



CHSS MEMBERSHIP NEWSLETTER

CHSS SPRING WORK WEEKEND: MARCH 18-20

The CHSS Spring Work Weekend is fast approaching! If you haven't already done so, be sure to book your accommodations at the Chelsea Hotel. If you would like to be acquainted with the details of the weekend's presentations & sessions, please visit the CHSS website and follow the 'Work Weekend' link to review the agenda.

For those of you who are unable to attend this meeting in person, webinar and conference details will be posted to the website shortly so that you may participate at your convenience. We look forward to another productive weekend and hope you can attend. If you have any further questions, please do not hesitate to contact us at **1-866-477-2477** or chss.dc@sickkids.ca



COHORT UPDATE: AVSD ENROLLMENT

Since the push for enrollment request in December 2015 went out, our enrollment has increased substantially, from 205 to 259 patients. We hope to keep this rate of enrollment up as the year goes on.

If your institution is not actively participating in this cohort, we encourage you to participate. If you have any questions please do not hesitate to contact us.

Enrollment criteria are outlined below.

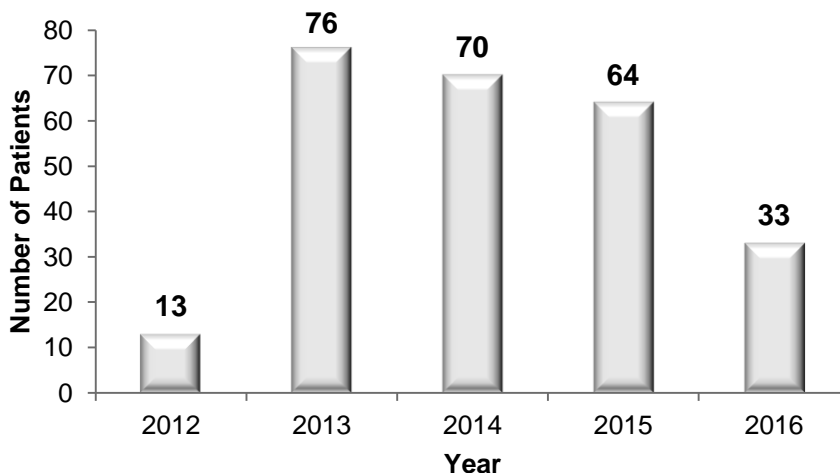


Figure 1 Yearly enrollment in AVSD from 2012 to February 2016

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> • Diagnosis complete AVSD • Admitted to a CHSS institution for surgery after January 1, 2012 • Age ≤ 365 days at admission for surgery • Atrioventricular and Ventriculoarterial concordance (includes Tetralogy of Fallot or Double Outlet Right Ventricle) 	<ul style="list-style-type: none"> • Partial or Transitional AVSD (separate AV valve orifices or non-existent ventricular septal defect) • Total or Partial Anomalous Pulmonary Venous Drainage (TAPVC or PAPVC) • Aortic Atresia • Heterotaxy • First Intervention at a non-CHSS institution



KA FELLOW PROJECT SPOTLIGHT – SURVEY

The Data Center will be performing a brief, 10 question survey of the CHSS and ECHSA membership to assess the current practice patterns around Stage 2 Palliation for Critical Left Ventricular Outflow Tract Obstruction. This survey will be part of the larger current CHSS project entitled 'The Optimal Timing of Stage 2 Palliation in Patients with Critical LVOTO' The survey will be distributed in early April and the results will be reported and discussed at the joint CHSS-ECHSA meeting in Venice, Italy in June. The Data Center is grateful for your participation!

