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Development of a multi-institutional clinical research consortium for pediatric surgery

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ABSTRACT

Background: Multicenter clinical research studies in pediatric surgery have been largely limited to relatively small case-series and retrospective reviews because of the rarity of many of the diseases we treat and difficulty coordinating and executing multi-institutional studies. Creation of a collaborative research network can provide the needed patient population and infrastructure to perform high quality multi-institutional studies.
Methods: In 2013, eleven academic pediatric surgery centers within the United States formed a research consortium to develop and conduct multicenter clinical research projects to advance the practice of pediatric surgery.
Results: We present our process for creating, developing, and maintaining this consortium including initial regional geographic limitation, charter development with by-laws and procedures for adopting studies, and research infrastructure including a central website for study monitoring and central reliance institutional review board process.
Conclusion: Our model could be reproduced or adapted by other institutions to develop or strengthen other research collaboratives.
Level of evidence: Type of study: retrospective, IV.

The rarity of many pediatric surgical diseases and the dispersion of care across a multitude of both adult and children's hospitals across the United States have limited the majority of clinical research in pediatric surgery to single center case-series and retrospective reviews [1,2,3]. In addition, time constraints and limited financial resources make both retrospective and prospective multi-institutional studies difficult to coordinate and perform. Barriers to performance of multicenter studies and trials include the lack of collaboration, variability in resources and expertise, and inconsistent commitment to academic research.

Based on a common sentiment that clinical pediatric surgical research could be improved by increased collaboration and commitment across large academic centers, several Chiefs of Divisions of Pediatric Surgery in the Midwest region of the United Sates initiated conversations to create a pediatric surgical research consortium to perform multi-institutional clinical research projects. The goals were to create a network of committed centers to capitalize on both the larger patient population and the combined clinical research expertise created by having multiple centers work together. In this manuscript, we present our process for creating, developing, and maintaining a pediatric surgery research consortium to perform multi-institutional clinical research studies.

1. Methods

1.1. Consortium inception

The Midwest Pediatric Surgery Consortium (MWPSC) was first conceived at the American Pediatric Surgery Association (APSA) meeting in 2013. An informal discussion about limitations in pediatric surgical clinical research prompted several Chiefs of Divisions of Pediatric Surgery to commit to creating a pediatric surgical research consortium to perform multi-institutional clinical research projects. To facilitate collaboration and ongoing commitment, it was decided to approach centers within geographic proximity to create the consortium to allow for easier coordination of in-person meetings and teleconferences. Subsequently the leaders of several pediatric surgery centers within the Midwest region of the United States were approached and committed to development of a regional pediatric surgery research consortium. Over the subsequent months, follow-up phone conversations led to plans for an in-person meeting of pediatric surgeons from participating institutions.

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The initial meeting of the MWPSC occurred in Ann Arbor, MI, in September 26–27, 2013. The chairperson for the Pediatric Surgery group and another pediatric surgeon interested in clinical research from each center attended. The goals of this two day retreat were to establish the mission of the consortium, define the level of commitment required to be a member institution, and begin to establish rules for governance, study selection, and accountability.

1.2. Development of consortium infrastructure and maintenance

As a result of the initial meeting, several infrastructure initiatives have been started and implemented including: 1) developing and approving consortium by-laws; 2) creation of a process for study selection with subsequent protocol devolvement and implementation; 3) development of central websites for study monitoring and tracking; and 4) creation of a central reliance institutional review board. The following section reports the process and resulting products of these initiatives.

2. Results

2.1. Establishment and commitment of member institutions

Ten institutions were represented at the initial meeting. The number of member institutions was limited to facilitate organization and attendance of in-person meetings, study coordination, and development of camaraderie and trust among group members. Shared qualities of the represented pediatric surgery departments/divisions included being from a children's hospitals affiliated academically with medical schools and location within the Midwest region. At this meeting, the mission of the research consortium was discussed extensively and established as improving the care of children with surgical conditions through performance of high quality clinical research studies that would leverage the multi-institutional nature of the consortium. Leaders from each pediatric surgical group expressed commitment of funds and resources to create, develop, and maintain the consortium including providing funding to support research studies approved to be performed by the consortium. Additionally, the decision was made to add an eleventh institution located within the Midwest whose leaders expressed interest and commitment but could not attend the initial in-person meeting. As such, a total of 11 centers agreed to work together and form the MWPSC (Table 1). Subsequently, an icon for the consortium has been developed and adopted to represent the consortium and its participating institutions (Fig. 1).

