Society for Pediatric Anesthesia Improvement Network – Chest Wall Deformity Outcomes Project

Please provide a brief summary or abstract of this research protocol.

Context: Chest wall deformities in children are relatively common. One such deformity, known as pectus excavatum (PE), involves a concavity of the chest and is the most frequent of these abnormalities ï present in approximately 1 out of every 400-1000births. This deformity is often a cosmetic problem for affected individuals. When severe, PE can also be associated with cardiopulmonary compromise.

Treatment of PE involves surgical correction. There are several potential methods for correcting PE. In the past the most common repair involved an open procedure which involves excision and reshaping of the ribcage. More recently a minimally invasive procedure has been adopted involving the placement of a stainless steel or titanium bar underneath the sternum to reshape the chest wall. This procedure, commonly known as the Nuss procedure, carries with it significant post-operative pain management problems. In fact the pain issues after Nuss procedure may be more significant than after open repair. The quality of postoperative pain control in these cases has been shown to affect several measurable objective outcomes during hospitalization including capacity for deep breathing, early mobilization, ambulation, and length of hospital stay.

Epidural analgesia (EA) has been one of the standard methods for managing pain in the early postoperative period after PE repair. Unfortunately severe pain may persist after the removal of an epidural catheter resulting in a difficult ñtransitionò period just prior to discharge from the hospital. In addition reports of neurological injury after epidural analgesia for Nuss procedures have appeared. In light of these issues, many institutions have opted for alternative methods of pain control including peripheral nerve blocks, patient controlled analgesia, and wound catheters. There remains significant debate as to which pain control methodology is best. There is little consistent data available on pain control or outcomes that occur after EA is stopped. Moreover there is reluctance in any one institution to trial or randomize patients to a variety of treatment modalities. For all of these reasons, we are proposing participation in a multi-institutional data sharing project concerning the repair of EA in which participating centers will collaborate to better understand the outcomes of perioperative care for patients undergoing correction of this problem.

Objectives: The primary objective is to create a multicenter registry which captures information relating to the perioperative anesthesia course and management of children undergoing repair of pectus excavatum surgery and to examine the practice patterns and incidence of complications. Data from any single institution involved in this registry will be used for local safety and quality improvement efforts. In addition data from each institution can be compared to the information from the entire group of institutions participating in the project, thus providing a measure for comparison with national practice. The aggregate multi-institutional data set will be used to develop quality benchmarks for national safety and quality improvement efforts and best practice recommendations. We believe that this registry can also demonstrate how web-based data collection can be used to evaluate clinical anesthesia outcomes for surgeries with a low incidence of critical events but with significant variability in medical management.

Study Design:
Basic design: Prospective observational multicenter data registry

Setting/Participants:
ÅPatients ages 8 to 30 years undergoing surgery for Pectus Excavatum Repair in a hospital setting
ÅUp to 20 hospital sites

Data Collection, Storage and Release:
The registry will capture data relating to the perioperative management of children undergoing PE repair. Measures will include demographic data, data on degree of deformity, perioperative management, intraoperative management, hospital course, surgical technique, complications, and long term pain/psychological outcomes.

The local Boston Childrenôs Hospital (BCH) database will be hosted on a secure site. The data that are transmitted to the data coordinating center will be stripped of all protected health information (PHI) except the date of service.

The multicenter registry database will be hosted on a secure server at the Dartmouth Bioinformatics Group at Dartmouth College with web-based data entry from participating institutions.

Although no research studies are planned at this time, in the event future requests for data sets are made, the data-coordinating center Dartmouth Bioinformatics will prepare and release de-identified and/ or limited data sets.

1. Specific Aims /Objectives
The primary objective is to create a multicenter registry which captures data relating to the perioperative course and management of children undergoing PE repair surgery. This effort is undertaken in order to augment safety and quality improvement activities at participating sites. We understand that there are multiple methodologies for accomplishing the anesthesia and perioperative pain control for this surgery. There is little comparative data on the outcomes from the different possible management strategies. Given the relative frequencies of these surgeries where few centers perform more than 20-50 of these procedures per year, it is not practical for any one (or two) centers to study this procedure in an observational manner or a controlled randomized trial. Our aggregate multi-institutional data set will be used for benchmarking for both local and national safety and quality improvement efforts. Participating sites will be provided with reports comparing the local site to the aggregate dataset for specific perioperative outcome variables (e.g. pain metrics) and factors that could be associated with improved outcomes. Outcome variables include but are not limited to intraoperative hemodynamics, pain control, emergence agitation, apnea/airway obstruction, hemodynamic stability, time to first ambulation, pain scores while in the hospital, total hospital days, time to school or work attendance, and symptoms of post-traumatic stress.

Secondary objective: We will ultimately look at the relationship between specific management metrics such as the use of epidural anesthesia vs. peripheral nerve blocks vs. local anesthesia wound infiltration and our primary outcome metrics. In addition we will consider the frequency of long term Post Traumatic Stress behaviors and the various measures of pain control in the perioperative period.

2. Background and Significance

Pectus excavatum (PE) is the most common congenital chest wall deformity, occurring in approximately 1 in 400-1000 births [1]. PE is characterized by a depression of the anterior chest wall. In cases of a severe deformity there can be varying degrees of pulmonary and cardiac compression.

