

## Building the future for national trauma research

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#### SUMMARY

This paper describes the current funding, infrastructure growth and future state of trauma research. It also introduces a group of review articles generated from The Future of Trauma Research: Innovations in Research Methodology conference hosted by the American College of Surgeons Committee on Trauma in July 2019.

#### INTRODUCTION

Traumatic injury is a major public health problem across the globe. In the USA, trauma is the leading cause of death from ages 1 to 46 years and accounts for more years of potential life lost before age 75 than any other medical problem.<sup>1</sup> The estimated cost of traumatic injury to our society in 2013 was \$671 billion per year.<sup>2-3</sup> Despite the well-known burden of disease imposed by injury, funding for trauma-related research remains profoundly deficient. Glass *et al* recently reported that only 3.7% of all National Institutes of Health (NIH) grants were trauma-related, representing 2.9% of the total NIH extramural budget.<sup>4</sup> A study by Moses *et al* evaluated NIH funding relative to the burden of disease, as measured by Disability-adjusted Life Years, and reported that injury was the least funded of 27 disease conditions.<sup>5</sup>

The issue of insufficient funding for trauma research is not new. A 1966 report published by the National Research Council, *Accidental Death and Disability*, first highlighted the lack of funding and called for the development of a National Institute at the NIH focused on trauma and emergency care.<sup>6</sup> In the ensuing five decades, the lack of a federal home for trauma research has continued. A report from the National Academies of Sciences, Engineering and Medicine (NASEM) in 2016 titled, *A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths after Injury*, further highlighted the gaps in research funding and the need for a coordinated approach.<sup>1</sup> Recommendation 7 from this report is as follows: *To strengthen trauma research and ensure that the resources available for this research are commensurate with the importance of injury and the potential for improvements in patient outcomes, the White House should issue an executive order mandating the establishment of a National Trauma Research Action Plan requiring a resourced, coordinated, joint approach to trauma care research across the US Department of Defense (DOD), US Department of Health and Human Services (National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, US Food and*

*Drug Administration, Patient-centered Outcomes Research institute, the US Department of Transportation, the US Department of Veterans Affairs, and others (academic institutions, professional societies, foundations))* (page 361). To date, there has been no federal response to the NASEM report's recommendations.

#### THE COALITION FOR NATIONAL TRAUMA RESEARCH

In response to the shortfalls in federal research funding, professional societies and trauma community stakeholders have struggled to find ways to support academic efforts in trauma research. Coalition for National Trauma Research (CNTR) was established in 2014 in an effort to bring together the major academic professional organizations focused on injury to develop strategies to enhance trauma research coordination and funding.<sup>7</sup> CNTR's mission is to enhance trauma research in the USA by advocating for sustainable funding commensurate with the burden of disease, coordinating research efforts across professional organizations which span the continuum of injury care, and strengthening the infrastructure for multicenter investigation. The current CNTR members include representatives from these professional societies: American Association for the Surgery of Trauma, American College of Surgeons Committee on Trauma (ACS COT), Eastern Association for the Surgery of Trauma, Western Trauma Association, and the National Trauma Institute (NTI). The NTI is a multi-specialty stakeholder organization with the mission to generate funding and provide infrastructure to sustain trauma research.<sup>8</sup> NTI manages CNTR research projects as well as the National Trauma Research Repository (NTRR).<sup>9</sup> The NTRR is a Department of Defense-funded, cloud-based data repository that supports national trauma research efforts (DoD Contract # W81XWH-15-2-0089). The repository provides trauma researchers with a means to securely share research data for secondary analyses as required by funders and journals.

#### DEVELOPING A NATIONAL TRAUMA RESEARCH ACTION PLAN

To date, CNTR has successfully advocated for an additional \$30 million in trauma research funding through the Department of Defense. However, this investment addresses only a small fraction of the burden of traumatic injury on society. Considering the 2013 \$671 billion cost of trauma in the USA, and given inflation of 10.22% since that time, to fund research commensurate with such a burden would require \$740 billion in today's dollars.<sup>3-10</sup>

