Looking Back to Looking Forward – Types of Studies

CHSS Annual Meeting
Chicago
October 22, 2017
Objectives

- Discuss longitudinal, observational studies
- Identify two types of study designs
- Discuss criteria to identify subject per cohort
- Discuss identification versus consenting of subject
Longitudinal Observational Studies
- Data is collected for the subject repeatedly and can extend over the life of the subject, or until the study closes or the patient chooses to withdraw from the study.
- Researchers consent and follow but do not interfere in the subject's life or environment.
- Cross-sectional follow-up done annually and key to CHSS studies.
Two Types of Study Designs
Prospective Cohort Study
Coordinator identifies patient through inclusion and exclusion criteria and starts data collection.

Ongoing data collection throughout life of patient.
Retrospective Cohort Study
Subject has events such as operations, echoes, caths during this time frame.

Specified time period: i.e., January 1, 2000 to December 31, 2008 for data collection.
Identification of Subjects by Cohort
LVOTO Cohort
Prospective observational study

Age <30 days at time of admission?
- No: Not Eligible
- Yes
  - AV and VA concordance?
    - No: AV or VA discordance - Not Eligible
    - Yes
      - Is source of critical LVOTO d/t any of the following: AV atresia/stenosis OR Anatomically normal but hypoplastic LEFT heart? (VSD is ok)
        - No: AVSD, DORV/DILV – Not Eligible
        - Yes
          - First intervention at a CHSS institution?
            - No: First intervention at non-CHSS institution – Not Eligible
            - Yes: ELIGIBLE FOR STUDY
AVSD Cohort
Prospective observational study

Age <365 days at admission for surgery

- Yes
- Not Eligible

Diagnosis/referral with complete AVSD

- Yes
- Not Eligible

- No

AV and VA Concordance – includes Tetralogy of Fallot and DORV

- Yes

- No

First intervention at a CHSS institution

- Yes

ELIGIBLE FOR STUDY

- No

Partial or Transitional AVSD, Total or Partial Anomalous Pulmonary Venous Drainage, Aortic Atresia or Heterotaxy – Not Eligible

AV and VA Discordance – Not Eligible

First intervention at non-CHSS institution – Not Eligible
TA Cohort
Prospective observational study

Confirmed diagnosis of Tricuspid Atresia

Yes

Not Eligible

No

Are the A-V connections & great arteries normally related? (AV and VA concordance (even though the right a-v connection is atretic))

Yes

Not Eligible

No

AV or VA discordance – Not Eligible

First intervention at a CHSS institution?

Yes

ELIGIBLE FOR STUDY

No

First intervention at a non-CHSS institution – Not Eligible
AAOCA Cohort

Now a prospective ONLY observational study

Age ≤ 30 years of age at time of diagnosis

Yes

Diagnosis/referral of AAOCA to CHSS institution (does not have to have/had surgery at CHSS institution)

Yes

Structurally normal heart or with a small hemodynamically insignificant lesion (PDA, ASD, VSD, mild PV stenosis, or bicuspid valve without aortic stenosis)

Yes

Coronary artery originates from the aorta?

Yes

ELIGIBLE FOR STUDY *

* If surgically repaired, is a completed operative note available?
If not, can have the subject sign a ‘Release of Medical Information’ form to obtain the operative note.
Identification versus Consent

- Identification occurs within the specific inclusion criteria
- Consent can be done at an alternate time from identification – but within limits
- Potential bias introduced into study
Potential Identification Scenarios

- New institution – new enrollment
- Established institution – clinic patient