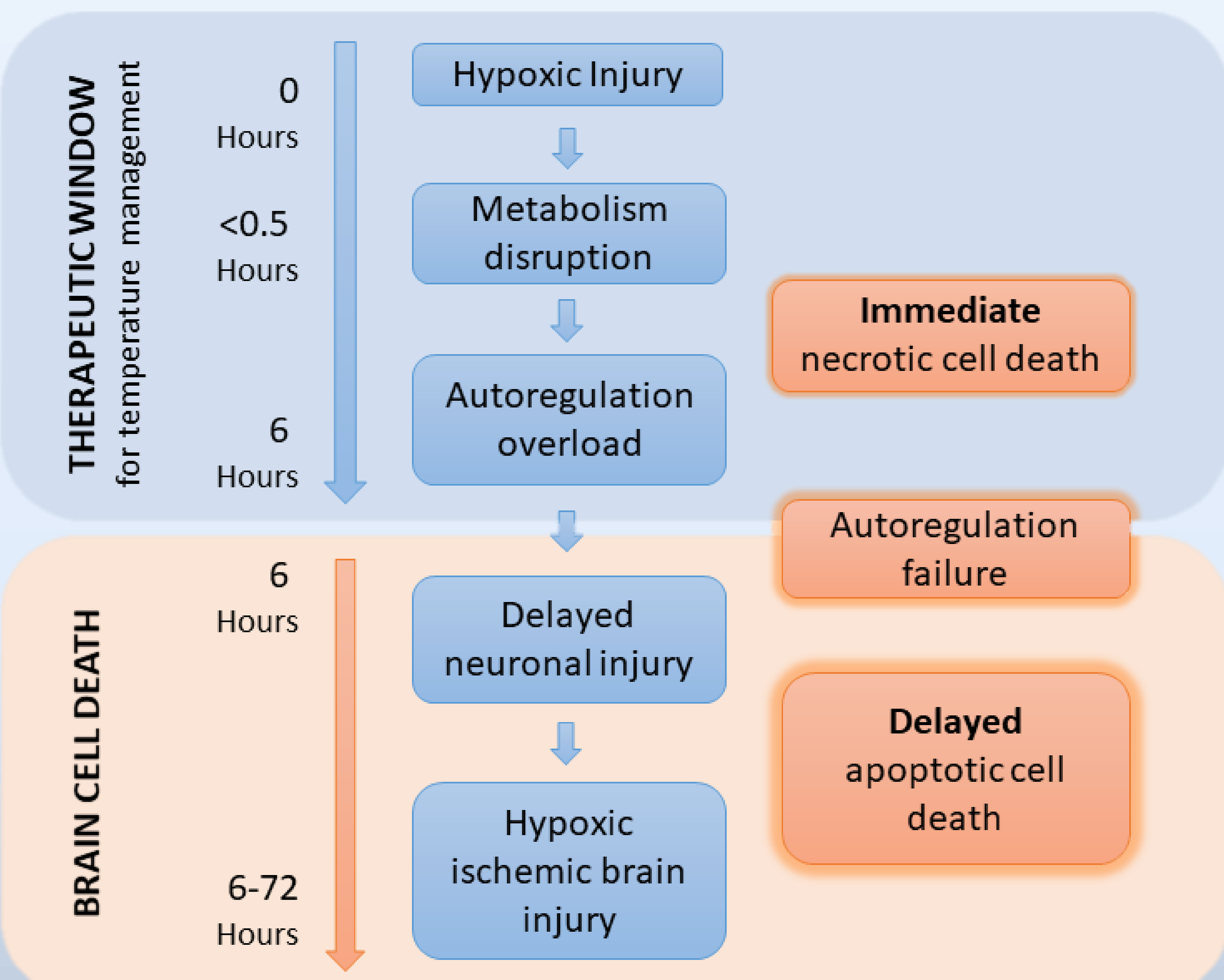
Intranasal Cooling for Encephalopathy Prevention in Combat Casualties (ICEPICC)

Ryan T. Myers, PhD[1*], Ryan Binette[1], Ian Cohen[1], Gordon Hirschman[1]
1-Vivonics, Inc., Bedford, MA
*-Principal Investigator

Background

- There were 361,092 brain injuries recorded in the US Military between 2000 and 2016[1]
- Secondary effects of TBI include ischemia, swelling, cerebral edema, and increased intracranial pressure
- These effects lead to cell death from lack of blood flow within 30 minutes
- Prolonged oxygen deprivation causes autoregulation failure and programmed cell death within 6 hours



- Cooling the brain within this time window can reduce these secondary injuries
- ***<u>Problem: there are currently no FDA approved and/or field-able options to cool the brain at the point of injury in far forward scenarios</u>***

Approach

- Intranasal cooling has been shown effective at reducing brain temperature back to normal and to therapeutic hypothermic levels (33ºC-35ºC)
- Possible intranasal cooling techniques include:
  - Evaporative Cooling (PFC gas spray)
  - Convective Cooling (Cold airflow)
  - Conductive Cooling (Chilled saline flow through)
- ***<u>Established Research Goal: Intranasally cool the brain to therapeutic hypothermic levels from point of injury through evacuation (>4 hours) via a self contained system (can not rely on external power, air, or material supply)</u>***

