



*"In 2019, there were 10,993 injury-related deaths among children and adolescents in the United States. More than 7.5 million children and adolescents are treated for injuries in the United States each year at a cost of \$23 billion."
"Pediatric trauma, in particular, remains underfunded at the federal level."*

RE: Reasons to join A+ Pediatric Trauma Research Network

Letter from the President

Trauma is not only the leading cause of death in children, but it is also the one of the most underfunded areas of research among leading cause of death in children. Pediatric cancer, the 3rd leading cause of death for children, is funded \$195,000 per death vs \$1,200 per death for traumatic injury research¹.

Part of the discrepancy in research funding is driven by the absence of a national organization dedicated to pediatric trauma research. Pediatric cancer had its first national organization in 1955.² By the 1990s, there were 9 groups with NCI funding. Around the year 2000, the Children's Cancer Group (CCG), Pediatric Oncology Group (POG), Intergroup Rhabdomyosarcoma Study Group (IRSG), and the National Wilms' Tumor Study Group (NWTSG) all came together to become the Children's Oncology Group (COG). COG has proven the benefits of an organized, disease-specific research organization on lowering mortality.

By contrast, pediatric trauma research has often been dominated by single center, or occasionally small groups of pediatric trauma centers developing protocols and/or small-scale projects with limited or no significant funding. Until now, the 11 center ATOMAC+ has been one of those small groups but is now taking on the transition to become a national pediatric trauma organization.

Originally formed as ATOMAC, 6 hospitals (Phoenix Children's Hospital (Arizona), Dell Children's Hospital (Austin, TX), Children's Medical Center (Dallas, TX), Oklahoma Children's (Oklahoma), Le Bonheur Children's (Memphis), Arkansas Children's (Arkansas)) expanded to 11 (adding Children's Mercy (Kansas City, MO), Children's Hospital of Atlanta (Georgia), Akron Children's (Akron, OH), and University of Wisconsin (Madison, WI)). Intermountain Primary Children's (Salt Lake City, UT) became the 11th center. A+PTRN currently has 36 active member institutions (www.aptrn.org)

The organization has published more 21 multicenter peer-reviewed publications in major pediatric surgery and trauma journals and presented its research more than 24 times at national trauma meetings in the last 8 years. The standards developed for choosing studies, analyzing data, authorship, data sharing, and collaboration have proven durable over the last decade.



Numerous questions in basic aspects of pediatric trauma care remain unanswered. With a proven track record of successful collaboration, A+PTRN is in a good position to improve care and answer these questions.

A+ currently runs about 9 projects in various stages of development, data collection, analysis, and writing at any given time. The expectation is that each hospital will have the opportunity to lead a study if they have the ability to do so. The lead site for each study must have the commitment to fully develop the protocol, but with input from the A+ Research Oversight team, and the members. A+ has strong support from very experienced, and well-funded pediatric trauma researchers with proven track records of meaningful contributions.

ATOMAC, and even ATOMAC+ have long ago outgrown their names. The organization became the A+ Pediatric Trauma Research Network (A+PTRN). While acknowledging its origin, the name sets the bar for future research goals. The organization is formed as an Arizona Non-profit Corporation and is a federally recognized not-for-profit 501c3.

Membership funds are used for a (1.0 FTE) research coordinator (RC), meeting costs, software licenses and may be used for data coordination center costs, ACS TQIP-associated costs, and research fellow salary in the future. The Childress Institute is currently funding our DCC through Wake Forest. Each member institutions will be responsible for providing a research site PI, and RC at their own sites. The ultimate goal will be to bring funding to underwrite the cost of site RCs through multicenter grants in the near future. We believe this will be achievable with 36 months.

A handwritten signature in black ink, reading 'David M. Notrica'.

David M Notrica, MD FACS FAAP

President

A+ Pediatric Trauma Research Network

The David M Notrica, MD Endowed Chair of Trauma/Kemper and Ethel Marley Foundation

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1. Groner JJ, Phuong J, Price MA, et al. Developing a National Trauma Research Action Plan: Results from the Pediatric Research Gap Delphi Survey. *J Trauma Acute Care Surg*. Sep 1 2022;93(3):360-366.
doi:10.1097/TA.0000000000003610
2. Children's Oncology Group. Accessed on 1/29/24,
<https://childrensoncologygroup.org/history#:~:text=The%20cooperative%20group%20system%20for,focused%20on%20childhood%20cancer%20research.>



Frequently Asked Questions

What will the funds to be used for?

