

Looking Back to Looking Forward – Types of Studies

CHSS Annual Meeting

Chicago

October 22, 2017

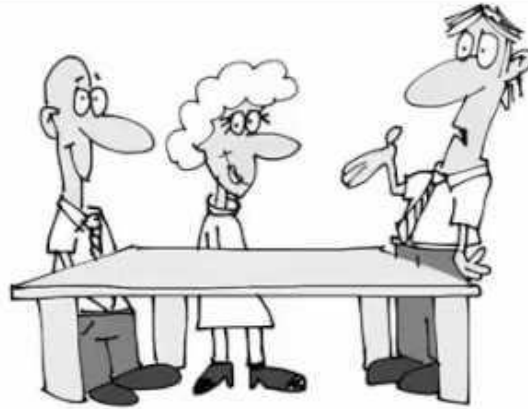
Objectives

- ❑ 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 subjects life or environment
- ❑ cross-sectional follow-up done annually and key to CHSS studies

Two Types of Study Designs



"WE KNEW THAT ALREADY! SEEMS LIKE WE DIDN'T NEED TO DO THE RESEARCH AFTER ALL!"

Prospective Cohort Study



Prospective

STUDY INCEPTION

Coordinator identifies patient through inclusion and exclusion criteria and starts data collection



Ongoing data collection throughout life of patient



Retrospective Cohort Study



Retrospective

Subject has events such as **operations**, echoes, caths during this time frame



Specified time period : ie. January 1, 2000 to December 31, 2008 for data collection

STUDY INCEPTION

Coordinator identifies patient through inclusion and exclusion criteria and starts data collection



Identification of Subjects by Cohort

LVOTO Cohort

Prospective observational study



http://www.chssdc.org/sites/default/files/LVOTO_Current_Protocol_Version_Date_22_Sep_2015.pdf

Age <30 days at time of admission?



Not Eligible



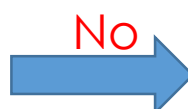
AV and VA concordance?



AV or VA discordance - Not Eligible



Is source of critical LVOTO d/t any of the following: AV atresia/stenosis **OR** Anatomically normal but hypoplastic **LEFT** heart? (VSD is ok)



AVSD, DORV/DILV – Not Eligible



First intervention at a CHSS institution?



