Overview of the Data Center

William M. DeCampli MD, PhD
Congenital Heart Surgeons Society Data Center
The Hospital for Sick Children, Toronto, CA
The Heart Center at Arnold Palmer Hospital for Children
University of Central Florida College of Medicine
October 23, 2017
1. Introduction  Carl Backer
2. Research Committee  Jim Kirklin
3. Data Center Overview  Bill DeCampli
4. Current Research  Paul Devlin
5. TGA Overview  Bill Williams
6. Data Center Operations  Brenda Chow
7. Awards  Linda Lambert
Personnel: Faculty

- Blackstone, Gene (CCF)
- DeCampli, Bill (UCF, APH)
- Fleishman, Craig (UCF, APH)
- McCrindle, Brian (U of T, HSC)
- Mertens, Luc (U of T, HSC)
- Williams, Bill (U of T, HSC)
Personnel: Staff

Brenda Chow, PhD
Linda Lambert, ARNP
Susan McIntyre, RN
Tina Kovach, RN
Katrina Pearson, RN, MN
Kathryn Coulter, MS
Sally Cai, MSc
Arti Singh, B. Tech, MPH
Julia Lo, BSc

Program Manager
Head, IDC Team
Research Coordinator
Research Coordinator
Research Coordinator
Regulatory Officer
Database Manager
Research Project Asst
Research Project Asst
9th Kirklin Ashburn Fellow 2017-2019

• Paul Devlin, MD
• Integrated GS/CTS Program, Northwestern University
## Prospective Inception Cohorts

<table>
<thead>
<tr>
<th>Diagnostic Group</th>
<th>Number of Institutions</th>
<th>Accrual Date</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transposition of Great Arteries</td>
<td>24</td>
<td>1985-1989</td>
<td>891</td>
</tr>
<tr>
<td>Pulmonary Atresia with Intact Ventricular Septum</td>
<td>33</td>
<td>1987-1997</td>
<td>448</td>
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<tr>
<td>Interrupted Aortic Arch</td>
<td>33</td>
<td>1987-1997</td>
<td>470</td>
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<tr>
<td>Coarctation of the Aorta</td>
<td>36</td>
<td>1990-1993</td>
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<tr>
<td>Aortic Valve Atresia</td>
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<td>1994-2000</td>
<td>566</td>
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<tr>
<td>Critical Aortic Stenosis</td>
<td>28</td>
<td>1994-2000</td>
<td>422</td>
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<tr>
<td>Tricuspid Atresia</td>
<td>38</td>
<td>1999-Present</td>
<td>382</td>
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<tr>
<td>Pulmonary Conduit</td>
<td>29</td>
<td>2002-2014</td>
<td>632</td>
</tr>
<tr>
<td>Critical Left Ventricular Outflow Tract Obstruction</td>
<td>27</td>
<td>2005-Present</td>
<td>1033</td>
</tr>
<tr>
<td>Anomalous Aortic Origin of Coronary Arteries</td>
<td>44</td>
<td>2009-Present</td>
<td>594</td>
</tr>
<tr>
<td>Atrioventricular Septal Defect</td>
<td>28</td>
<td>2012-Present</td>
<td>423</td>
</tr>
</tbody>
</table>

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[CHSS Data Center]
Cumulative Enrollment (as of October 5, 2017)

Number of Subjects

Cumulative Enrollment


Total Enrollment: 6843
Enrollment by Cohort (as of October 5, 2017)

- TGA: 168
- IAA: 470
- CoA: 975
- PA/IVS: 448
- AVA: 566
- AVS: 422
- PC: 632
- TA: 383
- LVOTO: 1038
- AAOCA: 594
- AVSD: 424

Number of Subjects
Subjects Presumed Alive (as of October 11, 2017)

- TGA: 671
- IAA: 274
- PA/IVS: 270
- AVA: 254
- AVS: 261
- PC: 581
- TA: 341
- LVOTO: 744
- AAOCA: 581
- AVSD: 382
## Follow-Up by Cohort

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Median (years)</th>
<th>Maximum (years)</th>
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<tr>
<td>AAOCA</td>
<td>0.67</td>
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<tr>
<td>AVA</td>
<td>1.19</td>
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<td>LVOTO</td>
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<td>TGA</td>
<td>22.6</td>
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</table>
Ebstein’s anomaly

- Drs. Dearani, Knott-Craig, Pizarro
- Kim Holst, MD
- Includes retrospective gathering of fetal echo data
- In regulatory process as of 10/23/17
- Separate proposal to prospectively enroll fetuses being considered
Publications 2016-7


4. Meza, JM; Elias, ME; Wilder, TJ; O’Brien, JE; Kim, RW; Mavroudis, C; Williams, WG; Brothers, J; Cohen, MS; McCrindle, BW; Congenital Heart Surgeons’ Society. Exercise restriction is not associated with increasing body mass index over time in patients with anomalous aortic origin of the coronary arteries. Cardiol Young. 2017 May 2:1-7. doi: 10.1017/S104795111700066X. PMID: 28460658

