

IRB Protocol
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A. Study Purpose and Rationale

Prior to the late 1970s, hypoplastic left heart syndrome (HLHS) was a uniformly fatal disease. In 1979 the introduction of the Norwood procedure offered physicians a window of opportunity for multistaged surgical palliation albeit with high rates of mortality. Application of cardiac transplantation to HLHS cases during the mid 1980s offered another approach. As surgical outcomes improved dramatically over the last three decades healthcare providers have begun to question whether or not offering comfort care for newborns with HLHS remains a moral choice.

Extensive literature review from 1979 to 2011 has revealed that academic institutions are increasingly pursuing the Norwood procedure while nationally approximately half of all HLHS patients are still receiving comfort care.

A survey of physicians and nurses was conducted at Columbia Presbyterian Medical Center in 1996 revealing a high level of resistance to pursuing surgery for infants with hypoplastic left heart syndrome. We expect a similar survey conducted this year to reveal an increased level of resistance to comfort care.

Surveys will be distributed to pediatric cardiologists, cardiothoracic surgeons, neonatologists, neonatal and pediatric intensive care unit and cardiology floor nursing staff. Survey results from 2012 will be compared to those collected in 1996. Primary outcome will be change in attitudes toward surgical intervention over time. Secondary outcomes will include how survival and neurodevelopmental outcome estimates impact surgical preference. A number of complicating social and medical patient factors will also be analyzed for impact on surgical preference.

B. Study Design and Statistical Analysis

An anonymous survey will be distributed to attendings, fellows and nurses in pediatric cardiology, neonatology, pediatric intensive care and cardiothoracic surgery. The 1996 survey had a total of 106 respondents. Our aim is to distribute the survey to a possible 236 respondents this year.

The survey consists of 33 total questions broken into three segments. The first 12 questions pertain to management of the "ideal surgical candidate" with hypoplastic left heart syndrome meaning that there are no other "complicating features" of either a medical or social nature. Questions 13-23 assess a variety of medical and social complications impact respondents' management decisions. The final 10 questions focus on provider demographic features including gender, parenthood, experience with HLHS patients, number of years in the field.

Primary outcome:

The first five questions will be used to assign each provider a surgical preference score scaled from 0 to 50. If these scores are normally distributed then an unpaired t-test can be used to compare responses between 1996 and 2012 as a primary outcome. Using $n = 106$ (the number of respondents from 1996) one can estimate the effect size that could be observed:

$$\begin{aligned}n &= 1 + 16 (\text{STDDEV}/\text{Effect})^2 \\2.56 &= \text{SD}/\text{Effect} \\ \text{Effect} &= \text{SD}/2.56 \\ \text{Effect} &= 0.4\text{SD}\end{aligned}$$

It data distribution is non-normal and it cannot be transformed then a nonparametric test will be applied.

Secondary outcomes:

Questions 6 and 7 have continuous variable answers estimating neurodevelopment and survival outcomes. These will be correlated with surgical preference score as a secondary outcome.

Personal choice as expressed in question 8 will be correlated with surgical preference score.

As for the impact of the various medical or social complications on management choices a sign test will be applied to identify factors that encourage respondents to favor comfort care.

C. Study Procedure.

Not applicable.

D. Study Drugs.

Not applicable.

E. Medical Device.

Not applicable.

F. Study Questionnaires

Attached.

G. Study Subjects

Attendings, fellows and nurses in pediatric cardiology, neonatology, intensive care and cardiothoracic surgery.

H. Recruitment of Subjects

As in 1996, the survey will be hand delivered to neonatology, cardiology and cardiothoracic surgery attendings and fellows as well as NICU, PICU and cardiology floor nurses. This population has the most exposure to management decisions surrounding hypoplastic left heart syndrome. Participants are identified via departmental directories and lists furnished by departmental administrators. A reminder e-mail will be sent to all potential participants to anonymously submit their surveys. No responses will be accepted via e-mail in order to maintain anonymity.

I. Confidentiality of Study Data

In each department there will be a centralized envelope for the top sheet with the participants' names on them as well as a separate envelope for the surveys to be placed anonymously. Ultimately all surveys will be combined and kept separate from the removed cover sheets. Although the surveys contain specific demographic data, no individual profiles will be published. All data will be reported in aggregate. For example, number of years in practice or age would be reported within a several year range and not as specific numbers. E-mail addresses will be kept in a secure location available only to investigators and used solely for raffle purposes.

J. Potential Conflict of Interest

None.

K. Location of the Study

CPMC departments of pediatric cardiology, neonatology, intensive care and cardiothoracic surgery.

