JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Hypothermia: Prevention and Treatment

This document provides updates to the Hypothermia Prevention Monitoring and Management CPG from 2012 and is applicable from the pre-hospital phase of care and beyond.

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HYPOTHERMIA

PREVENTION & TREATMENT

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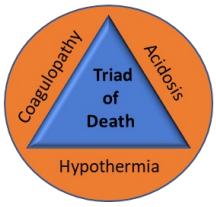
● Prehospital ● Tactical Combat Casualty Care ● En Route Care ● Prolonged Casualty Care ● Tips & Tricks ● Troubleshooting

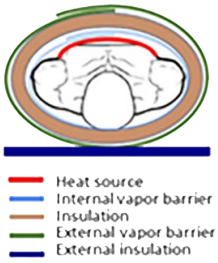
Hypothermia is a key contributor in the Triad of Death



Trauma-induced Hypothermia

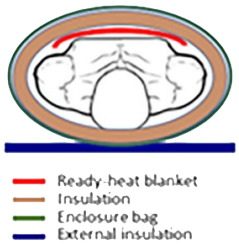
mild: 34-36°C
moderate: 32-34°C
severe: <32°C

- ✓ **Replace wet clothing** with dry clothing
- ✓ **Monitor patient's temperature** during rewarming. Convert to continuous temperature monitoring.
- ✓ **Warm resuscitation fluids/blood products** to 38-42°C with a flow rate up to 150 ml/min



Use passive and active methods of rewarming

- Passive warming: utilizing the patient's heat generation via shivering/metabolism.
- Active warming: applying an external heat source



METRICS

- Temperature and route will be documented on all patients upon admission and discharge.
- Core temperatures are obtained on patients with temperature < 97° F and > 100° F.
- Warming measures and sustainment of core temperature > 96°.F are initiated on all patients.

Clinical tips based on the Hypothermia: Prevention and Treatment CPG, Jun 2023, published by the Joint Trauma System.

JTS CPGs : HTTPS://JTS.HEALTH.MIL/INDEX.CFM/PI_CPGS/CPGS

SUMMARY OF CHANGES

1. Incorporates Tactical Combat Casualty Care (TCCC) Guidelines for Hypothermia from 2021.
2. Expands prevention of trauma-induced hypothermia to include not only trauma patients in hemorrhagic shock, but also burns and cerebrospinal injuries.
3. Outlines characteristics of hypothermia prevention and treatment systems that can be utilized in addition to the more widely used system, the Hypothermia Prevention and Management Kit (HPMK) and the Heat Reflective Shell (HRS).
4. Provides option if unable to remove wet clothing to include the enclosure of the casualty with a vapor barrier over the wet clothing.
5. Recommends upgrading the HPMK to an insulated system as soon as possible as it is non-insulated and therefore only suitable for short term hypothermia prevention.
6. Provides specific target for warm resuscitation fluids/blood products to 38-42 degrees Celsius.
7. Adds Prolonged Casualty Care (PCC) guidelines to the CPG.
8. Expands Field Expedient 'Tricks of the Trade' in the CPG.

BACKGROUND

Hypothermia, coagulopathy, and acidosis are the physiological derangements constituting the "triad of death" in trauma patients.[1–4] Here, we use the term trauma-induced hypothermia (TIH) as it relates more specifically to combat trauma including hemorrhagic shock, cerebrospinal injury, and burns - all of which lead to a significantly increased risk of mortality and presents as a separate, more severe entity than non-traumatic or environmental hypothermia. TIH is a ubiquitous concern regardless of the environment as it can occur even in warm climates, as has been the experience in the Middle East.[5]

The Hypothermia CPG, initially published in 2006, was one of the first JTS CPGs. Prior to this, the rate of hypothermia (Temp <97 F) in patients arriving to the first role of care was as high as 15.42% in 2004. The rate initially dropped by over half to 7.26%. While it slowly increased again, it should be noted that missing temperature data in the DoD Trauma Registry (DoDTR) was as high as 42% when large volumes of casualties were being seen in 2003. The rate of missing data dropped significantly when the CPG was published yet remained in the 10-20% range. It is unclear if the true incidence was higher before 2006, but this potentially shows a Hawthorne effect and the effectiveness of tracking information to inform clinical practice. Figure 1 shows the trend in hypothermia by U.S. Military patients by year at any medical treatment facility (MTF). The purpose of this CPG is to provide guidance for the prevention and management of TIH in the combat casualty throughout the escalating roles of care.

