DEFENSE HEALTH BOARD
FIVE SKYLINE PLACE, SUITE 810
5111 LEESBURG PIKE
FALLS CHURCH, VA 22041-3206

JUN 14 2011

FOR: JONATHAN WOODSON, M.D., ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Battlefield Trauma Care Research, Development, Test and Evaluation Priorities 2011-01

BACKGROUND

1. Tactical Combat Casualty Care (TCCC) is a set of trauma care guidelines customized for use on the battlefield. TCCC is currently used in training for medics by all Services in the Department of Defense and by many U.S. coalition partners.

2. The Committee on Tactical Combat Casualty Care (CoTCCC), a working group of the Defense Health Board (DHB) Trauma and Injury Subcommittee, performs a quarterly review of current evidence demonstrating the successes and shortcomings of the TCCC Guidelines, and considers proposed updates and revisions.

   a. An urgent need to improve the evidence base for trauma care has been reported in the literature. Due to the lack of opportunities to perform randomized controlled trials on the battlefield, challenges arise in maintaining these best practice guidelines for the combat environment.

   b. The CoTCCC makes the best possible use of available evidence and defines targeted studies to help fill critical knowledge gaps.

3. During its meeting held in November 2010, the CoTCCC recommended a list of research, development, testing, and evaluation (RDT&E) priorities, subsequently endorsed by the Trauma and Injury Subcommittee during its November 2010 meeting.

4. The Board reviewed the findings and proposed RDT&E priorities recommended by the Trauma and Injury Subcommittee, and approved them by unanimous vote on March 8, 2011.

FINDINGS

Non-Compressible Hemorrhage Control – Follow-Up Tranexamic Acid Studies

5. Hemorrhagic shock is the leading cause of potentially preventable death resulting from trauma in the U.S. military population. Approximately 15 to 20 percent of traumatic deaths within the U.S. military are preventable; of these, 66 to 80 percent occur from hemorrhage.

6. Systemic antifibrinolytic agents are used to mitigate blood loss and the need for transfusion or re-operation due to continued or recurrent hemorrhage. In efforts to identify optimal

methods of achieving timely control of non-compressible hemorrhage and mitigating trauma-induced coagulopathy, the comparative performance of antifibrinolytic agents has been examined.

a. The findings of the Clinical Randomization of Antifibrinolytic in Significant Hemorrhage (CRASH-2) were published in July 2010. CRASH-2 was a large international randomized placebo-controlled trial that examined traumatic hemorrhage with a focus on the effects of the early administration of tranexamic acid on death, vascular occlusive events, and blood transfusion requirements in trauma patients with significant hemorrhage. Trauma patients who received tranexamic acid demonstrated a significant decrease in mortality without any increase in venous occlusive events either accompanied by or at risk of significant bleeding

b. However, critical research questions remain, particularly for patients without a diagnosed hyperfibrinolytic state. Additional focused research is needed that includes clotting parameter measurements and better adverse events reporting.

7. The use of procoagulants such as factor VIIa has been controversial, with the lifesaving benefit of enhanced hemostasis weighed against the potential for increased venous occlusive events.

8. Tranexamic acid is a low-cost, FDA-approved agent.

9. The potential benefit and optimal use of tranexamic acid are not yet completely defined. Recently, a CRASH-2 sub-group analysis found that tranexamic acid produced the greatest decrease in mortality when administered within one hour, a less pronounced benefit when administered between one and three hours, and an increase in mortality when administered after three hours.

Tactical Damage Control/Hypotensive Resuscitation Studies

- *German Freeze-Dried Plasma Experience*
- *Prospective Study Using Food and Drug Administration-Approved Plasma Alone for Prehospital Resuscitation Fluid in Patients with Non-Compressible Hemorrhage*
- *Medical Emergency Response Team 1:1 Packed Red Blood Cells:Plasma Experience*

10. Current TCCC Guidelines recommend the use of a 1:1 ratio of plasma and packed red blood cells (pRBCs) for fluid resuscitation during Tactical Evacuation (TACEVAC) Care.

a. The British Medical Emergency Response Team (MERT) routinely administers PRBCs and plasma in a 1:1 ratio during TACEVAC. However, comparative analyses have not been conducted regarding outcomes from the MERT experience outcomes using Hextend® alone during evacuation.

b. The administration of blood products during Tactical Field Care and TACEVAC by pre-hospital personnel entails significant training and logistical costs.

11. Freeze dried plasma (FDP) was identified at the January 8-9, 2011 U.S. Army Institute of Surgical Research (USAISR)-Medical Research and Materiel Command (MRMC) Fluid Resuscitation Conference as the most promising agent for damage control resuscitation under circumstances in which FDA-approved blood products are unavailable, such as when Special Operations Forces (SOF) medics provide casualty care in very remote locations where evacuation may be delayed for several hours or days. FDP was encouraged as a top research priority among the subject matter experts at this conference.

    a. United States Special Operations Command (USSOCOM) is considering options to obtain a FDP product for use by medics in theater. The use of pooled plasma has been discontinued in the United States due to risk of infection.

    b. Although its use is appropriate on TACEVAC platforms, thawed fresh frozen plasma is not suited for inclusion for medic equipment on the battlefield.

    c. German military forces have been using FDP alone for pre-hospital fluid resuscitation in patients with non-compressible hemorrhage. Deutsches Rotes Kreuz Blutspendedienst West manufactures an FDP (LyoPlas N) that is blood typed; type "AB" can be administered if the recipient's blood type is unknown. Donors are re-tested at four months for human immunodeficiency virus, syphilis, hepatitis B and C, and parvovirus. This product costs $100.00 per unit and must be buffered before administered.

        i) Published data are currently unavailable that would document the efficacy and safety of LyoPlas in the pre-hospital trauma setting.

        ii) Attempts at establishing an investigational new drug (IND) status for further research have been hindered since the manufacturer's announcement of intending not to seek FDA approval.

    d. A non-FDA approved, universally compatible, buffered, leukocyte reduced FDP product is used by French military forces. The units are prepared from a pool of 10 donors who are re-tested for infection before the product is released. The cost of this product is approximately $800.00 per unit.

        i) The French manufacturer has expressed interest in offering this product for sale in the United States.

    e. HemCon Medical Technologies, Incorporated is currently developing an FDP product for FDA approval; however, it is still in Phase 1 of clinical trials. This product is currently anticipated to be ready for fielding in 2015.

    f. It is important to note that the consideration of this issue should not be limited to the Iraq and Afghanistan Areas of Operation.

    g. An important step in defining the potential benefit of FDP is to evaluate the benefits of plasma without accompanying PRBCs. Thus, there is a significant need for a high-

priority prospective study to be initiated in United States. Emergency Medical Service (EMS) systems use FDA-approved plasma alone as the sole pre-hospital resuscitation fluid for patients with non-compressible hemorrhage and/or hemorrhagic shock.

i) In order to better translate the findings of this study to the military setting, the study should preferably be done in EMS systems that have relatively long pre-hospital evacuation times. The pre-hospital resuscitation fluid choice may be less likely to alter outcomes in patients with only a 10 or 15-minute transport time to the hospital.