Repair of PE can be accomplished with two primary procedures: 1. The Ravitch procedure involves cutting the rib cartilages away on each side of the sternum ï then flattening the sternum. Bars or struts are then inserted to ensure that the sternum keeps its shape. A horizontal incision across the chest is used and drains are inserted to remove fluid from the surgical site. 2. Another surgical method for correction of PE is the Nuss procedure in which a convex bar is placed (sometimes with thoracoscopic guidance) under the

sternum with no resection or cutting of the costal cartilages. The presence of the bar reshapes the chest wall to achieve a more normal appearance. In this case small incisions are made on either side of the chest.

Although the Nuss procedure is less invasive than the open Ravitch procedure, it is frequently associated with severe and prolonged postoperative pain [2]. A variety of analgesic options including intravenous patient controlled analgesia (PCA), thoracic epidural catheter, paravertebral blocks, and thoracic wound catheters and have been used. At the present time, the optimal surgical and analgesic strategy for managing this patient population with PE has not been determined.

Nearly all of the existing published experience in pediatric pectus surgery is from individual institutions. Prospective data on complications, overall pain control, and practice patterns are lacking. In order to address some of these knowledge deficits, a large-scale multi-institutional data registry of children and adolescents undergoing pectus surgery is proposed. The creation of this prospective multicenter observational registry will provide a means to describe the incidence of clinically important perioperative adverse events and complications and to compare different types of surgical procedures across multiple institutions. Collecting data from multiple institutions is important because these procedures are performed relatively infrequently at even the busiest centers. The scientific literature describing perioperative morbidity and mortality and pain control in these patients comes from single institutions. Data collection from multiple centers will allow for benchmarking for both local and national safety and quality improvement efforts. The Society for Pediatric Anesthesia Improvement Network (SPAIN) has recruited six major academic pediatric anesthesia departments to serve as pilot sites for testing and refinement of the data collection tool, and have additional sites that will become part of the project once the data tool is finalized (approximately 15 investigative sites).

This registry will capture data relating to perioperative complications, some of which may be relatively infrequent. Collection of a robust multicenter data set will facilitate the identification of both risk factors and best practices. As a result of the infrequent occurrence of some complications and due to the modest size of this surgical population, registry enrollment is anticipated to span multiple years.

The goal of this group is to create this registry to be used for local safety and quality improvement and multi-center benchmarking in this population. Reports generated from the registry will provide individual institutions with comparative data showing how their site performs compared to composite averages from all participating sites. Queries of the composite data set may allow for identification of factors associated with improved outcomes in this population. Future queries of the data-base for research purposes will require approval of the participating members of SPAIN.

3. Preliminary Studies/Progress Report

The organization of The Society for Pediatric Anesthesia Improvement Network (SPAIN) came from the Society for Pediatric Anesthesia (SPA) Quality Improvement Committee. The group formed a steering committee and had its first official meeting in Las Vegas, Nevada at the SPA Winter Meeting on March 14, 2013. Members present at this meeting included Drs. Joe Cravero (Boston Childrenôs Hospital), Lynne Maxwell (Childrenôs Hospital of Philadelphia), Genie Heitmiller (Johns Hopkins), Rita Agarwal (Childrenôs Hospital of Colorado), Sabine Kost-Byerly (Johns Hopkins), Alan Bielsky (Childrenôs Hospital of Colorado), Sally Rampersad (Seattle Childrenôs Hospital), Allison Fernandez (All Childrenôs Hospital, St Petersburg), and Ty Muhly (Childrenôs Hospital of Philadelphia). The group agreed that SPAIN was intended to be a collaborative effort aimed at improving our understanding of perioperative anesthesia care and outcomes through sharing of information between institutions. The members present agreed that this would not be an effort to collect and study adverse outcomes (specifically). It is also *not* an attempt to collect a broad sweep of information on a large category or a large population of surgical

patients. Rather, it is an effort to collect a very targeted data set on specific procedures where there is considerable variation in practice and outcomes ï studied iteratively. Data and outcome metrics are intended to be truly targeted for the specific purposes of understanding important outcomes for chosen procedures. In addition, SPAIN will collect information on outcomes that are ñremoteò from the time of surgery (long term outcomes) ï exactly what time frame this will be is still to be determined and as long as 3 months was suggested. At this meeting the organizing committee discussed the survey concerning outcomes from the Nuss Procedure that had been written and circulated by Drs. Muhly and Maxwell of the Childrenôs Hospital of Philadelphia. The survey that was sent out to institutions across the US and internationally in an effort to study current practices for Nuss procedures. (Full abstract found in Appendix 1). Results were available from 55 institutions ï 85% US, 9% Europe, 3% Canada, 3% Australia/New Zealand. Numbers of procedures performed at each institute varied from less than 10 per year (24%) to greater than 100 (2%) The survey yielded extensive information on the nature of management of the Nuss procedure patients. Notably, the respondents reported performing these procedures on a large range of ages varying from less than 10 years old (16%) to greater than 21 years old (21%). The survey also revealed a variety of pain management strategies including IV opiates by patient controlled analgesia in 58% of reporting centers, epidural analgesia in 91% of centers, paravertebral blocks in 9% of centers, and thoracic wound catheters in 9% of centers. There was variability in the level at which catheters and block were placed as well as the solutions used as infusion for these analgesic modalities. The length of hospital stay for these procedures was reported to be between 3-5 days for 79% of centers and 6-9 days for 17% of centers. The survey also revealed that surgical requests had influenced the anesthesia management in a large percentage of reporting centers. The results of this survey were submitted and accepted for presentation to the American Society of Anesthesiologists Annual Meeting.

