INTRODUCING: BRENDA CHOW, MSc, PhD

We are pleased to announce that Dr. Brenda M. Chow has joined the Data Center as Research Program Manager. In this capacity, she will direct day-to-day operations of the Data Center, assess and optimize personnel work flow, integrate novel management concepts and technology into our structure and research processes, manage Data Center finances, assist in the development and administration of Data Center-originated grant applications, and interface with the Executive Director and Managing Director in meeting the CHSS expectations for achievement in its research enterprise.

Dr. Chow was previously Grants Officer in the Research Awards and Financial Services department at The Hospital for Sick Children. She received her B.Sc. in Anatomy and Cell Biology from McGill University, and her Ph.D. in Molecular Genetics and the collaborative program in neuroscience at the University of Toronto, and is published in her areas of scientific specialization. Since 2012, she has acquired broad and considerable experience in managing research operations and research project teams at SickKids. Her extracurricular interest has been in promoting science, health and literacy in the Toronto-area’s public school systems.

We are quite excited that Dr. Chow has accepted this position. Please welcome Dr. Chow to our team!

KIRKLIN/ASHBURN FELLOWSHIP RECRUITMENT

The CHSS Data Center is inviting applications for the next John W. Kirklin/David Ashburn Fellowship. The focus of the fellowship is outcomes research, primarily of the many multi-institutional prospective cohort studies of the Congenital Heart Surgeons’ Society. The Fellow will become expert in database management and in all aspects of biostatistics and epidemiology. Particular emphasis is placed on the research methods, presentation at national meetings, and manuscript preparation and publication. Previous fellows have made important contributions to the field, including high profile international presentations and publication on behalf of the CHSS. The next Fellowship will begin in July of 2017. The selection process will include the requirement for completed applications and letters of recommendation to have been received by the Data Center on September 1, 2016. To see the full announcement, including application information, please visit the Data Center website.

COHORT SPOTLIGHT: AAOCA ISCHEMIA

Are there morphologic variants of AAOCA that predispose to ischemic events? Among the 500 AAOCA patients enrolled in the CHSS AAOCA cohort study to date, 29 have tested positive for ischemia or had a sudden cardiac arrest. 180 patients who were tested for ischemia had negative tests. The initial diagnostic echos of the ischemic patients are being reviewed to discern any correlations with positive vs. negative ischemia tests. Anyone interested in this project is invited and welcome to join the working group. If you would like to participate in this study please contact Jim Meza.
Figure 1. Total enrollment in actively enrolling CHSS cohorts: AVSD, LVOTO, AAOCA and TA, as of May 18, 2016. The number of patients enrolled since January 1, 2016 in AVSD=55; LVOTO=30; AAOCA=19; TA=7. Total enrollment for each cohort: AVSD=279; LVOTO=884; AAOCA=504; TA=360.

DR. JIM MEZA, KA FELLOW – PROGRESS UPDATE

The Spring Work Weekend in March focused on the two LVOTO echo studies and the Timing of Stage 2 analysis. The discussion was productive and helpful to me. Since then, I have been working through the analyses, guided by the feedback from the Work Weekend. This will result in the submission of four abstracts for the late spring/early summer meeting deadlines from the current analyses. In addition, thank you very much to those who participated in the survey of timing of Stage 2. We anticipate that it will yield some interesting insights into current practices across the field of congenital heart surgery and will be presented at the Joint Meeting of the CHSS and ECHSA in late June.

While it is surprising to see that my first year at the Data Center is nearly complete, it is encouraging to see these projects evolve from proposals to analyses and now into abstract submissions. I look forward to another productive year, working alongside the diligent Data Center staff.
5th Annual CHSS Coordinator Meeting

We are in the process of planning the CHSS Annual Coordinator Meeting on October 23-24, 2016 in Chicago, IL. The focus will be our new cohort “Ebstein Anomaly”. We will be reviewing the protocol in detail, in addition to other topics of interest. If you have topics you would like discussed please feel free to submit them to Linda Lambert at linda.lambert@imail.org. We would love to have each member surgeon represented by his/her coordinator! We will be providing CEU credits for both the coordinator breakout sessions as well as those we attend with the surgeons. This is in thanks to the executive committee who has agreed to cover this cost. We view coordinator attendance at this meeting as a method of engaging coordinators and stressing the vital role that coordinators play in the success of CHSS studies. We encourage surgeon members to speak with their coordinators and support them in attending this annual meeting.