Improved Battlefield Analgesia – Ketamine

12. Oral transmucosal fentanyl (OTFC) is very effective in treating pain from combat trauma in theater; however, its use is currently limited, partly due to the FDA warning restricting its indication for use to opioid-tolerant cancer patients.

    a. However, the FDA Black Box warning is not well supported by the published literature for the TCCC-recommended dose of 800 mcg. In addition, the FDA warning refers to prescribing information, not to the supervised administration of OTFC by a trained combat medic.

    b. The military experience documented to date has shown OTFC to be safe and effective in relieving pain on the battlefield.

    c. Notwithstanding, there are casualties who do not respond well to the recommended dose of OTFC.

    d. Additionally, all opioids carry the known risk of cardiopulmonary depression.

13. Ketamine has been used in combat medicine as a pre-hospital analgesic for trauma patients, not only due to its effectiveness, but also its stable hemodynamic profile and lack of causing respiratory depression.

    a. However, central nervous system side effects and recent studies demonstrating the adverse effects of ketamine on intracranial pressure and cerebral blood flow, contributed to recommendation against its use for patients with brain injury. However, the alternative opioid analgesics may also cause respiratory depression, hypoxia, and worsening of TBI.

    b. As noted above, whereas narcotic analgesics such as OTFC could cause cardiorespiratory depression, ketamine could also lead to emergence dysphoria.

    c. Additional data are needed regarding the benefits and risks of using ketamine for pre-hospital analgesia in trauma patients to include the experience of MERT with this agent.

Pre-Hospital Care Documentation and Databasing

14. At present, the documentation of in-theater pre-hospital trauma care is inconsistent and incomplete, and is often not transferred to either unit-based pre-hospital trauma registries (such as that pioneered by the 75th Ranger Regiment) or to a trauma system registry (such as the Joint Theater Trauma Registry (JTTR)).

Enhanced Electronic TCCC Training

15. TCCC-specific training is critical for those who provide in-theater care for Service members.

16. Since TCCC Guidelines are updated frequently, periodic TCCC training is required to ensure that providers are equipped with the most recent evidence-based best practices.

17. Enhanced methods are currently lacking for the transfer of combat trauma management skills to deploying personnel, as well as for ensuring that trauma management informatics are available to deployed medical personnel whenever and wherever they need it.

Truncal Tourniquet

18. Combat trauma that causes hemorrhage in junctional areas (groin and axilla) may be difficult to control with tourniquets and Combat Gauze™.

19. In August 2010, the FDA approved a prototype truncal tourniquet, the Combat Ready Clamp™, designed to assist in controlling external junctional hemorrhage within the tactical environment. The current price is $300.00 per unit. Although well-designed to minimize weight and cube space requirements for the medic, data are lacking that document the efficacy of this device in eliminating distal pulses on extremities, the ability of users to apply it effectively, and the outcomes from its use in pre-hospital trauma management.

Use and Outcomes Data for Individual Elements of TCCC

20. Variability regarding in-theater compliance with existing TCCC Guidelines and pre-hospital trauma interventions have been observed and reported. For example, at the January 8-9, 2011 U.S. Army Institute of Surgical Research (USAISR)-Medical Research and Materiel Command (MRMC) Fluid Resuscitation Conference, multiple attendees indicated that Lactated Ringer's solution or normal saline is being used rather than Hextend® for the majority of in-theater large volume fluid resuscitation procedures.

    a. Studies such as those performed by Kragh on tourniquet use are essential in documenting the success or failure of recommended TCCC interventions and identifying areas for improvement.

    b. An observational TriService study is currently underway at USAISR that is examining pre-hospital trauma care interventions conducted in OPERATION IRAQI FREEDOM (OIF) and OPERATION ENDURING FREEDOM (OEF). The aim of the study is to

identify whether an indicated intervention was or was not carried out; if an intervention that was not indicated was provided; and, how well the intervention was performed. The results of this study will highlight potential areas for TCCC training improvement

Monitor-Driven Pre-Hospital Fluid Resuscitation

21. Existing pre-hospital fluid resuscitation techniques have the potential to be both harmful and beneficial; therefore, the data to support specific fluid resuscitation protocols need to be stronger. The results of several existing projects may result in a better definition of optimal volumes to be used in fluid resuscitation.

    a. An evaluation of benefits associated with using electronic physiological monitors to better identify trauma patients who require pre-hospital fluid resuscitation is currently underway at Memorial Hermann Hospital in Houston, Texas, the results of which would also assist in fluid volume titrations.

    b. A study is being conducted at USAISR in order to determine whether changes in arterial pulse wave character may foretell impending cardiovascular decompensation.

Comparison Testing of Celox™ Gauze, Combat Gauze™, and ChitoGauze™

22. Several new hemostatic agents/dressings have become available since Combat Gauze™ was introduced several years ago. Although there have been favorable reports from both pre-hospital and in-hospital use of Combat Gauze™, it would be useful to compare the new agents to Combat Gauze™ in the consensus bleeding model developed at USAISR to gain an understanding of their relative efficacy.

