The Impact of Observational and Retrospective Research

Jeremy G. Perkins, MD FACP
LTC(P) US Army, Medical Corps
Chief, Hematology-Oncology Service
Walter Reed National Military Medical Center
Bethesda, MD
The presenter does not have financial relationships with any commercial interests.

"The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense."

ACKNOWLEDGEMENTS

- Kurt Grathwohl, MD
- Phillip Spinella, MD
- Alec Beekley, MD,
- Ruth Lee, RN
- John Holcomb, MD
- Charlie Wade, PhD
- Andre Cap, MD PhD
- Susan West, BSN
- Kelly Warfield, PhD
Outline

• Historical Perspective
• Pre-trauma system planning/data collection
• 31st Combat Support Hospital Efforts
• Joint Theater Trauma Registry
• Deployed Trauma Research Teams
• Limitations of combat casualty research
• Clinical Practice Guidelines
• Need for post-conflict trauma care validation
Battlefield Research - perspective

The field army has an opportunity for research that cannot be duplicated by any other organization ... No other institution has an opportunity or responsibility in the field of trauma comparable to that of the Army Medical Service.

—Battle Casualties in Korea, Studies of the Surgical Research Team, 1955, p. 16.
Post-Vietnam to 2001

Deficiencies in combat casualty care had been identified

- 1990 First Gulf War – no rapid evacuation for critically injured casualties or system to support medical research.

- 1993 Somalia – no trauma registry to capture combat casualty data or a trauma system to track outcomes and disseminate lessons learned

- 2001 - needed better pre-hospital combat casualty care training, intensive care unit and burn teams

Data Systems in place at the beginning of OEF in 2001

- Basic demographics, general categories of diagnosis, injury
- Basic outcomes (ie, Killed in Action, Wounded in Action, Died of Wounds, and Returned to Duty).
- Clinically relevant admission, treatment, and outcome data tracked by individual providers but no integrated system
Early Efforts to understand combat casualty care

Mid-2003, the US Army Surgeon General sent consultants for surgery, trauma, orthopedics, and anesthesia into Iraq on a fact-finding mission to “identify what is wrong and fix it.”

* Recommendation: create a DoD Trauma system and registry

Case reports/case series by individuals or small groups of providers were already starting to come out in the literature

- Place 2003, Forward surgical team (FST) workload in a special operations environment: the 250th FST in Operation ENDURING FREEDOM. Curr Surg.
- Craig 2006, A novel device developed, tested, and used for warming and maintaining intravenous fluids in a forward surgical team during Operation Enduring Freedom. Mil Med.
Plan to create trauma system/registry

• In May 2004, Trauma System Director deployed

• The Theater Trauma System missions included:
  – Improve organization and delivery of trauma care
  – Develop and implement clinical practice guidelines
  – Ensure continuity/improve communication among clinicians in the evacuation chain
  – Facilitate morbidity and mortality conferences to promote real-time, data-driven clinical process improvements
  – Evaluate and recommend equipment or medical supplies for use in theater to improve efficiency, reduce cost, and improve outcomes
  – Populate a theater trauma registry to evaluate care provided across 3 continents connected with documented outcomes
  – Facilitate conduct of formal research.
31st Combat Support Hospital
Ibn Sina Hospital
ER/Triage/Mass Casualty Event
Transport from Balad to Germany
Critical Care Air Transport (CCAT)
31st CSH Database

- First OIF command-supported, organized effort to collect data on every combat casualty arriving to the hospital

- Typical limitations of provider-driven clinical databases
  - transcription errors
  - inexact definitions of data points
  - use of terminology with the potential for incorrect interpretation.
31st CSH Database

- This database provided an early glimpse of trauma system issues
  - Hypothermia during transport
  - Pre-hospital tourniquet underutilization/non-standard tourniquets
  - Importance of CT imaging for abdominal penetrating injuries
  - Associations between blood component ratios and mortality
  - Outcomes of major vascular injuries, damage control abdominal operations, colon and rectal injuries
  - Outcomes for casualties receiving fresh whole blood transfusions and rFVIIa
  - Improved outcomes in CSHs with dedicated intensivists
Joint Theater Trauma Registry (JTTR)

• With the nascent trauma system concept, the 31st CSH database effort served as a potent catalyst to begin the formal trauma registry to capture data across the military medical system

