Project: pIVot

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Title: Need Statement Rev. 2

Goal: To define the need statement.

Need Selection:

Need screening

Originally, the team wanted a way to address convective heat loss between the dermal layers of the skin and the external environment in patients undergoing surgery, in order to maintain normothermia. At the start of January 2020, the team revisited whether or not the device Bair Hugger had a strong hold on the hospital/surgical market that was too great to allow penetration of the market with a new potential device. For at least a month, the team devoted time to more ethnographic research, discussions with KOL and assessing literature research to decide if patient warming was still a need worth pursuing. By March, the team was positive that patient warming was worth pursuing, but decided to step away from the surgical/hospital setting and focus instead on pre-hospital patient warming. Patient warming of trauma patients is as valid of a need as patient warming of surgical patients. EMS is limited by space and finances. The EMS setting has devices to warm patients but no device that has a clear strong hold such as Bair Hugger in the OR.

As a result, the team decided to focus on patient warming in the pre-hospital setting.

Need statement

A non-invasive way to address heat loss in trauma patients in pre-hospital settings, in order to manage patient core body temperature.

Disease State Fundamentals:

The average normal body temperature in human beings is 98.6F (37°C) with an acceptable normothermic range of 97°F (36.1°C) - 99°F (37.2°C)[2]. Maintenance of normothermic body temperature is crucial for the body to function at its optimum capability. Body temperature regulation is maintained by the hypothalamus which is located at the base of the brain. The hypothalamus directs thermoregulation within the body as a mode of homeostasis. Thermoregulation inputs come from the skin, core tissues, spinal cord and the brain as well. When external temperatures change, afferent sensing receives a stimulus from receptors on the skin and send signals via sensory nerves to the hypothalamus. In the case that the stimuli registered is from a decrease in temperature, the hypothalamus works to establish homeostasis by increasing body temperature. Efferent signaling from the hypothalamus results in behavioral responses (such as putting on a jacket) and autonomic responses such as shivering, blocking sweat production, and vasoconstriction all to increase body temperature. The same mechanism occurs when an increased temperature is registered by afferent sensing, however the efferent signaling would instead be behavioral responses (such as taking off a jacket) and autonomic responses such as increased sweat production, and vasodilation all to decrease body temperature[2]. Efferent responses occur at as small as 0.1°C change in temperature.

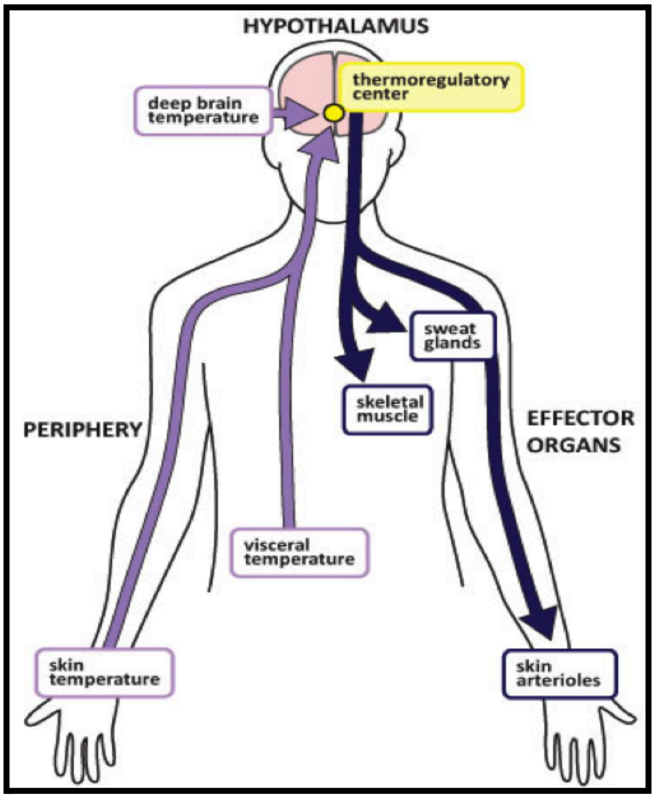

Figure C.1: Thermoregulation[3]

Per the Center for Disease Control and Prevention, accidents (unintentional injuries) are the third leading cause of deaths in the United States of America1. Hypothermia is one of the most important physiological predictors for early and late mortality in trauma patients2. Being so, the need to address heat loss in trauma patients in pre-hospital environments in order to foster core body temperature in the normothermic range is substantial.

Normothermia is defined as 37 ± 0.5 °C4. Hypothermia is conventionally defined as a temperature below 35°C4. Trauma patients lose heat at an increased rate than non-trauma patients, resulting in redefined ranges for hypothermia (table 1). Heat loss occurs at a rate of 60-75 kcal/hr; however, trauma patients lose heat at an increased rate of 400 kcal/hr, increasing mortality4. Heat is loss by four different methods: radiation, conduction, convection and evaporation (table 2).

Table 1. Classification of Hypothermia[3]

Classification	Conventional	Trauma patient
Mild hypothermia	35–32 °C (95.0–89.6 °F)	36–34 °C (96.8–93.2 °F)
Moderate hypothermia	32–28 °C (89.6–82.4 °F)	34–32 °C (93.2–89.6 °F)
Severe hypothermia	28–20 °C (82.4–68.0 °F)	32 °C (89.6 °F)
Profound hypothermia	20–14 °C (68.0–57.2 °F)	

Table 2. Mechanisms of Heat Transfer in Trauma[3]

Mechanism	Rate (kcal/h)	Description
Radiation	10–50	Transfer of heat energy via electromagnetic waves down a concentration gradient without direct contact according to Boltzmann's equation:[a] $Q = K(T1 - T2)$
		Methods to reduce losses include:
		• warming blankets
		• increasing environmental temperature
		• radiant heaters
		• avoid unnecessary anesthesia
Conduction	16–30	Transfer of energy between two solid objects in contact according to Fourier's equation:[b] $Q = KA\ dt/dx$
		Methods to reduce losses:
		• removal of wet clothing
		• avoid prolonged contact with cold surfaces
Convection	10–20	Transfer of heat energy during the mass movement of gas or liquid.
Evaporation	12–16	Heat energy transferred during change of phase (water to gas): 58 kcal/g water evaporated from skin, respiratory tract, and viscera
		Methods to reduce losses for convection and evaporation:
		• avoid prolonged surgery with an open abdomen
		• warming blankets

[a] Q = rate of radiant heat transfer, K = a constant, $T1$ = temperature of the first object, $T2$ = temperature of the second object
[b] Q = rate of heat transfer by conduction, K = thermal conductivity, A = area in contact, dt/dx = thermal gradient

Hypothermia is a contributor to the trauma "triad of death". The triad of death- hypothermia, metabolic acidosis, and coagulopathy, feed one another in synergistically leading to the demise of many trauma patients. Acidemia, a blood pH of less than 7.35, was proven to progressively worsen clot formation deficiency by Engström et al6. In a study conducted by Brohi et al, it was found that trauma-induced coagulopathy (TIC) presented in 25% of all severely injured patients and carried a 46% mortality rate7. TIC becomes even more detrimental when combined with acidemia and hypothermia.

Irreparable organ damage can occur during advanced hypothermia and above 106°F (41.1°C).This is all the more reason why it is crucial to maintain normothermia in trauma patients.