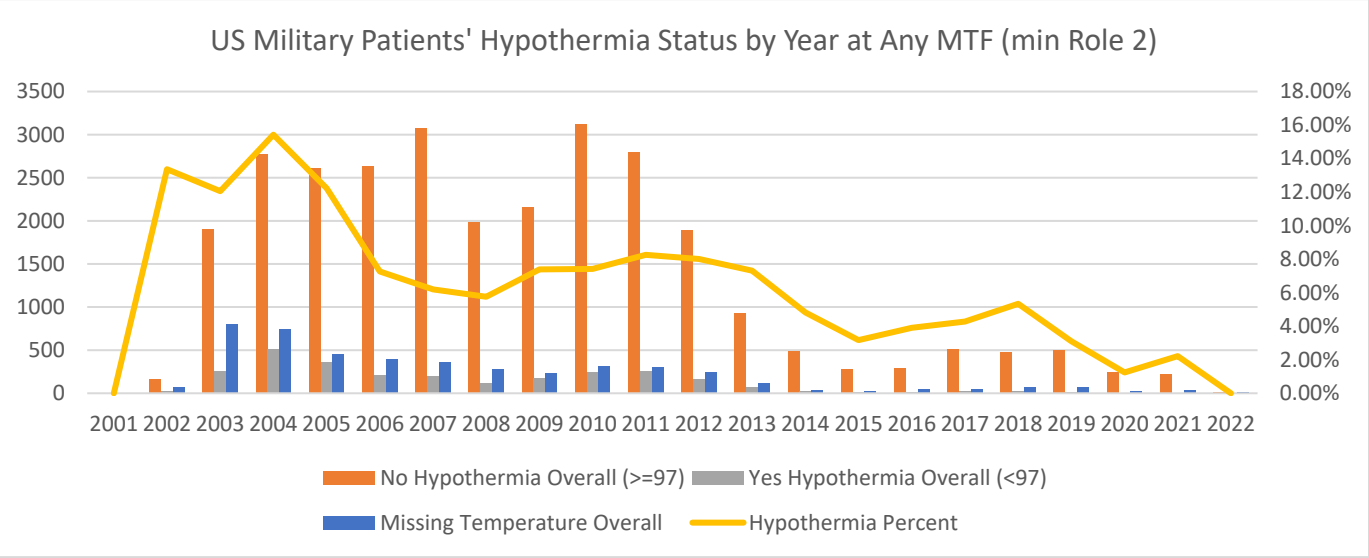
Current literature suggests that about one to two-thirds of trauma patients are hypothermic upon presentation to the emergency department. The mortality of hypothermic patients is approximately twice that of similarly injured normothermic patients.[7-10] In another large study of trauma patients requiring massive transfusion, hypothermia (< 36 deg C) on arrival was an independent predictor of mortality and associated with increased blood product

> TIH is classified as mild: 34-36 °C, moderate: 32-34 °C, and severe: <32 °C.[6]

consumption.[11-13] Furthermore, studies in civilian trauma have shown >80% of non-surviving patients arrived hypothermic with a core temperature < 34 deg C.[12] In both civilian and military trauma, 100% mortality has been demonstrated when core temperature reached < 32 deg C.[14,15] When hypothermic patients fall below the thermoregulatory threshold for shivering (around 30 deg C), shivering heat production ceases. Therefore, these patients have lost the ability to generate heat and will continue to cool unless actively rewarmed by external sources.[16] This can be further exacerbated by pharmacologic treatment with sedatives and paralytics.[17,18]

Innovation and improved outcomes-based research over the past two decades have improved survivability via addressing coagulopathy and acidosis .[1,5,19–22] Early recognition and treatment of hypothermia is an equally important consideration that begins at the point of injury and should be implemented for all combat casualties, particularly patients at risk of experiencing shock. As it is labor and resource intensive to re-warm a casualty, measures to prevent hypothermia should begin as soon as possible with thermal wraps and warmed resuscitation products.[5,23,24] There are varying degrees of abilities and resources availability at each echelon role of care, which are discussed in the following sections.

Figure 1. DoDTR Hypothermia Rate in US Combat Casualties (CENTCOM/AFRICOM) from 2001 to 2022.