L. Potential Risks

One risk includes possible distress when considering management options with which participants disagree. Including options such as “unable to decide” as well as allowing participants to not complete the questionnaire minimizes this risk. The anonymous nature of the survey eliminates any impact responses may have on employment status.

M. Potential Benefits

One benefit of the study is further insight into changes in attitudes toward management over time.

N. Alternative Therapies

No therapy.

O. Compensation to Subjects

We have received up to \$187.50 in funding from the Pediatric Residency Program to be applied towards copying costs and twenty-five \$5.00 Amazon gift cards to be raffled to survey participants who voluntarily and anonymously provide their e-mail address.

P. Costs to Subjects

Costs include participants’ time.

Q. Minors as Research Subjects

Not applicable.

R. Radiation or Radioactive Substances

Not applicable.

Hypoplastic Left Heart Syndrome – Attitudes and Beliefs

The following survey is meant to gauge your attitudes toward management of a newborn with hypoplastic left heart syndrome. Our aim is to better understand current feelings about surgical and non-surgical options for children born with hypoplastic left heart syndrome.

Your responses will be anonymous. Whether you choose to participate or not will in no way impact your employment status.

We appreciate your help completing this survey. If you provide your e-mail address below you will be entered into a contest to win one of the twenty-five available \$5 Amazon.com gift cards.

Please write your name below so that we may keep track of those who have completed the survey. And include your e-mail address below if you would like a chance to win an Amazon gift card. This information will be kept confidential and will only be used to notify you if you have been chosen to win.

Name: _____

E-mail Address: _____

When submitting your survey, please remove this front sheet and deposit it in the designated envelope.

Thank you for your assistance.

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Tom Starc, MD - tjs1@columbia.edu

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Hypoplastic Left Heart Syndrome – Attitudes and Beliefs

The following group of questions concerns your attitudes toward management of a newborn with hypoplastic left heart syndrome who is an “ideal candidate” for surgery and does not have any “complicating features” of either a medical or social nature. Supportive care is meant to signify pain control and comfort measures without life-prolonging intervention.

1. If you were in a position to provide guidance for the family the possible management option(s) you would discuss with the parents would include (please choose one):
 - A. Norwood approach alone
 - B. Transplant approach alone
 - C. Supportive care (No surgery)
 - D. All three options (A, B and C)
 - E. Norwood or Transplant (No supportive care)
 - F. Norwood or Supportive Care (No Transplant)
 - G. Transplant or Supportive Care (No Norwood)

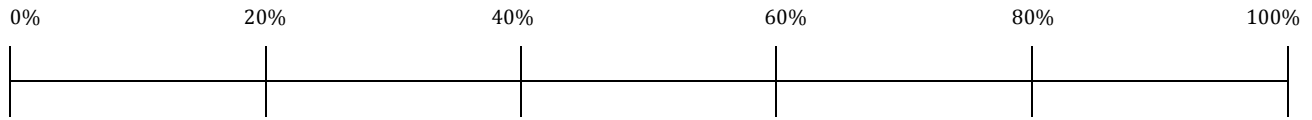
2. What recommendation would you give to the parents of this “ideal candidate” if they sought your advice and said they would do “whatever you recommend?”
 - A. I would refuse to choose for them
 - B. Recommend Norwood approach
 - C. Recommend transplant approach
 - D. Recommend supportive care (no surgery)

3. If an “ideal medical candidate” was a ward of the court, with no responsible family member, and you could choose the course of therapy:
 - A. I would refuse to choose
 - B. Norwood approach
 - C. Transplant approach
 - D. Supportive care (no surgery)

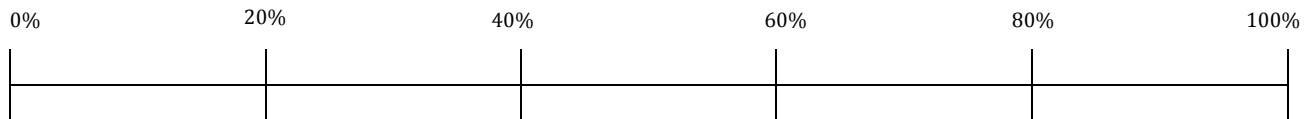
4. If you discuss Norwood surgery as an option, how strongly do you recommend it?
 - A. Insist (attempt to get a court order if needed)
 - B. Strongly encourage
 - C. Encourage it
 - D. Not push it
 - E. Barely mention it

5. If you discuss supportive care as an option, how strongly do you recommend it?
 - A. Insist
 - B. Strongly encourage
 - C. Encourage it
 - D. Not push it
 - E. Barely mention it

6. How would you estimate cumulative 5-year survival following the Norwood, Glenn and Fontan procedures? Please draw a line on the scale below reflecting your survival estimate:



7. What percentage of school age survivors of the Norwood, Glenn and Fontan procedures would you estimate have severe cognitive delays? Please draw a line on the scale below reflecting your estimate:



8. If you personally had a newborn with hypoplastic left heart syndrome what management option would you choose?
- A. Norwood Approach
 - B. Transplant Approach
 - C. Supportive Care
 - D. Unable to or Prefer Not to Answer

For the next three questions circle the answer that most closely matches your beliefs.

