"TRACIR: TRAuma Care In a Rucksack"

A closed loop & autonomous cardio-pulmonary resuscitation platform

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Problem to Solve

How can we initially treat & stabilize a casualty at point of injury using autonomous & non-invasive biosignals & clear the battlespace via unmanned evacuation?

Case example for a U.S. Army funded research program with civilian application

(DOD Funding: W81XWH19C0101)

Initial Capabilities Document (ICD)
For
Autonomous Care & Evacuation (ACE) Support of
Combat Casualty Care

5 January 2021

Validation Authority: Joint Capabilities Board (JCB)

Proposed Milestone Decision Authority: Defense Health Agency

Sponsor Organization: Office of the Assistant Secretary of Defense for Health Affairs (OASD/HA)

Point of Contact:

CAPT Travis Polk, MD - JPC6/Combat Casualty Care Research Program

Dr. Terry Rausch – Research & Development Policy & Oversight, OASD/HA

UNCLASSIFIED

THE JOINT STAFF
WASHINGTON, DC 20318-9999

JROCM 101-21
17 December 2021

MEMORANDUM FOR: SEE DISTRIBUTION

SUBJECT: DOTmLPF-P Change Recommendation for Autonomous Care and Evacuation Support of Combat Casualty Care

1. The Joint Capabilities Board (JCB) reviewed and endorsed the DOTmLPF-P Change Recommendation (DCR) for Autonomous Care and Evacuation Support of Combat Casualty Care. The JCB approved the attached actions and requests the Director of Research and Development Policy & Oversight, OASD (HA) as the lead organization for implementation.

2. The Autonomous Care and Evacuation Support of Combat Casualty Care DCR aim is to improve the DoD's ability to maintain readiness and preserve operational capability through Autonomous Care and Evacuation Support of combat casualty care research and development.

Areas of focus to support Autonomous Care & Evacuation

High-level recommendations in the ICD which include conducting R&D to:

• **Develop semi-autonomous, autonomous, robotic, and/or telemedicine solution sets that will enhance pre-hospital capability and capacity in future operating environments, including Prolonged Care or austere environments.

• Develop lightweight, energy-efficient autonomous or robotic devices to provide damage control procedures (e.g., control bleeding) and resuscitative care throughout the continuum of care.

• **Develop autonomous solutions that cognitively offload Combat Casualty Care providers in order to enable increased capabilities and capacity.

• **Develop telemedicine capabilities to support mental health resilience of forward deployed warfighters and facilitate reach back to stress management teams.

** Supported by the TRACIR project

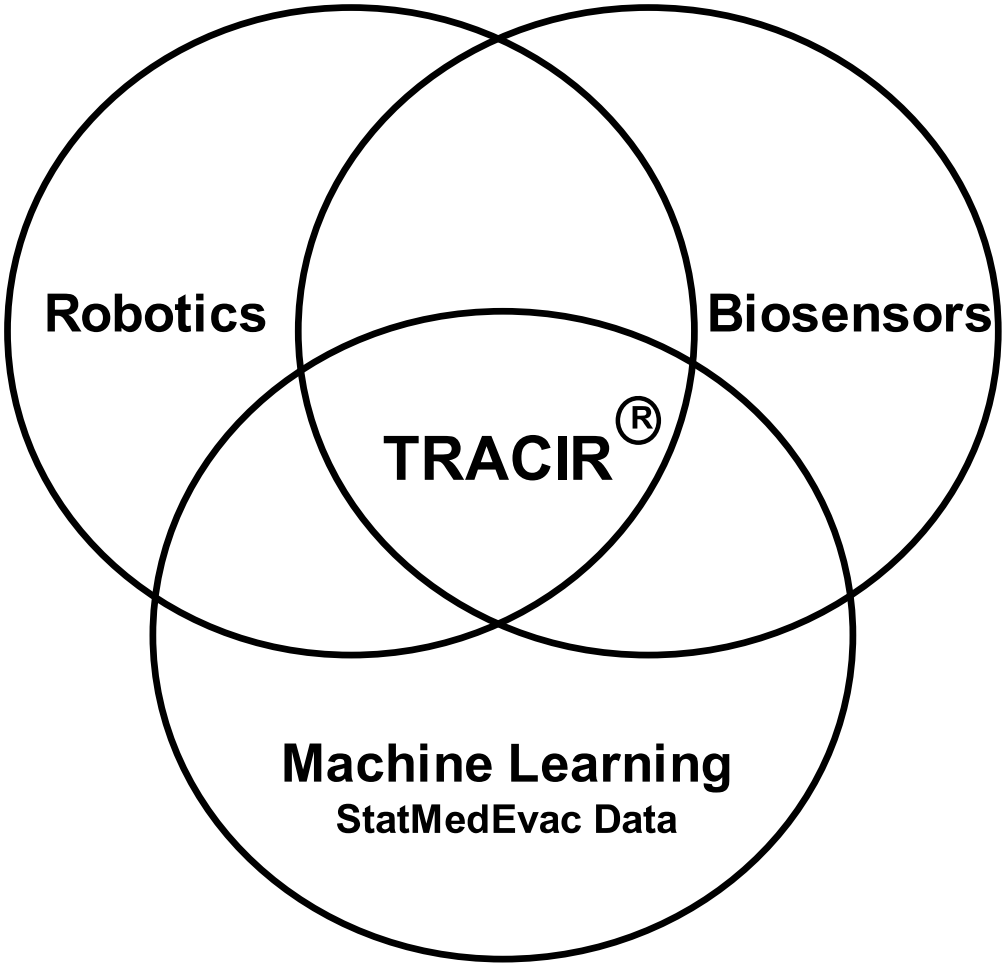
Sikorsky UH-60A Blackhawk Optionally Piloted Vehicle takes its first uninhabited flight on Saturday, Feb. 5, 2022. (Lockheed Martin)