5. Meza, JM; Hickey, EJ; McCrindle, BW; Blackstone, EH; Anderson, BR; Overman, DM; Kirklin, JK; Caldarone, CA; Guleserian, KJ; Kim, RW; DeCampli, WM; Jacobs, ML; Mitchell, ME; Chai, PJ; Williams, WG; Jaquiss, RDB. The J. Maxwell Chamberlain Memorial Paper for Congenital Heart Surgery – The Optimal Timing of Stage-2-Palliation after the Norwood Operation: A Multi-Institutional Analysis from the Congenital Heart Surgeons’ Society. In press at the *Annals of Thoracic Surgery*, June 21, 2017.

6. Meza, JM; Hickey, EJ; Blackstone, EH; Jaquiss, RDB; Anderson, BR; Williams, WG; Cai, S; Van Arsdell, GS; Karamlou, T; McCrindle, BW. The optimal timing of Stage-2-Palliation for Hypoplastic Left Heart Syndrome: An analysis of the Pediatric Heart Network Single Ventricle Reconstruction Trial public dataset. *Circulation*. 2017 Jul 7. pii: CIRCULATIONAHA.117.028481. doi: 10.1161/CIRCULATIONAHA.117.028481. [Epub ahead of print]

Pending - LVOTO descriptive echo (resubmitting to JASE), LVOTO cluster analysis (resubmitting to JASE), AVSD descriptive echo (re-submitted to JTCVS), LVOTO dynamic risk profiles (presenting at AHA, draft manuscript complete), several other (two I think) SickKids analyses
Presentations 2016-7

Meza, JM; Elias, ME; Wilder, T; O’Brien, JE; Kim, RW; Mavroudis, C; Williams, WG; Brothers, J; Cohen, M; McCrindle, BW. 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. Presented at the 96th Annual Meeting of the American Association for Thoracic Surgery, May 17, 2016, Baltimore, MD.

2. Mazine, A; Meza, JM; Guergerian, AM; Caldarone, C. Health Care Costs of Hybrid and Norwood Strategies. Presented at the 4th Joint Meeting of the ECHSA and CHSS, June 23, 2016, Venice, Italy.

3. Meza, JM; Hickey, EJ; Jaquiss, RDB; Blackstone, EH; Anderson, BA; Cai; S; Williams, WG; Van Arsdell, GS; McCrindle, BW. The optimal timing of Stage-2-Palliation for Hypoplastic Left Heart Syndrome: An Analysis of the Pediatric Heart Network Single Ventricle Reconstruction Public Database. Presented at the 4th Joint Meeting of the ECHSA and CHSS, June 23, 2016, Venice, Italy.


5. Meza, JM; McCrindle, BW; Blackstone, EH; Karamlou, T; Scholl, F; Lodge, AJ; Gruber, PJ; Dodge-Khatami, A; Jacobs, JP; O’Brien. JE; Alsoufi, B; Caldarone, CA; Guleserian, KJ; Pourmoghadam, K; Eghtesady, P; Manning, P; Jaquiss, RDB. Comparing Survival Through Staged Procedures in the Norwood and Hybrid Pathways: A Report from the CHSS Data Center. Presented at the 5th Scientific Meeting of the World Society for Pediatric and Congenital Heart Surgery, October 29, 2016, Abu Dhabi, UAE. (Highest scoring abstract)
6. Meza, JM; Slieker, MG; Mertens, L; Blackstone, EH; Eghtesady, P; Pourmoghadam, K; Kirklin, JK; DeCampli, WM; Jacobs, ML; Karamlou, T; Burch, PT; Karimi, M; Pearl, J; Fuller, SJ; Mascio, C; McCrindle, BW. A novel, data-driven approach to classify critical Left Ventricular Outflow Tract Obstruction using pre-intervention echocardiographic measurements: A report from the Congenital Heart Surgeons’ Society Data Center. Presented at the American Heart Association 2016 Scientific Sessions, November 15, 2016, New Orleans, LA.

7. Mazine, A; Meza, JM; Guerguerian, AM; Haller, C; Schwartz, SM, McCrindle, BW; Van Arsdell, GS; Honjo, O; Caldarone, CA. Costs of the Norwood and Hybrid strategies for single ventricle palliation. A report from the Congenital Heart Surgeons’ Society Data Center. Presented at the American Heart Association 2016 Scientific Sessions, November 15, 2016, New Orleans, LA.

8. Slieker, MG; Meza, JM; McCrindle, BW; Tchervenkov, C; Jacobs, ML; DeCampli, WM; Burch, PT; Mertens, L. Pre-intervention morphologic and functional echocardiographic characteristics of 651 neonates with critical left ventricular outflow tract obstruction. Presented at EuroEcho-Imaging 2016, December 9, 2016, Leipzig, Germany.