9. I believe that some type of surgery should be done for most infants with hypoplastic left heart syndrome.

Strongly Agree Agree Not Sure Disagree Strongly Disagree

10. I believe that if a parent refused to pursue surgery they should be taken to court.

Strongly Agree Agree Not Sure Disagree Strongly Disagree

11. I believe that parents should have the option of choosing "no surgery" for an infant with hypoplastic left heart syndrome.

Strongly Agree Agree Not Sure Disagree Strongly Disagree

12. With regard to recommending surgery for children with hypoplastic left heart syndrome, compared to 10 years ago, I am...

- A. Much More Likely to Recommend Surgery
- B. More Likely to Recommend Surgery
- C. No Change
- D. Less Likely to Recommend Surgery
- E. Much Less Likely to Recommend Surgery
- F. I Have Been in Practice for Less Than 10 Years

The following is a list of potential “influencing” factors, which may or may not change someone’s advice for surgery. Please circle the answer that most closely matches your belief.

Compared to newborns who are “ideal candidates,” how would these conditions affect the chances that you would be likely to recommend surgical intervention (either Norwood or transplant)?

13. Employed Single Mother:

Much More Likely More Likely No Change Less Likely Much Less Likely

14. Unemployed Single Mother:

Much More Likely More Likely No Change Less Likely Much Less Likely

15. Poor Financial Status of Parents:

Much More Likely More Likely No Change Less Likely Much Less Likely

16. First Child of Young Parents:

Much More Likely More Likely No Change Less Likely Much Less Likely

17. Older Parents with No Other Children and *in vitro* fertilization for this infant:

Much More Likely More Likely No Change Less Likely Much Less Likely

18. Mother in Poor Health:

Much More Likely More Likely No Change Less Likely Much Less Likely

19. Major Other Surgical Problem in Newborn, e.g. Tracheoesophageal fistula:

Much More Likely More Likely No Change Less Likely Much Less Likely

20. Major Chromosomal Abnormality in Newborn:

Much More Likely More Likely No Change Less Likely Much Less Likely

21. Newborn with extreme prematurity (<25 wks gestational age):

Much More Likely More Likely No Change Less Likely Much Less Likely

22. Very premature newborn (<32 wks gestational age):

Much More Likely More Likely No Change Less Likely Much Less Likely

23. Parents who previously lost a child following HLHS surgery:

Much More Likely More Likely No Change Less Likely Much Less Likely

Please circle the answers that best describe you:

1. Sex Male Female

2. Age _____ years

3. Position

A. RN

B. MD

C. PNP/NNP

D. LPN

E. Other _____

4. Department/Service

Nursing Staff:

- A. Neonatal ICU Nurse
- B. Pediatric ICU Nurse
- C. Cardiology Nurse (including 6 Tower, Cath Lab etc)

Fellow:

- A. Neonatal Intensive Care
- B. Pediatric Intensive Care
- C. Cardiology Fellow

Attending:

- A. Neonatal Intensive Care
- B. Pediatric intensive care
- C. Cardiology
- D. Cardiothoracic Surgery

If you selected the NICU or the PICU as your place of work, do you usually work in the cardiac intensive care unit area?

Yes No

5. How Many Years Have You Been Practicing?
_____ years

6. Are you a parent?

Yes No

7. Have you provided medical or nursing care for an infant or child with hypoplastic left heart syndrome who has completed the Norwood, Glenn and Fontan procedures and who survived and has "done well?"

Yes No Unsure

8. Have you provided medical or nursing care for an infant or child with hypoplastic left heart syndrome who has had a cardiac transplant for hypoplastic left heart syndrome and has survived and "done well?"

Yes No Unsure

9. Have you provided medical or nursing care for an infant or child with hypoplastic left heart syndrome whose parents chose no surgery?

Yes No Unsure

10. Did you complete a similar survey here at Columbia University Medical Center in the mid-1990s?

Yes No Unsure

Thank you for participating in this survey. If you have any comments or suggestions concerning care of children with hypoplastic left heart syndrome, please feel free to write them below or get in touch with any of us directly.

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Comments:

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