Trauma Experience and Lessons Learned from Iraq

Arkansas Trauma Update 2012
April 13, 2012
North Little Rock, AR

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Assoc Prof and Trauma Medical Director Saint Marys Hospital Rochester MN

MILITARY TRAUMA IS DIFFERENT THAN CIVILIAN TRAUMA
Military Surgery

- Military or war surgery is a subset of surgery (trauma surgery PLUS…)
- Emergency surgery done on mass production basis, in austere & resource-limited environment
- Do what must be done--not what can be done
- Care-givers are in danger themselves
  - 10% wounded while giving aid

Battlefield Injuries:

Weapons

- Penetrating Missiles: 90% casualties
- Other: 10% casualties
  - Blast injuries
  - Burns
  - Blunt injuries
Harvey Cushing

- Bovie cautery
- Father of neurosurgery
- WWI France

Will and Charlie Mayo
Michael DeBakey

• From 1942 to 1946, he was on military duty as a member of the Surgical Consultants' Division in the Office of the Surgeon General of the Army
• He helped develop the mobile Army surgical hospital (MASH) units

David Feliciano

• Between 1971 and 1973 he was a lieutenant in the U.S. Navy Medical Corps and was stationed at the U.S. Naval Hospital in Port Hueneme, California
Combat Surgical Innovations: What has worked in the past?

- Baron D. Larrey - ambulance system (Napoleonic wars)
- Florence Nightingale - nursing care (Crimea)
- Battlefield surgical units - US Civil War

- Fluid resuscitation for hemorrhagic shock - WWI
- Laparotomy for penetrating abdominal wounds - WWI
- Debridement: Depage - WWI
Combat Surgical Innovations: What has worked in the past?

- Surgical augmentation teams - WWII
- Blood transfusions - WWII
- IV antibiotics - WWII

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Combat Surgical Innovations: What has worked in the past?

- Helicopter transport - Korea
- MASH - Korea
Vietnam Era

- Vascular surgery in combat injuries codified (Norm Rich)
- Helicopter transport of injured perfected
- Sicker patients surviving (Da Nang lung = ARDS)
- Experience in war surgery caused surge in trauma center and system in continental US

Combat Trauma Surgical Committee

- Following the Gulf War reports found
  - surgeons and other health care providers lacked sufficient training or experience in trauma and military surgery
- Assistant SOD for Health Affairs identified proficiency in Combat Surgery Training as an essential mission
- CTSC
  - organized 1996 to study policy options for DoD
    - recommendations implemented
  - Responsible for establishing trauma training centers in Miami, Baltimore, LA, St Louis and Cincinnati
**Recommendations**

- DoD should have sufficient expertise & personnel to ensure *capable trauma surgical care in earliest stages of war*
- Services should be able to track trained trauma personnel
- Should establish trauma leadership to enhance training & teaching
- Most MTFs don’t see enough trauma to train all personnel internally

**Trauma Refresher Course for Surgeons**

- to best sustain wartime trauma surgery capability
- “hands-on” laboratory
  - human cadaver/live animal models
  - triage exercise
  - introduces new cutting edge concepts in trauma surgery from trauma center care to austere conditions
- covers numerous military specific subjects
• In a sudden conflict, medical channels that return soldiers to duty may be the only functional personnel replacement
• Primary goal is CONSERVATION OF FIGHTING STRENGTH
• Initial (salvage) surgery far forward to make casualty transportable for definitive surgery that may be far away, possibly in CONUS
  • (“smaller footprint”)

Echelons of Care

• Organized to distribute resources at various levels of location and function
• Not a rigid prescription, especially in today’s war or operations
• New scheme with “smaller footprint”
  • first responder
  • forward surgery
  • theater hospital
  • “in route care”
• Civilian trauma centers and battlefield/military triage situations differ
  • Civilian trauma centers
    • small numbers of patients, unlimited resources
  • Military setting
    • limited numbers for potentially unlimited patient numbers

Be Aware of Resources

• Resources
  • surgeons available/ fatigue factor
  • O.R.s/ anesthesia/ blood/ vents available
  • post-op holding availability
  • evac availability and time to next level of care
  • surgical instruments and supplies
General Principles of Care of Battlefield Wounds

- Battlefield are very contaminated places
- Frequently time lag between injury and treatment
- Combat wounds have extensive tissue destruction
- Some victims are immune compromised
  - prisoners, non-combatants, etc.
Early, Adequate Surgery is the Answer

- Most important steps are stopping hemorrhage and avoiding infection and sepsis
- Wounds debrided of nonviable, contaminated tissue with good blood supply are best able to resist infection
“Cold War” Doctrine: NATO vs Warsaw Pact

- Weeks of lead time for preparation
- Primarily armored conflict
- Large battlefield medical footprint
- DEPMEDS & prepositioned Contingency Hospitals
- 5 echelons of medical care
“Cold War” doctrine: DEPMEDS CSH

Since 1990: Change in mission, change in strategy

- Less time to prepare = greater mobility
- Mandate to decrease size
  - smaller battlefield footprint
  - less transport tonnage/“cube”
  - Negligible ramp-up time
- Smaller surgical team
  - Deployable
  - Far forward
New Doctrine: Battlefield medical support

Mission of Forward Surgical Team

• Far-forward surgical presence in areas of most intense conflict
• Life-saving operations for highly lethal wounds
  • laparotomy - vascular repairs
  • thoracotomy - amputation
  • craniotomy - external fixation
• “Damage Control” Surgery
What is “Damage control” surgery?

