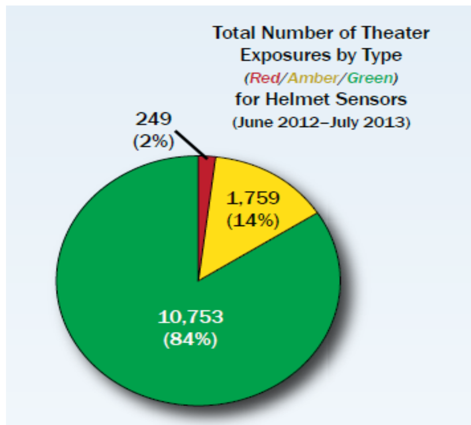


Figure 4-9: Distribution of Helmet Sensor Exposures

	Red	Amber	Green
Number of Service Members (SMs) Exposed	231	1,459	5,950
Number of SMs Exposed with Matching e-HR Entry	6	14	9
Number of SMs Exposed with Matching e-HR Entry and Diagnosed Concussed/ mTBI	1	3	3

Table 4-2: Corresponding Entries of Service Members to the e-HR

Figure 19. A secondary look at medical record linkage. Source: DoD Blast Injury Research PCO (n.d.d).

Without the linkage of returned data to service members and events, plus the overall linkage of exposures to TBI missing, should additional sensors be fielded?

You know of all of the research occurring with TBI and CTE, but you also know that there still is no link between exposures and developing CTE. The NFL seems to be much farther along, but they have years of studies and hundreds of NFL players participating in those studies and that information just is not there with the military yet. Even with the NFL studies, the exact mechanism of injury that causes CTE still is not fully understood. Does just one concussion cause it? If not what is the magic number and within what time period? Taking it one step further, you know that concussions NFL players are seeing are totally different than the blast exposures service members are seeing. NFL impacts are orders of magnitude different than a blast exposure (longer duration, amongst other physical differences). How can you explain this to the public and senior leaders to manage their expectations and perceptions?

In addition to your PM shop looking at these gauges, the Marine Corps Systems Command and Marine Corps Warfighting Laboratory, with technical support from the Naval Research Laboratory, evaluated blast sensors to include the helmet sensor and Blast Gauge (DoD Blast Injury Research PCO, n.d.c). The evaluation used controlled overpressure event testing and evaluation at the Breacher School. During the event testing, the Blast Gauges recorded values in line with the actual values; however, understanding how to interpret the values was difficult (DoD Blast Injury Research PCO, n.d.c). If the gauge was directly exposed to the blast wave, it would over-report the value due to summing of the primary and reflected blast waves (DoD Blast Injury Research PCO, n.d.c). If the gauge was not directly exposed, it would under-report the value because the Marine's body shielded the sensor (DoD Blast Injury Research PCO, n.d.c). The helmet sensor had time-date timestamp reliability issues and could not map to laboratory grade accelerometers (DoD Blast Injury Research PCO, n.d.c). At the end of the evaluation, the Marine Corps reported that the Blast Gauge did provide data that could be correlated to controlled blast events, but due to the directionality problem, interpretation of the data was difficult (DoD Blast Injury Research PCO, n.d.c). They also reported that the helmet senor failed to provide readings that correlated with controlled blast events (DoD Blast Injury Research PCO, n.d.c).

What about the policy in place that requires service members who are within 50 meters of a blast to undergo concussion protocol? There was data coming back that showed the efficacy of the policy in identifying concussions/TBI, but senior leaders wanted a device that would enforce the policy instead of enforcing the reporting. Is there a way that you could implement this policy as part of your path forward?

The Gen II HSs cost approximately $840 each, and were installed in the ACH. BGs came in sets of three, and were approximately $172 per set. In addition to the cost of the sensors, you and your team have to think about the cost of FSRs, as well as the data analysis. To date, $56.8 million has already been spent on procuring and fielding 45,000 helmet sensors (R. Mortlock, email to author, August 1, 2017). In order to fund and procure the additional HSs, and the BGs, $38.3M is required (R. Mortlock, email to author, August 1, 2017).

G. THE BALANCE OF MAKING PROGRAM DECISIONS AND CONSIDERING THE INTEREST AND PERSPECTIVE OF THE VARIOUS STAKEHOLDERS

Given all of the information at hand, and the pressures from stakeholders and the public, a decision had to be made on whether or not to buy and field the Blast Gauges and additional HSs. How do you as the PM come to a conclusion of whether or not to procure and field something that you already know does not provide the expected results, just to show that you are doing something?

Is there some middle ground solution that would be acceptable to both senior leaders, as well as the public and Congress? Can you justify spending the resources on a product that you know does not meet the intent just because there is so much weight behind the moving train?

You can present the different courses of action to senior leaders, making sure to clarify the lack of good data, voice your concerns, and then know that you did what you could to show the ground truth. The problem comes in where showing ground truth sometimes does not make a difference because no matter what, senior leaders have already made up their mind. Is there a way to present the information in a different way that would manage expectations and perceptions more efficiently?

This is an all too common situation that government PMs are put into. Unfortunately, there is no right or wrong answer, or prescribed method of handling it.

H. DISCUSSION QUESTIONS

- Who are the key stakeholders and their concerns?
- Is the decision complicated by the end of the fiscal year (FY) and why?
- How does the Army weigh the cost of procuring fielding HSs and BGs against the benefits?
- Does the fact that previous data shows no correlation to injury important?
- Can you think of any alternatives (non-materiel – think Doctrine, Organization, Training, materiel, Leadership and education, Personnel, Facilities and Policy (DOTmLPF-P) here) to help Soldiers and Marines deal with the effects of blasts or blunt head trauma events on the battlefield in effort to address concerns for concussions and TBI?
- Develop at least two courses of action (COA) that can be presented to senior leaders regarding the purchasing and fielding of the 108,000 blast gauges and the additional helmet sensors.

IV. INSTRUCTOR'S MANUAL AND CONCLUSIONS

A. RECOMMENDED TEACHING STRATEGY

Allow the students to read the case study prior to meeting. Be prepared to answer questions they may have on the background information presented. Present the slides included and go through the discussion questions. Allow the students to prepare answers to the questions and during the next meeting, hold a discussion on the pros and cons of deciding to field the additional sensors versus deciding not to field. Following the discussion, take the students through what actually happened, which can be found in the Epilogue.

B. ANSWERS TO DISCUSSION QUESTIONS FOR A LAB OR EXERCISE

- Who are the key stakeholders and their concerns?