- A UH-60 Alpha-model Black Hawk helicopter flew for the first time entirely unmanned as part of the Defense Advanced Research Projects Agency's Aircrew Labor In-Cockpit Automation System (ALIAS) program
- The aircraft performed pre-flight checks, took off and ran through a simulated Light Detection and Ranging (LiDAR) system depicting the congested and complex New York City skyline. The 14,000-lb aircraft responded autonomously to the simulated skyscrapers, weaving through Manhattan

Hypotheses, Specific Aims and Objectives:

- We hypothesize that data-driven Functional Hemodynamic Monitoring and ML approaches on trauma patients in prolonged field care settings will enable domain experts to accurately characterize polytrauma events and appropriate therapies leading to accurate autonomous prolonged treatment interventions.

Autonomous Unmanned Robotic Controlled Casualty Care



TRACIR Personnel – Team Science

Pitt-led project

University of Pittsburgh

Pulmonary/Crit Care Medicine
Ron Poropatich
Joo Yoon

Critical Care Medicine
Michael Pinsky (Scientific PI)
Gilles Clermont

Emergency Medicine
Frank Guyette
Lenny Weiss
David Salcido
Chase Zikmund

Surgery
Greg Watson

Animal Research Lab
Lisa Gordon

Project Manager
Howard Stein
Jan Berkow (IP/Regulatory)

