



Congenital Heart Surgeons' Society Data Center
Our Research Saves Lives

CHSS Coordinator Newsletter

Introducing: Brenda Chow, MSc, PhD



We are pleased to announce that Dr. Brenda 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!

Study Enrollment Updates

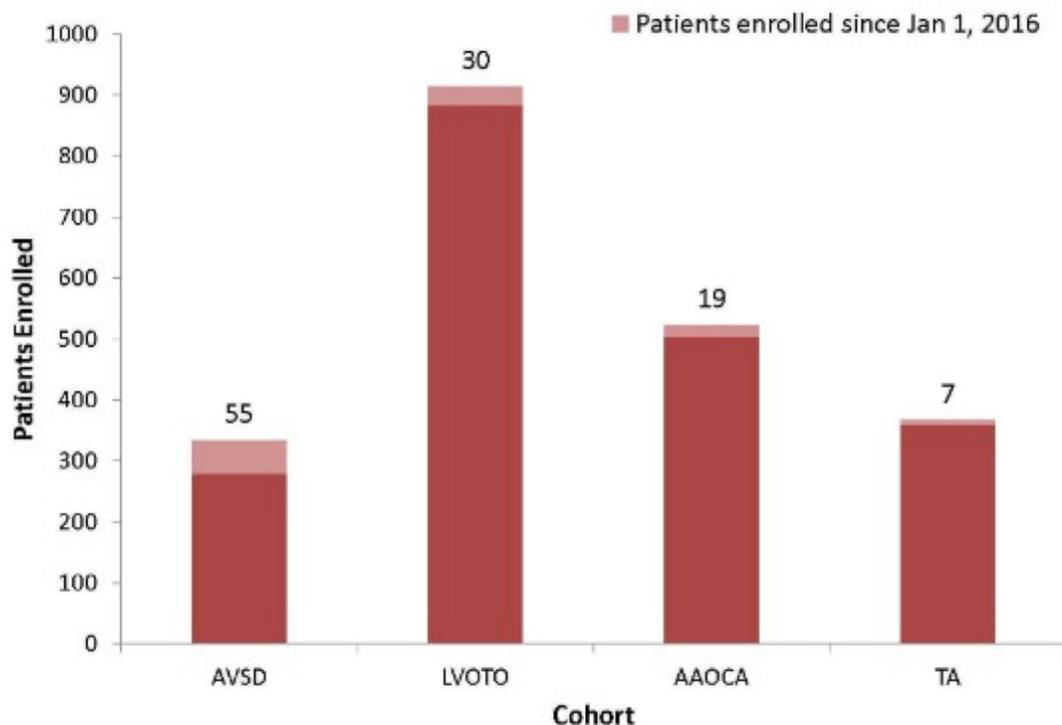


Figure 1. Total enrollment in actively enrolling CHSS cohorts: AVSD, LVOTO, AAOCA and TA, as of May 18, 2016. The number of patients enrolled since January 1, 2016 in AVSD=55; LVOTO=30; AAOCA=19; TA=7. Total enrollment for each cohort: AVSD=279; LVOTO=884; AAOCA=504; TA=360.

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

- Initial IRB/REB approval of the study
- IRB/REB approval of any amendments* subsequent to the initial IRB/REB approval of the study
- Any Privacy Board Approvals/Re-Approvals, as applicable [*US sites only*]
- Current IRB/REB-approved Consent Forms/Assent Forms, and for US sites only: any separate HIPAA Authorization used for the study (as applicable)
- 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](#) 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](#) – 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](#).

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](#).

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

[Kathryn Coulter](#)

Direct: 416-813-8477

Toll-free: 1-866-477-2477

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, **1 June 2016, at 2 pm (EST)** and Thursday, **2 June 2016, at 11 am (EST)**):

- AVSD: updates/additions to study-specific documents and generic documents (to be more in line with the other CHSS research studies)
- 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
- AAOCA, LVOTO: a few additions/updates to Data Collection Forms

Dr. Jim Meza, K/A 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. If you have any questions, feel free to contact [Jim Meza](#) directly.

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](#).

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 coordinators to speak with their surgeon members about supporting them in attending this annual meeting.



Banner courtesy of Congenital Heart Surgeons' Society Annual Meeting, © 2016 Congenital Heart Surgeons' Society

RIT-FTP

Research IT – File Transfer Program is a secure file transfer service provided by SickKids. Coordinators who would like to sign up can contact [Irina](#). When sending file(s) please communicate the PIN/Password to your recipient (Data Center staff) via telephone (**NOT** email). You may also leave a voicemail (for the corresponding staff member) with the password.

Note: Please ensure you have IRB/REB approval, as appropriate, in order to use this service

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