

**RESEARCH, DIAGNOSIS, AND TREATMENT FOR
TRAUMATIC BRAIN INJURY/CONCUSSION IN
SERVICEMEMBERS**

HEARING

BEFORE THE

SUBCOMMITTEE ON PERSONNEL

OF THE

COMMITTEE ON ARMED SERVICES
UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

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DECEMBER 13, 2017
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Printed for the use of the Committee on Armed Services



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RESEARCH, DIAGNOSIS, AND TREATMENT FOR TRAUMATIC BRAIN INJURY/CONCUSSION IN SERVICEMEMBERS

WEDNESDAY, DECEMBER 13, 2017

U.S. SENATE,
SUBCOMMITTEE ON PERSONNEL,
COMMITTEE ON ARMED SERVICES,
Washington, DC.

The committee met, pursuant to notice, at 10:09 a.m. in Room SR-222, Russell Senate Office Building, Senator Thom Tillis (chairman of the subcommittee) presiding.

Committee members present: Senators Tillis, McCaskill, Gillibrand, and Warren.

OPENING STATEMENT OF SENATOR THOM TILLIS

Senator TILLIS. We will bring the committee to order.

The witnesses on the first panel, please be seated.

Before I make an opening statement, I have to tell you that I am in my fifth day of what they call monocular vision. That is where my optometrist finally convinced me that I should try putting a contact lens in one eye, and then get my other eye to adjust to a distance. But right now, there is a fight between which eye is winning, so I had to get my staff to print the text a little bit larger, so I could make sure that I could go through the statement. But if you see me walking around in circles, you will know why.

[Laughter.]

Senator TILLIS. But thanks, everyone, for being here. I especially want to welcome some folks who will be speaking from North Carolina.

Before we get started, the Personnel Subcommittee of the Senate Armed Services Committee meets this morning to receive testimony from government and civilian witnesses on traumatic brain injury, or TBI. TBI occurs along a continuum, ranging from mild TBI (MTBI) or a concussion to severe and penetrating brain injury. While treatment for TBI varies with the severity of the injury, management of mild TBI includes treatment of symptoms such as headaches, memory problems, dizziness, and poor concentration, followed by slow return to normal activity.

From 2000 through the first half of 2017, the Department of Defense (DOD) diagnosed over 370,000 servicemembers with TBI. Of that total number of diagnoses, over 305,000 were mild TBIs.

We know, however, that mild TBI is not a unique problem within the Department of Defense. It is a national problem. Last year,

there were about 2.5 million emergency room visits related to concussions in the United States, and medical experts believe there were many more concussed individuals who did not seek medical care.

As a Nation, we must pursue multiple approaches to understand better the chronic effects of mild TBI, including the long-term neurodegenerative problems associated with multiple concussive injuries.

Today, we are fortunate to have a very distinguished group of witnesses joining us to discuss the diagnosis and treatment of mild TBI and to learn more about ongoing research on the effects of concussion on the brain.

On our first witness panel, we have Dr. David Dodick, professor of neurology, sports neurology, and concussion program director at Mayo Clinic; Steve Devick, CEO of King-Devick Technologies; and Dr. Chris Miles, medical director of athletics and associate director of sports medicine fellowship, Wake Forest University School of Medicine.

Dr. Miles, I already warned you that I want to welcome you because I have great regard for the academic programs at Wake. I have no regard whatsoever for your football program.

[Laughter.]

Senator TILLIS. With that stipulated, welcome to the committee. Ranking Member Gillibrand?

STATEMENT OF SENATOR KIRSTEN GILLIBRAND

Senator GILLIBRAND. Thank you so much, Mr. Chairman, for holding this hearing and for really shining a spotlight on something that is so important to both of us and to the entire military.

I join you in welcoming our witnesses today to discuss traumatic brain injury and the associated medical conditions. I am pleased that we have a variety of witnesses from different expertise inside and outside the government to discuss the current status of public and private advancements in diagnosis and treatment of TBI.

This is a very important topic not only for the military but for society at large. Every parent of a high school athlete worries about his or her son or daughter suffering a concussion, another word for mild TBI, and the long-term potential consequences of this injury. What we learn while studying TBI in the military may also apply to the treatment of their concussive injuries.

Certainly, we owe state-of-the-art care to our servicemembers who incur a traumatic brain injury as a result of their military duties. That is what this hearing is all about.

But it is more than that. Accurately diagnosing TBI is complicated by symptoms that overlap with post-traumatic stress disorder (PTSD), such as difficulty in concentrating, irritability or angry outbursts, and memory loss.

TBI and PTSD are commonly referred to as the signature wounds of war in our recent conflicts. Indeed, these are wounds of war, but there are other related wounds that also deserve more attention. We know that anxiety disorders, acute stress, sleep disorders, depression, substance use disorders, chronic pain, and other health conditions are also consequences of military service.

Reports indicate that there have been more than 370,000 servicemembers diagnosed with TBI from 2000 to 2017. At the same time, the Centers for Disease Control estimate that there are 2.8 million TBI-related emergency department visits, hospitalizations, and deaths a year.

The damage is not limited to the traumatic brain injury itself. Based on VA [Veterans Affairs] data, we know that veterans with a history of TBI are at higher risk for suicide, and other data shows an increase in diagnosis of dementia and Alzheimer's disease and chronic traumatic encephalopathy, commonly referred to as CTE, for those who have suffered a concussion and traumatic brain injury.

I am very concerned that servicemembers suffering from TBI, PTSD, and other service-connected conditions are too frequently disciplined and discharged with a bad-paper discharge for actions that are manifestations of these injuries. Servicemembers suffering from moderate or severe TBI can incur a lifetime of physical, cognitive, emotional and behavioral challenges. These challenges can manifest as drug- and alcohol-related misconduct, aggressive actions, charges, assaults, AWOLs [absent without leave], and failures to follow orders.

These bad-paper discharges are too often a consequence of suffering from military-induced conditions and result in veterans not being eligible for care for these conditions from the VA.

Military leaders must do a better job in taking these medical conditions into account when servicemembers are merely exhibiting the symptoms of their service-related injuries.

Mr. Chairman, thank you for the hearing.

Senator TILLIS. Thank you, Senator Gillibrand.

Gentlemen, each of you, we will just start from my left and go across, and you can spend up to maybe about 5 minutes on opening comments.

STATEMENT OF DAVID W. DODICK, M.D., SPORTS NEUROLOGY AND CONCUSSION PROGRAM DIRECTOR, MAYO CLINIC

Dr. DODICK. Mr. Chairman, Ranking Member, and distinguished members of the panel, it is, indeed, a privilege and honor to have this opportunity to appear before you today and provide testimony for this hearing on brain injuries in military servicemembers.

As was said, I am a professor of neurology and founder and director of the concussion program at the Mayo Clinic in Phoenix, Arizona. I have been involved in the evaluation and management of patients with concussion for over 21 years, and I currently oversee the clinical and research concussion programs at Mayo Clinic, several of which are funded by the Department of Defense and the National Institutes of Health.

I am the chair of the American Academy of Neurology's Concussion Committee, and I co-direct their annual Sports Concussion Conference. I am also the president-elect to International Concussion Society and co-founder of Concussion.org.

We will start with, what is a concussion? A concussion is often referred to as a head injury, but it is not synonymous with a head injury. It is, instead, an injury to the brain itself. This injury involves individual cells in the brain and the wiring that connects

them. There is both a primary and a secondary injury to the brain that results in dysfunction, disruption, and likely even death of living cells and their living connections.

The primary injury occurs from the direct impact of the blunt force or the rapid movement of the brain within the skull. But the secondary brain injury occurs because of an inflammatory response that occurs and the inability of stunned and sick cells to generate the energy required for their repair.

These primary and secondary injuries result in a breakdown of the normal electrical and chemical communication between cells, and it is this disruption of this extensive and interconnected communication grid that affects many sites in the brain and leads to the varied symptoms, several of which you already highlighted today, including physical, cognitive, emotional, and behavioral symptoms, that have an enormous impact on the individual, a very devastating one, and that actually affects the ability to function in daily life at work, at home, or in school.

So why is concussion a military and a public health priority? I think concussion by any measure is a health priority. It is very common, obviously. It can lead to permanent symptoms in some, and progressive neurological disease in others. Yet, as was alluded to, it remains significantly underdiagnosed.

For U.S. forces deployed in Afghanistan and Iraq in Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn, blast exposure was the leading cause of concussion. Blast injury results in the rapid transmission of an acoustic wave through the brain tissue.

Over the last 16 years, an estimated 320,000 U.S. troops, about 1 in 5, returning from active theater has sustained a concussion. Among those, almost half experienced symptoms consistent with post-traumatic stress or post-concussion syndrome.

Therefore, not surprisingly, there is a heavy personal, family, and financial cost of these injuries to our men and women in uniform. The cost of care alone has increased from \$21 million in 2003 to over \$650 million in 2010, and the median health care costs for veterans with traumatic brain injury is four times higher than those for veterans who do not experience traumatic brain injury.

Among civilians, nearly 4 million concussions occur every year. Among these, sport-related concussion has obviously received the most media and public attention. While there are several reasons for this, chief among them, I think, is the devastating, long-term neurological consequences that have been demonstrated in amateur and professional athletes who participate in contact sports. This should be of particular concern to all of us because there are over 46 million children and adolescents in the United States who participate in sport, and they, in particular, are uniquely vulnerable to the complications of concussion because of the effects of brain injury on a developing brain that hasn't fully matured.

Another vulnerable population that is often not talked about is women. Approximately 20 million women experience a domestic violence-related traumatic brain injury in this country every year. A recent study by the New York State Office for the Prevention of Domestic Violence revealed that 92 percent of the women in domestic violence shelters were hit in the head by their partners more

than once, and almost 1 in 10 were hit more than 20 times in the past year.

Concussion is underrecognized, as I said. While the reported number of concussions in this country is staggering, the actual number is much higher. It is estimated that only 1 in 6 concussions, especially in sport-related concussions, are recognized and diagnosed. This is due to a lot of different reasons, which I will get to.

One major reason for the lack of recognition of a concussive brain injury is the lack of symptoms. Just as brain injury from silent strokes and other silent lesions can occur in the brain, so too can silent concussions occur. These so-called subconcussive hits have been demonstrated to be far more frequent than actual concussions themselves, especially in contact sport athletes. These subconcussive injuries are especially important because the cumulative effect of subconcussive impacts results in a loss of the brain's normal architecture, and neurological and psychiatric consequences later in life.

Much of the research on subconcussive hits has been performed in athletes involved in contact sports. If you look at many of these studies, some of which I have outlined in the testimony, you will see that even in individuals who have not experienced a concussion, there is a loss of normal brain function in those individuals, both at a youth level as well as at a collegiate and a professional level.

These and other similar studies indicate that concussion is really the tip of the iceberg while subconcussive hits represent a larger, hidden danger that results in injury to the brain and lingering effects that are not being detected by current concussion assessment techniques.

While the majority of individuals, as was said, experience symptom resolution from a single concussion within a week or two, post-concussion syndrome or the persistence of symptoms beyond 4 weeks occurs in about 10 percent to 20 percent of individuals after a single concussion.

In children and adolescents, the percentage who experience persistent symptoms beyond 1 month has been shown to be at least 30 percent. Individuals who experience persistent symptoms may become functionally impaired or, indeed, permanently disabled.

In addition to post-concussion syndrome, repeated concussions and subconcussive hits can lead to permanent cognitive and psychiatric impairment, a syndrome known as traumatic encephalopathy syndrome (TES). In individuals with traumatic encephalopathy syndrome, symptoms persist for longer than 2 years and progress over time.

The symptoms and signs of TES, or traumatic encephalopathy syndrome, are similar to those seen in chronic traumatic encephalopathy, or CTE. As many of us know, CTE is a progressive degenerative brain disease that has been demonstrated to occur in individuals with a history of exposure to repeated head injuries.

Unfortunately, and this is something maybe we will get into, at this time, we do not yet know how to identify people who are at-risk of developing CTE, nor do we yet have a reliable method to

diagnose the disease before death or to intervene with treatment that prevents or disrupts the progression of the disease.

I will end with the challenge that we as clinicians taking care of these patients face. The diagnosis, I think, of concussion is challenging even for experts. The reasons for this are several.

First of all, many of the symptoms are subjective. They have to be reported by the athlete or the individual, and many times, they are not.

Or the symptoms, as I said, may be absent. They may have had a subconcussive hit or a silent concussion or brain injury. A lot of times, the visible signs may not be present. Even for those of us who have been examining patients for over 20 years, the signs can be so subtle that they are not picked up in the routine bedside neurological examination.

Finally, the detection of concussion often requires objective and quantitative tests that are not part of the routine neurological examination.

Even when the diagnosis of concussion is made, the challenge of managing the patient is difficult because there are no pharmacological agents, not a single one, that has been shown to be effective in improving symptoms or interrupting that secondary injury cascade that occurs that I alluded to earlier.

Another challenge for the clinician is knowing when the brain injury has stabilized. It has been well-demonstrated now that the brain injury continues and is not fully recovered long after the symptoms have resolved. So we are lulled into a sense of complacency, thinking that the examination is normal, the symptoms have resolved, and so that individual is ready to return to duty or ready to return to play, and that simply is not the case in many individuals.

It is during this window of time where the brain is uniquely vulnerable to repeat injury that may result in symptoms that persist or, more seriously, may result in permanent injury.

Determining if and when this window of vulnerability is closed is very challenging without expensive brain imaging that is not widely available, not feasible on a large-scale basis, and still not validated as a reliable clinical tool that can be used on an individual basis.

So what is needed? Given the challenges in diagnosis, treatment, and the ability to provide patients with a prognosis, I think there is an urgent need for objective, widely available, and cost-effective tests that do the following: rapidly and accurately identify when a concussion has occurred, allowing for the removal of that individual from the activities that place them at further risk; indicate when it is safe for an individual to return to their previous activities, and this will avoid exposing an individual to a repeat and potentially devastating injury; predict who is most vulnerable to repeated concussions; and predict who is at-risk of long-term symptoms and chronic neurological impairment from repeated concussions and subconcussive impacts.

We also need tests that accurately diagnose traumatic encephalopathy syndrome and chronic traumatic encephalopathy so that treatments, when developed, and I am optimistic they are

coming, can prevent the progression or at least ameliorate the symptoms of these diseases.

There is also, in addition to the diagnostic tests that are necessary, there is a serious need for treatments, treatments that can prevent these second injury cascades that are set in motion with that primary impact to the brain, because I think it is these second injury cascades that can persist for days, weeks, or longer that result in the progressive brain damage that occurs and likely results in the persistence of symptoms that these individuals experience.