  Project Manager Soldier Protection and Individual Equipment (PM SPIE)—concerned with meeting and managing the expectations of all internal (VCSA, chain of command and external (public, Congress)). Need to decide path forward for fielding, and what to do with the data that comes back.

  Vendors—concerned with getting their products out there and purchased.

  Warfighter—concerned with long term effects from exposures.

  Public—want to know what the Army is doing to address the issue of exposing our warfighters to situations that may cause traumatic brain injury (TBI).

- Is the decision complicated by the end of the fiscal year (FY) and why?

  Yes it is, you have funding in hand, but it expires end of FY. If you do not obligate the funding that was made available by the directed requirement (DR), it would be a political nightmare.

- How does the Army weigh the cost of procuring fielding helmet sensors (HSs) and Blast Gauges (BGs) against the benefits?

  The cost of procuring the HSs and BGs includes the actual materiel cost, plus the cost of supporting data downloads, and then data analysis. In addition, there are the political costs of fielding vs. not fielding. If you field and get bad data back, you will be chastised for a failed program and a colossal waste of resources. If you do not field because you know the benefit does not outweigh the cost, it will be a political and public nightmare. You will be considered as someone who does not care about the service member because in the public's eye, there are all of these amazing tools out there that will "prevent" TBI and you are choosing not to field them.

- Does the fact that previous data shows no correlation to injury important?

  It is very important for multiple reasons. First off it plays right into management of expectations. People assumed these sensors would be connected to actual injury. They were only intended to be exposure monitors. The second reason it is important is because it shows an immensely important gap that needs to be bridged. If the sensors got to the point where they were technically able, the data that would be collected from them could play directly into bridging the gap.

- Can you think of any alternatives (non-materiel – think Doctrine, Organization, Training, materiel, Leadership and education, Personnel, Facilities and Policy (DOTmLPF-P) here) to help Soldiers and Marines deal with the effects of blasts or blunt head trauma events on the battlefield in effort to address concerns for concussions and TBI?

  Enforcing the current policy (DoDI 6490.11). There is a database that has been created to collect and store the information when people do report in accordance with the policy.

- Develop at least two courses of action (COA) that can be presented to senior leaders regarding the purchasing and fielding of the 108,000 BGs and the additional HSs.

  There is no right or wrong answer to the courses of action here. See what approach students take and ensure that they are taking into account the various stakeholders.

C. EPILOGUE (WHAT ACTUALLY HAPPENED)

As of September of 2014, a total of 58,000 Gen II HSs were ordered, with 32,958 fielded in the ACH. PEO Soldier was anticipating fielding an additional 14,605 in ECH for a total anticipated fielding of 47,563. At this point in time, PEO Soldier had received delivery of 45,500 total HSs (R. Mortlock, email to author, August 1, 2017). In addition to the HSs, a total of 108,000 sets of BGs were ordered. First fielding was planned for the 3rd Brigade Combat Team, 101st Airborne Division in October of 2014. Of the total sets ordered, at this point in time (September of 2014), 43,000 sets had been received, and the final delivery was anticipated for June of 2015 (R. Mortlock, email to author, August 1, 2017).

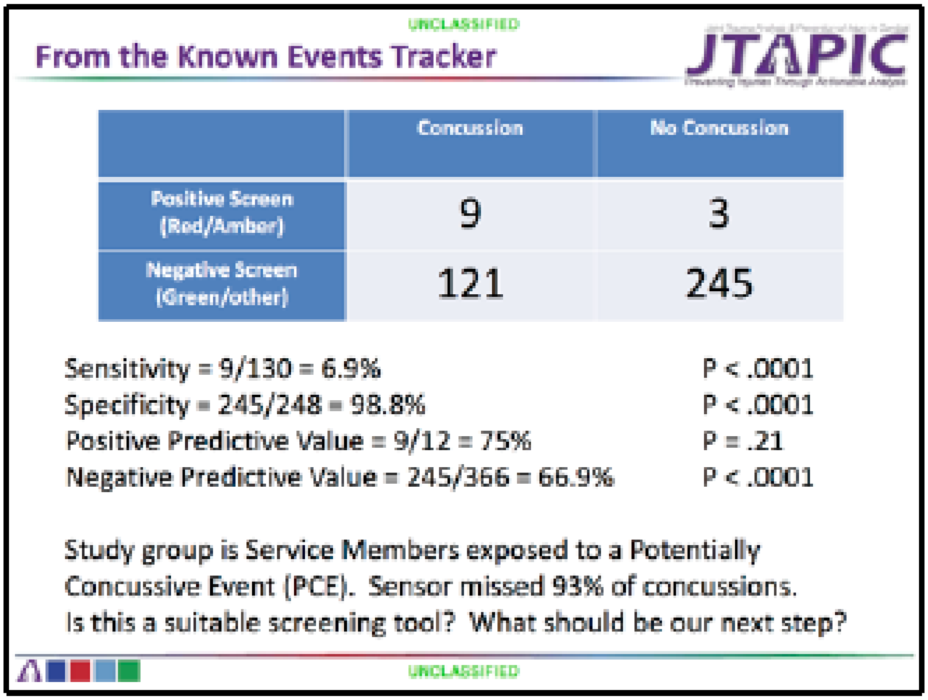
The data that came back from the fieldings did not meet expectations. For both the helmet sensors and blast gauges, there were a lot of events that were not captured by the items, and a lot of events that were captured but not traceable to an actual event (false positives). Even with the events that were recorded, not all of them could be linked to a service member properly.

In November of 2014, the Director of JTAPIC, COL Colin Greene presented at the International State-of-the-Science Meeting. The topic was "Considerations for Sensor Data Collection and Interpretation." Within his presentation, he presented preliminary data from the Known Events Tracker. Below is the excerpt from the meeting proceedings, and his slide can be found in Figure 20.

> Colonel Greene asked the meeting participants to consider the critical issues and questions surrounding use and efficacy of environmental sensors. For example, sensors measure conditions at the helmet, not necessarily at the

head (i.e., not the brain), and converting the helmet readings to head motion is challenging. Converting the data requires complex algorithms that can be a difficult to validate. Furthermore, response (risk) curves for the sensors have yet to be established. Other challenges to capturing accurate sensor data include software limitations such as date/time recording, unreadable waveforms, and issues with setting activation thresholds. Outputs from the sensor are not always readily interpretable. To ensure accurate sensor measurements, Service Members must be wearing the helmet when the blast exposure is measured, but empty helmets cannot always be detected and accounted for using algorithms. Finally, expectations for use and intended benefit of sensors are not clear, thus, more research and greater clarity is required to determine how collected blast injury data is to be used. The questions/issues above were not intended to dampen the pursuit of sensors as potential tools in the study of mTBI. Rather the questions/issues were intended to spur more critical examination of the purpose and applicability of sensors.