- Situation: rapid exsanguination, shock
- Avoid lethal triad: hypothermia, acidosis, coagulopathy
- Goals: stop bleeding, seal GI leak, pack, close skin, finish within 30 minutes
- Survival increases from 5% to 25%
- Requirements: more than a fast surgeon

Damage Control Surgery
Damage control surgery: requirements

- Surgeons and instruments
- General anesthesia: during and after
- Mechanical Ventilation
- Electricity
- Disposable supplies
- **Rapid access to ICU**
- Lighting
- Oxygen
- Suction
- Water
- Blood products, incl. FFP
- Resuscitative fluids

MFST Concept

- Mobile / rapid response team
- Small airlift requirement
- Emergent operative / non-operative trauma care

*Trauma care expertise moved closer to time of injury*
Field Surgery Limitations

Field Anesthesia Limitations
FST CAPABILITIES

• CONDUCT STRATEGIC DEPLOYMENT BY AIR, LAND AND SEA - PERSONNEL & EQUIPMENT
• RAPID DEPLOYMENT
• RAPID SETUP, TAKEDOWN, REDEPLOYMENT

FST CAPABILITIES

• FOOTPRINT: SINGLE GP-LARGE TENT or GP-LARGE PLUS GP-MEDIUM
• PROTECT THE FORCE
FST CAPABILITIES

- SELF-SUSTAINED FOR 72 HOURS
- OPERATIONAL SUSTAINABILITY THROUGH ABN DROPS, ATTACHMENT, OR LAND REINFORCEMENT

FST CAPABILITIES

- PROVIDE LIFESAVING SURGERY FOR 40 PATIENTS IN 48 HOURS
  - Trauma/General Surgery - abdomen, chest, vascular
  - Orthopedic
  - Neurosurgical
  - Anesthesia: general, spinal, local
- ATLS RESUSCITATION
- ICU CARE
FST EQUIPMENT

- OXYGEN CONCENTRATORS: 6
- MECHANICAL VENTILATORS: 4
- PRBCs: 40; LEVEL-1 INFUSOR
- DIESEL GENERATOR, LIGHTING
- LITTERS, STANDS, O.R. TABLES, MONITORS COMMUNICATION, HEAT
FST PERSONNEL

- PHYSICIANS: 4
  - 3 General Surgeons
  - 1 Orthopedic Surgeon
- NURSE ANESTHETISTS: 2
- NURSES: 3
  - 1 ER NURSE
  - 1 OR NURSE
  - 1 ICU NURSE
- 1 EXECUTIVE OFFICER
- 10 Enlisted Personnel

MAJ Mark D. Taylor, 41
Stockton, CA killed 20 MAR 2004
Field Critical Care
New Doctrine -

Joint Health Service Support Concept

- Evacuate “shock-treated” patients on C-Day
  - Project surgical capability forward
  - Intravascular fluid resuscitation
  - Hemorrhage controlled
  - Extremity fractures stabilized
- Provide continual care during patient transport
- Long flight back to definitive care hospital
Critical Care Air Transport Team

- CCAT teams for transport
  - 3-person team
- Intensive care capability
  - Just done in the ‘elevator’

**ARMY OIF/OEF SOLDIER EVACUATIONS 7 OCT 01 – 15 FEB 07**

<table>
<thead>
<tr>
<th>Total To CONUS:</th>
<th>Over 19,000</th>
<th>Over OIF: 17,500</th>
<th>Over OEF: 1,500</th>
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<tbody>
<tr>
<td><strong>Total</strong></td>
<td><strong>31,361</strong></td>
<td><strong>22,580</strong></td>
<td><strong>8,781</strong></td>
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<tr>
<td><strong>Combined %</strong></td>
<td><strong>100%</strong></td>
<td><strong>72%</strong></td>
<td><strong>28%</strong></td>
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<table>
<thead>
<tr>
<th>Total DISNBI</th>
<th>BI</th>
<th>NBI</th>
<th>DIS</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>4,077</td>
<td>8,781</td>
<td>18,503</td>
<td>31,361</td>
</tr>
<tr>
<td><strong>Combined %</strong></td>
<td>13%</td>
<td>28%</td>
<td>59%</td>
<td>100%</td>
</tr>
</tbody>
</table>

NARMC
Landstuhl Army Regional Medical Center
Kandahar
WRMC
GPRMC
PRMC

BI 8,781 22,580 31,361
28% 72% 100%

Inpatients Outpatients Total

25
En Route Care: Air Evacuation and Critical Care Transport

- Critical component of AF Global Mobility
- Joint, Interdependent, and Interoperable…
  - Modular A/E units / CCATT
  - Modular MASFs and CASFs
  - Aircraft independent
  - Total Force
- Move casualties to right level of care in the shortest time
  - Vietnam: 21 days
  - Desert Storm: 10 days
  - Today: 3 days
- Safe/rapid transfer of 44,000 OEF/OIF patients from AOR to stateside hospitals

CONTINUOUS EN ROUTE CARE

Current Route from Injury to Definitive Care

- CASEVAC 1 Hour
- BAS Level 1
- TACTICAL MEDEVAC 1-24 HOURS
- Forward Surgical Teams Level 2
- CSH, EMEDS, EMF Level 3
- STRATEGIC AE 24-72 HOURS
- Definitive Care Level 4
- SURGICAL CAPABILITY PUSHED FAR FORWARD
Trauma System

**DEFINITION**

“An arrangement of available resources that are coordinated for the effective delivery of emergency health care services in geographical regions consistent with planning and management standards.”

**GOAL**

Get the right patient to the right hospital in the right amount of time

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Joint Theater Trauma System Components

“The right care to the right casualty at the right location and right time”

**Components Across the Continuum of Care**

- **Prevention**
  - Linkage with Material developers
  - Center for Health Promotion and Preventive Medicine (CHPPM) and Readiness Center

- **Leadership & Communication**
  - Intra theater
  - Inter theater
  - Recognized lead facility and consulting assets
  - Director / Coordinators

- **Integrated Pre-Hospital, Levels 3-5**
  - Integrated approach for MTFs and divisional medical units
  - Coordinated divisional Evacuation Standard Operating Procedures
  - Adopt Clinical Practice Guidelines
  - Communicate, train

- **Education**
  - Linkage with Army Medical Department Center & School/Training & Doctrine Command (AMEDD C&S / TRADOC)
  - Joint Combat Trauma Management Course (JCTMC)

- **QA/PI**
  - Feedback mechanism for all providers throughout the continuum of care

- **Research**
  - AOR research team and mechanism
  - Deployed clinicians to conduct research