9. Meza, JM; Hickey, EJ; McCrindle, BW; Blackstone, EH; Anderson, BR; Overman, DM; Kirklin, JK; Caldarone, CA; Guleserian, KJ; Kim, RW; DeCampli, WM; Jacobs, ML; Mitchell, ME; Chai, PJ; Williams, WG; Jaquiss, RDB. The J. Maxwell Chamberlain Memorial Paper for Congenital Heart Surgery – The Optimal Timing of Stage-2-Palliation after the Norwood Operation: A Multi-Institutional Analysis from the Congenital Heart Surgeons’ Society. Presented at the 53rd Annual Meeting of the Society of Thoracic Surgeons, January 23, 2017, Houston, TX.


11. Jean-St-Michel, E; Meza, JM; McCrindle, BW. Risk factors for death or heart transplant after the Norwood procedure: A secondary analysis of the Single Ventricle Reconstruction Trial. Accepted for presentation at the International Society for Heart and Lung Transplantation, 37th Annual Meeting and Scientific Sessions, April 5-8, 2017, San Diego, CA.

12. Meza, JM; Mertens, L; Baffa, G; Cohen, MS; Quartermain, MD; Gremmels, D; Fakoury, C; Caldarone, CA; Williams, WG; DeCampli, WM; Overman, DM. The CHSS Complete Atrioventricular Septal Defect Inception Cohort: Pre-Intervention Echocardiographic Characteristics. Presented at the American Association for Thoracic Surgery Centennial Meeting, May 2, 2017, Boston, MA.

Pending - LVOTO dynamic risk profiles (AHA, Early Career Investigator Award abstract competition)
<table>
<thead>
<tr>
<th>Study Title</th>
<th>Authors</th>
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<tr>
<td>AAOCA: Ischemia subgroup descriptive (AATS abstract submitted)</td>
<td>Brothers, Jegatheeswaran &amp; WG</td>
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<tr>
<td>AAOCA: Ischemia vs. morphology</td>
<td>Brothers, Jegatheeswaran &amp; WG</td>
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<tr>
<td>AVSD baseline echo characteristics (accepted to <em>Seminars TCVS</em>)</td>
<td>Mertens &amp; WG</td>
</tr>
<tr>
<td>LVOTO: arch obstruction after stage 1 (AATS abstract submitted)</td>
<td>Eghtesady, Karamlou &amp; WG</td>
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<tr>
<td>LVOTO: Stage II timing vs outcome II</td>
<td>Jaquiss, WG</td>
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<tr>
<td>LVOTO: Baseline echo descriptive analysis (to be submitted to JASE)</td>
<td>Burch, Mertens &amp; WG</td>
</tr>
<tr>
<td>LVOTO baseline echo cluster analysis (to be submitted to JASE)</td>
<td>Mertens, Slieker &amp; WG</td>
</tr>
<tr>
<td>AVSD pre-discharge echo vs outcome</td>
<td>in development</td>
</tr>
</tbody>
</table>
Proposals in development

TGA: late follow up, survival, neo-aortic root, coronary artery status

Coarctation late follow up

Starnes

Poirier
Enrollment Challenges

Institutional Enrollment (Oct 1, 2016 - Sept 30, 2017)

<table>
<thead>
<tr>
<th>Number of Institutions</th>
<th>TA</th>
<th>LVOTO</th>
<th>AAOCA</th>
<th>AVSD</th>
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<tbody>
<tr>
<td></td>
<td>9</td>
<td>17</td>
<td>21</td>
<td>21</td>
</tr>
</tbody>
</table>

Number of Institutions
• For 10 yr period 2007-2016, we enrolled 2100 patients, or 210 per year
• If every center enrolled 1 patient/month, then in next 5 years we would have 6200+4800 =
  • 11,000 enrollees
• Would be close to 2000 patients enrolled in LVOTO
<table>
<thead>
<tr>
<th>Institution</th>
<th>Inst Code</th>
<th># Enrolled over 12 months</th>
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<tbody>
<tr>
<td>Cincinnati Children's Hospital Medical Center</td>
<td>A</td>
<td>24</td>
</tr>
<tr>
<td>SickKids</td>
<td>B</td>
<td>21</td>
</tr>
<tr>
<td>Primary Children's</td>
<td>C</td>
<td>20</td>
</tr>
<tr>
<td>St. Louis Children's Hospital</td>
<td>D</td>
<td>19</td>
</tr>
<tr>
<td>University of Alabama</td>
<td>E</td>
<td>18</td>
</tr>
<tr>
<td>Children's Hospital of Philadelphia</td>
<td>F</td>
<td>17</td>
</tr>
<tr>
<td>Children's Mercy Hospital, Kansas City</td>
<td>G</td>
<td>17</td>
</tr>
<tr>
<td>Minnesota, Children's Heart Clinic of MN</td>
<td>H</td>
<td>15</td>
</tr>
<tr>
<td>Indiana University</td>
<td>I</td>
<td>13</td>
</tr>
<tr>
<td>University of Mississippi Medical Center</td>
<td>J</td>
<td>11</td>
</tr>
</tbody>
</table>

