Pediatric Heart Network (PHN)

COLLABORATIVE LEARNING PROJECT OF PERIOPERATIVE CARE OF INFANTS WITH CONGENITAL HEART DISEASE PUBLIC USE DATASET

ABOUT THE STUDY

The NHLBI Collaborative Learning Study was conducted by the Pediatric Heart Network (PHN) at 10 centers in North America. It was initiated with the goal of using collaborative learning techniques with specific emphasis on site visits to identify the major components of postoperative care that might be improved by sharing expertise. Five of the hospitals were selected to participate in this collaborative learning project as "Active Sites." The centers were chosen to provide geographic and institutional surgical volume variation. The five remaining hospitals were not directly involved in the collaborative learning element of the study and represent "control sites". One of the five active sites had already devoted time and effort to advance the concept of early extubation. Observation of care at this site suggested that early extubation could lead to an acceleration of the postoperative care process including earlier introduction of enteral feeds and shorter duration of sedation. As such, this practice became an attractive target for the collaborative learning model. This institution is referred to as the "model site" owing to its expertise in early extubation, and this expertise was used to guide clinical practice guideline (CPG) protocol development for the four other active sites (none of which routinely used the strategy of early extubation in the target patient populations). After rotational site visits in which a team of clinicians including a cardiac surgeon, intensivist, respiratory therapist, and cardiac ICU nurse from each of the five Collaborative Learning active sites visited one other active center and hosted a second center, the collaborative set out to construct a CPG for early extubation.

Two index operations were selected: complete repair of tetralogy of Fallot (TOF) and repair of isolated coarctation of the aorta. The specific inclusion criteria for the TOF cohort were as follows: diagnosis of TOF, patients more than 28 and less than 365 days on the date of index surgery and planned complete surgical repair (including those patients who had undergone prior palliative Blalock-Taussig shunt). For the coarctation of the aorta cohort, the inclusion criteria were as follows: planned complete surgical repair without the need for cardiopulmonary bypass and age less than 365 days on the date of index surgery. Patients with coarctation of the aorta with ventricular septal defect undergoing a concomitant pulmonary artery band were eligible for the CPG. CPG exclusion criteria included corrected gestational age less than 36 weeks, known primary lung disease, known airway anomalies, pulmonary hypertension requiring medication therapy, mechanical ventilation immediately prior to surgery, known congenital or acquired neurological injury likely to impact respiratory function, known chromosomal abnormality or syndrome likely to impact airway or lung function.

The primary outcome measure was the proportion of subjects extubated within 6 hours of return to the ICU from the operating room (OR) following one of the index operations. All outcome measures were collected for the 12 months immediately preceding (preimplementation) and 12 months immediately following (postimplementation) the introduction of the CPG at active sites. Data on the same outcome measures at control sites were collected during contemporaneous time intervals although the CPG was not implemented at these sites. The number of subjects enrolled at the "model" site was 82 (44 in preimplementation and 38 in postimplementation). Enrollment at the other four active sites was 240 (119 in preimplementation and 121 in postimplementation), and at the five control sites it was 259 (120 in preimplementation and 139 in postimplementation).

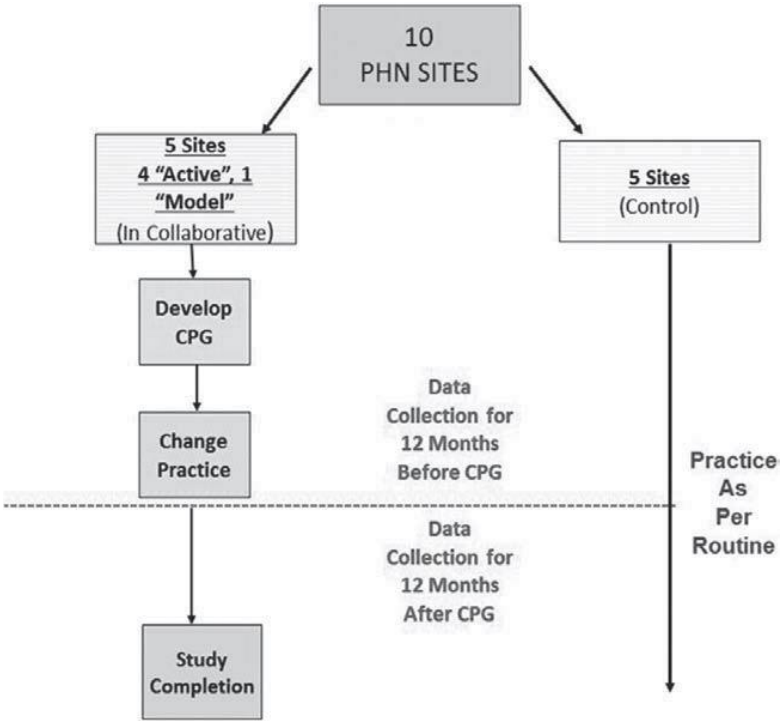
The aims of the study were:

1. To perform site visits among participating centers to catalyze collaborative learning

2. To determine whether a model that employs collaborative learning can effectively guide the development of, and subsequent adoption of, an early postoperative ventilation and extubation clinical practice guideline (CPG) for infants across congenital heart centers
3. To determine if the collaborative learning CPG results in an increased rate of early extubation

The study design has been described in great detail in Mahle et al. (*Pediatric Critical Care Medicine* 2016), Wolf et al. (*Am Heart J* 2016), and in the study protocol (all available to users with approved logins). Figure 1 provides a schema of the study design. Additional information can be found in the published articles on specialized topics (see posted Bibliography at http://pediatricheartnetwork.com/ResourcesPublications/Publications.aspx#73551-collaborative-learning

Figure 1. Scheme of the study design. CPG = clinical practice guideline, PHN = Pediatric Heart Network.



