

### Management of Hypothermia in Tactical Combat Casualty Care

TCCC Guideline Proposed Change 20-01

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#### ABSTRACT

As an outcome of combat injury and hemorrhagic shock, trauma-induced hypothermia (TIH) and the associated coagulopathy and acidosis result in significantly increased risk for death. In an effort to manage TIH, the Hypothermia Prevention and Management Kit<sup>™</sup> (HPMK) was implemented in 2006 for battlefield casualties. Recent feedback from operational forces indicates that limitations exist in the HPMK to maintain thermal balance in cold environments, due to the lack of insulation. Consequently, based on lessons learned, some US Special Operations Forces are now upgrading the HPMK after short-term use (60 minutes) by adding insulation around the casualty during training in cold environments. Furthermore, new research indicates that the current HPMK, although better than no hypothermia protection, was ranked last in objective and subjective measures in volunteers when compared with commercial and user-assembled external warming enclosure systems. On the basis of these observations and research findings, the Committee on Tactical Combat Casualty Care decided to review the hypothermia prevention and management guidelines in 2018 and to update them on the basis of these facts and that no update has occurred in 14 years. Recommendations are made for minimal costs, low cube and weight solutions to create an insulated HPMK, or when the HPMK is not readily available, to create an improvised hypothermia (insulated) enclosure system.

#### KEYWORDS: trauma, coagulopathy, shock, hypothermia; rewarming; improvised

#### Proximate Reasons for This Proposed Change

Military forces have historically experienced significant loss of the fighting strength from exposure during cold weather operations that results in hypothermia and other cold-related morbidities.<sup>1,2</sup> For over a century, research has been reported on combat casualties with hemorrhagic shock, coagulopathy, acidosis, and trauma-induced hypothermia (TIH).3-15 When combat casualties incur hemorrhage and shock, the effects of TIH result in significantly increased mortality. Consequently, hypothermia prevention and rewarming are an essential component of prehospital and hospital trauma care guidelines.<sup>16,17</sup>

The Committee on Tactical Combat Casualty Care (CoTCCC) decided to review hypothermia prevention and management guidelines in 2018 and to update them on the basis of the following rationales:

- (1) There has been no update in the TCCC Hypothermia Prevention and Management guidelines (initiated November 2005) for 14 years.<sup>18</sup>
- (2) Hypothermia prevention is the third most frequent life-saving intervention in battlefield casualties after vascular access and hemorrhage control.<sup>19</sup> Before 2006, wool blankets were primarily used to prevent or manage TIH before and during medical evacuation.<sup>11</sup> In 2006, CoTCCC published hypothermia prevention guidelines and the US Central Command Joint Theater Trauma System published the first Clinical Practice Guideline to address a

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high rate of hypothermia in combat casualties. The use of a commercial device that included an external heat source (Hypothermia Prevention and Management Kit [HPMK]; North American Rescue, http://www.narescue.com) was recommended.<sup>20,21</sup>

- (3) A recent publication supported the effectiveness of the HPMK as an enclosure system for rapid application; however, it was ranked last in objective (physiological heat transfer and balance indices) and subjective (human volunteers ranking each enclosure system) measures, compared with four other hypothermia enclosure systems when evaluated in a 60-minute cold chamber study at  $-22^{\circ}C$  (-7.6°F).<sup>22</sup>
- (4) Feedback from the field indicates that the HPMK (a noninsulated enclosure [cover] with chemical heating blanket) has limitations keeping casualties warm during coldweather use. Other commercially available hypothermia prevention products and rewarming techniques may work better than the HPMK used alone. By providing other validated hypothermia-prevention methods, medics will have additional options for casualty rewarming as they advance through the phases of casualty care or into prolonged field care.
- (5) Current CoTCCC hypothermia guidelines do not provide recommendations for insulated rewarming enclosure system options for casualties in cold environments.
- (6) Current CoTCCC hypothermia prevention guidelines do not mention the use of battery-powered intravenous (IV) blood/fluid warming devices with ideal output temperature and flow rates. Furthermore, current Food and Drug Administration (FDA)-approved, portable fluid-warming devices have large variance in output temperature.

#### Background<sup>44</sup>

Primary hypothermia is defined as the involuntary drop in body core temperature (i.e., of the heart, lungs, and brain) below a core temperature of 35°C (95°F). The associated pathophysiology and clinical management have been well described.<sup>17,23–27</sup> Primary hypothermia occurs in healthy individuals when the body's heat production is overcome by excessive cold exposure in air or water. In contrast, hypothermia secondary to trauma (i.e., trauma-induced hypothermia) is associated with hemorrhagic shock and cerebrospinal injury and destabilizes the body's thermoregulatory capacity. TIH can occur even in very warm climates. The CoTCCC hypothermia update focuses on TIH to strengthen the current recommendations for prevention and management in combat casualties.

Hypothermia is one leg of the "lethal triad" caused by a vicious metabolic cycle of tissue hypoperfusion causing decreased ATP production, which leads to hypothermia, coagulopathy, and acidosis; this is associated with increased mortality.<sup>28–30</sup> In burn patients, a similar relationship exists between hypothermia in the lethal triad and worse patient outcomes.<sup>31–33</sup> In burn patients ( $\geq$ 20% total body surface area [TBSA]), hypothermia on hospital admission is directly linked to increased mortality.<sup>32</sup> In a retrospective study, risk factors for burn-related hypothermia are: extensive TBSA (>33%), full-thickness burns, and inhalation injury.<sup>33</sup> The authors concluded that beginning in the prehospital setting, patients with severe burn trauma benefit from any methods to prevent heat loss and, when possible, use of an active, external, warming enclosure system. Other burn-related trauma studies also recommend using

active warming techniques in the prehospital environment to prevent hypothermia in severely burned patients.<sup>32,34,35</sup>

One potential risk factor for hypothermia is active cooling of extensive TBSA burns. It has been generally recommended to limit cooling to small burns to avoid accelerating convective heat loss, which is likely to occur with large TBSA burns. The relationship of burn cooling and hypothermia in the prehospital setting has not always been found in retrospective studies independent of methods used to cool.<sup>33,36,37</sup> However, in burn management of combat casualties, as a comorbidity of trauma, extensive TBSA burns can independently cause hypothermia and death, and this relationship becomes synergistic with polytrauma, anesthetized, and artificially ventilated patients when in cold climates.<sup>33</sup> Thus, it is essential to prevent and manage hypothermia in all types of trauma and to cool the burn initially, and not the patient, by avoiding uncontrolled burn cooling.<sup>37</sup>

Civilian and military trauma centers have linked TIH and coagulopathy on arrival with increased mortality.<sup>7,8,38,39</sup> Acute traumatic coagulopathy (ATC) is a complex, multifactorial process involving biochemical and physiological changes. Recent descriptions of this pathophysiological cascade have focused on the underlying mechanisms of coagulopathy.<sup>12,39,40-42</sup> In general, there are six primary mechanisms contributing to ATC: tissue trauma, shock, hemodilution, hypothermia, acidemia, and inflammation.<sup>40</sup> Consequently, patients with TIH have a worse prognosis and increased mortality rate compared with patients with primary hypothermia who have comparable decreases in core temperature.<sup>13,43,44</sup>

Eastridge et al.9 retrospectively reviewed >1,100 combat casualties presenting to surgical support hospitals during Operation Iraqi Freedom from January to July 2004 and found that the TIH mortality rate was twice that of normothermic casualties with similar injuries.<sup>45</sup> TIH is not unique to combat casualties.13 The majority of the TIH studies emanated from civilian trauma and mostly were reported beginning in the 1980s.<sup>6,45–47</sup> Retrospective and prospective studies reported the relationship among trauma, hypothermia, coagulopathy, and increased mortality. Hemorrhagic shock leads to decreased metabolic heat production and uncouples normal metabolic pathways, such as the clotting cascade. Hypothermia is common in trauma patients, with approximately 40% to 50% of moderate to severely injured patients arriving in a hypothermic state at civilian hospitals and >80% of nonsurviving patients arriving with a core temperature <34°C (93°F).<sup>48,49</sup> In both civilian and military trauma, it has been reported that 100% mortality occurred when core temperature is <32°C (89.6F).<sup>6,7</sup>

Based on the difference in mortality between primary hypothermia and TIH, the hypothermia classification specific to trauma begins at  $<36^{\circ}$ C (96.8°F) (Table 1).