Previous studies on the various modalities available for pain control after pectus repair have yielded conflicting results. In 2008 St. Peter and colleagues published a retrospective analysis of 203 patients who underwent pectus repair with the Nuss procedure. [3] Of these patients, 188 committed to an epidural catheter while the others had intravenous analgesia via patient controlled delivery. Sixty five of the epidural catheters were found to provide inadequate analgesia or were non-functional immediately after the surgery. In addition, operating room time was longer for epidural patients and urinary catheterization was required for a longer time, while intravenous analgesia patients had decreased hospitalization time, and lower maximal pain scores. On the other hand, Webber et. al. [4] published a prospective, randomized comparison of thoracic epidural analgesia vs. morphine intravenous PCA for pain control after minimally invasive pectus repair involving a total of 40 patients. Their results showed lower pain scores in the epidural group with similar rates of side effects such as sedation, nausea or pruritis. In another retrospective study, Soliman et al. evaluated the effectiveness and side effect of epidural vs. intravenous analgesia after pectus repair using the Nuss technique[5]. In this analysis of 18 patients, epidural analgesia resulted in better pain control and there was no difference in the minor adverse event rate between the two groups. Finally, in 2012 St Peter et al. published a prospective, randomized trial of epidural vs. intravenous pain control after Nuss procedure in 110 patients [6]. In this case there was no difference in total length of hospital stay between the two groups. The epidural group had greater hospital charges and took longer in the operating room (also more calls to anesthesia for management in the first 24 hours) but had better pain scores for the first three days post-operatively. Subsequently there was no difference in pain scores when compared to the intravenous cohort.

Similar differences of opinion still exist concerning the primary operation for pectus repair. In a recent literature review by Nasr and colleagues [7] - nine prospective and retrospective studies were found comparing the Ravitch (open) procedure to the Nuss (minimally invasive) correction. No difference was found in the rates of complications between the two procedures when the data was considered collectively. There was no difference in the length of hospital stay or patient satisfaction with surgery. The rate of reoperation and pneumothorax was higher in the Nuss group.

4. Design and Methods

a. Study Design

Database collection for a registry.

This registry will capture data relating to the perioperative care and hospital course of children undergoing chest wall reconstruction procedures at participating institutions. Data will be collected by review of the data sources described below. The only protected health information (PHI) that will be collected in the multicenter registry is the date of service. Individual participating institutions will maintain a local master list linking registry cases to patient identifiers. Local master lists will not be shared and will be stored securely and separately. Subject data from individual institutions will be assigned a two-part registry identification number containing an institution code and a registry subject ID number.

Participating data collection sites will initially include approximately six free-standing pediatric academic medical centers. After the feasibility of data collection has been established at these initial sites, data collection will begin at additional sites.

At the local site (BCH), data will be collected through review of the eligible childrenôs medical records, including the preoperative evaluation, intraoperative electronic anesthesia record, and the daily inpatient notes until hospital discharge following surgery. Data on Post-Traumatic Stress Disorder (PTSD) symptoms, pain symptoms, and physical function assessment will be collected through a survey that will be completed at two weeks and three months after the surgery. Patients will be given the option to fill this out in hard copy on line, or over the phone. Protected health information (PHI) that will be collected include the elements of date of birth, admission/discharge details, date of surgery and medical record numbers.

The data that is transmitted to the Dartmouth Bioinformatics Group will be stripped of all protected health information (PHI) except the date of service. Each institution will designate an individual who will ensure that eligible children are captured and that the case report forms are completed accurately. Institutions will retain locally the ability to re-identify their data for QI purposes using their local master list.

b. Patient Selection and Inclusion/Exclusion Criteria

Inclusion Criteria

Males and females ages 8 years to 30 years.

Patients undergoing surgical procedures on the chest wall region performed to correct pectus excavatum deformities.

Exclusion Criteria: None

c. Recruitment Methods

1. HOW, WHERE and WHEN will potential subjects be recruited?

Potential patients will be identified by the primary investigators, anesthesia research team nurses or research coordinators by screening the surgical schedule for eligible patients. When patients are identified, the research coordinator will send a recruitment letter, the study brochure, and the consent by mail at least two weeks in advance of the scheduled surgery to all potential qualifying participants. No more than one week in advance of the scheduled surgery, the research coordinator will make contact by telephone to inform the patient and family that there is an outcomes-based study of patients undergoing chest wall surgery. Patients/families will be asked to sign informed consent either at a preoperative visit (if that occurs) or on the day of their surgery.

Patients undergoing chest wall reconstructive surgery between the ages of ages 8 to 30 will be enrolled in the registry. Six other major academic pediatric anesthesia departments will also serve as pilot sites for testing and refinement of the data collecting tool. As soon as the feasibility of the data collection has been established we will enroll all other institutions to participate in this project.

d. Description of Study Treatments or Exposures/Predictors

The study will consist of only three procedures:
Collecting and recording of data from the medical record, including preoperative assessment, operating room records, electronic anesthesia record, electronic medical charts, and quality improvement reports. Surgical and anesthesia management will be standard of care and not changed or influenced by the presence of this registry.
The patients will be asked to complete a Child Post Traumatic Stress Disorder Symptom Scale at two weeks and three months after their surgery.
The patients will be asked to rate their level of pain, the medications they are taking for pain, and their level of function at two weeks and three months after the surgery.

This study does not impose any intervention that involves risk to health.
There are no comparison treatments in the study.
There is no randomization involved.
Compliance is not required by subjects.
There are no exposures studied.

e. Definition of Primary and Secondary Outcomes/Endpoints

The primary outcome is the development of a multi-center registry of all chest wall reconstructive procedures performed in the pediatric population with pectus excavatum. The data will be used for safety and quality improvement at a local and national level, to further evaluate the incidence and nature of perioperative complications, and to compare outcomes for pain control and psychological well-being between different pediatric institutions.