To highlight the current state of sensors as a potential screening tool for mTBI, Colonel Greene presented preliminary data from the Known Events Tracker (Figure 3), a list of PCEs defined by the four criteria set forth by the DoD. From this list of events, 378 occurred while the service member was outfitted with a sensor. Of these 378 events, sensors triggered a warning (defined as a red or amber light output) in 12 cases; 9 of the 12 warnings were eventually confirmed concussions, a positive predictive value of 75%. The sensors issued no warning (defined as a green light or no output) in 366 of the events, 121 of which were confirmed concussions. Therefore, the sensitivity of the sensor was 9/130 (6.9%, Figure 3). In other words, the sensors missed 93.1% of concussions amongst the potentially concussive events. Further research into sensors and their relationship to mTBI is required for these sensors to be able to more accurately predict concussive events. (DoD Blast Injury Research PCO, 2014)



UNCLASSIFIED

From the Known Events Tracker

JTAPIC

	Concussion	No Concussion
Positive Screen (Red/Amber)	9	3
Negative Screen (Green/other)	121	245

Sensitivity = 9/130 = 6.9% P < .0001
Specificity = 245/248 = 98.8% P < .0001
Positive Predictive Value = 9/12 = 75% P = .21
Negative Predictive Value = 245/366 = 66.9% P < .0001

Study group is Service Members exposed to a Potentially Concussive Event (PCE). Sensor missed 93% of concussions. Is this a suitable screening tool? What should be our next step?

UNCLASSIFIED

Figure 3 from original source. Data were obtained from the Known Events Tracker, a list of events that are potentially concussive as defined by the four criteria set by DoD.

Figure 20. Comparison of concussion outcomes. Source: DoD Blast Injury Research PCO (2014).

From COL Greene's presentation, the main takeaway was that "the sensors missed 93.1% of concussions amongst the potentially concussive events" (DoD Blast Injury Research PCO, 2014, p. 11).

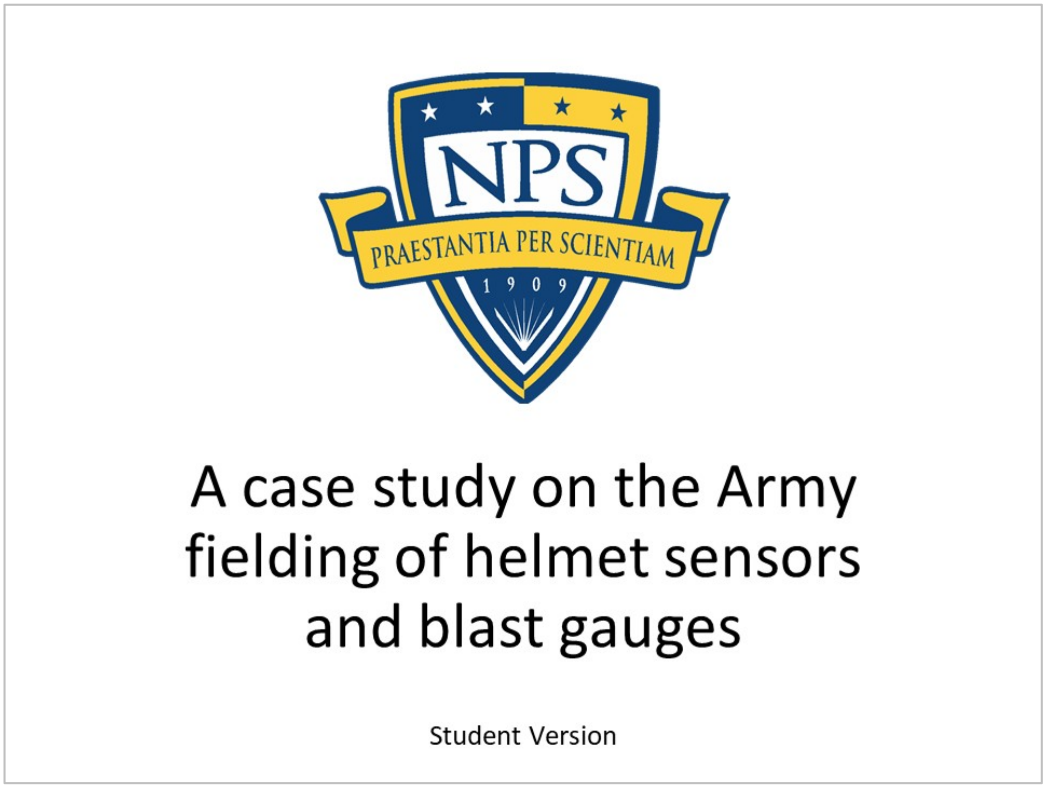
As of March 2015, there were a very small number of data files recorded from BGs (R. Mortlock, email to author, August 1, 2017). In a PM SPIE briefing dated 2 April 2015 and titled "Blast Gauge Data" it is stated that of the BG data that came back, only 31 gauges out of 1653 recorded data, but none of the data was traceable to a real event (R. Mortlock, email to author, August 1, 2017). Another key takeaway from the same briefing was that the "majority of traces have no blast overpressure characteristics" (R. Mortlock, email to author, August 1, 2017).

