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PERSONNEL AND
READINESS

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

SEP 17 2026

Dear Mr. Chairman:

The Department's response to House Report 119–231, pages 192-193, accompanying H.R. 3838, the Streamlining Procurement for Effective Execution and Delivery and National Defense Authorization Act for Fiscal Year 2026, "Brain Cooling for TBI and Mild TBI Treatment," is enclosed.

Traumatic Brain Injury (TBI) can have profound impacts on the readiness and long-term well-being of military personnel. The need for compact, portable, and non-invasive treatment to prevent or limit symptoms following TBI has led researchers to investigate the use of brain cooling. While some early evidence suggests a potential benefit of brain cooling following TBI, no brain cooling devices are cleared by the Food and Drug Administration for TBI use in a clinical setting. Although this precludes their current use for treating TBI patients, the Department is collaborating with research partners to evaluate and monitor the development of these systems, with the ultimate goal of determining their clinical and operational feasibility for military populations in support of its mission to advance TBI care and maximize Service member readiness.

Thank you for your continued strong support for the health and well-being of our Service members and veterans.

Sincerely,

[redacted]

Sean O'Keefe
Deputy Under Secretary of War for Personnel
and Readiness

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

Report to the Committee on Armed Services of the House of Representatives

Brain Cooling for TBI and Mild TBI Treatment

September 2026

The estimated cost of this report or study for the Department of War (DoW) is approximately $1,990 for the 2026 Fiscal Year. This includes $0 in expenses and $1,990 in DoW labor.
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INTRODUCTION

This report is in response to House Report 119–231, pages 192-193, accompanying H.R. 3838, the Streamlining Procurement for Effective Execution and Delivery and National Defense Authorization Act for Fiscal Year 2026, "Brain Cooling for TBI and Mild TBI Treatment." House Report 119–231, pages 192-193, requests that the Assistant Secretary of War for Health Affairs, in coordination with the Defense Health Agency Traumatic Brain Injury Center of Excellence, assess a brain cooling "Breakthrough Device" for inclusion in existing Department of War (DoW) traumatic brain injury (TBI) treatment and treatment research programs and provide a report back to the House Armed Services Committee. The report assesses the Pro2Cool® system developed by TecTraum Inc., designated in 2021 by the Food and Drug Administration (FDA) as a "Breakthrough Device" with the potential for treating mild traumatic brain injury (mTBI), also known as concussion. DoW will continue to review research findings for possible applications to operational and clinical environments that further advances the Department's mission to maximize readiness and lethality. The Department is working with our research partners to add brain cooling technologies such as the Pro2Cool system in treatment research programs, with a specific aim to evaluate effects in military populations.

BACKGROUND

TBI from training, blast, or other trauma is common in the military. Since 2000, more than 525,000 Service members have been diagnosed with at least one TBI, and more than 80 percent of these injuries were classified as mild. Approximately 15-20 percent of these individuals will go on to have persistent symptoms that can impair their operational readiness.[1] There is an urgent need for compact, portable, and non-invasive treatment that can prevent or limit symptoms following mild TBI. To this end, some researchers have begun to investigate the use of brain cooling strategies.

The Impact of Brain Temperature on TBI

Brain temperature influences the pathological processes associated with TBI, and even small deviations in temperature can worsen neuronal damage.[2-4] Elevated brain temperatures can result in damage to the blood-brain barrier (BBB), inflammation, and other pathological processes and considerably increase energy demand in injured brain tissue.[3] Hyperthermia after a moderate to severe TBI can result in enlarged lesion sizes, worsened ischemia, poorer functional outcomes, and higher mortality.[2] Even mild hyperthermia can result in an increased brain contusion volume. Thus, prevention and treatment of fever is considered a key modifiable risk factor for pathology following TBI.

Evidence on the Therapeutic Effect of Brain Cooling Following TBI

Brain cooling reduces the rate of oxygen and glucose metabolism in the brain and thereby lowers the energy demand when the blood flow and oxygen supply to the brain may be limited following the trauma.[5] This adjustment can help prevent energy failure and cell death.[6] Surface cooling for as little as 30 minutes can result in a significant increase in cerebral blood flow

(CBF).[7] In addition, cooling addresses many of the pathological changes that occur in the brain following TBI, such as oxidative stress, inflammation, and BBB damage.[6, 8, 9]

