



Funding Research ■ Changing Practice ■ Creating Awareness



## Our History

- Began in San Antonio due to the presence of 3 Level 1 Trauma Centers: Wilford Hall Medical Center, BAMC/ISR, and University Hospital / University of Texas Health Science Center—San Antonio
- San Antonio had a long- standing culture of civilian/military collaboration
- The Burn Center at BAMC had recently lost its ABA verification due to lack of board-certified burn surgeon as a director
- Brought to the attention of Sen. Kay Bailey Hutchison, who assisted with FY03 congressional earmark of \$1.8M to fund initial project titled “A Feasibility Study and Demonstration Project for a Joint Military/Civilian Trauma Program with a Burn Center”



## Feasibility Study

- The project commissioned a financial assessment of civilian and military trauma programs to identify the incremental revenue that could be generated by improved billing
- At military centers this would mean greatly improved procedures to bill insurance companies for civilian trauma care, and commitment to the operations enhancements needed to achieve that level
- Core issues addressed were
  - Military/civilian billing issues
  - Physician/facility licensure & malpractice issues
  - How to provide a consolidated Trauma Physician /Facility patient bill
  - What federal issues constrain the ability to conduct joint physician billing and what could be done to resolve them
- The study included comparison of ISS, length-of-stay, patient cost per stay, patient cost per day, and payer mix



## Conclusion of Study

- Study concluded that \$4 million/year could be gained if 2 military trauma centers billed for civilian trauma care more effectively
- A consolidated trauma billing program was determined to be feasible
- University Hospital implemented their portion of recommendations
- Military hospitals did not implement their portions for a primary reason, that being the *United States Code Armed Forces Title 10* that sets out CHAMPUS rates, which limits how much civilians could be charged for care at a Military Treatment Facility; this problem would have taken a Congressional solution to change the rates to meet actual costs of care.
- These other factors contributed to the difficulty of achieving a solution:
  - Escalation of war changed priorities
  - Uncertainty of committing to continuing care of civilian trauma patients
  - Lack of acceptance of operational changes needed to bill for civilian trauma care



## TRISAT

- The next evolutionary step created the organization known as TRISAT (Trauma Institute of San Antonio, Texas) which still exists today
- Focus of the project centered on coordination of education, research and clinical care among the 3 centers
- Within 2-3 years TRISAT had met its goals
  - Surgical and Anesthesia Critical Care Fellowship programs consolidated
  - Multi-center clinical trials
  - Improved sharing/transport of civilian trauma patients



## At the National Level

- Once local needs were addressed, attention turned to national needs
- Trauma surgeons' frustration with lack of research funding led to decision to become a national organization to begin solving problems
- Established NTI as a 501 (c) 3 organization in 2006 and became independent in 2008 (had been housed within UTHSC-SA until this point)
- Developed national board with representation from Army, Air Force and Navy along with national professional and academic societies in trauma, emergency medicine, neurotrauma, orthopedic trauma



## A National Problem

- Lack of centralized, organized infrastructure to guide the direction of study and dispersal of research funding
- Research topics are unfocused and not prioritized
- Multicenter trials are very few and underfunded, but are critical
- Many studies that require a multicenter approach are done as single-center studies, without cohesive use of funds and resources
- Military's battlefield innovations are not transferred to the civilian setting



## 2007 Institute of Medicine Recommendation

- An example of one of many recommendations from recognized national bodies, with no results:  
*"The Secretary of the Department of Health and Human Services should conduct a study to examine the gaps and opportunities in emergency and trauma care research....this study should include consideration of training of new investigators, development of multicenter research networks, funding of General Clinical Research Centers...involvement of emergency and trauma care researchers in the grant review and research advisory processes, and improved coordination through a dedicated center or institute."*  
*IOM, 2007*



## 2009 NIH Roundtable Recommendations

- Another unrealized example:
  - NIH Task Force on Research in Emergency Medicine to consider NIH support for emergency care research
  - Outlined challenges to NIH inclusion of trauma research
  - Concluded that an infrastructure; clinical trial network; and investigator training opportunities are necessary
  - Made no plan to address those needs and no progress since then



## So...Why NTI?

- Numerous national calls for federal funding since the 1960s
- No existing agency has taken responsibility for trauma research, and no new agency has been created.
- We exist to fill that gap and have the support of the national trauma professional and academic societies, among others:
  - American College of Surgeons/Committee on Trauma
  - American Association for the Surgery of Trauma
  - Eastern Association for the Surgery of Trauma
  - Western Trauma Association
  - American Trauma Society



