Research Advances In Medical Care For Polytrauma Injuries And Blast Injuries

The Quadruple Aim: Learning & Growth, Readiness, Experience of Care

COL Dallas Hack MD
25 January 2011
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<th>1. REPORT DATE</th>
<th>2. REPORT TYPE</th>
<th>3. DATES COVERED</th>
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<td>25 JAN 2011</td>
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<tbody>
<tr>
<td>US Army Medical Research and Materiel Command, Combat Casualty Care Research Program, Fort Detrick, MD, 21702</td>
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<th>12. DISTRIBUTION/AVAILABILITY STATEMENT</th>
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<th>13. SUPPLEMENTARY NOTES</th>
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<td>presented at the 2011 Military Health System Conference, January 24-27, National Harbor, Maryland</td>
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<td>c. THIS PAGE unclassified</td>
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std Z39-18
Problems/Threats

- 19% of Combat Deaths are considered preventable, major cause is uncontrolled hemorrhage*
- 42,167 battle injuries as of 21 January 2011**
  - 82% of battle injured have an extremity injury
  - Avg 2.3 per injured Soldier (Owens, JTrauma, 2007)
  - Accounts for 64% of disability ($1.1B) (Masini, 2008)
- As of 30 Sep 2010, 195,542 Servicemembers suffered a Traumatic Brain Injury since 9/11***, 150,222 of which are classified as mild

*(Kelly et al., J Trauma, Feb 2008
Causes of Death on the Battlefield

Non-survivable injuries:
- Catastrophic TBI
- Cardiac laceration / puncture
- Thoracic great vessel injury
- Intra thoracic tracheal injury
- Open pelvis

Top cause of preventable DOW*:
- Hemorrhage 76%
- Burn 13%
- TBI 6%
- MOF 3%
- Airway 1%

*DOW: Died of Wounds at Role 3+

Potentially survivable: 19%

Central Nervous System

Airway Compromise

Hemorrhage: 84%

33% Tourniquetable
67% Non-compressible/ non-tourniquetable (internal injuries)

Non-survivable: 81%

Other

Causes of Death on the Battlefield

Non-survivable: 81%

Potentially survivable: 19%

All Deaths

Kelly et al., J Trauma, Feb 2008 Suppl
OIF and OEF Dominant Mechanism of Injury

OIF
- Blunt: 49%
- Penetrating: 42%
- Burns: 9%

OEF
- Blunt: 38%
- Penetrating: 57%
- Burns: 5%

1-Year’s Data: Sep 08 – Aug 09
Combat Casualty Care
“Big Problems”

- Mortality
  - Non-compressible Hemorrhage
    - Coagulopathy
  - Compressible Hemorrhage
    - Extremity
    - Ax/neck/groin
  - Central Nervous System
  - Pneumothorax
  - Airway Compromise
  - Deep Vein Thrombosis
  - Multisystem Organ Failure
  - Sepsis

- Morbidity
  - Traumatic Brain Injury
    - Mild to Severe
  - Orthopedic Trauma
  - Massive Soft Tissue Injury
  - Burn
  - Eye Trauma
  - Ear Trauma
  - Craniofacial Injury
  - Pain Control
  - Wound Infection

- Training
  - Medic
  - Specialty Surgeon
  - Other Providers

2011 MHS Conference
Accepted by American College of Surgeons
*Published in Pre-Hospital Trauma Life Support Manual (Chapters 24-35)*

- Casualty continues as combatant if able
- Early use of tourniquets
- Hypotensive Resuscitation
- Intraosseous access if IV difficult
- PO fluids OK in combat casualties
- Hextend instead of Hespan
- Combat Gauze & Woundstat dressings
- PO meds (Combat Pill Pack) if able to use
  - Gatifloxacin 400 mg
  - Acetaminophen 1000mg
  - Meloxicam 15 mg
- Blood products on helicopters
- Changed oxygen guidelines for Tactical Evacuation

**2011 MHS Conference**

**Seventh Edition – Now Available**
### Core Skills - Point of Wounding Providers

<table>
<thead>
<tr>
<th>CORE SKILLS</th>
<th>CLS</th>
<th>Medic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear an upper airway obstruction</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Perform CPR</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Insert a nasopharyngeal airway</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Perform a surgical cricothyroidotomy</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Perform a trauma casualty assessment</td>
<td>+/-</td>
<td>YES</td>
</tr>
<tr>
<td>Control bleeding using pressure dressings</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Apply a tourniquet to control active bleeding</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Recognize signs and symptoms of shock</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Start an intravenous infusion</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Perform needle chest decompression</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Initiate an intraosseous infusion</td>
<td>NO</td>
<td>YES</td>
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</table>