DATA AND DOCUMENTATION

The following datasets and descriptor files are available for download. A login and password (request access via http://www.pediatricheartnetwork.org) are required for download capability. The lock date used for creation of the public dataset was July 16, 2015. Privacy protection of these data is described in Appendix A.

1. Study data collection forms

2. SAS version 9.4 datasets

3. Excel datasets (with variable formats applied) – These data have a .csv extension, which means that the file may also be opened either in Excel, OR in a text editor, appearing as a comma-delimited file.

4. Codebooks for each dataset – These contain variable names, labels, and descriptive statistics for each variable on the data collection forms. Key created variables are included as well.

5. The file *formats.sas7bcat* – Include this file in your program using:

```
options fmtsearch = (fmtlib.formats);
```

where fmtlib is specified using a libname statement as the path name.

STUDY RESOURCES

Resources posted on the pediatricheartnetwork.org website include:

- Collaborative Learning Study bibliography (see http://pediatricheartnetwork.com/ResourcesPublications/Publications.aspx#73551-collaborative-learning)

- Collaborative Learning Study protocol (with login access)

DATA USE POLICY

- REQUIRED ACKNOWLEDGEMENTS: All presentations and publications using these data must include the following statement: *"The NIH/NHLBI Pediatric Heart Network Collaborative Learning Study dataset was used in preparation of this work. Data were downloaded from http://pediatricheartnetwork.org/ForResearchers/PHNPublicUseDatasets.aspx on mm/dd/yyyy"."*

- PAPER, ABSTRACT, and PRESENTATION TITLES: Titles may, at the authors' discretion, mention the PHN database but should not imply that the work is from the PHN. An example of an acceptable phrase would be, "an analysis of the Pediatric Heart Network public database." Whether or not the title makes mention of the PHN, acknowledgement should be made as described in bullet 1.

- All users are requested to send a copy of published abstracts and articles to the PHN Data Coordinating Center at New England Research Institutes (PHNpubs@neriscience.com) within one month of publication. This will allow the PHN and the NHLBI to document the continued impact of this study on the field.

- The login and password provided to each user are valid for 6 months. If a user decides to complete analyses leading to more than one presentation or publication in that time period, it is requested that they notify the PHN Data Coordinating Center at New England Research Institutes of their additional analysis topics, solely for the purposes of tracking.

- The login and password to access the public dataset is provided to a single user. If a colleague would like to access the public dataset for a different analysis topic, a separate request for login and password should be submitted via the www.pediatricheartnetwork.org website.

- As an approved user, you agree that you will not attempt to establish the identities of research participants through use of this dataset.

- As an approved user, you agree to not place these data in other public locations.

TIPS ON USING THESE DATA

1. Identification numbers for study subjects and study sites have been re-assigned for privacy protection.
    - *random_id*: Subject ID ranging from 53001 to 53831
    - *site_id*: Site ID ranging from 1 to 12 [only available for eligible subjects]; there were 10 sites

2. Prior to analysis, original variables must have any special values (typically negative numbers, see Appendix B) set to missing. Created variables (labelled as <created> in the codebooks) already contain a SAS missing value if the measurement is unavailable.

3. The study data are contained in multiple individual forms. These forms may be used jointly by merging on *blind_id.*

4. The data contain 831 screening records and 581 eligible subjects (82 at the “model” site, 240 at other active sites, and 259 at control sites).

5. The General Information dataset contains the blinded site ID for the 581 eligible subjects, as well as data on the collaborative vs. control subjects, those at the “model” site, and the time period: retrospective/pre-implementation vs. prospective/post-implementation.

6. The Preoperative, Operative, and Postoperative Information datasets contain data for the 322 subjects at active sites; the Operative Data dataset contains data for the 259 subjects at control sites.

ADDITIONAL ASSISTANCE

If you have questions about the study dataset that this documentation and the above resources (protocol, articles) have not answered, please email the PHN Mailbox at PHNmailbox@neriscience.com.

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APPENDIX A

Implementation of Privacy Protection Rules for Public Use of the PHN Marfan Study Dataset

Variables that could lead to subject identification were eliminated in the public dataset. Steps included:

1. Removal of original study ID number (replaced with *blind_id*, a random consecutive numbering ranging from 53001 to 53831). Of note, no subject names, addresses, or medical record numbers were ever contained in the original study dataset.

2. All dates in the original datasets were removed, and replaced with number of days from procedure.

3. Free (write-in) text variables were sometimes removed from the public datasets. When included as clinically relevant, they were first scanned for any identifying information (e.g., dates) and deleted accordingly.

4. Race categories with small sample size were recoded into an “other” category.

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APPENDIX B

Special Value Codes

-9 = missing

-8 = don't know/indeterminate

-7 = refused to answer

-6 = not recorded

-5 = measurement could not be reliably recorded or is not interpretable (study technically inadequate)

-4 = illegible

-2 = programmed skipped field based on results of or response to a previous question

-1 = not applicable/structure not present