The early recognition and prevention of hypothermia are essential during casualty assessment and care in battlefield trauma. Hypothermia interventions should be implemented for every patient in shock or at risk of shock. Prevention of additional heat loss can be achieved with the use of a hypothermia wrap either without (passive) or with (active) an external heat source, and warming all infused fluids.

Another essential hypothermia intervention is restoration of blood volume by transfusing warm whole blood or blood

All articles published in the Journal of Special Operations Medicine are protected by United States copyright law and may not be reproduced, distributed, transmitted, displayed, or otherwise published without the prior written permission of Breakaway Media, LLC. Contact publisher@breakawaymedia.org. esholds for Primary (Accidental) It was not until recently that the HPMK's effectiveness was

**TABLE 1** Core Temperature Thresholds for Primary (Accidental)
 Versus Secondary (Trauma-Induced) Hypothermia Classification<sup>43</sup>

| Classification          | Accidental<br>Hypothermia    | Trauma-Induced<br>Hypothermia |
|-------------------------|------------------------------|-------------------------------|
| Mild hypothermia        | 32°C–35°C<br>(89.6°F–95.0°F) | 34°C-36°C<br>(93.2°F-96.8°F)  |
| Moderate<br>hypothermia | 28°C-32°C<br>(82.4°F-89.6°F) | 32°C–34°C<br>(89.6°F–93.2°F)  |
| Severe hypothermia      | <28°C (<82.4°F)              | <32°C (<89.6°F)               |

components.12,29,30,50 A lack of warm IV fluids is an iatrogenic contributor to the lethal triad, particularly when administering large fluid volumes.<sup>51</sup> In a prospective multicenter study of trauma patients who required massive transfusion, it was reported that hypothermia on arrival was an independent predicator of mortality.52 Furthermore, the authors reported that every decrease of 1.0°C (1.8°F) in core temperature below 36°C (96.8°F) resulted in a 10% increase in red blood cell (RBC) consumption in the first 24 hours of admission. These authors and others<sup>15</sup> concluded that hypothermia (<36°C) is associated with increase in blood-product consumption and mortality. These data emphasized the need for effective hypothermia prevention at the point of injury (POI) and continued patient warming during massive transfusion with warmed (38°C-42°C [100.4°F-107.6°F]) whole blood.

Commercial, battery-powered, in-line IV warming devices, as well as improvised IV warming methods, inconsistently warm blood to the target temperature from cold ambient temperatures.53-56 Also, battery-powered, in-line IV warming devices do not have equal performance characteristics or easy set-up methods for IV delivery of blood.55-59

One basic requirement for managing cold-stressed (>35°C [95°F]) or hypothermic (<35°C) combat casualties is the ability to enclose them in a hypothermia wrap consisting of an enclosure, insulation, vapor barrier, and an external heat source.<sup>57</sup> Wool blankets have been the standard for treating hypothermic combat casualties dating back to World War I.<sup>4,11,20</sup> This long-standing hypothermia management approach did not advance significantly after many wars and conflicts until the implementation of the use of the HPMK.<sup>18</sup> The HPMK was one component of the Joint Theater Trauma System's (JTTS) theater-wide strategy to address hypothermia in battlefield casualties and was recommended in the clinical practice guidelines.<sup>21</sup> This ITTS strategy demonstrated the need for a systematic approach to performance improvement, which includes research and development, clinical practice guidelines, education, training, and monitoring outcomes for care at the POI during medical evacuation, and at each role of care in the operational environment to decrease TIH mortality.8,11,60 However, a survey of battlefield medical care from 2009 and 2011 revealed that wool blankets, not the HPMK, were still being used in some cases for managing and preventing hypothermia.<sup>19,20</sup> The decision to add the HPMK to the CoTCCC Guidelines was supported by the findings of Allen et al.,<sup>61</sup> who evaluated three passive and five active hypothermia-warming systems. Even though there were good results with the HPMK, this study was not conducted with human volunteers; the researchers measured heat flux changes in warmed fluid bladders as a method to simulate a human torso. These authors noted this was a study limitation and made a recommendation that future studies on hypothermia enclosure systems be conducted with human volunteers.

evaluated using human volunteers in a cold (-22°C [-7.6°F]) chamber study.22 Five active, heated hypothermia enclosure systems (also known as hypothermia wraps) were compared. The results indicated that the HPMK (noninsulated), as compared with three other commercial, insulated, active heated hypothermia enclosure systems and one user-assembled, insulated, active heated hypothermia enclosure system, was ranked the lowest in both subjective ratings and objective physiological heat transfer and balance indices.22

These findings by Dutta et al.<sup>22</sup> and feedback from the field regarding HPMK limitations resulted in the CoTCCC undertaking a comprehensive literature review to update the current recommendations for treating casualties with hypothermia. The following are specific questions addressed by the CoTCCC in 2019 regarding the battlefield (prehospital) management of all-cause hypothermia:

- (1) Is adding an external heat source to a hypothermia wrap effective?
- (2) Is an improvised, user-assembled, heated hypothermia wrap effective?
- (3) What is the most effective method to apply an active heat source to the casualty in a hypothermia wrap to prevent and/or treat hypothermia?
- (4) What are the indications, contraindications, safety issues, and complications associated with applying an external heat source inside a hypothermia wrap during field management?
- (5) What are the required characteristics of a portable IV warming device for infusion of fluids and blood products?
- (6) What are the relevant safety concerns for a portable, battery-operated, IV warming device?11

#### **Overview of Prehospital** Hypothermia-Wrap Systems

The evidence for both passive and active external rewarming treatment options has been discussed for decades<sup>23,24</sup> and was recently reviewed for treating hypothermic patients in the prehospital environment.<sup>57</sup> The authors concluded that prehospital warming inside a hypothermia wrap is safe and advantageous, especially for a nonshivering hypothermic patient with or without injuries. This review revealed that hypothermia enclosure systems that include more insulation and active heat sources perform better for patient treatment. Table 2 lists relevant prehospital passive<sup>62-66</sup> insulation and active<sup>22,56,57,61,67-69</sup> rewarming enclosure systems, graded by the level of evidence.<sup>70</sup> The prevention of heat loss should begin aggressively soon after injury, as should active external heating, if possible.

Rewarming hypothermic patients can be passive, using the casualty's own heat production from shivering, or active, providing external heat to the casualty. Active warming is recommended, especially for trauma patients; it will warm the skin; decrease shivering (without negative effects on core rewarming) and, therefore, decrease the work of the heart; and increase the casualty's comfort level and general psychological outlook. Although active warming may not be necessary, it will do no harm in hypothermic patients and will be helpful.57