### Core Skills

<table>
<thead>
<tr>
<th>CORE SKILLS</th>
<th>CLS</th>
<th>Medic</th>
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<tbody>
<tr>
<td>Recognize cardiac arrest / defibrillation with AED</td>
<td>+/-</td>
<td>YES</td>
</tr>
<tr>
<td>Splint extremity fractures</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Evaluate and provide initial treatment for burns</td>
<td>+/-</td>
<td>YES</td>
</tr>
<tr>
<td>Perform initial triage of casualties</td>
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<td>YES</td>
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<tr>
<td>Request medical evaluation</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>International Humanitarian Law / Detainee Care</td>
<td>NO</td>
<td>YES</td>
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<tr>
<td>Minor surgical procedures</td>
<td>NO</td>
<td>YES</td>
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<tr>
<td>Emergency surgical procedures</td>
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<td>Blast injuries</td>
<td>NO</td>
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<tr>
<td>Tactical combat casualty care concepts</td>
<td>YES</td>
<td>YES</td>
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</table>
DESCRIPTION: The C-A-T (patent pending) is a small and lightweight one-handed tourniquet that occludes arterial blood flow in an extremity. The C-A-T uses a Self-Adhering Band and a Friction Adaptor Buckle to fit a wide range of extremities combined with a one-handed windlass system. The windlass uses a free-moving internal band to provide true circumferential pressure to an extremity.

REQUIREMENT: FOC 09-06 Health Services Support b. 7 (d) – intelligent tourniquets to limit blood loss, without irreparable tissue damage

PARTNER: North American Rescue, Inc.

TRANSITION: Commercially available

COST: $25.98 each
QTY: As of January 2009, about 2.6M C-A-Ts have been fielded.

SCHEDULE: Fielded. Issued one per soldier with the Individual First Aid Kit
Soldier Training/Improved First Aid Kit (IFAK

- All Soldiers now trained as Combat Lifesavers during Basic Training
  - Basic casualty evaluation
  - Airway management
  - Chest injury and tension pneumothorax mgmt
  - Control bleeding
  - Request medical evacuation
Joint Theater Trauma System (JTTS) & Joint Theater Trauma Registry (JTTR)

- Integrated systems approach to Combat Casualty Care
- Right patient, right place, right time, right care
- Trauma Registry
  - Real time data, 90 dedicated personnel
- Data driven method of making changes
  - Better body armor
  - Impact of helicopter evacuation times
  - Employment of Forward Surgical Teams
- Merge registry with operational data and medical record
- Training
- Research

TRAUMA SYSTEMS TEAM: TRAUMA NURSE COORDINATORS
Joint Theater Trauma System

- World Wide Telecommunications:
  - Weekly f/u conf call with Level II+, III, IV, V and VA share lessons learned
  - Weekly Trauma Nurse Coordinators call, including all theater and LRMC/CONUS
  - Monthly System-wide VTC for system issues
    - Includes VA, JPMRC, GPMRC, AMC, CENTAF, CENTCOM
  - Bi-monthly JTTS Directors conference call
- Committee on Tactical Combat Casualty Care
- Joint Forces Combat Surgical Training
- War Surgery Manual
- Clinical Practice Guidelines
- Surgeon General Policies
- Integrate clinical guidelines from the war into mandatory training
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<thead>
<tr>
<th>No.</th>
<th>Topic</th>
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<td>Acoustic Trauma and Hearing Loss</td>
<td>February 16, 2010</td>
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<tr>
<td>2</td>
<td>Amputation</td>
<td>February 16, 2010</td>
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<td>3</td>
<td>Blunt Abdominal Trauma</td>
<td>June 30, 2009</td>
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<td>Burn Care</td>
<td>December 20, 2009</td>
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<td>5</td>
<td>Catastrophic Care</td>
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<td>6</td>
<td>Cervical Spine Evaluation</td>
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<td>Compartment Syndrome (CS) and the Role of Fasciotomy in Extremity War Wounds</td>
<td>April 30, 2009</td>
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<td>Damage Control Resuscitation at Level IIb/III Treatment Facilities</td>
<td>February 13, 2009</td>
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<td>Emergent Resuscitative Thoracotomy</td>
<td>May 6, 2009</td>
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<td>Fresh Whole Blood (FWB) Transfusion</td>
<td>January 12, 2009</td>
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<td>Frozen and Deglycerolized Red Blood Cells (RBCs)</td>
<td>June 30, 2010</td>
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<td>Hypothermia Prevention, Monitoring, and Management</td>
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<td>13</td>
<td>Infection Control</td>
<td>February 16, 2010</td>
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<td>14</td>
<td>Inhalation Injury and Toxic Industrial Chemical Exposure</td>
<td>November 7, 2008</td>
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<td>15</td>
<td>Initial Care of Ocular and Adnexal Injuries</td>
<td>February 16, 2010</td>
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<td>16</td>
<td>Intratheater Transfer and Transport of Level II and III Critical Care Trauma Patients</td>
<td>November 19, 2008</td>
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<td>Management of Patients with Severe Head Trauma</td>
<td>November 23, 2010</td>
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<td>18</td>
<td>Management of Patients with Severe Head Trauma</td>
<td>June 30, 2010</td>
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<td>Management of War Wounds</td>
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<td>Nutrition</td>
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<td>Pelvic Fracture Care</td>
<td>June 30, 2010</td>
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<td>Post-Splenectomy Vaccination</td>
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<td>24</td>
<td>Spine Injury Surgical Management and Transport</td>
<td>July 9, 2010</td>
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<td>25</td>
<td>Trauma Airway Management</td>
<td>June 30, 2010</td>
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<td>26</td>
<td>Urologic Trauma Management</td>
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<td>27</td>
<td>Use of Electronic Clinical Documentation in the CENTCOM AOR</td>
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<td>Use of Trauma Flow Sheets</td>
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<td>Ventilator Associated Pneumonia -</td>
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<td>30</td>
<td>Vascular Injury</td>
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**DESCRIPTION:** Medical practice guidelines are provided for applying existing products/methods singly or in combination to stop bleeding and restore normal metabolism of the combat casualty.

