



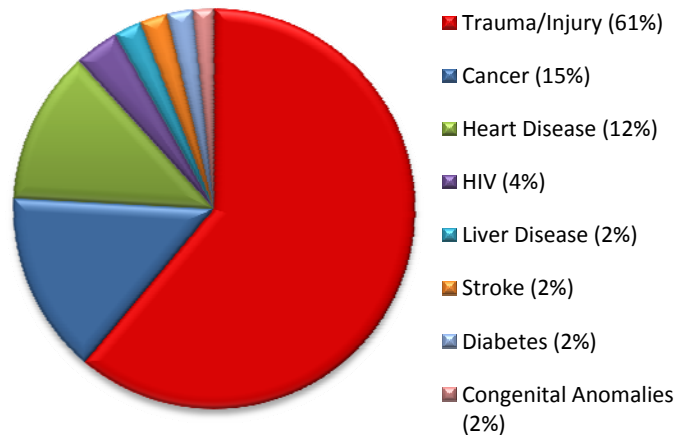
**Statement to the Patient-Centered Outcomes Research Institute
Board of Governors Meeting
May 16, 2011**

TRAUMA – AMERICA’S UNRECOGNIZED EPIDEMIC

Trauma/injury is an enormous and largely unrecognized public health problem. In 1966, a seminal report by the National Research Council declared that both the public and government were "insensitive to the magnitude of the problem of accidental death and injury" in the U.S. That is still true today, over 40 years later.

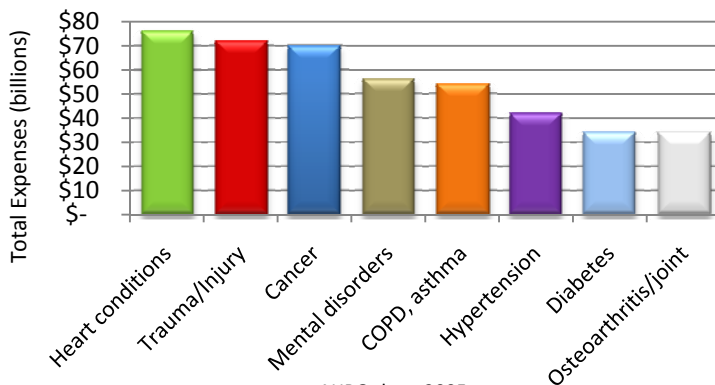
Trauma/injury is responsible for over 61% of the deaths of Americans between the ages of 1 and 44 each year. That’s more than all forms of cancer, heart disease, HIV, liver disease, stroke and diabetes combined. An American dies every three minutes due to trauma. That’s 179,000 deaths in addition to 29.6 million injuries **every year.**

Top Eight Causes of Death in Americans Aged 1-44 Years



CDC data, 2007

Trauma is the second most expensive public health problem facing the United States. AHRQ



AHRQ data, 2005

data on the ten most expensive health conditions puts the annual medical costs from trauma at \$72 billion, second only to heart conditions at \$76 billion, and ahead of cancer, mental disorders, asthma and COPD, and diabetes. The National Safety Council estimates the true economic burden to be more

than \$690 billion per year, since trauma has an ongoing cost to society due to disability, and is the leading cause of years of productive life lost.

Although often associated with military conflicts, trauma is largely a civilian catastrophe. During the current wars, 250 times more civilians have died of trauma than military in combat, and 6,000 times more civilians have been injured.

It has been proven repeatedly that medical research makes an impact and saves lives. For instance, in 1950 a diagnosis of leukemia was tantamount to a death sentence. Research led to chemotherapy treatments in the 1950s and bone marrow transplantations in the 1970s. A substantial investment in research has led to safer and more effective treatments, and today there is a 90% survival rate for leukemia. Another example is breast cancer. Thirty years ago only 74% of the women who were diagnosed lived for another five years. Due to research into early detection, chemotherapy and pharmaceuticals, the ten-year survival rate for breast cancer is now 98%.