An improvised rewarming method is used to create a hypothermia wrap (also known as a "burrito wrap"). This consists All articles published in the Journal of Special Operations Medicine are protected by United States copyright law and may not be reproduced, distributed, transmitted, displayed, or otherwise published without the prior written permission of Breakaway Media, LLC. Contact publisher@breakawaymedia.org. TABLE 2 Passive and Active External Rewarming Options for Field and Evacuation Platforms

|                                 | Prehospital  | Reference  | Rewarming<br>Effectiveness | Level of<br>Evidence <sup>a</sup> | Comments   |
|---------------------------------|--|--|----------------------------|-----------------------------------|--|
|                                 | Sleeping bag   | Giesbrecht et al. <sup>62</sup>  |                            | В                                 | Insufficient alone to prevent heat loss; works better<br>with vapor barrier wrap with a when patient is<br>shivering   |
|                                 | Impermeable outer<br>layer with sleeping<br>bag insulation<br>(burrito wrap) | Grissom et al. <sup>63</sup>   | $\sqrt{}$                  | В                                 | Traditional passive rewarming approach in austere<br>medicine courses. Works well with shivering patient<br>with mild hypothermia to retain heat production and<br>prevent body heat loss; active external heating source<br>not required  |
|                                 | Wool blanket   | Allen et al. <sup>61</sup>   | NE                         | С                                 | Prospective randomized study. No human volunteers.<br>A single WB was least effective to prevent heat loss in<br>fluid-bag torso simulation.   |
|                                 | Space blanket  | Allen et al. <sup>61</sup>   | NE to √                    | С                                 | Prospective randomized study. No human volunteers;<br>SB was placed over the simulation torso and tucked in<br>and was not as effective to prevent heat loss but better<br>than the wool blanket.  |
| Passive                         | Human remains<br>pouch   | Allen et al. <sup>61</sup>   | $\checkmark$               | С                                 | Prospective randomized study. No human volunteers.<br>The HRP did not maintain torso bladder temperature<br>better than the wool blanket.  |
| Passive<br>Rewarming<br>Methods | Heat-reflective shell  | Allen et al. <sup>61</sup>   | $\sqrt{\sqrt{1}}$          | С                                 | Prospective randomized study. No human volunteers.<br>New shell version was used as a passive bag. There was<br>no statistical difference between the HRS and BB in<br>heat loss between first- and second-generation HPMKs.   |
|                                 | Hot Pocket<br>(HRP, wool<br>blanket, and space<br>blanket)                   | Allen et al. <sup>61</sup>   | $\sqrt{\sqrt{1}}$          | С                                 | Prospective randomized study. No human volunteers.<br>The use of the HP system was very effective and one of<br>two best passive methods of heat-loss prevention that<br>performed the same as two of the three active heating<br>methods tested at 120 min.   |
|                                 | Blizzard Blanket   | Allen et al. <sup>61</sup>   | $\sqrt{\sqrt{2}}$          | С                                 | Prospective randomized study. No human volunteers.<br>The use of the BB alone was one of two best passive<br>methods of heat-loss prevention that performed the<br>same as two of the three active heating methods tested<br>at 120 min.   |
|                                 | Vapor barrier +<br>hypothermia wrap  | Thomassen et al. <sup>64</sup><br>Henriksson et al. <sup>65</sup><br>Henriksson et al. <sup>66</sup> | $\sqrt{\sqrt{2}}$          | A                                 | Strong evidence in favor of vapor barrier wrapped<br>around human volunteers who were then placed inside<br>hypothermia "burrito wrap" system. These three<br>studies are the evidence for the recommendations<br>on how to assemble an improvised a hypothermia<br>enclosure system <sup>78</sup>             |
|                                 | Small chemical packs   | Co-author<br>Consensus   | NE                         | С                                 | Small chemical heat packs used for hands are<br>insufficient to provide heat transfer to core or to<br>prevent further heat loss. Better options available.  |
| Active<br>Rewarming<br>Methods  | Warm IV/IO fluids/<br>blood products   | Lehavi et al. <sup>56</sup><br>Haverkamp et al. <sup>57</sup>  | NE                         | А                                 | Do not infuse fluids cooler than 100°F (38°C). Fluids<br>alone not effective for core temperature rewarming. Use<br>fluids adjunctively with HPMK during MEDEVAC.  |
|                                 | Body-to-body skin<br>contact   | Giesbrecht et al. <sup>62</sup><br>Hultzer et al. <sup>68</sup>                                      | $\checkmark$               | В                                 | Suppresses shivering in victim with skin-to-skin contact;<br>no more effective than shivering for mild accidental<br>hypothermia; lack of evidence for any benefit in<br>nonshivering hypothermic patient; loss of manpower  |
|                                 | Hot water bottles  | Co-author<br>Consensus   | $\checkmark$               | С                                 | Impractical. Insufficient to transfer heat to effect core<br>temperature. Many bottles are needed; hot water<br>replacement every 20 min   |
|                                 | Walking  | Giesbrecht et al. <sup>67</sup>  | $\sqrt{}$                  | В                                 | Use to generate heat production in cold-stressed (>35°C [95°F]) victims with shivering intact; well protected from cold, wet, and wind; and with observer; use with caution—may cause afterdrop, 0.91°C core temperature decrease lasting nearly 30 min  |
|                                 | Ready-Heat<br>Blanket  | Allen et al. <sup>61</sup>   | $\sqrt{}$                  | С                                 | Prospective randomized study. Whole-body heat<br>blanket – 8h at 104°F (40°C); wrap torso and avoid<br>direct placement on skin; use vapor barrier as outside<br>layer   |
|                                 | HeatPac  | Giesbrecht et al. <sup>67</sup><br>Kulkarni et al. <sup>69</sup>                                     | $\sqrt[n]{\sqrt{1}}$       | В                                 | Effective to deliver heat and maintain thermal balance;<br>costly; long-term experience in Scandinavian militaries<br>and in research studies; resource dependent; uses<br>charcoal as a consumable; potential carbon monoxide<br>risk in low-ventilation space; use outdoors only. Newer<br>options available |

(continues)

TABLE 2 Cont.

|   | Prehospital  | Reference  | Rewarming<br>Effectiveness   | Level of<br>Evidence <sup>a</sup>                | Comments   |
|---|--|--|--|--|--|
|   | НРМК   | Allen et al. <sup>61</sup>   | $\sqrt{\sqrt{2}}$  | С  | Prospective randomized study. Did not use human<br>volunteers, but simulated torso with fluid bladder<br>system. Effective outcome compared with all active<br>heating systems studied.<br>CoTCCC, JTTS, and DoD preferred system since<br>2006; outer vapor-barrier garment and 10-hour<br>(110°F) chemical blanket; low cost, weight, and size;<br>effective system only for short-term use due to lack of<br>insulation; patients will get cold in <60 min; use in cold<br>environments <sup>22</sup> |
| Active  | Improvised<br>hypothermia wrap<br>(user-assembled<br>system)                         | Dutta et al. <sup>22</sup>   | $\sqrt{\sqrt{\sqrt{2}}}$   | В  | Randomized controlled study with human volunteers.<br>The user-assembled and Doctor Down systems were<br>most effective.   |
| Rewarming<br>Methods<br>(cont.)               | Doctor Down<br>Rescue Wrap   | Dutta et al. <sup>22</sup>   | $\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{$ | В  |  |
|   | НРМК   | Dutta et al. <sup>22</sup>   | $\sqrt{}$  | В  | Randomized control study with human volunteers.<br>HPMK was least effective because of lack of insulation.   |
|   | MARSARS<br>Hypothermia<br>Stabilizer Bag   | Dutta et al. <sup>22</sup>   | $\sqrt{\sqrt{2}}$  | В  | Randomized control study with human volunteers.<br>These two systems were not as effective for retaining<br>thermal balance when compared with the DD and user-<br>assembled system systems.   |
|   | Wiggy's Victim<br>Casualty Bag   | Dutta et al. <sup>22</sup>   | $\sqrt{\sqrt{\sqrt{1}}}$   | В  |  |
|   | Ready-Heat<br>Blanket and<br>PrimaLoft synthetic<br>sleeping bag<br>hypothermia wrap | Phillips et al. <sup>77</sup>  |  | С  | Single case report with high efficiency to rewarm patient  |
| Abbreviation<br>bat Casualty<br>IV, intraveno | s: √, mildly effective; v<br>Care; DoD, Departm<br>us; JTTS, Joint Theate            | √, moderately effect<br>ent of Defense; HP, I<br>er Trauma System; M | ive; √√√, highly e<br>Hot Pocket; HR<br>EDEVAC, medic  | effective; BB,<br>P, human ren<br>cal evacuation | Blizzard Blanket; CoTCCC, Committee on Tactical Com-<br>nains pouch; HRS, heat-reflective shell; IO, intraosseous;<br>n; NE, not effective; SB, space blanket; WB, wool blanket.   |