**REQUIREMENT:** FOC 09-06 Health Services Support 7 (d) Stabilize Casualty – management of hemorrhage, replacement of fluids, replacement of blood components, and stabilization of vital functions

---

### Damage Control Resuscitation – Greater use of plasma

Damage control resuscitation is structured intervention to treat the most severely injured casualties at greatest risk of dying.

![FFP: RBC effect on mortality](image)

P<.05 for all comparisons within groups


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### Standard Resuscitation

- Lactated Ringer’s Solution
- Packed Red Blood Cells (RBCs) (up to 10 units)
- Fresh Frozen Plasma (FFP) (2 units)
- Platelets
- Cryoprecipitate

### Damage Control Resuscitation

- Hypotensive Resuscitation
- Packed RBCs + FFP (1:1 Ratio)
- Platelets
- Cryoprecipitate
- Activated Factor VII

**One of the Army’s “Top 10 Greatest Inventions of 2007”**

---

**TRANSITION:** Forward medical treatment facilities

**COST:** None.

**QTY:** N/A

**SCHEDULE:** Fielded via ALARACT, Optimal Resuscitation of Severely Injured Soldiers, January 2007.
Hypothermia Impact

Mortality at Level III

79 vs 1878 casualties
Acidosis Effect

- Activity of the tissue factor/factor VIIa complex decreases 55% and prothrombinase complex declines by 70% as pH declines from 7.4 to 7.030
- Plasma clotting times prolong as pH is reduced
Coagulopathy of Trauma

- Syndrome of non-surgical bleeding from mucosal lesions, serosal surfaces, wound and vascular access sites associated with serious injury
- INR > 1.5 (reliably predicts those casualties who will require massive transfusion)
- Seen in most severely injured upon admission to ED
  - Coagulopathy correlated with ISS
- Also associated with:
  - Hypothermia (temp ≤ 35°C)
  - Acidosis (pH < 7.2 or BD ≥ 6)
  - Hemodilution
- “Trauma-induced coagulopathy can develop in 24.4% of patients independent of acidosis and hypothermia but secondary to trauma by itself” – J Trauma, Aug 08, p272
Description
• Dried Plasma (DP) is fresh frozen plasma (FFP, standard of care) that has been dehydrated. DP is less temperature sensitive & reconstitutes more quickly than FFP

• DP will augment FFP use by allowing use closer to point of injury & earlier in the treatment regime. There is a potential to reduce mortality of salvageable hemorrhage deaths by 2/3 with improved intravascular hemostatic agents, like plasma.

Benefits
• Life-saving technology for massive blood loss on the battlefield.
• Reduce the logistical footprint by reducing the refrigeration requirements associated with fresh frozen plasma.
• Extended shelf-life and temperature stability.
• Can be used in far-forward medical treatment facilities (combat support hospital and forward surgical teams) for casualty management, by the physician assistant or surgeon.