Although not the primary objective, it is likely that the analysis of the multicenter registry data regarding various perioperative outcome measures will be published. Only de-identified data sets (limited datasets that only include dates of service, which are therefore de-identified to the receiving institution) or limited data sets will be released by the data coordinating center after approval of the request from the members of the Society for Pediatric Anesthesia Improvement Network. Research (SPAIN). Uses of the data gathered for this registry will acknowledge the registry as the source of the data. No identifiable data will be released to investigators seeking to use the registry data for research purposes.

f. Data Collection Methods, Assessments and Schedule (what assessments performed, how often)

Data will be collected through review of the eligible patientôs medical records at participating sites, including operating room records, anesthesia records and operative notes, progress notes, and the Child Post Traumatic Stress Disorder Symptom Scale (at two weeks and three months after the procedure).

Standardized data collection forms for the registry will be completed. The data elements that will be extracted by the research team can be found in the registry data sheet in Appendix 2. Individual registry subject data will be identified using a two-part registry identification number containing an institution code and a registry subject number. These standardized data collection forms will be prepared by the Bioinformatics group at Dartmouth College to facilitate subsequent web-based data entry.

The data that is transmitted to the Dartmouth Bioinformatics will be stripped of all protected health information (PHI) except the date of service prior to inclusion in the registry. Each institution will

designate a Primary Investigator who will ensure that eligible children are captured and that the case report forms are completed accurately. The local PI will be responsible for periodic data audits every six months. At those intervals the PI will evaluate the number of records sent to the Informatics group and compare that number to the number of records created at his/her institution. In addition the PI will fully review at least one record every six months to ensure that no systematic errors in data entry are being made. Institutions will retain locally the ability to re-identify their data for QI purposes using their local master list.

At the local site of BCH we will collect PHI for local safety and quality improvement purposes including patient name, date of birth, medical record number, and date of service. However, the only PHI that will be collected and transmitted to the registry is the date of service. Therefore, the data in the registry will constitute a limited data set as defined by HIPAA and none of the data will be readily identifiable if used in the future for research purposes. Individual participating institutions will maintain a local master list linking registry cases to patient identifiers. Local master lists will not be shared and will be stored separately in a password-protected file.

g. Study Timeline (as applicable)

Data collection for the registry will include preoperative data and data collected from the time of admission for pectus surgery until hospital discharge following surgery. Each childôs participation is limited to the time taken to abstract the required clinical information from the medical record.
It is expected that an average of approximately two to ten children per week will be enrolled to produce approximately 250-350 evaluable children per year. It should be noted that the frequency of this surgery is seasonal with many more cases occurring during the summer months when school is not in session. We anticipate conducting the study for 18 months.

h. Adverse Event Criteria and Reporting Procedures

As no additional treatment, medication or procedures will be added to the patientôs care regarding the study participation and the study is limited to existing data and specimens, we do not anticipate any adverse events related to our study other than breach of confidentiality. Breach of confidentiality will be reported at each local institution in accordance with local requirements and policies. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study these will be reported to the IRB at BCH.
Because there are no interventions involved with this study, adverse events are treated and reported as they would be without participation in the study, according to the standard of care of the BCH Anesthesia department.

In the case that a patient were to respond to the Child PTSD Symptom Scale with answers that indicated significant problems with PTSD, the patient and family will be encouraged to seek consultation with his/her primary care provider and potentially obtain treatment from a child psychiatrist.

i. <u>If the Investigator is the Sponsor/Assignee (IND or IDE-holder)</u>, he/she is responsible for selecting a qualified monitor who will monitor the progress of all clinical investigations conducted under the IND or IDE. Please describe the monitoring plan for this protocol below:

↳ Note: the EQuIP office provides monitoring services and advice. For info, contact EQuIP @ 5-7052.

5. Data Management and Statistical Analysis

a. Data Management Methods

Data will be uploaded to the data Dartmouth Bioinformatics Group through a secure web portal. Data will be stored on a password encrypted BCH computer and access will be limited to BCH investigators and BCH database managing staff. Participating institutions may enter data into the registry and can request

aggregate data by making a request through the SPAIN Steering Committee. Participating institutionôs will have access to their local data and retain the ability to re-identify their patients using locally maintained master lists.

b. Quality Control Method

All server hardware is securely located in a dedicated offsite institutional research data center hosted by Dartmouth Bioinformatics Group. Physical access to the data center is monitored, logged, controlled, and limited to approved personnel. System administration and support is provided by Dartmouth Bioinformatics. Servers and applications are actively monitored 24/7/365 and replicated between two geographically separate, fully redundant data centers. Server backup at the file system level is performed multiple times per day, and where appropriate for volatile data, a multi-day real-time accessible rolling archive can be made available. System and data recovery are accomplished through documented standard operating procedures. The system includes computer code designed to validate data at the time of data entry, preventing logical errors, and branching logic which ensures that only relevant questions are asked, thus minimizing the total number of questions asked in each survey.

The study data are collected using the Sybase database management system, with interfaces dynamically generated using Java and html coding. The production database resides on a server within the BioInformatics facility at Dartmouth, with a parallel development instance of the system loaded on a separate machine to accommodate the alteration and testing of the data collection system. The study website and data entry portal are secured using Secure Socket Layer (SSL), and each study participant is authenticated through the website and authorized to access only the parts of the website relevant to his or her institution. All data traveling among participating institutions are encrypted to ensure that data is neither intercepted nor corrupted in transfer. In addition, all data collected in this study meet HIPAA requirements for de-identification. No patient identifiable data is transmitted during this study.