STATUS OF CURRENT STUDIES‡

Study Name	P.I.	Start Date	Status	Working Group
LVOTO – Hybrid and Norwood survival comparison	C. Pizarro	Apr. 2014	Manuscript resubmitted to JTCVS	T.J. Wilder, E.J. Hickey, G. Ziemer, C.I. Tchervenkov, M.L. Jacobs, P.J. Gruber, E.H. Blackstone, B.W. McCrindle, W.G. Williams, W.M. DeCampi, C.A. Caldarone, C. Pizarro
LVOTO – Descriptive Echo Review	L. Mertens	Sep. 2014	Next meeting Mar 18-20	J. Meza, J. St. Louis, P. Gruber, K. Guleserian, D. Morales, J. Kirklín, J. Pearl, P. Eghtesady, P. Burch, A. Phillips, S.Fuller, C. Mavroudis, K. Pourmoghadam, P. Kirshbom, C. Mascio, A. Dodge-Khatami, A. Charaf Eddine, R. Kim, L. Mertens, M. Sliker
LVOTO – Analytic Echo Review	B. McCrindle	Dec. 2015	Analysis in progress	J. Meza, J. St. Louis, P. Gruber, K. Guleserian, D. Morales, J. Kirklín, J. Pearl, P. Eghtesady, P. Burch, A. Phillips, S.Fuller, C. Mavroudis, K. Pourmoghadam, P. Kirshbom, C. Mascio, A. Dodge-Khatami, A. Charaf Eddine, R. Kim, L. Mertens, M. Sliker
LVOTO – Optimal Timing of Stage 2	J. Jaquiss	Nov. 2015	Next meeting Mar 18-20	J. Meza, J. Jaquiss, B. McCrindle, E. Hickey, B. Anderson, E. Blackstone, S. Fuller, M. Jacobs, J. Kirklín, K. Pourmoghadam, J. Jacobs, D. Overman, P. Eghtesady, C. Tchervenkov, G. Mavroudis, R. Kim, W. Douglass, P. Chai, J. St Louis, G. Alfieris, P. Gruber, P. Manning, T. Yeh, A. Lodge, A. Dodge-Khatami, J. O'Brien, J. Gangemi, B. Peeler, B. Alsoufi, M. Mitchell, C. Huddleston, A. Fiore, T. Karl, M. Mill, E. Mendeloff, P. Burch, F. Scholl, R. Mosca, G. Lofland, G. Van Arsdell, C. Caldarone
AAOCA – BMI in weight restricted patients	B. McCrindle	Sep. 2014	Abstract accepted, to be presented at AATS in May 2016	J. Meza, M. Elias, T.J. Wilder, J. E. O'Brien, R. W. Kim, C. Mavroudis, W. G. Williams, J. Brothers, M. Cohen, B. W. McCrindle

‡We would like to encourage CHSS members to contact the Data Center if they wish to join a future working group



CURRENT PROJECTS

Project	Summary	Status	P.I.	Working Group
Ebstein's Anomaly	Study cohort	REB submission in progress	J. Dearani	C. Knott-Craig, C. Pizarro, K. Holst, J. Meza
Technical Assessment Project	Web program for members use	Active	G. Cohen	J. Karamichalis, T. Karamlou, M. Nathan, A. Grady
Registry of Biobanks	Registry of Registries	REB approved	P. Gruber	W.G. Williams, W.M. DeCampli
Imaging Core Lab	LVOTO/AOCA/AVSD	Active	L. Mertens	C. Fleishman

