GREATER DOD MEDICAL RESEARCH FUNDING IS REQUIRED FOR THE TOP COMBAT MEDICAL RESEARCH PRIORITY – NON-COMPRESSIBLE HEMORRHAGE

Testimony of

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GREATER DOD MEDICAL RESEARCH FUNDING IS REQUIRED FOR THE TOP COMBAT MEDICAL RESEARCH PRIORITY – NON-COMPRESSIBLE HEMORRHAGE

Mr. Chairman, Vice Chairman Cochran and Members of the Subcommittee:

Thank you for the opportunity to testify today to urge the subcommittee to invest a greater amount of DoD medical research funds in the primary conditions which kill our soldiers. According to military medical officials, non-compressible hemorrhage is the leading cause of death among combatants whose deaths are considered "potentially survivable." The National Trauma Institute (NTI) believes an accelerated program of research into non-compressible hemorrhage will result in the first truly novel advances in treating this difficult problem, will save the lives of soldiers wounded in combat, and will have tremendous impact on civilian casualties and costs.

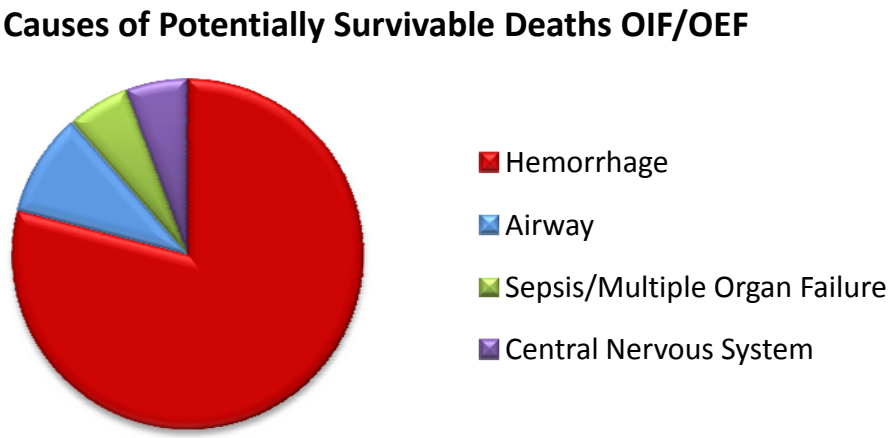
I am currently the Chief of Trauma for the Mayo Clinic and serve on the Defense Health Board. Prior to retiring from the Air Force in 2008, I was Director of the Joint Theater Trauma System, Chair of General Surgery and Chief of Trauma Services at Wilford Hall Medical Center, the Air Force's flagship medical facility. During my Air Force career, I also served as principal advisor to the Air Force Surgeon General on all surgery and trauma-related issues for first-strike deployable teams.

I am here today in my capacity as vice-chairman of the non-profit National Trauma Institute which was formed in 2006 by leaders of America's trauma organizations in response to frustration over lack of funding of trauma research. With the support and participation of the national trauma community, NTI advocates and manages funding for trauma research and is a national coordinating center for trauma research funding. 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, the organization awarded $3.9 million to 16 proposals – seven single-center studies and nine multi-center studies involving an additional 32 centers. Studies are on-going, and NTI expects the first research outcomes within six months. However, $3.9 million is a drop in the bucket, and these studies will barely begin to build the

body of knowledge necessary for improved treatments and outcomes in the field of trauma in the United States.

Non Compressible Hemorrhage

According to military documents and officials, the major cause of death from combat wounds is hemorrhage. Nineteen percent (19%) of combat deaths are judged to be potentially survivable[1]. In other words, 1100 warriors wounded in Iraq or Afghanistan might have survived to come home to their loved ones, but didn't because treatment strategies were lacking. Over 900 (84%) deaths were due to hemorrhage, and 66% of these, about 600 potentially survivable deaths, resulted from hemorrhage in regions of the body such as the neck, chest, abdomen, groin, and back that couldn't be treated by a tourniquet or compression[1].