Key Participants
• USAMMDA
• ONR
• Industry
• US Army Institute of Surgical Research
• Combat Casualty Care Research Program
• AMEDDC&S
Description
Platelets are a key element in normal blood clotting after injury or surgical incision. The current blood-banked platelet product can be stored for only 5 days and is generally not available on the battlefield. Platelets continue to be absent in Operation Enduring Freedom but fresh whole blood and deployment of platelet apheresis have been used to fill the gap in Operation Iraqi Freedom. A platelet substitute will fill the current gap in effective medical management of hemorrhage at the combat support hospital.

Benefits
• The functional activity of this blood product is similar to native platelets with regard to the clotting function.
• Key attributes of this product are battlefield availability, potentially prolonged shelf-life, and greatly enhanced temperature stability if the lyophilized preparation is successful.
• Greatly enhanced shelf-life at ambient temperatures and the capability to be deployed far forward, including the forward surgical team and perhaps the battalion aid station for casualty management

Key Participants
• AMEDDC&S
• USAISR
• Combat Casualty Care Research Program
• USAMRAA
• Regulatory Affairs, USAMMDA
• Industry
Description

The logistical burden of resupply and refill of oxygen cylinders will be eliminated.

RVPS: The generator replaces the standard “D” cylinder for patient care and transport and yields increased efficiency and reduced size and weight.

Ceramic: Uses a minimum of mechanical parts; instead it uses a thin, hot ceramic membrane that has a voltage applied to it. It is insensitive to environmental conditions.

Benefits

The generation of oxygen where it is needed reduces the logistical requirements for the transport of oxygen cylinders to and within the operational theater.

Ceramic Oxygen Generator uses a metal reinforced composite, thin-film ceramic membrane to generate oxygen. Producing 1 liter of oxygen requires 30 watts of electricity. The device will be battery powered and weigh only 10 pounds.

RVPS is a smaller, more efficient product and will reduce the logistical burden of the oxygen generator for forward-deployed medical assets for use in single-patient care and transport.

Key Participants

• USAMMDA
• Industry
• US Army Institute of Surgical Research
• Combat Casualty Care Research Program
• AMEDDC&S
Description
The noise immune stethoscope can be used in high-noise environments. The new stethoscope uses a traditional acoustic listening mode with the addition of ultrasound-based technology that is “noise immune.” Current research is assessing the utility and durability of the new stethoscope under field conditions and in patients with cardiopulmonary pathology.

Benefits
• The ability to perform auscultation in the field environment or during evacuation, whether by air or ground ambulance.
• A stethoscope that can be used to listen to heart and breath sounds in the challenging environment.
• The ability for military medical personnel to evaluate and treat patients under the most difficult environmental conditions.
• Dramatically improved diagnostic ability of medical personnel in both military and civilian settings.

Key Participants
• USAARL
• USAMMDA
• Combat Casualty Care Research Program
• AMEDDC&S
• USAMRAA
Description
This device is a wireless vital signs monitor that transmits sensor information from patients to a smart monitor worn by a medic. This device includes smart monitoring software to predict patient trends. This is a Wi-Fi device that will work with other Wi-Fi monitors or laptops. It is intended for use from Battalion Aid Stations through to the CSH level, and can be used during transport to Level IV facilities.

Benefits
• Allows medical personnel to monitor numerous casualties simultaneously.
• Assists in triaging casualties by constantly monitoring their vital signs and alerting medical personnel of critical physiological changes.
• Has both military and commercial applications.
• Technical enhancements include wireless modules for frequency spectrum selection for communication, wireless ECG and improved embedded processing power while maintaining the small product footprint.

Key Participants
• Industry
• USAISR
• Combat Casualty Care Research Program
• AMEDDC&S
• USAMRAA
• Regulatory Affairs, USAMMA
Early Detection of Significant Blood Loss

Figure 1. A graphic approximation of the pressure-volume relationship of the circulation in healthy adult trauma patients with a circulating blood volume of 5 L.\textsuperscript{4-8}
Medical Care During Transport

- **Extended Evacuation Times**
- **Pre-hospital Care:**
  - Noisy, chaotic, dirty

**C**: Control Hemorrhage: continually reassess tourniquets and hemostatic dressings for rebleeding. Administer fluid only for signs of profound hypotension or mental status changes.

**B**: Identify and treat tension pneumothorax: Especially important in at-risk patients at altitude.

**A**: Control Airway if necessary: Generally, <1% of casualties need airway interventions.

- “Smart” monitoring equipment with decision-assist algorithms
- “Closed-Loop” ventilation, resuscitation, and CNS homeostasis

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Total Intravenous Anesthesia (TIVA)

**Description**
Total intravenous anesthesia (TIVA) uses only IV agents without the use of inhalational agents. Drugs used are generally of short duration of action and half-life in order to reduce the risks associated with accumulation. TIVA avoids unwanted effects of inhalational agents and the need for complex apparatus.