Comparison Testing of New Tourniquets

23. Since 2005, new tourniquets have been developed and existing ones modified. Although there have been favorable reports from both pre-hospital and in-hospital use of Combat-Application-Tourniquet® (C-A-T®), SOF® Tactical Tourniquet (SOF®TT), and pneumatic Emergency Medical Tourniquet (EMT), it would be useful to compare the new tourniquets to these currently-fielded devices.

    a. Kragh's studies of pre-hospital tourniquet use in OIF and OEF document its effectiveness in saving lives without causing preventable limb loss from tourniquet induced ischemia. Whether tourniquets should be used for massive hemorrhage control is no longer an issue; however, specific aspects of their use, such as identifying an optimal tourniquet for the battlefield environment, remain valid questions.

Surgical Airway Training Methods

24. Surgical airways have been shown in multiple case presentations at CoTCCC meetings and Joint Theater Trauma System (JTTS) Trauma Teleconferences to be the most technically difficult pre-hospital trauma skill to train and sustain.

25. Comparison studies of different training modalities used to teach this skill are needed. Live tissue training should be included in the training modalities evaluated. Proposed "gold standards" for skills mastery are the ability to successfully perform a surgical airway on a human cadaver and the time spent in accomplishing this task.

    a. Reports from both JTTS and Armed Forces Medical Examiner System (AFMES) have indicated multiple episodes of surgical airways being performed incorrectly.

    b. Following a review of cricothyroidotomy training methods used in the four-day TCCC course taught at Naval Medical Center Portsmouth, the following five training gaps were identified: 1) limited airway anatomy instruction; 2) lack of "hands-on" human laryngeal anatomy demonstration; 3) non-standardized technique for the surgical airway procedure; 4) inferior anatomic detail in the cricothyroid membrane region on mannequins used to teach the cricothyroidotomy procedure; and 5) lack of standardized refresher training frequency.

Clinicopathological Review of Every U.S. Combat Fatality in Iraq and Afghanistan

26. Current process improvement efforts in pre-hospital care suffer from a lack of comprehensive data regarding the incidence of potentially preventable fatalities on the battlefield and how they might have been prevented.

    a. The Armed Forces Medical Examiner performs autopsies on all U.S. Service members killed in theater. Information obtained from autopsy records for all fatalities in the current conflicts could assist in determining the causes of death and which deaths were potentially preventable.

    b. A study conducted by Holcomb examined the causes of death among SOF during the Global War on Terror (GWOT) between 2001 and 2004, while a similar study conducted by Kelly compared injury severity and causes of death during OIF and OEF from 2003 to 2004, with those during 2006.

        i) The findings of these studies demonstrate the potential for saving additional lives among our combat casualties through improvements in care; however, they only address a small fraction of the total fatalities sustained in the wars in Iraq and Afghanistan. The remaining fatalities have yet to be reviewed and examined for preventable deaths.

Optimal Management of Traumatic Brain Injury in TCCC

27. The incidence of traumatic brain injury (TBI) among combat casualties has increased dramatically in recent years. JTTR data indicate that 19 percent of patients had incurred a traumatic head injury. In addition, more patients are surviving injuries that include severe neurologic disabilities due to improvements in personal protective equipment (PPE) and trauma care.

28. The prevention of secondary brain injuries, and the presentation of complex combat-related injuries, including polytrauma, severe hemorrhage, and long evacuation times, present added complications to treating combat casualties with TBI.

    a. There may be opportunities to improve TBI outcomes beyond current TCCC practice to emphasize hypoxia and hypotension prevention among casualties who incur both polytrauma and TBI, (for example the aggressive management of trauma-related coagulopathy).

Impact of TACEVAC Provider Level and Skill Sets on Survival

29. The transport of patients with serious casualties from the point of injury (POI) to the first medical treatment facility (Tactical Evacuation Care) is a critical step in the continuum of care.

    a. Favorable combat casualty outcomes depend in part on the clinical skills and resources available for casualty management during TACEVAC. The complexities of providing in-flight care for polytrauma casualties are daunting and require a provider skilled in trauma management to achieve best outcomes.

    b. There are at least three models of evacuation platform staffing in use in the United States Central Command (USCENTCOM) Area of Operations at present: the MERT model, which includes an emergency medicine consultant; U.S. air ambulance platforms with flight paramedics; and, U.S. air ambulance platforms with 68 Whiskey (Emergency Medical Technician-Basic (EMT-B) enhanced flight medics.

    c. A recent study indicated a positive effect on survival when critical-care trained flight paramedics rather than EMT-B flight medics were present on evacuation aircraft.

    d. Determining the optimal model for TACEVAC platform staffing would require an analysis of casualty outcomes obtained to date and the different provider levels employed.

Hypothermia Prevention Equipment Comparative Studies

30. Current TCCC Guidelines recommend the Ready-Heat Blanket™ and Heat-Reflective Shell™ for the hypothermia prevention among combat casualties. However, new and improved technologies for hypothermia prevention are currently being developed. To date, a program dedicated to providing ongoing evaluations of these technologies as they evolve has not been established.

Combat Medic/Corpsman/PJ Equipment Evaluations

31. Formal data are lacking regarding the experience of seasoned combat medics/corpsmen and Pararescuemen (PJs) with the battlefield trauma care equipment they, carry, despite nine years into the current conflicts.

32. Equipment after-action evaluations conducted through such venues as the biannual refresher training for Special Operations Forces (SOF) medics offered at the Joint Special Operations Medical Training Center and for arriving new instructors at the U.S. Army Medical Department, Department of Combat Medic Training, would allow for quantitative evaluations and specific comments about the merits of currently fielded combat medical equipment to be obtained from individuals who are experienced in using these items for in-theater casualty care.

Focused Analysis of JTTR Data Regarding Specific TCCC Interventions

33. The JTTR serves as a data repository capturing information for every serious casualty event in OIF and OEF, from the point of injury to patient outcome. These data permit evaluations that address various issues such as the effectiveness of current combat casualty care practices and help ensure that the TCCC Guidelines reflect the most up to date information and knowledge.

34. Analysis of JTTR data may yield valuable insight regarding either successes or deficiencies related to current TCCC Guidelines.

    a. Examples of such studies are the airway study recently performed by LTC Robert Mabry, Director of the Prehospital Division of the Joint Theater Trauma System, in regard to surgical airways, and the tourniquet studies performed by COL John Kragh at ISR.