Extremity wounds are amenable to compression to stop bleeding, and new tourniquets and hemostatic bandages have had a major impact on the decline in combat deaths due to extremity hemorrhage. But compression is rarely effective for penetrating wounds to the torso and major vessels can be damaged resulting in massive hemorrhage. At present, such wounds are normally only treatable through surgical intervention and typically such patients do not survive to reach the operating room.

Currently, there is no active intervention for noncompressible hemorrhage available to military medics, who along with civilian responders have only the tools their predecessors had in the early 20th century. There is not even a method to detect whether the wounded warrior is bleeding internally, and if so, how much blood has been lost. The current Tactical Combat Casualty Care guidelines for medics and corpsmen do not include strategies to stem bleeding from non-

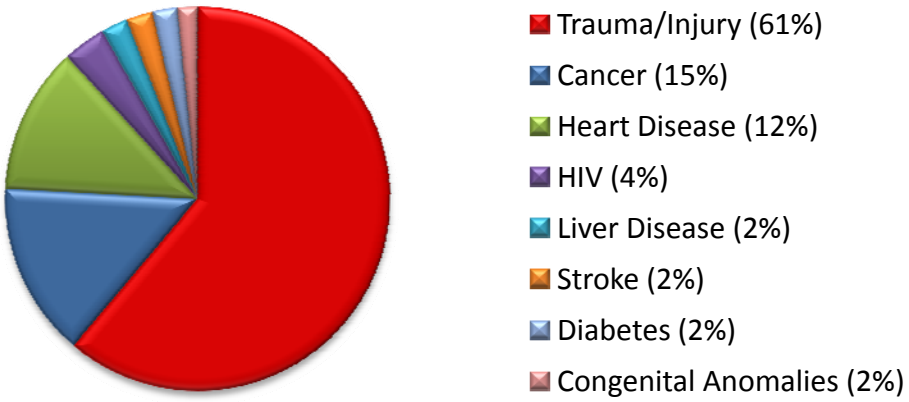
compressible hemorrhage because no solutions are available[2]. NTI hopes to decrease the mortality of severely injured patients suffering from torso hemorrhage. This can only be accomplished through research into the development of simple, rapid and field-expedient techniques which can be used by medics on the battlefield or first responders in a civilian context to detect and treat non-compressible hemorrhage. Examples of current NTI research in non-compressible hemorrhage include:

- The use of ultrasonography to measure the diameter of the vena cava to determine whether this will give an accurate indication of low blood volume.
- An observational study to determine the incidence and prevalence of clotting abnormalities in severely injured patients and to study the complex biology of proteins to better understand, predict, diagnose and treat bleeding after trauma.
- Supplementation of hemorrhagic shock patients with vasopressin, a hormone needed to support high blood pressure. Vasopressin at high doses has been shown to improve blood pressure, decrease blood loss and improve survival in animal models with lethal blood loss. This study will investigate the use of vasopressin in trauma patients.