<sup>a</sup>Level A: Evidence from multiple randomized trials or meta-analyses. Level B: Evidence from a single randomized trial or non-randomized studies. Level C: Expert opinion, case studies, or standards of care.7

of an outer layer (e.g., a tarp), ground insulation pad(s), and one to three sleeping bags. When multiple sleeping bags are available, each bag should be placed within each other to create a multilayered insulation with the patient placed inside the innermost bag. For maximum insulation around the patient, each bag should be completely zipped up to prevent any cold spots on the sides of the bags, and an outer waterproof layer wrapped around all layers to prevent body heat loss while blocking wind and moisture entry.<sup>17</sup>

When hypothermic patients (core temperature <28°C [82.4°F]) are below the thermoregulatory threshold for shivering (~30°C [86°F]), shivering heat production ceases.<sup>23,25</sup> Thus, these primary hypothermic patients will continue to cool, and they cannot warm up spontaneously without external heat, even if they are well insulated from the environment; this is especially true for trauma patients. During prehospital trauma management, the administration of pain medications, such as ketamine, opioids, and benzodiazepines, per TCCC guidelines, may abolish shivering, which can further exacerbate the magnitude of hypothermia.71,72

The benefits of removing wet clothing and improving thermal balance were reported in a study that used a thermal manikin to evaluate three different insulation ensembles consisting of one, two, or seven wool blankets.65 Additionally, five different test conditions were evaluated for all three levels of insulation: (1) dry underwear; (2) dry underwear with a vapor barrier wrapped around the manikin; (3) wet underwear; (4) wet underwear with a vapor barrier wrapped around the manikin; and (5) no underwear. Heat loss and thermal resistance were determined from continuous monitoring of ambient air temperature, manikin surface temperature, heat flux, and evaporative mass loss rate. The authors reported that independent of insulation thickness or ambient temperature, the removal of wet clothing or the addition of a vapor barrier over the wet clothing resulted in a reduction in total heat loss of 19% to 42%. These findings were subsequently validated in human volunteers and confirmed equal benefit for either removing wet clothing and providing one blanket for insulation, or leaving wet clothes intact and wrapping a vapor barrier around the patient. These two-treatment conditions both significantly decreased metabolic rate, increased skin temperature, and decreased shivering thermogenesis, resulting in an overall improvement of the patient's thermal stress.<sup>66</sup>

Given this evidence, prompt treatment with active rewarming is now recommended in both Prehospital Trauma Life Support (civilian and military versions) and Advance Trauma Life Support trauma management guidelines.73,74

#### Q1. Is adding an external heat source to a hypothermia wrap effective?

Many studies have evaluated the effectiveness of external heat sources in transferring heat to the body.<sup>17,57</sup> A variety of heat sources have been reviewed, including electrical and chemical heating pads/blankets of various sizes, warmed water bottles, hot water bottles or bags, charcoal-burning heat packs, and

forced air warming<sup>57</sup> (Table 2). Each heat source has limitations based on (1) amount and duration of heat generated; (2) amount of heat transferred; (3) quantity of heat source required; (4) placement location; (5) logistics for replenishing the heat source; and (6) failure of heat source. Recommendations for specific external heat sources are made by Dow et al.<sup>17</sup> and Haverkamp et al.<sup>57</sup> and are summarized in Table 2.

Providing an external heating source against the torso inside a hypothermia-wrap enclosure system is recommended for treatment of hypothermic victims (injured and noninjured) by the Wilderness Medical Society, International Commission for Mountain Emergency Medicine, and the State of Alaska.<sup>17,75,76</sup>

Placing a healthy, normothermic person inside a sleeping bag with close skin contact with a hypothermic patient does not provide significant heat transfer to the core (i.e., heart, lungs, and brain). There are various reports of cold-water immersion accidents in which this technique was used to resuscitate hypothermic victims and, in some situations, may be the only heat source available; however, a significant benefit has not been reported. In mildly hypothermic volunteers, body-tobody rewarming blunted shivering and resulted in rewarming rates no greater than shivering alone.62 There was also no advantage to body-to-body warming when shivering was pharmacologically inhibited.<sup>68</sup> Alternatively, the authors of these studies stated that there is some benefit to consider with bodyto-body warming to make the patient more comfortable and decrease shivering intensity. However, there are drawbacks by a potential delay of evacuation and the loss of manpower in a resource-deprived environment.

There are two comparative studies of hypothermia wraps that are most relevant to the military.<sup>22,61</sup> The study by Allen et al.<sup>61</sup> supported the decision in 2006 to implement the HPMK kit in the US military. These authors tested three active external warming hypothermia wraps: HPMK, Ready-Heat Blanket (RHB; TechTrade, https://www.ready-heat.com/), and Bair Hugger<sup>™</sup> (electric powered; not relevant for field use and not discussed further; 3M Corp, https://www.bairhugger .com/3M/en\_US/bair-hugger-us/) and five passive hypothermia wraps (Table 2). The US military adopted the first- and second-generation HPMK, containing the Blizzard Blanket™ (first generation) or the Heat Reflective Shell (HRS) (second generation; both North American Rescue), both containing the RHB (a four-cell, oxygen-activated chemical heat pack). All enclosure systems were tested on a fluid torso (nonhuman) model (nine 5,000-mL bags of a dialysate solution) warmed to 37°C (98.6°F) versus a control with no warming device applied, in a room in which the temperature was maintained between 22.3°C and 22.7°C. The first- and second-generation bags were not statistically different from each other and both maintained significantly higher bladder temperatures than all other enclosure systems tested. One limitation of this study is that these data were never validated on human volunteers as recommended by the authors. Another limitation is that this study was not conducted with cold air temperatures. The HPMK manufacturer subsequently redesigned the HRS so it is now water- and windproof; this is an important update because the RHB will not generate heat effectively if the chemical heat packs get wet. Also, there are observations that some of the four cells in the RHB will fail to generate heat when exposed to air and the RHB will need to be replaced with another.77

Currently, the HPMK configuration consists of the outer HRS and the RHB. The RHB has been enhanced and is now rated with a maximum temperature of 52°C (125°F) for 10 hours of continuous dry heat; this is an increase from a maximum temperature of 40°C (104°F) for 8 hours used during the Allen et al. study.61 It is important to follow the manufacturer's recommended guidelines for use. The RHB should preferentially be placed on the casualty's torso to provide active warming but not directly on bare skin, to prevent possible burns (discussed under Safety of External Heat Sources). The HRS allows easy access to the casualty for reassessment and possible interventions (e.g., IV access or tourniquets) with the use of Velcro strips down each side of the HRS. The HRS also uses a spacious mummy-shaped shell configuration that covers the head, reducing heat loss from the neck and head. Both the RHB and the HRS are commercially available individually or combined to form the HPMK.

Another study of hypothermia treatment devices, by Dutta et al.,<sup>22</sup> compared enclosure systems containing a vapor-barrier enclosure and heat source to improve total-body heat balance in human volunteers exposed to cold air. All enclosure systems evaluated are designed for use in the prehospital environment, although some are too bulky and heavy to be carried to the victim. This study compared the effectiveness of five heated hypothermia wrap systems (four heated systems were insulated and one system [the HPMK] had no insulation): (1) a user-assembled system (three-season, hooded sleeping bag with an internal vapor barrier and three gel heat packs); (2) Doctor Down<sup>™</sup> (an insulated system with two gel heat packs; http://www.doctordown.com/); (3); Wiggy's Victims Casualty Hypothermia Bag<sup>™</sup> (an insulated system with dry chemical heat pad; Wiggy's, https://www.wiggys.com/); (4) MARSARS Hypothermia Stabilizer Bag<sup>™</sup> (an insulated system with three gel heat packs; MARSARS Water Rescue Systems, https:// marsars.com/); and (5) the HPMK (a noninsulated system with a four-cell chemical heating blanket; Figures 1 and 2).