**Benefits**
- Reduction of the logistical footprint.
- Ability to control sedation before induction and post-operatively.
- Decreased post-operative nausea and vomiting.
- Ability to maintain hypoxic vasoconstrictor reflex and an unrestricted access to airway.
- Oxygen conservation (particularly useful for the field).
- Reduction of waste gases and other pollution, resulting in easier OSHA compliance.

**Key Participants**
- Industry
- USAMMDA
- Combat Casualty Care Research Program
- AMEDDC&S
- USAMRAA
Post 9/11 Fielded Products
Hemostasis

HemCon Bandage
One of Army’s “Top Ten Greatest Inventions of 2004”

QuikClot
One of Army’s “Top Ten Greatest Inventions of 2005”

Combat Gauze
One of Army’s “Top Ten Greatest Inventions of 2008”

NovoSeven Injectable Clotting Agent

Combat Application Tourniquet (CAT)


↓ Mortality by ↑ Plasma:RBC Ratio
Post 9/11 Fielded Products

Hypothermia Prevention and Management Kit (HPMK)

Improved First Aid Kit (IFAK)

Warrior Aid and Litter Kit (WALK)

Combat Pill Pack

Golden Hour Container

Stand Alone Patient Simulator (METI - iSTAN)

BUILT-IN SYSTEM
Blood, fluids, and power is 100% board and built into the mannequin.

FULLY LOADED
Body secretions; diaphoresis; jugular vein distention; bilateral chest movement; flail chest; real breath, heart and bowel sounds.

TRUE ARTICULATED MOTION
Realistic skeletal structure provides true-to-life articulated motion.

WIRELESS AND TETHERLESS
Controlled wirelessly and without tethers. Allows more freedom, versatility, and realism.

HUMAN-LIKE SKIN
Looks and feels like real human skin, including pores and hair follicles.
Combat Lifesaver (CLS) Bag
DESCRIPTION: Combat Gauze™ is an advanced hemostatic agent combined with standard gauze bandage material. The active ingredient absorbs water from blood and promotes clot formation.

REQUIREMENT: FOC 09-06 Health Services Support 7 (d) Stabilize Casualty – naturally enhanced and synthetic materials to promote blood clotting, whether externally applied or injected into the body

PARTNER: Z-Medica Corporation

TRANSITION: Commercially available

COST: $38.99
QTY: Fielded. Issued one per soldier with the Individual First Aid Kit
DESCRIPTION: The RVPSAOG is designed to replace the "D" cylinder for patient care and transport. The RVPSAOG is a substantial simplification of existing pressure swing adsorption oxygen generator technology. The use of a rotary valve, driven directly by a small motor, eliminates complex valve and control systems used in conventional oxygen generators. Taking advantage of the reduced complexity reduces the weight and size of the oxygen generator and increases the efficiency of the generation process.

REQUIREMENT: The ambulance medical equipment set required oxygen bottles that could not be used because of the threat environment.

PARTNERS: U.S. Army Medical Materiel Development Activity (USAMMDA), SeQual

TRANSITION: March 2008

COST: $4,000
QTY: 1,500
SCHEDULE: Delivered
Characterization of Extremity Wounds in Operation Iraqi Freedom and Operation Enduring Freedom

Brett D. Owens, MD, John F. Kragh, Jr, MD, Joseph Macaitis, BS, Steven J. Svoboda, MD, and Joseph C. Wenke, PhD

(J Orthop Trauma 2007;21:254-257)

- 1,566 soldiers sustained 6,609 combat wounds
  - 4.2 wounds per soldier
- 3,575 extremity wounds
  - 82% of soldiers with at least one extremity wound
- 2.3 Extremity injuries/wounded soldier
- 1.3 OMF injuries/wounded soldier
Injury Severity Relative to Civilian Medicine - Fractures

1 Johnson, Burns et al. 2007; 2 Gustilo and Anderson 2002
Five Areas of Emphasis

1. Cranio-Facial Reconstruction
2. Healing Without Scarring
3. Limb and Digit Salvage and Reconstruction
4. Compartment Syndrome
5. Burn Repair
Continuum of TBI Care Determines Research Approach

**RESEARCH NEEDS**

- **Injury Prevention**
  - Medical Standards for Protective Equipment
  - Objective Measure of Head Impact Exposure

- **RDT&E: Combat Casualty Care**
  - Portable Fieldable Diagnostic Device (In Theatre & Garrison)
  - Valid Criteria & Objective mTBI/Concussion Screening Tool

- **Psych Health and Related Symptoms**
  - Pharmaceutics & Surgical Technology
  - Recovery Timecourse & Rehabilitation