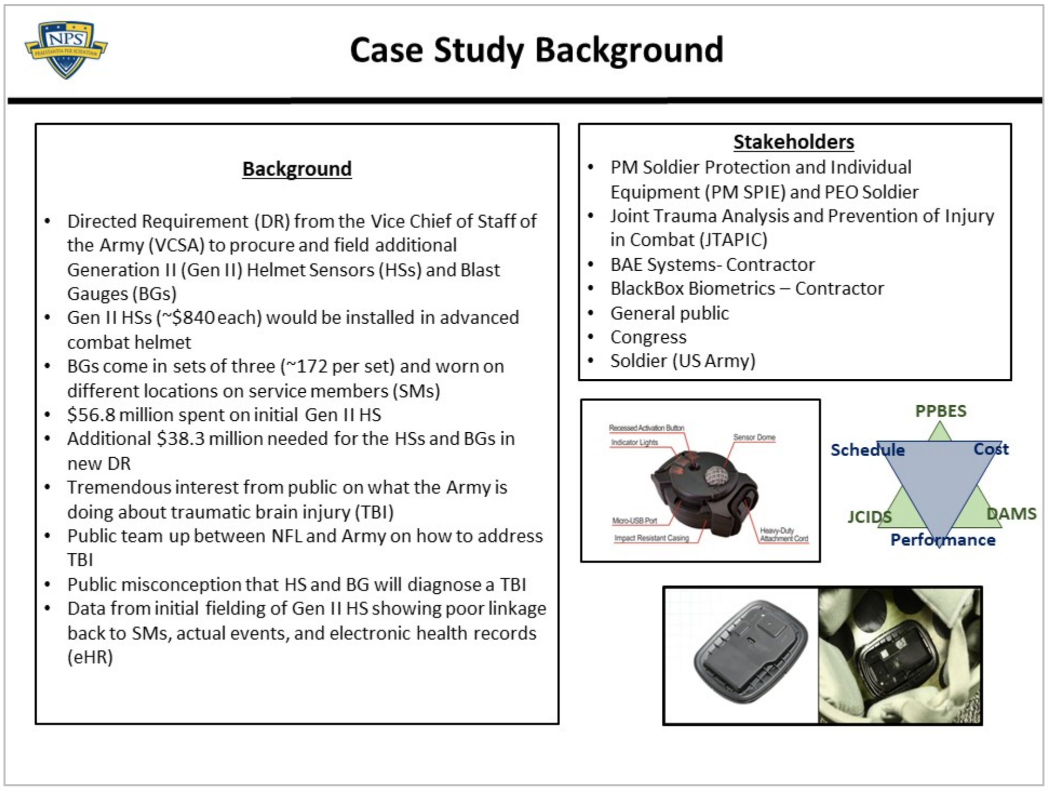
In a study called "Role of Department of Defense Policies in Identifying Traumatic Brain Injuries Among Deployed U.S. Service Members, 2001–2016," data was presented showing that policies in place were indeed effective in screening TBIs. The objectives, methods, results and conclusions are seen below.

> Objectives. To examine the role of Department of Defense policies in identifying theater-sustained traumatic brain injuries (TBIs).
>
> Methods. We conducted a retrospective study of 48172 U.S. military service members who sustained their first lifetime TBIs between 2001 and 2016 while deployed to Afghanistan or Iraq. We used multivariable negative binomial models to examine the changes in TBI incidence rates following the introduction of Department of Defense policies.
>
> Results. Two Army policies encouraging TBI reporting were associated with an increase of 251% and 97% in TBIs identified following their implementation, respectively. Among airmen, the introduction of TBI-specific screening questions to the Post-Deployment Health Assessment was associated with a 78% increase in reported TBIs. The 2010 Department of Defense Directive Type Memorandum 09–033 was associated with another increase of 80% in the likelihood of being identified with a TBI among soldiers, a 51% increase among sailors, and a 124% increase among Marines.
>
> Conclusions. Department of Defense and service-specific policies introduced between 2006 and 2013 significantly increased the number of battlefield TBIs identified, successfully improving the longstanding problem of underreporting of TBIs. (Agimi, Ivins, Malik, Helmick, & Marion (2018).

BGs are still being used in training environments, specifically within the ESiT program. “The envisioned end state of the ESiT Program is a wearable sensor capability for recording acute and chronic environmental blast exposures across training environments and deployment. Sensor data would be available in an integrated system to inform not only evacuation and RTD decisions, but ultimately clinical treatment strategies” (DoD Blast Injury Research PCO, n.d.f, p. 31).

D. CASE INTRODUCTION SLIDES FOR INSTRUCTORS





Case Study Background

Data returned from theater on initial Gen II HS fielding

	Data Collected as of 10/28/2013	Theater Cumulative to Date	
		Number	%
	Number of events analyzed	205,436	100%
	Number of non-analyzable events (anomalies / errors)	96,672	47.1%
Non-Analyzable Events	False Trigger Anomalies	71,206	34.7%
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Analyzable Events	Empty Helmets	98,200	47.8%
	R-A-G Exposures	10,564	5.1%

Helmet Sensor Theater Data. Originally presented in a briefing titled "Helmet Sensor Slides for BRP," November 2013. Slide created by PM SPIE.

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Case Study Setup

- You are the PM from PEO Soldier
- New DR for additional HSs and BGs
- Data from Gen I HSs not ideal
- Pressure from media and public on what the Army is doing to address traumatic brain injury (TBI)
- Army and NFL team up on TBI
- Vendors pressuring Congress
- VCSA listed BG as top priority
- DoDI 6490.11

Case Study Discussion Questions

- Who are the key stakeholders and their concerns?
- Is the decision complicated by the end of the FY and why?
- How does the Army weigh the cost of procuring fielding HSs and BGs against the benefits?
- Does the fact that previous data shows no correlation to injury important?
- Can you think of any alternatives (non-materiel – think Doctrine, Organization, Training, materiel, Leadership and education, Personnel, Facilities and Policy (DOTmLPF-P) here) to help Soldiers and Marines deal with the effects of blasts or blunt head trauma events on the battlefield in effort to address concerns for concussions and TBI?
- Develop at least two courses of action (COA) that can be presented to senior leaders regarding the purchasing and fielding of the 108,000 blast gauges and the additional helmet sensors.

E. CASE DISCUSSION STORYBOARD FOR INSTRUCTORS

A case study on the Army fielding of helmet sensors and blast gauges

Instructor Version

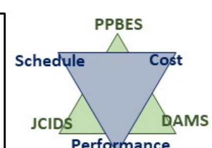
Case Study Background

Background

- Directed Requirement (DR) from the Vice Chief of Staff of the Army (VCSA) to procure and field additional Generation II (Gen II) Helmet Sensors (HSs) and Blast Gauges (BGs)
- Gen II HSs (~$840 each) would be installed in advanced combat helmet
- BGs come in sets of three (~172 per set) and worn on different locations on service members (SMs)
- $56.8 million spent on initial Gen II HS
- Additional $38.3 million needed for the HSs and BGs in new DR
- Tremendous interest from public on what the Army is doing about traumatic brain injury (TBI)
- Public team up between NFL and Army on how to address TBI
- Public misconception that HS and BG will diagnose a TBI
- Data from initial fielding of Gen II HS showing poor linkage back to SMs, actual events, and electronic health records (eHR)

Stakeholders

- PM Soldier Protection and Individual Equipment (PM SPIE) and PEO Soldier
- Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC)
- BAE Systems- Contractor
- BlackBox Biometrics – Contractor
- General public
- Congress
- Soldier (US Army)