The highest percentage of hypothermia occurred in 2004. The first hypothermia CPG was published in 2006. Over time the missing temperature recordings from the records decreased and starting in 2014, the percentage of combat casualty with hypothermia was less than 5%.

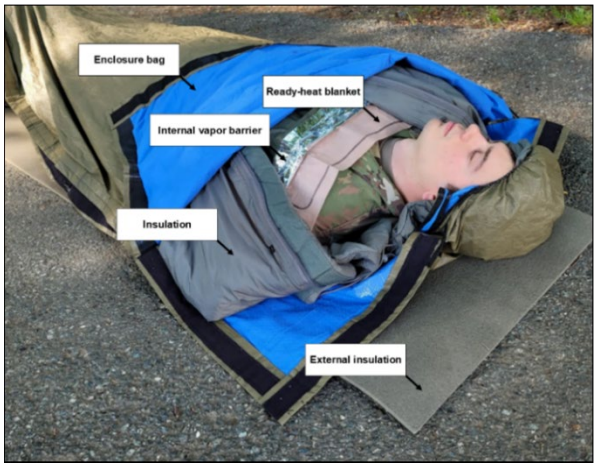
TREATMENT

PREHOSPITAL – TCCC

1. Take early and aggressive steps to prevent further body heat loss and add external heat, when possible, for both trauma and severely burned casualties.
2. 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.
3. Replace wet clothing with dry clothing or another thermal barrier (i.e. sleeping bag), if possible, and protect from further heat loss. If unable to replace the dry clothing, wrap an impermeable vapor layer around the casualty. Leave the vapor barrier in place until a warm environment has been reached.
4. 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). Avoid placing the heat in high pressure areas (i.e. on the back of a supine patient). Regularly monitor the skin under these areas for burns. [25,26,27] See below for information on hypothermia wraps.
5. Enclose the casualty with the exterior impermeable enclosure bag. As soon as possible, upgrade hypothermia enclosure system to a well-insulated enclosure system using a hooded sleeping bag or other readily available insulation (i.e. wool blankets) inside the enclosure bag/external vapor barrier shell. The HPMK is non-insulated and therefore suitable only for short term hypothermia prevention, especially in cold climates.
6. Pre-stage an insulated hypothermia enclosure system with external active heating for transition from the non-insulated hypothermia enclosure systems; improve upon existing enclosure system when possible.
7. Use a battery-powered warming device to deliver IV resuscitation fluids, in accordance with current TCCC guidelines, at flow rate up to 150 ml/min with a 38°C output temperature. (See Appendix A.)
8. Protect the casualty from exposure to wind and precipitation on any evacuation platform.
9. The priority remains the recognition of shock and implementation of heat-loss prevention techniques as outlined above. Rewarming hypothermic patients can be achieved passively (utilizing the patient's heat generation via shivering/metabolism) and actively (applying an external heat source). If available, active re-warming should be initiated along with passive warming interventions.
10. Active heating: there are no contraindications other than do not use on a heat casualty or those not at risk for hypothermia.[28,29] See Figure 2 for the indications, contraindications, and other considerations for active rewarming below.
11. Regarding extremity/trauma and tourniquets, research is ongoing regarding the use of extremity tourniquets.[30] Priority in TIH is to prevent additional core cooling to mitigate the effects of shock, hypothermia, coagulopathy, and acidosis. Providers may consider leaving the extremity with a tourniquet outside of the insulating wrap, in order to monitor for re-bleeding. This is not recommended as standard practice as the priority should be on the life saving measures of TIH prevention.
12. Utilize an insulated hypothermia wrap with an active heating source for all potentially hypothermic trauma patients. Systems that include more insulation and active heating sources perform better for treating/preventing hypothermia but may present limitations when considering portability for field applications.[5,24] One of the more widely used systems due to portability, cost, and effectiveness is the HPMK which contains the Ready-Heat Blanket (RHB) - an active warming source and the HRS - essentially an impermeable vapor layer (previous version was the Blizzard blanket).