I also think there is a need for treatments that facilitate the brain's ability to repair, adapt, and compensate for previous injury; to prevent the development of chronic neurodegenerative diseases; and to interfere with the progression of those diseases when they have already begun.

Until this occurs, I think we need to implement validated examination techniques that are sensitive for the detection of concussion immediately.

I am confident of the dedication and commitment of the scientists and clinicians involved in this field, several of whom are in this room. I am optimistic that the scientific and treatment advances will be realized for the benefit of millions of men, women, and children affected by concussion.

Mr. Chairman, Ranking Member, and distinguished members of the committee, thank you again for this opportunity and for your precious time and attention.

[The prepared statement of Dr. Dodick follows:]

PREPARED STATEMENT BY DAVID W. DODICK, M.D.

INTRODUCTION

Mr. Chairman, Ranking Member Gillibrand, and distinguished Members of the Committee, it is indeed a privilege and honor to have this opportunity to appear before you today and provide a testimony for this hearing on brain injuries in military servicemembers. I am a Professor of Neurology and the Founder and Director of the Concussion Program at the Mayo Clinic in Phoenix Arizona. I have been involved in the evaluation and management of patients with concussion for over 21 years, and I currently oversee the clinical and research concussion programs at Mayo Clinic. I am the co-director of the neuroimaging laboratory that is conducting brain imaging research in patients with concussion. This research is funded by the Department of Defense and National Institutes of Health. I helped develop a laboratory at Mayo Clinic that investigates the underlying pathological mechanisms involved after a concussive brain injury and collaborate closely with our basic research scientists in attempting to identify new targets for treatment that could ameliorate some of the consequences of concussive brain injuries. I am the Chair of the American Academy of Neurology's Concussion Committee, Director of the Concussion educational courses at the American Academy of Neurology's Annual Meeting, and Co-director of the Annual Sports Concussion Conference of the American Academy of Neurology. I am the President-elect of the International Concussion Society and Co-founder of Concussion.org.

WHAT IS A CONCUSSION?

- A concussion, often referred to as a head injury, is instead an injury to the brain itself. The injury involves individual cells and the wiring that connects them.
- There is both a primary and a secondary injury. The primary injury occurs from the direct impact of the blunt force or the rapid movement of the brain within the skull. The second injury occurs because of an inflammation response and the inability of stunned and sick cells to generate the energy required to repair.

- The primary and secondary injuries result in a breakdown in the normal electrical and chemical communication between cells. The disruption of this extensive and interconnected communication grid affects many sites in the brain and leads to the many symptoms that patients report.
- The symptoms of concussive brain injuries are physical, cognitive and emotional,
 - *Physical* symptoms include severe headache, nausea, vomiting, visual impairment, extreme sensitivity to light and sound, dizziness, vertigo, loss of coordination and balance, and in some cases, seizures.
 - *Cognitive* symptoms include amnesia, confusion, and decreased ability to concentrate, plan, reason, remember, problem solve, communicate, and make decisions.
 - The *emotional* symptoms of depression, agitation, impulsivity, aggression and violence, and rapid mood swings are often very distressing to patients and those around them.
 - Add to this a disruption in sleep-wake patterns, and the result is a pervasive and devastating impact on an individual and her/his ability to function in daily life at work, home or school.

WHY IS CONCUSSION A MILITARY AND PUBLIC HEALTH PRIORITY?

Concussion is by any measure a public and military health priority.

Most importantly, concussion is very common and yet significantly underrecognized, and can lead to permanent symptoms in some and progressive neurological disease in others.

Concussion is common

- For US forces deployed to Afghanistan and Iraq in Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OF), and Operation New Dawn (ONI), blast exposure is the leading cause of concussion. Blast injury is the result of the rapid transmission of an acoustic wave through the brain tissue. Over the last 16 years, an estimated 320,000 US troops (1 in 5) returning from active theater has sustained a concussion, and among those, almost half experience symptoms consistent with post-traumatic stress disorder (PTSD) or post-concussion syndrome.
- Therefore, not surprisingly, there is a heavy personal, family, and financial cost of these injuries to our men and women in uniform. The cost of care alone has increased from \$21 million in 2003 to \$646 million in 2010 and the median healthcare cost for veterans with traumatic brain injury is 4 times higher than those for veterans without traumatic brain injury.
- Among civilians, nearly 4 million concussions occur every year. Among these, sport-related concussion has received the most media and public attention. While there are several reasons for this, chief among them is the devastating long-term neurological consequences that have been demonstrated in amateur and professional athletes who participate in contact sport. This is of particular concern since there are over 46 million children and adolescents in the United States who participate in sport, and they are uniquely vulnerable to complications from concussion because of the effects on a developing brain.
- Another vulnerable population is women.
 - Approximately 20 million women experience a domestic violence-related traumatic brain injury each year.
 - A study conducted by the New York State Office for the Prevention of Domestic Violence (OPDV) revealed that 92 percent of the women in domestic violence shelters were hit in the head by their partners more than once, and 8 percent were hit in the head more than 20 times in the past year.

Concussion is under recognized

While the reported number of recognized concussions that occur each year is striking, the actual number is much higher.

- It is estimated that only 1 in 6 concussions, especially in sport-related concussions, are recognized and diagnosed. This is due in part to underreporting:
 - In a study of varsity athletes from the University of Pennsylvania, one-third of athletes who play a contact sport have hidden a concussion to stay in the game, and over 50 percent said they would be extremely unlikely or unlikely to report a concussion in a game situation.

- o Among high school athletes, 70 percent report playing with concussion symptoms and 70 percent did not think that the injury was serious enough to report.

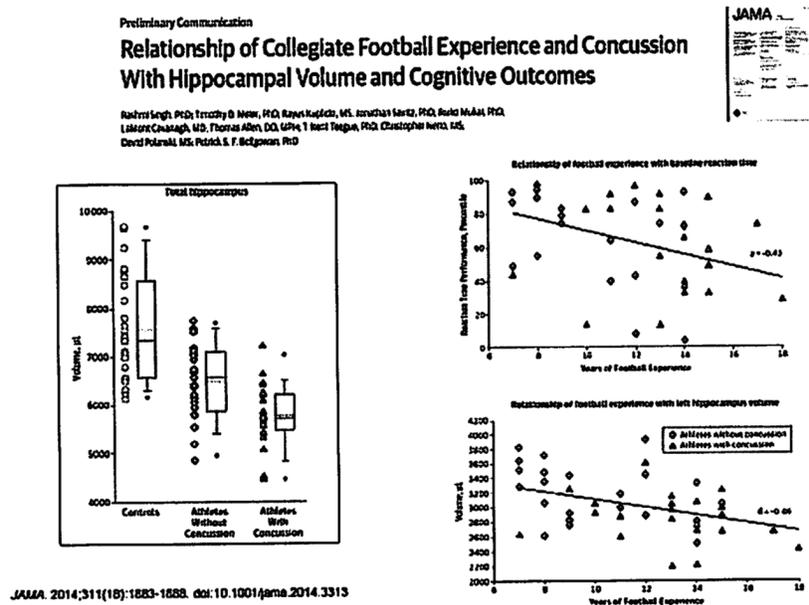
Another major reason for the lack of recognition of a concussive brain injury is the lack of symptoms. Just as brain injury from silent strokes and silent lesions of multiple sclerosis can occur, so too can silent concussions occur. These so-called “subconcussive” hits, have been demonstrated to be far more frequent than actual concussions, especially in contact sport athletes.

- o Offensive lineman in football can experience over 1000 subconcussive hits to the head in a single collegiate season.
- o The average child or adolescent playing youth ice hockey or football sustains over 200 hits to the head in a season.

These subconcussive injuries are especially important because the cumulative effect of subconcussive impacts results in a loss of the brain’s normal architecture and neurological and psychiatric consequences later in life. Much of the research on subconcussive hits has been performed in athletes involved in contact sport.

- o For example, in a study of collegiate football athletes, there was a significant correlation between years of football played, the size of the brain’s hippocampus (a vital brain structure involved in cognitive and emotional function), and cognitive performance. This association occurred in athletes with and without a prior diagnosis of concussion. (Figure 1).

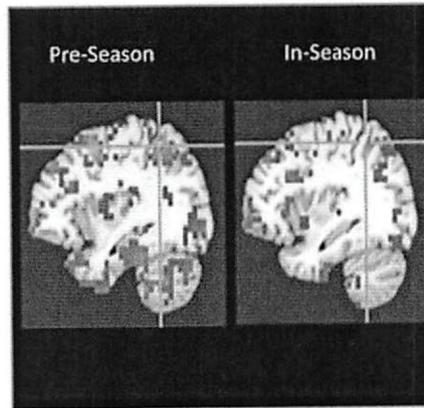
Figure 1:



- Similar results have been shown in youth athletes. In one study of male high school football athletes (ages 15–19) evaluated mid-season, those without a history of concussion showed alterations in working memory that correlated with abnormal changes on their functional brain MRI scans. (Figure 2).

Figure 2:

**Functional Brain Imaging Changes in
15-19 year old Football Players *Without* Concussion**

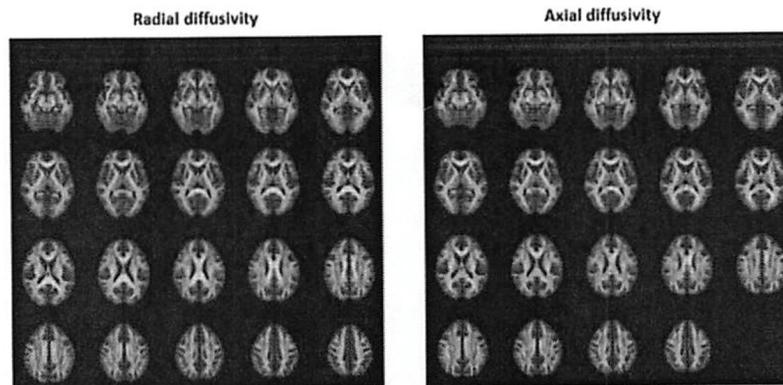


Talavage T.M., et al. J Neurotrauma 2010

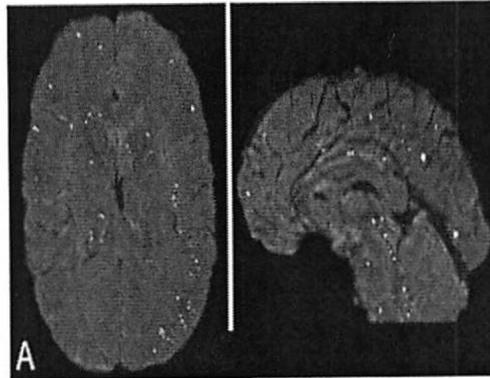
The effects of subconcussive brain injury has also been demonstrated in athletes participating in other contact sports. Changes in the integrity of the brain's wiring (white matter tracks) has been demonstrated in professional soccer players who did not report concussion (Figure 3), while small brain hemorrhages (bleeding) has been shown to occur in concussed and non-concussed hockey players (Figure 4).

Figure 3:

**White Matter Integrity in Brains of Pro Soccer Players *Without*
Symptomatic Concussion**



Koerte IK, et al. JAMA 2012;308:1859-1861

Figure 4:**Very Small (<5mm) Cerebral Microhemorrhages in Athletes With and Without Symptomatic Concussion**

Heimer KG, et al. *J Neurosurg* 2014; 120:864–872.

These and other similar studies indicate that concussion is the tip of the iceberg while subconcussive hits represent a large hidden danger that results in injury to the brain and lingering effects that are not being detected by current concussion assessment techniques.

Concussion can result in persistent/permanent/progressive brain injury and neuropsychiatric impairment

While the majority of individuals experience symptom resolution from a single concussion within several weeks, postconcussion syndrome (PCS), or the persistence of symptoms beyond 4 weeks, occurs in 10–20 percent of individuals after concussion. In children and adolescents, the percentage who experience persistent symptoms beyond 1 month has been shown to be at least 30 percent. Individuals who experience persistent symptoms may become functionally impaired or permanently disabled.

In addition to PCS, repeated concussions or subconcussive hits can lead to permanent cognitive and psychiatric impairment—a syndrome known as

Traumatic encephalopathy syndrome (TES). In individuals with TES, symptoms persist for longer than 2 years and progress over time. The symptoms and signs of TES are similar to those seen in chronic traumatic encephalopathy (CTE). CTE is a progressive degenerative brain disease that has been demonstrated to occur in individuals with a history of exposure to repeated head injuries. You will hear much more about this devastating disease from my esteemed colleague, Professor Robert Stern.

THE CHALLENGE FOR THE CLINICIAN

The diagnosis of concussion is challenging, even for experts. The reasons for this are several:

- Symptoms are subjective and may not be reported
- Symptoms may be absent (subconcussive brain injury)
- Visible signs may not be present
- Detection of concussion often requires objective and quantitative tests that are not part of the routine neurological examination

Even when the diagnosis of concussion is made, the challenge of managing the patient is difficult because there are no pharmacological agents that have been shown to be effective in improving symptoms or interrupting the secondary injury that occurs in the brain.

Another challenge for clinicians is knowing when the brain injury has stabilized. There is a period of instability in the brain that may last weeks or months beyond the time point when symptoms resolve.

During this window of time, the brain is vulnerable to a repeat injury that may result in symptoms that persist, are more serious, or may become permanent. Determining if and when this window of vulnerability has closed is very challenging without expensive brain imaging that is not widely available, not feasible on a large-scale basis, and still not validated as a reliable clinical tool that can be used on an individual basis.

WHAT IS NEEDED?

Given the challenges in diagnosis, treatment, and ability to provide patients with a prognosis, there is an *urgent need for objective, widely available, and cost-effective diagnostic tests* that:

- Rapidly and accurately identifies *when a concussion has occurred* allowing for the removal of the individual from activities that place them at risk of a repeat and more devastating injury.
- Indicate *when it is safe to return the individual to their previous activities*. This will avoid exposing an individual to a repeat and potentially more devastating injury.
- Predict *who is most vulnerable to repeat concussion(s)*.
- Predict *who is at risk of long-term symptoms and chronic neurological impairment* from repeat concussions and subconcussive impacts. This will facilitate the ability of health care providers and patients to make informed decisions about the risks associated with activities that increase their exposure.
- *Accurately diagnose traumatic encephalopathy syndrome and chronic traumatic encephalopathy*, so that treatments, when developed, can prevent the progression or ameliorate the symptoms of these diseases.

