



CHSS DATA CENTER NEWSLETTER

THE 2017 KIRKLIN-ASHBURN FELLOW: DR. PAUL DEVLIN



The Data Center is pleased to announce the appointment of Dr. Paul Devlin as the 8th Kirklin-Ashburn (KA) Fellow, who will start his fellowship in July 2017.

Originally from Annapolis, Maryland, Paul attended Northwestern University for his undergraduate studies where he received his degree in Biology with a concentration in Neurobiology. His interest in congenital cardiac surgery started there, when he raised money for the Children's Heart Foundation in the Dance Marathon. He remained at Northwestern for medical school as a part of the Honor's Program in Medical Education.

In medical school, Paul pursued his interest in congenital cardiac surgery via an internship at Northwestern's Bluhm Cardiovascular Institute. He conducted clinical research at Lurie Children's hospital with his mentor, Dr. Carl Backer. He studied clinical outcomes of patients with doubly committed juxta-arterial VSDs and partial atrioventricular septal defects, resulting in several presentations at conferences and two publications in the Annals of Thoracic Surgery. He has fond memories learning the anatomy of these diseases with Dr. Robert Anderson during his visiting professorship at Lurie Children's. The physiology of a heart defect, its direct linkage to the heart's anatomy, and the ability to fix it is what draws Paul into congenital cardiac surgery.

Paul is currently a second-year resident in the Integrated Cardiothoracic Surgery program at Northwestern Medicine. In his role as the Kirklin/Ashburn Fellow, Paul looks forward to learning from the CHSS membership as they work to answer

clinical questions uniquely suited to the CHSS registry's longitudinal data set. Through this work, he will gain the toolset he will need in his future career as an academic congenital cardiac surgeon.

Paul would like to thank all of the patients and their families who have contributed their health information, as well as the many coordinators who facilitate its collection, to form the CHSS registry. It has enabled life-changing research and he is humbled by the opportunity to take part in the process.

RECIPIENT OF THE J. MAXWELL CHAMBERLAIN AWARD: DR. JAMES M. MEZA

We at the Data Center would like to congratulate James Meza, KA Fellow, who was recently awarded the J. Maxwell Chamberlain Memorial Paper. Jim's work focuses on the Optimal Timing of Stage 2 Palliation after Norwood. He will be presenting his work at the 53rd Society of Thoracic Surgeons (STS) in Houston in January 2017. Please congratulate Jim, P.I. Jake Jaquiss, and the entire team of investigators on this well-deserved recognition.

DR. JAMES MEZA, KA FELLOW – PROGRESS UPDATE

The summer rapidly transitioned into the fall here in Toronto, the Data Center's most busy time. The 4th Joint Meeting of the CHSS and ECHSA was a great meeting held in a beautiful city, in Venice, which will be a true highlight of my fellowship. More recently, I enjoyed providing a brief snapshot of the variety of analyses that are in progress at Data Center currently at the Annual Meeting at the end of October. Any member who wishes to participate in the studies is definitely encouraged to contact me. In addition, I just



returned from presenting at the 5th Scientific Sessions of the World Society for Pediatric and Congenital Heart Surgery in Abu Dhabi, UAE. I'll be next heading to the AHA to present the results of the cluster analysis of the Critical LVOTO baseline echocardiography data set. A few days later, I'll return to Toronto to help lead discussions at my 3rd Work Weekend. A major focus will be the project entitled, "Timing of Stage 2 Palliation after the Norwood," as it was selected for the Chamberlain Paper in Congenital Heart Surgery for presentation at the 53rd Annual Meeting of the STS in Houston in late January. I look forward to your input on this project and the others. I'm very grateful for the time, suggestions, and revisions that many of you have provided to me so far and look forward to continued collaboration.

DC STAFF SPOTLIGHT: KRISTINA KOVACH, RN

Kristina Kovach has proven herself to be a valuable and dedicated member of the Data Center team. Since April, she has taken on 2 of the most active and highest enrolling cohorts: AVSD and LVOTO. She has worked extensively with Dr. Meza in data extraction for multiple LVOTO abstracts and manuscripts. She has also worked closely with echo sonographer Cheryl Fackoury, from the Imaging Core Lab, and fellow Data Center colleague, Iliana Ristevska, in reconciling the AVSD echo database, reports and images. These responsibilities are in addition to her daily tasks, which she has so seamlessly incorporated into her routine. We are pleased to have her as a member of our team and appreciate all of her hard work thus far!