Data Analysis Plan

The local BCH database will be analyzed for benchmarking anesthesia-related course and complications and quality of pain control with the multicenter database. The concept of benchmarking will refer to comparisons of each site to the aggregated standard for all participating sites in the registry database combined in order to facilitate objective comparisons and identify safety and quality performance standards. QI reports will be sent to sites every quarter - or as requested by participating sites. In addition, all sites will have access to their own data at any time they desire to access them. Aggregated data that are released to sites as part of the safety and quality improvement initiative will not include identifiable subject information. The reports will be descriptive in nature. Institutions will not be identified by name; they will instead be reported using codes. Each site will be able to identify their own data but will not know the identities of the other sites. We will obtain median patient age, sex, median weight, coexisting illnesses, and peri-operative opiate use. Operative data will include the type of procedure performed (Ravitch vs. Nuss), the agents used for general anesthesia, the type of regional anesthesia used (if any), insertion technique incidence of various postoperative complications (hemodynamic, respiratory, infection), and surgical time. Post-operative data will include pain measures, median length of hospital stay, time to first ambulation, incidence of nausea and vomiting, incidence of reoperation as well as the information on Post-Traumatic Stress symptomatology recorded at two weeks and three months after the operation.

Data collected for this registry will be analyzed by examining clustering of data or distribution and variability to determine the specific analysis technique. Descriptive statistics with frequencies will be used to describe type of surgeries, type of anesthesia/analgesia, complications. Data will be analyzed for overall degree of pain control between groups as well as trends. Data will be stratified by age, degree of preoperative of pectus deformity, primary surgical procedure, primary analgesic strategy, and

preoperative opioid use to assess differences evaluated during intra- and post-operative care. We will examine data within institutions as well as between institutions using multivariable, logistic regression analysis to establish relative pain control outcomes and best practice standards and to determine whether age, gender, analgesic technique, surgical technique, or pre-existing opioid requirement/pain syndromes predicted relative pain control outcomes ï or influenced the final incidence of PTSD symptoms.

Statistical Power and Sample Considerations

Prospective multicenter data on practice patterns, pain control and complications during intraoperative and postoperative anesthesia for pectus excavatum repair are lacking. Data from single centers are variable and difficult to compare. At this time point statistical power and sample considerations will be aimed at enrolling sufficient numbers of patients for estimating the relative effectiveness of pain control in this cohort within a 10% margin or precision using a 95% confidence interval approach.

e. Study Organization

Boston Childrenôs Hospital will be the primary coordinating site to begin this study. Joseph Cravero MD is the Principal Investigator at BCH. The registry will be housed at the Dartmouth Bioinformatics Group. All sub-sites will collect the data and enter it into the database as designed and maintained by Dartmouth Bioinformatics. Overall decisions will be made at the primary site with consultation of all sites involved.

f. Data and Safety Monitoring Plan

There is no additional risk to study participants other than possible breach of confidentiality. Please see the steps taking to minimize that risk below.

6. Risks and Discomforts

The primary risk of this registry is breach of confidentiality. The Pediatric Society for Pediatric Anesthesia Improvement Network is taking several steps to minimize this risk:

The only PHI that will be collected is date of service.
All data will be transmitted and stored securely and in an encrypted fashion online.
Hard data will be stored in locked cabinets.
Participating institutions requesting data will receive de-identified aggregate data.
Only a small group of investigators will have access to the data set.
The SPAIN registry will never request any other protected health information from each site and will never attempt to identify patients from other participating institutions.

7. Potential Benefits

There will be no direct benefits to participants. The intent of the registry is to provide benchmarking data that will enable sites to identify issues and improve local practices related to the care of patients undergoing chest wall reconstructive surgery. It offers indirect benefits to future children with similar conditions.

8. Privacy Provisions

Data will be uploaded through a secured web portal that is password protected. Each site will have access to their local data only. The principal investigator and research team at the Dartmouth Bioinformatics Data Coordinating Center will have access to all uploaded data to ensure data integrity and compliance.

9. Confidentiality Provisions

The patient data will be kept in accordance with HIPAA. Data will be stripped of all PHI except the date of service before transmission to the registry. The Dartmouth Bioinformatics Data Coordinating Center will hold strictly confidential all data contributed to the registry under the policies approved by their institutional IRB and HIPAA.

Participating sites will have access to their local data and aggregate reports from the registry.

Cases will be identified sequentially in the registry; cases will be labeled with a site prefix (institution code) and a sequential case number. When aggregate data is released, sites will be coded such that sites will not be able to identify the originating site for the data except their own. The principal investigator and research team at the Dartmouth Bioinformatics Group will have access to a master list linking the institution codes with the identities of the individual participating sites.

The only PHI that will be transmitted to Dartmouth Bioinformatics is the date of service. Therefore, the data in registry will constitute a limited data set as defined by HIPAA and none of the data will be readily identifiable if used in the future for research purposes. Although individual centers will have the ability to re-identify patients to facilitate the safety and quality improvement process using local master lists, the Dartmouth Bioinformatics will not be able to re-identify individuals based on the data provided by the sites.
Participating institutions who request data will receive aggregated non-identifiable data.
If an investigator in the future requests a data set for analysis, only de-identified data will be provided.