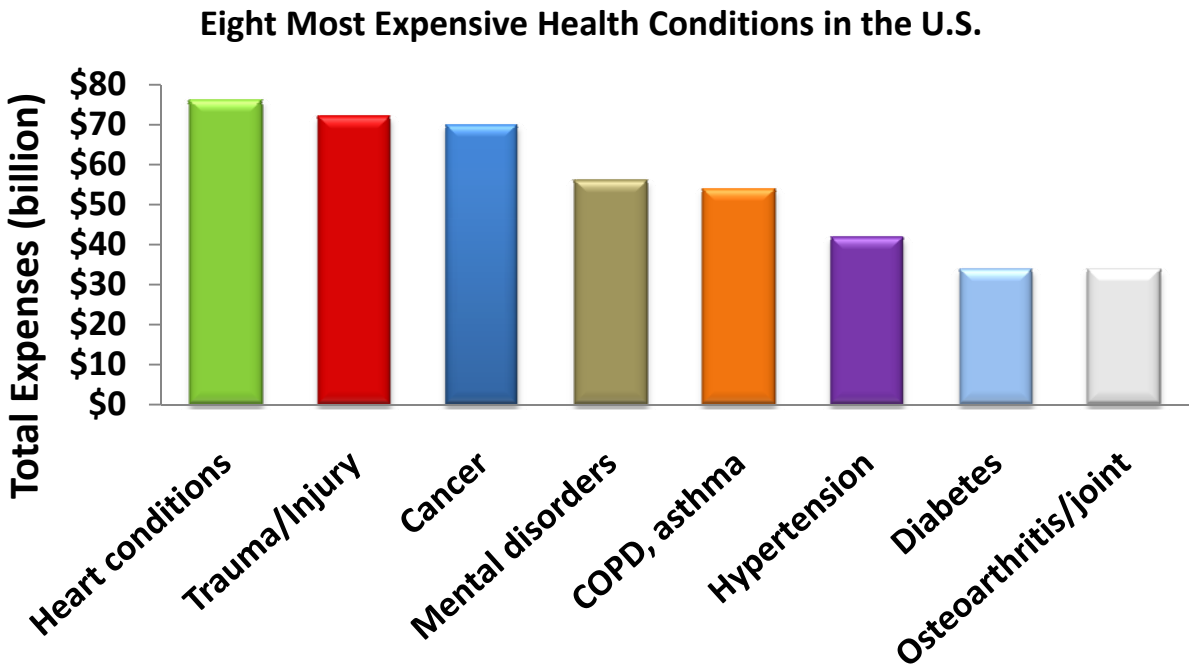
Another challenge in hemorrhage is resuscitation – the restoration of blood volume and pressure. Traditional resuscitation includes large volumes of intravenous fluids followed by blood and finally plasma. However, now this large intravenous fluid load is thought to worsen the trauma patient's coagulopathy (blood clotting problems), increasing bleeding. There is strong retrospective evidence that for patients requiring massive transfusion, a higher proportion of plasma and platelets, when compared to red cells, results in improved survival. Based on a 2004 research study[3], the current Joint Theater Trauma Clinical Practice Guideline for Forward Surgical Teams and Combat Support Hospitals advocates a plasma, platelet, and red cell resuscitation regime in lieu of the standard intravenous fluids. Currently, there is no blood substitute available for in-theater use. The Army Medical Department/USA Institute of Surgical Research is working on a freeze dried plasma solution; however this product has not yet received FDA approval. Remarkably, current treatments used by military medics for restoration of blood volume are very similar to those originally used in 1831 when saline was first given as an intravenous fluid to cholera patients[4].

Impact of Trauma on United States Civilians

Traumatic injury is the cause of death of nearly every soldier in combat. On the civilian front, trauma/injury is responsible for over 61% of the deaths of Americans between the ages of 1 and 44 each year[5]. 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[5].



Trauma is the second most expensive public health problem facing the United States. Data from the Agency for Healthcare Research and Quality (AHRQ) 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 and all other diseases[6]. 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[7].



Advances in research can be applied to both military and civilian casualties. Many of the problems associated with hemorrhage of all kinds are potentially solvable and are transferable between military and civilian trauma care. The funding recommended by NTI could have a dramatic impact on civilian mortality in the U.S. Hemorrhage is responsible for 30% to 40% of deaths following a traumatic injury to civilians[8].

Why Trauma Research Is So Challenging

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 or military treatment facility. Placebos are not usually an option, because real treatment must be given to injured patients.

In trauma, there is no time to try different treatments, consider alternatives or have multiple appointments to discuss care. We MUST arm medical personnel with the tools they need to make

the right decisions quickly. Lives can be saved. Focused clinical research will provide knowledge, tools and answers.

Often a single Level 1 Trauma Center can't recruit enough patients with specific enrollment criteria to conduct a statistically significant study that provides enough evidence to reach a conclusion that would alter clinical practice. Therefore large, multi-center studies are required, and these necessitate substantial funding. Due to limited funding, studies have often been narrow in size, sporadic, and/or conducted on the basis of a physician's personal interest, rather than a cohesive approach borne from a national trauma research agenda.