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Case Study Discussion Question Answers

- Who are the key stakeholders and their concerns?
  - Project Manager Soldier Protection and Individual Equipment (PM SPIE) - concerned with meeting and managing the expectations of all internal (VCSA, chain of command and external (public, Congress)). Need to decide path forward for fielding, and what to do with the data that comes back.
  - Vendors – concerned with getting their products out there and purchased.
  - Warfighter – concerned with long term effects from exposures.
  - Public – want to know what the Army is doing to address the issue of exposing our warfighters to situations that may cause traumatic brain injury (TBI).
- Is the decision complicated by the end of the FY and why?
  - Yes it is, you have funding in hand, but it expires end of FY. If you do not obligate the funding that was made available by the DR, it would be a political nightmare.
- How does the Army weigh the cost of procuring fielding HSs and BGs against the benefits?
  - The cost of procuring the HSs and BGs includes the actual materiel cost, plus the cost of supporting data downloads, and then data analysis. In addition, there are the political costs of fielding vs. not fielding. If you field and get bad data back, you will be chastised for a failed program and a colossal waste of resources. If you do not field because you know the benefit does not outweigh the cost, it will be a political and public nightmare. You will be looked at as someone who does not care about the service member because in the public's eye, there are all of these amazing tools out there that will "prevent"TBI and you are choosing not to field them.

Case Study Discussion Question Answers Cont.

- Does the fact that previous data shows no correlation to injury important?
  - It is very important for multiple reasons. First off it plays right into management of expectations. People assumed these sensors would be connected to actual injury. They were only intended to be exposure monitors. The second reason it is important is because it shows an immensely important gap that needs to be bridged. If the sensors got to the point where they were technically able, the data that would be collected from them could play directly into bridging the gap.
- Can you think of any alternatives (non-materiel – think Doctrine, Organization, Training, materiel, Leadership and education, Personnel, Facilities and Policy (DOTmLPF-P) here) to help Soldiers and Marines deal with the effects of blasts or blunt head trauma events on the battlefield in effort to address concerns for concussions and TBI?
  - Enforcing the current policy (DoDI 6490.11). There is a database that has been created to collect and store the information when people do report IAW with the policy.
- Develop at least two courses of action (COA) that can be presented to senior leaders regarding the purchasing and fielding of the 108,000 blast gauges and the additional helmet sensors.
  - There is no right or wrong answer to the courses of action here. See what approach students take and ensure that they are taking into account the various stakeholders.

Case Study Discussion – What Actually Happened

- Does the fact that previous data shows no correlation to injury important?
  - It is very important for multiple reasons. First off it plays right into management of expectations. People assumed these sensors would be connected to actual injury. They were only intended to be exposure monitors. The second reason it is important is because it shows an immensely important gap that needs to be bridged. If the sensors got to the point where they were technically able, the data that would be collected from them could play directly into bridging the gap.
- Can you think of any alternatives (non-materiel – think Doctrine, Organization, Training, materiel, Leadership and education, Personnel, Facilities and Policy (DOTmLPF-P) here) to help Soldiers and Marines deal with the effects of blasts or blunt head trauma events on the battlefield in effort to address concerns for concussions and TBI?
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  - There is no right or wrong answer to the courses of action here. See what approach students take and ensure that they are taking into account the various stakeholders.

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V. CONCLUSIONS

A. SUMMARY/CONCLUSIONS

The case study on fielding helmet sensors and blast gauges presents a real-life scenario of decision making that is shaped more so by more external stakeholders, than the quality and performance of the product and data itself. Unfortunately, this scenario occurs too often within the acquisition community.

There was a large public interest in what was happening to our service members with regards to concussion and traumatic brain injury (TBI), and there were vendors who were promising that their products would solve the problems. The vendors had the attention of Congress, which meant the attention of senior leaders was captured as well.

After fielding of generation I (Gen I) helmet mounted sensor system (HMSS), and the initial fielding of generation II (Gen II) helmet sensors (HSs), it was clear to see that there was still a lot of work to be done with both the technology and the fielding/data collection plans in order for the programs to be successful. It was hard to match the data with actual events in theater, as well as with individual service members. Without those links, the data was not useful. In addition to that link missing, the huge gap of linking exposures to injury was also missing.

The Vice Chief of Staff of the Army (VCSA) put out a new directed requirement (DR) requiring a new product (Blast Gauge (BG)) to be fielded, as well as additional HSs. Funding was available and expiring. Knowing that the data that was coming back was not useful, the project manager (PM) was put into a predicament regarding what to do. The easiest thing to do is to take the funding, procure and field the additional sensors regardless of the quality of data coming back. This would satisfy the majority of the stakeholders, but is this the right thing to do? Allowing students to sit back and evaluate what they would do in this situation is an effective way to build up the knowledge and understanding of the many nuances that present themselves within the acquisition program management community.

B. RECOMMENDATIONS FOR FUTURE WORK

It is recommended that the progression of soldier worn sensors and exposure monitors be monitored in the future. Blast gauges are still currently being used in the Environmental Sensors in Training (ESiT) program, and may eventually get fielded again. The current work being done should be leveraged to develop a plan for any potential future fielding. The HSs and Integrated Soldier Sensor System (ISSS) are dormant but that does not mean they will not come back. As this is being written, information is being collected daily on service members who have been exposed to potentially concussive events.

The intent of the HS and BG programs were meant to eventually help address a huge problem; however, the public as well as senior leaders were expecting something that just was not quite there yet. That is not to say that these products and medical linkages will not ever get there, but many things need to happen first. Technology is constantly advancing, and there are promising studies coming out often shedding more and more light on the linkage of exposures (both blunt and blast) to injury. I expect that in the future, a PM will be revisiting this exact topic and will be able to take the lessons learned from Gen I HS, Gen II HS and BG, and apply them which will hopefully allow for a successful execution of a new acquisition program, and in the end provide lasting benefits to our Warfighters.

APPENDIX. DoDI 6490.11

Department of Defense
INSTRUCTION

NUMBER 6490.11
September 18, 2012

USD(P&R)

SUBJECT: DoD Policy Guidance for Management of Mild Traumatic Brain Injury/Concussion in the Deployed Setting

References: See Enclosure 1

1. PURPOSE. This Instruction:

a. In accordance with the authority in DoD Directive (DoDD) 5124.02 (Reference (a)), establishes policy, assigns responsibilities, and provides procedures on the management of mild traumatic brain injury (mTBI), also known as concussion, in the deployed setting. See Glossary for definition of mTBI.

b. Incorporates and cancels Directive-Type Memorandum 09-033 (Reference (b)).

c. Standardizes terminology, procedures, leadership actions, and medical management to provide maximum protection of Service members.