- **Information Systems**
  - Joint Theater Trauma Registry (JTTR)
  - Linkages to Joint Trauma Analysis System
  - Linkages to Theater Medical Information Program (TMIP)
  - Longitudinal trauma registry
  - Provide data and information needs for Services / DoD
In JTTR Today

- To date >20,000 cases are in JTTR:
  - Air Force: 400+
  - Army: 16,000+
  - Coast Guard: 1
  - Marine: 3,000+
  - Navy: 400+

Communities of Dialogue

- Weekly conference call with Role II+, III, IV & V
- Weekly Trauma Nurse Coordinators call
- Monthly System-wide VTC for system issues
  - Includes Veterans Hospitals and Commands
- Bi-monthly JTTS Directors conference call
**JTTS Clinical Practice Guidelines**

- Factor VIIa
- Fresh Whole Blood Draw & Field Administration
- Vascular Injury
- DVT
- Adult Severe Head Injury
- Mild Traumatic Brain Injury & Military Acute Concussion Eval Guidelines
- Transport/Transfer Guidelines
- Pelvic Fracture Protocol
- Abdominal Blunt Trauma
- Urologic Trauma
- Trauma Airway Mgmt
- EMT Thoracotomy
- Burn Protocol
- Hypothermia
- Damage Control Resuscitation
- Irrigation of War Wounds

**Data Driven Results**

- Tourniquet ‘All Army Activity’ (ALARACT) Message
- Hemostatic Dressing ALARACT
- Burn ALARACT
- Hypothermia prevention
- ICU teams
- Tactical Combat Casualty Care
  - C,B,A (circulation, breathing then airway)
  - Hextend
  - Tourniquets
- Training
Vascular Injury and Treatment

Temporary Vascular Shunts

Prevalence of shunts per Quartile
Sept 2004 – Dec 2006 (N = 64)
Vascular Shunts: Patency & Limb Viability

Damage control: shunt in femoral artery wound already debrided of dead tissue

24/25 shunts successful
At 2nd operation, shunt replaced with vein graft, little further debridement required

Muscle mobilized and placed over vein graft, wound vacuum system placed over wound
Enter the Wound Vac System

4th operation, skin graft placed due to large skin defect, secured with wound vacuum system
Vein graft harvest site and fasciotomy sites closed primarily over drains at 4th operation

Wounds healed one month after injury
Published Results with Wound Vac

- 77 patients with 88 wounds studied
- 63% IED; 37% GSW
- 65% extremity
- Length of stay = 7.5 days (historical = 30 days)
- Operations = 2.2
- Time from wounding to wound closure = 4.2 days
- 0% wound complication rate (vac = safe)
- 0% infection rate (historical >80%); vac = good

J Trauma Nov 2006

Burns Management

- Burn Care Guideline
  - Development and Implementation
- Deployment of Burn Care Expert
  - Theater Consultant
- Use of Burn Flow Sheets
  - Compliance Monitored
Burns May-July 2006

- 28 US Troops identified with burns transferred to Level III:
  - 82% due to IED; 68% Soldiers
  - 64% required surgery in theater
  - 70% > 10% Total Body Surface Area
  - 39%TBSA (avg 2003-05 = 14%)
  - Burn outcome: DOW = 5 (18%)
    (mortality 2003-2005 = 3.8%)
- Good Data = Good Decisions
  - $25 million in Nomex uniforms distributed to all troops going outside the wire

Trend is from 3 US troops burned/month Jun 05 to 12 burned/month June 06
Decision to use Nomex uniforms

COL Brian D. Allgood
Army surgeon killed 20 JAN 2007
Blood Product Administration

- Use of Whole Blood
  - Change in Philosophy
  - Screening
  - Whole Blood Drives
- Massive Transfusion
- Tracking of Products given

Fresh Whole Blood Improves Survival Compared To Component Therapy

- 111 patients (55 Fresh Whole Blood [FWB] vs 56 Component Therapy [CT])
- All had a massive transfusion and ISS>15

<table>
<thead>
<tr>
<th></th>
<th>FWB</th>
<th>CT</th>
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</thead>
<tbody>
<tr>
<td>ISS</td>
<td>25 (16-50)</td>
<td>19 (16-35)</td>
</tr>
<tr>
<td>Mortality</td>
<td>21.8% (12/55)</td>
<td>33.9% (19/56)</td>
</tr>
</tbody>
</table>

This represents a 15% absolute reduction in mortality or a 39% relative reduction in mortality.

Variables included in analysis
- ISS, admission (HR, SBP, INR, CBC, base deficit) total RBC, FFP, PLT, cryo transfused in 7 days, rFVIIa use
- After adjusting for ISS, p=.09
Diagnostic criteria for Damage Control Resuscitation

- BD ≥ -6
- INR ≥ 1.5
- SBP ≤ 90 mm Hg
- Hgb ≤ 11
- Temp ≤ 96°F
- Weak or absent radial pulse
- Abn mental status
- Age ≥ 55
- Pattern recognition
  - Bilat prox amputations
  - Truncal bleeding and one prox amputation
  - Large Chest tube output

All associated with MT or death ~ 25%
Normal values, minimal injury, usually associated with very low death rates (~ 1%)

Mortality by Plasma : RBC Ratio

The ratio of blood products transfused affects mortality in patients receiving massive transfusions at a combat support hospital. Borgman MA, et al.
Distribution of U.S. Military Massive Transfusion Patient Deaths

Patients receiving ≥10 units of RBCs (including whole blood)

Preliminary Experience with Thromboelastography (TEG)

- Over 4 months in 2004 in Iraq
  - >1200 trauma evaluations; >1000 surgical procedures
  - >1700 units blood products administered
  - 30 doses of rVIIa given
- Now theater-wide use by protocol
Captain Maria I. Ortiz 40
Pennsauken NJ, killed 10 JUL 2007

How People Die In Ground Combat
(From COL Ron Bellamy)

- 31% KIA- CNS Injury
- 31% KIA- Tension Pneumothorax
- 7% KIA- Blast Mutilating Trauma
- 9% KIA- Exanguination From Extremity Wounds
- 10% KIA- Surgically Correctable Torso Injury
- 25% KIA- Surgically Uncorrectable Torso Trauma
- 12% DOW- Largely Infections & Complications Of Shock
- 1% KIA- Airway Obstruction
Impact on KIA – It’s the Medic (Self & Buddy Care?)