First intervention at non-CHSS institution – Not Eligible



ELIGIBLE FOR STUDY

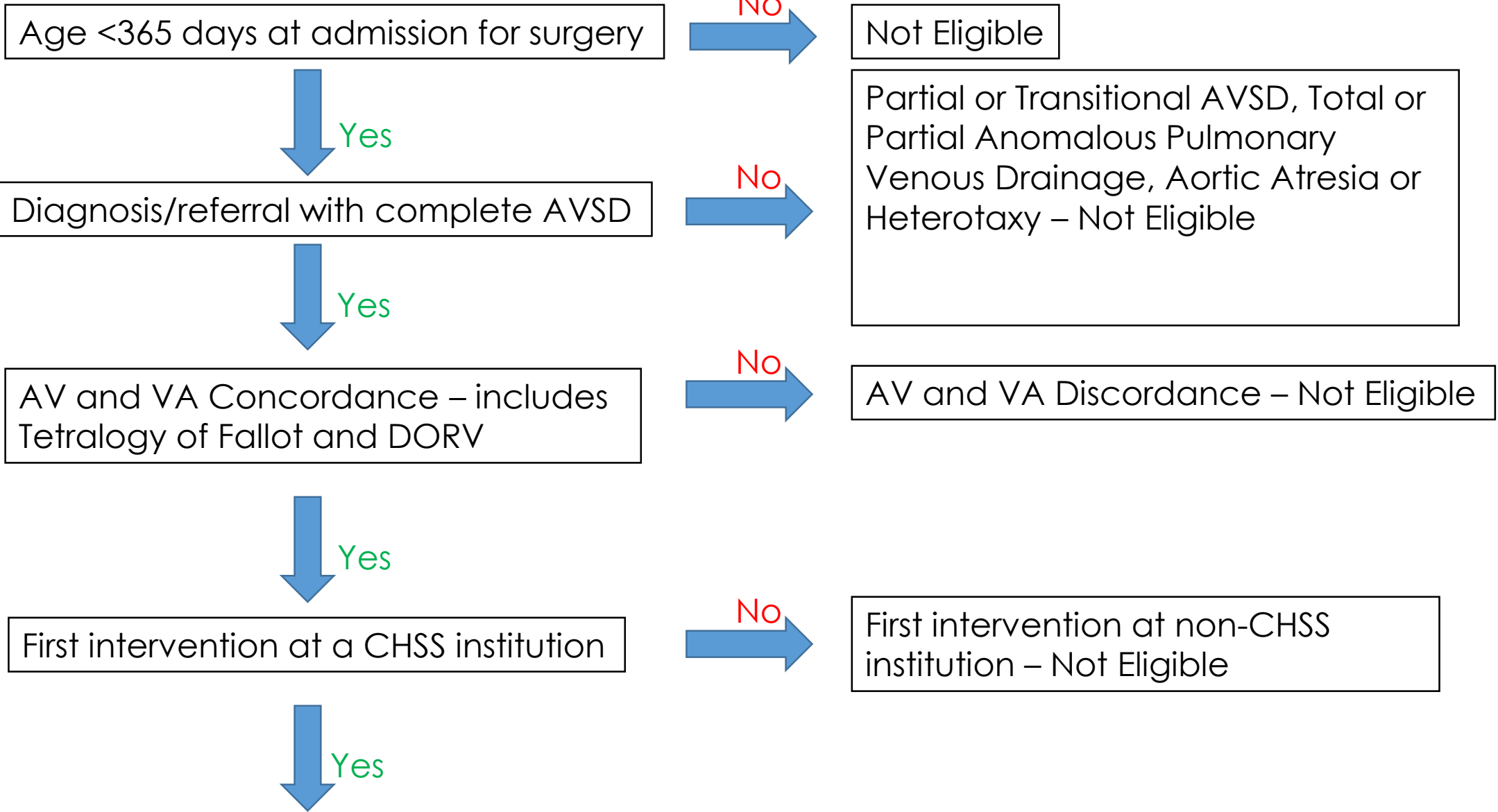
AVSD Cohort

Prospective observational study

OBJECTIVES

- 1.
- 2.
- 3.

http://www.chssdc.com/sites/default/files/AVSD_Current_Protocol_Version_Date_16_Feb_2016.pdf



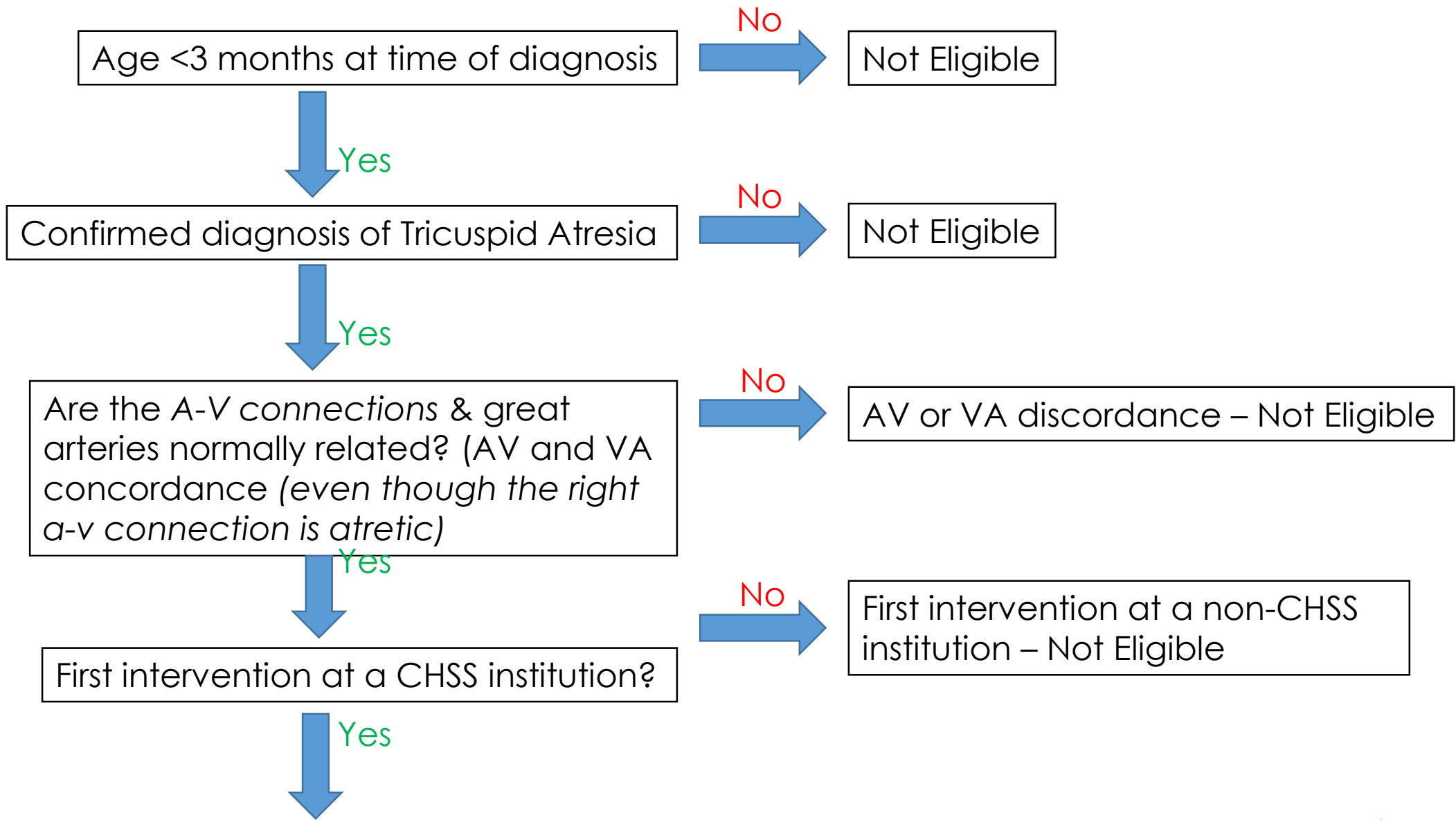
ELIGIBLE FOR STUDY

TA Cohort

Prospective observational study



http://www.chssdc.org/sites/default/files/TA_Current_Protocol_Version_Date_22_Sep_2015.pdf