> 50% of institutions enrolled ZERO patients
Follow up challenges

• “Lost to follow up” tends to be progressive
• Follow up is regulated by IRB of the original institution
• Multiple transitions of care impede acquisition of medical records
• Ebsteins and AAOCA mostly followed by cardiologists, out of the purview of the surgical services (and its IDC)
Ratio of Follow-Up Responses to Subjects Presumed Alive

- TGA: 0.14
- IAA: 0.24
- PA/IVS: 0.35
- AVA: 0.33
- AVS: 0.44
- PC: 0.46
- TA: 0.40
- LVOTO: 0.37
- AAOCA: 0.33
- AVSD: 0.20
Growth challenges

• Fixed income, no substantial grant support
• Cohort populations will grow in number
• Scope of work will increase (outsourcing process, regulation)
• Personnel costs will rise, space demands will increase
Operational projects in progress

• Data outsourcing
• Digitalization of stored data
• Follow up by social media and/or app
• Convert to direct relationship between patient and Data Center *vis-à-vis* follow up medical records
• Centralized or “single” IRB (sIRB in NIH jargon)
<table>
<thead>
<tr>
<th>Perceived Advantages of Local IRBs</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Claims that local IRBs reflect community values</td>
</tr>
<tr>
<td>- Local knowledge of subjects</td>
</tr>
<tr>
<td>- Of vulnerable populations</td>
</tr>
<tr>
<td>- Therefore, easier to judge risks and benefits</td>
</tr>
<tr>
<td>- Local knowledge of PIs</td>
</tr>
<tr>
<td>- &quot;Track records&quot;/reputations</td>
</tr>
<tr>
<td>- Protecting &quot;our own&quot; subjects</td>
</tr>
<tr>
<td>- Perceived responsibilities to protect local patients</td>
</tr>
<tr>
<td>- &quot;Curbside consults&quot; with PIs</td>
</tr>
<tr>
<td>- Formal and informal</td>
</tr>
<tr>
<td>- Can facilitate mutual trust</td>
</tr>
<tr>
<td>- More dialogue</td>
</tr>
<tr>
<td>- Appreciation of local institutional culture</td>
</tr>
<tr>
<td>- Desires for local autonomy, authority, and comfort</td>
</tr>
<tr>
<td>- Against &quot;being told what to do&quot;</td>
</tr>
<tr>
<td>- Wariness of centralized, federal bureaucracy</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Perceived Problems with CIRBs</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Differences between CIRBs</td>
</tr>
<tr>
<td>- Depends on who are members of the committee</td>
</tr>
<tr>
<td>- For-profit CIRBs may have conflicts of interest</td>
</tr>
</tbody>
</table>

The National Institutes of Health (NIH) is issuing this policy on the use of a single Institutional Review Board (IRB) for multi-site research to establish the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States. The goal of this policy is to enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible. Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies without diminishing human subjects protections. The shift in workload away from conducting redundant reviews is also expected to allow IRBs to concentrate more time and attention on the review of single site protocols, thereby enhancing research oversight.
## Annualized Revenues (CDN)*

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
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<tr>
<td>CHSS Institutional Dues**</td>
<td>$647,500</td>
</tr>
<tr>
<td>Cardiovascular Surgery, SickKids</td>
<td>62,364</td>
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<tr>
<td>NWU Feinberg School of Medicine</td>
<td>38,672</td>
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<tr>
<td>Competitive Grants</td>
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<tr>
<td>Charitable contributions</td>
<td>75,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>823,536</strong></td>
</tr>
</tbody>
</table>

*9/1/2016 – 8/31/2017

**based on anticipated receipts from 83 institutions (21 outstanding)

Note: current exchange rate 1.25, down from 1.35 12 mos ago
## Annualized Expenses (CDN)

<table>
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<th>Description</th>
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<tr>
<td>Staff Salaries &amp; Benefits</td>
<td>$604,606</td>
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<tr>
<td>KA Fellow S&amp;B + Tuition</td>
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<td>KA Fellow support</td>
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<td>Supplies &amp; Services</td>
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<td>Work Weekends</td>
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<tr>
<td>Imaging Core Lab</td>
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<td><strong>Total</strong></td>
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Charitable Support

Ludwig Foundation
Berlin Heart
Dr. Rich Lorber
Medtronic
Cryolife
Children’s of Minnesota
Fall 2017 Work Weekend: Nov 17-19

chss work weekend
chss fall 2017 work weekend

When: November 17-19, 2017
Where: Peter Gilgan Centre for Research & Learning
686 Bay Street
Toronto, Ontario
M5G 0A4, Canada