The gap in funding for trauma research has been studied and documented for decades. Four significant reports by the National Research Council (1966), the NIH (1994), and the Institute of Medicine (1999 and 2007) have recommended more funding for trauma research, and called for the formation of a National Institute for Trauma, but little funding has been appropriated, and no such federal institute has been established. In spite of the enormity of the crisis, in fiscal year 2011 only about 3% of NIH funding is estimated to be for trauma-related research.

Trauma research is challenging for many reasons. Injury can be severe, and diagnosis of extent and location of injury can be difficult. Sometimes the patient is unconscious or unable to communicate, unable to give consent. Patients are often unaccompanied by next-of-kin to assist in decision-making. Enrolling patients in trauma studies sometimes requires community consent and involvement because treatments may need to be started en route to the hospital. Placebos are not usually an option, because real treatment must be given to injured patients. Often a single Level 1 Trauma Center can't recruit enough patients with specific enrollment criteria to conduct a statistically significant study, so large, multi-center studies are required.

In 2009, the NIH held a Roundtable on Emergency Trauma Research, involving members of the military, trauma researchers, and representatives from NINDS, NIAID, NHLBI, NIA, NIH, HHS, AHRQ, and CDC. The report issued from this roundtable states that real-time strategies for approaches and responses to therapy will facilitate personalized optimization of care interventions, that the effect of emergency trauma research on society could be profound, and that clinical research in the emergency care setting has the potential to improve outcomes and reduce resource use. This report also offered insight into how to address the problem – it stated that a centralized institutional review board with domain expertise in acute illness and injury and the difficulties inherent in emergency research could be very beneficial. It noted that many current review panels and NIH study sections lack expertise on consent and enrollment issues in acute illness and trauma research, and suggested that a solution could be the development of a trans-institute review body for acute care research.

Tired of waiting for national recognition of the trauma tragedy, and deeply aware of the benefit of research, the leaders of America's trauma organizations formed the non-profit National Trauma Institute in 2006. With the support and participation of the national trauma community, NTI raises and manages funding for trauma research and is a national coordinating center for trauma research funding.

NTI has a representative national board that is responsible for the direction of its mission. NTI's Board and Scientific Review Committee is made up of senior leaders from America's trauma organizations including:

- The current Vice-Chair of the American College of Surgeons-Committee on Trauma
- The Executive Director of the American College of Surgeons
- Three Past-Presidents of the American Association for the Surgery of Trauma
- The current Commander of the US Army Institute of Surgical Research
- The Chief of the integrated trauma service for both Walter Reed Army Medical Center and the National Naval Medical Center
- The Chair of the Trauma and Injury Subcommittee of the Defense Health Board
- The President of the Eastern Association for Surgery of Trauma (EAST)
- Both the Associate Editor and Editor of the Journal of Trauma
- The Past Chair of the National Advisory Committee for Injury Prevention and Control
- The Chair of the Extremity War Injuries and Disaster Preparedness Project Team for the American Association of Orthopedic Surgeons

The Board also includes representatives from the Western Trauma Association (WEST), the American College of Emergency Physicians (ACEP), the Shock Society, the American Association of Neurological Surgeons, and the American Burn Association, and at least one representative from each of the United States Army, Navy and Air Force.

Since September 2009, NTI has issued two national calls for proposals and has received a total of 177 pre-proposals from 32 states and the District of Columbia. After rigorous peer-review, we have awarded \$3.9 million to 16 proposals – 7 single-center studies and 9 multi-center studies involving an additional 32 centers. Studies are on-going, and we expect the first research outcomes within six months. However, \$3.9 million is barely beginning to build the body of knowledge necessary for improved treatments and outcomes in the field of trauma in the United States.

The legislation establishing PCORI, states that "PCORI shall enter into contracts for the management of funding and conduct of research with federal agencies, academic research, private sector research, or study-conducting entities." We believe that NTI offers PCORI a well-developed, experienced and capable institute for the selection, management and conduct of rigorously peer-reviewed research proposals in trauma. We further maintain that due to the caliber of the NTI Board and Science Committee, NTI can advise PCORI on national research priorities, evidentiary gaps and new clinical evidence in the field of trauma.