Most major collaboratives require funding to support the organization itself. A+PTRN minimizes the expenses and uses the funds for a Research Coordinator 1.0 FTE to make sure projects are progressing. The real 'cost' for membership is the hospital's research commitment. Hospitals able to participate in the A+PTRN will already have their own research coordinators and trauma leaders. Once the group fully vets and votes to proceed with a study, the member hospitals will need to allocate time from their research coordinators to meet the study commitments. A+ will provide the infrastructure needed to do collaborative studies. When fully running, A+ projects will require 1 FTE of Research Coordination/project management per site.

The goal is for A+ to be receiving the majority of NIH funding for pediatric trauma research, and for that funding to reflect the importance of pediatric trauma as a major source of morbidity and mortality. But that will take time.

My hospital is already doing regional multicenter studies. Why should we join A+?

Many regional multicenter collaboratives are doing great research in the field of pediatric surgery. A+ is a disease-specific organization which only studies questions related to injury on a national level. The goal will be to eventually have every major pediatric level I trauma center participating, and to have a process that allows important clinical question to be answered in a short period of time. When ATOMAC+ did its first study of solid organ injury, it took 10 hospitals 3 years to accumulate 1,000 patients. Future studies should be able to do these studies in a year with higher power, and less effort per center.

Why now?

Recent major publications and expert panels are now calling for an improved focus and funding for pediatric trauma research. At the same time, a recent \$5 Million NIH-funded Phase IIb randomized, controlled, double-blinded trial of bone marrow derived stem cells has shown promise for mitigating severe traumatic brain injury.³ Given the results of the trial, numerous subsequent and spin-off studies will be required. An organization of numerous hospitals caring for injured children will be required to complete the studies. The recent results from UT-Houston (lead site) and Phoenix Children's (2nd site) are the first study in children to ever show a meaningful improvement in outcomes from traumatic brain injury. The treatment involves early



patient identification, bone marrow harvest, processing, and reinfusion within 48 hours of injury. These time-sensitive interventions require the skills of high-level specialists at level I pediatric trauma centers. That organization is, effectively, A+PTRN.

In general, the need for translational research in pediatric trauma is huge. For example, multiple well-done animal studies have shown the protective effect of valproic acid after traumatic brain injury. An organization will need to do the randomized controlled trial to assess the impact in real-world settings, and this will require emergency waivers of informed consent (EFIC). Undertaking complex studies will require a robust, well-funded organization.

How is A+PTRN organized?

ATOMAC+ Pediatric Trauma Research Network is organized as an Arizona corporation. The corporation hired a law firm to do the full 1023 application for 501c3 (not-for-profit) status. This is the version that allows tax exempt status without the usual financial limits on 1023EZ filers. The Board of Directors are trauma leaders from multiple institutions with extensive experience leading multicenter trials. They will lead the organization, and guide members through the submission process. The 'members' of A+PTRN, however, are the hospitals themselves. The members (one vote per hospital) will vet projects and decide if the clinical impact warrants the effort, risk, and resources required. Studies require a 50% vote to pass.

Do I have to do every study?

Members must participate in >75% of all non-exempt studies. Some studies require special expertise or populations and may be approved by the organization as 'exempt' from required participation, either because special equipment is required (i.e., pediatric ERCP) or if the study does not require a large data sample.

What are the requirements for joining?

Members will pay yearly dues of \$10,000. Each center is required to have adequate access to a research coordinator for multiple A+ studies, the institutional commitment to participating in multicenter trials, and the ability to enter into the membership contract by the end of year 2024. The membership contract contains a Data Use Agreement similar to that of the Western Pediatric Surgery Research Consortium (WPSRC) for sharing non-PHI data.

What do I get for this money?



Opportunities for authorship will be given to each site that participates in a given study. A+ will generally range produce from 4 to 8 manuscripts per year. This goes a long way to meeting the ACS level I publication requirements. Each site that contributes data to a project will have at least one author on the manuscript. The number of authors per site will be explicitly stated in the project “pitch.”

Membership not only increases the number of publications, but also the research skills of young faculty and will facilitate their academic promotion. On a national level, members will have the ability to help and control guideline development in trauma.

Each center will have the opportunity to “pitch” and (if successful) lead an A+ PTRN study. After assuring feasibility, the member hospitals will choose the studies A+ will undertake. As a center’s first study is completed, the center can pitch their next study. The number and timing of studies will be limited based on the resources available, which may increase over time as we gain external funding. Initially, the expectation is that the total workload of combined A+ studies will not exceed the workload of 1.0 FTE Research Coordinator.

How many hospitals will join A+?

Based on current assessments, we plan to limit membership to approximately 20 to 25 hospitals initially.