Agenda: Please see the agenda here. Last updated on October 19, 2017.
Event Website: Please see our event website here.
Registration: Please use this link here.
END
Kirklin-Ashburn Fellow Report

Paul Devlin
Project Updates

• Atrioventricular Septal Defect

• Anomalous Aortic Origin of a Coronary Artery

• Critical Left Heart Obstruction [LVOTO]
Atrioventricular Septal Defect
• Baseline Echo Review and Correlation Analysis:
• 257 pre-operative echoes reviewed and analyzed

The CHSS Complete Atrioventricular Septal Defect Cohort:

Baseline, Pre-intervention Echocardiographic Characteristics

James M. Meza, MD\textsuperscript{1}; Paul J. Devlin, MD\textsuperscript{1}; David M. Overman, MD\textsuperscript{2}; David Gremmels, MD\textsuperscript{3}; Gina Baffa, MD\textsuperscript{4}; Meryl S. Cohen, MD\textsuperscript{5}; Michael D. Quartermain, MD\textsuperscript{5}; Christopher A. Caldarone, MD\textsuperscript{1}; Kamal Pourmoghadam, MD\textsuperscript{6}; William M. DeCampli, MD, PhD\textsuperscript{6}; Cheryl T. Fackoury, RDCS\textsuperscript{7}; and Luc Mertens, MD, PhD, FASE\textsuperscript{7}
AVVI

RV LV Inflow Angle

LVII

LVII/RVII

Minor Index

LAVV Annulus Diameter

RAVV Annulus Diameter

RV Area end diastole

LV Area end diastole
<table>
<thead>
<tr>
<th></th>
<th>AVVI</th>
<th>RVLV Inflow Angle</th>
<th>LVII</th>
<th>LVII/RVII</th>
<th>Minor Index</th>
<th>LAVV Annulus Diameter</th>
<th>RAVV Annulus Diameter</th>
<th>RV Area end diastole</th>
<th>LV Area end diastole</th>
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<td>0.07</td>
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<td>AVVI</td>
<td>RVULV Inflow Angle</td>
<td>LVII</td>
<td>LVII/RVII</td>
<td>Minor Index</td>
<td>LAVV Anulus Diameter</td>
<td>RAVV Anulus Diameter</td>
<td>RV Area end diastole</td>
<td>LV Area end diastole</td>
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</table>
Conclusions

• There was less correlation than anticipated among commonly used measures of unbalance

• Future analysis will relate unbalance indices and post-operative echoes to outcome
Echo Quality Feedback

• AVSD Imaging Protocol distributed at study initiation
• Varying degree of quality among submitted echoes
• AVVI was unable to be analyzed in 56/257 (22%)
<table>
<thead>
<tr>
<th>ECHO Image</th>
<th>n</th>
<th>Complete (%)</th>
<th>Quality (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcostal Enface View of Common AV Valve</td>
<td>9</td>
<td>100</td>
<td>67</td>
<td>17</td>
</tr>
<tr>
<td>Apical Four Chamber View</td>
<td>6</td>
<td>100</td>
<td>33</td>
<td>67</td>
</tr>
<tr>
<td>Color Inflow into LV</td>
<td>6</td>
<td>100</td>
<td>33</td>
<td>17</td>
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</tbody>
</table>
## Institution Name (enrolled n=10, reviewed n=9, full review n=6)

<table>
<thead>
<tr>
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<th>Complete (%)</th>
<th>Quality (%)</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Subcostal Enface View of Common AV Valve</td>
<td>9</td>
<td>100</td>
<td>67 17 17 0</td>
<td>&quot;A clear outline of both sides of the valve at the same time was not seen well&quot;</td>
</tr>
<tr>
<td>Apical Four Chamber View</td>
<td>6</td>
<td>100</td>
<td>33 67 0 0</td>
<td>&quot;Wonderful! Not foreshortened! Yay!&quot;</td>
</tr>
<tr>
<td>Color Inflow into LV</td>
<td>6</td>
<td>100</td>
<td>33 17 33 17</td>
<td>&quot;Another clip of the A4C view would be appreciated.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&quot;all your colour in A4C is zoomed to look at valve regurg. Nice, but not useful for measuring. Require colour box to include entire LAVV annulus and LV inflow.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&quot;no zoom please. Need to see the entire inflow&quot;</td>
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<td></td>
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<td>&quot;please ensure colour box is covering entire LV inflow, several cycles&quot;</td>
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<tr>
<td>ECHO Image</td>
<td>Complete (%)</td>
<td>Quality (%)</td>
<td>Comments</td>
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<td>100</td>
<td>67</td>
<td>Have a clear outline of both sides of the valve at the same time.</td>
<td></td>
</tr>
<tr>
<td>Apical Chamber View</td>
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<td>Wonderful! Not foreshortened! Yay!</td>
<td></td>
</tr>
<tr>
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</tr>
<tr>
<td></td>
<td></td>
<td>17</td>
<td>Need to see the entire inflow.</td>
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<td></td>
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### ECHO Image