There is also a *serious need for treatments* that can:

- *Prevent the secondary injury cascades* that are set in motion in the brain after the primary injury from the initial impact. These changes can persist for hours, days, and potentially longer after the initial impact. The ability to disrupt these damaging cascades must be a focus of future research since they lead to further damage that increase the risk of persistent symptoms and progressive brain degeneration.
- Facilitate the brain's ability to repair, adapt, and compensate for previous injury.
- Prevent the development of chronic neurodegenerative diseases in those at risk
- Interfere with the progression in those in whom these diseases have already begun.

Until this occurs, diagnostic tools that have been validated and examination techniques that are sensitive for the detection of concussion should be implemented immediately.

I am confident in the dedication and commitment of the scientists and clinicians involved in this field and optimistic that scientific and treatment advances will be realized for the benefit of millions of men, women and children affected by concussion.

Mr. Chairman, Ranking Member Reed, and distinguished Members of the Committee, thank you again for this opportunity and for precious time and attention.

References

1. Wojcik BE, et al. Traumatic brain injury hospitalizations of U.S. army soldiers deployed to Afghanistan and Iraq. *Am J Prev Med.* 2010;38:S108–16.
2. Hoge CW, et al. Mild traumatic brain injury in U.S. Soldiers returning from Iraq. *N Engl J Med.*
3. Bell RS, et al. Military traumatic brain and spinal column injury: a 5-year study of the impact blast and other military grade weaponry on the central nervous system. *J Trauma.* 2009;66:S104–11.
4. Terrio H, et al. Traumatic brain injury screening: Preliminary findings in a U.S. Army Brigade Combat Team. *J Head Trauma Rehabil.* 2009;24:14–23.
5. DOD worldwide numbers for TBI. <http://dwbic.dcoemil/dod-worldwide-numbers-tbi.2016>.

6. Frieden T, Collins F. Report to Congress on expenditures for activities on traumatic brain injury and psychological health, including post-traumatic stress disorder. U.S. Department of Defense. 2010.
7. National Center for Injury Control and Prevention, Costs of Intimate Partner Violence Against Women in the United States. Atlanta: Centers for Disease Control and Prevention, 2003. Available online at: <https://www.cdc.gov/violenceprevention/intimatepartnerviolence>.
8. McCrea M, et al. Unreported concussion in high school football players Implications for prevention, Clin J of Sport Med 2004;14:13–17.
9. Talavage T., et al. Functionally-detected cognitive impairment in high school football players without clinically-diagnosed concussion. J Neurotrauma 2013. <https://www.ncbi.nlm.nih.gov/pubmed/20883154>.
10. Singh R, et al. Relationship of Collegiate Football Experience and Concussion With Hippocampal Volume and Cognitive Outcomes. JAMA. 2014;311:1883-1888. doi:10.1001/jama.2014.331
11. Koerte IK, et al. White Matter Integrity in the Brains of Professional Soccer Players Without a Symptomatic Concussion. JAMA. 2012;308:1859–1861. doi:10.1001/jama.2012.1373
12. Helmer KG, et al. Hockey Concussion Education Project, Part 1. Susceptibility-weighted imaging study in male and female ice hockey players over a single season. J doi: 10.3171/2013.12.JNS132093.
13. Barlow KM. Postconcussion Syndrome. A Review. J Child Neurology. 2014; 31:57–67.
14. Reams N, et al. A Clinical Approach to the Diagnosis of Traumatic Encephalopathy Syndrome: A Review. JAMA Neurol. 2016;73:743–749. doi:10.1001/jamaneur01.2015.5015
15. Mez J, et al. Clinicopathological Evaluation of Chronic Traumatic Encephalopathy in Players of American Football. JAMA 2017;318:360–370. doi:10.1001/jama.2017.8334

Senator TILLIS. Thank you.
Dr. Devick?

STATEMENT OF STEVEN D. DEVICK, M.D., CHIEF EXECUTIVE OFFICER KING-DEVICK TECHNOLOGIES, INC.

Dr. DEVICK. Mr. Chairman, Ranking Member Gillibrand, and distinguished members of the committee, it is a high honor for me to appear before you today.

I am the CEO of King-Devick technologies (KDt). We develop objective, physical, electronically transmittable tests of eyes and brain function, which are validated in peer-reviewed medical journals, and that are able to be administered by laypersons.

Before beginning, I would like to recognize Tregg Duerson, who is right there. Tregg is the son of NFL [National Football League] two-time Super Bowl winner Dave Duerson of the Chicago Bears and the New York Giants. Dave was a friend of mine. He was a brilliant scholar-athlete who graduated with honors from Notre Dame and later took his own life at 50 years old by shooting himself in the chest, so that his brain could be evaluated, because he was fairly certain he had chronic traumatic encephalopathy (CTE). He did, indeed, have an advanced case of CTE, although he was diagnosed with very few concussions in his career.

Tregg is a highly successful businessman now, and he is also a former Notre Dame athlete. His dad was drafted by a Montreal baseball franchise, too. Tregg has often said, if he played baseball, he probably would still be alive today.

But anyway, he has dedicated his life to doing something about CTE, which is a prevalent problem, called to attention again this week when the NFL had an issue with a diagnosis on the sidelines.

As far as our products are concerned, in a DOD- and NCAA-[National Collegiate Athletic Association] funded study published in November 2017 in a peer-reviewed journal, it was found that King-Devick tests were shown to have the highest test-retest reliability when compared with more than a dozen other concussion tests. This article was authored by members of the CARE Consortium, the NCAA, and the Department of Defense.

In May of 2017, King-Devick Technologies was one of a group of participants ranging from Federal Government representatives, private industry, professional medical research and veteran communities invited to compete in the VA's annual Brain Trust Innovation summit. King-Devick Technologies was selected as a winner of the 2017 Innovation awards for its brain injury remediation and rehabilitation applications utilizing technology that allows for faster recovery from TBI and from concussions as well.

Because the diagnosis of MTBI concussions in servicemembers and everyone often relies on history alone, the DOD-VA clinical practice guidelines indicate that a confirmatory, objective test for concussions that could be used to direct support and/or predict outcomes would be desirable. In 2016, a group of military officers who were doctors identified the King-Devick test as a solution.

The quote from their article was, "We recommend the King-Devick test be utilized as a supplementary screening tool in those who have suffered a concussive event. Having preinjury King-Devick test data will allow more precise determination. Therefore, we recommend the test be included as a baseline for all warfighters prior to exposure to risk of MTBI. Having a validated, rapid, easy-to-assess brain-screening test can assist frontline providers in making return-to-duty decisions."

Since 2011, more than 110 peer-reviewed articles have been published in elite medical journals validating these King-Devick applications. These articles describe the products as clinical biomarkers, not serum biomarkers, and other aspects of the test helped in remove-from-play decisions. The effectiveness of this detection led to its cobranding with the Mayo Clinic, the first cobranding agreement ever entered into throughout Mayo Clinic's 150-year history. The test, now known as the King-Devick test in association with Mayo Clinic, is the most validated sideline screening tool for concussions currently available.

Changes in performance can easily be transmitted to inform diagnostic and related clinical service provision and guide clinical decision-making from theater to medical treatment facility.

Thank you.

[The prepared statement of Dr. Devick follows:]

PREPARED STATEMENT BY STEVE DEVICK

Mr. Chairman, Ranking Member, and distinguished Members of the Committee, it is a high honor for me to appear before you today.

I am the Chief Executive Officer of King-Devick technologies, inc. We develop objective, physical and electronically transmittable tests of eyes and brain function which are validated in peer reviewed medical journals and are able to be administered by lay persons. Before beginning I'd like to recognize Tregg Duerson. Tregg is the son of NFL two-time Super Bowl winner Dave Duerson of the Chicago Bears and NY Giants. Dave was a friend of mine, brilliant scholar athlete who graduated with honors from Notre Dame and later took his own life at 50 years old by shooting himself in the chest, so that his brain could be evaluated for chronic traumatic

encephalopathy (CTE). He did indeed have an advanced case of CTE, although was diagnosed with very few concussions in his career. Tregg is himself a high-quality individual, who is also a former Notre Dame football player and successful businessman. For Tregg, prevention of this neuro-degenerative disease, which can only be caused by repetitive head trauma, is one of his life's priorities.

Improving the population health of servicemembers at risk for traumatic brain injury (TBI) is fundamental to the DOD- operated Military Health System (MHS). A key role involves supporting the medical personnel and programs that address the needs of servicemembers who have had and/or are at risk for TBI as well as mild TBI (mTBI), often referred to as a concussion, both on the battlefield and off. In a DOD/NCAA funded study, published in November, 2017, in the peer reviewed journal, *Sports Medicine*, it was found that the King-Devick test was shown to have the highest test-retest reliability when compared with more than a dozen other concussion tests. This article was authored by members of the Care Consortium, the NCAA, and the Department of Defense.¹

An estimated 10 to 30 percent of concussions result in a prolonged recovery period (i.e., post-concussion syndrome) and individuals can report new/persistent/worsening symptoms weeks, months, or sometimes years post-injury that require ongoing intervention? In addition, servicemembers exposed to repetitive concussive or sub-concussive events, especially those lacking early identification and accurate diagnosis of prior TBI, are at high risk for a myriad of long-term negative consequences to brain health including the development of neurodegenerative diseases as Dr. Dodick described.³

KDt was recently one of a group of participants ranging from the Federal Government, private industry, professional medical research, and veterans communities, invited to compete in the VA's annual Brain Trust InnoVation Summit. KDt was selected as a winner of the 2017 VA InnoVatlon Award for its brain injury remediation and rehabilitation applications utilizing technology that allow for faster recovery from TBI and concussion.

These applications are a readily available resource for the DOD to meet the unique needs of servicemembers. Some of the benefits are:

- *Rapid, reliable, mobile, quantitative screening and detection of mTBI eliminates subjectivity,*
- *Immediate administration by laypersons/caregivers in real time, both in theater and out, which facilitates earliest possible intervention and treatment*
- *Validated, objective, physical performance metrics inform the full spectrum of clinical decision making with high strength of evidence*
- *Cost-effectiveness and ease of implementation expedites screening and monitoring of all target populations, including acute and chronic care*
- *Telehealth compatibility extends applications for use in treatment and rehabilitation of mTBI*

The 2016 Department of Defense (DOD), Department of Veterans Affairs (VA) and Clinical Practice Guideline (CPG) for the Management of Concussion-mTBI benchmarks current recommendations and protocols for servicemembers.² In addition to including a review of earlier reports, the DOD/VA/CPG serves as an evidence-based resource for procedures, recommendations, and health care information relative to the comprehensive continuum of mTBI in the Armed Services. The DOD/VA/CPG recommends that early identification and management of mTBI/concussion in servicemembers close to the time of injury is best for providing optimal care and preventing persisting symptoms.² Because the diagnosis of mTBI/concussion in servicemembers often relies on history alone, the DOD/VA/CPG evidence indicates that:

“... a confirmatory objective test [for concussion-mTBI] ... that could be used to direct support treatment and/or predict outcomes would be desirable ...”²

¹ Broglio SP, Katz BP, Zhao S, McCreary M, et al. Test-retest reliability and interpretation of common concussion assessment tools: finding from the NCAA–DOD CARE Consortium. *Sports Med*. 2017 Nov 14. doi: 10.1007/s40279-017-0813-0.

³ McKee AC, Cairns NJ, Dickson DW, Folkerth RD, et al. The first NINDS/NININ consensus meeting to define neuropathic criteria for the diagnosis of chronic traumatic encephalopathy. *Acta Neuropathol*. 2016;131:75–86.

² The Defense Health Agency 2016 Report. Downloaded from: <https://health.mil/ReferenceCenter/Reports/2017/06/08/Defense-Health-Agency-2016-Stakeholder-Report>. Accessed August 21, 2017.

and the *King-Devick Test* was identified as a solution to this need in a 2016 peer reviewed article published in the Journal for the Neurological Sciences which was authored by U.S. military officers:

*“... we recommend the King-Devick Test be utilized as a supplementary screening tool in those who have suffered an MTBI event ... having pre-injury K-D test data will allow a more precise determination; therefore we recommend that this test be included as a baseline test for all warfighters prior to exposure to risk of mTBI/concussion ... having a validated, rapid, easy-to-assess mTBI brain screening test can assist frontline providers in making (return-to-duty) decision”*⁴

Further, the DOD/VA/CPG confirms the existence of a critical gap involving objective physical assessment of individuals suspected of mTBI as stated in the reported finding that:

*“... unfortunately, at this time, evidence does not support the use of any laboratory (i.e., serum biomarkers), neuroimaging, or physiological (i.e., EEG) test” for the definitive diagnosis of mTBI or to direct treatment.*²

As a solution to this issue, this product provides a validated objective physical measure which both assists in the diagnosis and treatment of TBI, and serves as a real-world screening tool for identification of neurological insult.

CONCUSSION/MTBI SOLUTIONS FOR SERVICEMEMBERS:

Since 2011 more than 110 peer reviewed articles have been published in elite medical journals validating these applications (please see *Abstracts Summary* available at <https://kingdevicktest.com/ResearchAbstracts>). These articles demonstrate the efficacy of these products as:

- *clinical biomarkers to aid in the prompt and accurate diagnosis of mTBI;*
- *a remediation tool in the rehabilitation of mTBI and*
- *an outcome measure for monitoring function relative to sleep deprivation, hypoxia, and progressive neurodegenerative diseases*

The effectiveness of this product in concussion detection led to its co-branding with the Mayo Clinic, the first co-branding agreement ever entered into throughout Mayo Clinic’s 150-year history. The test, now known as the *King-Devick Test in association with Mayo Clinic* is the most validated sideline tool for the screening and diagnosis of concussion currently available.

We propose full scale adoption and integration of this test and related suite of mTBI/concussion applications by the DOD for servicemembers and the MHS. It has been assessed across a variety of cohorts that include all levels of contact sports (football, boxing, mixed martial arts, rugby, hockey). The test provides an objective performance measure that utilizes eye movement, attention, concentration and language function. These functions involve the integration of brainstem, cerebellum, and cerebral cortex, and K-D Test performance correlates with suboptimal brain function in concussion/mTBI. A 2015 meta-analysis and systematic review confirmed *K-D Test as a highly sensitive (86 percent) and specific (90 percent) rapid objective sideline tool for the detection of concussion.*⁵ These products are tablet-based and can be routinely administered by non-physician health care professionals and laypersons alike. Performance metrics are electronically stored on the tablet for synchronization to EHR databases when convenient. Changes in performance can be easily transmitted to inform diagnostic and related clinical service provision and guide clinical decision making from theater to medical treatment facility.