## Our Solution

- Work with Congress, health care agencies and the giving community to advocate for financial support of a national center to coordinate and fund trauma research
- Set national trauma research priorities and agenda
- Engage with wide range of researchers across the U.S. including military research community
- Encourage growth in trauma research community, including young investigators
- Provide forum for dissemination of research outcomes to the trauma community via annual trauma symposium



## NTI Mission

To reduce injury, death, and disability by:

- Elevating trauma on the national research agenda;
- Generating funds and awarding research grants for near-term translational research projects to increase scientific knowledge related to trauma, burns, and injury prevention; and
- Changing clinical practice throughout the nation



## NTI Vision

- To stop unnecessary suffering from trauma through prevention, education, and research
- Ultimately to decrease rates of death and disability in trauma patients
- To be recognized as a major grant making institution for translational trauma research



## Board Representation

- American Association for the Surgery of Trauma
- American College of Surgeons/Committee on Trauma
- EAST (Eastern Association for Surgery of Trauma)
- Western Trauma Association
- American College of Emergency Physicians
- Shock Society
- Journal of Trauma
- Orthopedic Trauma Association
- American Association of Neurological Surgeons
- US Army Institute of Surgical Research (ISR)
- US Army
- US Navy
- US Air Force



## Current Board of Directors

- Timothy Fabian, MD, Chair      University of Tennessee—Memphis
- Donald Jenkins, MD, Vice-Chair      The Mayo Clinic
- David Adelson, MD      Phoenix Children's Hospital
- COL Lorne Blackburn, MD      US Army Institute of Surgical Research
- Stephen Cohn, MD      University of Texas Health Science Center—San Antonio
- CAPT James Dunne, MD      US Navy
- COL Brian Eastridge, MD      US Army Institute of Surgical Research
- Angela Gardner, MD      University of Texas—Southwestern
- John Holcomb, MD      University of Texas Health Science Center—Houston
- David Hoyt, MD      American College of Surgeons
- Jerry Jurkovich, MD      Harborview Medical Center, Seattle
- Peggy Knudson, MD      University of California—San Francisco
- Andrew Peitzman, MD      University of Pittsburgh
- Andrew Pollak, MD      University of Maryland
- Basil A. Pruitt, Jr., MD      Journal of Trauma/University of Texas Health Science Center—San Antonio
- Col. Todd Rasmussen, MD      USAISR/Wilford Hall Medical Center
- Ronald Stewart, MD      University of Texas Health Science Center—San Antonio
- Steve Venticinque, MD      Audie L. Murphy Veterans Hospital/UTHSCSA
- Steven Wolf, MD      UT-Southwestern



## Advantage: Expertise

- Board members have wealth of knowledge about past and current research, successes vs. failures, strength of investigator community
- Science Committee provides strong peer-review process for all submissions; all members review all proposals



## Advantage: Leadership

- All Board members are serving or have served as leaders in national trauma organizations
- All voluntary leadership
- Includes academic organizations and military experience
- Bylaws require representatives from all relevant academic and professional societies, and active Army, Air Force and Navy



## Advantage: Efficiency

- Speed and ability to streamline the process for investigators
- Experience with the funding process, contract management and compliance



## Funding History

- Requested/received \$11.7 million in Congressional Appropriations:

FY03	\$1.8 million
FY06	\$2.4 million
FY08	\$1.6 million
FY09	\$2.1 million
FY10	\$3.8 million

- Managed additional \$5.2 million federal contract over 3 years
- Was awarded \$3.8 million in Texas Emerging Technology Funds for Wireless Vital Signs Monitor, now FDA approved and in clinical testing phase
- **Total funds managed = \$20.7 million**



## CSI funds

- All funds generated through “earmarks”, or Congressional appropriations, are known as CSI—Congressional Special Interest funds.
- All CSI funds are directed to an existing federal agency; in NTI’s case this is the DoD
- TATRC is the DoD agency that manages NTI’s CSI funds
- NTI has generated \$16.9M in CSI funds since 2003 (TRISAT and NTI history combined)
- TATRC’s indirect rate is 14.9%
- NTI has generated over \$2.5 million for MRM/DoD in indirect funds