Therapeutic hypothermia in individuals with TBI is typically achieved through various surface cooling techniques, and research findings on the effects are mixed. In 1997 a single-center study of patients with severe TBI found that cooling the brain to 32-34° C (89.6-93.2° F) improved recovery at 6 months post-injury.[10] However, four larger, multicenter trials did not find a therapeutic benefit of mild hypothermia (32-35° C or 89.6-95.0° F) for 72 hours or more at 6 months after severe TBI.[11, 12, 13, 14] One of those studies actually found that the hypothermia group had worse functional outcomes and a higher mortality rate.[12] Additionally, cooling to this level using surface cooling techniques has many challenges. It must be done in an intensive care unit with sedation, ventilation, medically induced paralysis to prevent shivering, and continuous monitoring. Thus, it is only feasible for patients with severe TBI. To address these challenges, some researchers have aimed to develop cooling devices that can non-invasively achieve brain cooling, making them more amenable for use in individuals with mild TBI.

DISCUSSION

Pro2Cool® Device

The Pro2Cool® system is a portable hypothermia therapy device developed by TecTraum, Inc., specifically marketed as a concussion therapy system to treat and reduce the clinical signs and symptoms of concussions, particularly in youth and adolescent athletes. The system involves a cooled (approximately 6° C or 42.8° F) water/isopropyl alcohol mixture that is circulated through a wearable cooling garment that covers and selectively cools the head and neck. The device automatically cools and then maintains the temperature during treatment. Surface cooling of the head and neck is intended to reduce brain temperature and the temperature of the blood circulating to and from the brain through the carotid arteries and jugular veins in the neck. The goal is to lessen metabolic demand and mitigate concussion-related pathophysiology.

The device is designed to be used by trained medical personnel, including athletic trainers, in a variety of care settings, such as athletic training rooms, clinics, and emergency departments. The recommended treatment for a concussed athlete is two 30-minute cooling sessions, including the first within 8 days of the injury and the second occurring within 48 hours of the first. Pro2Cool® is not FDA approved, but in June of 2021 it received "FDA Breakthrough Device" designation. This designation speeds up review for innovative devices addressing serious conditions such as concussion, but the device is not fully approved for marketing. The Pro2Cool® website states that "Currently, the Pro2Cool® system is an investigational use only device and has not yet received market authorization from the FDA."

The company conducted two published studies evaluating the efficacy of the Pro2Cool® system in individuals with TBI. First, TecTraum, Inc., conducted a single center pilot study of 55 student athletes aged 12-17 with 28 treated and 27 control subjects, followed by a multicenter clinical trial with 79 treated and 88 control subjects including students and athletes aged 12-19. Both studies used the Sport Concussion Assessment Tool version 5 (SCAT5) to measure post-concussion symptoms. Both studies found that those who received treatment reported

significantly fewer and less severe symptoms. In the pilot study, these findings were observed at 72 hours, 10 days, and 4 weeks after two 30-minute treatments.[15] The subsequent study reported a 14.4 percent reduction in SCAT5 symptoms immediately following the first 30-minute treatment session and a 25.5 percent reduction in symptoms following the second treatment at 72 hours after the first, but only a 3.4 percent reduction in symptoms at 10 days after the first treatment.[16] There were 13 mild adverse events thought to be related to treatment, the most common of which were heart rate fluctuations in 4 cases, an increase in blood pressure in 4 cases, and dizziness in 3 cases, none of which were considered serious while being monitored in a controlled research setting. The authors of the multicenter study concluded that Pro2Cool® treatment for 30 minutes was relatively safe in pediatric and adolescent patients, but that further investigation is needed before any recommendation for clinical or operational use can be made, especially for military populations where injuries are often sustained in a kinetic field setting.

Evidence for Other Head and Neck Cooling Technologies for Concussion Treatment

In addition to Pro2Cool®, several other head and neck cooling systems have been developed and tested in concussed patients and healthy volunteers (Table). Of these systems, only the EMCOOLS Flex.Pad and WElkins Temperature Management System are FDA cleared as thermal regulatory systems to reduce body temperature when clinically indicated. While the Pro2Cool® has FDA breakthrough designation to treat concussion symptoms, no head, neck, or brain cooling devices have regulatory approval for medical use to treat concussions or post-concussion symptoms.

Two studies have assessed whether a system known as the PolarCap® head-neck cooling device accelerates the time to return to play in Swedish ice hockey players. The studies differed in treatment duration (30 minutes in one study, 45 minutes in the other), but both studies found that concussed players who received treatment returned to play faster than those who did not.[17, 18] In one of the studies, however, events associated with the treatment included blurred vision, headache, feeling unpleasant, or "pressure against the head,"[17] and in the other, four players still reported post-concussion symptoms. Neither study reported the effect of cooling on blood pressure or heart rate.