• United States Army Institute of Surgical Research (USAISR), deployed trauma registry nurses to Iraq in November 2004 to CSHs.
  – Tasked to capture data from all casualties requiring surgical care
  – Standard data collection sheet
  – Input these data into the Joint Theater Trauma Registry
  – Dictionary of terms for data entry

• JTTR captured mechanistic, physiologic, diagnostic, therapeutic, and outcome data

• Using data, the Joint Theater Trauma System (JTTS) could develop metrics to:
  – Guide medical practice (Clinical Practice Guidelines)
  – Aid medical command to allocate resources
  – Track casualty trends, and trauma care outcomes
Deployment of Trauma Research Teams

- Approved research merited data collection beyond typical deployment of providers
- Complex clinical / lab data outside what was collected in JTTR
- Problems for continuity and validity of data/conclusions.

- USAISR Commander established a dedicated research team in theater

- Deployed Combat Casualty Research Team
  - Ensure continuous high-quality data collection
  - Integrate into military hospital/direct clinical care
  - Serve as principal investigators/conduct research
  - Spread research activities to other military treatment facilities in Iraq, Afghanistan, and Kuwait

- Sept 2009, DC2RT renamed Joint Combat Casualty Research Team
Limitations to Combat-Casualty Research

• Thus far largely retrospective reviews or prospective observational data
  – Minimal risk: often qualifies for a waiver of informed consent
  – Descriptive: numbers/types of face and neck trauma; chest trauma;
  – Observational: Document relationship between clinical interventions and patient outcomes
    • ratios of blood products
    • use of tourniquets

• Practical barriers to conducting greater than minimal risk research
  – Casualties unable to give consent, and no legal authorized representatives/surrogates
  – Military personnel potentially vulnerable to undue influence from commanders/medical officers
  – Potential involvement of nonmilitary personnel (civilians, security forces, and also detainees)

• A few nontrauma interventional studies for participants who can provide advance informed consent and remain available during data collection
Development of Clinical Practice Guidelines

- With notable exceptions, trauma data are often retrospective or anecdotal/consensus opinion

- CPGs help guide clinical management, particularly when few or conflicting data exist.
  - Based on input from a balanced and multidisciplinary group
  - Using the highest level of available evidence
  - Undergo periodic review / update
  - Intended to optimize the care of patients
  - Not to be blindly followed: not a substitute for clinical judgment.

- Useful for pre-deployment training to educate/familiarize with common problems involving combat casualty care

- As of 2 Jun 2014, there are 40 CPGs posted on the Joint Trauma System Web site
Fig. 1. Timeline of milestones of data collection, trauma system development, oversight, research team deployment, and clinical practice guideline development.

CENTCOM, US Central Command; CPG, clinical practice guideline; CSH, combat support hospital; DC2RT, Deployed Combat Casualty Research Team; DoD, Department of Defense; JTTS, Joint Theater Trauma System; MNC-I, Multi-National Corps Iraq; OEF, Operation Enduring Freedom; OIF, Operation Iraqi Freedom; USFOR-A, US Forces—Afghanistan.
Evaluation/Validation In the Civilian Arena

- This process described is not unique, and existed in some form during World War II and Vietnam.

- Serious errors made if civilians blindly adopt military guidelines
  - Classic example:
    - After World War II - mandatory colostomy for all colon wounds.
    - Not until the 1980s, after randomized trials – practice changed to consider primary repair for most colon wounds

- Infrastructure and capacity exists for performing prospective, randomized research projects in the civilian arena.

- It is hoped that the exchange of ideas and data-driven practices will remain robust between military and civilian trauma populations.
Summary/Conclusion

• The wars in Iraq and Afghanistan have introduced new concepts and understanding, particularly in the field of trauma.

• Efforts to understand patterns of injury and care evolved from case reports/case series into systematic data collection by groups, and ultimately into the first ever formal combat trauma registry within a theater trauma system.

• Research in a warzone required oversight and development. Dedicated trauma research teams were deployed to perform and facilitate research.

• Combat casualty data in a trauma registry as part of a theater trauma system and trauma research enabled clinical practice guidelines, and tracking of clinical outcomes after implementation.

• New concepts in medical care introduced during war are often integrated into civilian practice, but need to be validated through prospective research.