Physiologic and subjective responses were assessed in five normothermic volunteers during 60 minutes of exposure to  $-22^{\circ}$ C (-8°F) in a laboratory cold chamber. The user-assembled enclosure system and Doctor Down system were most effective physiologically and subjectively, with higher skin temperatures, lower metabolic heat production, and less heat loss, resulting in higher net heat gain. The subjects were coldest and had the highest level of shivering in the noninsulated HPMK and subjectively rated greater "whole body cold discomfort" and lower "overall temperature" ratings than the other four systems tested.

The authors commented that the enclosure systems had significant variability in weight, size, and heat-pack characteristics. The user-assembled system (estimated cost \$170) and Doctor Down<sup>™</sup> system (estimated cost \$900) had the best physiologic performances. However, only the user-assembled enclosure system and HPMK system were suitable to be carried in backpacks, because of their weight and volume. Larger, insulated, commercial systems could be prepositioned in vehicles for convoys, or ground and air medical evacuation platforms, and in medical treatment facilities. The authors also noted that all the enclosure systems could be effective; however, clinically important differences between the systems evaluated might be seen with extended cold exposures, particularly in severe-trauma patients who might be already cold stressed.

All articles published in the Journal of Special Operations Medicine are protected by United States copyright law and may not be reproduced, distributed, transmitted, displayed, or otherwise published without the prior written permission of Breakaway Media, LLC. Contact publisher@breakawaymedia.org. FIGURE 1 Specifications for four commercial and a self-assembled hypothermia enclosure wraps.<sup>22</sup>



| System                    | MARSARS (A) | Doctor Down (B) | Wiggy's (C) | User-assembled (D) | HPMK (E) |
|---------------------------|-------------|-----------------|-------------|--------------------|----------|
| Volume (L)                | 62.6        | 39.5            | 37.4        | 28.8               | 6.1      |
| Enclosure<br>Weight (kg)  | 5.4         | 6.4             | 3.6         | 2.3                | 0.8      |
| Heat packs<br>Number/type | 3 gel       | 2 gel           | 2 dry       | 3 gel              | 4 dry*   |
| Weight (kg)               | 3.3         | 1.1             | 0.4         | 3.2                | 0.8      |
| Tight fit around face     | no          | yes             | no          | yes                | yes      |
| List price (USD)          | \$528       | \$900           | \$335       | \$170              | \$108    |

\*Four dry chemical heat packs inserted in one heat blanket.

Phillips et al. reported a case of an adult with moderate hypothermia who was rewarmed in the field using an RHB from a HPMK inside a user-assembled insulated hypothermia wrap.77 The casualty, a 53-year-old woman, became lost and was found by search-and-rescue personnel after about 24 hours in a cool and rainy mountain environment. Initially alert and oriented, she subsequently became less responsive, her initial shivering had stopped, and she had peripheral cyanosis. Wet clothes were removed and she was covered with an RHB inside a synthetic sleeping bag, and an outer tarp was wrapped to enclose the entire ensemble. After 90 minutes inside the hypothermia wrap, she was evacuated and while en route to the emergency department, she complained of being hot, was fully alert and oriented, and was removed from the hypothermia wrap. At the hospital, her temporal artery temperature was 37.7°C (100°F) and vital signs were normal. To our knowledge, this is the only case report in a primary hypothermia patient, and it demonstrated the effective use of an external warming enclosure system that can rewarm a nonshivering patient who was likely moderately hypothermic.

#### Conclusion

An active heat source within an insulated hypothermia wrap is recommended for all cold-exposed or hypothermic trauma victims. The noninsulated HPMK is effective only for short-term use in cold environments and should be upgraded to an insulated system as soon as possible. Level of evidence: A (insulation to decrease heat loss, active heat sources to increase heat gain); Level of evidence: C (benefit from active heat sources to rewarm patients and to reverse hypothermia)

## Q2. Is an improvised, user-assembled, heated hypothermia wrap effective?

The six passive insulation systems studied by Allen et al.<sup>61</sup> were (1) a US Army wool blanket, (2) a space blanket, (3) the Blizzard Blanket<sup>™</sup>, (4) the HRS (both the Blizzard Blanket and HRS are part of the original HPMK), (5) a humanremains pouch, and (6) "Hot Pocket" (a space blanket and a US Army issue wool blanket used together as insulation inside a human-remains pouch). The best-performing passive enclosure systems in this study were the Hot Pocket and Blizzard Blanket<sup>™</sup>. It was noted that these two enclosure systems were more effective than a wool blanket for reducing heat loss. It is important to stress that, at room temperature, the Blizzard Blanket<sup>™</sup> and the Hot Pocket passive enclosure systems, but not the HPMK.

As a result of feedback from many civilian first responders and prehospital care providers, a concise and simplified primary hypothermia decision aid (the Cold Card) was specifically designed for field use.<sup>78</sup> This two-sided card summarizes the current consensus regarding how to assess and manage cold-exposed patients. The principles from the Cold Card for making a hypothermia wrap are the same for managing a TIH casualty. The hypothermia wrap includes (1) an outer vapor barrier (tarp or plastic sheet), (2) an insulated ground pad, (3) a hooded sleeping bag, (4) an internal vapor barrier (plastic or foil sheets), and (5) a heat source applied to the torso but *not directly on skin* (e.g., the RHB). The casualty is then wrapped up like a burrito. Such equipment has multiple uses in the field

FIGURE 2 Four commercial and one User-assembled hypothermia enclosure systems with heat source locations. (A) User-assembled (control); (B) Doctor Down Wrap; (C) Wiggy's Victims Casualty Hypothermia Bag; (D) MARSARS Hypothermia Stabilizer Bag; (E) Hypothermia Prevention, and Management Kit.<sup>22</sup>



environment and is reasonable to transport by backpack in many situations. This evidence-based method for making a hypothermia wrap is described by Giesbrecht.<sup>78</sup>

#### Conclusion

There is evidence that an improvised hypothermia wrap is effective when high-quality insulation with a cold-rated sleeping bag is combined with a heat source, an internal vapor barrier, and an outer impermeable enclosure. Level of evidence: B

## Q3. What is the most effective method to apply an active heat source to the casualty in a hypothermia wrap to prevent and/or treat hypothermia?

External heat sources are most effective if concentrated on the upper torso and not on the extremities, in the following order of preference: (1) axillae, (2) chest, and (3) back. These are the areas with the highest potential for heat transfer to the core.<sup>17,57,79,80</sup>

Lundgren et al.<sup>81</sup> evaluated the differences among three external heat sources applied in combination to the chest and back of volunteer subjects whose shivering was pharmacologically suppressed. Two chemical heat pads, two flexible hot water bags, and a charcoal heater (HeatPac) were assessed. The core rewarming rates for the hot-water bags (0.7°C/h) and the charcoal heater  $(0.6^{\circ}Ch)$  tended to be higher than that for the chemical heating pads  $(0.2^{\circ}C/h)$ ; all were significantly higher than the spontaneous warming rate  $(0.1^{\circ}C/h)$ . The authors recommended the use of charcoal heaters, chemical heating pads, or hot-water bags in that order of preference, based on effectiveness, when applied to cold-stressed or hypothermic patients in the field or during transport. Although the hot-water bags  $(55^{\circ}C \ [131^{\circ}F])$  are effective, there is a logistical challenge to maintain a warmed-water supply, particularly when moving during transport.

Small chemical heat packs, as commonly used inside gloves and shoes for hand and foot warming, are not recommended for hypothermia management. These low-volume units do not provide sufficient heat to affect core temperature, although they may provide warm comfort and prevent local cold injury of the hands and feet.

#### Conclusion

There is evidence to support application of a heat source to the upper torso of a hypothermic casualty sufficient to transfer heat to the body core and provide comfort to the patient. Level of evidence: B

# Q4. What are the indications, contraindications, safety issues, and complications when adding an external heat source inside a hypothermia wrap during field management?