**Continuing Education and Reinforcement for Soldiers, Leaders and Service Providers**

- Nutraceuticals, Standards for Helmets, education/CPG’s for Soldiers, Leaders & Service Providers
- Head Impact/Blast Injury Dosimeter
- Validated Definition and Technologies: EEG, TCD, Eye Tracking, Vestibular Ocular Assessment, ICP Device, Biomarkers
- Cognitive, Behavioral, and Neurological Assessments (CT, EEG, FMRI, DTI, MRS, etc.)
- Medications, Novel Interventions
- Evidence-Based Rehabilitation Protocols, Measures of Rehabilitation Progress

**SOLUTIONS**

- 2011 MHS Conference
1. Basic Science

The Importance of Neurogenic Inflammation in Blast-Induced Neurotrauma

PI: Cernak, Ibolja
Johns Hopkins University, Applied Physics Laboratory
$1.132 m
1 Oct 2010 to 30 Sep 2013

Aims

• Identify vital mechanisms of neurodegeneration initiated by blast exposure thus defining novel diagnostic and therapeutic targets

Approach

• Military-relevant blast scenarios are being replicated in controlled laboratory conditions using a multichamber, compressed gas-driven shock tube
• Mice are being exposed to graded (low, moderate, or high) intensity shock waves
• Mice are being imaged using superparamagnetic iron-oxide particle (SPIO)-enhanced T2-weighted (T2-w) magnetic resonance imaging (MRI), gadofluorine-enhanced T1-weighted (T1-w) MRI, and manganese chloride-weighted MRI
• Mechanisms of inflammatory response are being measured by various means

Deliverables

• Knowledge on brain inflammation due to blast and information on the importance of changes originating in the periphery on integrity

2011 MHS Conference
mTBI Prevention: Pharmaceutical for Neuroprotection and Resilience - DHA

Aims/Approach

- Develop and evaluate efficacy of docosahexaenoic acid (DHA) for neuroprotection against negative consequences of blast exposures and improved recovery following blast exposure and/or traumatic brain injury
- Study comparing DHA versus placebo administration in a special operations unit with a high rate of blast exposure

Deliverables

- If effective, DHA may provide some degree of neuroprotection against negative consequences associated with blast exposures

Project Status

- DHA formulation is being redesigned to be more readily fieldable and feasible for special operations unit use
- Evaluation of DHA compared to placebo will be conducted once formulation is complete

PI: COL Michael Lewis
Defense Veterans and Brain Injury Center

$1.0m
Oct 2009-Oct 2011

<table>
<thead>
<tr>
<th>MILESTONES</th>
<th>FY 11</th>
<th>FY 12</th>
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<tr>
<td>Develop supplementation formulation and procedures; get approvals</td>
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<tr>
<td>Conduct efficacy studies</td>
<td></td>
<td></td>
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<tr>
<td>Dissemination of findings</td>
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3. Objective Measure of Head Impact/Blast Exposure

**Helmet Mounted Sensor System (HMSS)**

- Army and Marine Corps fielded nearly 9,000 HMSS to deploying Soldiers and Marines
- Two versions fielded: Internal and External
- **HMSS:**
  - Recorded helmet acceleration & pressure from impacts/explosions
  - An exposure monitor, not a diagnostic tool
- **Value of HMSS:**
  - Monitor/document head impact exposures
  - Provide data for development of an objective head injury screening tool
  - Provide data for Next Generation Combat Helmet

**Internal HMSS**
- Weight: Internal 1.2oz & External 6oz
- Records linear helmet accelerations (3 axes) + peak pressure
- Download via USB
- Acceleration trigger threshold: internal/100g & external/50-70g
- Data downloaded monthly & after each event
- Attack event data captured in NGIC Anti Armor Incident Reports

**External HMSS**
- Weight: Internal 1.2oz & External 6oz
- Records linear helmet accelerations (3 axes) + peak pressure
- Download via USB
- Acceleration trigger threshold: internal/100g & external/50-70g
- Data downloaded monthly & after each event
- Attack event data captured in NGIC Anti Armor Incident Reports

**HMSS Data Analysis (Performers: USAARL, NHRC, and L-3/Jaycor [USAMRMC contract] with JTAPIC PMO lead)**
- Developed mathematical model that estimates acceleration-caused concussion “dose” using data from lab sensors. Identified HMSS performance problems and data artifacts
- Developed data screening criteria and found ~60,000 of 250,000 HMSS recordings characteristic of blast/impact.
- Determined there were too few HMSS and injury data matches to draw meaningful conclusions
  - Reasons: sensors that had incorrect starting dates, sensors that failed to record events, and unit compliance with sensor downloading requirements
4. Head Injury Screening