13. Other options include user assembled kits or commercial hypothermia kits, but the recommended characteristics of any hypothermia prevention/treatment system are outlined below. A list of active and passive external rewarming options for field use are shown in (Table 2 - Appendix A).
14. Burrito wrap concept with 5 layers as referenced per Bennet et al.
15. Active heat source applied to the torso in the following order of precedence: axillae, chest, back. These are the areas with the highest potential for heat transfer.[24,25,31] The heat source should not be in direct contact with the patient's skin.
16. Internal vapor layer (plastic or foil sheets)
17. Hooded sleeping bag or other insulation (wool blankets)
18. Complete with an outer impermeable layer wrapped around all other layers to prevent heat loss, water entry and to block the wind.[25]
19. Use a ground-insulating pad

Figure 2. Improvised wrap with internal vapor barrier



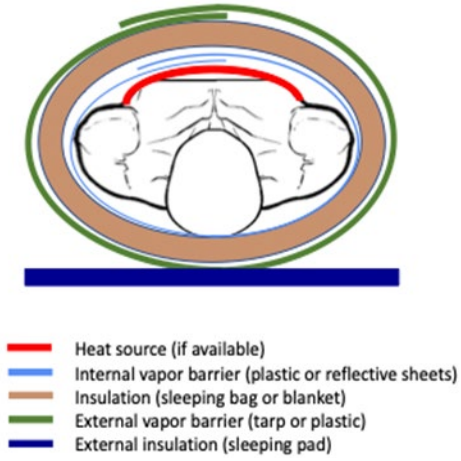


Figure 3. HPMK with improvised insulation (wool blanket).

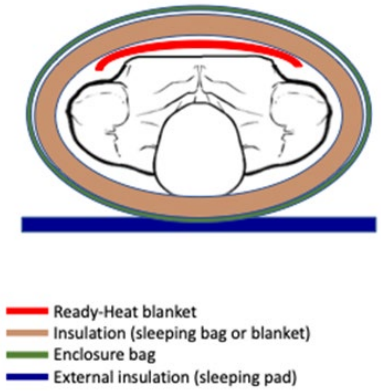


Table 1. Indications, contraindications, and other considerations for active warming.[5]

	Criteria	General Comments
Indications	• Moderate to severe trauma • Central nervous system trauma • Burn patients 20% TBSA with 2nd or 3rd degree. • Alerted level of consciousness; unresponsive; in cold environment. • Impaired shivering; in cold environment	Combat casualties with moderate to severe trauma should be managed with active heating inside a hypothermia wrap as soon as possible.
Contraindications	• None for TIH • Only when a casualty presents with signs and symptoms of hyperthermia (severe heat illness)	• There are no restrictions to use active warming inside a hypothermia wrap for TIH casualties. • It is contraindicated to use active warming for any casualty who presents with heat exhaustion or exertional heat stroke.
Safety	1st, 2nd, 3rd degree burns	• Never place any active heat source directly on skin. Follow manufacture directions for correct use of heating source.
Complications	Potential for enhanced muscle damage on an extremity distal to a tourniquet.	• Increased temperature of non-perfusion extremity distal to a tourniquet can cause further muscle damage. • Attempt to keep that part of the extremity from increasing temperature. • Do not pack extremity with a tourniquet in ice or snow.

~2-4 HOURS - TCCC, ERC, PCC

1. Continue and/or initiate above hypothermia interventions.

2. Upgrade 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. Best: Improvised hypothermia wrap with high-quality insulation with cold-rated sleeping bag combined with heat source, internal vapor barrier, outer impermeable enclosure.

3. Continue to use a battery-powered warming device to deliver blood at a flow rate up to 150 ml/min hr with a 38°C output temperature. (Table 2).

4. Convert to continuous temperature monitoring.
   - **Minimum**: Scheduled temperature measurement with vital sign evaluations.
   - **Better**: Continuous forehead dot monitoring.
   - **Best**: Continuous core temperature monitoring.
5. When using the HPMK Ready-Heat Blanket, perform frequent skin checks to monitor for contact burns.

~>6 HOURS - ERC, PCC

Continue and/or initiate the ruck/truck phases as detailed above. Replace Ready-Heat Blanket when using >10 hours.

ROLE 2 AND ROLE 3 PRIORITIES

- On patient arrival to the Role 2/3 facility, every effort must be made to prevent hypothermia; this should be a priority throughout resuscitative efforts and operative procedures. Control of ambient air temperature should be utilized to maintain a warm environment.
- Wet clothing and blankets should be removed immediately and a warming device applied if not done prior to arrival or if the device was damaged during transport.
- Use of warmed blood and blankets is indicated, where available, as well as forced air warming devices (Bair Hugger) as applicable.
- Continuous temperature monitoring is preferred, and temperatures should be documented on arrival to and discharge from the facility. A temperature sensing Foley catheter is a viable option to monitor temperature as well as the response to ongoing resuscitation efforts.
- If non-core temperature (oral, axillary, or tympanic) is outside of an expected range (<97F or >100F), use core temperature (rectal or esophageal) measurement for best accuracy.