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</tr>
</tbody>
</table>
Subcostal En-Face View of Common AV Valve

Color Inflow into LV
Subcostal En-Face View of Common AV Valve

Color Inflow into LV
Improvement of Image Quality

• Echo quality reports will be distributed to each institution

• Imaging protocol will be re-circulated

• Concurrent quality monitoring in future imaging analyses
Anomalous Aortic Origin of a Coronary Artery
Ischemic Patient Descriptive Analysis

• We sought to describe anatomic features of patients who present with ischemia

• Ischemic at initial presentation defined as:
  • Exertional syncope
  • Exertional arrhythmia
  • Positive exercise test, stress echo, nuclear perfusion defect
  • Aborted sudden death
  • Sudden death
Ischemic Patient Descriptive Analysis

• 49/560 (9%) of patients with AAOCA presented with ischemia
AAOCA Patients

AAOCA Cohort
n=560

No Testing
n=275

Ischemic Patients
n=49

Negative Ischemia Testing
n=236

Sudden Event
n=18

No Sudden Event
n=31
Ischemic patients vs. negative ischemia testing (n=49) vs. (n=236)

- Anomalous Left Coronary
  - 28/49 (57%) vs. 46/236 (19%)

- Ischemic AAOLCA (28pts)
  - intramural course
  - high orifice
  - slit-like orifice
AAOCA Cohort
n=560

No Testing
n=275

Ischemic Patients
n=49

Negative Ischemia Testing
n=236

Sudden Event
n=18

No Sudden Event
n=31
Ischemia Patients with (n=18), vs. without (n=31) Sudden Event

- No significant differences in anatomic features

- Anomalous Right Coronary
  - 6/18 sudden event patients
Management of 49 Ischemic Patients

- 40 repairs
  - 39 unroofed
  - 4 reoperations for ostial stenosis
- 9 Non-surgical:
  - 4 died
  - 4 referred for surgical repair
  - 1 lack of follow up
• Abstract submitted to AATS Annual Meeting

Anomalous aortic origin of a coronary artery (AAOCA): Are we closer to risk stratification?

A Jegatheeswaran MD, PhD, P Devlin MD, BW McCrindle MD, MPH, WG Williams MD, CA Caldarone MD, WM DeCampli MD, PhD, JW Gaynor MD, ML Jacobs MD, JK Kirklin MD, RO Lorber MD, CM Mery MD, MPH, S Molossi MD, JD St. Louis, MD, J Brothers MD
Critical Left Heart Obstruction
[LVOTO]
Interstage Intervention for Arch Obstruction After Norwood

• We sought to determine the prevalence and risk factors

• 593 patients underwent Norwood, 2005 – 2017

• 119 (20%) had interstage arch interventions
Arch Interventions After Norwood and Before or during Stage II Procedure

Arch interventions
n=151

119 patients

Catheter
n=115
(21 at pre-stage II cath)

100 patients

Surgical
n=36

33 patients

Balloon Dilation
n=112

Stenting of Coarctation
n=4

Isolated Arch Repair
n=14

Concurrent with SVCPA
n=17

Concurrent with HTX
n=3

Concurrent with Yasui
n=2
Arch Obstruction Post-Norwood

• Risk factors:
  • Decreased Risk:
    • Interdigitating distal arch repair
  
  • Increased Risk:
    • PA-Aorta connection without patch (Brawn type anastomosis)
    • Longer cardiopulmonary bypass time
    • Presence of sinusoids on pre-op echo
Interdigitating Repair

Igor Konstantinov © 2002
Institutional Variability

• Proportion of patients with arch re-intervention:
  Range: 0 – 46%

• Pre-intervention gradient for catheter arch intervention
  Median: 20.0mmHg (2 to 62)
Conclusions

- There is a high risk of arch obstruction during the interstage period after Norwood.

- Interdigitating repair of the distal aortic anastomosis is protective against arch obstruction.

- A standardized definition of arch obstruction is needed.
Critical Left Heart Obstruction

• Abstract submitted to AATS Annual Meeting

Intervention for Arch Obstruction in the Interstage Period Following Norwood: Prevalence, Risk Factors, and Practice Variability

Paul J. Devlin, MD, Brian W. McCrindle, MD, MPH, Pirooz Eghtesady, MD, PhD, Bahaaladin Alsoufi, MD, PhD, Eugene H. Blackstone, MD, James M. Meza, MD, William M. DeCampli, MD, PhD, James K. Kirklin, MD, Jeffrey P. Jacobs, MD, Ali Dodge-Khatami, MD, Kristine J. Guleserian, MD, James E. O’Brien, MD, Erle H. Austin III, MD, Peter J. Gruber, MD, PhD, and Tara Karamlou, MD, MSc
Critical Left Heart Obstruction

Manuscripts being revised for submission to Journal of the American Society of Echocardiography:

• Baseline Descriptive Echocardiography

• Cluster Analysis of Baseline Echoes
Future Questions

**AVSD**
- What determines success of a biventricular repair?

**AAOCA**
- Can (CT/MRI) add to understanding morphology?
- Is negative ischemia testing reassuring?
Future Questions

Critical Left Heart Obstruction

• Does arch obstruction impact function of RV & TV?