EYE-TRAC: Eye-Tracking Device
Objective Test for Post Concussion Syndrome

PT075553
Eye-Tracking Rapid Attention Computation
Brain Trauma Research Foundation
$4,644 ($K), PH/TBI CSI
15 Sep 2008 to 14 Oct 2012

Aims
Develop a ruggedized eye-tracking device, EYE-TRAC, which has been proven to rapidly and accurately detect attention and memory deficiencies in civilian mild TBI

Approach
- Baseline measurements are being obtained in a large number of subjects to establish thresholds in different age groups and varying fatigue levels
- Validated standards that characterize attention deficits are being developed
- A prototype eye-tracking system is being built
- A battery of neurocognitive tests is being applied to test the EYE-TRAC device

Deliverable
A portable, goggle-like prototype of an eye-tracking device for attention deficit assessment that distinguishes fatigue and PTSD from Post Concussion Syndrome

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<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
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<tbody>
<tr>
<td>Collect EYE-TRAC data</td>
<td></td>
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<tr>
<td>Develop test methods and appropriate software</td>
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<tr>
<td>Ruggedize and build a prototype EYE-TRAC testing device</td>
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2011 MHS Conference
4. Head Injury Screening

Pre- and Post- Deployment Longitudinal Screening for Traumatic Brain Injury with a Hand-Held Real-Time Multichannel Algorithmic EEG Platform

PI: COL De Lorenzo, MD, Brooke Army Medical Center

Problem, Hypothesis and Military Relevance

- Screening for TBI is cumbersome, requires provider training, and can lack objectivity
- A means to objectively and rapidly screen for TBI in deploying warfighters is needed.
- Emerging technology in portable, real-time algorithmic digital signal processed EEG system show promise.
- Proposal will study a new DSP-EEG device (Brainscope Ahead M-100) in a group of warfighters about to deploy and with follow-up on re-deployment home.
- Correlation of potential exposures, symptoms and diagnosis to changes in DSP-EEG results.

Proposed Solution

- The device integrates DSP-EEG and computerized assessment to create a noninvasive, low-cost portable device:
  - Real-time, functional assessment at point of care
  - Non-invasive, painless and rapid
  - Portable, battery-operated for use anywhere
- Primary objective focuses on obtaining baseline data and comparing to post-deployment DSP-EEG, standardized neurocognitive testing, and follow-up.
  - A matched group of non-deploying warfighters will be recruited.
  - DSP-EEG changes within subjects and between groups will be analyzed.

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<tr>
<td>IRB approval (min risk), Study run-in, subject enrollment</td>
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<tr>
<td>Subject enrollment, deployment of group, gather exposure histories</td>
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<tr>
<td>Re-deployment, acquire f/u data analysis, presentation, and publication</td>
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Brainscope Ahead M-100

2011 MHS Conference
Biomarker Assessment for Neurotrauma Diagnosis & Improved Triage System (BANDITS)

No test is currently approved to objectively diagnose TBI, particularly mTBI. The goal of the BANDITS program is to develop a blood test for brain cell damage, much like the current blood test (Troponin) for heart damage.

BANDITS will be embedded in an automated system available to Level III or lower echelons of care from an open benchtop system to a handheld device.

**GOALS**
- Minimal- to non-invasive medical device to identify and assess internal brain injuries
- State-of-the-art lightweight, sturdy and reliable diagnostic systems appropriate for far forward screening, assessment, and care
- Designed to diagnose mild, moderate and severe traumatic brain injury
### UCH-L1 (Serum)

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<th>Mean</th>
<th>SEM</th>
<th>P value</th>
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<td>Normal</td>
<td>176</td>
<td>0.06</td>
<td>0.004</td>
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<td>Ortho</td>
<td>11</td>
<td>0.16</td>
<td>1.04</td>
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<td>TBI 2-6 hrs</td>
<td>37</td>
<td>3.140</td>
<td>0.53</td>
<td>*&lt;0.0001</td>
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<td>TBI 24 hrs</td>
<td>101</td>
<td>1.35</td>
<td>0.18</td>
<td>* 0.0005</td>
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(\(p\) values of the Mann-Whitney test for differences between the groups [*TBI versus Ortho Controls]).