Status of Current Studies

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<th>Study Name</th>
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CURRENT PROJECTS

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<td>Ebstein’s Anomaly</td>
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<td>Technical Assessment Project</td>
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<td>J. Karamichalis, T. Karamlou, M. Nathan, A. Grady</td>
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<td>Registry of Registries</td>
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<td>P. Gruber</td>
<td>W.G. Williams, W.M. DeCampli</td>
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MANUSCRIPTS

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Trends in Right Ventricular Dysfunction and Tricuspid Regurgitation after Single Ventricle Palliation of Hypoplastic Left Heart Syndrome and their Differential Impact on Survival

E. Hickey  JACC, March 2016  Submitted


Exercise restriction is not associated with increasing body mass index over time in patients with coronary arteries of anomalous aortic origin: A report from the CHSS AAOCA registry

B. McCrindle  JTCVS, May 2016  Submitted


Health-Related Quality of Life and Healthcare Responsibility in Adolescents with Aortic Valve Atresia

E. Blackstone  Nearing completion to Circulation or Pediatrics  Revisions

Stackhouse, K.

Aortic Valve Atresia: Neonatal Transplantation or Palliative Reconstruction? Insights from Long-Term Survival and Beyond

E. Blackstone  Nearing completion to JTCVS  Revisions

Stackhouse, K.

REGULATORY CONNECTION

Study Documentation Request to Participating Institutions/Sites

If you have not already done so, please provide a copy of the following to the CHSS Data Center for each CHSS research study in which your institution/site is participating (and the CHSS Data Center is the Coordinating Site for the study):

1. Institutional Review Board (IRB)/Research Ethics Board (REB)/Privacy Board

   a) Initial IRB/REB approval of the study

   b) IRB/REB approval of any amendments* subsequent to the initial IRB/REB approval of the study

   c) Any Privacy Board Approvals/Re-Approvals, as applicable [US sites only]

   d) Current IRB/REB-approved Consent Forms/Assent Forms, and for US sites only: any separate HIPAA Authorization used for the study (as applicable)

   e) Each IRB/REB re-approval/renewal/continuing approval of the study, subsequent to the initial IRB/REB approval of the study

   * Please ensure you have submitted recent amendments (approved by The Hospital for Sick Children (SickKids) REB in January 2016, and discussed at Study-Specific Coordinator Conference Calls in February 2016) to your IRB/REB (for AAOCA, LVOTO, TA and CHSS non-enrolling study cohorts, the submission target date was on or by 07 March 2016). The submission target date for the AVSD amendment and other amendments (approved by SickKids REB in May 2016) is on or by 02 July 2016. Please ensure you submit a copy of your IRB/REB
amendment approval letter(s) (and also any revised IRB/REB-approved consent/assent forms) to Kathryn Coulter as soon as these are received.

2. Contract – Data Transfer Agreement (DTA)

Please ensure that you have a fully executed DTA to cover all CHSS research studies in which your institution/site is participating (and CHSS Data Center is the Coordinating Site). A copy of the fully executed DTA needs to be on file at your institution/site, as well as at the CHSS Data Center.

*For your convenience, the current DTA templates are located on our website: www.chssdc.org – these are general DTA templates (one template for US institutions; one template for Canadian institutions), set up to cover all CHSS Data Center research studies you are/may be participating in. If you need a word document of the DTA template, please contact Kathryn Coulter.

If you are not sure if your institution/site has provided the above-requested documents/if you need to provide the requested documents/if you have any questions regarding this, please contact: Kathryn Coulter.

Please Note: There is no need to re-submit any documents that have already been submitted to the CHSS Data Center.

Study-Specific Coordinator Conference Calls

Please note that Amendments (approved by SickKids REB in May 2016) for the following studies will be discussed at the upcoming Study-Specific Coordinator Conference Calls (on Wednesday, 01 June 2016, at 2 pm (EST) and Thursday, 02 June 2016, at 11 am (EST)):

a. AVSD: updates/additions to study-specific documents and generic documents (to be more in line with the other CHSS research studies)

b. AAOCA, LVOTO, TA, CHSS non-enrolling study cohorts: some updates in the PedsQL™ inventories/questionnaires, and to the accompanying document – PedsQL™ & Conditions and Problems Questionnaire, Age & Consent/Assent Status

c. AAOCA, LVOTO: a few additions/updates to Data Collection Forms

If you have any questions or comments about these study amendments or processes, or about navigating the website to obtain study documents, or required timelines, please email Kathryn Coulter or call 1-866-477-2477 ext. 208477

GRANTS

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