The only one close enough to make a difference in the first half-hour needs best materials, training & sustainment

The Committee on Tactical Combat Casualty Care

- Standing Tactical Medicine committee
- Sponsored by USSOCOM and BUMED
- Naval Operational Medicine Institute
- Tri-Service and civilian
- Trauma Surgeons, ER, SOF unit physicians, USMC, combat medics
- Monitor literature and technology
- Periodic updates to guidelines
Tactical Combat Casualty Care

Good Medicine Can Sometimes Be Bad Tactics

1. Bad tactics can get everyone killed.

2. Bad tactics can cause the mission to fail.

| The Right Things To Do | AND | The Right Time to Do Them |

Phases of Care
- Care under Fire
- Tactical Field Care
- Casualty Evacuation (CASEVAC) Care

TCCC Principles 1996
- Combine good tactics and good medicine
- 3 Phases of TCCC
- Tourniquets
- Battlefield antibiotics
- Tactically appropriate fluid resuscitation
- Improved battlefield analgesia
- Nasopharyngeal airways
- Surgical airways for maxillofacial trauma
- Aggressive needle thoracostomy
- Combat medic input to guidelines
- Scenario-based training
TCCC Changes 2003

- **HemCon dressings**
- Hextend instead of Hespan
- Casualty continues as combatant
- Disarm casualties with altered sensorium
- Fluid resuscitation if no radial pulse or unconscious
- Combat pill pack
- Intraosseous access if IV difficult
- PO fluids OK in combat casualties
- Blood products on helos

TCCC Changes 2006 6th Edition PHTLS

- Hypothermia prevention techniques
- Fentanyl 400ug lozenges as alternative for battlefield analgesia
- Meloxicam 15 mg instead of Vioxx
- Management of wounded hostile combatants
- Tourniquet removal guidelines
- Ertapenem as alternate antibiotic
- QuikClot as backup hemostatic agent
- Medic pulse oximetry guidelines
- Blood product transfusion guidelines
HemCon
Wedmore J Trauma 2006
• 64 uses of HemCon in combat casualties
• 97% resulted in cessation of bleeding or improvement of hemostasis
• 66% followed treatment failure with standard gauze dressings
• Most important in sites not anatomically amenable to tourniquet

Combat Application Tourniquet
6515-01-521-7976

Windlass
Omni Tape Band
Windlass Strap
Tourniquet Study

- 232 patients
- 309 limbs
- 428 tourniquets

• Iraq Theater Protocol 06-010
• 19 Mar 06 to 4 Oct 06
• Ibn Sina Hospital, Baghdad

<table>
<thead>
<tr>
<th>Body Region</th>
<th>Patients</th>
<th>Limbs</th>
<th>Tourniquets</th>
<th>Effective (N)</th>
<th>Effective (%)</th>
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</thead>
<tbody>
<tr>
<td>Forearm</td>
<td>9</td>
<td>9</td>
<td>13</td>
<td>12</td>
<td>92</td>
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<tr>
<td>Arm</td>
<td>62</td>
<td>71</td>
<td>97</td>
<td>79</td>
<td>81</td>
</tr>
<tr>
<td>Leg</td>
<td>22</td>
<td>27</td>
<td>32</td>
<td>32</td>
<td>100</td>
</tr>
<tr>
<td>Thigh</td>
<td>162</td>
<td>205</td>
<td>285</td>
<td>203</td>
<td>71</td>
</tr>
</tbody>
</table>

Mortality

- 31 patients died in the study group
  - Crude, all-cause mortality was 13% (31/232)
- Early v. late application of tourniquet
  - 10% v. 90% (21/222 v. 9/10)
  - Late use had higher mortality
- Prehospital v. hospital application
  - 11% v. 26% (21/193 v. 10/39)
  - Hospital use had higher mortality
- Apply tourniquet(s) as soon as indicated
  - Before extrication and transportation
Tourniquet Complication and Effectiveness Rates

- CAT
- EMT
- SOF
- All Others

Complication and Effectiveness Rates

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- **QuikClot as backup hemostatic agent**
- Medic pulse oximetry guidelines
- Blood product transfusion guidelines
TCCC 2006
Extremity Hemorrhage

- Care Under Fire
  - Tourniquet if possible
  - HemCon for sites not amenable to tourniquet

- Tactical Field Care
  - Discontinue tourniquets when able to control bleeding by other means
  - Direct pressure
  - HemCon
  - QuikClot

Filling in the Gaps:
Proposed Updates to the Tactical Combat Casualty Care Guidelines

Defense Health Board Meeting
August 8, 2011
Preventable Deaths

Study data has historically shown that 15 to 25 percent of combat deaths in Iraq and Afghanistan resulted from potentially survivable injuries.

Over 80 percent are due to hemorrhage.

Of those, 70 percent had nontourniquetable or noncompressible wounds.


Preventable Deaths (cont’d.)

Table 4 Causes of Death Among Potentially Survivable Casualties

<table>
<thead>
<tr>
<th>Cause of Death*</th>
<th>Group 1 (n = 93)</th>
<th>Group 2 (n = 138)</th>
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<tbody>
<tr>
<td></td>
<td>(% Total of PS)</td>
<td>(% Total of PS)</td>
</tr>
<tr>
<td>CNS</td>
<td>12 (13)</td>
<td>8 (6)</td>
</tr>
<tr>
<td>Head</td>
<td>11 (12)</td>
<td>6 (4) (p &lt; 0.04)</td>
</tr>
<tr>
<td>Neck</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Spinal cord</td>
<td>1 (1)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>81 (87)</td>
<td>116 (83)</td>
</tr>
<tr>
<td>Tourniquetable (ext)</td>
<td>31 (33)</td>
<td>46 (33)</td>
</tr>
<tr>
<td>Noncompressible (torso)</td>
<td>47 (51)</td>
<td>68 (49)</td>
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<tr>
<td>Nontourniquetable (ax/neck/groin)</td>
<td>19 (20)</td>
<td>29 (21)</td>
</tr>
<tr>
<td>Airway</td>
<td>14 (15)</td>
<td>14 (10)</td>
</tr>
<tr>
<td>Septis/MSOF</td>
<td>2 (2)</td>
<td>9 (6)</td>
</tr>
<tr>
<td>Total causes of death identified</td>
<td>219</td>
<td>299</td>
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</tbody>
</table>

* Casualties could have 1 or more cause of death. MSOF indicates multisystem organ failure.