FALL 2016 WORK WEEKEND NOVEMBER 18-20 – SAVE THE DATE!

The biannual Data Center Work Weekend is fast approaching. This year we are piloting the use of an

online event planning platform, CVENT, in order to more efficiently manage the coordination of these meetings in the future. The membership should have received an email invitation to register for the meeting. Please ensure that you have registered **before November 14, 2016**. If you haven't received an invitation, please [email us](#) as soon as possible in order to be added to the list.

Note: You may also register to attend the Work Weekend remotely, via webinar.



ENROLLMENT UPDATE

We have had a major enrollment increase (total=273) in our actively enrolling cohorts, particularly in AVSD and LVOTO. A big thanks goes to those coordinators and members who went above and beyond to meet (and exceed) the call for enrollment for AVSD this past year. Your engagement and commitment is evident in these totals.

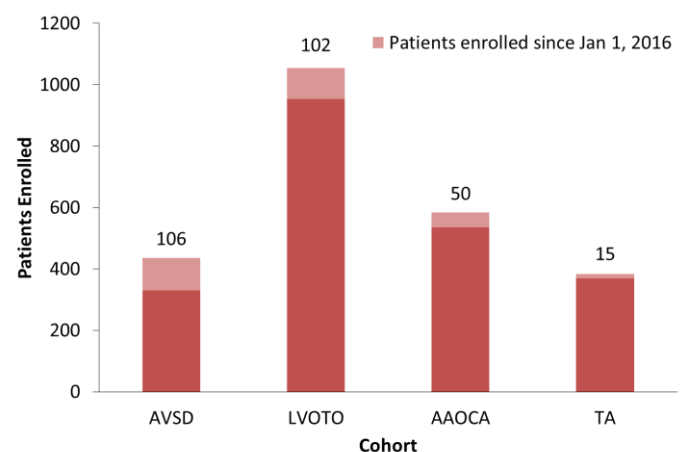


Figure 1. Total enrollment in actively enrolling CHSS cohorts: AVSD, LVOTO, AAOCA and TA, as of October 27, 2016. The number of patients enrolled since January 1, 2016 in AVSD=106; LVOTO=102; AAOCA=50; TA=15. Total enrollment for each cohort: AVSD=330; LVOTO=953; AAOCA=535; TA=369.



5TH ANNUAL COORDINATOR MEETING: A RECAP

We would like to thank all of the coordinators that were able to attend the 5th Annual Coordinator meeting, held in conjunction with the CHSS annual meeting in Chicago, as well as the executive committee, member surgeons and institutions for their support. This has been the best attended meeting to date!

Dr. Bill Williams welcomed the coordinators and presented an overview of the current status of enrollment, stressing the importance of maintaining current IRB/REB approval. Dr. Brenda Chow, the Data Center manager, presented the organizational structure of the Data Center, enrollment and follow up process, as well as roles and responsibilities of each of the data center staff. Dr. Jim Meza, discussed the important role that the coordinators play in contributing the data to each of the studies and responding to the follow up requests. He reviewed the abstracts and publications that were completed as a result. Dr. Kim Holst presented Ebstein Anomaly, anatomy and physiology as well as the protocol for the upcoming “new study” Ebstein Anomaly. It is hopeful that this study will be launched in 2017. Kathryn Coulter updated all on the regulatory requirements and encouraged us all to review the status at our sites to ensure all IRB/REB submissions have been completed and approved documents have been sent to the data center. Our last session, led by Susan McIntyre, gave the group an opportunity to openly discuss issues of enrollment and follow-up strategies as well as administrative hurdles.

In addition to the coordinator breakout sessions, coordinators were encouraged to attend the surgeon sessions and data center report. As part of the data center report we were honored to present awards to two outstanding coordinators. Igor Bondarenko was presented an award for “long standing coordinator” having attended all coordinator meetings, calls and work weekends as well as contributing to the various

studies. Margaret Graupe was presented an award for the “newest coordinator”. Her attention to detail and enrollment of over 30 subjects over the past year was outstanding. We are hopeful that this will become an annual event.

For those of you in attendance, we hope you found this year's meeting informative and educational. You will be receiving an email shortly to complete an evaluation; once completed, you will receive your certificate for continuing education credits. For coordinators who weren't able to attend, you should have received a link with the presentations. We encourage you to make plans for next year's meeting to be held once again in Chicago in conjunction with the surgeons' annual meeting.