#### Indications for Active Heating

For decades, the indications for, and benefits of, an active external heating source placed inside a hypothermia wrap have been well accepted.<sup>17,23–25</sup> With traumatic injury, hypothermia must be actively prevented starting at the POI, because of the increase in mortality risk from hypothermia that begins at a temperature of 35.6°C (<96°F).<sup>13,43,44</sup> Other indications for active warming are central nervous system trauma, shock, acute spinal cord transection, altered level of consciousness, unresponsiveness, opioid administration, and impaired shivering in a cold environment.<sup>82</sup>

#### Conclusion

For all cold patients with the potential for TIH, hypothermia prevention is of utmost importance and should be accomplished by using all available resources to stop core heat loss after serious injury. Insulation should be maximized, and a heat source should be added to the torso as soon as possible. It is recommended to prepare and train for TIH on the battlefield with an HPMK or insulated, active rewarming hypothermia wrap. Level of Evidence: B

#### Contraindication for Active Heating

For TIH, there is no absolute contraindication for using an HPMK or other active rewarming hypothermia wraps. The only relative contraindication would be a scenario on the battlefield when someone has minor trauma and presents with signs and symptoms of moderate to severe heat illness (i.e., heat exhaustion and exertional heat stroke).<sup>83,84</sup> In this scenario, there is no ongoing noncompressible hemorrhage or derangement of thermoregulation with core heat loss at the POI. This casualty would not benefit from active heating, which actually may exacerbate the severity of heat illness.

Although it is accepted that hypothermia, as an outcome of trauma, results in increased mortality, it is less known that

All articles published in the Journal of Special Operations Medicine are protected by United States copyright law and may not be reproduced, distributed, transmitted, displayed, or otherwise published without the prior written permission of Breakaway Media, LLC. Contact publisher@breakawaymedia.org. thermia and severe trauma are also indicative of a poor Complications With an External Heat Source

hyperthermia and severe trauma are also indicative of a poor patient outcome, as reported for both civilian and military ca-

patient outcome, as reported for both civilian and military casualties.<sup>45</sup> A casualty should be treated on the basis of their core temperature; ambient temperature should not be relied on. During Operation Iraqi Freedom and Operation Enduring Freedom, military surgical trauma teams frequently observed hypothermia in combat casualties even during extreme high temperatures in the Middle East deserts.<sup>8,10,85</sup>

#### Conclusion

With moderate to severe injuries, trauma-induced hypothermia can occur during combat operations in high ambient temperatures and should be prevented or managed with an HPMK or other active heating hypothermia wrap. With minor trauma, it is not recommended to use any active heating when there is evidence of moderate to severe heat illness in a combat casualty. Level of Evidence: C

#### Safety of External Heat Sources

Most external heat sources available in the field are safe, with a low chance of additional injury during hypothermia management; exceptions include a hot water bath or shower, fire, fire-warmed rocks, and ovens.<sup>24,57</sup> It is generally safe to use an RHB as part of the HPMK, but anecdotal reports from military trauma surgeons and published case reports show these heating sources can cause first- to third-degree burns when applied directly to skin.<sup>61,86,87</sup> These injuries may occur through misuse or be the result of unexpected consequences to application. Cold and underperfused skin is very susceptible to injury from pressure or heat.<sup>17,87</sup> The user should follow manufacturer instructions and place a protective layer of material between the heat source and the skin to prevent burns.<sup>17</sup>

#### Conclusion

There are three recommendations suggested to mitigate the risk of burns: (1) place a thin layer of material between the skin and heat source; (2) avoid placing the heat in highpressure areas (e.g., the back of a supine patient) unless the skin can be observed regularly; and (3) regularly monitor the skin for burns. Level of Evidence: C Cooling ischemic muscle has the potential to reduce muscle damage.88-90 When compared with baseline muscle temperature, there is indirect evidence to suggest that a 2°C-3°C reduction in muscle temperature may reduce muscle necrosis after extended tourniquet application.91 Furthermore, successful limb salvage of a cool extremity after tourniquet applications for 8 and 16 hours was reported in two cases.92,93 A Department of Defense medical panel recommended in 2003 to take advantage of cool ambient temperatures when a tourniquet is applied to an extremity.94 However, others do not recommend packing snow or ice directly on an injured limb after tourniquet application, because of the risk of additional tissue trauma, such as frostbite.93 In 2015, a CoTCCC working group updated the recommendations for tourniquet use and agreed with the recommendation made by Walters and Mabry<sup>94</sup> that when a tourniquet is applied, keep the nonperfused portion of the extremity exposed to cooler environmental temperature.95 This recommendation also has the added advantage of allowing close observation of the limb for rebleeding, but this 2005 recommendation needs to be considered for each casualty on the basis of the severity of trauma, and particularly if the casualty is hypothermic or at risk of becoming hypothermic.

#### Conclusion

For combat casualties with extremity trauma requiring a tourniquet to control hemorrhage, consider keeping the nonperfusing extremity distal to the tourniquet exposed to a cooler environmental temperature. However, with moderate to severe trauma resulting in TIH, the priority is to prevent additional core cooling in an effort to decrease the complications of shock, hypothermia, coagulopathy, and acidosis. Consequently, in TIH cases, it is not advisable to expose any extremity with a tourniquet, through an exterior opening of the hypothermia wrap. Level of Evidence: C.

See Table 3 for a summary of the indications, contraindications, safety issues, and associated complications of hypothermia wraps with external heat sources.

TABLE 3 Indications, Contraindications, Safety Issues, and Complications for Active Rewarming of Battlefield Casualties

|                   | Criteria   | General Comments   |
|-------------------|--|--|
| Indications       | <ul> <li>Moderate to severe trauma</li> <li>Central nervous system trauma</li> <li>Burn patients &gt;33% TBSA with second- or third-degree burns</li> <li>Altered level of consciousness/unresponsive; in cold environment</li> <li>Impaired shivering; in cold environment</li> </ul> | Combat casualties with moderate to severe trauma<br>should be treated with active heating inside a<br>hypothermia wrap as soon as possible.  |
| Contraindications | <ul> <li>None for TIH</li> <li>Only when a casualty presents with signs and symptoms of hyperthermia (severe heat illness)</li> </ul>  | There are no restrictions to use active warming inside<br>a hypothermia wrap for TIH casualties.<br>It is contraindicated to use active warming for any<br>casualty who has heat exhaustion or exertional heat<br>stroke.                                |
| Safety            | • First-, second-, and third-degree burns  | Never place any active heat source directly on skin.<br>Follow manufacture directions for correct use of<br>heating source.  |
| Complications     | • Potential for enhanced muscle damage on an extremity distal to a tourniquet  | Increased temperature of nonperfused extremity distal<br>to a tourniquet can cause additional muscle damage.<br>Attempt to keep that part of the extremity from<br>increasing temperature.<br>Do not pack extremity with a tourniquet in ice<br>or snow. |

Abbreviations: TBSA, total body surface area; TIH, trauma-induced hypothermia.

**Q5.** What are the required characteristics of a portable IV warming device for infusion of fluids and blood products? Resuscitation with blood products facilitates a return to baseline aerobic metabolism, increasing the body's intrinsic ability to produce heat. Blood must be stored at 4°C–8°C (39°F–46°F); however, infusion of fluid at this temperature leads to a drop in core temperature. With as little as 500mL of cold blood, a patient's core temperature will drop by about 1°C and coagulation factor activity is reduced approximately 10%–15% for each 1°C drop in temperature.<sup>96</sup> Prehospital providers require a fast, effective, and easy-to-use warming device for rapid delivery of fluids or blood at the POI.