MANUSCRIPTS

Title	PI	Target Journal & Submission Date	Status	Working Group
Anomalous Aortic Origin of Coronary Arteries in the Young: Echocardiographic Evaluation and Surgical Correlation; A multicenter Congenital Heart Surgeons Society study	R. Lorber	Accepted to JACC Imaging, Apr. 2015	Published, Nov. 2015	R. Lorber, S. Srivastava, T.J. Wilder, S. McIntyre, W.M. DeCampli, W.G. Williams, P. Frommelt, I.A. Parness, E.H. Blackstone, M. Jacobs, L. Mertens, J. Brothers, J. R. Herlong
Surgical Management of Competing Pulmonary Blood Flow Affects Survival Before Fontan/Kreutzer Completion in Patients with Tricuspid Atresia Type I	G. Ziemer	Accepted to JTCVS, June 2015	Published, Nov. 2015	T.J. Wilder, G. Ziemer, E.J. Hickey, P.J. Gruber, T. Karamlou, P.M. Kirshbom, E.H. Blackstone, W.M. DeCampli, W.G. Williams, B.W. McCrindle
Hybrid Alternatives to Norwood Stage-1 are not a Lower Risk Alternative: Norwood-RVPA Offers Better Outcome in Comparable Neonates	C. Pizarro	JTCVS	Submitted, Feb. 2016	T.J. Wilder, E.J. Hickey, G. Ziemer, C.I. Tchervenkov, M.L. Jacobs, P.J. Gruber, E.H. Blackstone, B.W. McCrindle, W.G. Williams, W.M. DeCampli, C.A. Caldarone, C. Pizarro
Late survival and right ventricular performance for matched children with critical left ventricular outflow tract obstruction: Norwood with modified Blalock-Taussig shunt versus Norwood with right ventricle to pulmonary artery conduit	A. Phillips	Accepted to JTCVS, July 2015	Published, Dec. 2015	T.J. Wilder, B.W. McCrindle, E.H. Blackstone, R. Jeevanantham, W.G. Williams, W.M. DeCampli, J.P. Jacobs, M.L. Jacobs, T. Karamlou, P.M. Kirshbom, G.K. Lofland, A.B. Phillips, G. Ziemer, E. J. Hickey



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	To be submitted in March	T.J. Wilder, E. Blackstone, J. Rajeswaran, C. Caldarone, P.J. Gruber, B. Alsoufi, R. Jaquiss, C.I. Tchervenkov, J. Jaggars, M. Si, C. Mascio, C. Pizarro, D. Overman, E.J. Hickey
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.
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	To be discussed at Work Weekend	J. Meza, M. Elias, T.J. Wilder, J. E. O'Brien, R. W. Kim, C. Mavroudis, W. G. Williams, J. Brothers, M. Cohen, B. W. McCrindle

REGULATORY CONNECTION: CHSS STUDY AMENDMENTS

Overview of Amendments

There have been two sets of amendments:

First Set

1. AAOCA - Protocol Version 3 - 29 Jun 2015
 2. LVOTO - Protocol Version Date: 30 Jun 2015
 3. TA - Protocol Version Date: 01 Jul 2015
- Addition of accompanying documents, both study specific **AND** generic

Second Set

1. AAOCA - Protocol Version 4 - 22 Sep 2015
 2. LVOTO - Protocol Version Date: 22 Sep 2015
 3. TA - Protocol Version Date: 22 Sep 2015
 4. CHSS Studies (non-enrolling)- Protocol Version Date: 22 Sep 2015
- Addition of/and revisions to current accompanying documents, both study-specific **AND** generic

AAOCA Amendment: Protocol Version 3 - 29 Jun 2015

- To further detail/clarify current processes, and add process changes (e.g., use of Consent for Release of Medical Information; use of CHSS Data Center Registration Form);
- Added current process of welcoming parents/guardians of new subjects and new subjects enrolled into the study;
- Privacy, Security, Confidentiality sections reworded/updated for further clarify

Note: SickKids Scientific Peer Review recommendations, resulted in updates to the following sections of the Protocol: Follow-Up, Confidentiality



LVOTO Amendment: Protocol 30 June 2015

- To further detail/clarify current processes, and add process changes (e.g., use of Consent for Release of Medical Information; use of CHSS Data Center Registration Form);
- Now including waiver/alteration to include deceased subjects;
- Added current process of welcoming parents/guardians of new subjects enrolled into the study;
- Confidentiality and Security section added to further detail processes;
- Risk Assessment section added;
- Statistical Analysis section revised;
- Publications section added

Note: SickKids Scientific Peer Review recommendations, resulted in updates to the following sections of the Protocol: Background, Study Population, Study Design, Follow-up, Outcomes/Follow-up, and Statistical Analysis