• Does arch obstruction affect transition to Fontan?

• Does baseline morphology affect outcomes?
Future Questions

Critical Aortic Stenosis
• Does 2-V repair improve late functional health?

• Your ideas
Thank you

Friday November 17th – Sunday November 19th 2017
Congenital Heart Surgeons’ Society
TGA Enrollment 1985 to 1989
24 CHSS institutions

2017 update
# Congenital Heart Surgeons’ Society
## TGA Enrollment 1985 to 1989
### 24 CHSS institutions

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>N</th>
<th>% of Total</th>
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<tr>
<td>Simple TGA</td>
<td>661</td>
<td>74.2 %</td>
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<tr>
<td>TGA / VSD</td>
<td>184</td>
<td>20.7 %</td>
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<tr>
<td>TGA / VSD / PS</td>
<td>43</td>
<td>4.8 %</td>
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<tr>
<td>TGA / IVS / PS</td>
<td>3</td>
<td>0.3 %</td>
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</table>

891 neonates
Congenital Heart Surgeons’ Society
TGA Enrollment 1985 to 1989
24 CHSS institutions

Repair Type for Isolated TGA or TGA/VSD

**Atrial**

- Mustard: 110
- Senning: 175

**Arterial**

- Rastelli: 29

Total: 830 neonates
Survival after Repair of Transposition
CHSS 1985 to 2017

Survival after repair of transposition CHSS 1985 to 2017

N= 830
685           635
572          474          378          107           0

% Survival

Years post repair

TGA (830/171)

77%
Mortality PRIOR TO Repair of Transposition
CHSS 1985 to 1989

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Pre-repair Deaths</th>
<th>Mortality</th>
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<tbody>
<tr>
<td>ASO</td>
<td>8</td>
<td>1.5%</td>
</tr>
<tr>
<td>Mustard</td>
<td>12</td>
<td>10.0%</td>
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<tr>
<td>Senning</td>
<td>12</td>
<td>6.5%</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>32</strong></td>
<td><strong>3.9%</strong></td>
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Survival after Repair of Transposition
CHSS 1985 to 2017

% Survival

Years post repair

N= 285  239  225  211  167  127  48  0
N= 516  419  385  338  289  242  58  0

ASO(516/101)

ATR(285/66)

74%  79%  74%
Survival after Atrial Repair of TGA
CHSS 1985 to 2017

% Survival

Years post repair

Mustard (110/17)

Senning (175/49)
Hazard after Repair of Transposition
CHSS 1985 to 2017

ASO (516/101)

Senning (175 / 49)

Mustard (110/17)
### Late (Silent) Pulmonary Hypertension in Adult TGA post Atrial Repair

<table>
<thead>
<tr>
<th>ACHD Center</th>
<th>Clinic Patients</th>
<th>Caths</th>
<th>Mean Age</th>
<th>Pulmonary Hypertension</th>
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<tbody>
<tr>
<td>Montreal 1</td>
<td>144</td>
<td>33</td>
<td>34</td>
<td>18 (54%)</td>
</tr>
<tr>
<td>Toronto 2</td>
<td>≈ 250</td>
<td>96</td>
<td>39</td>
<td>48 (50%)</td>
</tr>
</tbody>
</table>

1. Chaix et al Late onset pulmonary hypertension with TGA post atrial repair J Am Heart Assoc. 2017;2 006481
1. Van De Bruaene & Roche. Personal communication
Survival after Repair of Transposition
CHSS 1985 to 2017

% Survival

Years post repair

N= 29
27
25
23
18
9
1
0

% Survival

84%

Rastelli 29/4)
Congenital Heart Surgeons’ Society
TGA Enrollment 1985 to 1989
24 CHSS institutions

Acknowledgment & Thanks.

Sally Cai  MSc.
What are potential TGA research projects?

