



# 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
- 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 (< 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 the 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

### EXCLUSION CRITERIA

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

### For CHSS Data Center Use Only

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

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

Patient: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Parents' Names: \_\_\_\_\_ Death Date (if applicable): \_\_\_\_\_  
Address: \_\_\_\_\_ Gender: Male ☐ Female ☐ Race: \_\_\_\_\_  
Birth Weight: \_\_\_\_\_ Birth Height: \_\_\_\_\_  
Email Address: \_\_\_\_\_  
Phone: \_\_\_\_\_ Surgeon: \_\_\_\_\_  
Institution: \_\_\_\_\_ Pediatric Cardiologist: \_\_\_\_\_  
Hospital Number: \_\_\_\_\_ Local Physician: \_\_\_\_\_  
Date of first admission: \_\_\_\_\_  
Cardiac Diagnosis: \_\_\_\_\_

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

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

**SickKids®**

555 University Avenue  
Toronto ON M5G1X8 Canada  
Toll Free: 1-866-477-CHSS (2477)  
Fax: 416-813-8776  
Email: [chss.dc@sickkids.ca](mailto:chss.dc@sickkids.ca)  
Website: [www.chssdc.org](http://www.chssdc.org)

#### CHSS DATA CENTER STAFF

William G. Williams, MD, FRCSC  
Director  
Christopher Caldarone, MD, FACS  
Staff Surgeon  
Maulik Baxi, MD, MPH  
Research Program Manager

#### CHSS DATA CENTER STAFF

Sally Cai, MSc  
Database Manager  
Anusha Jegatheeswaran, MD  
Kirklin/Ashburn  
CHSS Data Center Fellow

#### CLINICAL RESEARCH PROJECT COORDINATORS

Olga Levesque, BA  
Candice Cumberbatch

#### STATISTICAL CONSULTANTS

Dr Brian McCrindle, MD, MPH  
Dr Eugene Blackstone, MD