TA Amendment: Protocol 01 July 2015

- A newly created TA protocol (Version Date: 08 June 2015) was created to describe our current processes, containing the essential elements per standard protocol requirements in observational research
- Revisions to that version were made, after SickKids Scientific Peer Review and prior to submission to SickKids REB (resulting in Protocol Version Date: 01 Jul 2015)
- Those further updates to the protocol include:
 - The process of welcoming newly enrolled, CHSS registered participants;
 - Revisions in Statistical Considerations section

AAOCA, LVOTO, TA Amendments: June/July 2015

- Coordinators were notified via email on September 30th regarding SickKids REB approval of the amendments for TA, AAOCA, and LVOTO studies
- Approved documents were posted on the website at that time
- Some participating institutions chose to submit the above mentioned amendments to their IRB/REB shortly after the September 30th notification
- The majority of participating institutions did not submit their amendments at that time and instead decided to await the second round of amendments initiated in September, thus only dealing with one submission instead of two

AAOCA, LVOTO, TA Amendments: September 2015

These amendments were initiated to streamline the Follow Up and other processes outlined below:

Previous Version	Updated Version
1. AAOCA: Protocol Version 3 – 29 Jun 2015	1. AAOCA: Protocol Version 4 – 22 Sep 2015
2. LVOTO: Protocol Version Date: 30 Jun 2015	2. LVOTO: Protocol Version Date: 22 Sep 2015;
3. TA: Protocol Version Date: 01 Jul 2015	3. TA: Protocol Version Date: 22 Sep 2015
4. CHSS Non-enrolling Study Cohorts: Protocol Version Date: 2013 10 23	4. CHSS Non-enrolling Study Cohorts: Protocol Version Date: 22 Sep 2015

Numerous (revised and/or new) accompanying documents (some study-specific; some generic: for use in AAOCA, LVOTO, TA, and CHSS non-enrolling Study Cohorts) Version Date range: Sep to Dec 2015



AAOCA, LVOTO, and TA Cohorts

Revisions to Protocols:

- To further detail/clarify current processes and add process changes (e.g. addition of questionnaires for annual follow-up);
- Clarification with respect to consent process, to include authorization, as applicable;
- Clarification of process of welcoming subjects into the study when they consent for themselves to continue participation
- Clarification with respect to obtaining consent for release of medical information
- Privacy section: further details provided with respect to the transfer of information to the CHSS DC
- References: PedsQL references added as well as other minor administrative changes in text

CHSS Non-enrolling Study Cohorts Amendment - Protocol 22 Sep 2015

Revisions to Protocol:

- To clarify that this is the protocol for the non-enrolling CHSS study cohorts (closed to enrollment), that are in follow-up phase only (see separate Appendices in the protocol, addressing details of each of these cohorts)
- To further detail/clarify current processes, and add process changes (e.g., addition of Questionnaires for annual follow-up);
- Clarification with respect to consent process, including the role of the CHSS Data Center with respect to the consent process (specifically, obtaining consent from parents/guardians and subjects who are eligible to provide consent, in cases where the subjects are no longer followed by the institutions where they were originally enrolled into the study in or before the year 2000);
- Clarification with respect to obtaining consent for release of medical information;
- Confidentiality section: further details provided with respect to the current processes, including the transfer of information to the CHSS Data Center;
- References: PedsQL™ references added;
- Other minor administrative changes in text

SickKids REB Approval granted for:

- AAOCA
- LVOTO
- TA
- CHSS non-enrolling cohort studies (amendments initiated in September 2015) in January 2016

Where to Find Documents

- Current SickKids REB Approved documents are posted on the website. To locate study documents please visit our website and choose a specific study from the menu.

Approval was also obtained for 50 PedsQL™ Inventories (these are not posted on the website, as they are copyright protected materials). We've outlined specific processes in the document PedsQL™ Quality of Life and Cardiac Module Inventories... Age & Consent/Assent Status (Version Date: 22 Oct 2015)

What Documents Will I Find?