Veres Needle for Needle Thoracostomy

35. The Veres Needle is a spring-loaded needle used in laparoscopic surgical procedures that is designed to allow entry into body cavities without trauma to underlying organs.

36. Data are needed regarding its use for needle thoracostomy that will help determine whether it reduces the potential for iatrogenic injury during needle decompression of tension pneumothorax.

Improved Suction Devices

37. Combat medics have voiced the need for improved suction devices for battlefield use. Several tactical suction devices are currently available; however, their performance has not been comparatively assessed.

Improved TCCC Training Metrics

38. Current metrics used to assess the effectiveness of various training methodologies (including presentations, buddy practice, simulators, and Live Tissue Training) have not been shown to adequately address the full range of skills required in TCCC, to include both technical skills such as establishing surgical airways, and cognitive skills, such as decision-making in a complex tactical casualty scenario.

Spinal Cord Protection in Casualties with Suspected Spine Injury in Tactical Settings

39. The increased incidence of IED attacks in Iraq and Afghanistan has produced an increasing number of spinal injuries. Advancements in PPE and vehicle armor, as well as improved TCCC techniques and surgical care, have contributed to increased survival rates among casualties who incur spinal trauma.

40. Current Advanced Trauma Life Support protocols indicate that spinal precautions should be in place when a casualty has sustained trauma from a significant mechanism of injury likely to damage the cervical spine.

    a. In hostile environments, adherence to these precautions may place pre-hospital medical teams at significant or prolonged risk. Current techniques used to manage suspected spinal cord trauma are not well-supported by the literature, especially for penetrating trauma.

    b. In addition, cervical collars may hide potential life-threatening conditions.

41. Additional data are required regarding tactically-appropriate techniques that should be used by combat medics when moving casualties with suspected spinal cord injuries on the battlefield. The benefit of current techniques for spinal cord protection during pre-hospital transport of casualties with suspected spinal fractures are not well supported by existing data.

Enhanced Pelvic Protection in PPE

42. Deployed forces currently sustain severe blast injuries to the pelvic, urogenital, and perineal areas, predominantly from dismounted IED blasts. IED explosions have significantly increased as a mechanism or cause of injury, and have contributed to greater injury severity as well as number of simultaneous injuries.

43. Historically, injuries to the genitalia account for 0.5 to 4.2 percent of all war injuries. In 2007, a retrospective review was conducted of casualties who incurred trauma to the external genitalia during OIF, and found that patients with these injuries composed 4.7 percent of all combat casualties, in line with historical data.

44. However, the incidence of dismounted complex blast injuries has increased significantly since January 2010 in the Afghanistan Theater of Operations (ATO), particularly multiple amputations and genital injuries.

    a. Both genitalia injury and amputation rates for evacuated Marines have increased among patients admitted to Landstuhl Regional Medical Center (LRMC) between January 2009 and December 2010, particularly between June and December 2010.

        i) Within this period, amputation rates increased by 200 percent over baseline among this population, with an increase of 295 percent in double amputation rates over

baseline. Of all LRMC admissions, 38 percent received an amputation, most of which were significantly disabling high proximal injuries. .

ii) Genital injuries increased 175 percent over baseline during this time.

iii) Typically not fatal, these injuries result in severe complications, including long-term urinary, hormonal, and sexual dysfunction, as well as concomitant acute psychosocial distress.

45. Data are currently needed that would facilitate the identification of optimal interventions to protect the genital region while minimizing additional weight and discomfort to the combatant.

CONCLUSION

46. Battlefield trauma care research performed by the U.S. military should focus on issues that possess the greatest potential benefit for U.S. casualties. Since the greatest percentage of fatalities occur in the pre-hospital phase of care, this should be an area of increased emphasis.

RECOMMENDATIONS

47. The Board advises the Department to endorse the following high-priority medical RDT&E issues and forward them to the Armed Services Biomedical Research and Evaluation Management Committee and Service Surgeons General as high priority RDT&E efforts for improving battlefield trauma care. Note that some projects are ongoing at present. There is no intent to prioritize this list of research topics in regard to other DoD research efforts.

a. Non-Compressible Hemorrhage Control: Follow-Up Tranexamic Acid Studies

i) Follow-up studies should be conducted to determine the benefits and risks of using tranexamic acid for trauma patients with non-compressible hemorrhage.

b. Tactical Damage Control/Hypotensive Resuscitation Studies

i) The German experience with FDP should be documented in both the pre-hospital and hospital settings, since it would help to define the potential benefits that might be obtained by the use of this agent in the pre-hospital setting by U.S. Forces.

ii) A prospective study should be conducted using FDA-approved plasma alone for pre-hospital resuscitation fluid for patients with non-compressible hemorrhage.

a) This study would provide a basis for judging the benefit to be gained from fielding a dried plasma product when one becomes available in the U.S.

b) Because the primary use of dried plasma alone in a military setting would be in a delayed evacuation scenario, this study would best be done in EMS systems that have relatively long pre-hospital evacuation times. Innovations in pre-hospital resuscitation fluids may be less likely to improve outcomes with the short 10 or 15-minute transport time seen in many urban trauma centers in the United States.

iii) With British MERT teams routinely giving PRBCs and plasma in a 1:1 ratio during TACEVAC, the outcomes from their experience should be studied and compared to outcomes using Hextend alone during evacuation.

c. Improved Battlefield Analgesia: Ketamine

i) Additional case series detailing the benefits and risks of using ketamine for pre-hospital analgesia in trauma patients are needed, to include the experience of the British MERT with this agent.

d. Pre-Hospital Care Documentation and Databasing

i) Research and transition efforts are needed to aid in the capture of battlefield trauma care rendered and the transfer of this information to both unit-based pre-hospital trauma registries, such as that pioneered by the 75th Ranger Regiment, and to a trauma system registry, such as the JTTS's JTTR.

e. Enhanced Electronic TCCC Training

i) Training to encompass enhanced methods for accomplishing combat trauma management skills transfer to deploying personnel to include: presenting tactical medical personnel with complex casualty scenarios to help develop sound tactical decision-making skills, e-training designed to teach physicians and nurses the principles of TCCC, and information technology to make trauma management informatics available to deployed medical personnel whenever and wherever they need it.

f. Truncal Tourniquet Studies

i) 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.