Source: Kelly et al, J Trauma, 2008
Recent Findings

Preliminary findings of an ongoing analysis of the causes of death in U.S. fatalities from Iraq and Afghanistan indicate that among those Killed in Action (KIA), the most common cause of death is junctional hemorrhage.

-COL Brian Eastridge, M.D., Trauma Consultant, U.S. Army Surgeon General, August 3, 2011

Junctional (truncal) Hemorrhage

Junctional/truncal=
- Groin proximal to inguinal ligament
- Buttocks
- Gluteal and pelvic areas
- Perineum
- Axilla and shoulder girdle
- Base of the neck

terminology as established by Kraugh/Walters/Baer. Et al, J Trauma 2008 / Ann Surg 2009
Recent Injury Patterns

• Recently, the incidence of dismounted complex blast injury (DCBI) has increased significantly

• Dr. John Holcomb’s presentation to the DHB, March 2011

• U.S. Army Surgeon General appointed Task Force on DCBI

Recent Injury Patterns (Cont’d.)

• Urogenital injuries

• Multiple amputations

• High, extremely proximal amputations that are not amenable to traditional tourniquet application
Recent Injury Patterns (Cont’d.)

Single and Multiple Limb Amputations
Sep 2010 – Dec 2010

- 200% increase in double amputation rate

Recent Injury Patterns (Cont’d.)

Percent of LRMC Trauma Admissions with GU Injuries 2009-2010

- 4% over first 17 months
- 11% over last 7 months
- a 175% increase
DHB RDT&E Recommendation
Memorandum, June 14, 2011

• The DHB called for further study of hemorrhage control mechanisms, particularly non-compressible hemorrhage

• Specifically, the memo stated:
  • Follow-up studies should be conducted to determine the benefits and risks of using tranexamic acid for trauma patients with non-compressible hemorrhage.

  • Studies documenting the efficacy of truncal tourniquets as well as the ability of users to apply it effectively are needed. Case series describing outcomes from using this device in pre-hospital trauma management would also be useful.

In the Interim…

There is a substantial gap in Tactical Combat Casualty Care that will result in further fatalities due to exsanguination on the battlefield.

We now have options to address this gap.
Treatment Options for Non-Compressible & Junctional Hemorrhage

- Combat Gauze™ is the only TCCC-endorsed tool for treating non-compressible hemorrhage

- Studies suggest that it is safe and efficacious

- However, fatality data suggest that it is unable to stop all significant hemorrhages

Particularly given recent DCBI patterns, medics need an alternative/additional option

Proposed Solutions

- Mechanical pressure devices to control hemorrhage (i.e. Combat Ready Clamp™)

- Use of an Antifibrinolytic, Tranexamic Acid, to reduce bleeding by preventing activation of anti-clotting factor
Junctional Hemorrhage Control

MSG Montgomery
August 8, 2011

Hemorrhage- A Look Back: Mogadishu, 1993

- CPL Jamie Smith injury – exsanguination from groin injury too proximal for a tourniquet.
- An injury pattern we have since been attempting to solve for TCCC
Recent Injury Examples

-In excerpt of a health care record of a case submitted by COL Kragh

Preventable Death

“In 6 months there were over 1000 IEDs found in the Sangin area by 3/5 Marines. Additionally, 3/5 Marines suffered over 200 casualties and 29 KIA in the same time. Many of these Marines had severe amputations that may have benefitted from proximal hemorrhage control.”

Keith S. Gates, M.D.
LT (FMF/DV/FPJ), MC, USNR
Assistant Battalion Surgeon
1/23 Marines (FWD)
FOB Delaram, Afghanistan
Requirement

• USAMRMC posted request for information for device ideas that could potentially stop bleeding at compressible sites where regular tourniquets cannot be applied.
  – W81XWH-RFI-003, 03 MAR 2009

1) Will be able to occlude deep bleeding from intracavitary hemorrhage, including parenchymal injuries. As a minimum, the device should stop bleeding at compressible sites where standard tourniquets cannot be applied;
2) Can be applied easily in a tactical environment with a minimum level of familiarization;
3) Must not slip during tightening or following application;
4) Be capable of easy release and re-application;
5) Be of light weight;
6) Have long shelf life, low cost and low cube.

Key Premise

If we are going to ask a medic or corpsman to perform a medical intervention on the battlefield, we want to be very confident that it will benefit the casualty.

Anything we ask a medic or corpsman to perform must be have a training and equipping solution that is relatively easy to implement.
Combat Ready Clamp
FDA Approved Target Application Points

• INGUINAL: Direct pressure over packed inguinal injury site.
• PELVIC: Pressure point midway between anterior superior iliac spine and pubic tubercle (occludes external iliac artery).
  – Recommend using pubic symphysis instead of tubercle.

Current Fielding & Use

• SOF
  – U.S. Army Special Missions Unit (SMU)
  – 75th Ranger Regiment
  – U.S. Navy SMU

• Memorial Hermann Hospital Life Flight, Houston, TX
Equipping & Carrying

- Medic/Corpsman carried device
- Aidbag-based
  - Partially broken-down
  - 1.5 lbs

Testing Conducted

- Massive bleeding (perfused) models in fresh human cadavers at Wake Forest University School of Medicine

- Publication Pending: *Emergency Inguinal Clamp Controls Prehospital Hemorrhage in Cadaver Model*, Kragh, et al
Potential Issues

- Stabilization during transport
- Device Impact with Pelvic Fracture
- Clinical decision-making on the right time and place to apply device
  - NOT exclusive to this device!!!!
  - Applies to virtually ALL TCCC concepts.

