



THE CONGENITAL HEART SURGEONS SOCIETY DATA CENTER

SURVEY AND REQUEST FOR PROPOSALS

I. OVERVIEW: THE CHSS

The Congenital Heart Surgeons' Society is a not-for-profit charitable corporation organized under Section 501(c) (3) of the Internal Revenue Code. The CHSS' purpose is as follows:

- To associate persons interested in, and carry on activities related to, the science and practice of congenital heart surgery.
- To sponsor and oversee multi-institutional clinical studies evaluating the application of surgical interventions in congenital heart disease.
- To encourage and stimulate investigation and study that will increase the knowledge of congenital cardiac physiology, pathology and therapy, and to correlate and disseminate such knowledge.
- To hold scientific meetings featuring free discussion of problems and developments relating to congenital heart surgery.
- To succeed to, and continue to carry on the activities formerly conducted by The Congenital Heart Surgeons Society, an unincorporated association.

III. HISTORY

The Congenital Heart Surgeons Society came into existence over four decades ago, when 16 surgeons met annually to relate their early pioneering experiences with surgical management of patients with congenital heart disease. As the field of congenital (and pediatric) heart surgery grew, the organization became progressively larger, stabilizing for a period of time at a membership of approximately 40. Annual meetings became more structured, with oral presentations of clinical and scientific topics by members, and occasionally by members' guests. The programs, always of high quality, were characterized by presentations that were timely, and candid. Often the speakers discussed controversial questions and unresolved issues. The annual meeting became an opportunity for presentation of clinical and investigational projects that may still be in a formative or preliminary stage. This fact, together with the informality and candor of discussion by the members, made the annual meeting an important forum for dialogue, with substantial opportunity to contribute in a timely fashion to the advancement of the field. In

addition to the focus being entirely on topics related to congenital heart surgery, the character of the meeting set it apart from the more formal sessions of the scientific meetings of larger cardiothoracic professional organizations. The benefits of incorporating as a not-for-profit charitable educational organization were recognized. With the establishment of bylaws, membership was expanded to a maximum of one hundred active members.

Many years earlier, the Society had recognized the need and the opportunity to advance the “state of the art” through a more formalized process of pooling clinical experience and undertaking structured clinical research. This was accomplished through the establishment of the CHSS Data Center, and the organization of multi-institutional studies.

II CHSS RESEARCH

The Data Center was first established at the University of Alabama in Birmingham (UAB) under the direction of Drs. John Kirklin and Eugene Blackstone. The premise was that virtually all congenital heart malformations are “rare diseases,” and as such the opportunity to elucidate essential issues pertaining to surgical management would be greatly enhanced by studying much larger cohorts of patients than were treated and available for analysis at even the largest of individual programs. Thus, the original concept was to learn fundamental lessons about the surgical management of certain of these “rare lesions” by establishing multi-institutional inception cohorts based upon a diagnosis, and to prospectively collect data that would then be subjected to rigorous analyses leading to inferences about risk factors and their interaction with outcomes (expressed as time-related hazard functions for various end-points or outcome measures). The first several studies concerned the treatment of neonates with Transposition of the Great Arteries. The initial cohort consisted of 245 patients, enrolled between January 1, 1985 and June 1, 1986! Enrollment in the TGA study eventually included patients from all of the 23 institutions represented by CHSS member surgeons at the time. The power of such multi-institutional studies became immediately apparent.

The Data Center staff at UAB consisted, for the most part, of Drs. Kirklin and Blackstone, and a data manager who “recruited” enrollment from CHSS member institutions and collected and collated data. Programmers and information technology staff who worked with Dr. Blackstone in the Lyons Research Labs of the Department of Surgery at UAB played a significant role. CHSS member surgeons joined Dr. Kirklin and Dr. Blackstone in these investigations, representing the membership and sharing in authorship on behalf of the CHSS. On the strength of large numbers of subjects, and rigorous statistical methodology, the CHSS studies came to be recognized as the paragon of clinical investigations in the field of congenital heart surgery. Parametric methodology for risk-hazard analyses of time-related events became recognized as an exceptional methodology for evaluating the consequences of surgical strategies to treat congenital cardiac malformations. The decomposition of the time-related risk into “hazard phases” made it possible to identify separate risk factors that influence one particular phase or

another. Cohorts of patients with TGA, IAA, Coarctation with and without VSD, PA/IVS or Critical Pulmonary Stenosis, and Aortic Atresia were eventually recruited and analyzed while the Data Center was at UAB. For each of these latter group of studies, an element of the process was travel to UAB by either one, or a small group of members, to review the actual clinical data submissions, consider the relevant questions and goals of the investigation, and “crunch the data,” in often lengthy work sessions with Drs. Kirklin and Blackstone. These sessions obviously represented tremendous opportunities to learn about outcomes research, and to earn a coveted position of authorship of one or more of the CHSS manuscripts. Presentations of the analyses at various stages of maturation were a part of the annual scientific meeting of the Society, and matured analyses were typically submitted and accepted for presentation at national meetings such as those of the AATS and the American Heart Association.