g. Use and Outcomes Data for Individual Elements of TCCC

i) Studies concerning tourniquet use are essential to documenting the success or failure of recommended TCCC interventions and identifying areas for improvement.

h. Monitor-Driven Pre-Hospital Fluid Resuscitation

i) Pre-hospital fluid resuscitation has the potential to cause both harm and benefit. Stronger data are needed to support specific fluid resuscitation protocols.

i. Comparison Testing of Celox™ Gauze, Combat Gauze™, and ChitoGauze™

i) Although there have been favorable reports from both pre-hospital and in-hospital use of Combat Gauze™, it would be useful to compare the new agents to Combat Gauze™ in the consensus bleeding model developed at USAISR to gain an understanding of their relative efficacy.

j. Comparison Testing of New Tourniquets

i) A comparative analysis should be conducted between currently-fielded tourniquets (C-A-T®, SOF® TT, and pneumatic EMT) with new tourniquets.

k. Surgical Airway Training Methods

i) Comparison studies of different training modalities used to teach this skill are needed. Live tissue training should be included in the training modalities evaluated.

l. Clinicopathological Review of Every U.S. Combat Fatality in Iraq and Afghanistan

i) A multidisciplinary team to include trauma surgeons, forensic pathologists, and combat medics should review AFME autopsy records for all fatalities in the current conflicts in order to determine the causes of fatality and potentially preventable deaths.

m. Optimal Management of Traumatic Brain Injury in TCCC

i) Studies should be conducted that better define optimal airway and fluid resuscitation management for casualties with polytrauma in addition to their TBI, in order to provide the potential to enhance both survival and the clinical outcomes.

n. Impact of TACEVAC Provider Level and Skill Sets on Survival

i) Determination of the optimal model for TACEVAC platform staffing should follow an analysis of the outcomes obtained to date using these different options.

o. Hypothermia Prevention Equipment Comparative Studies

i) An ongoing program should be established to evaluate new hypothermia prevention technologies as they evolve.

p. Combat Medic/Corpsman/PJ Equipment Evaluations

i) Equipment after-action evaluations could be conducted through such venues as the biannual refresher training for United States SOF medics at the Joint Special Operations Medical Training Center and for arriving new instructors at the Army Department of Combat Medic Training. It would enable both quantitative evaluations and specific comments regarding the merits of currently fielded combat medical equipment to be obtained from individuals with experience using these items.

q. Focused Analysis of JTTR Data Regarding Specific TCCC Interventions

i) Analysis of the information contained in the trauma system trauma registry may yield valuable insights about the success or deficiencies of the current TCCC Guidelines.

ii) Examples of such studies are the recent study by LTC Bob Mabry regarding surgical airways and the tourniquet studies published by COL John Kragh.

r. Veres Needle for Needle Thoracostomy

i) Studies using this needle for needle thoracostomy should be conducted to determine if it reduces the potential for iatrogenic injury during needle decompression of tension pneumothorax.

s. Improved Battlefield Tactical Suction Devices

i) A market survey should be conducted and followed by testing of the currently available tactical suction devices.

t. Improved TCCC Training Metrics

i) A better definition of "gold standard" used to evaluate training methodologies (including presentations, buddy practice, simulators, and Live Tissue Training) for TCCC-recommended interventions and skills should be established. These metrics should include decision-making, cognitive training, and technical skill-building.

u. Spinal Cord Protection in Casualties with Suspected Spine Injury in Tactical Settings

i) Research should be conducted and data collected regarding tactically-appropriate techniques for combat medics to use when moving these casualties on the battlefield.

v. Enhanced Pelvic Protection in Personal Protective Equipment

i) Research should be carried out that would identify options to protect the pelvic region, while minimizing additional weight and discomfort to the combatant. Although not a clinical issue, it is highly recommended for review and appropriate

action by those responsible for oversight and development of personal protective equipment.

48. The Board recommends the Department track the research regarding these priority issues and provide regular updates concerning their status to the DHB.

49. The above recommendations were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:

Nancy Dickey, M.D.
DHB President

Donald Jenkins, M.D.
Chair, Trauma and Injury Subcommittee

Frank K. Butler, M.D.
Chair, Committee on Tactical Combat Casualty Care

REFERENCES

Presentation: Trauma and Injury Subcommittee Decision Brief, by Dr. Frank Butler, to the Defense Health Board March 8, 2011.

Presentation, Devastating Dismounted IED Injuries in OEF: Increasing Amputation and Genital Injury Rates Admitted to LRMC 2009-2010, to the Defense Health Board, by Dr. John Holcomb, March 8, 2011.

Presentation: Feedback to the Field: Cricothyrotomy Observations, by the Armed Forces Medical Examiner System and Defense Medical Material Program Office, 2011.

Presentation: Pre-Hospital Trauma Care Research, Development, Test and Evaluation Priorities, to the Trauma and Injury Subcommittee, by Dr. Frank Butler, November 17, 2010.

Presentation: Pre-Hospital Trauma Care Research, Development, Test and Evaluation Priorities, to the Committee on Tactical Combat Casualty Care, by Dr. Frank Butler, November 16, 2010.

Presentation: Pre-Hospital Trauma Care Research, Development, Test and Evaluation Priorities, to Defense Health Board, by Dr. Frank Butler, November 13, 2010.

Presentation: Pre-Hospital Trauma Care Research, Development, Test and Evaluation Priorities, to the Trauma and Injury Subcommittee, by Dr. John Holcomb, November 4, 2010.

Presentation: Pre-Hospital Trauma Care Research, Development, Test and Evaluation Priorities, to the Committee on Tactical Combat Casualty Care, by Dr. Frank Butler, November 3, 2010.

Arishita GI, Vayer JS, and RF Bellamy. Cervical Spine Immobilization of Penetrating Neck Wounds in a Hostile Environment. *J Trauma* 1989; **29**(3):332-7.

Aroni F, Iacovidou N, Dontas I et al. Pharmacological Aspects and Potential New Clinical Application of Ketamine: Reevaluation of an Old Drug *J Clin Pharmacol* 2009; **49**(8):957-64.

Barkana Y, Stein M, Scope A, et al. Prehospital Stabilization of the Cervical Spine for Penetrating Injuries of the Neck – Is It Necessary. *Injury* 2000; **31**(5)305-9.