EN- ROUTE CARE (ERC)

***NOTE**: Patient packaging with treatment for TIH is a core skill that should be deliberately planned and rehearsed prior to mission execution. A patient packaged for hypothermia prevention/treatment is difficult to access. Medical providers need to be cognizant of this fact and have a plan to monitor their patient's status as well as their prior medical interventions.*

- Ensure hypothermia management from the field is still in place and has not moved and or shifted during turnover. Ensure the hypothermia management system is covering the back and the system is protecting the patient from wind blowing over or under the casualty, especially in a rotary wing environment.
- Use of vehicle or aircraft Environmental Control Systems (ECS) should be used to create an ambient control temperature to allow passive room warming. ECS Systems can be unreliable, especially in rotary wing when power is limited. In preplanning, the ECS can be used to set a warm environment prior to or after receiving the casualty, to prevent drastic temperature loss.
- The use of continuous temperature monitoring should be conducted to establish and track warming trending.
- When moving patients in the maritime environment, doubling up of outer layering impermeable systems should be utilized to protect the patient from winds and sea spray.

FIELD "TRICKS OF THE TRADE" + ANECDOTAL "TROUBLE SHOOTING"

- Use RHB/active rewarming systems in maritime environment.
- On scene materials/clean trash bags or saran wrap may be helpful improvised insulation materials.

- Vehicle heating systems may help direct hot air to a patient in a field expedient Bair Hugger in certain platforms. This requires prior coordination and setup and is a non-standard equipment load.
- Use of thermal heat packs (crush packs, Ready Heat 1 Panel Blanket, MRE heater, even Foley bag in extremis) or body heat for fluid pre-warming (of most utility in Ruck-Truck-House phases when fluid warmers might be in short supply)
  Note: Do not place directly on skin to prevent thermal injury to patient.
- Expect issues with finger pulse-ox devices. If value shown does not correlate to patient presentation, remember to treat the patient, not the device. Taping heat pack over hand, but not in direct contact with the skin and device, may aid in accuracy/operation.
- In extreme cold weather (below -20°F), exhalation gas from intubated patients may cause ice to instantly form in the ET tube and vent tubing. Care should be taken to insulate all interventions while exposed to these conditions.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All trauma patients meeting DoDTR inclusion criteria with ISS>1.

INTENT (EXPECTED OUTCOMES)

- Temperature and route will be documented on all patients upon admission and discharge.
- Core temperatures are obtained on all patients with temperature <96 F and > 100° F.
- Warming measures and sustainment of core temperature > 96°.F are initiated on all patients.

PERFORMANCE/ADHERENCE MEASURES

- Temperature and route will be documented on all patients upon admission and discharge.
- Core temperatures are obtained on all patients with temperature <96 F and > 100° F.
- Warming measures and sustainment of core temperature > 96°.F are initiated on all patients.

DATA SOURCES

- Patient Record
- DoDTR

SYSTEM REPORTING & FREQUENCY

- The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.
- The system review and data analysis will be performed by the JTS Chief and the JTS PI Branch.
- For more information on metrics, email: dha.jbsa.healthcare-ops.list.jts-pips@health.mil

RESPONSIBILITIES

It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance, and PI monitoring at the local level with this CPG.

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APPENDIX A – EQUIPMENT LIST

SECTION 1: PATIENT WARMING[1,2]

Table 1. Passive Rewarming Methods

- 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.
- NE = not effective; √ = mildly effective; √√ = moderately effective; √√√ = highly effective