These products are utilized by many elite sports professional sports leagues, college and schools around the world.

The strengths of these applications are in their versatility to address a myriad of issues that can dramatically improve individual and population health of servicemembers while reducing negative impacts of mTBI and its sequelae.

Senator TILLIS. Thank you.

Dr. Miles, I should say that my senior member from North Carolina probably has a decidedly different view of the Wake program,

⁴ Walsh DV, Capo-Aponte JE, Beltran T, Cole WR, et al. Assessment of the King-Devick Test for screening acute mTBI/concussion in warfighters. *J Neurol Sci.* 2016;370:305–309.

⁵ Coldren RL, Russell ML, Parish RV, Dretsch M, et al. The ANAM lacks utility as a diagnostic or screening tool for concussion more than 10 days following injury. *Mil Med.* 2012;177:179–83.

so you have some balance there in the delegation. You can provide your opening statement.

STATEMENT OF CHRISTOPHER M. MILES, M.D., ASSOCIATE DIRECTOR, SPORTS MEDICINE FELLOWSHIP, WAKE FOREST UNIVERSITY

Dr. MILES. Very good, sir. Chairman Tillis, Ranking Member Gillibrand, and honorable members of the committee, thank you for this opportunity to discuss concussion from an academic clinician's perspective.

I currently serve as the medical director of athletics and the head team physician for Wake Forest University, the associate director of the Primary Care Sports Medicine Fellowship at the School of Medicine, and the site principal investigator to the NCAA- and Department of Defense-sponsored CARE Consortium Research Study.

As a former college football player who has experienced concussion, I have seen all sides of this condition. Unlike many medical diagnoses, concussion is not yet well understood. This enigmatic condition not only has different presentations, causes, and outcomes for patients, but it also has very little evidence-based guided evaluation and management options, though research is changing this. Much of the management recommendations for sport-related concussion have been driven by consensus statements released over the last decade.

The most recent release of this came in 2017 as the result of the fifth International Consensus Conference on Concussion in Sport. Although the conference makes a distinction between sport-related concussion and nonsport-related concussion, many of the key principles are shared between these two entities.

I have been fortunate to be part of several different research studies investigating the natural history of the condition, evaluation tools, and management options. The largest and most well-known of these is the NCAA and DOD CARE study. As part of the Grand Alliance, the CARE study is designed to answer scientific questions about the course and neurobiology of concussion in a definitive way. With 30 sites, including the four military academies, over 37,000 athletes and cadets have been enrolled, and over 2,500 concussive events have been captured and studied. This is nearly 100 times the number of subjects in the average concussion study.

Through this study, the NCAA and DOD Grand Alliance is setting the standard for concussion research and clinical care. The collaboration between universities and the military academies has provided data that is absolutely unprecedented.

Although it has been just over 3 years since its inception, this consortium has impacted the practice of concussion management in several ways. Perhaps most important to this committee is the finding that, historically, there have been some undue delays in the return to duty of nonathlete cadets. This finding has changed management of concussion at the academies.

Unfortunately, the consortium is at a watershed moment. Funding for continuation of this highly important research has expired. An application for CARE 2.0, a study to further our knowledge, especially in areas of neurobiology and long-term outcomes, was declined by the Department of Defense.

The NCAA has agreed in principle to supporting the CARE 2.0 initiative, but funding from the DOD has not yet been secured. It is my hope that this committee sees the benefit in continuing this highly important work.

In addition to the work with the CARE study, our group at Wake Forest is involved in force sensor research through helmet and mouthpiece sensors, post-concussive biomarker data, and the role of genetics in post-concussion syndrome. We are also particularly active with the study of concussions in youth football.

Also being studied are blood and saliva tests to determine if we can predict which patient will have prolonged symptoms, and brain imaging techniques that may provide similar predictability information.

These types of studies are vitally important as, clinically, no two concussions are created equal. It is crucial that we develop an objective test that will help diagnose and guide the management of this condition.

There are current tools, such as the King-Devick, but there is not yet a gold standard for concussion testing. If an imaging or a blood test similar to what we have for evaluating heart attacks were to be discovered, the evaluation and management could be standardized.

Perhaps of equal importance, if we were able to identify a gene that may predispose patients to the long-term sequelae of concussion, we could counsel those patients on avoiding potentially higher risk activities.

We are still too early in the study process of biomarkers, imaging, and gene identification to include them in clinical decision-making. More research funding will help to determine if these advances are, in fact, predictive and, if so, which ones do this the best.

I believe the importance of the collaboration between military and civilian clinicians and researchers in tackling the best way to diagnose and treat concussions is crucial.

Although the causes of injuries may be different, though certainly not always, the importance of being able to accurately diagnose and provide the best treatment is the same.

When a condition does not have an objective test that cannot be manipulated, there is always the risk that symptoms may be feigned. A student or soldier that wants to avoid an activity could falsely report symptoms. A truly objective test will assist in guiding not only diagnosis of actual concussion injuries but will allow for a more rapid return to learning and activity in those who would not test positive.

Many entities have helped raise awareness of concussion to our society at large. We are likely more educated on the prevention and identification of concussion than ever before. Most athletes and military personnel recognize the importance of this topic for their safety and well-being.

However, there is still great work to be done. We must make activities safer and less of a burden on long-term health and the health care system. Researchers and clinicians must continue to grow the data needed to make evidence-based recommendations and funding bodies must continue to make this topic a priority.

Thank you for your time, and I look forward to your questions.
[The prepared statement of Dr. Miles follows:]

PREPARED STATEMENT BY CHRISTOPHER MILES, MD

Chairman Tillis, Ranking Member Gillibrand, and Honorable Members of the Committee, thank you for this opportunity to discuss concussion and its research, evaluation, and management from an academic clinician's perspective.

My name is Christopher Miles, MD, and I currently serve as the medical director of athletics for Wake Forest University, the associate director of the primary care sports medicine fellowship at Wake Forest University School of Medicine, and as the site Principal Investigator (PI) for the National Collegiate Athletic Association (NCAA)-Department of Defense (DOD) sponsored CARE Consortium research study. In addition, I maintain other academic and research duties involving concussion (also referred to as mild traumatic brain injuries). As a former college football player who has experienced concussion injuries as an athlete, I have seen all sides of this condition.

Unlike many medical diagnoses, concussion is not yet well understood. This enigmatic condition not only has different presentations, causes, and outcomes among patients, it also has very little evidence-based guided evaluation and management options. Through research, this is changing; we are growing our understanding of the many facets of this condition.

Much of the management recommendations have been driven by consensus statements released over the last decade. The most recent release of this came in 2017, as a result of the Fifth International Conference on Concussion in Sport, held in Berlin in 2016. This conference gathers scientists and clinicians to evaluate current research to help guide evaluation and management of sport related concussion (SRC). Although the conference makes a distinction between SRC and non-SRC, many of the key principals are shared between these two entities.

A commonly accepted definition of SRC is:

[A] traumatic brain injury induced by biomechanical forces. Several common features that may be utilized in clinically defining the nature of a concussive head injury include:

- *SRC may be caused either by a direct blow to the head, face, neck or elsewhere on the body with an impulsive force transmitted to the head.*
- *SRC typically results in the rapid onset of short-lived impairment of neurological function that resolves spontaneously. However, in some cases, signs and symptoms evolve over a number of minutes to hours.*
- *SRC may result in neuropathological changes, but the acute clinical signs and symptoms largely reflect a functional disturbance rather than a structural injury and, as such, no abnormality is seen on standard structural neuroimaging studies.*
- *SRC results in a range of clinical signs and symptoms that may or may not involve loss of consciousness. Resolution of the clinical and cognitive features typically follows a sequential course. However, in some cases symptoms may be prolonged.*

The clinical signs and symptoms cannot be explained by drug, alcohol, or medication use, other injuries (such as cervical injuries, peripheral vestibular dysfunction, etc.) or other comorbidities (e.g., psychological factors or coexisting medical conditions). (McCrorry, 2017)

This definition has stayed consistent since 2000, though prior to that an exact or reproducible definition did not exist—making studies performed prior to that date hard to interpret and non-recognizable.

I have been fortunate to be a part of several different research studies investigating the natural history of this condition, evaluation tools, and management options.

The largest and well known of these studies is the NCAA–DOD CARE study, the largest study of concussion to date.¹ As part of the NCAA–DOD Grand Alliance, the CARE study is designed to answer scientific questions about the course and neurobiology of concussion in a definitive way. With 30 sites, including four military academies, over 37,000 athletes and cadets have been enrolled and over 2,500 con-

¹For the specific details on the Grand Alliance and the CARE study, please see www.careconsortium.net.

ussion events have been captured and studied—nearly 100 times the number of concussions in the average concussion study.

Through this study, the NCAA–DOD Grand Alliance is setting the standard for concussion research and clinical care. The collaboration between colleges and universities at all levels of athletic participation and the military academies has provided data that is absolutely unprecedented. Although it has been just over three years since its inception, this consortium has impacted the practice of concussion management in several ways. The identification that there is a difference between “asymptomatic” and being ready to return to contact has improved safety. Perhaps most important to this Committee is the finding that, historically, there has been some undue delay in return to duty of non-athlete cadets. This finding has changed management of concussion at the academies.

Unfortunately, the consortium is at a watershed moment. Funding for continuation of this highly important research has expired. An application for CARE 2.0, a study to further our knowledge—especially in areas of neurobiology and long-term outcomes—and capitalize on the work already invested, was declined by the DOD. The NCAA has agreed in principle to supporting the CARE 2.0 initiative, but the funding from the DOD has not yet been secured. It is my hope that this Committee sees the benefit in continuing this highly important work.

In addition to the work with the CARE study, our research group at Wake Forest University School of Medicine is also involved in force sensor research through helmet and mouth piece sensors, as well as with post-concussion biomarker data. Our bioengineering department has been a leader in helmet sensor research and highly active in the study of concussion in youth football. Our group has also been studying the role of brain injury bio-markers (substances released into the bloodstream after brain injury) and the role of particular genes that may predispose an individual to post-concussive syndrome.

Other groups across the country are studying similar blood tests to determine if we can predict which patients will have prolonged symptoms and which may recover sooner. Similar areas of study both with our group at Wake Forest University School of Medicine and other institutions are looking for brain imaging techniques that may provide similar predictability information.

These types of studies are vitally important; clinically, no two concussions are created equal. It is crucial that we develop an objective test that will help diagnose and guide the management of concussion. There are currently tools, such as neurocognitive testing, balance testing, and eye-tracking testing, that provide some insight, but there is no gold standard for concussion testing.

If a blood test or an imaging test, similar to what we have for evaluating heart attacks, were to be discovered, the evaluation and management of concussion could be standardized. Perhaps of equal importance, if we were able to identify a gene that may predispose patients to the long term sequela of concussion, we could counsel those patients on avoiding potentially higher risk activities. Attempts to identify genes such as the apolipoprotein E (APOE) as potential risks for concussion to date have been inconclusive.

We are still too early in the study process of biomarkers, imaging, and gene identification to include them in the clinical decision-making. More research funding will help to determine if any of these advances are in fact predictive and, if so, which ones do this the best.

We currently know that concussion risk and natural history appears to be different in females and males. As more females become active in military and athletic activities, the importance of identifying and understanding these differences becomes greater. If we can identify a role of hormonal fluctuation in the course of this condition, treatment options for both men and women may be improved. We performed a pilot study looking at the use of progesterone in the acute phase of concussion to determine if this type of study would be feasible. Although the study was not powered for the outcome of the drug intervention, we were able to determine that this type of study was possible. Others in the research arena continue to investigate treatment options and unfortunately to date there are no good options.

I believe the importance of the collaboration between military and civilian clinicians and researchers in tackling the best way to diagnose and treat mild traumatic brain injuries is crucial. The findings from research in one group are certainly applicable to the care of the other. Although the causes of injuries may be different (though certainly not always), the importance of being able to accurately diagnose and provide the best treatment is most often the same. When a condition does not have an objective test (blood test, imaging) that cannot be manipulated, there is always the risk that condition may become a condition of convenience. The risk that a student who does not want to take a test or a soldier who does not want to participate in a certain activity may feign symptoms of a concussion is real. A truly objec-

tive test will assist in guiding not only diagnosis of actual concussion injuries, but allow for a more rapid return to learning and activity in those who may not test positive.

Medical organizations, athletic groups, the military, and the media have helped raise awareness of concussions to society at large. Parents, coaches, and other superiors are likely more educated on concussion prevention and treatment than ever before. Similarly, most athletes and military personnel recognize the importance of this topic for their safety and well-being.

However, there is still great work to be done. Evaluation, diagnosis, and treatment of concussion should be just as standardized as other injuries or illnesses, driven by solid evidence-based practice. We must make activities safer, more enjoyable, and less of a burden on long-term health and the health care system.

Researchers and clinicians must continue to grow the data needed to make evidence-based recommendations. Funding bodies must continue to make this topic a priority.

Thank you for your time, and I look forward to your questions.

References:

McCrorry P, Meeuwisse WI-I, Dvorak J, et al. Consensus statement on concussion in sport: the 5th international conference on concussion in sport held in Berlin, October 2016. *Br J Sports Med*

McCrorry P, Meeuwisse WH, Aubry M, et al. Consensus statement on concussion in sport: the 4th international conference on concussion in sport held in Zurich, November 2012. *Br J Sports Med* 2013 ; 47:250-8.

www.careconsortium.net

Senator TILLIS. Thank you all.

I have a question for Dr. Devick. Can you give me an idea of the cost, the timing of the tests, and where these tests can be administered?

Dr. DEVICK. Did you say the cost?

Senator TILLIS. Yes.

Dr. DEVICK. The cost is less than \$20 per year per individual for unlimited testing. So there is very little cost involved.

Senator TILLIS. When is the test administered? After somebody has experienced an injury that you are testing for? Or is it something that you do on a recurring basis to a larger population?

Dr. DEVICK. The sideline application that we are partners with Mayo Clinic on is at the point of sidelines, immediately after the concussion occurs.

Senator TILLIS. Is this a sort of test that could be reliably administered in a battlefield situation?

Dr. DEVICK. Yes. As a matter of fact, thousands of teams and leagues around the world use King-Devick tests, and they do it on a noisy—the NFL doesn't use it yet, but I think they will get there. The Canadian Football League does. All of the administration can be done on the sidelines where there is noise and whatever else goes on on the sidelines.