Fiscal Management
Brian Smith

Carnegie Mellon University

Robotics Institute
Artur Dubrawski
Howie Choset
John Galeotti
Luke Scuilli

National Robotics Engineering Center
Herman Herman
Robert Toth

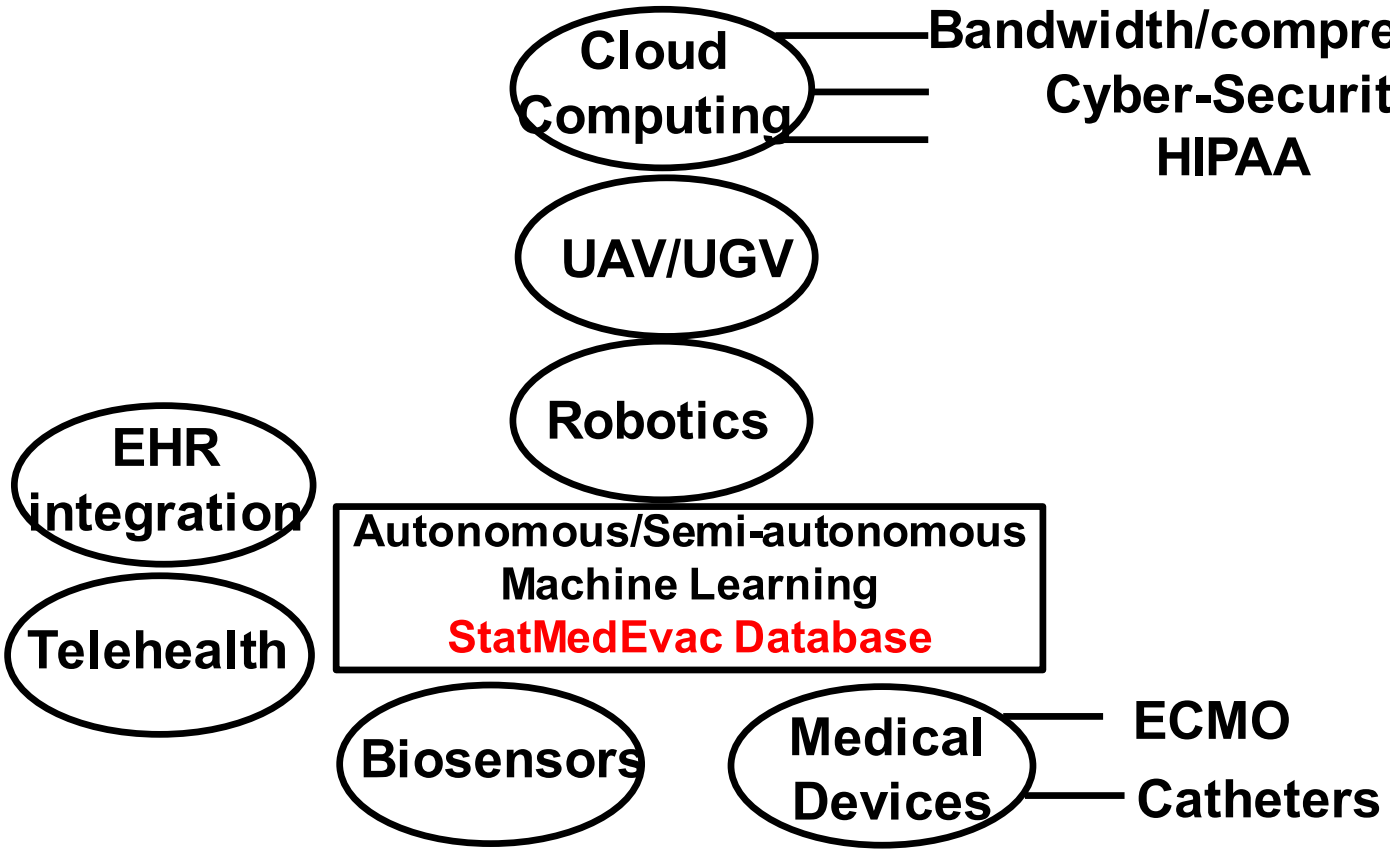
University of Arizona

Engineering
Wolfgang Fink

* Denotes prior military

TRACIR Construct

DoD, Industry & Academia Collaborations



Functional Data Elements in the TRACIR Program

- **Large animal (porcine) laboratory – 40 animals**
  - Create autonomous diagnosis and treatment algorithm
  - Explore alternative biosignal monitoring devices
  - Validate autonomous prolonged field care in swine
- **STAT MedEvac database (largest pre-hospital trauma dataset)**
  - Annotate Cardio-Respiratory Injury events & need for Life-Saving Interventions in transport or in ED
  - STATMedevac pre-hospital dataset linked to inpatient EHR (22 June 2022):
    - **63,753 total patients – trauma and non-trauma (MI, ARF, Sepsis, GI bleed)**
    - **20,313 total trauma patients**
  - *In silico* validation of autonomous diagnosis and resuscitation algorithm
- **Lower Body Negative Pressure chamber (human volunteers)**
  - Validated model for hemorrhage resuscitation and autonomous diagnosis of hypovolemia in humans using existing and novel monitoring devices

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Trauma Care in a Rucksack (TRACIR) Concept

Physiological Closed-Loop Control (PCLC) Device

TRACIR "Rapid Assess & Treat" Closed-loop Control Software

Software as a Medical Device application resides either on a portable ruggedized tablet computer or on a centralized server with thin client access to manage a small ward.