1. (7) Protocol Amendment Summary Documents (under the applicable specific study section)
 - Information from these Summary documents may be used if needed for your IRB/REB amendment submissions
2. Current SickKids REB-approved Protocols:
 - Clean copy: needed for IRB/REB submission;



- Track changes copies, if needed for IRB/REB submission, *and*
- Current accompanying documents (some 'study-specific'; some 'generic'): as needed for IRB/REB submission (as applicable)

Note:

- Some documents are *study-specific* [applicable only to that one Study (and listed under that Study specifically on the website)], and
- Some documents are *generic* (i.e., current SickKids REB-approved for use for all the following studies: CHSS non-enrolling cohorts; TA; LVOTO; AAOCA)
 - The *generic* documents can be accessed only through each of the above-noted Study sections, which links up with the 'generic documents for enrollment, registration & follow up' section
- If your institution is participating in, or would like to participate in, any of the studies, you may copy the documents, as needed, for your own IRB/REB initial or amendment submissions, as applicable (except for the consent/assent documents and related cover letters, which are posted for *reference only*; for those documents: you may adapt the text if you wish and make it specific to your own institution (as applicable), for submission to your IRB/REB for review/approval)

Study Documents NOT Posted to Website

1. PedsQL™

- PedsQL™ Inventories will be (or have been) sent to you, under separate cover, for IRB/REB submission, as needed
- These PedsQL™ Inventories may only be used for your IRB/REB submission for the above-noted studies (***may not*** be used by sites to administer the PedsQL™; ***may not*** be used for any other purpose)

2. Amendment Instructions Document

- An Amendment Instructions document for each of the amended studies (AAOCA; LVOTO; TA; CHSS non-enrolling Cohorts) was sent to participating institutions (in Feb 2016)
- For the study/ies your institution is participating in: please submit the(se) amendment(s) to your IRB/REB on or by 07 Mar 2016)

Tracking Amendment Approval

You will receive email communications, on an approximately monthly basis, or as needed, to track your amendment progress up to your IRB/REB amendment approval. Please submit a copy of your IRB/REB amendment approval document(s) [including any approved revised consent (and authorization, as applicable) and assent forms] directly to **Kathryn**, as soon as obtained from your IRB/REB.

Consent/Assent and/or Re-Consent/Re-assent

- After receiving your IRB/REB amendment approval, if you are required to re-consent your study participants/parents-guardians, and/or re-assent (or obtain assent), please obtain this ASAP thereafter
- Then submit most recent re-consent; re-assent (or assent) signed documents, via secure file transfer or via secure courier, to the CHSS Data Center, ASAP, but no later than **01 August 2016**
- Your IRB/REB amendment approval letter, signed consent/assent documents [and/or pertinent explanations (e.g., written re-consent/re-assent is not required, as implied consent is sufficient for Questionnaire completion; or assent is not applicable, as Subject lacks capacity to provide assent)] will be used/reviewed by the CHSS Data Center to determine what Annual Follow-up Questionnaires are to be administered by CHSS Data Center



- Please also refer to the 'generic' document: PedsQL™ Quality of Life and Cardiac Module Inventories ... Age & Consent/Assent Status (Version Date: 22 Oct 2015) for further process and examples of explanations
- Submission of the above-noted documentation and adherence to these timelines are very important, to keep the Annual Follow-up timelines on schedule for 2016

Upcoming AVSD Study Amendment

Revisions to the AVSD Study have been made to address the processes already addressed and approved in the other studies and have been submitted to SickKids REB for renewal and approved. You will be notified when SickKids REB Approval is granted for this AVSD Study Amendment.

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

Agency	Start Date	End Date	P.I.	Status
The Children's Heart Foundation	2012	Extended to 2015	J. Jacobs	Ongoing
The Michael H. Ludwig Memorial Foundation	2012	Renewed in 2014	J. Brothers	Ongoing

During the CHSS Work Weekend, we will be having two breakout sessions that will focus on grant writing. We will be targeting the Gerber Foundation and the American Heart grant. We hope to adopt this process and incorporate grant writing into future Work Weekend meetings in order to garner more support for upcoming studies and/or projects.