11. Appendix Materials ï please check off as appropriate if included with submission.

- ☐ Sponsorôs Protocol
- ☐ Investigator brochure (3 copies)
- ☐ Flow charts, schemas
- ☐ Other
- ☐ Federal grant application (3 copies)
- ☒ Survey, questionnaires, assessments
- ☐ Recruitment letters, postings, flyers
- ☐ Materials given to subjects (reminders, letters, thank-you, etc.)*

** see instructions for further information*

Appendix 1. Pectus Survey Abstract:

Postoperative management of patients following the Nuss procedure: A survey of practice

Wallis T Muhly[1], Lynne G. Maxwell[1], Joseph P Cravero[2]
[1]Department of Anesthesiology and Critical Care, The Children's Hospital of Philadelphia, Perlman School of Medicine at the University of Pennsylvania; [2]Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston, Harvard Medical School

Background: Pectus excavatum (PE) is the most common congenital chest wall deformity, occurring in approximately 1 in 1000 births [1]. PE is characterized by a depression of the anterior chest wall with varying degrees of pulmonary and cardiac compression. The most common surgical method for correction of PE is the Nuss procedure in which a convex bar is placed with thoracoscopic guidance under the sternum with no resection or cutting of the costal cartilages. Although the Nuss procedure is less invasive than the open Ravitch procedure, it is frequently associated with severe and prolonged postoperative pain [2]. A variety of analgesic options including intravenous patient controlled analgesia (PCA), thoracic epidural catheter and more recently thoracic wound catheters and paravertebral catheters have been used. At the present time, the optimal analgesic strategy for managing this patient population has not been determined.

Methods: A web-based survey was sent to representatives from 108 primarily pediatric hospitals in North America, Europe, Asia and Australia. Individuals were identified via the Society for Pediatric Anesthesia pain interest group and through personal experience. One individual per institution was contacted to complete the survey on behalf of their department to prevent larger institutions from being over represented. The survey consisted of 51 questions that included single answer, multi-answer, and free text responses.

Results: The survey was competed by 58 institutions and 55 reported use of the Nuss procedure for correction of PE. The most relevant responses regarding epidural, PCA and adjuvant medication use are highlighted in tables 1 and 2. Annual case volume is less than or equal to 25 cases in 57% of institutions and the most common age of patients is 14 to 17 years old. A clinical protocol for patient management is used in 45% of institutions. Thoracic epidural is commonly used (91%) and concomitant use of PCA is reported by 27% of institutions. Nine respondents (16%) reported that they had recently stopped performing epidurals and surgeon request was the most common reason for the change in practice. Referral of one or more patients for chronic pain management annually was reported in 22% of surveys. Mean satisfaction score regarding analgesic management of this population is 77% (SD +/- 20) amongst pain management providers and 79% (SD +/- 18) amongst surgeons.

Conclusions: Large inter- and intra-institutional variability exists in the postoperative management of patients undergoing the Nuss procedure. Further studies are needed to identify optimal management. Clinical trials comparing the safety and efficacy of primary modalities such as epidural, PCA and newer methods such as thoracic wound catheters and paravertebral blocks would enable evidence-based decision making for management of these patients. Additional investigation into the natural history of patients following the Nuss procedure, the incidence of chronic pain in this population and the role of adjuvant medications, such as gabapentin, that mitigate pain related to nerve stretch/irritation would also be of value.

Appendix 2: Data Acquisition For SPAIN Pectus Repair Registry

Date of Service:_____

Affix patient identification sticker here or complete blanks below:

Patient Name:_____

Patient MR#:_____

Demographics: **Institution ID#:_____ Registry ID#:_____**

Date of Service:_____

Age:____ y Gender: M / F Weight (kg):_____ Height (cm):_____ ASA PS:___

Diagnosis:_____

Procedure: ___Nuss ___Ravitch

Surgeon #: 1 / 2 / 3 / 4 / 5

Preoperative History:

Pectus Excavatum ï Haller index: _____

Medical Comorbidities:
psychological/developmental issues, autism, metabolic disease, cardiac (murmur, mitral valve prolapse, congenital heart disease, h/o dysrhythmia), pulmonary issues (asthma).
Other:
1. _____

2. _____

Preoperative Medications:

Pain Meds? 1. non-opioid (gabapentin, Motrin, Tylenol) 2. opioid ï oxycodone, hydrocodone, OxyContin, methadone (How long preop) Include ADHD drugs or other psych medications.
Other:
1. _____
2. _____

Intraoperative Management:

Times (24 hour format):

Anesthesia Start:_____ Anesthesia Finish:_____

Surgery Start:_____ Surgery Finish:_____

Anesthetic Technique:

*Induction Med***:** Propofol/Etomidate/Inhalation agent, **Opiate:** fentanyl, morphine, hydromorphone, sufentanyl

*Muscle Relaxant***:** rocuronium,vecuronium,cisatracurium

*Anesthetic Maintenance***:** Inhalational / Propofol infusion / Dexmedetomidine infusion / Ketamine infusion / Other

Opioids: Intermittent bolus (fentanyl, morphine, hydromorphone, sufentanyl) / Fentanyl infusion / Remifentanil infusion / Other opioid infusion)

Adjunctive Medications: Ondansetron (or similar), Dexamethasone, Antibiotics, Paracetamol, NSAIDs

Analgesia:

_____Epidural- placed at Level T 4,5,6,7,8,9,10,11

Technology: Fluoro/Epidurogram/ultrasound

Position = ___sitting ___lat debitus

___awake ____sedated ____asleep

_____Block Paravertebral level T4,5,6,7,8,9,10,11,12 Technology: Ultrasound/Nerve Stim

_____Wound Catheter

Block Drugs:___ Bupivacaine .1% ____Bupivacaine .25% _____Bupivacaine 0.50%

___ Ropivacaine 0.1% ____Ropivacaine 0.2%

___ Clonidine ____Opiate - ___Fentanyl ___Morphine____Hydromorphone

Totals: Total opioid dose in OR

____fentanyl

____morphine

____hydromorphone

____sufentanyl

____Remifentanil

Total local anesthetic dose in OR

____Bupivacaine

____Ropivacaine

____Lidocaine

Surgical Data:

a. Operation performed Nuss/Ravitch
b. Nuss
    i. How many bars 0 1 2
    ii. Stabilizer clips
        1. Bar #1 (lower) 0 1 2
        2. Bar #2 (upper) 0 1 2
    iii. Secured to chest
        1. None
        2. Sutures around bar/rib
        3. Sutures around stabilizer clip
        4. Wires around bar/rib
        5. Wires around stabilizer clip
        6. other
    iv. Thoracoscopy used Y/N R/L
    v. Bar passed from R → L L → R

c. Ravitch
   i. Bar/Strut used 0 1 2 3+
   ii. Levels dissected 0 1 2 3 4+
2. Foley ___intraop ___postop ___none or ___Straight cath
3. CT/drain ___intraop ___postop ___none

Intraoperative Fluid Totals:

LR (mL): _____

0.9%NS(mL): _____

Plasmalyte (mL): _____

PRBCs (mL): __

Hetastarch (mL): __

Autologous blood __

Intraoperative Complications:

☐ Cardiac Arrest	☐ Death	☐
☐ Inadvertent extubation	☐ Bradycardia requiring Rx	☐ Suspected transfusion reaction
☐ Difficult ventilation	☐ Pneumothorax	☐ Reintubation in OR
☐ Laryngospasm	☐ Bronchospasm	☐ Pulmonary edema
☐ Carotid artery puncture	☐ Cardiac dysrhythmia	☐ Thromboembolic event
☐ Hypotension	☐ Other:_____ __	☐ Other:_____ __

Post Operative Information:

PACU:

Block information will come from OR.

Analgesia: Systemic strategies for opiates:
___ PCA ____Intermittent Bolus
___ Morphine
___ Dilaudid
___ Fentanyl
___ Bolus only
___Bolus plus continuous

Other Medications: non-opioid - systemic

____benzodiazepine (midazolam, valium, Ativan, Xanax),
____NSAIDS (ketorolac, Ibuprofen)
____acetaminophen

Outcomes:

1. Pain: (Subjective numerical rating, or Objective FLACC)
   Highest pain level (at least 5 mintues) during PACU stay____
   Treatment of Pain
   ____catheter bolus needed (dose)
   ____Systemic Opiates (total dose and type given)
   ____Tylenol (dose)
   ____NSAIDS (total dose and which one given)
   ____ Benzodiazepines_(total dose and which one given)__

2. Agitation on Emergence? (PAED >10 - If yes Treatment- medication/dose)

3. Adverse Events in PACU:

____Apnea
____Need for airway intervention
____Hypotension
____Nausea and Vomiting require extra treatment
____Itching If Yes, then Treatment?
____Oxygen supplementation (blow by, nasal cannula, facemask)

Post PACU – Floor or ICU: **This Information Repeated Everyday until discharge.**

Recorded pain management should reflect the modality that was used for the majority of the day.

1. **Pain Scores on floor** ï (numerical pain score developmentally appropriate patients/FLACC score for developmentally impaired):
   a. Mean pain score for 24 hours beginning and ending at 10 AM _____
   b. Maximal Pain Score during the day_____

2. **Functionality.**
   Patient out of bed to chair - yes/no
   Bathroom - yes/no How many times___
   Foley in place - yes/no
   Walking in hallways - yes/no
   po fluids - yes/no
   regular diet - yes/no
   passing gas - yes/no
   stool - yes/no
   abdominal distention yes/no

3. **Epidural in place yes/no:**
   a. If yes then ï Opiates (fentanyl, dilaudid, morphine)
      i. clonidine
      ii. local anesthetics (bupivacaine,
      iii. ropivacaine)
      iv. What infusion rate____ PCEA or continuous infusion.

4. **Wound catheter in place?** yes/no
    a. If yes then local anesthetics (bupivacaine, ropivacaine)? What infusion rate?

5. **Analgesia: Systemic – Include total dose for 24 hours**
    _____PCA - ___Morphine
        i. ___Dilaudid
        ii. ___Fentanyl
        iii. ___Bolus only
        iv. ___Bolus plus continuous

Other Medications: enteral/parenteral:
____benzodiazepine (midazolam, valium, Ativan, Xanax),
____NSAIDS (ketorolac, Ibuprofen)
____acetaminophen,
____opioid *(Not PCA)* (morphine, fentanyl, hydromorphone, methadone)
____Neurontin/lyrica

Post operative analgesia managed by
___Anesthesiology operative team
___Anesthesiology pain service
___Anesthesiology block team
___Surgical team
other -_____

1. Side effects specific to pain managemebnt: Respiratory depression? Apnea? Need for airway intervention? Hypotension? Treatment? Reversal medications used for respiratory depression? Transfer to higher level of care? Itching? Nausea and vomiting? Need for urinary catheter/intermittent cath for urinary retention.