2. APPLICABILITY. This Instruction applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (hereinafter referred to collectively as the "DoD Components").

3. DEFINITIONS. See Glossary.

4. POLICY. It is DoD policy that:

a. DoD shall identify, track, and ensure the appropriate evaluation and treatment of Service members exposed to potentially concussive events, to include blast events.

b. Service members exposed to a potentially concussive event shall be medically assessed as close to the time of injury as possible.

c. Medically documented mTBI/concussion in Service members shall be clinically evaluated, treated, and managed according to the most current DoD clinical practice guidance for the deployed environment found at the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injuries (DCoE) website (Reference (c)).

d. Recurrent concussion shall be managed according to the most current DoD clinical practice guidance for the deployed setting found at Reference (c).

e. Potentially concussive events, results of concussion screening, and diagnosed concussions shall be appropriately documented, to the maximum extent possible in the Service member's electronic health record.

f. All individually identifiable information will be protected in accordance with DoDD 5400.11, DoD 5400.11-R, and DoD 6025.18-R (References (d), (e), and (f)).

g. DoD civilian employees will be treated and managed the same as military Service members to the extent practical and consistent with DoDD 1404.10 (Reference (g)).

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. INFORMATION COLLECTION REQUIREMENTS. The report on mTBI/concussion sustained in the deployment setting referred to in paragraphs 4.b, 6.e., and 8.b. of Enclosure 2 and section 3 of Enclosure 3 of this Instruction has been assigned report control symbol DD-HA(AR)2404 in accordance with the procedures in Directive-type Memorandum 12-004 (Reference (h)) and DoD 8910.1-M (Reference (i)).

8. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Website at http://www.dtic.mil/whs/directives.

9. EFFECTIVE DATE. This Instruction:

a. Is effective September 18, 2012.

b. Must be reissued, cancelled, or certified current within 5 years of its publication in accordance with DoD Instruction 5025.01 (Reference (j)). If not, it will expire effective September 18, 2022 and be removed from the DoD Issuances Website.

Erin Conaton
Under Secretary of Defense
for Personnel and Readiness

Enclosures
1. References
2. Responsibilities
3. Procedures
Glossary

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ENCLOSURE 1

REFERENCES

(a) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
(b) Directive Type Memorandum 09-033, "Policy Guidance for Management of Concussion/ Mild Traumatic Brain Injury in the Deployed Setting," June 21, 2010 (hereby cancelled)
(c) DCOE Website, "TBI Clinical Documents," http://www.dcoe.health.mil/ForHealthPros/TBIInformation.aspx
(d) DoD Directive 5400.11, "DoD Privacy Program," May 8, 2007, as amended
(e) DoD 5400.11-R "Department of Defense Privacy Program," May 14, 2007
(f) DoD 6025.18-R, "DoD Health Information Privacy Regulation," January 24, 2003
(g) DoD Directive 1404.10, "DoD Civilian Expeditionary Workforce," January 23, 2009
(h) Directive Type Memorandum 12-004, "DoD Internal Information Collections," April 18, 2012
(i) DoD 8910.1-M, "Department of Defense Procedures for Management of Information Requirements," June 30, 1998
(j) DoD Instruction 5025.01, "DoD Directives Program," October 28, 2007, as amended
(k) DoD Instruction 6200.05, "Force Health Protection (FHP) Quality Assurance (QA) Program," February 16, 2007
(l) DoD Directive 6025.21E, "Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries," July 5, 2006
(m) DoD 6025.13-R, "Military Health System Clinical Quality Assurance Program Regulation," June 11, 2004
(n) Cicerone, K.D. and Kalmar, K., "Persistent post-concussion syndrome: The structure of subjective complaints after mild traumatic brain injury," Journal of Head Trauma Rehabilitation 1995; 10(3): 1-17

ENCLOSURE 2

RESPONSIBILITIES

1. UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS (USD(P&R)). The USD(P&R) shall establish mTBI/concussion management policy for the DoD.

2. ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS (ASD(HA)). The ASD(HA), under the authority, direction, and control of the USD(P&R), shall:

a. Advise the USD(P&R) on the physical and medical aspects of operationally relevant mTBI/concussion management training standards.

b. Plan, program, budget, and execute the development and fielding of new technologies and programs to support this Instruction.

3. DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR FORCE HEALTH PROTECTION AND READINESS (DASD(FHP&R)). The DASD(FHP&R) under the authority, direction, and control of the USD(P&R) through the ASD(HA), shall:

a. Develop policy and provide guidance on the implementation of this Instruction.

b. Identify the capability gaps of current technologies and programs and, through the Defense Health Program, support research, development, testing, and evaluation programs to support the DoD mTBI/concussion policy.

c. Develop Force Health Protection quality assurance metrics in accordance with DoD Instruction 6200.05 (Reference (k)).

d. Develop and modify this Instruction as necessary based upon reporting summaries received from the DCoE.

e. Provide policy direction and strategic oversight to the Director, Tricare Management Activity (TMA) in the implementation of DCoE procedures.

4. DIRECTOR, TMA. The Director, TMA, under the authority, direction, and control of the ASD(HA) through the DASD(FHP&R), shall ensure the DCoE executes the following responsibilities:

a. Coordinate mTBI/concussion exposure surveillance and data analysis and promote data sharing with the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)), the

Director of the Joint Improvised Explosive Device Defeat Organization, and the Secretary of the Army in his or her capacity as DoD Executive Agent for Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries as designated in DoDD 6025.21E (Reference (l)).

b. Generate comprehensive, retrospective analytical reports of relevant event-triggered mTBI/concussion data and activities of the Services and Combatant Commanders and coordinate blast-specific data analyses with the Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) Program Office. Disseminate results to Combatant Commands, Military Department Secretaries, Service Chiefs, and ASD(R&E) summarizing injury trends. Recommend modifications to the policy based upon summary reports.

c. Develop event-specific monitoring summaries in coordination with the Services and Commander of Combatant Commands.

d. Review and analyze mTBI/concussion clinical guidance to provide updates, as indicated.