Bartolacci RA, Munford BJ, Lee A, et al. Air Medical Scene Response to Blunt Trauma: Effect on Early Survival. *Med J Aust* 1998; **169**:612-6.

Belmont PJ Jr., Schoenfeld AJ, and G. Goodman. Epidemiology of Combat Wounds in Operation Iraqi Freedom and Operation Enduring Freedom: Orthopaedic Burden of Disease. *J Surg Ortho Adv* 2010; **19**(1):2-7.

Bilukha OO, Brennan M, and M. Anderson. Injuries and Deaths from Landmines and Unexploded Ordnance in Afghanistan, 2002-2006. *JAMA* 2007; **298**:516-8.

Boffard KD, Riou B, Warren B, et al. Recombinant Factor V11a As Adjunctive Therapy for Bleeding Control in Severely Injured Trauma Patients: Two Parallel Randomized, Placebo-Controlled, Double-Blind Clinical Trials. *J Trauma* 2005; **59**:8-15.

Boylan JF, Kalinich JR, Sandler, AN, et al. Tranexamic Acid Reduces Blood Loss, Transfusion Requirements, and Coagulation Factor Use in Primary Orthotopic Liver Transplantation. *Anesthes* 1996; **85**(5):1043-1048.

Butler FK Tactical Combat Casualty Care: Update 2009. *J Trauma* 2010; Suppl 1:S10-3.

Calderbank P, Woolley T, Mercer S et al. Doctor on Board. What is the Optimal Skill-Mix in Military Pre-Hospital Care. *Emerg Med J* 2010 Sept 15 [Epub ahead of print].

Carr ME, Jr. Monitoring of Hemostasis in Combat Trauma Patients. *Mil Med* 2004; **169**(12 Suppl):11-5.

Caravalho, Joseph Jr. Dismounted Complex Blast Injury Task Force Report: Executive Summary, April 28, 2011.

Carless PA, Moxey AJ, Stokes BJ, et al. Are Antifibrinolytic Drugs Equivalent in Reducing Blood Loss and Transfusion in Cardiac Surgery. A Meta-Analysis of Randomized Head-to-Head Trials. *BMC Cardiovasc Disord* 2005; **5**:19.

Casati V, Guzzon D, Oppizzi M, et al. Tranexamic Acid Compared with High-Dose Aprotinin in Primary Elective Heart Operations: Effects on Perioperative Bleeding and Allogeneic Transfusions. *J Thorac Cardiovasc Surg* 2000; **120**(3):520-7.

Clifford CC. Treating Traumatic Bleeding in a Combat Setting. *Mil Med* 2004; **169**(12 Suppl):8-10.

Coats T, Roberts I, and H Shakur. Antifibrinolytic Drugs for Acute Traumatic Injury. *Cochrane Database Syst Rev* 2011; **19**(1):CD004896.

Cohen MJ, Brohi K, Calfee C, et al. Early Release of High Mobility Group Box Nuclear protein 1 After Severe Trauma in Humans: Role of Injury Severity and Tissue Hypoperfusion. *Crit Care* 2009; **13:**R174.

CRASH-2 Collaborators, Roberts I, Shakur H, et al. The Importance of Early Treatment with Tranexamic Acid in Bleeding Trauma Patients: An Exploratory Analysis of the CRASH-2 Randomized Controlled Trial. *Lancet* 2011; **377**(9771):1096-101, 1101.e1-2.

CRASH-2 Trial Collaborators, Shakur H, Roberts I, et al. Effects of Tranexamic Acid on Death, Vascular Occlusive Events, and Blood Transfusion in Trauma Patients with Significant Hemorrhage. *Lancet* 2010; 376(9734):23-32.

CRASH-2 Trial Collaborators. Improving the Evidence Base for Trauma Care: Progress in the International CRASH-2 Trial. *PLoS Clinical Trials* 2006; **1**(6):e30.

Curry N, Hopewell S, Doree C, et al. The Acute Management of Trauma Hemorrhage: A Systematic Review of Randomized Controlled Trials *Crit Care* 2011; **15**(2):R92.

Daban JL, deSaint Maurice G, Blot RM, et al. Hemostatic Agents: Which is Better. *J Trauma* 2010;**69**(6):1636.

Darlington DN, Delgado AV, Kheirabadi BS, et al. Effect of Hemodilution on Coagulation and Recombinant Factor VIIa Efficacy in Human Blood In Vitro. *J Trauma* 2011 May 23 [Epub ahead of print].

Davis PR, Rickards AC, and JE Ollerton. Determining the Composition and Benefit of the Pre-Hospital Medical Response Team in the Conflict Setting. *J R Army Med Corps* 2007; **153**(4):269-73.

Deal VT, McDowell D, Benson P, et al. Tactical Combat Casualty Care February 2010 Direct from the Battlefield: TCCC Lessons Learned in Iraq and Afghanistan, *J Spec Oper Med* 2010; **10**(3):77-119.

DoD Task Force on Dismounted Complex Blast Injury Report, April 28, 2011.

Dutton RP, Parr M, Tortella BJ, et al. Recombinant Activated Factor VII Safety in Trauma Patients : Results from the CONTROL Trial. *J Trauma* 2011 May 23 [Epub ahead of print].

Eastridge BJ, Mabry RL, Blackbourne LH, et al. We Don't Know What We Don't Know: Prehospital Data in Combat Casualty Care. *US Army Med Dep J* 2011; Apr-Jun:11-4.

Eastridge BJ, Wade CE, Spott MA, et al. Utilizing a Trauma Systems Approach to Benchmark and Improve Combat Casualty Care. *J Trauma* 2010; **69**(Suppl 1):S5-9.

Eastridge BJ, Costanzo G, Jenkins D, et al. Impact of Joint Theater Trauma System Initiatives on Battlefield Injury Outcomes. *Ann Surgery* 2009; **198**(6):852-7.

Explosion and Blast-Related Injuries: Effects of Explosion and Blast from Military Operations and Acts of Terrorism eds. Elsayed NM and JL Atkins London: Elsevier Academic Press, 2008.

Fareed J, Iqbal O, Cunanan J, et al. Changing Trends in Anti-Coagulant Therapies. Are Heparins and Oral Anti-Coagulants Challenged. *Int Angiol* 2008; **27**(3):176-92.