It is just a 2-minute test that checks your ability to move your eyes and—

Senator TILLIS. What are the other alternative tests? Give me some idea. I would guess they would be competing against a test that has obviously gotten a lot of attention. But what does the landscape look like out there, in terms of options?

Dr. DEVICK. Right now, it is kind of a three-legged tool for sideline testing. One is oculomotor function, which is what our test applies to. One is balance. Then one is cognition, like, "Who is the President? What day is it?" those kinds of questions.

I think that when you apply all three of those that can be done quickly on the sideline, you get very high specificity and sensitivity.

So as Dr. Miles said, ours is a tool. There are other tools that they should be combined with. But again, the whole suite of tools doesn't take long, and it can be done on the sidelines.

Senator TILLIS. Is there any data out there with respect to false positives? I mean, is it highly accurate? Do we sweep in those that may not have suffered an injury?

Dr. DEVICK. The false positives we aren't nearly as concerned about as false negatives.

Senator TILLIS. Right.

Dr. DEVICK. So the specificity in the biggest meta-analysis ever done on our products, they combined 15 studies together, and the sensitivity was 86 percent, and the specificity was 90 percent, which is higher than anything like a Pap smear or anything else, and it is done on the sidelines.

No, it is not 100 percent, but it is certainly a better indication than asking a player how he feels.

Senator TILLIS. Okay.

Anyone who has information on it, what research has been done—this actually speaks to something I will spend more time on with the second panel, but Senator Blumenthal and I and others on the Veterans' Affairs Committee are worried about PTS and TBI that may have resulted in behavioral problems that ultimately precipitated an other-than-honorable discharge.

So what research has been done on the population who experience a concussion or something on the spectrum of TBI where there are measured behavioral differences in the person after that are virtually unrecoverable? They just become a part of who they are, in this case, a soldier.

Anyone who has any information on that, I would like to hear it.

Dr. DEVICK. The DARPA [Defense Advanced Research Projects Agency], DOD, VA study just done by Dr. Scher found with comorbidity—that is what you described, where there is PTSD or something else in addition to a concussion. She found, in this article that is pending publication that Dr. Dodick may know more about than I, that when there is comorbidity, the defect under oculomotor test on King-Devick test—

Senator TILLIS. Dr. Dodick or Dr. Miles?

Dr. MILES. So part of the CARE Consortium study is looking at behavioral changes long term, both acutely and in the long-term setting. There is some speculation, and I think some data to support, that premorbid conditions, such as depression, anxiety, those sorts of things, may also play into some of the behavioral changes that occur post-concussively.

Senator TILLIS. Dr. Dodick?

Dr. DODICK. Yes. I would say there actually has been quite a bit of work, especially imaging work, that has been done with some of these individuals. What they found, first of all, is actually the temporal lobe, which is sometimes referred to as the limbic lobe, where many of the structures in the brain are housed that govern and control emotional function, is altered. Its architecture is altered after a concussive brain injury. Such that I saw a recent study indicating that the amygdala, which is part of the brain that drives the fear response, part of the brain that is responsible for

impulsivity, aggressive behavior, is actually enlarged after a concussive brain injury, while other areas in the temporal lobe, such as the hippocampus, for example, which is what allows us to remember what we are being told, actually shrinks over time.

Senator TILLIS. So are you able to determine a change without having a reference point, let's say an image of the brain prior to the event?

Dr. DODICK. Very good question. So not exactly, but the studies that I am talking about compare to age- and sex-matched, or age- and gender-matched controls.

Obviously, it would be ideal to have a preinjury MRI [magnetic resonance imaging] scan on all these individuals, but it is not feasible or practical, so it ends up being compared. It is within the 95 percent confidence interval of change in that individual.

So there are a variety of imaging studies. There are also some molecular studies that have been done showing an upregulation in something called the corticotropin receptor, which is a sensitive surrogate marker of stress response.

So there are physiological, biological, and imaging changes that occur in individuals who exhibit this impulsive-aggressive behavior after a traumatic brain injury.

Senator TILLIS. Very good. Thank you all.
Ranking Member Gillibrand?

Senator GILLIBRAND. Thank you, Mr. Chairman.

While the symptoms of TBI may appear right away, others may not be noticed for days or months after injury or until the person resumes everyday activities. In some cases, servicemembers do not recognize or admit that they are having problems or understand the problem and how the symptoms they are experiencing impact their daily activities.

Are you looking at delayed onset TBI in your research?

Dr. MILES. Absolutely. One of the nice pieces of the CARE study are the data points currently during symptom stage, in the asymptomatic stage, once they have returned and then again at the 6-month follow-up. The hope with CARE 2.0 is to continue that out for many years to see if there are potentially behavioral changes, mood changes, et cetera, that may occur.

That is part of the reason why the funding is so important, so that we can complete that part of the study.

Senator GILLIBRAND. Do you think it is getting enough research? Do you think there is any way we can integrate awareness of delayed onset into policies and procedures at the DOD and VA?

Dr. MILES. I think, just simply, as you mentioned, that it is out there, and we should be aware of it and educating not only physicians but commanders of units and those sorts of things that this is certainly something they should watch for.

Dr. DODICK. I alluded to the secondary injury cascades that are set in motion after the primary impact, and I think it is these inflammatory cascades that are set in motion that continue for days, weeks, or even months that are responsible for some of the delayed onset symptoms and signs that you are talking about.

We and others are doing preclinical work in animal models showing what some of those changes are, because that allows us to sort of tee up high-value targets for therapy.

We are also doing some imaging work following patients prospectively over time to see some of the structural and functional changes in the brain that occur well after the injury.

Senator GILLIBRAND. Yes. I have seen those images. They are remarkable.

Dr. DODICK. They are startling.

Senator GILLIBRAND. They do some of it locally, I think at Walter Reed.

Dr. DODICK. Yes. So I think there really needs to be a public awareness campaign. We have seen the results of massive public awareness campaigns where individuals are educated about the signs and symptoms of stroke, for example, because now we have all these clot-busting therapies, and we need patients to recognize them and get into the hospital as quickly as possible.

We need the same sort of public awareness campaign around concussion. As I said, 20 million women have suffered traumatic brain injury. Forty-six million kids exposed are in contact sport.

It is a massive public health problem, and we need a public awareness campaign that matches the importance of this problem.

Senator GILLIBRAND. I agree, which is why I think if we can have the military be state-of-the-art, we can then have a better conversation about sports and particularly kids in sports.

I mean, I do not want my child playing football. It would scare the heck out of me. Even soccer scares the heck out of me. I was glad when they finally said no headers until you are at least, I think, 13 or 14.

But these are real issues, and I think if the military figures it out, then the rest of us can figure it out. That is why it is so important.

A second question. Based on your expertise and research into the diagnosis and treatment of TBI in the civilian population, what do you think the military and the VA can do to improve their approaches to prevention, diagnosis, and treatment? What ways can you guys influence the civilian world?

Dr. DODICK. I will start by just saying that I can only talk about what I can control in my own center, and in that control, we have implemented what we believe is an evidence-based objective and quantitative neurological assessment preseason—I am talking about sport athletes now—preseason and after injury.

That is why I said earlier I think it is really important that we at least use the tools that we have. While not perfect, they are objective, they are quantitative, and they are sensitive for detecting concussion.

So I think an evidence-based approach needs to be implemented. This field is evolving. Every day, new research comes out. It is incumbent upon us, on behalf of our patients, to be able to adapt and evolve with the changing science.

Senator GILLIBRAND. Do you think that the military and VA's approaches to diagnosis and treatment are effective methods for preventing the potential long-term consequences of injury?

Dr. DODICK. I am not intimately familiar with the military concussion protocol. But again, I would just say that, as science becomes available, I think that military physicians, civilian physicians, we all need to adapt and evolve with that.

Dr. DEVICK. I think that there are new things available all the time. One of the things is the oculomotor aspect that the military hasn't used much so far, but is being used in branches of the military, and, of course, balance and cognition are being used.

So I think that package of three evaluating tools is becoming more and more the state-of-the-art, at least in sports.

Senator GILLIBRAND. Thank you.

Dr. DODICK. It really needs to be objective and quantitative, because I have been examining patients for over 25 years, and even to this day, when an individual comes in with a concussive brain injury, I would have a hard time picking up, on a bedside neurological examination, deficits that I could hang my hat on and say, "Yes, this individual has a brain injury."

That is why I think the guesswork needs to be taken out of it. The subjectivity needs to be taken out of it. We have quantitative, objective tools. We need to implement them now. We need to continue the research and work hard to find better tools.

Senator GILLIBRAND. Thank you.

Thank you, Mr. Chairman.

Senator TILLIS. Senator Warren, before I recognize you, I want to thank you for your consistent participation in these subcommittee hearings. This is a very important one. I appreciate you being here.

Senator WARREN. Thank you. I apologize for running in. I am trying to cover another hearing at the same time.

Senator TILLIS. I should also say there are a number of hearings happening at the same time. This is a very important subject.

Senator WARREN. But this is really important, and I really do appreciate your holding this hearing, Mr. Chairman. This is critical.

I thank all of you for being here today.

Since 2000, more than 370,000 servicemembers have received a first-time diagnosis of traumatic brain injury. It is one of the most common and least understood injuries that servicemembers experience.

Thanks to the work that you and others have done, we now understand that exposure to blast pressure can result in an impact-related concussion where the brain is damaged because it bangs around inside the skull.

But we are also now coming to understand that the blast pressure wave can also cause harm by damaging the brain at the sub-cellular level. While most people think of TBI as being the result of exposure to an IED explosion on the battlefield, we are now learning that it is not the only or even the most common source of blast exposure for servicemembers.

So I was very glad to get an amendment into this year's defense bill that requires the Pentagon to begin a longitudinal study of the blast exposure that our servicemembers experience on the battlefield and when firing larger weapons during training.

Can I just ask you, Dr. Dodick, can you explain why tracking blast exposure over time is essential to helping us get a handle on this problem?

Dr. DODICK. I think a blast exposure traumatic brain injury is in some ways different than the kind of brain injury that one might experience on a football field or on an ice hockey rink. There is an

acoustic wave, as I mentioned earlier, that travels through the brain at very high velocity that, at a microstructural level, damages the tissues and disrupts the connections between cells, in addition to, as you say, rattling the brain around inside its skull.

So there are multiple mechanisms of injury that I think are distinct and unique. I know that there are some research labs in the country looking specifically at the cellular level, at the injury cascades that are set in motion after an acoustic blast like that.

So I do think the injury is different, and I think the work is ongoing right now to see whether or not, at the end of the day, does it really matter? Are the same cascades still set in motion? Is the initial impact injury from a blunt force to the head versus a blast injury, is that the same? How different are they?

There is no question in my mind, as you allude to, that— up until recently, we have always said concussion is a functional brain injury from which 90 percent of individuals recover fully. That may not be the case, because even when you do an MRI scan, which is certainly more sophisticated and can see the brain at a finer detail than a CT scan, you may not see the injury until you peer at a microscopic level with special types of MRIs. Then you see these fiber tracks that are just completely disrupted, like you took a pair scissors to them, that you do not see on a routine MRI scan.

So I agree with you completely. There is a lot happening at a cellular level, at a microstructural level, that we cannot pick up on routine clinical imaging. We definitely need more imaging research, and we definitely need more basic research to understand whether or not these two injuries, the blunt force versus the acoustic blast, is similar in the damage to the brain that occurs as a result of them.

Senator WARREN. That is very helpful, and it looks like we are going to get this one passed into law.

I also want to note that my amendment requires that the Pentagon consider the feasibility of a blast exposure log, analogous to a servicemember's jump log for airborne operations.

So let me ask about that one. Could data collection like this help ensure that blast exposure is fully documented, so that servicemembers get appropriate care if they later develop post-concussive symptoms?

Dr. Miles, could I ask you to weigh in on that?

Dr. MILES. Certainly. I think that the idea behind that helmet sensor and mouthpiece sensor data that we are researching is to determine if we can get a sense of how many blows and at what force those blows are occurring, that same technology could certainly be applied to our servicemembers.

Dr. Dodick had mentioned earlier the cumulative effect of sub-concussive blows. That same effect, whether that is because of blast injuries from using firearms or explosions in the field, although subconcussive at that time, when added up, can lead to these same symptoms.

I think the idea behind keeping track of the amount of force that the brain sees over a given time is a very good concept and may lead to a threshold identified that, when a servicemember reaches that, you pull them out of their activity or whatever they are doing that is leading to those exposures.

Senator WARREN. Thank you, Dr. Miles. That is a powerfully important point. We all know that traumatic brain injury can have devastating, lifelong consequences for our servicemembers and our veterans, and I am grateful for the work you are doing in this area. I hope you will let us know if there is more we can do.

I have a question about protective equipment, but I am already over my time.

Is that all right, Mr. Chairman? Is that all right?

Senator TILLIS. That is fine.

Senator WARREN. Thank you. Good.

So I want to go to another area here. The Pentagon is at the forefront of research into equipment that protects the lives of our soldiers and sailors and airmen and marines. For example, I am very proud of the cutting-edge research that the Army Natick Soldier Systems Center in Massachusetts is doing, everything from improving body armor to preventing stress injuries.

Natick is also at the cutting edge of helmet technology, and the research has shown that different helmet designs and shapes can change the way that blast pressure impacts the brain. But right now, most of the military helmets that we give to deploying soldiers are designed principally just to protect against bullets and other blunt injuries rather than blast injuries.

So Dr. Miles or Dr. Dodick, whoever would like to do this, what does the research tell us about the types of helmet modifications that might reduce pressure transmitted to the brain in a blast? Who would like to go?

Dr. Miles?

Dr. MILES. So I can speak to that in a hockey helmet and football helmet. I cannot speak to it in the military helmet. So if that is okay?

Senator WARREN. Let me just ask, Dr. Dodick, would you like to speak to it in the military context?

Dr. DODICK. I do not know a lot about the actual helmet design that is being developed to prevent that acoustic wave or those pressure waves coming from a blast injury, so I am not familiar with that technology.

Senator WARREN. But I take it what you would tell me, Dr. Miles, let's just do this one in a short summary, is that helmet design may have a powerful impact, and this is something you think might be worth studying in greater detail?

Dr. MILES. I think you said that very well. It may have an impact. There is a lot of discussion on whether or not football helmets are able to be designed to decrease concussive risk. Again, the injuries may not be the same, but it seems like a very important area of research for the military.

If that can be designed, and we can reduce the forces that the brain is seeing inside the skull, there is a great likelihood that you will—

Dr. DODICK. I would say, Senator Warren, that there is no evidence to date that any technology, helmet or otherwise, has actually been able to reduce the incidence of concussion, because as you said very early on, it is that movement of the brain within the skull.