2.2. Establishment of shared governance

The initial commitment among institutional representatives was clearly evident, and attendees had a simple, clear desire to jointly perform research to improve the care of children by pediatric surgeons. The agenda for the initial meeting is shown in Appendix 1. The first few hours were spent on jointly deciding on governance, how we would review proposals and select projects, the process for determining authorship, how we would fund projects, who would own the data, how we would decide to add more centers to the consortium, etc. There was intense discussion regarding these issues felt to be critical to developing a working research collaborative (Table 2). One of the consortium tenets was the recognized need for group collaboration and consensus rather than direction by an individual or single center; therefore, all decisions regarding formation of the consortium and selection of consortium studies were decided with equal input from all centers. These upfront discussions resulted in a sense of camaraderie and trust among the participants which has facilitated all subsequent interactions.

2.3. Development of operating procedures and research infrastructure

Discussions were held to develop consortium meeting schedules that would ensure accountability, but allow for interim progress. It was decided that telephone meetings would occur every 2 months, such that calls would be substantive, but close enough together to maintain momentum. In addition, we decided to have an in-person meeting every 6 months with the host center revolving among the participating centers with the initial few hosts at the locations where the projects originated. After the initial meeting, it was necessary to have a common location for all the documents, presentations, agenda, and resources. Therefore, a web-based shared folder was created, and representatives from all consortium centers were given access. All presentations, rankings, projects, dashboards, meeting agendas and minutes, and documents are placed in organized folders to allow for transparency and shared access. In addition, dashboard documents have been created and used to monitor study status at each institution.

To formalize the relationship and commitment of the consortium members and the agreed upon rules for governance, a consortium member agreement was developed by an investigator at one of the sites in conjunction with their legal department. Over the ensuing year, this document was revised and subsequently approved by the legal and contracting group at all consortium member institutions (Appendix 2). In this way, the consortium was formally and legally recognized for grant submission and other purposes and it provides us with an accepted set of procedures and policies that can be referenced during our discussions.

To facilitate study performance, the group decided to develop a central IRB reliance process for the consortium. This was spearheaded by investigators at two of the institutions in conjunction with leaders from their respective IRBs. Over the ensuing year, the group worked with representatives from each institution's IRB to develop an IRB Reliance Agreement (Appendix 3). This IRB arrangement allows the IRB at the institution of the study principal investigator (PI) to serve as the primary IRB with all other IRB's relying on that IRB. This document has now been approved by all institution. The reliance IRB process is currently being used to support three of our ongoing studies.

Table 1
Names of initial 11 centers forming the MWPSC.

Hospital name	Affiliated academic institution	Location
American Family Children's Hospital	University of Wisconsin	Madison, WI
Ann and Robert H. Lurie Children's Hospital of Chicago	Northwestern University	Chicago, IL
C.S. Mott Children's Hospital	University of Michigan	Ann Arbor, MI
Children's Hospital of Wisconsin	Medical College of Wisconsin	Milwaukee, WI
Cincinnati Children's Hospital and Medical Center	University of Cincinnati	Cincinnati, OH
Comer Children's Hospital	University of Chicago	Chicago, IL
J. W. Riley Hospital for Children	Indiana University	Indianapolis, IN
Kosair Children's Hospital	University of Louisville	Louisville, KY
Mercy Children's Hospital	University of Missouri-Kansas City	Kansas City, MO
Nationwide Children's Hospital	The Ohio State University	Columbus, OH
St. Louis Children's Hospital	Washington University in St. Louis	St. Louis, MO