In one study of the WElkins Temperature Management System, 12 concussed student athletes self-reported temporary relief from the physical symptoms of concussion after 30 minutes of cooling.[7] In that study, the investigators performed neuroimaging before and immediately after cooling, which revealed a significant increase in CBF associated with cooling.

Table – Clinical Studies of Head and Neck Cooling Devices for Sport-Related Concussion

Device Name	Sport	Number of Subjects	Duration of Cooling	Outcome	Adverse Events
Pro2Cool® (pilot study)[15]	Middle and high school sports	28 cooled/27 controls; ages 12-17	2 separate 30 min treatments	Faster symptom recovery on the SCAT5	None
Pro2Cool® (multicenter study)[16]	Middle and high school sports	79 cooled/88 controls; ages 12-19	2 separate 30 min treatments	25.5% reduction of SCAT5 symptoms at 72 hours but only 3.4% at 10 days	13 associated with cooling, nonserious; increased blood pressure (BP), decreased heart rate and dizziness
PolarCap®[17]	Ice-hockey	61 cooled/71 controls; mean age of 18 or older, mean 26	45 min	Significant reduction in days to return to ice-hockey	None reported
PolarCap®[18]	Ice-hockey	29 cooled/52 controls; mean age of 25-26 years	>30 min	Significant reduction in days to return to ice-hockey	None reported
WElkins Temperature Management System[7]	College athletes, sport not reported	12 with concussion/12 controls; both groups cooled; ages 18-24	30 min	Temporary headache and dizziness reduction in concussed subjects immediately after cooling; significant increase in CBF in the concussed group	None reported

An alternative to head and neck cooling is intranasal cooling with a balloon catheter inserted into both nostrils, through which cooled fluid is circulated. Some have argued that intranasal cooling is not capable of inducing selective brain cooling[19] and have not found it to be an effective technique to alleviate hyperthermia in intubated brain-injured patients.[20] However, a study of 10 awake and healthy adults found that intranasal cooling for 60 minutes resulted in a decrease in brain temperature, measured with magnetic resonance spectroscopic imaging, by 1.7-1.8° C (35.06-35.24° F).[21] Intranasal cooling for 60 minutes did not cause a significant change in blood pressure or heart rate in any of the 10 subjects.

Treatment Research Programs

An investigation of the PolarCap® head and neck cooling system for the treatment of boxers currently is ongoing (NCT06386484). The study is looking at the effect of 45 minutes of cooling on serum levels of blood-based biomarkers immediately after the fight and at 3 and 6 days.

Logistical and Implementation Considerations

Review of current available technologies suggests that size and power requirements may pose significant logistical barriers in the operational setting. Mission requirements may also impede implementation in austere environments.

CONCLUSION

There is compelling preclinical and clinical evidence that increased brain temperature can worsen brain tissue damage following TBI, so it is likely that prevention of fever or therapeutic cooling could help prevent this. Several head and neck cooling devices, including Pro2Cool® and PolarCap®, have been evaluated in clinical studies of adolescent and young adults with sport-related concussions. These studies report that treatment durations of 30-45 minutes can reduce symptoms, at least in the short term, and accelerate return to play with no significant adverse treatment effects. However, these studies also show that treatment for 1 hour or more increases blood pressure, which is likely because longer cooling durations can reduce core body temperature.

This evidence is promising with regard to the potential beneficial effects of brain cooling following sports-related TBI. However, there are several key limitations for translating the currently available evidence into existing DoW treatment protocols for TBI:

- Most of these devices have two or fewer published studies evaluating their safety and efficacy. The limited volume of evidence makes it difficult to conclude on the appropriate duration and timing of treatment for each device that is required to achieve lasting benefits.

- These tools must be independently validated by investigators who are not affiliated with the developing companies to reduce the risk of bias.

- Studies of an adult population and adult military populations are needed.

- The gold standard for proving that a novel treatment is safe and effective is the randomized, double-blind placebo controlled clinical trial. That type of trial is not possible with head and neck cooling devices because cooling is felt by the study subject, and they are aware that they are receiving the treatment.

Recommendations for the use of head and neck cooling devices for the treatment of concussion would therefore need to be based on multiple independent, unblinded clinical trials that address these limitations and reach similar findings across populations relevant to the military.

DoW will continue to review research findings for possible applications to operational and clinical environments that further advance the Department's mission to maximize readiness and lethality. The Department is working with our research partners to add brain cooling technologies such as the Pro2Cool system in treatment research programs, with a specific aim to evaluate effects in military populations.

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