In 2004, representatives from AHRQ, Centers for Medicare and Medicaid Services, the FDA and the HHS Office of the Secretary established United States national priority areas for comparative effectiveness research. The criteria for selecting priority areas were **impact** (the extent of the burden on society); **improvability** (the opportunity for improvement in care); and **inclusiveness** (the relevance to a broad range of individuals). Despite trauma being the second most expensive health condition, the fact that trauma does not discriminate, and the significant impact that research could have on both treatment options and technological advancements, trauma was not on the initial list of national priority conditions. Nor was it included in 2008 when four more priority conditions were added. Subsequently, in July 2009, NTI suggested the addition of trauma to the list of priority conditions, but to our knowledge AHRQ has not conducted another review of priority conditions since our nomination was forwarded.

Trauma knows no bounds of race, age, gender, or socioeconomic status. It can happen to anyone at any time. Trauma is brutal, bloody and unexpected. No one expects to be a trauma victim. Trauma is the quintessential example of a patient-centered event – no trauma incident is quite the same as another – it’s different because of the location, or the mechanism of injury, or the age or gender of the patient. However, large gaps in the evidence base impact many patients.

The teenager wounded in a drive-by shooting at 1:00 a.m. in south LA will require care similar to that provided to the experienced hunter accidentally shot by his 11-year-old son at 2:00 p.m. in rural Wisconsin. They will both need to get help fast or they will die due to blood loss. When they make it to the nearest hospital, how will surgeons know the severity of the internal bleeding? There is no technology to determine this. What will the trauma surgeons use to restore blood volume? Will it be lactated Ringers, saline solution that was first used in 1831 and is still used today, a colloid solution with uncertain efficacy, or maybe whole blood? But is the blood that’s been stored for five weeks just as good as the new blood that was collected yesterday? What is the optimal blood pressure to restore? How much volume should be given? Too much and the blood pressure will increase, blood clotting will be disrupted, and the patient will bleed out even faster. Too little volume and this man will go into shock and die in three days due to multiple organ failure. It’s **emergency** care – decisions must be made in seconds or minutes, and these decisions have life and death consequences.

Of all the medical conditions physicians confront, NTI believes patient centered research is most crucial for trauma because there is no time to try different treatments, consider alternatives or have multiple appointments to discuss care. We **MUST** arm the trauma surgeons, emergency physicians and emergency medical service personnel with the tools they need to make the right decisions. Lives can be saved. It shouldn’t be the luck of the draw whether you live or die after a traumatic injury; the patient’s treatment should be supported with knowledge and tools and answers. Congresswoman Gabby Giffords, shot in the head at point-blank range on January 8 of this year, is now in intensive physical therapy and expected to largely recover from her catastrophic injury. According to CNN’s Sanjay Gupta, in a documentary on Giffords that aired in May, only about five percent of people with this type of gunshot injury survive. Gupta says the speed of the medical care delivered to her was essential

to saving her life, as was the proximity of a Level 1 Trauma Center and the fact that a former Navy trauma surgeon, with vast gunshot wound experience, oversaw her care. The chances are awfully slim that, should you or I be similarly injured, all of these factors would line up in our favor.

In conclusion, 50 years of dedicated research into proper diagnosis and treatment of leukemia has led to an 80% reduction in the death rate. Imagine even a 5% reduction in trauma deaths, injuries and economic burden – this would save the United States \$35 billion, prevent 1.5 million injuries, and save 9,000 lives *every year*.

We ask the members of the PCORI Board to make trauma a national research priority, and provide research funding for advancements in trauma practice.

Submitted by:

Sharon Smith
Executive Director
National Trauma Institute
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Contact Information:

Sharon Smith
Executive Director
National Trauma Institute
16500 San Pedro
San Antonio, TX 78232
(210) 233-6162 Ext. 205
Sharon.smith@nationaltraumainstitute.org

Vivienne Marshall, PhD.
Director of Research
National Trauma Institute
16500 San Pedro
San Antonio, TX 78232
(210) 233-6162 Ext. 205
vivienne.marshall@nationaltraumainstitute.org

National Trauma Institute Website: www.nationaltraumainstitute.org