5. ASSISTANT SECRETARY OF DEFENSE FOR RESERVE AFFAIRS (ASD(RA)). The ASD(RA), under the authority, direction, and control of the USD(P&R), shall ensure policies are developed that support the administrative management rules addressing the unique concerns of the Reserve Component relating to the prevention and rehabilitation of traumatic brain injury for the Ready Reserve.

6. SECRETARIES OF THE MILITARY DEPARTMENTS. The Secretaries of the Military Departments shall:

a. Develop Service mTBI/concussion policies and procedures consistent with this Instruction and recommend suggested procedural changes to the ASD(HA).

b. Program and budget for necessary manpower and resources to implement this Instruction.

c. Develop and support effective training plans for:

(1) Early detection of potentially concussive events for line leadership and Service members.

(2) Medical personnel on the use of mTBI/concussion algorithms in accordance with Service policies.

d. Develop Service reporting guidelines for potentially concussive events in accordance with section 3 of Enclosure 3 of this Instruction.

e. Ensure Service submission of monthly tracking reports to the JTAPIC Program Office.

f. Support medical management and event tracking and follow-up medical care for Service members.

7. CHAIRMAN OF THE JOINT CHIEFS OF STAFF. The Chairman of the Joint Chiefs of Staff shall:

a. Incorporate this Instruction into relevant joint doctrine, training, and plans.

b. In consultation with the Commanders of Combatant Commands and the Secretaries of the Military Departments, monitor the execution of this Instruction.

c. Monitor compliance with the requirements for documented tracking and reporting of Service members involved in a potentially concussive event.

8. COMMANDERS OF THE GEOGRAPHIC COMBATANT COMMANDS. The Commanders of the Geographic Combatant Commands, through the Chairman of the Joint Chiefs of Staff, shall:

a. Develop command-specific procedures for Service component reporting of potentially concussive events and support training programs for leaders on event-triggered screening guidelines.

b. Submit monthly tracking reports of potentially concussive events to the JTAPIC Program Office for Service members in accordance with section 3 of Enclosure 3 of this Instruction.

c. Monitor Service component compliance of monthly reporting requirements and quality management.

ENCLOSURE 3

PROCEDURES

1. POTENTIALLY CONCUSSIVE EVENTS. Events requiring mandatory rest periods and medical evaluations and reporting of exposure of all involved personnel include, but are not limited to:

a. Involvement in a vehicle blast event, collision, or rollover.

b. Presence within 50 meters of a blast (inside or outside).

c. A direct blow to the head or witnessed loss of consciousness.

d. Exposure to more than one blast event (the Service member's commander shall direct a medical evaluation).

2. COMMAND GUIDANCE

a. Commanders or their representatives are required to assess all Service members involved in potentially concussive events, including those without apparent injuries, as soon as possible using the Injury/Evaluation/Distance (I.E.D.) checklist (see Figure).

Figure. I.E.D. Checklist

Injury	Physical damage to the body or body part of a Service member?	(Yes/No)
Evaluation	**H** – Headaches and/or vomiting?	(Yes/No)
	E – Ear ringing?	(Yes/No)
	A – Amnesia, altered consciousness, and/or loss of consciousness?	(Yes/No)
	D – Double vision and/or dizziness?	(Yes/No)
	S – Something feels wrong or is not right?	(Yes/No)
Distance	Was the Service member within 50 meters of the blast? Record the distance from the blast.	(Yes/No) Not Applicable

b. Service members will be referred for a medical evaluation if involved in a potentially concussive event as defined in section 1 of this enclosure, if there is a "Yes" response on the I.E.D. Checklist, or if they demonstrate any of the symptoms listed at any point after an injury event (see Figure). After the I.E.D. assessment is complete, record the results for each individual involved in the event and submit as part of the significant activities (SIGACT) report required for blast-related events or the events outlined in paragraphs 1.a. through 1.d. of this enclosure.

3. REPORTS. The line commander is responsible to ensure all reports are completed as operational conditions permit, preferably within 24 hours. The minimum required data fields for the monthly reports to the JTAPIC are:

a. Date of potentially concussive event.

b. Type of potentially concussive event triggering evaluation.

c. SIGACT number (if applicable).

d. Personal identifier (e.g., DoD identification number or Battle Roster Number).

e. Service member's name.

f. Unit name, unit identification code, and home duty station.

g. Combatant Command in which the event occurred.

h. Service member's distance from the blast when applicable.

i. The disposition following the medical evaluation (return to duty after 24 hours, commander's justification to return to duty prior to 24 hours, or did not return to duty after 24 hours).

4. MEDICAL GUIDANCE. All deployed medical personnel must use, and commanders support, the most current clinical practice guidance for the deployed environment when possible. A complete listing of the most current guidance is provided on the DCoE website at http://www.dcoe.health.mil/ForHealthPros/TBIInformation.aspx and is summarized in this section.

a. Potentially Concussive Event. Service members involved in a potentially concussive event as described in section 1 of this enclosure are required to rest for 24 hours, beginning at the time of the event. Commanders may determine that mission requirements supersede these recommendations in certain circumstances. If the 24-hour rest period is delayed or postponed, document the circumstance in the monthly report to the JTAPIC.

b. First Diagnosed Concussion. All Service members diagnosed with a mTBI/concussion must have, at a minimum, 24 hours' recovery unless the results of subsequent clinical evaluation indicate a longer period is needed.

c. Second Diagnosed Concussion (Within a 12-month Period). If two diagnosed mTBI/concussions have occurred within the past 12 months, return to duty is delayed for an additional 7 days following symptom resolution.

d. Recurrent Concussion (Within a 12-month Period). If three diagnosed mTBI/concussions have occurred within the past 12 months, return to duty is delayed until a recurrent concussion evaluation has been completed.

(1) The recovery period for Service members experiencing recurrent concussions depends on the number of incidents.

(2) Recovery care includes uninterrupted sleep and pain management.

(3) All sports and other activities with risk of concussion are prohibited until the Service member is cleared by a licensed independent practitioner as defined in DoD 6025.13-R (Reference (m)).

(4) Commanders may impose longer recovery periods based on mission requirements and after consultation with medical personnel.

e. MTBI/Concussion Screening and Initial Evaluation. Use section one of the Military Acute Concussion Evaluation (MACE) to complete the initial screening of Service members involved in a potentially concussive event. Complete the evaluation as close as reasonably possible to the time of initial injury. If a concussion is suspected, report the results of all three scored sections in the electronic health record as follows:

(1) C - Cognitive score (reported with 30 point score).

(2) N - Neurological exam (reported as "Green" (normal) or "Red" (abnormal)).