**Table 1** NIH funding for various research and conditions related to injury (in millions)

Research area	FY2015 actual	FY2016 actual	FY2017 actual	FY2018 actual	FY2019 estimate	FY2020 estimate
Emergency care	\$122	\$129	\$139	\$146	\$156	\$135
Homicide and legal intervention	\$1	\$1	\$1	\$2	\$2	\$2
Injury (total) accidents/adverse	\$399	\$447	\$496	\$639	\$725	\$609
Suicide	\$46	\$52	\$68	\$96	\$117	\$96
Suicide prevention	\$24	\$33	\$35	\$51	\$69	\$55
Violence research	\$107	\$111	\$115	\$131	\$140	\$122
Total (in millions)	\$699	\$773	\$854	\$1065	\$1209	\$1019

In reality, the NIH reports its annual funding for injury-related research (table 1) from 2015 through 2020 is less than 1% of the disease burden. To make matters worse, the agency's reporting likely includes duplication (across categories) and funding for other non-trauma emergency conditions.<sup>11</sup>

To achieve the goal of research funding at a level commensurate with societal burden requires the full commitment of the federal government, including the creation of a Trauma Institute within the NIH. Until such time as a Trauma Institute is established, CNTR has made an effort to implement NASEM report recommendations, and has received grant funding from the DOD to develop a National Trauma Research Action Plan (NTRAP). The proposal's three aims are to (1) perform a gap analysis of military and civilian trauma research to identify priorities across the continuum of care; (2) define optimal metrics to assess long-term functional outcomes in injured patients following hospital discharge; and (3) identify research regulatory barriers, develop best practices for investigators, and collaborate with federal entities to define optimal endpoints for clinical research. While this project will not attempt to quantify the exact amount of research funding necessary, the results will serve as a roadmap for research funding priorities.

The NTRAP proposal was funded in 2018 and is underway (DOD Contract # W81XWH-18-CO179). Aim 1 will provide a comprehensive research agenda through the work of stakeholder panels that are currently engaging in a Delphi process to identify research gaps in 11 focus areas: prehospital care & mass casualty triage; acute resuscitation, evaluation, & imaging; post-admission critical care; neurotrauma; orthopedic trauma; burns & reconstructive surgery; long-term functional outcomes & rehabilitation; geriatric trauma, pediatric trauma, injury prevention, and trauma systems & informatics. In addition to CNTR, 18 professional societies provided representatives to the panels comprising more than 400 experts and stakeholders. Aim 2 was initiated in conjunction with a Patient Reported Outcomes Consensus Conference hosted by the ACS COT in January 2019, which brought together experts from across the globe to review the current evidence for long-term outcome assessment. Systematic literature reviews are now underway, which will be followed by Delphi panels to build consensus regarding the optimal patient reported outcomes after injury. Aim 3 will engage trauma researchers, federal regulatory agencies, and experts in clinical trial design to address human subjects protection barriers and meaningful clinical outcomes for trials. In all, NTRAP will provide a road map for future investigators and support for ongoing advocacy for sustainable federal research funding.

## DEVELOPING CNTR INFRASTRUCTURE FOR MULTICENTER INVESTIGATIONS

In 2019, to address the goal of improving the infrastructure for multicenter clinical trials in trauma, CNTR formed a Scientific Advisory Council (SAC) that includes representatives appointed from each member organization. This council is charged with identifying opportunities to leverage the resources of all the CNTR organizations to support grant submissions addressing key clinical questions in trauma care. For example, one option is to leverage the data collection infrastructure of the ACS Trauma Quality Improvement Program (TQIP) to conduct pragmatic clinical trials or design implementation studies for best practices. To facilitate the work of the SAC, CNTR held a 1-day educational symposium focused on novel and innovative clinical trial methodologies applicable to care of the injured patient hosted by the ACS COT in July 2019. The meeting was co-chaired by Drs Eileen Bulger, current Chair of the American College of Surgeons Committee on Trauma and member of the CNTR Executive Committee, and Avery Nathens, Medical Director for Trauma Quality Programs at the ACS. The symposium, *The Future of Trauma Research: Innovations in Research Methodology* included both experienced and emerging surgical researchers, all nominated by the CNTR organizations. Representatives from the American College of Emergency Physicians and the Pediatric Trauma Society also participated.