I make the analogy that it is like an egg. It is like a yolk inside of an egg. You shake it and you can break the yolk, but the egg looks fine.

Helmets have done a very good job at preventing skull fractures and preventing major, catastrophic intracranial bleeding, for example, but there is no evidence yet that they have been able to reduce the incidence of concussion.

Senator WARREN. My view on this is that we owe it to our servicemembers, anyone who is put in harm's way, to have the best possible equipment and the best possible equipment starts with research to figure out what works and what doesn't work. So I hope this is an area where we are doing more in trying to determine what we can do to best protect those who are in the field fighting for us.

Thank you, Mr. Chairman. I appreciate, again, your having this hearing.

Senator TILLIS. Thank you, Senator Warren.

Dr. Miles, I am not going to ask other questions except to request that our offices get together to talk about the consortium and see what we can do to try and help, because that really is a collaboration where it is not just DOD, it is private sector, everybody coming together. I think that holistic approach is probably going to produce the best result.

Thank you all for being here. We appreciate your time.

We can have just a brief transition. We will bring up the second panel and a brief introduction and get to opening statements.

Thank you all, and in the interest of time, I am going to go ahead and do a brief introduction and get right to the opening statements. I want to welcome the second panel: Captain and Dr. Michael Colston, director of military health policy and oversight for the Assistant Secretary of Defense for Health Affairs, Department of Defense; Dr. Joel Scholten, associate chief of staff for rehabilitation services for the Veterans Affairs Medical Center,

Washington, D.C.; and David Cifu, senior TBI specialist and principal investigator, Chronic Effects of Neurotrauma Consortium, Department of Veteran Affairs.

Welcome all to the committee, and we will do a windshield wiper. We will start from the right and go to the left this time.

STATEMENT OF CAPTAIN MICHAEL J. COLSTON, M.D., U.S. NAVY, DIRECTOR, MILITARY HEALTH POLICY AND OVERSIGHT FOR THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

Captain COLSTON. Chairman Tillis, Ranking Member Gillibrand, members of the subcommittee, thank you for the opportunity to discuss the Department of Defense's efforts regarding traumatic brain injury.

I am honored to testify alongside my esteemed VA colleagues. I would also like to thank you for your sustained leadership in support of our Nation's servicemembers, families, and veterans, especially those dealing with complex issues around TBI.

The Department's approach to evaluation and treatment of TBI at the point of injury facilitates rapid identification and recovery, reducing the chance of another concussion before a servicemember

has healed from a first. DOD's mandatory screening program promotes early identification of servicemembers with concussion, ensuring effective treatment of physical, cognitive, and emotional effects of the injury.

We know that after a brief period of rest, a concussed individual can begin a progressive return to activity. The vast majority of individuals who sustain a concussion improve clinically and do not have any sequelae. On the other hand, we see patients who continue to suffer.

In my practice as a psychiatrist, I have seen a number of TBI patients with comorbidities, such as adjustment disorders, pain, anxiety, depression, PTSD, and substance use disorders.

So in short, we find that TBI is a protean disorder that can present with a wide range of cognitive, behavioral, and physical deficits.

But we need to meet patients where they are on the road to recovery. So DOD remains focused on hard problems around diagnostic clarification, because we need to get return-to-duty determinations, administrative dispositions, and medical disability findings right.

DOD conducts state-of-the-science research as part of the National Research Action Plan, which coordinates our research priorities with the VA and NIH [National Institutes of Health]. DOD also collaborates in the national effort to characterize degenerative conditions stemming from subconcussive events or blast exposures. The Army STARRS [Study to Assess Risk & Resilience in Servicemembers] study is characterizing TBI's possible contribution to our suicide problem. Interaction between mental health and TBI research portfolios lets us know what we know so we can rehabilitate more servicemembers who present with complex symptoms.

As we look to the future of TBI research, we appreciate that the human brain represents the most complex organization of living structures in all of biology.

Our investments will pay returns. With your continued support, I am confident that our research discoveries, clinical innovations, and focus on readiness will bear fruit.

I look forward to answering your questions.

[The prepared statement of Captain Colston follows:]

PREPARED STATEMENT BY CAPTAIN MIKE COLSTON, M.D.

Chairman Tillis, Ranking Member Gillibrand and members of the Subcommittee—thank you for the opportunity to discuss the Department of Defense's efforts regarding traumatic brain injury (TBI). I am honored to testify alongside my esteemed colleagues from the Department of Veterans Affairs. I would also like to thank you for your sustained leadership and support of our nation's servicemembers, veterans and their families, and especially those dealing with complex issues related to TBI. Your investments in TBI research have led to important advances in care and a greater understanding of where future research should be targeted.

The Military Health System's overriding mission, centered on readiness, is to ensure a medically ready force and this includes our management of the TBI Pathway of Care within the Department. Since 2000, more than 370,000 servicemembers were diagnosed with at least one TBI, of which more than 80 percent of those were mild TBI, also known as concussion. The vast majority of TBIs are diagnosed in non-deployed settings and are caused by training incidents, motor vehicle crashes, and falls. Concussions, which often lack obvious visible injury, have potential to impact the readiness of the force, which is why the Department continues to empha-

size and focus on advances in concussion diagnostic testing and evaluation, treatment, and research.

TBI DIAGNOSTIC TESTING AND EVALUATION

The Department's approach to evaluation and treatment of TBI at the point of injury promotes servicemember's health by facilitating rapid identification and recovery, reducing the chance of another concussion before the servicemember has healed from the first one, and decreasing secondary injury. DOD's mandatory screening programs, outlined in policy, promote early identification of servicemembers with concussion to ensure effective treatment for the physical, cognitive, and emotional effects of the injury. Medical screening, triggered by servicemembers involved in a potentially concussive event; leads to medical evaluation. Examples of potentially concussive events include being within 50 meters of a blast event, being in a vehicle associated with a blast event, collision or rollover, sustaining a direct blow to the head, repeated blast exposures or any instance where an event leads to an evaluation directed by a commander.

The Department is aggressively leveraging new and emerging research to better identify servicemembers with a suspected head injury and identify servicemembers who are unlikely to recover in the anticipated timeframe of a few days to weeks. In addition, the Department is actively pursuing new technologies that can detect intracranial mass lesions, abnormal cerebral physiology, and other signs of brain injury, to objectively inform point-of-injury care for these servicemembers. Technology is being developed and some assessment tools have been FDA-cleared for combat medics and corpsmen that will enable them to make the best clinical decisions for injured servicemembers, allowing them to diagnose, assess and treat servicemembers closer to the point of injury and to provide prolonged field care in an austere environment. These include portable devices to measure brainwave patterns, physiological determinants, autonomic dysfunction, environmental sensors and portable neurocognitive assessment tools.

TBI TREATMENT

We know that, after a brief period of rest, a concussed individual can begin a gradual and progressive return to pre-injury activity. The vast majority of individuals who sustain a concussion improve clinically. Due to rapid natural recovery seen after injury and no FDA-approved pharmacotherapy for mild TBI, medication use for acute concussion is based on management of symptoms. Emerging technology may begin to provide insight into treatment response. The Department continues to aggressively pursue advances in TBI treatment, allowing servicemembers to return to the battlefield, and importantly, to lead rich, fulfilling lives post-injury. Novel interventions for symptomatic mild TBI are under study and selectively used in some of our intensive outpatient programs, including neurofeedback, biofeedback, computer-based cognitive rehabilitation, transcranial magnetic stimulation, and non-invasive electrical stimulation devices.

TBI RESEARCH

The DOD designed and cultivated a gap-driven TBI research portfolio that includes a full spectrum of knowledge and materiel solutions covering prevention, diagnosis and treatment, and long-term studies capturing the natural progression of TBI.

Priority areas for research include precise TBI classification, biomarkers, improving diagnostic capabilities from the point of injury to the post-acute period, symptom presentation and treatment response to novel treatments, long-term effects of TBI and understanding sex differences in TBI. The Department is studying innovative technologies such as portable devices to measure the brain's electrical activity, environmental sensors, portable neurocognitive assessment tools and other concussion evaluation systems.

The Department has sustained efforts to track the long-term effects of TBI. At the request of Congress, several large, longitudinal research programs are underway including the "15-Year Longitudinal Studies" to understand the long-term effects of TBI on servicemembers and veterans and the needs of injured servicemembers' caregivers. Some of the findings highlight the need to reduce fractured health care delivery and to promote the utilization of existing programs that support caregivers. The second, "Improved Understanding of Medical and Psychological Needs in Veterans and Servicemembers with Chronic Traumatic Brain Injury," or "IMAP," make it clear that comorbidities, such as PTSD, acute stress, and sleep disruption, complicate TBI recovery and create a need for a complementary suite of mental health and rehabilitation services for effective TBI treatment.

The Department is conducting state-of-the-science research as part of the National Research Action Plan, which coordinates execution of research priorities with other Federal agencies including the Department of Veterans Affairs and the National Institutes of Health (NIH). One of several large-scale portfolios researching the relationship between TBI and neurodegenerative conditions is the Chronic Effects of Neurotrauma Consortium (CENC), a DOD and VA collaboration exploring the long-term effects of combat-acquired mild TBI. Additionally, the DOD–National Collegiate Athletic Association Grand Alliance targets collegiate athletes, including those at the military service academies, and leverages critical academic partnerships to more rapidly amass information on acute concussion assessment and return to activity strategies.

To support the coordinated collection of large data sets across the entire TBI research field, DOD and NIH developed and maintain the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system to enhance the speed of knowledge translation to best clinical practices.

ISSUES AFFECTING FUTURE POLICIES

DOD is focused on the hard problems of comorbidity and diagnostic clarification, because these issues inform return-to-duty determinations, administrative dispositions including misconduct proceedings or separations, and medical disability findings downstream. We have found that TBI is a complex disorder that can present with a wide range of cognitive, behavioral and physical deficits. Epidemiological studies inside and outside of the TBI portfolio are ascertaining why TBI often presents with duty-limiting conditions such as PTSD, depression, substance use disorders, chronic pain and suicide risk.

We are beginning to understand social determinants and outcomes in TBI. We know that functional deficits and impaired psychological health interact to influence employment instability in the years after TBI. Disruption in activity can lead to lower satisfaction. The Army Study to Address Risk and Resilience in Soldiers is characterizing TBI's possible contribution to our suicide problem. Interaction between mental health and TBI research portfolios helps us to “know what we know,” so we can rehabilitate more servicemembers who present with complex symptomatology and, just as important, tailor policy toward appropriate and humane dispositions of servicemembers with TBI.

WAY AHEAD AND CONCLUSION

As we look to the future of TBI research, we wholly appreciate that the human brain represents the most complex organization of living structure in all of biology. I was struck, during my four years of service on the NIH advisory council for the National Institute of Neurological Disorders and Stroke, how wide-ranging and organized the national brain research portfolio is, with superb differentiation of expertise and research scope between agencies. This investment will pay returns.

The current state of MHS [Military Health System] TBI care is supported by a robust pathway of care that leverages a network of advanced TBI centers with coordination by the Defense and Veterans Brain Injury Center. Synchronization of evaluations, treatments and outcomes provides opportunities for rapid translation of research findings to enhance clinical care. With your continued support, I am confident that our research discoveries, clinical innovations and relentless focus on readiness will continue to bear fruit in the years ahead. I look forward to answering your questions.

Senator TILLIS. Thank you.

Dr. Cifu?

Dr. CIFU. I defer to my colleague, Dr. Scholten.

STATEMENT OF JOEL D. SCHOLTEN, M.D., ASSOCIATE CHIEF OF STAFF FOR REHABILITATION SERVICES FOR THE VETERANS AFFAIRS MEDICAL CENTER, WASHINGTON, D.C., ACCOMPANIED BY DAVID X. CIFU, M.D., PRINCIPAL INVESTIGATOR, CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM, DEPARTMENT OF VETERAN AFFAIRS

Dr. SCHOLTEN. Good morning Chairman Tillis, Ranking Member Gillibrand, and members of the subcommittee. Thank you for the opportunity to discuss traumatic brain injuries, or TBI.

I am accompanied today by Dr. David Cifu, my colleague who is the senior TBI specialist for VHA [The Veterans Health Administration].

VA's TBI-polytrauma program delivers world-class rehabilitation services for veterans and servicemembers. Through this program, VA continues to advance the diagnosis, evaluation, and treatment of TBI.

TBI severity is determined at the time of injury and is based on the individual's ability to respond to the environment and to questioning. The majority of TBI is categorized as mild, which is usually more difficult to identify than severe TBI due to a lack of visible injury and unspecific symptoms.

In 2007, VA established a systemwide TBI screening and assessment program.

Senator TILLIS. You may need to pull your mike a little bit closer. I think they are having a problem recording.

Dr. SCHOLTEN. In 2007, VA established a systemwide TBI screening and assessment program. All post-9/11 veterans are screened when they access VA for health care. Those who screen positive are then evaluated by a TBI specialist.

Between 2007 and 2017, VA screened over 1.1 million veterans and diagnosed over 93,000 of these veterans with a history of a mild TBI. These veterans then received an individualized rehabilitation plan of care for their specific needs.

Individualized rehabilitation treatment plans are paramount to TBI care as these plans consider the impact of symptoms on the veteran's unique functional abilities and are developed with active input from the veteran and their caregiver to develop recovery goals.

Of the post-9/11 veterans with the TBI diagnosis, over 70 percent also have a PTSD diagnosis, and over 50 percent have both a PTSD and a pain diagnosis. This highlights the importance of active integration of mental health and pain care providers when treating individuals with TBI.

The complexity of care needed for veterans with TBI and polytrauma is best provided through an integrated medical system, such as VA's polytrauma system of care. This system includes over 100 facilities that provide specialized rehabilitation programs.

In the field of brain injuries, VA collaborates with multiple partners to advance care and research by working directly with our veteran service organizations, academic partners, the NFL, the NCAA, and Federal agencies such as DOD, NIH, and CDC [Center for Disease Control].

VA and DOD have worked together to develop a common definition for TBI. In addition, VA has collaborated with DOD, NIH, and academic partners to develop and implement evidence-based clinical practice guidelines to help both standardize and enhance care.

VA continues to invest heavily in TBI-related research. In fiscal year 2017, VA spent over \$35 million in TBI research on 164 projects, which includes four research centers and VA's annual \$5 million contribution to the VA-DOD Chronic Effects of Neurotrauma Consortium, or CENC. The goal of this research consortium is to better understand the lifetime impacts of military service, particularly combat-associated concussions and their asso-

ciation with mental health disorders, dementia, and related neurodegeneration.