The majority of the funding added by Congress in FY11 did not go to trauma-related research[9]. The Congressionally Directed Medical Research Program did fund some research into areas that cause a high degree of disability in wounded warriors returning home, such as orthopaedic, eye, ear, craniofacial, and traumatic brain injury. NTI urges the sub-committee to equally fund the major cause of preventable death of our soldiers, sailors, airmen and marines.

For fiscal year 2011, Congress added over $700 million to the President's budget request for DoD medical research funding. Recognizing the need to reduce overall federal spending, this sum is significantly less than Congress provided in FY2009 and FY2010 when over a billion dollars was added each year.

The National Trauma Institute believes that whatever additional sum Congress determines can be allocated to DoD medical research for Fiscal Year 2012 should be directed more specifically to research of the traumatic medical conditions which most severely affect our soldiers.

Research Works

It has been proven repeatedly that medical research 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[10]. Another example is breast cancer. Thirty years ago only 74% of 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%[11].

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

RECOMMENDATION: Hence NTI recommends that Congress set aside a major portion of DoD medical research funding – at least $15 million – in the Defense Health Program account for a peer-reviewed research program to spur better technology to treat non-compressible hemorrhage.

References Cited

1. Kelly, J.F., Ritenour, A.E., McLaughlin, D.F., Bagg, K.A., Apodaca, A.N., Mallak, C.T., Pearse, L., Lawnick, M.M., Champion, H.R., Wade, C.E., and Holcomb, J.B. (2008) Injury severity and causes of death from Operation Iraqi Freedom and Operation Enduring Freedom: 2003-2004 versus 2006. *J Trauma* 64, S21-26

2. (2009) Tactical Combat Casualty Care Guidelines. http://www.usaisr.amedd.army.mil/tccc/TCCC%20Guidelines%20091104.pdf Accessed June 2nd, 2011

3. Holcomb, J.B., Jenkins, D., Rhee, P., Johannigman, J., Mahoney, P., Mehta, S., Cox, E.D., Gehrke, M.J., Beilman, G.J., Schreiber, M., Flaherty, S.F., Grathwohl, K.W., Spinella, P.C., Perkins, J.G., Beekley, A.C., McMullin, N.R., Park, M.S., Gonzalez, E.A., Wade, C.E., Dubick, M.A., Schwab, C.W., Moore, F.A., Champion, H.R., Hoyt, D.B., and Hess, J.R. (2007) Damage Control Resuscitation: Directly Addressing the Early Coagulopathy of Trauma. *The Journal of Trauma* 62, 307-310

4. Blackborne, L.H.C. (2011) 1831. *The Army Department Medical Journal* April-June 2011, 6-10

5. CDC (2006) Centers for Disease Control/WISQARS. http://webappa.cdc.gov/sasweb/ncipc/mortrate10_sy.html Accessed March 16, 2011

6. AHRQ (2008) Big Money: Cost of 10 Most Expensive Health Conditions Near $500 Billion. Agency for Healthcare Research and Quality http://www.ahrq.gov/news/nn/nn012308.htm Accessed June 2nd, 2011

7. NSC (2011) Summary from Injury Facts, 2011 Edition. National Safety Council http://www.nsc.org/news_resources/injury_and_death_statistics/Documents/Summary%202011.pdf Accessed March 16th, 2011

8. Holcomb, J.B. (2010) Optimal Use of Blood Products in Severely Injured Trauma Patients. *Hematology*, 465-469

9. (2011) H.R.1473.

10. (2011) Research Successes. Leukemia and Lymphoma Society http://www.lls.org/#/aboutlls/researchsuccesses/ Accessed June 2nd, 2011

11. (2011) Our Work. Susan G. Komen For the Cure http://ww5.komen.org/AboutUs/OurWork.html Accessed June 2nd, 2011