	Prehospital	Reference	Rewarming	Level	Comments
Passive Rewarming Methods	Sleeping bag	Giesbrecht et al.[3]	√	B	Insufficient alone to prevent heat loss; works better with vapor barrier wrap with a when patient is shivering.
	Impermeable outer layer with sleeping bag insulation (burrito wrap)	Grissom et al.[4]	√√	B	Traditional passive rewarming approach in austere medicine courses. Works well with shivering patient in mild hypothermia to retain heat production and prevent body heat loss; active external heating source not required.
	Wool Blanket (WB)	Allen et al.[5]	NE	C	Prospective Randomized Study. No human volunteers. A single WB was least effective to prevent heat loss in fluid bag torso simulation.
	Space Blanket (SB)	Allen et al.[5]	NE to √	C	Prospective Randomized Study. No human volunteers: SB was placed over the simulation torso and tucked in. Was not as effective to prevent heat loss but better than the wool blanket.
	Human Remains Pouch (HRP)	Allen et al.[5]	√	C	Prospective Randomized Study. No human volunteers. The HRP did not maintain torso bladder temperature better than the wool blanket.
	HRS	Allen et al.[5]	√√√	C	Prospective Randomized Study. No human volunteers. New shell version was used as a passive bag. There was no statistical difference between the HRS and BB in heat loss between Gen 1 vs. Gen 2 HPMK.
	Hot Pocket (HP) (HRP, wool blanket, and space blanket)	Allen et al.[5]	√√√	C	Prospective Randomized Study. No human volunteers. The use of the HP system was very effective and one of two best passive methods of heat loss prevention, which performed the same as two of the three active heating methods tested at 120 minutes.
	Blizzard Blanket (BB)	Allen et al.[5]	√√√	C	Prospective Randomized Study. No human volunteers. The use of the BB alone was one of two best passive methods of heat loss prevention, which performed the same as two of the three active heating methods tested at 120 minutes.
	Vapor barrier + Hypothermia wrap	Thomassen et al.[6] Henriksson et al.[7] Henriksson et al.[8]	√√√	A	Strong evidence in favor of vapor barrier wrapped around human volunteers who were then placed inside hypothermia "burrito" wrap system. These three studies are the evidence for the recommendations for how to assemble an improvised a hypothermia enclosure system by Giesbrecht G.[9]

Table 2. Active Rewarming Methods

- **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
- NE = not effective; √ = mildly effective; √√ = moderately effective; √√√ = highly effective

Active Rewarming Methods	Prehospital	Reference	Rewarming	Level	Comments
	Small Chemical Packs	Co-author Consensus	NE	C	Small chemical heat packs used for hands are insufficient heat transfer to core or to prevent further heat loss. Better options available.
	Warm IV/IO fluids/blood products	Lehavi et al.[10] Haverkamp et al.[11]	NE	A	Do not infuse fluids less than 100°F (38°C). Fluids alone not effective for core temperature rewarming. Use fluids adjunctively with HPMK during MEDEVAC
	Body to body skin contact	Giesbrecht et al.[3] Hultzer et al.[12]	√	B	Suppresses shivering in victim with skin-to-skin contact; no more effective than shivering for mild accidental hypothermia; lack of evidence for any benefit in non-shivering hypothermic patient; loss of manpower.
	Hot water bottles	Co-author Consensus	√	C	Impractical. Insufficient to transfer heat to effect core temperature. Many bottles are needed; hot water replacement every 20 min.
	Walking	Giesbrecht et al.[13]	√√	B	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 minutes.
	Ready-Heat Blanket	Allen et al.[5]	√√	C	Prospective Randomized Study - Whole body heat blanket – 8 hours at 104 F (40°C); wrap torso and avoid direct placement on skin; use vapor barrier as outside layer.
	HeatPac	Giesbrecht et al.[13] Kulkarni et al.[14]	√√√	B	Effective to deliver heat and maintain thermal balance; costly; long-term experience in Scandinavian militaries and in research studies; resource dependent; uses charcoal as a consumable; potential carbon monoxide risk in low ventilation space; use outdoors only. Newer options available.
	HPMK	Allen et al.[5]	√√√	C	Prospective Randomized. Did not use human volunteers, but simulated torso with fluid bladder system. Effective outcome compared to all active heating systems studied. Committee on TCCC, JTS and DoD preferred system since 2006; outer vapor barrier garment and 10-hour (110°F) chemical blanket; low cost, weight, and size.; Effective system only for short-term use due to lack of insulation; patients will get cold <60 min use in cold environments per Dutta et al.[15]
	Improvised hypothermia wrap UAS	Dutta et al.[15]	√√√√	B	Randomized controlled study with human volunteers. The user-assembled and Doctor Down systems were most effective.
	Doctor Down Rescue Wrap (DD)	Dutta et al.[15]	√√√√	B	
	HPMK	Dutta et al.[15]	√√	B	Randomized control study with human volunteers. HPMK was least effective due to lack of insulation.