Infusion of fluids warmed to 38°C–42°C (100°F–108°F) is recommended for moderate to severe hypothermia.<sup>17,50,57,82</sup> Administration of room-temperature fluid contributes to iatrogenic hypothermia.<sup>13</sup> The current damage-control approach to resuscitation includes minimizing crystalloid or colloid fluids in favor of blood products, preferably whole blood.<sup>97,98</sup>

The goal of infusing warmed IV fluids/blood is to reduce negative heat balance rather than to actively warm the patient.<sup>57</sup> Several studies have evaluated portable fluid-warming device characteristics, including parameters such as time to reach maximum temperature and final delivery temperature, for use with combat casualties<sup>50,54,56</sup> or in the civilian prehospital setting.<sup>59,99–101</sup>

In a recent study, Lehavi et al.<sup>56</sup> evaluated the following four in-line, battery-operated fluid warmers that were developed for use in the prehospital environment: Belmont Buddy Lite<sup>™</sup> (Belmont Medical Technologies; https://belmontmedtech.com/ portable-iv-pump), enFlow<sup>™</sup> (Vyaire Medical, https://www .vyaire.com/), Thermal Angel<sup>™</sup> (Estill Medical Technologies, https://thermalangel.com/), and QinFlow Warrior<sup>™</sup> (https:// qinflow.com/). Using normal saline, they studied three warming device characteristics: (1) heating performance over time, (2) the volume that can be effectively heated, and (3) the flow resistance. The authors reported that the performance characteristics of these fluid warmers varied with flow and initial input temperatures. They studied two input fluid temperatures, 10°C and 20°C, and two fluid flow rates, 50 and 200mL/min.

Among the portable fluid warmers evaluated in the Lehavi et al. study,<sup>56</sup> the Warrior<sup>™</sup> provided the best warming performance at high infusion rates and low input temperatures (i.e., average output temperatures were 37.8°C [100°F] at 50mL/min; 36.1°C (97°F) at 100mL/min; and 34.4°C (94°F) (at 200mL/min). Only the enFlow<sup>™</sup> and Warrior<sup>™</sup> functioned reliably in accordance with the manufacturer's specifications. The Buddy Lite<sup>™</sup> was limited to moderate input temperature and low flow rates, and the Thermal Angel<sup>™</sup> was limited by battery capacity to low fluid volumes and low output temperature in cold environmental conditions. This study only evaluated these devices within a limited environmental temperature range with fixed input-fluid temperatures and flow rates, and it did not evaluate infusion of blood products.

The most recent FDA-approved portable fluid/blood-warming device is the Quantum<sup>™</sup> (Life Warmer, www.lifewarmer.com). There are no published studies comparing this device with other portable IV warming devices, to our knowledge; however, the device was developed to military prehospital specifications with US Special Operations Command funding.

To date, there is no optimal portable fluid/blood-warming device that has been evaluated independently among other devices with ideal features and performance characteristics for use on the battlefield. New products are in development. See Table 4 for recommended ideal device specifications and performance characteristics.<sup>26</sup>

**TABLE 4** Ideal Fluid- and Blood-Warming Device Specifications andPerformance Characteristics

| • Portable   | • Rapid battery recharge duration (<100 min)  |
|--|---|
| • Lightweight (~2 lb)  | • Recharger unit for two to three batteries   |
| • Small dimensions<br>(height, width, length)  | Optional intravenous tubing lengths   |
| Rugged for field use   | • Flight approved (airworthy)   |
| • Rapid start up (<30 s)   | <ul> <li>Functions in hypo/hyperbaric<br/>environments</li> </ul>   |
| • Water resistant  | • Operating conditions for<br>battlefield temperature<br>(-10°C to 45°C) and humidity<br>(5%-95% relative humidity) |
| • Low noise and light signature  | • Fluid and blood products output<br>temperature at least 38°C at<br>≥100–150mL/min (4°C starting<br>temperature)   |
| • Long-life battery powered with easy replacement  | Reusable warming device   |
| <ul> <li>Battery duration for<br/>4 units of whole blood at<br/>≥100 to 150mL/min</li> </ul> |   |

#### Conclusions

Currently available, FDA-approved portable infusion fluid warming devices vary significantly in regard to ideal device specifications (e.g., weight, size, cost, flow rates, output fluid temperature). Selected devices should be tested to ensure that desired performance characteristics are met. Level of evidence: B

## Q6. What are the relevant safety concerns for a portable, battery-operated, IV warming device?

The safety of fluid and blood warming devices can be categorized in two areas of concern:

- (1) The risk of aluminum toxicity with fluid- and bloodwarming devices with an uncoated heating plate and
- (2) The risk of hemolysis when heating blood

#### Aluminum Toxicity

The enFlow<sup>™</sup> fluid- and blood-warming unit by Vyaire Medical has been used as a prehospital device in the United States and Europe. In a recent study, Perl et al.<sup>102</sup> reported that uncoated aluminum plates in fluid-warming systems, as used in the enFlow system, yielded potentially harmful concentrations of aluminum (between 3,400 and 8,000µg/L) when using electrolyte solutions. Vyaire Medical issued a statement indicating they are not aware of a single incident related to enFlow<sup>™</sup> in a clinical setting where aluminum was observed to have been transmitted to a patient, nor have there been any reported adverse events. Since the article by Perl et al.<sup>102</sup> was released, the manufacturer has issued a recall notice Class 1 Device Recall for enFlow IV Fluid Warmer because of aluminum elution from the enFlow disposable warming-plate cartridge during fluid warming.<sup>103</sup> At this time, there are no reports from other All articles published in the Journal of Special Operations Medicine are protected by United States copyright law and may not be reproduced, distributed, transmitted, displayed, or otherwise published without the prior written permission of Breakaway Media, LLC. Contact publisher@breakawaymedia.org. facturers of fluid- and blood-warming devices regarding FIGURE 3 Preferred method to create an insulated Hypothermia

manufacturers of fluid- and blood-warming devices regarding any risk of aluminum toxicity.

#### Conclusion

Recent research on the enFlow<sup>™</sup> warmer device show elevated aluminum level in IV fluid after it passes through the uncoated aluminum heating plate in this device. No other portable warming device has a similar warming-plate system with aluminum contacting blood. Level of evidence: B

#### Hemolysis

Current, FDA-approved, portable IV warming devices use a heating plate that comes in direct contact with the fluid. One concern is that rapid heating and the coating agent used in the heating plate can cause RBC damage. Heating RBCs to >42°C will cause cell injury and hemolysis.104-106 However, when studies evaluate warming blood between 38°C and 42°C (100°F-108°F) with either a hospital electrical AC-powered IV warming device or portable battery-powered IV warming device, there is no evidence of RBC damage at or below this temperature range.<sup>107-109</sup> Poder et al.<sup>108</sup> conducted a meta-analysis of 17 observational studies on hemolysis with blood heating. The descriptive analysis indicated that multiple factors can influence the level of hemolysis during blood heating, including blood age, anticoagulant type, and duration of exposure to heat. They concluded that at temperatures of  $\leq$ 43°C (109°F) and even up to 45°C-46°C (113°F-115°F), blood heating is safe and hemolysis, as indicated by free hemoglobin, is negligible.

#### Conclusion

The risk of hemolysis when administering blood with a battery-powered warming device is clinically negligible with blood warmed to 42°C (108°F), which is higher than the recommended output temperature by the Joint Trauma System damage-control resuscitation guideline. Level of evidence: B

#### Implications for TCCC

It is now evident that there are limitations when using the noninsulated HMPK in cold environments. These data are supported by feedback from the field in various Special Operations Forces units who already have begun transitioning to an insulated and external heat-source enclosure system for better thermal protection and patient comfort. Improved hypothermia enclosure systems can be transitioned to the US military by implementing the most effective, logistically supportable, and evidence-based rewarming methods as a solution to the current limitation of the noninsulated HPMK by using either (1) HPMK with added insulation, (2) an improvised hypothermia enclosure system using high-quality insulation and heat source, or (3) a commercial hypothermia enclosure system for combat casualties with TIH or burn trauma-related hypothermia during initial treatment and during prolonged field care and evacuation. It is essential to anticipate, plan, prepare, and train for TIH and implement an effective hypothermia enclosure system as soon as possible after injury.<sup>28</sup> The benefit to the US Department of Defense is that the user-assembled hypothermia enclosure system is a low-cost insulation option and can be improvised with a hooded sleeping bag (various weight, size, and styles), or by using an RHS with an internal vapor barrier, two or more wool blankets, or other readily available insulation material and an RHB as one proposed insulation modification with the HPMK. See Figure 3 for the cross-sectional layers of the recommended method to create an insulated HPMK with a hooded sleeping bag.