VA's research portfolio, coupled with its integrated TBI system of care, provides an optimal setting to better understand TBI and translate these findings to enhance clinical care.

Many veteran populations are recognized to be at higher risk for suicide, including those living with a history of TBI. Because military and veteran suicide rates are elevated compared to civilian rates, VA has made suicide prevention a top priority. VA offers wide-ranging suicide prevention efforts to identify veterans at greatest risk. In July 2017, VA changed its policy to allow urgent mental health treatment for veterans with an other-than-honorable discharge.

Mr. Chairman, thank you again for the opportunity to testify about the importance of TBI diagnosis, treatment, and research. We believe VA is a leader in each of these areas, delivering the best care available to our veterans. We welcome the opportunity to advance collaboration with our Federal and private partners.

We also thank the subcommittee and Congress as a whole for their support in getting our veterans the care they have earned and deserve.

My colleagues and I would be pleased to answer your questions. Thank you.

[The prepared statement of Dr. Scholten follows:]

PREPARED STATEMENT BY JOEL SCHOLTEN M.D.

Chairman Tillis, Ranking Member Gillibrand, and Members of the subcommittee; thank you for the opportunity to discuss the current state of research, diagnosis, and treatment for traumatic brain injuries (TBI). I am accompanied by Dr. David Cifu, Senior TBI Specialist for the Veterans Health Administration (VHA).

The Department of Veterans Affairs (VA) TBI/Polytrauma program delivers world-class medical and rehabilitation services for veterans and servicemembers with TBI and associated polytrauma. Through this program, VA continues to advance the diagnosis, evaluation, treatment, and understanding of TBI in a variety of ways, including: establishing standardized diagnostic and assessment protocols; developing and implementing best clinical practices for care; collaborating with strategic partners; educating and training in TBI-related care and rehabilitation; and conducting, interpreting, and translating research findings into improved clinical patient care and caregiver support.

DEFINITION AND DIAGNOSIS OF TBI

VA and the Department of Defense (DOD), collaboratively, have defined TBI as: a traumatically-induced, structural injury or physiological disruption of brain function from an external force as indicated by; a loss or alteration of arousal, a loss of memory, an alteration of mental state, new neurological deficits or an intracranial lesion.

TBI severity is determined at the time of the injury based on the individual's ability to respond to the environment and to questioning. The vast majority of TBI is categorized as mild. Mild TBI, which is commonly called concussion, is usually more difficult to identify than severe TBI, due to the lack of a visible head injury and non-specific symptoms, which can also be seen with other diagnoses, such as acute stress, depression, and Post Traumatic Stress Disorder (PTSD). The vast majority of individuals with mild TBI are symptom-free in two to four weeks, but a minority will experience ongoing symptoms, sometimes lasting for several months or longer.

The diagnosis of mild TBI is made historically, determined by the individual's loss or alteration of consciousness following the traumatic event. Efforts to develop objective measures for a mild TBI diagnosis, including advanced imaging and biomarkers, are currently in the research phase and not yet useful in the clinical setting.

VA established a system-wide screening and assessment program in 2007 to identify veterans with a history of TBI and persistent symptoms, so as to provide a de-

finitive diagnosis and allow for the development of a treatment plan. This validated screening tool consists of questions that VA health care professionals must ask all veterans, with a service separation date after September 11, 2001, when they are accessed for VA healthcare. Veterans who screen positive are offered follow-up evaluations with TBI specialists. Between 2007 and 2017, VA has screened over 1.1 million veterans from Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn (OEF/OIF/OND); more than 213,000 of these veterans screened positive for possible TBI and were referred for a comprehensive TBI evaluation. To date, over 93,000 of those veterans with a positive screen were diagnosed with having sustained a mild TBI, and had an individualized rehabilitation and reintegration Treatment Plan of Care developed for their ongoing rehabilitation services.

TREATMENT

Evidence-based treatment following mild TBI is determined by symptoms. VA and DOD published Clinical Practice Guidelines in 2009 and updated them in 2016 for the management of mild TBI utilizing the highest level of medical evidence to guide care (<https://www.healthquality.va.gov/guidelines/Rehab/mtbi/>). Treatment includes a combination of therapy, including cognitive, physical, speech, and occupational therapy, along with medications to manage specific symptoms, such as headaches or anxiety. Individualized rehabilitation treatment plans are paramount to TBI care as they consider the impact of symptoms on functional abilities with active input from the individual and their caregiver to develop recovery goals.

The complexity of care needed for veterans with TBI and polytrauma is best provided through an integrated medical system, as is available in VA's Polytrauma System of Care (PSC). Of the new cohort of veterans with a TBI diagnosis, over 70 percent also have a PTSD diagnosis, and over 50 percent have both PTSD and Pain diagnoses, highlighting the importance of active integration of mental health and pain care providers in the care for individuals with TBI.

VA provides the full continuum of care for veterans with TBI of all severity through its Polytrauma System of Care, a nationwide coordinated system of over 100 facilities providing specialized rehabilitation programs. Polytrauma, defined as two or more injuries occurring as a result of the same traumatic event that result in physical, cognitive, or mental health impairments and functional disability, is best served in an integrated medical system. VA's TBI/Polytrauma System of Care collaborates with primary care and other specialty services, such as mental health, complementary and alternative medicine, and vocational rehabilitation, to deliver integrated and innovative treatment options that promote veterans' choice and support successful community reintegration. VA strives to improve access to specialized rehabilitation services and programs for veterans with TBI and Polytrauma. These nationwide programs include:

- Transitional Rehabilitation Programs, focusing on promoting independence, community reintegration and return to work after injury;
- Telehealth services for veterans living at a distance from the medical centers;
- Assistive Technology Labs to maximize the functional status of veterans with disabilities through the use of adaptive and assistive technology;
- Emerging Consciousness Programs serving veterans who are slow to recover awareness after severe brain injuries.

VA also instituted long-term follow-up of veterans with chronic problems related to TBI, initially for all those with moderate to severe initial injury, and now including those with mild injuries who fail to reintegrate successfully into the community. Understanding the multifactorial etiologies involved in chronic mild TBI, VA promotes health and wellness initiatives, including self-management with mobile technologies and collaboration with community partners to offer additional services in the areas of fitness and recreational activities.

Military and veteran suicide rates are elevated compared to civilian rates and VA has made suicide prevention a top priority. Many veteran patient populations are recognized to be at higher risk for suicide, including those with psychiatric conditions, and those living with a history of TBI. Veterans with mild and moderate to severe TBI who sought VA services, died by suicide at 1.8 to 1.3 times the rate of all veterans using VA for healthcare. VA offers wide-ranging suicide prevention efforts, including the Veterans Crisis Line, suicide prevention coordinators, and the rollout of REACHVET, to identify those veterans at greatest risk.

RESEARCH

VA research related to TBI is wide-ranging and is coordinated under the National Research Action Plan (NRAP) in response to Executive Order 13625, Improving Ac-

cess to Mental Health Services for veterans, servicemembers, and military families. Under the NRAP, VA partners with DOD and HHS [Health & Human Services] to coordinate research strategies to accelerate discovery and rapidly translate new knowledge into diagnostics and treatments of servicemembers and veterans with TBI. Among these NRAP-related goals, VA researchers are working: to shed light on brain changes in TBI; improve screening methods and refine tools for diagnosing TBI; and develop ways to treat brain injury. VA researchers are also designing improved methods to assess the effectiveness of treatments, and learning the best ways to help family members cope with the effects of TBI and support their loved ones. VA Research in mild TBI continues to grow. In fiscal year 2017, VA spent \$35.5 Million in TBI research on 164 projects, including 4 Research Centers. Also included in this investment is VA's \$5 million per year contribution to the NRAP-related VA/DOD Chronic Effects of Neurotrauma Consortium (CENC).

VA has several research centers that are working together to better understand TBI and translate findings to enhanced clinical care. These include, 1) the Translational

Research Centers for TBI and Stress Disorders, at the VA Boston Healthcare System and at the Michael E. DeBakey VA Medical Center in Houston, which study TBI and PTSD, 2) the Brain Rehabilitation Resource Center, at the Malcolm Randall VA Medical Center in Gainesville, Florida, that seeks to harness neuroplasticity to improve recovery, 3) The Research Center for the Prevention and Treatment of Visual Loss at the Iowa City VAMC that includes specific research in TBI and vision, and 4) The National Center for Rehabilitative Auditory Research at the Portland VAMC that includes specific research related to TBI and hearing loss.

As mentioned above VA is part of CENC, which is a coordinated, 30-center research collaboration between VA and DOD, centered at the Hunter Holmes McGuire VA in Richmond, Virginia. It has been jointly funded for \$62.2 million since 2013. The focus of CENC is to link basic, translational, and clinical neuroscience researchers from VA, the military, academia, and the private sector, to effectively address the diagnostic and therapeutic ramifications of TBI and its long-term effects. CENC's goal is to better understand the lifetime impacts of military service, combat-associated concussions (mild TBI), and being a veteran, in particular with respect to the development of mental health disorders, Alzheimer's, dementia, and related neurodegeneration. Some early important findings from CENC include:

- In a cohort of more than 1,100 veterans and servicemembers with persistent difficulties after combat concussions and related issues, more than two-thirds are high functioning, employed and managing well in the community more than seven years after injury. The remaining one-third demonstrate ongoing and increasing difficulties that require significant health care utilization.
- Servicemembers and veterans with combat-related concussions and associated conditions (PTSD, pain, depression, substance use, elevated suicide risk) represent a unique and high-risk population for long-term difficulties and decline.
- Using big data techniques, among 1.6 million servicemembers and veterans, linkages have been identified between elevated lifetime risks for neurodegeneration, including Alzheimer's dementia, for those with TBI.

VA tracks TBI rehabilitation outcomes of veterans with TBI and compares them to those from the private sector, through collaborative research between the five VA Polytrauma Rehabilitation Centers and the National Institute of Disability, Independent Living, and Rehabilitation Research (NIDILRR) TBI Model Systems' 16-center database. Through fiscal year 2017, VA has enrolled over 1,000 veterans in the study, generated 24 peer-reviewed scientific publications and delivered nearly 90 conference presentations. This Federal interagency collaboration enhances VA's ability to define the unique needs of veterans following TBI and translate those findings into policy, to create continuous quality improvement for TBI rehabilitation within VA.

Evidence of VA's leadership in TBI research and clinical care has been highlighted in several recent special issues of medical journals, including: the September 2016 issue of Brain Injury covering results from CENC; the October 2017 issue of Brain Injury reporting on outcomes from VA's TBI State of The Art Conference;

and the July 2017 issue of the Journal of Head Trauma Rehabilitation showcasing results of VA's involvement in the Federal interagency TBI Model Systems program.

Mr. Chairman, thank you again for the opportunity to testify about the importance of TBI diagnosis, treatment, and research. We believe VA is a leader in each of these areas, delivering the best care available to our veterans, and we welcome the opportunity to advance collaboration with our Federal and private partners. We also thank the subcommittee and Congress as a whole for their support of getting

our veterans the care they have earned and deserve. My colleagues and I would be pleased to answer your questions.

Senator TILLIS. Dr. Cifu?

Dr. CIFU. I actually would be open to just answering any questions.

Senator TILLIS. You are just here to provide all the answers?

Dr. CIFU. Yes, in the interest of time, sir.

Senator TILLIS. Thank you all for being here.

I want to jump to something. Dr. Colston, we now are going to implement an electronic medical record (EMR) in the VA that is a platform that has already been implemented in the DOD. So I am trying to think and I want to talk a little bit in two different buckets.

One is the concern that I have with people who have received other-than-honorable discharge and I am glad to hear from Dr. Scholten that we are helping with crisis intervention with persons with other-than-honorable discharge. I think that that is good.

But it seems to me that, on the one hand, looking forward, if we do a better job of whether it is their MOS [Military Occupational Specialty], the role that they are playing when they are deployed where we know that they are going to be exposed to events that could potentially have this cumulative impact that Senator Warren pointed out, it would seem like we should really think through, maybe not in phase one of the EMR but in subsequent phases, how we capture some of these life events so that we can cumulatively look back and have a high degree of certainty that this person may be suffering from TBI.

Does that make sense to you?

Captain COLSTON. Absolutely, sir, and I couldn't agree more. If I can relay a story, 30 years ago, I was a nuclear engineer on USS *Carl Vinson*. I wore a dosimeter, and every month in my medical record the amount of radiation that I got was put in my medical record. That reactor on *Carl Vinson* could have killed me inside of a second, but between occupational protections that I had, medical protections that I had, we reduced the risk to zero.

Now, TBI is a much harder problem. The brain is a considerably more complex organism than just the body as a whole. Blast physics presents a number of challenges.

I know when Senator Warren spoke there, we are working on helmets. We are working on things to maybe get the blast wave to go around.

There are many separate things that happen when you get a blast or an impact, and it is really hard to document those things. It is a very hard thing to ascertain. So I think, for right now, it is very important to get good histories. That is where our corpsmen and medics come in with our concussion evaluations that discuss what the circumstances were.

We also have an obligation as clinicians to get really good histories and document exposures. I am heartened that the VA is going to have the same medical record as us, because I have worked in both systems, and I can say it has been very hard over the years to kind of figure out what is going on, or the delay has been inordinate.

So I am excited that that is where we are going moving forward.

Senator TILLIS. To any of the panelists, I think it was Dr. Dodick that said even if you do not have a prior image that it was about a 95 percent confidence interval in being able to look at a brain image and reasonably determine that they had suffered some sort of a concussive trauma.

Is that possibly something we should look at as a way to go back to some members who have been other-than-honorably discharged and say maybe there was something there that we did not take into account?

Dr. SCHOLTEN. I believe that the evidence may not be there to support that type of implementation at this time. I think the approach right now is to have a no-wrong-door approach for veterans or servicemembers with an other-than-honorable discharge.

With implementation of that policy for those individuals who can access for urgent mental health needs, during that time, that episode of care can last up to 90 days, during which time we can investigate the background, their clinical presentation, and determine possibly if their benefit profile should be changed.

Dr. CIFU. In addition to that, as part of the Chronic Effects of Neurotrauma Consortium, the large VA–DOD study, we are looking at exactly this issue of dose effect from brain injury. We have a validated measure to figure out, did they have prior concussions?

Actually, the biggest challenge we have is to find veterans and servicemembers who have not had a prior concussion in their records. That is the hardest challenge. But we have a validated metric.

So we are recording that, and it is published, and it is standardized. But we are recording that as well as monitoring serial MRI scans, eye-tracking scans, all the things the prior panel talked about.