COORDINATOR SURVEY

The CHSS Data Center is always interested in staying in touch with all coordinators regarding the CHSS studies. However, with over 70 active sites and busy schedules, it is difficult to arrange conference calls to accommodate everyone's schedules and agendas. To ensure that the Data Center is meeting coordinators' needs, we will be launching a survey in November to obtain general feedback on current procedures and to ask for your opinion on future initiatives. Please feel free to let us know your thoughts on all issues big and small. If you would like to see a specific question included in the survey, please [contact us!](#)

REGULATORY CONNECTION

Study Documentation Request to Participating Institutions/Sites

I. Institutional Review Board (IRB)/Research Ethics Board (REB)

Please provide a copy of the following directly to Kathryn Coulter **ASAP** for each CHSS research study in which your institution/site is participating:



1. Your **current** IRB/REB re-approval/renewal/continuing approval of the study
2. Your **current** IRB/REB-approved Consent Forms/Assent Forms, and for US sites only: any separate HIPAA Authorization used for the study (as applicable)
3. Your **2016** IRB/REB approval of any ***amendments** [i.e., amendment approvals received from your IRB/REB in 2016]

If you are not sure if your institution/site has provided the above-requested documents or if you have any questions regarding this, please contact: [Kathryn Coulter](#).

***2016 Amendments:**

For the CHSS studies in which your institution/site is participating, please ensure you have submitted:

- (a) the **amendments** for AAOCA, LVOTO, TA and CHSS non-enrolling study cohorts (approved by The Hospital for Sick Children (SickKids) REB in January 2016, to your IRB/REB

Note:

(i) target date for providing a copy of your IRB/REB amendment approval letters (and any revised IRB/REB-approved consent/assent forms/HIPAA authorizations) to Kathryn Coulter was on or by 01 August 2016

(ii) target date for providing a copy of any re-consent/assent required by your IRB/REB for the amendment (as applicable), to the CHSS Data Center, via secure file transfer or secure courier, was on or by 01 August 2016

- (b) the **amendments** for AVSD (approved by SickKids REB in January 2016 and May 2016, to your IRB/REB

Note:

(i) target date for providing a copy of your IRB/REB amendment approval letters (and any revised IRB/REB-approved consent/assent forms/HIPAA authorizations) to Kathryn Coulter was on or by 01 October 2016

(ii) target date for providing a copy of any re-consent/assent required by your IRB/REB for the amendment (as applicable), to the CHSS Data Center, via secure file transfer or secure courier, was on or by 01 October 2016

- (c) the **amendments** for AAOCA, LVOTO, TA and CHSS non-enrolling study cohorts (approved by SickKids REB in May 2016 to your IRB/REB

Note:

(i) target date for providing a copy of IRB/REB amendment approval letters to [Kathryn Coulter](#) was on or by 01 October 2016

Please Note: There is no need to re-submit any parent/guardian or subject signed consent/assent forms that have already been submitted to the CHSS Data Center.

II. 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, or if you have any questions regarding this, please contact: [Kathryn Coulter](#).

Please Note: There is no need to re-submit any fully executed DTA that has already been submitted to the CHSS Data Center.

Special Consideration:

Not having your institutional/site IRB/REB approvals, as indicated above and any re-consents/assents required by your IRB/REB as a result of an amendment (if applicable), and the fully executed DTA, on file at the CHSS Data Center, impacts the CHSS Data Center's ability to continue with cross-sectional annual follow-up.

CRITICAL AS CALCULATOR: A CORRECTION



HOME | SUCCESS STORIES | GET INVOLVED | CHSS FORUM | RESOURCES & KNOWLEDGE

chss score for neonatal critical aortic stenosis

calculator

for neonatal critical aortic stenosis

data collection

Weight (kg):

Height (cm):

BSA:

Presence of moderate or severe aortic regurgitation:

Mean aortic velocity (cm):

Presence of large ventricular septal defect:

Length of aortic stenosis ventricle (mm):

Minimum diameter of the left ventricular outflow tract (mm):

Presence of left ventricular dysfunction:

Grade of endocardial brown pigmentation:

Diameter of the mitral valve annulus (mm):

CHSS Score:

[Click here to get score](#)

It was brought to our attention that the explanation under the [Critical AS calculator](#) was incorrect. With careful consideration we have corrected it to read:

“The score is the predicted difference in 5-year survival for a UVR minus a BVR. A positive number favors a BVR; a negative number favors a UVR, with the magnitude of the difference expressed by the number. For example, a CHSS Score of +10 predicts that 5-year survival is 10% greater for a BVR versus a UVR. A score of -20 predicts that 5-year survival after a UVR is 20% greater than after a BVR.”