FDA Cleared Equipment Bundle

Zoll Patient Monitor integrated with key physiological sensors

(future sensors) Combined Impedance Cardiography & Tomography: Catheter Accuracy for Hemodynamic & Ventilatory Monitoring (Bilab Healthcare)

Hamilton Ventilator

NeuroWave Infusion Pumps

Future integrated equipment bundle with shared power & communications addresses portability needs

TRauma Care In a Rucksack (TRACIR) Program

- Starting Yr 4 of 4-year USAMRDC contract (W81XWH19C01013); Jose Salinas, PhD/USAISR is the COR
- Deliverables:
  - To develop a closed-loop high acuity patient management solution prototype for a Role 2/Forward Surgical Team use case
  - Diagnoses trauma injuries and drives automated personalized titrated interventions; uses both animal and human hypovolemia models
- Consists of:
  - **Software as a Medical Device** application loaded on a ruggedized tablet or monitor
  - **Equipment enclosure** that includes FDA cleared non-invasive sensors, fluid infusion pumps for pharma & blood products, and a ventilator
- Year 4 goals:
  - To run TRACIR software in Emergency Department alongside usual care for trauma patients
  - To incrementally refine the "bio-signature" algorithms
  - To "blindly" run TRACIR software in a rotary wing medevac helicopter during trauma/casualty care transport

Hardware Enclosure: FDA cleared devices include non-invasive sensors, ventilator (Thornhill Medical), infusion pumps (NeuroWave)

Ruggedized Tablet Software Applications: "Rapid Assess & Treat"™ semi-autonomous control software plus manual screens for FDA cleared devices [*future: to be placed on Zoll Monitor*]

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TRACIR Use Cases

Physiological Closed-Loop Control (PCLC) Device

ACIR "Rapid Assess & Treat" Closed-loop Control Software

Military Fixed Wing Long Duration Casualty Transport

FDA Cleared Equipment Bundle

Zoll Patient Monitor integrated with key physiological sensors

Hamilton Ventilator

NeuroWave Infusion Pumps

(future sensors) Combined Impedance Cardiography & Tomography: Catheter Accuracy for Hemodynamic & Ventilatory Monitoring (Bilab Healthcare)

Civilian Tele-ED Applications

Military Field Tent or Mass Casualty Response

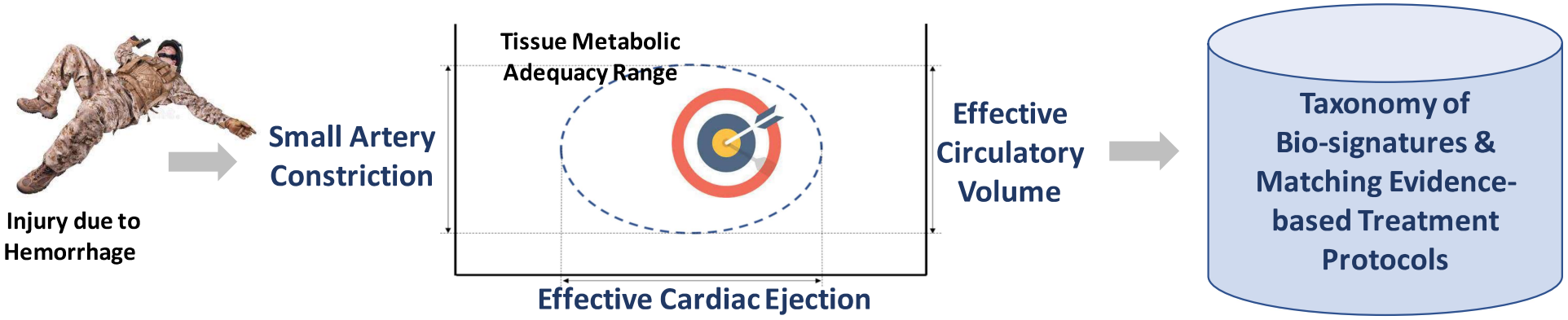
Military or Civilian Casualty Transport

Military or Civilian Ground Vehicle Casualty Transport

TRACIR Provides a Novel Precision Medicine Approach to Casualty Care

- Non-invasive sensors enable ongoing recognition to an evidence-based bio-signature
- Bio-signature algorithms characterize the degree of compensatory mechanism activation
- Bio-signatures are then matched to an optimal treatment protocol based upon ground truth data
- Key value: **<u>patient-specific continuously optimized autonomous care</u>**

Our Cardiovascular Compensatory Bio-signature is the sum of these 3 contributions:



Overview (BLUF)

- **Goal**: to develop a **smart triage device** and a **Physiological Closed-Loop Control (PCLC) device** to manage unstable patients to support **Unmanned CASEVAC Transport**
- **Team**: University of Pittsburgh, Carnegie Mellon, Zoll Medical, Thornhill Medical, NeuroWave
- **Existing funding support**
  - "TRACIR": Started year 4 of 4-year USAMRDC funded program to complete TRL 4 for a PCLC device prototype for Role 2 field use
  - "RAPTER": Recently notified of DoD award to build a smart triage prototype

- **Novelty**
  - Devices are based on proven **"Functional Hemodynamic"** (Xavier Monet, 2016) principles to recognize and manage volume insufficiency in the OR and ICU using invasive measures
  - New approach applies AI-based Predictive Analytics to translate Functional Hemodynamics captured via non-invasive sensors into "bio-signatures" to recognize severity/need for life-saving interventions and correlates to an optimal intervention
- **Device Utility Progression**

Triage Decision Support → Resuscitation Decision Support → Semi-autonomous Stationary Care → Semi-autonomous En Route Care → Fully Autonomous Triage & En Route Care

TRACIR Deliverables

-Collated high frequency pre-hospital medevac data (voice, data, waveform) linked to inflight medical records and their in-hospital EHR data on over 20,000 trauma patients during air transfer from sites to UPMC. This is both the most well documented trauma dataset existing and the most high-frequency data available, which will allow for more accurate model development for predictive analytics.

-Using both large animal (porcine) and human experimentation for validation, we were able to create and successfully run a completely autonomous closed loop monitoring and resuscitation platform using non-invasive biosignals.

-Developed the completely non-invasive monitoring protocol (**Resuscitation from Shock Using Functional Hemodynamic Monitoring: ReFit 2.0**) and provided it to the DoD program officer Jose Salinas, PhD (USAISR, San Antonio, TX) in June 2022.

-Completed both porcine controlled and uncontrolled hemorrhage model resuscitation experiments using our machine learning algorithms for autonomous care.

-Plan to demonstrate in January/February 2023 successful resuscitation of an uncontrolled hemorrhage in 3 separate porcine experiments during in-flight helicopter medevac transport to the University of Pittsburgh from a nearby airport achieving a TRACIR TRL5 product maturity.

TRACIR Dashboard

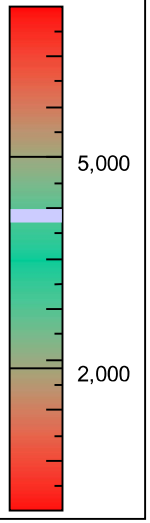
Vital Signs

100	40	105
BP		HR

Circulatory Sufficiency

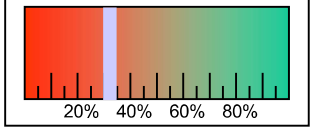
-blood transport-

Global Cardiovascular Status



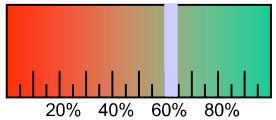
Volume Status

-pre-load responsiveness-

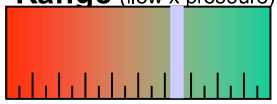


Vasomotor Tone

-vasomotor responsiveness-



Cardiac Power Range-(flow x pressure)



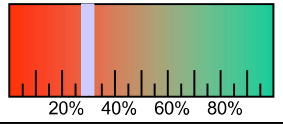
Metabolic Sufficiency

-Urine output

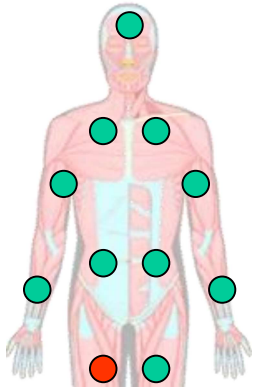
?

Global Perfusion Status

-buccal PCO_2-



Regional Ultrasound Sensors



Status indicators
key: red denotes <50%
O_2 saturation??

Medical Condition

Action

Needle thoracostomy

Infuse 500 ml bolus

Start or increase norepinephrine .05 µg/kg/min

Start dobutamine .05 µg/kg/min

Stage of Care

Care under fire

Forward Surgical Team

Combat Support Hospital

Air transport

Questions?

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