Major adverse events (general) Postop Data: 24hrs

☐ Cardiac arrest	☐ Death	☐ Transfusion reaction
☐ Hypovolemic shock or hypotension	☐ Unplanned extubation	☐ Reintubation in ICU
☐ Pulmonary edema	☐ Respiratory failure	☐ Pneumonia
☐ CLABSI or blood stream infxn	☐ Sepsis	☐ Surgical site infection
☐ Unplanned 2nd surgery	☐ DVT	___
☐ Thromboembolic event	☐ Other:_____	___

Meds prescribed for adverse effects:
____HT3 drugs,
____Benadryl, nubain, etc. If nubain/stadol given, need to question whether it was for pruritus, pain, or urinary retention.
____Bowel regimen ï colace, dulcolax, senna. Ordered per routine/problems with passing gas, stooling.

Discharge Medication:

1. Who orders (surgeon, pain service, hospitalist, etc.?),
2. Opioid (oxycodone, OxyContin, hydrocodone)
3. Gabapentin/pregabalin
4. Benzodiazepine
5. NSAIDS
6. acetaminophen.
7. Neurontin/Lyrica
8. Other _____

2 Week/2 Month F/U:

1. PTSD questions for patients (questionnaire)

2. Pain measures ï daily pain level (Max)_____

3. Functional level relative to baseline. _____school attendance, ___Sports

4. Still taking medications? Which ones_____

Appendix 3.

The Child PTSD Symptom Scale (CPSS) – Part I

Below is a list of problems that kids sometimes have after experiencing an upsetting event. Read each one carefully and circle the number (0-3) that best describes how often that problem has bothered you IN THE LAST 2 WEEKS.

Please write down your most distressing event:

_____

Length of time since the event:

_____

0	1	2	3
Not at all or only at one time	Once a week or less/ once in a while	2 to 4 times a week/ half the time	5 or more times a week/almost always

1.	0	1	2	3	Having upsetting thoughts or images about the event that came into your head when you didn't want them to
2.	0	1	2	3	Having bad dreams or nightmares
3.	0	1	2	3	Acting or feeling as if the event was happening again (hearing something or seeing a picture about it and feeling as if I am there again)
4.	0	1	2	3	Feeling upset when you think about it or hear about the event (for example, feeling scared, angry, sad, guilty, etc)
5.	0	1	2	3	Having feelings in your body when you think about or hear about the event (for example, breaking out into a sweat, heart beating fast)
6.	0	1	2	3	Trying not to think about, talk about, or have feelings about the event
7.	0	1	2	3	Trying to avoid activities, people, or places that remind you of the traumatic event
8.	0	1	2	3	Not being able to remember an important part of the upsetting event
9.	0	1	2	3	Having much less interest or doing things you used to do
10.	0	1	2	3	Not feeling close to people around you
11.	0	1	2	3	Not being able to have strong feelings (for example, being unable to cry or unable to feel happy)

12.	0	1	2	3	Feeling as if your future plans or hopes will not come true (for example, you will not have a job or getting married or having kids)

0	1	2	3
Not at all or only at one time	Once a week or less/ once in a while	2 to 4 times a week/ half the time	5 or more times a week/almost alway

13.	0	1	2	3	Having trouble falling or staying asleep
14.	0	1	2	3	Feeling irritable or having fits of anger
15.	0	1	2	3	Having trouble concentrating (for example, losing trac of a story on the television, forgetting what you read, r paying attention in class)
16.	0	1	2	3	Being overly careful (for example, checking to see wh is around you and what is around you)
17.	0	1	2	3	Being jumpy or easily startled (for example, when someone walks up behind you)

The Child PTSD Symptom Scale (CPSS) – Part 2

Indicate below if the problems you rated in Part 1 have gotten in the way with any of the following areas of your life DURING THE PAST 2 WEEKS.

	Yes	No	
18.	Y	N	Doing your prayers
19.	Y	N	Chores and duties at home
20.	Y	N	Relationships with friends
21.	Y	N	Fun and hobby activities
22.	Y	N	Schoolwork
23.	Y	N	Relationships with your family
24.	Y	N	General happiness with your life

References:

1. Goretsky MJ, Kelly RE, Jr., Croitoru D, Nuss D. Chest wall anomalies: pectus excavatum and pectus carinatum. Adolesc Med Clin 2004;15:455-71.
2. Densmore JC, Peterson DB, Stahovic LL, et al. Initial surgical and pain management outcomes after Nuss procedure. J Pediatr Surg 2010;45:1767-71.
3. St Peter SD, Weesner KA, Sharp RJ, Sharp SW, Ostlie DJ, Holcomb GW, 3rd. Is epidural anesthesia truly the best pain management strategy after minimally invasive pectus excavatum repair? Journal of pediatric surgery 2008;43:79-82; discussion
4. Weber T, Matzl J, Rokitansky A, Klimscha W, Neumann K, Deusch E. Superior postoperative pain relief with thoracic epidural analgesia versus intravenous patient-controlled analgesia after minimally invasive pectus excavatum repair. The Journal of thoracic and cardiovascular surgery 2007;134:865-70.
5. Soliman IE, Apuya JS, Fertal KM, Simpson PM, Tobias JD. Intravenous versus epidural analgesia after surgical repair of pectus excavatum. American journal of therapeutics 2009;16:398-403.
6. St Peter SD, Weesner KA, Weissend EE, et al. Epidural vs patient-controlled analgesia for postoperative pain after pectus excavatum repair: a prospective, randomized trial. Journal of pediatric surgery 2012;47:148-53.
7. Nasr A, Fecteau A, Wales PW. Comparison of the Nuss and the Ravitch procedure for pectus excavatum repair: a meta-analysis. Journal of pediatric surgery 2010;45:880-6.