Bottom Line

- FDA approved
- Currently fielded
- No other options to meet current need
Bleeding Control
Tactical Field Care - Current

4. Bleeding

a. Assess for unrecognized hemorrhage and control all sources of bleeding. If not already done, use a CoTCCC-recommended tourniquet to control life-threatening external hemorrhage that is anatomically amenable to tourniquet application or for any traumatic amputation. Apply directly to the skin 2-3 inches above wound.

b. For compressible hemorrhage not amenable to tourniquet use or as an adjunct to tourniquet removal (if evacuation time is anticipated to be longer than two hours), use Combat Gauze as the hemostatic agent of choice. Combat Gauze should be applied with at least 3 minutes of direct pressure. Before releasing any tourniquet on a casualty who has been resuscitated for hemorrhagic shock, ensure a positive response to resuscitation efforts (i.e., a peripheral pulse normal in character and normal mentation if there is no traumatic brain injury (TBI)).

c. Reassess prior tourniquet application. Expose wound and determine if tourniquet is needed. If so, move tourniquet from over uniform and…

Bleeding Control
Tactical Field Care - Proposed

4. Bleeding

(keep 4a. as is)

b. For compressible hemorrhage not amenable to tourniquet use... a casualty who has been resuscitated for hemorrhagic shock, ensure a positive response to resuscitation efforts (i.e., a peripheral pulse normal in character and normal mentation if there is no traumatic brain injury (TBI)).

If a lower extremity wound is not amenable to tourniquet application and cannot be controlled by hemostatics/dressings, consider immediate application of mechanical direct pressure including CoTCCC recommended devices such as the Combat Ready Clamp™ (CROc).
Proposed Addition to TCCC Guidelines:

Tranexamic Acid

Review of Evidence

- **CRASH-2 Study:**
  - Large prospective RCT of TXA use in trauma patients
  - Concluded: TXA reduces mortality in trauma patients
  - CoTCCC and JTTS Directors reviewed thoroughly and were not convinced that this was enough evidence to field TXA.
  - Cochrane Review, 2011, concluded that TXA is inexpensive and easy to administer; should be added to normal management of hemorrhaging trauma patients worldwide.

- **MATTERS Study:**
  - Retrospective study analyzing U.K. experience with TXA in Afghanistan
  - Patients admitted to Bastion (busiest MTF in theater)
  - 28-Day mortality was significantly lower in group administered TXA, overall, and in a subset of patients that were massively transfused
Tranexamic Acid: Clinical Randomization of an Antifibrinolytic in Significant Hemorrhage-2 Consortium (CRASH-2) Trial

- The randomized, double-blind, placebo-controlled trial, which was conducted in 40 countries, randomized 20,211 adult trauma patients at high risk for significant bleeding to tranexamic acid or placebo within eight hours of injury.
- Tranexamic acid was given at a loading dose of 1 g over 10 minutes and then an infusion of 1 g over eight hours.
- Treatment with tranexamic acid reduced the risk of fatal bleeding events by 15% compared with placebo.

CRASH-2 Study

*Lancet, Online Article, 2010*

Effects of tranexamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo-controlled trial

- Prospective, randomized controlled trial
- 20,211 patients
- TXA significantly reduced all cause mortality from 16.0% to 14.5%
- TXA significantly reduced death due to bleeding from 5.7% to 4.9%

The importance of early treatment with tranexamic acid in bleeding trauma patients: an exploratory analysis of the CRASH-2 randomised controlled trial

- Subgroup analysis of 20,211 trauma patients based on time of administration of TXA
- Timing; only deaths due to bleeding
- 3076 overall deaths; 1063 due to bleeding
- Risk of death due to bleeding was significantly reduced (5.3% vs 7.7%) if TXA given within 1 hour of injury. At 1-3 hrs after injury, also significant (4.8 vs 6.1%)

The MATTERS Study

Retrospective Study Analysing UK Experience of TXA in CCC

MATTERS Inclusion Criteria

- Combat Injury
- Admitted to Bastion
- Jan 09 to Dec 10 inclusive
- Received ≥ 1 unit PRBC

**End Points**

- Mortality (<24 hr and 28-day)
- Blood product use within 24 hrs of wounding
- (Coagulation, arterial and venous thrombosis)

Team Aerospace Begins Here!
Patients

- MERT Retrieval
  - n = 411
  - (PHB = 182)
- FOB Dwyer
  - n = 8
- Other
  - n = 477

Point of Wounding

- Bastion
  - n = 896

TXA
- n = 293
- MT n = 125
- Mean dose: 2.3g ± 1.3

No-TXA
- n = 603
- MT n = 196

Mortality Analysis

<table>
<thead>
<tr>
<th>Overall</th>
<th>TXA</th>
<th>No-TXA</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 24 Hr</td>
<td>8.2%</td>
<td>8.5%</td>
<td>0.892</td>
</tr>
<tr>
<td>28 Day</td>
<td>16.4%</td>
<td>23.2%</td>
<td>0.018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MT</th>
<th>TXA</th>
<th>No-TXA</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;24 Hr</td>
<td>8.8%</td>
<td>9.2%</td>
<td>0.907</td>
</tr>
<tr>
<td>28 Day</td>
<td>13.6%</td>
<td>27.6%</td>
<td>0.003</td>
</tr>
</tbody>
</table>
Conclusions

- Tranexamic acid is the only drug to have a demonstrated benefit in treating significant trauma induced hemorrhage.
- Timing of administration appears to be critical in trauma.
- Use only within 3 hours of injury; earlier is better.
- Overall safety profile is very reassuring.
- Only available dosing guidance provided by CRASH-2 (1gm load over 10 minutes, then 1gm over 8 hours).
- Bastion experience includes 1 gm dose intravenous push followed by 1 to 2 additional grams within the next few hours.