Fareed J, Hoppensteadt DA, Fareed D, et al. Survival of Heparins, Oral Anticoagulants, and Aspirin After the Year 2010. *Semin Thromb Hemost* 2008; **34**(1):58-73.

Fox CJ, Gillespie DL, Cox ED, et al. The Effectiveness of a Damage Control Resuscitation Strategy for Vascular Injury in a Combat Support Hospital: Results of a Case Control Study. *J Trauma* 2008; **64**(2Suppl):S99-106; discussion S106-7.

Fox CJ, Gillespie DL, Cox ED, et al. Damage Control Resuscitation for Vascular Surgery in a Combat Support Hospital. *J Trauma* 2008; **65**(1):1-9.

Gando S, Sawamura A, and M. Hayakawa. Trauma, Shock, and Disseminated Intravascular Coagulation: Lessons from the Classical Literature. *Ann Surgery* 2011; Mar 1 [Epub ahead of print].

Garner A. The Role of Physician Staffing of Helicopter Emergency Medical Services in Prehospital Trauma Response. *Emerg Med Australas* 2004; **16**:318-23.

Garner A, Crooks J, Lee A, et al. Efficacy of Prehospital Critical Care Teams for Severe Blunt Head injury in the Australian Setting. *Injury* 2001; **32**(6):455-60.

Garner A, Rashford S, Lee A, et al. Addition of Physicians to Paramedic Helicopter Services Decreases Blunt Trauma Mortality. *Aust N Z J Surg* 1999; **69**:697-701.

Gerhardt RT, De Lorenzo RA, Oliver J, Holcomb JB, and JA Pfaff. Out-of-Hospital Combat Casualty Care in the Current War in Iraq. *Ann Emerg Med* 2009; **53**:169-74.

Granville-Chapman J, Jacobs N, and MJ Midwinter. Pre-Hospital Haemostatic Dressings: A Systematic Review. *Injury* 2011; **42**(5)447-59.

Grathwohl KW, Black IH, Spinella PC, et al. Total Intravenous Anesthesia Including Ketamine versus Volatile Gas Anesthesia for Combat-Related Operative Traumatic Brain Injury. *Anesthes 2008;* **109**(1):44-53.

Gruen RL and B Mitra. Tranexamic Acid for Trauma. *Lancet* 2011; **377**(9771):1052-4.

Guerriero C, Cairns J, Perel P, et al. Cost-Effectiveness Analysis of Administering Tranexamic Avid to Bleeding Trauma Patients Using Evidence from the CRASH-2 Trial. *PLoS One* 2011; **6**(5):e18987.

Henry DA, Carless PA, Moxey AJ, et al. Anti-Fibrinolytic Use for Minimizing Perioerative Allogeneic Blood Transfusion. *Cochrane Database Syst Rev* 2011; **16**(3):cd001886.

Henry H, Carless P, Fergusson D, et al. The Safety of Aprotinin and Lysine-Derived Antibibrinolytic Drugs in Cardiac Surgery: A Meta-Analysis. *CMAJ* 2009; **180**(2):183-93.

Holcomb JB, McManus JG, Kerr ST, et al. Needle Versus Tube Thoracostomy in a Swine Model of Traumatic Tension Hemopneumothorax. *Prehosp Emerg Care* 2009; **13**(1):18-27.

Holcomb JB, McMullin NR, Pearse L, et al. Causes of Death in U.S. Special Operations Forces in the Global War on Terrorism (2001-2004). *Ann Surgery* 2007; **245**(6):986-991.

Holcomb JB, Stansbury LG, Champion HR, et al Understanding Combat Casualty Care Statistics. *J Trauma 2006;* **60**(2):397-401.

Holcomb JB. Use of Recombinant Activated Factor VII to Treat the Acquired Coagulopathy of Trauma. *J Trauma* 2005; **58**(6):1298-303.

Jenkins DW Jr, McKinney MK, Szpak MW, et al. Veres Needle in the Plural Space. *South Med J* 1983; **76**(11):1383-5.

Kang DG and RA Lehman, Jr. Spine Immobilization: Prehospitalization to Final Destination. *J Surg Ortho Adv* 2011; **20**(1):2-7.

Kelly JF, Ritenour AE, McLaughlin DF, et al. Injury Severity and Causes of Death From Operation Iraqi Freedom and Operation Enduring Freedom: 2003-2004 Versus 2006. *J Trauma* 2007; **64**(2):S21-7.

Kheirabadi BS, Scherer MA, Estep JS, et al. Determination of Efficacy of New Hemostatic Dressings in a Model of Extremity Arterial Hemorrhage in Swine. *J Trauma* 2009; **67**:450-60.

Kragh JF, Jr, Murphy C, Dubick MA et al. New Tourniquet Device Concepts for Battlefield Hemorrhage Control. *US Army Med Dep J* 2011; Apr-Jun:38-48.

Kragh JF, Jr, O'Neill ML, Beebe DF, et al. Survey of the Indications for Use of Emergency Tourniquets. *J Spec Oper Med* 2011; **11**(1):30-8.

Kragh JF, Jr, Wade CE, Baer DG et al. Fasciotomy Rates in Operations Enduring Freedom and Iraqi Freedom: Association with Injury Severity and Tourniquet Use. *J Orthop Trauma* 2011; **25**(30):134-9.

Kragh JF, Jr., Littrel ML, Jones JA, et al. Battle Casualty Survival with Emergency Tourniquet use to Stop Limb Bleeding. *J Emerg Med* 2009 Aug 28 [Epub ahead of print].

Kragh JF, Jr., Walters TJ, Baer DG, et al. Practical Use of Emergency Tourniquets to Stop Bleeding in Major Limb Trauma. *J Trauma* 2008; **64**(2Suppl):S38-49; discussion S49-50.

Kragh, JF, Jr., Baer DG, and TJ Walters. Extended (16-hour) Tourniquet Application After Combat Wounds: A Case Report and Review of the Current Literature. *J Orthop Trauma* 2007; **21**(4):274-8.