National experts in each topic area were solicited to present (table 2). Dr Avery Nathens discussed the potential for better utilizing the ACS TQIP as infrastructure to conduct clinical trials; Dr Carly Parry, a senior advisor on Healthcare Delivery and Disparities Research for the Patient-Centered Outcomes Research Institute (PCORI), offered strategies for obtaining research funding through PCORI, particularly for comparative effectiveness research; and Dr David Chambers, Deputy Director for Implementation Science at the National Cancer Institute, shared the NIH perspective on methods of implementation science. Additional speakers included experts on adaptive trial design, platform trials, pragmatic clinical trials, and de-implementation studies. The group also heard from Dr Robert Fowler on the lessons learnt from the highly productive Canadian Critical Care Clinical Trials Group.

This day-long seminar made it clear that there is opportunity to apply these innovative approaches to trauma research. The following day, members of CNTR SAC, chaired by Dr Rosemary Kozar, met to discuss ways to best design and implement these novel approaches to advance the field. The goals of the SAC are to identify innovative, pragmatic research methods appropriate for trauma research, build a clinical research network, and determine study priorities that use TQIP data infrastructure. The SAC is developing projects for prospective clinical research/clinical trials that will be attractive and relevant to federal agencies. These proposals will be based on research frameworks that

**Table 2** *The Future of Trauma Research: Innovations in Research Methodology Agenda*

Topic	Speaker
Methods of Implementation Science: NIH Perspective	David Chambers, DPhil
Studying Implementation and De-Implementation	Christian Helfrich, MPH, PhD
Transitional Care Network (PICORI)	Carly Parry, PhD
Adaptive Clinical Trial Design and Platform Trials	Robert Silbergleit, MD
Pragmatic Clinical Trials	Paul Karanicolas MD, PhD
Pragmatic Trials in PTSD	Douglas Zatzick, MD
Integrating Health Economics into Clinical Research	Ricardo Pietrobon MD, PhD
Secrets to Success from the Canadian Critical Care Trials Group	Robert Fowler, MDCM, MSc

NIH, National Institutes of Health; PCORI, Patient-Centered Outcomes Research Institute.

will eventually support the implementation of the NTRAP as described above. Anticipated benefits from this cross-society collaboration include the following: (1) Increased collaboration across professional society-sponsored multi-site studies to maximize funding and reduce duplication; (2) A coordinated network approach to apply for funding and conduct multi-site studies; (3) Harmonization of research data through the adoption of common data elements; and (4) Increased secondary analyses through data sharing and research repositories. As it evolves, CNTR SAC will provide resources and guidance to support investigators to develop project proposals and leverage the CNTR infrastructure to support application submissions for multicenter trials.

## THE FUTURE

This series is a CNTR initiative to promote sustainable, high-quality research that further advances the care of injured patients at a funding level commensurate with the burden of disease in the USA. The companion articles in this publication aim to inform the trauma research community on innovative study designs, implementation research, and patient-centered research opportunities. In the manuscript titled, “Alternative Clinical Trial Designs,” Dr Harvin *et al* describe the limitations of traditional clinical trials and how types of alternative trial designs can mitigate those limitations. Additionally, the authors discuss how Bayesian methods of inference may provide more knowledge to trauma researchers compared with traditional, frequentist statistical methods. In “Dissemination, implementation, and de-implementation: The trauma perspective,” Dr Ho and her co-authors describe the principles of implementation science and propose their wider use in trauma care. The manuscript reviews implementation, dissemination, and de-implementation, as well as research frameworks, study design, and related research funding opportunities. Finally, in “Patient-centered outcomes research and the injured patient: A summary of application,” Dr Godat *et al* review the basics of patient-centered outcomes research, priorities for funding from PCORI, resources for collaboration around patient-centered outcomes research, and a unique career development opportunity for early career trauma surgeons to develop a skillset in patient-centered outcomes research.

CNTR is committed to advancing the care of the injured patient through impactful trauma research. CNTR seeks to broaden the engagement of other medical specialty societies who share a significant focus on injury research. We believe that to successfully achieve the goal of a dedicated NIH Institute for

Trauma research with sustainable funding commensurate with the burden of traumatic injury on our society, we need to be maximally inclusive and united in our advocacy efforts. As Dr Ronald M. Stewart, Founding Chairman of the NTI has stated, “It has been proven in many other major disease categories that research works—it establishes the evidence that improves outcomes and saves lives. Accelerated progress in trauma care requires significant and sustained funding of trauma research.”<sup>12</sup>

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