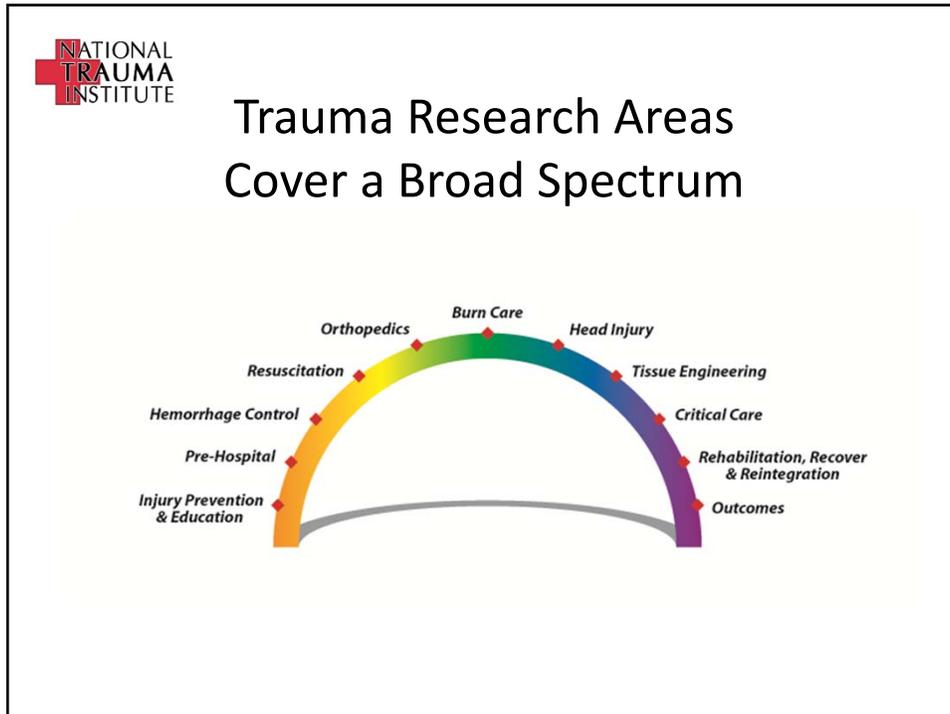


## NTI Science Committee



### Science Committee Members

- M. Margaret Knudson, MD, Chair (UC San Francisco)
- David B. Hoyt, MD, Vice-Chair (Executive Director, ACS)
- Timothy C. Fabian, MD (University of Tennessee-Memphis)
- Donald H. Jenkins, MD (The Mayo Clinic)
- Gregory J. Jurkovich, MD (University of Washington)
- Ellen J. MacKenzie, PhD (Johns Hopkins University)
- Andrew B. Peitzman, MD (University of Pittsburgh)
- Basil A. Pruitt, Jr., MD (Editor, Journal of Trauma)
- Ronald M. Stewart, MD (University of Texas—San Antonio)





## What We Do

- Science Committee determines priorities for each RFP, which is then broadly distributed
- Pre-proposals are reviewed by Science Committee; invitations are issued for full proposals
- Science Committee evaluates proposals, makes proposal selections, and recommends awards and funding decisions to the Board
- The Board considers recommendations and has ultimate approval



## What We Do

- NTI manages compliance with granting agencies for each study
- NTI prepares scientific reports and processes disbursements to awardees
- NTI requires and manages annual, face-to-face meeting of awarded investigators
- NTI holds annual trauma conference to disseminate results and provide education to multidisciplinary military/civilian trauma providers



## Review Criteria

- Scientific merit
- Clinical relevance
- Clinical impact
- Innovation
- Feasibility of completing study on time
- Military relevance
- Appropriate budget
- Potential for follow-on studies
- Multicenter involvement



## Current Awards

- \$4 million in funded studies
- 16 clinical/translational studies
- 52 trauma centers/universities
- 35 cities and 22 states



## Proposals and Awards

- January, 2010
  - 85 pre-proposals from 25 states
  - 15 invitations for full proposals
  - 7 awarded studies, with 22 participating sites
  
- January, 2011
  - 92 pre-proposals from 25 states
  - 21 invitations for full proposals
  - 8 awarded studies, with 20 participating sites

### Award Distribution

Lead Sites



Participating Sites





## Current Strategies



## Desired Goals

- *Continue in our mission*
- Develop and support Trauma Clinical Trials Networks
- Support/facilitate interactions between military and civilian trauma research sectors
- Generate private funds/philanthropy
- Receive permanent federal funding
- Develop the next generation of trauma researchers