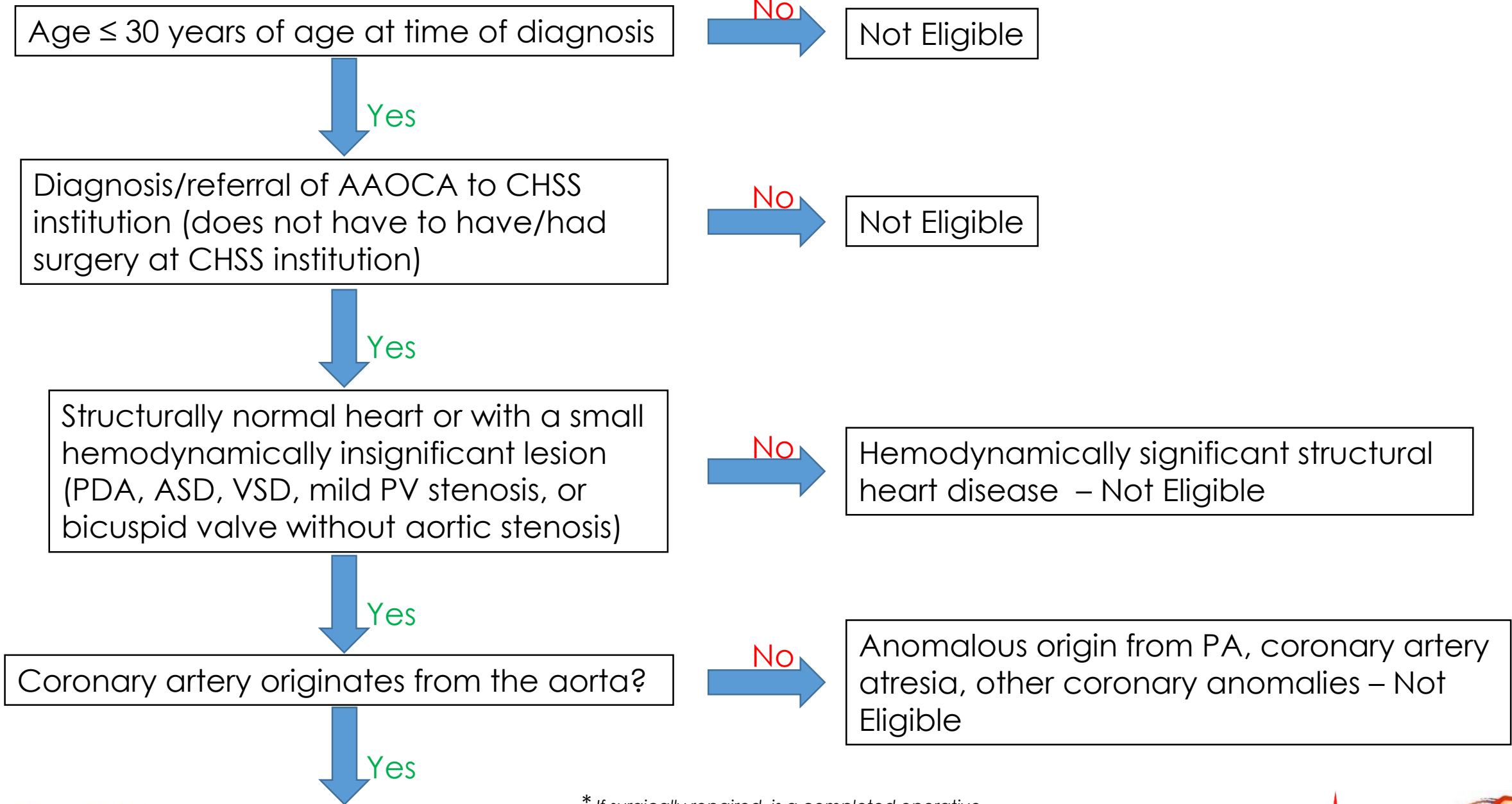
AAOCA Cohort

Retrospective component started January 1, 1998 and ended January 20, 2009. Retrospective component closed.

Now a prospective ONLY observational study



http://www.chssdc.org/sites/default/files/AAOCA_Current_Protocol_Version_4_22_Sep_2015.pdf



* 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
- ❑ Consenting 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

Question?