	MARSARS Hypothermia Stabilizer Bag (M)	Dutta et al.[15]	√√√	B	Randomized control study with human volunteers. These two systems were not as effective to retain thermal balance when compared to the DD and UAS systems.
	Wiggy's Victim Casualty Bag (W)	Dutta et al.[15]	√√√	B	
	Ready-Heat Blanket & PrimaLoft synthetic sleeping Bag hypothermia wrap	Phillips et al.[16]	√√√	C	Single case report with high efficiency to rewarm patient.

Other Patient Warming Devices

CAUTION: *Devices A-B should NOT be placed under the patient's back or directly on bare skin. Doing so may increase the likelihood of thermal burns or render the device inoperable.*

HAWK Warming Grid

- https://soldiersystems.net/2020/01/28/nsns-for-hawk-warming-grid/
- Air activated and heat adjustable. Can reseal individual cells for optimal performance.
- Conditions below 0F may require extended time (+15 minutes) to reach operating temperature
- 4-32 hours of operation

Ready-Heat Panel Blanket

- https://www.ready-heat.com/products/military/
- Air activated, NOT heat adjustable
- Conditions below 0F require extended time (+ 30 minutes) to reach operating temperature.
- Rendered inoperable by fluids and must ensure patient is dry prior to application and keep away from potential fluid sources.
- 8-10 hours of operation

Geratherm Mini Rescue II Hypothermia Kit

- www.rgmd.com
- Currently in the SOCOM Tribalco T-5 CASEVAC Kit

Chill Buster Blanket

Wiggy's or down sleeping bag

SECTION 2: FLUID WARMING[5]

Desirable Characteristics of a Resuscitation Fluid Warming Device

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

List of warming devices available on the market.

- **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.

Abbreviations: √, mildly effective; √√, moderately effective; √√√, highly effective

Warming Device	FDA Approval	Flight Approved	Rewarming Efficacy >100mL/Min	Level	Reference	Comments
Belmont Buddy Lite	Yes	Yes	√	A	Bruells et al.[17] Kim et al.[18] Lehavi et al.[10] Milligan et al.[19] Weatherall et al.[20]	Higher administration rates will cause the cartridge to pop out of the locking block.
Thermal Angel	Yes	Yes	√	A	Weatherall et al.[21]	Higher administration rates drastically drop the end output temperature. At colder input temperatures, the Thermal Angel administration rate drops.
enFlow	Yes	Yes	√	A	Bruells et al.[17] Kim et al.[18] Lehavi et al.[10] Zoremba et al.[21]	Device performs best when working with warmer fluids, as cited in Kim et al. study. *****DEVICE RECALLED due to aluminum elution from warming cartridge*****
QinFlow Warrior	Yes	Yes	√√√	A	Lehavi et al.[10]	Performed the best in comparison to the other warmers with colder input temperatures.
QinFlow Warrior Lite	Yes	Yes	√√√	C	N/A Peered Research	Same warming cartridge as QinFlow Warrior.
MEQu M Warmer	No	Yes	√√√	A	Blakeman et al.[22] Weatherall et al.[20]	NATO approved, awaiting FDA approval, performed best in side-by-side comparison of the Buddy Lite, Buddy Liter, and Thermal Angel with packed red blood cells
Lifewarmer Quantum*	Yes	Yes	√√√	C	N/A Peered Research	Not currently peer reviewed. **SOCOM funded device.*

SECTION 3: TEMPERATURE MONITORING

Temperature Monitoring Devices

- Temperature sensing Foley
- (Forehead) temperature sensing 'dots'
- DataTherm(R)II Continuous Temperature Monitor - in the SOCOM Tribalco T-5 Cardiac Ki
- Propaq MD
  - Airworthiness approved

    - BATDOK (Battlefield Assisted Trauma Distributed Observation Kit) enabled
    - Several different options available for real-time temperature monitoring
- Philips Tempus Pro - Airworthiness approved
- Welch Allyn SureTemp - Airworthiness approved
- 3M Bair Hugger Temperature Monitoring System[23] - Portable device still under development, but may have applicability in the trauma setting

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APPENDIX B: INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command-requested, unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.