What we are trying to do is actually get the knowledge so that, if we had that information, we could actually act on it. Because it is scary to know that you have had this dose effect, whether it is from radiation or from brain injuries. What is even more scary is if your clinicians have no clue what to do with it.

What we are trying to do is, instead of just thinking we know what to do with it, we are trying to really put some data around that so we are on top of it.

We hope next time we are able to report in front of you, we will be able to give you hard evidence on that.

Senator TILLIS. Thank you.

Senator Gillibrand?

Senator GILLIBRAND. Thank you for being here.

What is the military doing overall to ensure that it will do a better job in assessing program effectiveness on more evidence-based practices, providing appropriate training to providers, and collaborating across the services? Because the October report from the Secretary of Defense evaluating specific tools, processes, and best practices to improve the Armed Forces identification, treatment, and mental health conditions in TBI identified six areas to improve service provision, including frequent use of evidence-based practices and better specialty certification for providers.

Captain COLSTON. I can speak to that, ma'am.

We just spent \$50 million from CAPE [The Center for the Army Profession and Ethic] to look at programs for effectiveness, and I think one of the things that we really struggled with was outcomes and fiscal granularity as we looked back.

So going forward, that needs to be a part of the way that we do business. So we created a behavioral health data portal that, in essence, gets outcomes that are in the medical record and will be there for perpetuity.

We also need to make good choices with regard to programs. We need to have a stop-doing list. So if a program is not effective, it needs to come off, because it is presenting an opportunity cost, and that is something that we definitely need to focus on going forward.

Senator GILLIBRAND. So I did not feel like you answered Senator Tillis' question fully in the last question, because he is really saying, what are you doing to create an opportunity for someone who may well have been discharged dishonorably because of behavior that is absolutely against the rules but that would have been caused by traumatic brain injury or PTSD?

So, specifically, can you address that? What are you doing to protect those servicemembers who may well have been punished for inappropriate behavior that was actually caused by these diseases?

Captain COLSTON. Yes, ma'am.

First, there are opportunities for reclama, so there are boards of correction for military records.

The second thing that we implemented was an across-the-board look at people who had medical boards stopped for one reason or another, say for disciplinary reasons. We had a Physical Disability Board of Review actually look at those, and opposed to like a BCMR [Board of Correction for Military Records] where maybe 5 percent of cases get recharacterized, that board was around 30 percent.

We also wrote special guidance for the boards of correction for military records, secondary to some of Senator Blumenthal's efforts, for Vietnam vets and other folks who may have had illnesses before we even had the capability to recognize this.

Really, the first good literature about PTSD and TBI and really good literature about post-concussive symptoms and mental health systems that were sustained well beyond having those two things together was an epidemiological study by Lisa Brenner in 2010 at the MIRECC [Mental Illness Research, Education, and Clinical Center] in Denver, one of my VA colleagues.

So the science is still nascent, but we really need to protect folks.

I think that we have tried to get ahead of the problem in a lot of ways. So now before we administratively separate someone, we do an evaluation for PTSD and TBI.

When I was a resident at Walter Reed in 2000, we would administratively separate people from the emergency room. In fact, we had about 4,000 administrative separations for mental health issues a year. We have reduced that to 300 now. So that was a round turn. That happened really quickly in the late 2000s.

Senator GILLIBRAND. Great. Related, many survivors of military sexual trauma suffer from PTSD as a result of that trauma. What is the military doing to diagnose and treat PTSD that results from military sexual trauma? Is their diagnosis and treatment different

from the diagnosis and treatment for PTSD caused by a blast injury or other combat activity where there might be a co-occurring brain injury?

Captain COLSTON. Absolutely. I think that Edna Foa's group at the University of Pennsylvania, I think CPT [Cognitive Processing Therapy] and prolonged exposures, those are both very good treatments for military sexual trauma.

I think one of the things that I have noticed as a psychiatrist is you can take a person who really did not have a lot of premorbid illness, who did not have adverse childhood experiences, they can be sexually assaulted, and they can just break apart. So as leaders, it is really incumbent upon us to set up a system where we are vigilant for those types of injuries.

The incidence of sexual harassment and abuse in this Nation is horrible, and in the cohort of patients that I treat, of course, it is much higher.

So we need to be really focused on access to care for that group, meeting patients where they are, and the ability of confidential care.

For instance, a servicemember can actually walk into a VA vet center and get treatment for military sexual trauma. But as a clinician who is actually writing things in the record, I also need to be sensitive to that patient's needs. I do not need to be writing details about what is going on, nor do I have to have a close contact with command. I need to be focused on that patient's needs and making that patient better.

Senator GILLIBRAND. I appreciate that.

Can I ask a follow-up?

Senator TILLIS. Sure.

Senator GILLIBRAND. So to Dr. Scholten and Dr. Cifu, please describe the VA programs that have been developed to diagnose and treat military sexual trauma-induced PTSD in veterans seeking treatment for TBI. Are we doing enough?

Dr. SCHOLTEN. Thank you for that question.

So VA has an extensive military sexual trauma program and implementation of screening at all VA medical centers. We screen every veteran accessing VA for care for military sexual trauma. Actually, the screening rate was 98.7 percent in fiscal year 2016.

Senator GILLIBRAND. Can you do it from the other end? If someone comes in for PTSD, do you check that it might be not a blast but actually trauma? Meaning, they do not come in for sexual trauma; they come in for PTSD.

Dr. SCHOLTEN. Exactly. Right. That is a good point, because military sexual trauma is not a diagnosis. It is an experience. They are screened for the diagnosis as well as the experience, and then their individual treatment plan is based upon their symptomatology and their presentation.

In addition, VA has a large research portfolio trying to better understand the impact of military sexual trauma and its effect on associated mental health conditions.

Dr. CIFU. Importantly, so if they come in, they get screened, for example, for TBI, they are also going to be screened for the PTSD diagnosis. That PTSD diagnosis could be due to military sexual trauma.

The beauty of the integration of the VA system across every VA is that the team doesn't just treat TBI or PTSD from a blast or a depression. The team is set up to treat all the diagnoses within the same setting with the same core of providers.

That is a huge difference. Nobody wants to come back 3 days later or go to another setting.

Senator GILLIBRAND. Exactly.

Dr. CIFU. So we are very aware that each patient is unique, but we are doing it within the same team context, what used to be called a medical home. Primary care is involved, but the specialists are too.

So each diagnosis is vitally important but military sexual trauma, it has a uniqueness to it. But that is also handled in the same setting, which we think is an advantage across the United States.

Senator GILLIBRAND. Thank you very much.

Senator TILLIS. Just one final question for Dr. Colston.

Dr. Colston, when you were describing your experience working near a reactor, the beauty of that is you knew where it was, and you had precise measurement devices to make sure that you were in a safe environment. Is there any work being done to, again, look at the MOS or the task?

Let's say that you are in artillery or you are in various conditions where—again, the cumulative impact that we were talking about is something that I have not spent a lot of time studying, and I will, but any way—where we could reasonably predict that some people need to be tested or we have to provide research just based on the—until we have helmets that can deflect the waves and do the sorts of things to minimize the injury, is there any research being done in DOD in that light?

Captain COLSTON. Yes, sir. In fact, I was speaking with my colleague, Dr. Bennett, who is in the audience, at the Office of Naval Research yesterday about a lot of the work that is being done around blast physics and attempt to ascertain what happens with any particular blast.

You shoot a .50 caliber, that is about a half PSI pressure wave. A breacher is seeing maybe 2 PSI. But a breacher may see 400 or 500 of those. Then, certainly, an IED can be something much higher than 10 or 15.

We are very worried about what we see downstream. Dr. Perl at the Uniformed Services University has seen almost a pathognomonic lesion associated with blast injury.

Now, there is a lot of crossover in between lesions that we see in the brain, but this particular lesion was at density junctions, in other words, right where you would deposit injury from a blast wave.

A blast wave is not just running 25,000 feet a second through the brain. There is also a coup-contrecoup injury, where your brain is sloshing around in your skull, and, obviously, fragments.

So there is all kinds of work to do in the research realm that we are working on assiduously, and we need to do it fast, because, certainly, the next battles are out there.

Senator TILLIS. I want to thank all of the panelists from the first and second panel for being here. I think this has been a very informative hearing, and it is one that we need to focus a lot of atten-

tion on. I think we have all highlighted our concern prospectively for men and women serving in uniform but also for the veterans.

So I thank you all for your testimony and your time here today.

We will hold the committee record open through the end of business tomorrow so that you can submit any other information. We may also submit some questions for the record, and other members will be allowed to do the same.

Senator TILLIS. Thank you all for being here today. Thank you for your service to our veterans and our men and women in uniform.

This committee is adjourned.

[Whereupon, at 11:23 a.m., the subcommittee was adjourned.]

[Questions for the record with answers supplied follow:]

QUESTIONS SUBMITTED BY SENATOR JONI ERNST

MENTAL HEALTH

1. Senator ERNST. Captain Colston, will OSD be adopting any new policies relating to the mental health counseling profession in time to save the jobs of counselors serving as Directors of Psychological Health in the Air National Guard who scheduled to lose their positions in September 2018?

Captain COLSTON. There are no new OSD policies currently being considered to address this issue. Department of Defense Instruction 6025.13, Medical Quality Assurance and Clinical Quality Management in the Military Health System, dated February 17, 2011, delegates the responsibility for determining privileging standards and requirements to the individual Military Departments. The position of Director of Psychological Health (DPH) in the Air National Guard's Psychological Health Program was determined by the Air Force to require a privileged mental health provider. This determination did not result in a reduction in positions. However, in response to the conversion from contracted to Title 5 civilian positions during fiscal year 2015, it was discovered that some currently serving DPHs did not meet the requirements to be a privileged mental health provider, per Air Force Instruction 44-119. Local commanders were given the choice of offering the incumbent DPHs who did not meet privileging requirements a temporary 4-year position in a lower grade, or immediately hiring a privileged provider. There were 12 DPHs retained in the lower graded position, and their terms will expire on September 30th, 2018. DPHs are ANG's first line of defense at addressing operational, occupational and combat stressors all of which directly impact mission readiness. Limited-capability DPHs are not able to conduct needed mental health assessments, which could negatively impact the mission. The ANG plans to recruit and fill the DPH positions with privileged health care providers.

SPECIAL OPERATORS

2. Senator ERNST. Captain Colston, one area of concern for me, for our Special Operators in particular, is brain trauma that can only be evaluated post-mortem. I recently visited Navy SEALs who are now baselining brain conditions prior to combat operations to better diagnose unseen injuries throughout a member's lifecycle. Is this an approach that should be adopted across the Force?

Captain COLSTON. USSOCOM's 70,000 operators likely see the highest exposure to precipitants of traumatic brain injury, including blast injury, among our servicemembers. For that reason (and in accordance with DOD policy) USSOCOM continues its efforts to document baseline brain function prior to combat and training exposures. Yet, there is currently insufficient evidence to recommend a baseline evaluation of brain conditions for all servicemembers. However, the baseline brain function data currently being gathered from USSOCOM personnel in response to Section 722 of Fiscal Year 2011 NDAA Public Law 111-383 will prove invaluable to the research efforts in this arena. If the future evidence supports the baseline evaluation of brain function in Special Operators, expansion of that approach across the force would be warranted. Research to date does not support the utility of baselining individual function over the use of normative (or pooled) data in the clinical realm. This case mirrors other aspects of evidence-based patient care, where preci-

sion medicine efforts compete with population-based approaches on a case by case basis.

QUESTIONS SUBMITTED BY SENATOR ELIZABETH WARREN

MEDICAL MARIJUANA RESEARCH

3. Senator WARREN. Dr. Scholten, Dr. Cifu, Captain Colston, 29 States and the District of Columbia have laws allowing the prescription of medical marijuana, but the Federal Government continues to classify marijuana as a Schedule one narcotic. This makes it difficult to conduct serious research on the therapeutic benefits of medical marijuana—such as the drug’s potential as a treatment for PTSD or as an alternative pain treatment to prescription opioids. The Federal classification of medical marijuana also means that the VA can’t reimburse vets who use it to treat PTSD or chronic pain. As medical professionals, do you believe that we should be making it harder or easier to conduct research on potential treatment options for PTSD?

Dr. SCHOLTEN. and Dr. CIFU. VA Response: Marijuana has not been found to be safe or effective for therapeutic use for individuals who have persistent symptoms resulting from post-traumatic stress disorder (PTSD) or mild TBI (concussion), including pain. Given the central acting effects (e.g., altered mentation, drowsiness), potential for insult to the central nervous system, and the risk of addiction in the population of individuals with symptoms and difficulties arising from either PTSD or mild TBI, the use of or research into the potential therapeutic effects of marijuana must be considered with extreme caution. That said, more research is needed in this area. In general, clinical trials conducted by the scientific research community will inform decisions on whether marijuana is a safe and effective treatment agent. It remains critical that drug approvals and policy decisions be evidence based. The Controlled Substances Act, the Food, Drug, and Cosmetic Act, and other legal frameworks that govern the process for undertaking research on marijuana do provide a pathway for that research, although Federal Departments continue to explore ways to improve the process. DEA’s [Drug Enforcement Agency] January 2018 launch of an online application process for Schedule I researchers is one recent result of these efforts.

Captain COLSTON. Effective treatments for PTSD remain elusive. Any high quality research that could provide better treatment options to improve patient care would be welcomed by medical professionals. With respect to research involving medical marijuana, there are important caveats that must be considered, primarily the principle of non-maleficence, or not doing harm to patients or research subjects. Legal and logistical issues will continue to complicate research. In order to complete rigorous studies, patients need to be recruited from a wide demographic base and given treatments that are measurable with respect to doses and response. Recruitment is complicated by great variance in state laws, limiting feasible research protocols. The recent Justice Department decision notwithstanding, disparity across the states in laws governing cannabis use will hamper patient recruitment and randomization. Further, cannabis readily available to the public, in dispensaries and elsewhere, varies widely in potency and psychoactive properties. The result is that cohort studies and other population-based inferences will continue to have limited utility in answering questions about salutary or deleterious effects of marijuana used to decrease suffering, and only focused, highly funded multi-site protocols will likely be productive. The National Institutes for Health, and National Institute for Drug Abuse in particular, have the capability to do such studies and the authority to research the medical effects of schedule one drugs such as Methylendioxyamphetamine and marijuana. Researchers there, with whom DOD researchers interact regularly, have a wider base of expertise and technical competence to answer these important questions, from which DOD could undoubtedly benefit.