1. Why does the late hazard for atrial repairs differ?
2. What can be learned from the Rastelli experience?
3. What factors affect late functional health outcomes?
4. What are late re-interventions after the ASO?
What each institution needs in 2017:

1. IRB agreement
2. Data Transfer Agreement
3. IRB (annual) renewal
4. Informed consent
5. IRB Amendment approval
6. Assent
7. Continuing consent
8. Re-consent
9. Documentation of all of the above

- Principal Investigator
- Data Coordinator
Survival after Repair of Transposition
CHSS 1985 to 2017

% Survival

Years post repair

Mustard (110/17)

ASO (516/101)

Senning (175/49)

N = 516
N = 419
N = 385
N = 338
N = 289
N = 242
N = 58
N = 0

0 5 10 15 20 25 30 35

N = 110
N = 103
N = 99
N = 97
N = 73
N = 50
N = 24
N = 0
Hazard after Repair of Transposition
CHSS 1985 to 2017

ASO(516/101)

Senning (175 / 49)

Mustard (110/17)
Long term outcome up to 30 years after the Mustard or Senning operation: a nationwide multi-centre study in Belgium

Moons, Gewillig et al Heart:2004:90(3);307–313.
### Re-Intervention post TGA Repair

<table>
<thead>
<tr>
<th>Repair Type</th>
<th>N</th>
<th>Total</th>
<th>% Re-ops.</th>
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<tbody>
<tr>
<td>ASO</td>
<td>514</td>
<td>122</td>
<td>24%</td>
</tr>
<tr>
<td>Mustard</td>
<td>108</td>
<td>27</td>
<td>25%</td>
</tr>
<tr>
<td>Senning</td>
<td>173</td>
<td>35</td>
<td>20%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>795</td>
<td>184</td>
<td>23%</td>
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<tr>
<th>Repair</th>
<th>Pacer</th>
<th>AoValve</th>
<th>Baffle</th>
<th>ASD</th>
<th>Coronary</th>
<th>HtTx</th>
<th>PA St.</th>
<th>Ablation</th>
<th>Misc</th>
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<tbody>
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<td>10</td>
<td>15</td>
<td>0</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>82</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Mustard</td>
<td>10</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Senning</td>
<td>17</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>37</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>1</td>
<td>5</td>
<td>83</td>
<td>6</td>
<td>16</td>
</tr>
</tbody>
</table>
Hazard after Mustard Repair of TGA HSC - Mustard (442/125)
Hazard after Repair of Transposition
CHSS 1985 to 2017

Rastelli 29/4)
Hazard after Repair of Transposition
CHSS 1985 to 2017

Senning (175 / 49)

Mustard (110 / 17)
Data Center Update

Brenda Chow, PhD
Manager, CHSS Data Centre
New CHSS Data Center Staff

Clinical Project Research Assistants

Arti Singh
- BTech in Biotechnology
- Masters in Public Health
- Clinical Research Diploma

Julia Lo
- BSc Health, Disease & Sociology
- Clinical Research Diploma
Congratulations on Your Retirement!

Annette Flynn

• Clinical Research Project Coordinator
• 27 years at SickKids
• 6 years with Data Centre

Susan McIntyre

• Clinical Research Nurse Coordinator
• 36 years at SickKids
• 8 years with Data Centre
Joining CHSS Studies

• Choose an enrolling study/studies
  • AAOCA, AVSD, LVOTO and/or TA

• Study coordinator

• IRB Approval Letter

• Data Transfer Agreement
## Initial Commitment

Assumption: enrollment is 10 subjects/year for a prospective study

<table>
<thead>
<tr>
<th>Task</th>
<th>Month</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial IRB/REB Approval</td>
<td>1, 2</td>
<td>4</td>
</tr>
<tr>
<td>DTA</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Training</td>
<td>5, 6</td>
<td>10</td>
</tr>
<tr>
<td>Identify and Consent New Subjects</td>
<td>7, 8, 9</td>
<td>20</td>
</tr>
<tr>
<td>Collect Documents and Send to DC</td>
<td>10, 11, 12</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>41</strong></td>
</tr>
</tbody>
</table>

- **IRB/REB**
- **Legal**
- **Coordinator**
Informed Consent

Consent (Parent/Guardian) 0-17 years old

Assent (Child) 7-17 years old

Continuing Consent (Adult) 18+ years old
Subsequent Commitment

- Enrollment continues at 10 subjects/year
- An IRB/REB Amendment is required
- A new DTA is required (template or PI change)

<table>
<thead>
<tr>
<th>Task</th>
<th>Month</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB/REB Renewal</td>
<td>1</td>
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<tr>
<td>IRB/REB Amendment</td>
<td>4</td>
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<tr>
<td>DTA Update</td>
<td>2</td>
<td>2</td>
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<tr>
<td>Training</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Identify and Consent New Patients</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Update Informed Consents - Enrolled Patients</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Collect Data and Send to DC</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
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<td><strong>47</strong></td>
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</table>
CHSS Studies are for Life

• IRB/REB Oversight is **ALWAYS** Required!
  
  • Follow-up is life-long
  
  • Renew even if the study participant is no longer at your institution
  
  • Must **always** have a study PI at site
Summary

• Maintain IRB/REB oversight
  • PI at site
  • Renewals approved
  • Amendments approved

• Update DTAs

• Study Coordinator
Coordinator Awards