In 1989, at the fall meeting of the CHSS, the Society voted to adopt a policy of assessing an annual participation fee from the institutions of member surgeons, to offset some of the costs of carrying out the multi-institutional research program. At that time, the fee was set at \$1000 per year. Prior to that time, Data Center funding had come entirely from the Department of Cardiac Surgery at UAB and from benevolent grants held by Dr. Kirklin and Dr. Blackstone. It is certain that, even after 1989, dues collections from participating member institutions (which numbered in the thirties for many years) were sufficient to support only a small fraction of the overall research enterprise.

A little more than a decade ago, the CHSS considered relocation of the “Data Center” from Birmingham, Alabama to a new site. In the late 1990’s a leadership group from within the Society addressed the question, culminating in a Request for Proposals from potential new Data Center sites. After review of strong proposals to house the Data Center, the Hospital for Sick Children in Toronto was chosen. The Data Center has been there since 1998, under the Directorship of Dr. William G. Williams. Dr. Williams was also elected the first President of the CHSS by acclamation when bylaws and official governing procedures were established.

The era of the Data Center at Toronto has been one of enormous productivity. Dr. Williams, who has been “the heart” of the Center, built a staff which included a phenomenally capable and energetic Nurse Data Manager (Geraldine Cullen-Dean), Information Technology and Data Entry personnel, and Clinical Research Project Assistants. Dr. Blackstone has continued to have a major, central role in operations, not only of statistical analysis, but of study conceptualization, design, and eventual abstract and manuscript production. He has continually enhanced the quality of CHSS investigations, introducing cutting edge analytic tools (e.g. competing risks analysis, “bootstrap bagging”), and applied these to CHSS data sets. His contribution to the overall quality and impact of CHSS multi-institutional outcome studies is enormous, as is his contribution to the training of many member surgeons as clinical investigators. A Toronto HSC cardiologist, Dr. Brian McCrindle, showed aptitude and strong interest in outcomes research, and emerged as a key member of the Data Center Research Team. The recruitment by Dr. Williams

of Dr. Chris Caldarone brought to Toronto another surgeon with a passion for, and strong commitment to CHSS research.

Several major accomplishments of the past decade deserve mention:

- 1) *The establishment of the Kirklin (now Ashburn/Kirklin) Fellowship*, which customarily includes course work leading to a Master's Degree in Biostatistics or a related field at the University of Toronto. The fellows have been extraordinarily productive, and have benefitted tremendously from the experience. Mentorship by Dr. Williams and Dr. Blackstone has been perceived as a key feature of their very positive experiences.
- 2) *The development of "work weekends"* – an extension of the UAB process, which now includes an average of two sessions per year when interested CHSS members travel to Toronto to review data, formalize research questions, create abstracts, revise manuscripts, etc.
- 3) *The availability of Data Center support of individual institution's processes to obtain IRB approval for CHSS study participation.* This has included provision of template IRB applications, and the ability to arrange support, including site visits by data coordinators from Children's Mercy Hospital in Kansas City, Missouri.
- 4) *The first instances of external funding of CHSS studies.* This was facilitated by incorporation of the CHSS, establishing the Society's ability to receive funds that would be tax deductible by the donor. It began with a Patient Family Foundation that donated funds to a member physician who passed them along to the Data Center. In 2004, a Resource and Development Committee was established. One of its first accomplishments was the submission of a grant application to the Children's Heart Foundation (Illinois) on behalf of the CHSS. \$100,000 was awarded over two years to fund the RV Conduit Study. A subsequent grant from the same Foundation currently provides funding for the "Late Follow-up and Quality of Life Study" of patients in the original PA/IVS cohort. A third grant application to the Children's Heart Foundation has been funded this year to support the Anomalous Aortic Origin of a Coronary Artery Study.
- 5) *Staff at the Data Center has worked very hard on NIH grant proposals* to fund the Critical Left Ventricular Outflow Tract Study, but have so far not reaped rewards from this strategy.
- 6) *An additional new concept has arisen as a means of providing partial funding support for studies.* Individual members who have proposed investigations have come forward with "seed money" to support CHSS activities. Most often, the source of these funds has been a charitable foundation that historically supports endeavors at the member's own institution. Support of this type has provided funding for a subset analysis within the pulmonary conduit cohort dataset, and for the start-up phase of an Unbalanced AVSD study.

- 7) Upon approval of the measure by the Executive Council, the Resource and Development Committee has initiated a program to recruit outside support from industry, to offset some of the costs of CHSS Research Activities.
- 8) The work of the Data Center, together with CHSS members, has resulted in a series of productive investigations culminating in podium presentations at major national and international meetings. Publications in top flight peer reviewed journals and continued recognition of CHSS multi-institutional outcome studies as major contributions to the body of scientific knowledge concerning management of congenital heart disease, have resulted from the Society's research projects and the tremendous work of the Data Center Staff at Toronto Hospital for Sick Children.