Proposed Changes

Tactical Field Care and Tactical Evacuation Care sections:
(Add in both sections before Intravenous Fluids section)

- If a casualty is anticipated to need significant blood transfusion (for example: presents with hemorrhagic shock, one or more major amputations, penetrating torso trauma, or evidence of severe bleeding)
  - Administer 1 gram of tranexamic acid in 100 cc in Normal Saline or Lactated Ringer’s as soon as possible but not later than 3 hours after injury.
  - Begin second infusion of 1 gm TXA after Hextend or other fluid treatment.
Proposed Recommendation

• That the Board approve the proposed addition to the TCCC Guidelines
• That the Board note in its recommendation memorandum that ongoing analysis of the use of TXA in theater be a critical element in Performance Improvement Measures by the Services

Pre-Hospital Thawed Plasma: A Preliminary Report

Smoot DL, Park MS, Berns KS, Osborn JB,
Jenkins DH, Zietlow SP
Mayo Clinic Rochester, MN
Presented Feb 2011 WTA
COL Hachey, Dr. Butler, and Dr. Jenkins: I thought that perhaps the DHB should include something along these lines in the memo---this is my attempt to capture COL Blackbourne's comment noted on COL Dorlac's last slide in his presentation that ongoing monitoring of TXA use and outcomes be a part of QA/improvement measures. Please edit and/or remove as necessary.

Hillary Peabody, 8/4/2011
Background

Plasma first used on military transports in 2001 (fixed wing)

*but*...

To date, no civilian program has described in the literature using thawed plasma on rotary medical transport.

Our Rationale

- Current evidence supports increased ratio of plasma:PRBC and early use of plasma in trauma
- Packed Red Blood Cells (PRBCs) and plasma are optimal resuscitative fluids for patients with serious hemorrhage and/or impairment of coagulation
- Emergency use of Fresh Frozen Plasma is limited by time to thaw (15-30 minutes)
Protocol – ED Phase

- Developed in Feb 2008 with input from:
  - Division of Transfusion Medicine
  - Division of Medical Transport
  - Division of Trauma, Critical Care and General Surgery
- Initial 12 months were restricted to in-hospital Emergency Department use
- Medical and Surgical emergencies
  - Safety concerns
  - Utilization of resources

- Product immediately available in the Trauma Resuscitation Area:
  - 4 units thawed plasma (A+)
  - 4 units PRBCs (0 negative)
• Order of transfusion for trauma patients was:
  • 2 units PRBC
  • 2 units thawed Plasma
  • 2 units PRBC
  • 2 units thawed Plasma

Protocol – Helicopter Phase

**Indications for PRBC and Plasma administration in adult trauma patients**

<table>
<thead>
<tr>
<th>pRBC + Plasma</th>
<th>Plasma Alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hypotension (single reading of systolic blood pressure ≤ 90mmHg)</td>
<td>1. Point of care INR ≥ 1.5</td>
</tr>
<tr>
<td>2. Tachycardia (single reading of heart rate ≥ 120)</td>
<td>2. Stable Hemodynamics</td>
</tr>
<tr>
<td>3. Penetrating mechanism</td>
<td></td>
</tr>
<tr>
<td>4. Point of care lactate ≥ 5.0 mg/dl</td>
<td></td>
</tr>
<tr>
<td>5. Point of care INR ≥ 1.5</td>
<td></td>
</tr>
</tbody>
</table>
• On board product availability
  - 4 units PRBC (0 negative)
  - 2 units thawed plasma (A+)
• Order of Transfusion
  - 2 units PRBC
  - 2 units thawed plasma
  - 2 units PRBC
Waste Prevention

Division of Transfusion Medicine monitors usage

- Thawed plasma is removed from the satellite blood refrigerator on Day #3 and sent to the Operating Theater for immediate use.

RESULTS

10 TRAUMA PATIENTS TRANSFUSED IN FLIGHT 2/2009 – 9/2010

• 5 for hemorrhage
  • 3 required massive transfusion (> 10 units/24 hours)
• 5 pts transfused for history of trauma and coumadin use
  • All 4 deaths were in this group
• All pts entered into protocol required ongoing blood product transfusion after arrival to the hospital.
### Trauma Patients (n=10)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>71.5 [30-75.3]</td>
</tr>
<tr>
<td>Male</td>
<td>8/10</td>
</tr>
<tr>
<td>ISS</td>
<td>25.5 [16.8-29.3]</td>
</tr>
<tr>
<td>LOS (days)</td>
<td>4.5 [1.8-24.8]</td>
</tr>
<tr>
<td>Mortality</td>
<td>4/10</td>
</tr>
</tbody>
</table>

### Admission Laboratory Values

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coumadin</td>
<td>5/10 (50%)</td>
</tr>
<tr>
<td>Lactate</td>
<td>2.8 [1.7-5.7]</td>
</tr>
<tr>
<td>Base</td>
<td>-4.1 [-12.5- -0.5]</td>
</tr>
<tr>
<td>PLT</td>
<td>149 [114-180]</td>
</tr>
<tr>
<td>PTT</td>
<td>30 [28-42]</td>
</tr>
<tr>
<td>HgB</td>
<td>10.8 [10.1-13.5]</td>
</tr>
<tr>
<td>Post-Flight INR</td>
<td>1.6 [1.3-2.8]</td>
</tr>
<tr>
<td>Pre-Flight INR</td>
<td>2.7 [1.6 – 4.0]</td>
</tr>
</tbody>
</table>


Feasibility

- Excellent utilization
  - No discarded units of plasma to date
- No transfusion reactions documented to date; use of product parallels massive transfusion in the standard setting

Protocol Evolution

- During the study period, total of 771 flights
  - Only two pts received all 4 units of PRBC during transport
- Product Order and Ratio
  - 2009: 2 PRBC, 2 Plasma, 2 PRBC
  - 2010: 2 Plasma, 2 PRBC, 2 PRBC
  - 2011: 3 Plasma, 3 PRBC
CONCLUSION

• We successfully implemented pre-hospital thawed plasma use into our rural Level-I trauma system
• Initial results (e.g. feasibility, INR reduction), while not conclusive, are promising
• Feasibility studies now underway to see if the protocol can be expanded to other transports in our system

Hemostatic Resuscitation in Our Trauma Center

• Pre-hospital plasma and POC testing
• Early Diagnosis in ED
• 1:1 ratio (thawed plasma to RBC)
  • Plasma-first transfusion sequence
  • ED use of rFVIIa or PCC?
• Frequent TEG and early platelet use
• Minimal crystalloid
• Repeated doses of PCC in OR and ICU as required by TEG
Summary

- Trauma patients die from shock
- Our job is to limit preventable trauma death
Background

• Hemorrhage is the leading cause of potentially preventable death in combat
• Coagulopathy increases the risk of hemorrhagic death
• Crystalloids and colloids dilute existing clotting factors in the blood
• Plasma replaces clotting factors lost through hemorrhage. PRBCs do not. Crystalloids do not.