(3) S - Symptoms reported as "A" (none reported) or "B" (at least one symptom reported).

(4) Example of summary documentation of MACE screening evaluation can be "24/Red/B" indicating a cognitive score of 24, abnormal neurological examination, and patient reporting presence of at least one symptom.

(5) Document the results of the MACE evaluation including the cognitive score, neurological examination, and symptoms in the electronic health record using the most current International Classification of Diseases codes.

5. RECURRENT CONCUSSION EVALUATION. Service members who have sustained three diagnosed concussions within a 12 month period must receive a recurrent concussion evaluation. Additionally, a recurrent concussion evaluation may be performed any time it is clinically indicated, i.e., if symptoms are persistent. Use the results of the evaluation to guide management, treatment, and return-to-duty determinations. The recurrent concussion evaluation is comprised of the following:

a. Comprehensive Neurological Evaluation. A careful examination of the injury history is required to make clinically sound decisions. Such information includes, but is not limited to, the level of mTBI/concussion severity, the nature and duration of symptoms, and the result of sustained exertion on symptoms (e.g., recurrence of headaches after 2 days of normal duty). The Neurobehavioral Symptom Inventory, a validated Acute Stress Reaction assessment, and a vestibular assessment must occur as part of this examination. The Neurobehavioral Symptom Inventory tool can be obtained by accessing http://www.dvbic.org/images/pdfs/Clincal-Tools/F--Neurobehavioral-Symptoms.aspx.

b. Neuroimaging. Neuroimaging will be initiated according to current clinical practice guidelines and evidence-based practices.

c. Neuropsychological Assessment. A variety of neuropsychological assessment tools are available as clinically indicated. No one tool is recommended over another. The assessment, if conducted, should include an effort measure. The following are examples of domains that can be affected by concussion and should be evaluated.

(1) Attention.

(2) Memory.

(3) Processing speed.

(4) Executive functioning.

d. Functional Assessment. The evaluating rehabilitation provider may initiate a functional assessment based on his or her clinical judgment. Rehabilitation providers should evaluate the Service member's performance and monitor symptoms before, during, and after functional assessment. Selected assessment activities should concurrently challenge specific vulnerabilities associated with mTBI including cognitive, sensorimotor, and physical endurance.

e. Duty Status Determination. The neurologist or other qualified licensed independent practitioner trained according to Service policies in the care of mTBI/concussion will determine the return-to-duty status after reviewing the results of the recurrent concussion evaluation. Medical providers must be vigilant for persistent signs and symptoms of mTBI/concussion with any recurrent concussion, as there is an increased risk of longer recovery time with multiple concussions.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASD(RA)	Assistant Secretary of Defense for Reserve Affairs
ASD(R&E)	Assistant Secretary of Defense for Research and Engineering
DASD(FHP&R)	Deputy Assistant Secretary of Defense for Force Health Protection and Readiness
DCoE	Defense Center of Excellence for Psychological Health and Traumatic Brain Injury
DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
I.E.D.	injury/evaluation/distance
JTAPIC	Joint Trauma Analysis and Prevention of Injury in Combat
MACE	Military Acute Concussion Evaluation
mTBI	mild traumatic brain injury
SIGACT	significant activities
TMA	Tricare Management Activity
USD(P&R)	Under Secretary of Defense for Personnel and Readiness

PART II. DEFINITIONS

Unless otherwise noted, the following terms and their definitions are for the purpose of this Instruction.

amnesia. A lack of memory. Amnesia related to trauma, such as concussion, can be either antegrade or retrograde.

antegrade amnesia. The inability to form new memories following the traumatic event (typically not permanent).

retrograde amnesia. The loss of memory for events that occurred prior to the traumatic event.

deployed. All troop movement of Active Component and Reserve Component personnel resulting from a Joint Chief of Staff or unified command deployment for more than 30 continuous days to a location outside the United States that does not have a permanent military treatment facility (funded by the Defense Health Program). This includes naval personnel afloat who might be subjected to concussive injuries.

effort measure. A tool used to evaluate the validity of scores obtained from a neurocognitive assessment test battery.

functional assessment. A functional assessment evaluates the service member's performance of military-relevant activities that simulate the multi-system demands of duty in a functional context.

licensed independent practitioner. Any individual permitted by law and Service regulations to provide care, treatment and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. This term is equivalent to healthcare provider.

MACE. A medical screening and assessment tool with four sections, three of which are scored. It was developed by the Defense and Veterans Brain Injury Center as a standardized form in which the history of a concussive event can be assessed. It also includes cognitive, neurological and symptoms sections designed to evaluate the status of a concussed Service member. This tool is available to medical personnel by e-mailing: info@DVBIC.org.

medical evaluation or assessment. A meeting between a Service member and a person with medical training such as medic or corpsman, physician assistant, physician, or nurse to ensure the health and well-being of the Service member. Components of this evaluation include reviewing the history, events surrounding the injury, review of symptoms, a physical examination, and a review of the treatment plan with the Service member.

mTBI/concussion. The diagnosis of mild traumatic brain injury also known as concussion is made when two conditions are met. In the absence of documentation, both conditions are based on self-report information.

An injury event must have occurred.

The individual must have experienced a normal structural neuroimaging by head CT or conventional brain MRI and one of the following:

Alteration of consciousness lasting less than 24 hours.

Loss of consciousness, if any, lasting for less than 30 minutes.

Memory loss after the event, called post-traumatic amnesia, for events immediately surrounding the injury that lasts for less than 24 hours.

Neurobehavioral Symptom Inventory. A 22-item assessment commonly used to aid in determining mTBI. Symptoms such as decision-making difficulty or change in taste or smell are rated on a scale of 0-4. See Cicerone and Kalmar (1995) (Reference (n)) for additional explanation.

neuroimaging. A radiographic imaging study to evaluate the brain, to include computerized tomography scan or magnetic resonance imaging.

neuropsychological assessment. A series of tests carried out to assess the extent of impairment to a particular skill and to attempt to locate an area of the brain that may have been damaged after brain injury. A core part of a neuropsychological assessment is the administration of tests of cognitive functioning. Aspects of cognitive functioning that are assessed typically include attention, new-learning/memory, intelligence, processing speed, executive-functioning, and social pragmatics.

potentially concussive event. Events or incidents that may result in an individual experiencing a mTBI or concussion.

quality assurance. The systematic monitoring and evaluation of the various aspects of medical care to maximize the probability that minimum standards of quality are being met.

recurrent concussion. Three or more diagnosed mTBI/concussions within a 12 month period.

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