### GFAP (Serum)

<table>
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<th>Group</th>
<th>#</th>
<th>Mean</th>
<th>SEM</th>
<th>P value</th>
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<td>Normal</td>
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<td>TBI 2-6 hrs</td>
<td>37</td>
<td>4.08</td>
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<tr>
<td>TBI 24 hrs</td>
<td>101</td>
<td>2.65</td>
<td>0.49</td>
<td>*&lt;0.0001</td>
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BANDITS PROGRAM
Biomarkers in Mild TBI Patients

**Commercial GFAP, A = 0.63**

**Banyan GFAP, A = 0.87**

**UCH-L1, A = 0.91**

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<tr>
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<th>Commercial GFAP</th>
<th>Banyan GFAP</th>
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<td>ROC Curve Area</td>
<td>0.6328</td>
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<td>0.9072</td>
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<tr>
<td>Sample Size - Normal</td>
<td>166</td>
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**NNZ-2566 – Drug for Treatment of TBI**

No effective treatment is approved for treating TBI, although multiple drugs have shown promise in preclinical tests.

- Other drugs in Phase II clinical trials include progesterone, growth hormone, erythropoetin, huperzine, pregnenalone, and atorvastatin, and others.

**Non-Convulsive Seizure Reduction with NNZ-2566 Administration**

After Middle Cerebral Artery Occlusion

- NNZ-2566, a portion of the naturally occurring hormone, Insulin-like Growth Factor, has demonstrated a remarkable ability to reduce non-convulsive seizures in animal studies with TBI. Phase I safety studies have shown an excellent safety profile.
- A multicenter Phase II clinical trial in civilian TBI patients should be completed by the end of 2012.
- This clinical trial is unique in that it combines more than 15 biomarker and neurocognitive tests to assess functional outcome.
- NNZ-2566 has been formulated as a water-soluble IV form and an oral form.

2011 MHS Conference
7. TBI / Concussion Recovery

**Study of Cognitive Rehabilitation Effects (SCORE):**
A randomized treatment trial in a military population with mild traumatic brain injury incurred during deployment to OIF/OEF

Director, Military Brain Injury Rehabilitation Research Consortium, SAMMC-N (Dr. Cooper)
Chief, Traumatic Brain Injury Service SAMMC-N (Dr. Bowles)
DVBIC (Dr. Kennedy, COL Grimes, Dr. Vanderploeg)
WRAMC (Dr. French)
Jun 2010 – Dec 2013

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**Aims/Approach**
- Determine the effectiveness of cognitive rehabilitation in individuals with a history of mild TBI
- Determine which components of cognitive rehabilitation treatment (or combination of components) are most effective
- Determine which participant characteristics are associated with better treatment outcomes.
- Conduct an 18 week RCT investigating the effectiveness of cognitive rehabilitation on subjects with mild TBI
- Subjects will be randomly assigned to one of four treatment arms of the study: 1. Psycho-educational, 2. Self-administered computerized cognitive rehabilitation, 3. Therapist-directed individualized cognitive rehabilitation 4. Integrated interdisciplinary cognitive rehabilitation combined with cognitive behavioral psychotherapy.

**Deliverables**
Empirically-validated cognitive rehabilitation interventions for service members with a history of mild TBI

**Project Status**
- Steering committee workshop
- Scientific advisory review
- IRB Submission

2011 MHS Conference
8. TBI / Concussion Reset/RTD

**TBI Return To Duty Assessment Tools**

US Army Aeromedical Research Laboratory (USAARL)
(Catherine Webb; Thomas Harding; Angus Rupert)
Abbott Northwestern Hospital MN
(Mary Radomski)

$2.6m
Oct 2009-Sep 2012

**MILESTONES**

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<td>Develop tools and operationalize procedures</td>
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<td>Validation studies</td>
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<td>Advanced development; dissemination of findings</td>
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**Aims/Approach**

- Develop objective repeatable assessments to aid RTD decisions following mTBI
- Weapon utilization tasks in conjunction with physiologic measures; battery of balance and vestibular tasks to aid RTD decisions
- Dual-task paradigm Combat readiness check (CRC) assessment which involves a highly familiar soldiering task with a second cognitive task to simulate operational demands and reveal safety-jeopardizing impairments

**Deliverables**

- Cognitive, vestibular/oculomotor, and performance assessment tools to aid determination of readiness for RTD following mTBI

**Project Status**

- Development of tools is underway and validation studies will be conducted
- Findings will inform test battery/measures improvement and standards for RTD decisions
- Establishing IPT and advanced development team to identify and transition most promising technologies

2011 MHS Conference
Summary/Conclusion

• U.S. Trauma Research is largely the purview of the Department of Defense, as there is no Trauma Institute at the NIH, although trauma accounts for the largest loss in years of productive life

• Improvements in the medical care of battle casualties are being adopted by the civilian trauma system

• Recent increases in funding for military trauma funding are yielding important advances, particularly in hemorrhage control, brain injury diagnosis, and traumatic orthopedic injury

• There is a large backlog of clinical trials that need to be performed in trauma care