Background

• One of the dramatic advances in the care of the trauma patient realized from the U.S. experience in Afghanistan has been the use of higher ratios of plasma to red blood cells in casualties requiring massive transfusions.
• This increased emphasis on in-hospital plasma is now the standard of care for the military and is rapidly being adopted by the civilian sector.
Prehospital Plasma

- Liquid plasma not an option for ground troops
- Dried plasma (freeze-dried or spray-dried) is currently the best option for units not able to utilize liquid plasma
- Dried plasma contain approximately the same levels of clotting proteins as liquid plasma
- French, German, British militaries are using freeze-dried plasma at present
- Outcomes data pending
- No FDA-approved dried plasma product at present

FDA-Approved Dried Plasma Product

- None at present
- HemCon freeze-dried product in development
- Entegrion spray-dried product in development
- Velico spray-dried product in development
- Arrival of an FDA-approved dried plasma product is not imminent – ETA 2015
- A solution is needed now
- Think beyond Afghanistan - especially for SOF and other early entry forces in the next conflict
Prothrombin Complex Concentrates

- PCCs are human derived clotting factors
- *Bebulin VH* (Vapor Heated) is one of several PCCs available in the U.S. (Westlake Village, CA: Baxter)

PCC versus Plasma

- German animal study using Beriplex
- Hemodilution and hypothermia followed by injury to spleen or femur
- Administered 25 IU/kg PCC versus 15 cc/kg plasma
- Prolonged PT and decreased thrombin generation effects reversed by PCC but not by plasma

*Br J Anesth* 2009: 102: 345-54 Dickneit and Pragst
Beriplex in Surgery

- Coumadin reversal (n=12) versus coagulopathic bleeding (n=38)
- Coumadin reversal seen with 1500 IU
- Hemorrhage reversal seen with 2000 IU with cessation of bleeding in 96%


Properties of Bebulin

- Bebulin is a purified concentrate of the coagulation Factors IX (Christmas Factor) as well as II (Prothrombin) and X (Stuart-Prower Factor)
- In addition, there are small amounts of Factor VII and heparin (0.15 IU per IU Factor IX)
  - The amount of heparin is miniscule, sufficient only to balance the potential thrombogenic effect of acute drops in serum levels of protein S (ie. similar to early warfarin therapy)
- Bebulin VH is standardized by the Factor IX content in each vial and is labeled accordingly
- One International Unit of Factor IX corresponds to the activity of Factor IX in one millimeter of fresh normal human plasma.
Bebulin Clinical Effects

- Half-life is 24 to 32 hours (Factor VII: 3 to 6 hours)
- Onset: 10-30 minutes
- Rebound INR after 12 to 24 hours without vitamin K

---

**Warfarin, dosing based on INR: Exsanguinating hemorrhage requiring massive transfusion**

<table>
<thead>
<tr>
<th>INR</th>
<th>Bebulin Dose in International Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 4.0</td>
<td>50 x wt (kg)</td>
</tr>
<tr>
<td>3.5 – 4.0</td>
<td>45 x wt</td>
</tr>
<tr>
<td>2.9 – 3.5</td>
<td>40 x wt</td>
</tr>
<tr>
<td>2.3 – 2.8</td>
<td>35 x wt</td>
</tr>
<tr>
<td>1.8 – 2.2</td>
<td>30 x wt</td>
</tr>
</tbody>
</table>
Current Definitions of Clinical Rates

- \( \%CFR = \frac{KIA + DOW}{KIA + WIA} \times 100\% \)
  
Case Fatality Rate  

- \( \%KIA = \frac{Deaths \ before \ MTF}{KIA + (WIA – RTD)} \times 100\% \)
  
Killed in Action  

- \( \%DOW = \frac{Died \ after \ reaching \ MTF}{(WIA – RTD)} \times 100\% \)
  
Died of Wounds  

Comparison of Statistics for Battle Casualties, 1941-2005

<table>
<thead>
<tr>
<th></th>
<th>World War II</th>
<th>Vietnam War</th>
<th>Iraq &amp; Afghanistan</th>
</tr>
</thead>
<tbody>
<tr>
<td>%KIA</td>
<td>23.7%</td>
<td>21.3%</td>
<td>12.5%</td>
</tr>
<tr>
<td>%DOW</td>
<td>3.4%</td>
<td>3.5%</td>
<td>4.1%</td>
</tr>
<tr>
<td>%CFR</td>
<td>22.8%</td>
<td>16.5%</td>
<td>8.8%</td>
</tr>
</tbody>
</table>
Combat Casualty Statistics OIF/OEF

OIF Cumulative Monthly Avg CFR%, DOW%, KIA% and ISS
Jan 2004 - Feb 2008

Cum Avg ISS

Cum KIA %

Cum DOW %

Cum Avg ISS

Month and Year

Data Source: Defense Manpower Data Center Statistical Analysis Division, OSD, JTTR v3.0

U.S. Military Battle Injured Observed vs. Expected
Monthly Death Rate Jan – Dec 2007

Comparison of Observed vs. Expected Deaths
U.S. Military Battle Injuries, January - December 2007
MAJ John P. Pryor, 42
MooRESTOWN NJ KILLED 25 DEC 2008