Methods

- Pugh Chart analysis revealed Convective Cooling as the appropriate approach for the established treatment environment
- Literature suggests that 10ºC nasal airflow at a rate of 10-30 L/min is sufficient to cool to therapeutic hypothermic levels[2]
- Two heat removal strategies were evaluated through benchtop model testing:
  - Vortex Tube Cooling (leverages high flow and pressure to generate cold air outlet)
  - Thermoelectric Cooling [TEC] (leverages Peltier effect to convert electricity to a temperature differential)

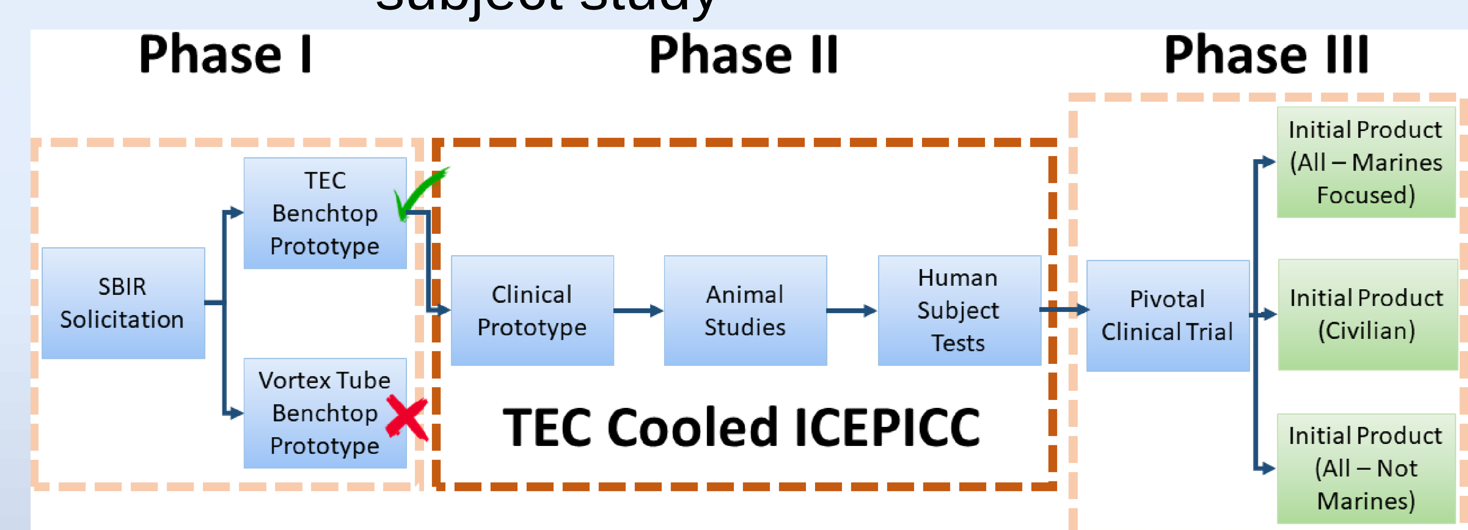
Results

- Two benchtop systems were compiled and operated as designed
- Both Vortex Tube and TEC cooling methods demonstrated as feasible:
  - Vortex Tube: 4.1ºC at 2 minutes @ 25 L/min
  - TEC: 6.0ºC at 5.4 minutes @ 25 L/min
- Under current configuration:
  - TEC: 13 hours of continuous use, < 20 lbs., 0.35 ft^3
  - Vortex Tube: 4 hours of continuous use, ~ 175 lbs., 3.00 ft^3

	Functional component does not require electricity	Small form factor	Low pressure	Small air supply	Can be feasibly run on battery	Can use hospital air supply	Variable temp and/or flowrate	Can deliver temp and/or flowrate required	Can Control Temperature Bi-Directionally
Vortex	X	X				X	X	X	
TEC		X	X	X	X	X	X	X	X

Conclusions and Future Work

- Vortex tube system likely optimized where TEC system can be optimized in future work
- Vortex tube system requires ~175 lbs. of gas tanks to operate for 4 hours
- TEC system operates on military approved Li-ion batteries for >15 hours using control strategies
- ***<u>Conclusion: TEC cooled ICEPICC system will be pursued in Phase II</u>***
- Future Work (Phase II):
  - Develop an ICEPICC clinical prototype
  - Perform an efficacy and safety animal study
  - Perform a dose response animal study
  - Perform a healthy volunteer human subject study



Acknowledgements

- This work was funded in part under US Marine Corps contract M67854-17-C-6548

- **Contact Information**

  Ryan T. Myers PhD
  585-613-5349
  rmyers@Vivonics.com
  Vivonics., Inc.
  Bedford, MA 01730

References:

1. **http://dvbic.dcoe.mil/dod-worldwide-numbers-tbi**
2. **Bakhsheshi, M.F., L. Keenliside, and T.-Y. Lee, Rapid and selective brain cooling method using vortex tube: a feasibility study. The American journal of emergency medicine, 2016. 34(5): p. 887-894.**

MHSRS-18-0152