FEEDBACK & SUGGESTIONS

If you have any ideas or suggestions for content you would like to see in the next issue of the Data Center Newsletter, please [contact us](#) with your contributions. We welcome the opportunity for the membership, associates and coordinator group to communicate topics of interest and provide the Data Center with feedback.



STATUS OF CURRENT STUDIES

Study Name	P.I.	Start Date	Status	Working Group
AAOCA – Predictors of Ischemia	J. Brothers	Nov. 2015	Study design in progress	W. Williams, M. Jacobs, J. Brothers, L. Mertens, S. Srivastava, R. Lorber, J.R. Herlong, C. Fleishman, W. Gaynor, R. Dabal, M. Elias, J. Johnson, P. Koenig, C. Mavroudis, M. McCullouch, C. Mery, S. Molossi, S. Paridon, A. Sing, I. Bondarenko, W. DeCampi, T. Karamlou, T. Wilder, S. McIntyre
LVOTO – Survival through staged procedures in the Norwood and Hybrid pathways	J. Jaquiss	May 2016	Accepted to World Society Scientific Sessions	J. Meza, R. Jaquiss, B. McCrindle, E. Hickey, B. Anderson, E. Blackstone, S. Fuller, M. Jacobs, J. Kirklin, K. Pourmoghadam, J. Jacobs, D. Overman, P. Egtesady, 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
AVSD – Baseline echo descriptive analysis	D. Overman	Oct. 2016	Submitted to AATS	J. Meza, L. Mertens, G. Baffa, M. Cohen, M. Quartermain, D. Gremmels, C. Fackoury, C. Caldarone, W. Williams, W. DeCampi, and D. Overman
LVOTO – Descriptive Echo Review	L. Mertens	Sep. 2014	Accepted to EuroEcho meeting	J. Meza, J. St. Louis, P. Gruber, K. Guleserian, D. Morales, J. Kirklin, J. Pearl, P. Egtesady, 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. Slieker
LVOTO – Analytic Echo Review	B. McCrindle	Dec. 2015	Accepted to AHA	J. Meza, J. St. Louis, P. Gruber, K. Guleserian, D. Morales, J. Kirklin, J. Pearl, P. Egtesady, 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. Slieker
LVOTO – Optimal Timing of Stage 2	J. Jaquiss	Nov. 2015	Accepted to STS	J. Meza, R. Jaquiss, B. McCrindle, E. Hickey, B. Anderson, E. Blackstone, S. Fuller, M. Jacobs, J. Kirklin, K. Pourmoghadam, J. Jacobs, D. Overman, P. Egtesady, 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
LVOTO – Timing of Stage 2 Survey	B. McCrindle	May 2016	Accepted to WJPCHS	J. Meza, R. Jaquiss, B. Anderson, M. Moga, J. Kirklin, W. Williams, B. McCrindle
AAOCA – BMI in weight restricted patients	B. McCrindle	Sep. 2014	Resubmitted to Cardiol Young	J. Meza, M. Elias, T. Wilder, J. O'Brien, R. Kim, C. Mavroudis, W. Williams, J. Brothers, M. Cohen, B. McCrindle



MANUSCRIPTS

Title	PI	Target Journal & Submission Date	Status	Working Group
Is a Hybrid Strategy a Lower-Risk Alternative to Stage 1 Norwood Operation?	C. Pizarro	JTCVS, Aug. 2016	Published	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
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	Accepted	T.J. Wilder, E. Blackstone, J. Rajeswaran, C. Caldarone, P.J. Gruber, B. Alsoufi, R. Jaquiss, C.I. Tchervenkov, J. Jagers, M. Si, C. Mascio, C. Pizarro, D. Overman, E.J. Hickey
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	Cardiology in the Young, May 2016	Resubmitted	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
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.



CURRENT PROJECTS

Project	Summary	Status	P.I.	Working Group
Ebstein's Anomaly	Study cohort	Protocol submitted to REB, awaiting approval	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/AAOCA/AVSD	Active	L. Mertens	C. Fleishman