



# Critical Left Ventricular Outflow Tract Obstruction (LVOTO) Study

## PATIENT ENROLLMENT FORM

### OVERALL GOAL & OBJECTIVES:

- Assemble a multi-institutional inception cohort of infants with critical LVOTO undergoing all currently available treatment strategies is proposed.
- Identify risk factors that are predictive of late outcomes
- Determine the value of emerging management strategies
- Assess late outcomes by functional assessment, quality of life, developmental outcomes and identification of electrophysiological complications.

### INCLUSION CRITERIA:

- Neonate ( $\leq$  age 30 days at admission to a CHSS institution) Date of Admission AFTER December 31, 2004.
- AV & VA concordance whose LVOTO precludes an adequate systemic cardiac output through the aortic valve. This may include Critical LVOTO due to either aortic valve stenosis **OR** anatomically normal but hypoplastic left heart (*refer to study protocol for details*).
- Informed consent from patient's parent or guardian

**NOTES:** 1. Patients with a VSD will be included. 2. Patients who meet criteria but have died prior to surgery will be included.  
3. Patients in the NIH Pediatric Network Studies will be included.

### EXCLUSION CRITERIA:

- First intervention at non-CHSS institution
- AV or VA discordance.
- Atrioventricular Septal Defect

### To be completed by Enrollment Institution, for EACH patient being enrolled

Patient: \_\_\_\_\_ Date of first admission: \_\_\_\_\_  
 Parent Name: \_\_\_\_\_ Hospital #: \_\_\_\_\_  
 Address: \_\_\_\_\_ Cardiac Diagnosis: \_\_\_\_\_  
 \_\_\_\_\_  
 Phone: \_\_\_\_\_ Paediatric Cardiologist: \_\_\_\_\_  
 Date of Birth: \_\_\_\_\_ Institution: \_\_\_\_\_  
 Death Date (if applicable): \_\_\_\_\_ Surgeon: \_\_\_\_\_  
 Gender:  Male  Female Race: \_\_\_\_\_ Local M.D. \_\_\_\_\_

### What needs to be sent for each patient?

- Copy of signed consent.
- A copy of the initial echo tape for independent, blinded review and qualitative analysis.**
- Admission slip or equivalent for demographic information.
- Echo reports (*pre & post cardiac procedures*).
- Admission history and physical.  
(to include height, weight, oxygen saturation, signs and symptoms)
- Discharge summaries.
- All cardiac catheter reports.
- Autopsy report / Death report (*if applicable*).
- Operative reports, including perfusions sheet & anesthetic flow sheet.
- MRI (if performed).
- ICU flow sheet for 24 hours pre-op & 24 hours post-op.
- Clinic letters.

### For CHSS Data Center Use Only

Date placed on Registry: \_\_\_\_\_ Study Number: \_\_\_\_\_



THE HOSPITAL FOR SICK CHILDREN 555 University Avenue, Toronto, ON, Canada M5G 1X8  
 Fax: 416-813-8776 • Toll Free 1-866-477-CHSS (2477) • Website: [www.chssdc.org](http://www.chssdc.org)  
 Geraldine Cullen-Dean, RN, MN, Study Coordinator • Telephone: 416-813-8477 • E-mail: [gcdean@sickkids.ca](mailto:gcdean@sickkids.ca)