## OSTP

- White House Office of Science & Technology Policy
- Met with staff in April, 2012
- Discussed Trauma Clinical Trials Network and Military/Civilian Translational Research
- Important to leverage this opportunity for the highest good
- Follow-up occurring now



## Strategy—Federal Funds

- FY11
  - Successfully advocated for Congress to support DoD with \$10M plus-up for hemorrhage control projects, FY11
  - This resulted solely from NTI advocacy in both House and Senate
- FY12
  - Repeated these efforts by testifying before Senate Defense Appropriations Committee, requesting \$15M plus-up for hemorrhage control projects



## Strategy—PCORI

- PCORI (Patient Centered Outcomes Research Institute), a new quasi-federal, non-profit entity with \$150-300M a year for research
- Trauma has never been included in research priorities of NTI, AHRQ or other entities
- PCORI issued its first major RFP in May, 2012
- NTI strategized to have Trauma included in PCORI research priorities:
  - NTI Board members and selected trauma surgeons attended PCORI Board meetings for one year to give public comments re: trauma as a priority



## NTI's Future



## Military/Civilian Translational Research

- **Military successes:**
  - Lowest KIA rate in military history, OIF/OEF
  - Rapid translation of innovative therapies into practice management guidelines in all 3 branches
  
- **Civilian obstacles to adoption of military successes:**
  - Lack of traditional clinical trials in academic settings
  - Relative lack of dissemination from military to civilian trauma community
  - Absence of a “repository” for storage of military advances that can be accessed
  - Lack of a clinical trials network that generates prospective data to validate military medical advances



## Research in Peacetime

- War defines gaps in combat casualty care capabilities.
  
- Peace provides time for advances to gain approval, acceptance and readiness for the next military need.
  - Example: pre-hospital data is collected only within the civilian sector but is needed by military sector to address major gap: pre-hospital medic care capability



## Mil/Civ Challenge

- To provide the necessary support for medical R&D during peacetime without the historical impetus from active combat operations
- To fund the necessary clinical trials to meet this challenge
- To create processes to assure that knowledge flows both ways between military and civilian sectors



## Identified Clinical Topics

- Identified by military surgeons
- Pre-hospital:
  - Tourniquets
  - Hemostatic dressings
  - Junctional tourniquets for noncompressible penetrating injuries
  - Field treatment for pneumothorax and hemothorax
  - Fluid resuscitation
  - Pre-hospital care of TBI
  - Medical Emergency/Evacuation Response



## Identified Clinical Topics

- Deployed Hospital Care
  - Damage control resuscitation
  - Treatment of penetrating brain injury
  - Vascular surgical techniques
  - Burn care
  - Regional anesthesia techniques
  - Negative-pressure dressings
  - Intravenous tranexamic acid
  - Point-of-care coagulation testing to guide resuscitation



## Identified Clinical Topics

- En-route Care
  - Portable rescue therapy technologies
  - Global en-route care
    - Critical Care Air Transport Teams
    - Burn Flight Teams



## Identified Clinical Topics

- Trauma Systems
  - Pre-deployment training and combat readiness sustainability
  - Joint Trauma Registry
  - Verification programs for military trauma centers
  - Expansion of the Senior Visiting Surgeon Program



## Proposed Solution

- Initial conference to set agenda and timetable, to be held Nov. 10 in Phoenix (prior to AMSUS)
- Relatively small group that includes:
  - Trauma surgeons who worked in theater during OIF/OEF (active, reservist and now-retired)
  - DoD medical researchers
  - Senior civilian trauma surgeons, thought leaders that influence education curriculums, clinical practice
  - FDA senior personnel who understand different processes for approval of military vs. civilian treatments and understand the need for cross-over



## Anticipated Results

- A process for the real transfer of military advances to civilian trauma providers
- Selection/prioritization of military issues for civilian study
- Clinical Trial Network that includes military and civilian facilities
- Involvement of FDA to clarify approval processes within both sectors
- FUNDING TO ACCOMPLISH OBJECTIVES



## NTI's Role

- Convener and facilitator, since both military and civilian surgeons and researchers participate
  - Well-established Science Committee
  - Considerable experience working with both military and civilian surgeons and researchers
  - Experience in conducting prospective multi-center clinical research
  - Ability to disseminate findings promptly with Board members who are in leadership positions in national organizations and societies



Questions?