**FIGURE 3** Preferred method to create an insulated Hypothermia Prevention, and Management Kit for hypothermia heated wrap (a cross-sectional view: heat-reflective shell outer layer to inner layer Ready-Heat Blanket over casualty).



Alternatively, when no HPMK is immediately available to create an insulated HPMK, there is good evidence for how best to create an effective improvised hypothermia enclosure system, as mentioned previously. See Figure 4 for cross-sectional layers of an improvised insulated hypothermia wrap. When a sleeping bag is not immediately available, due to operational logistics, use at least two wool blankets wrapped around the casualty. If no insulation is readily available at the POI, apply the HPMK to the casualty, as originally recommended.

**FIGURE 4** An improvised, insulated, hypothermia heated wrap (a cross-sectional view outer layer to inner layer).



#### Summary

The HPMK has worked well since implementation when used for initial casualty management and rapid transition to medical treatment facilities, and the HPMK has the best evidence to date for effectiveness as a hypothermia enclosure system for the majority of operational applications. However, the HPMK potentially has limitations in maintaining thermal balance in cold environments, due to the lack of insulation. In situations that may result in prolonged exposure of a casualty to a cold environment, it is essential to provide insulation inside the shell of the HPMK (preferably with a hooded sleeping bag or other readily available insulation materials). When no HPMK is available, responders should assemble an improvised hypothermia enclosure system that contains a hooded sleeping bag (preferred), wool blankets, or cold-weather issue gear

(alternatives) with a heat source inside a water-impermeable outer shell. Commercial insulated and heated hypothermia enclosure systems are bulky, heavy, expensive, and not more effective than improvised systems as long as high-quality insulating layers and heat sources are used.

The use of IV fluid/blood-warming devices is an essential component for managing hypothermia caused by either penetrating, blunt, or burn trauma and should deliver consistent output temperatures at 38° (100°F) but no higher than 42°C (108°F) at a flow rate of up to 150mL/min and perform to standard within the extremes of military environments.

#### PROPOSED CHANGE TO THE TCCC GUIDELINES

#### **Current Wording**

#### Care Under Fire

- 7. Hypothermia Prevention
  - a. N/A

#### **Tactical Field Care**

#### 7. Hypothermia Prevention

- a. Minimize casualty's exposure to the elements. Keep protective gear on or with the casualty if feasible.
- b. Replace wet clothing with dry if possible. Get the casualty on to an insulated surface as soon as possible.
- c. Apply the Ready-Heat blanket from the Hypothermia Prevention and Management Kit (HPMK) to the casualty's torso (not directly on the skin), and cover the casualty with the Heat Reflective Shell (HRS).
- d. If a HRS is not available, the previously recommended combination of the Blizzard Survival Blanket and the Ready-Heat blanket may also be used.
- e. If the items mentioned above are not available, use dry blankets, poncho liners, sleeping bags, or anything that will retain heat and keep the casualty dry.
- f. Warm fluids are preferred if IV fluids are required.

#### Tactical Evacuation Care

#### 7. Hypothermia Prevention

- a. Minimize casualty's exposure to the elements. Keep protective gear on or with the casualty if feasible.
- b. Replace wet clothing with dry if possible. Get the casualty onto an insulated surface as soon as possible.
- c. Apply the Ready-Heat Blanket from the Hypothermia Prevention and Management Kit (HPMK) to the casualty's torso (not directly on the skin) and cover the casualty with the Heat-Reflective Shell (HRS).
- d. If an HRS is not available, the previously recommended combination of the Blizzard Survival Blanket and the Ready Heat blanket may also be used.
- e. Use a portable fluid warmer capable of warming all IV fluids including blood products.
- f. Protect the casualty from wind if doors must be kept open.

#### Proposed New Wording (Proposed new material in red text)

#### Care Under Fire

7. Hypothermia Prevention a. N/A

#### Tactical Field Care & Tactical Evacuation Care

- 7. Hypothermia Prevention
  - **a.** Take early and aggressive steps to prevent additional body heat loss and add external heat when possible for trauma and severely burned casualties.
  - b. Minimize casualty's exposure to cold ground, wind, and air temperatures. Place insulation material between the casualty and any cold surface as soon as possible. Keep protective gear on or with the casualty if feasible.
  - c. Replace wet clothing with dry clothing, if possible, and protect from additional heat loss.
  - d. Place an active heating blanket on the casualty's anterior torso and under the arms in the axillae (to prevent burns, do not place any active heating source directly on the skin or wrap around the torso).
  - e. Enclose the casualty in the exterior impermeable enclosure bag.
  - f. As soon as possible, upgrade a hypothermia enclosure system to a well-insulated enclosure system using a hooded sleeping bag or other readily available insulation inside the enclosure bag/external vapor-barrier shell.
  - **g.** Prestage an insulated hypothermia enclosure system with external active heating for transition from the non-insulated hypothermia enclosure systems; seek to improve on existing enclosure system when possible.
  - h. Use a battery-powered warming device to deliver IV resuscitation fluids, in accordance with current CoTCCC guidelines, at flow rate up to 150mL/min with a 38°C (100°F) output temperature.
  - i. Protect the casualty from exposure to wind and precipitation on any evacuation platform.

#### Level of evidence:30

The levels of evidence used by the American College of Cardiology and the American Heart Association were outlined by Tricoci et al.<sup>70</sup>

- Level A: Evidence from multiple randomized trials or meta-analyses
- Level B: Evidence from a single randomized trial or non-randomized studies
- Level C: Expert opinion, case studies, or standards of care

Using the taxonomy above, the level of evidence for each statement below is shown:

## Recommendations for Additional Research and Development

- Comparison of commercial hypothermia warming systems in hemorrhagic shock model
- Comparison of warming capability between the batterypowered Warrior<sup>™</sup> and Quantum<sup>™</sup> warming devices with crystalloid and whole blood at various input temperatures and flow rates
- Logistical comparison of Warrior<sup>™</sup> and Quantum<sup>™</sup> (e.g., weight, cube, battery life)
- Evaluation of various insulated IV tubing wraps
- Compare hypothermia enclosure systems (e.g., userassembled system, HPMK, HPMK with insulation and internal vapor barrier) in normothermic and cold-stressed volunteers.
- Conduct cold-chamber studies with human volunteers with longer cold exposures, potentially with hypothermic conditions starting with normothermia (37°C [98.6°F]) and/or

All articles published in the Journal of Special Operations Medicine are protected by United States copyright law and may not be reproduced, distributed, transmitted, displayed, or otherwise published without the prior written permission of Breakaway Media, LLC. Contact publisher@breakawaymedia.org. Id stress (35°C [95°F]) to further examine the efficacy of 13. Søreide K. Clinical and translational aspects of hypothermia in

cold stress (35°C [95°F]) to further examine the efficacy of rewarming enclosure systems.

• Conduct randomized controlled clinical trials by comparing passive and active external rewarming enclosure systems in multiple emergency medical services regions.

#### Authorship and Contribution Statement

B.L.B. conceived and wrote the initial draft of this manuscript. All 11 authors contributed to the development of all drafts. Final approval was jointly agreed among all 11 authors and the members of the Committee on Tactical Combat Casualty Care.

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The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Defense Health Agency, the Department of Defense, or the US Government. This recommendation is intended to be a guideline only and is not a substitute for clinical judgment.

#### Disclosures

J.B.H. serves on the Board of Directors of QinFlow Inc. E.M. is the President/CEO of Aptus Volens and consults for North American Rescue. All other authors have no disclosures to make.

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