Kumar AR, Grewal NS, Chung TL, Bradley JP. Lessons from Operation Iraqi Freedom: Successful Subacute Reconstruction of Complex Lower Extremity Battle Injuries. *Plast Reconstr Surg* 2009; **123**:218-29.

Levy JH. Antifibrinolytic Therapy: New Data and New Concepts. *Lancet* 2010; **376**:3-4.

Ling GS, Rhee P, and JM Ecklund. Surgical Innovations Arising from the Iraq and Afghanistan Wars. *Annu Rev Med* 2010; **61**:457-68.

Littlejohn LF, Devlin JJ, Kircher SS, et al. Comparison of Celox-A, ChitoFlex, WoundStat, and Combat Gauze Hemostatic Agents versus Standard Gauze Dressing in Control of Hemorrhage in a Swine Model of Penetrating Trauma. *Acad Emerg Med* 2011; **18**(4):340-50.

Mabry RL and RA DeLorenzo. Sharpening the Edge: Paramedic Training for Flight Medics. *US Army Med Dep J* 2011; Apr-Jun:92-100.

Mabry RL, Edens JW, Pearse L, et al. Fatal Airway Injuries During Operation Enduring Freedom and Operation Iraqi Freedom. *Prehosp Emerg Care* 2010; **14**(2):272-7.

Mangano DT, Mial Y, Vuylsteke A., et al. Mortality Associated with Aprotinin During Five Years Following Coronary Artery Bypass Graft Surgery. *JAMA* 2007; **297**(5):471-9.

Mangano DT, Tudor IC, Dietzel C, et al. The Risk Associated with Aprotinin in Cardiac Surgery. *NEJM* 2006; **354**(4):353-65.

Masini BD, Waterman SM, Wenke JC, et al. Resource Utilization and Disability Outcome Assessment of Combat Casualties from Operation Iraqi Freedom and Operation Enduring Freedom. *J Orthop Trauma* 2009; **23**:261-6.

Mitra B, Fitzgerald M, Cameron PA, et al. Tranexamic Acid for Trauma. *The Lancet* 2010; **376**(9746):1049.

Moore EE, Knudson MM, Burlew CC, et al. Defining the Limits of Resuscitative Emergency Department Thoracotomy: A Contemporary Western Trauma Association Perspective. *J Trauma* 2011; **70**(2):334-9.

Morrison CA, Carrick MM, Norman MA, et al. Hypotensive Resuscitation Strategy Reduces Transfusion Requirements and Severe Postoperative Coagulopathy in Trauma Patients with Hemorrhagic Shock: Preliminary Results of a Randomized Controlled Trial. *J Trauma* 2011; **70**:652-63.

O'Connell KA, Wood JJ, Wise RP, et al. Thromboembolic Adverse Events After Use of Recombinant Human Coagulation Factor VIIa. *JAMA* **295**(3):293-8.

Perkins JG, Cap AP, Weiss BM, et al. Massive Transfusion and Nonsurgical Hemostatic Agents. *Crit Care Med* 2008; **36**(7 Suppl):S325-39.

Ramasamy A, Midwinter M, Mahoney P, et al. Learning the Lessons from Conflict: Pre-Hospital Cervical Spine Stabilization following Ballistic Neck Trauma. *Injury* 2009; **40**(12):1342-5.

Ruff R L, Ruff S S, and XF Wang. Headaches among Operation Iraqi Freedom/Operation Enduring Freedom Veterans with Mild Traumatic Brain Injury Associated with Exposures to Explosions. *J Rehabil Res Dev* 2008; 45:941-52.

Schoenfeld AJ, Goodman GP and PJ Belmont, Jr. Characterization of Combat-Related Spinal Injuries Sustained by a U.S. Army Brigade Combat Team During Operation Iraqi Freedom *Spine J* 2010 [Epub ahead of print].

Spear M. Outcomes of Lower Extremity Injuries Sustained During Operation Iraqi Freedom and Operation Enduring Freedom *Plast Surg Nurs* 2009; **29**:155-7.

Stansbury LG, Lalliss SJ, Branstetter JG, et al. Amputations in U.S. Military Personnel in the Current Conflicts in Afghanistan and Iraq. *J Ortho Trauma* 2008; **22**(1):43-46.

Shuja F, Finkelstein RA, Fukudome E, et al. Development and Testing of Low Volume Hyperoncotic, Hyperosmotic Spray-Dried Plasma for the Treatment of Trauma-Associated Coagulopathy. *J Trauma* **70**:664-71.

Sydenham E. Thousands of Lives Could Be Saved Using Tansexamic Acid for Patients with Bleeding Trauma. *Inj Prev* 2011; May 5 [Epub ahead of print].

Taber KH, Warden DL, and RA Hurley. Blast-Related Traumatic Brain Injury: What is Known. *J Neuropsych Clin Neurosci* 2006; 18:141-5.

Tobin JM, Via DK, and T Carter. Tactical Evacuation: Extending Critical Care on Rotary Wing Platforms to Forward Surgical Facilities. *Mil Med* 2011; **176**(1):4.

Vandromme MJ, Griffin RL, Kerby JD, et al. Identifying Risk for Massive Transfusion in the Relatively Normotensive Patient: Utility of the Prehospital Shock Index. *J Trauma* 2011; **70**:384-90.

Walters TJ, Kragh JF, Jr., Kauvar DS, et al. The Combined Influence of Hemorrhage and Tourniquet Application on the Recovery of Muscle Function in Rats. *J Orthop Trauma* 2008; **22**(1):47-51.

Walters TJ and RL Mabry. Issues Related to the Use of Tourniquets on the Battlefield. *Mil Med* 2005; **170**(9):770-5.

Wang HE, Mann NC, Mears G, et al. Out-of-Hospital Airway Management in the United States. *Resuscitation* 2011; **82**:378-85.

Warner KJ, Copass MK, and EM Bulger. Paramedic Use of Needle Thoracostomy in the Prehospital Environment. *Prehosp Emerg Care* 2008; **12**(2):162-8.

Waxman S, Beekley A, Morey A, et al. Penetrating Trauma to the External Genitalia in Operation Iraqi Freedom. *Int J Impot Res* 2009; **21**:145–8.

Yeguiayan JM, Rosencher N, and M Freysz. Tranexamic Acid for Trauma. *Lancet* 2010; **376**(9746):1050-1.