This list of accomplishments reflects very positively on the last decade of activity at the Data Center. There have been other developments that must be considered in fleshing out a complete and accurate picture. It was perhaps inevitable that substantial growth of the organization would be accompanied by some growing pains. Over the years, the number of member institutions enrolling patients in new CHSS studies did not keep pace with the growth in size of the organization. While this trend was already evident during the period of Dr. Kirklin's leadership, there are probably a multitude of contemporary factors that complicate the problem. . One is undoubtedly the increasing complexity of patient enrollment and follow-up in a manner compliant with HIPPA constraints. The Data Center has devoted an enormous amount of time and energy, and made significant accomplishments in terms of re-configuring the consent processes associated with cohort enrollment, working with individual institutional IRBs, and for a majority of patients establishing direct follow-up through the Data Center.

Some of the CHSS membership felt that authorship of CHSS study manuscripts was habitually dominated by a somewhat recurrent short list of names of senior members. There were occasions wherein physicians who felt they had made significant contributions to studies (both by enrolling patients and by participating in data analysis during work weekends in Toronto) believed that they were unfairly excluded from authorship. In 2006, the leadership of the Society, together with the leadership of the Data Center, considered strategies to meet the challenge of improving member institutions' enrollment of patients in the Society's multi-institutional studies. It was agreed that future success of research endeavors would depend upon increasing individual member participation and satisfaction. The Chair of the Research Committee was appointed from an institution other than the one that houses the Data Center, in order to optimize the role of the Research Committee as a liaison between the general membership and the Data center. (This was incorporated into a Bylaws amendment). In this capacity, the Committee advocates for studies proposed by members, announces studies and recruits membership participation in Working Groups, helps to organize preliminary phases of investigations that can be utilized to create substrate for funding applications, and finally, helps to adjudicate questions of authorship on abstracts and manuscripts.

III. DATA CENTER

In addition to Dr. Williams, the Director, the Data Center personnel include: an additional staff surgeon consultant (Dr. Caldarone), two statistical consultants (Dr. Blackstone, and Dr. McCrindle, who is a CHSS member physician in the Department of Cardiology at Toronto HSC), and the current Kirklin/Ashburn Fellow. The Data Center is currently staffed by a Research Program Manager, a Database Programmer, and two Clinical Research Project Assistants. CHSS funds (institutional dues and grant support) provide the salary support for these latter four individuals, whose benefits are provided by the hospital for Sick Children. The Data Center has dedicated space within the hospital (1,200 sq. ft.), and the requisite information technology resources and support.

The finances of the CHSS have changed considerably over the past several years in ways that have impacted positively on budgetary support for the Data Center. Institutional member dues were increased to \$2,000 per year in 1997 and to \$4,000 per year in 2007 (multiplied by approximately 60 participating institutions). All of these funds support the work of the Data Center (which has an annual budget of \$350,000 to \$400,000).

. In recent years, competitive grants from The Children's Heart Foundation, support for projects from member institutions or foundations, and most recently industry support brought about through the efforts of the Resource and Development Committee supplement the Institutional Dues in providing funds to support the Data Center. It is clear however, that the viability of the research effort, past and present, has depended in large part upon significant financial support from the host institution, which for more than a decade has been the Hospital for Sick Children in Toronto.

IV. SURVEY AND REQUEST FOR PROPOSALS

To remain at the cutting edge of the field of clinical research concerning the management of congenital heart malformations, the CHSS must continue to be creative and forward-thinking, and must continue to adapt to the changing environment in which outcomes research is undertaken at present and in the future. To achieve these goals, the CHSS periodically reviews its vision and strategic plans for the organization and conduct of its research initiatives. **At this time, all CHSS physician members are asked to complete the Survey Questionnaire which accompanies this document. The survey instrument, with complete instructions, can be accessed through the following link: <http://members.chss.org/forms/CHSS-RFP-Questionnaire.cgi?a=-1> . In addition, all member institutions are invited to submit proposals articulating their vision for the future of the CHSS Data Center.** These proposals must come from hospitals, medical centers, or academic institutions which currently are dues

paying participants in the CHSS multi-institutional research endeavors, and must include on their staff at least one CHSS member physician. These institutions should have a demonstrated track record of conducting and publishing the results of major clinical studies, and their staff should include a physician member with the background, tools, and availability to oversee the activities of the Data Center. Proposals should describe the institution's resources and capabilities to house and conduct the work of the Data Center, and should indicate proposed structure and criteria for Data Center staff. Institutions are encouraged to propose new paradigms. For example, consideration might be given to merging and collating data gathered through other multicenter databases with focused CHSS Data Center studies. An important element of the overall environment is the where-with-all to provide a meaningful educational experience for the Kirklín/Ashburn Fellow, which optimally should include the possibility of enrollment in a degree granting program (in a field such as biostatistics, public health, or clinical effectiveness.). The institution which is the current home of the Data Center is encouraged to submit a proposal, as are any and all other institutions which meet the aforementioned requirements.

Institutions which are contemplating a formal response to the "Request for Proposals" are asked to submit a preliminary "letter of intent" by **May 1, 2009** to:

Donna Kohli, Executive Director
Congenital Heart Surgeons Society
900 Cummings Center
Suite 221-U
Beverly, MA 01915
Phone: 978-927-8330
Fax: 978-524-8890