Children’s Healthcare of Atlanta

Friends Research Funding Application

Title of Project: **Effect of an accelerated discharge protocol following posterior spinal fusion for adolescent idiopathic scoliosis**

Principal Investigator:

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Dates of Proposed Project: December 2013-June 2015

Direct Cost From Budget Page: $48330

Are Human Subjects Involved? Yes  No

Where will Research Occur?

Scottish Rite Hospital

Egleston Hospital

Satellite Location (Specify)

Physician Office (Specify) Emory Orthopaedics & Spine Center

Other (Specify)

Co-Investigators:

Timothy S. Oswald, MD

Robert W. Bruce Jr., MD

Dennis P. Devito, MD

Institutions where funding will be applied for:

Emory University Application Deadline      Funding Limit

      Application Deadline      Funding Limit

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Principal Investigator Date

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Division Director Date

OR

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Practice Representative Date

**Research Plan**

A 5-page\*, single-spaced, Arial 11 font, 0.5” margin scientific plan document that provides the following if applicable to your study. At minimum all applications should include Sections A, B, C, D, E and F.

\* References should be listed but are not included in these page limitations. Appendices are not allowed.

1. Introduction
   1. Study Abstract

The Spinal Outcomes Program (SOP) is designed to evaluate the efficacy, safety, quality, and value offered by a post-operative protocol aimed to accelerate discharge following posterior spinal fusion (PSF) for Adolescent Idiopathic Scoliosis (AIS). A prospective analysis of patients treated by eleven different children’s orthopaedists in three practices will allow clinical, patient related quality and economic analysis of the protocol’s effect on scoliosis care. Safety will be evaluated with regard to postoperative complications. Quality will be assessed by survey of patient and familyquality of life. Direct cost analysis will be performed by querying direct hospital charges and assessing return to work for parents.

* 1. Primary Hypothesis

The use of an accelerated discharge protocol following posterior spinal fusion for adolescent idiopathic scoliosis decreases hospital stay without any significant difference in complication rate, allowing earlier return to school and work. Additionally, this protocol will result in a small, but realized, cost savings.

* 1. Purpose of Study

This study will evaluate the safety, quality, and direct costs of an accelerated discharge protocol on patients undergoing PSF for AIS.

1. Background
   1. Prior Literature and Studies

Adolescent Idiopathic Scoliosis (AIS) is characterized by a progressive curvature of the spine initially presenting during the pre-adolescent and adolescent growth spurt. By definition, there is no underlying neuromuscular or structural abnormality and the vast majority of patients are otherwise healthy with few comorbidities. Scoliosis affects between 2%-4% of the population between 10 and 16 years of age with surgical grade scoliosis occurring in 0.1% of teenagers. Surgical treatment of AIS is undertaken when the spinal curvature is progressive and cannot be managed conservatively in a brace or by other conservative means. Posterior spinal fusion for AIS remains a costly procedure due to the price of modern instrumentation systems and prolonged hospital stays with average hospital charges of $113,303 and average length of stay of 5.6 days (Daffner et al Spine 2010). Kamerlink et al found that implants represented the highest percentage of overall hospital costs ($9950±$6784, 29.0%) while hospital room comprised 22.0% of costs ($7538±$2780). While this study found that the number of pedicle screws used, the number of vertebral levels fused, and the surgical approach were independent predictors of hospital cost, there was no analysis of length of stay. (Kamerlink et al JBJS 2010) Length of stay following spinal fusion is dependent on geographic region but averages 5.2 to 6.5 days (Daffner Spine 2010). Recent studies have shown the feasibility of post operative admission to the floor without an initial stay in the intensive care unit. (Skaggs et al, SRS 2012). No studies, to our knowledge, have been performed evaluating factors that are responsible for the length of post operative inpatient stays.

Our hospital system began development of an accelerated post operative protocol in 2005 to maximize post operative efficiency without compromising care. The protocol focused on nursing education, aggressive post operative mobilization with a physical therapist, early transition to oral narcotics, and discharge prior to complete return of bowel function. Without formal mandate, one of the two hospitals in our system had adopted the newer accelerated protocol in 2005 while the other used a more traditional post operative protocol following posterior spinal fusion. This afforded us the ability to perform a retrospective clinical and cost analysis evaluating the benefits realized by the protocol over our two hospitals, thus directly comparing the clinical and cost related outcomes between groups. A retrospective analysis comparing patients treated with and without the accelerated pathway revealed a 31.7% decrease in length of stay, and 33% decrease in cost of room and board, with no increase in adverse affect. (Fletcher et al, POSNA 2013) The major limitation of this study was the lack of patient specific quality outcomes due to the retrospective nature. A prospective study would allow for better assessment of patient-related clinical outcomes including disease specific scoring (SRS-22), general health (SF12), return to school and/or work, transition from oral narcotic pain medication to non-narcotic analgesics, and general satisfaction with the post operative pathway.

* 1. Rationale for this study

The results of this project may allow for more widespread adoption of accelerated discharge protocols following spinal fusion. As previously described, hospital stay represents up to 22% of the costs related to posterior spinal fusion. Expediting discharge without detracting from clinical care or increasing complications could potentially mitigate some of these costs and increase bed availability, and allow for earlier return to school and work for children and their parents. Additionally, patient satisfaction would increase in the short term by enabling earlier restoration of normalcy in the household.

1. Study Objectives
   1. Primary Aim

The primary objective of this project is to prospectively evaluate the feasibility, efficacy, safety, and quality provided by a post-spinal fusion protocol designed to expedite discharge.

* 1. Secondary Aim

The secondary objective is to analyze cost savings generated by early discharge and analyze the benefits realized by the family with regard to earlier return to work.

* 1. Rationale of selected outcomes

Surgical management of AIS continues to impose significant costs on patients and the healthcare system. Approximately 38,000 patients undergo spinal fusion for scoliosis each year in the United States with per-patient average charges between $103,256 and $152,637 depending on geographic region due to costly implants and extensive hospital stays. This study seeks to evaluate an accelerated discharge pathway developed at CHOA to improve efficiencies within the post operative hospital stay. This has resulted in 31.7% shorter hospital stays without an increase in complications. Clinical outcomes and patient satisfaction with this pathway are still unknown, as are the immediate benefits to the family with regards to return to work or school.

1. Study Design
   1. Overview of Design Summary

This will be a prospective, longitudinal data collection study enrolling up to 248 subjects. All subjects will be selected according to the study criteria as described below. All evaluations and procedures will be completed according to the surgeon’s standard of care.

Data will be collected pre-operatively, intra-operatively, and during the subjects in-hospital stay. Follow-up data will be collected at 1 month, 6 months, 12 months, and 24 months post-surgery.

Our hospital system has recently increased our number of providers and currently performs approximately 500 posterior spinal fusions yearly. Using data from our retrospective analysis, approximately 75% of these (375) are for AIS. Our first objective is to evaluate the feasibility, quality, and safety of the AD protocol. This will be performed by prospectively enrolling patients scheduled for PSF for AIS. Patients will be enrolled in the hospital prior to surgical procedures due to the large number of satellite clinics used by the groups

Our second objective is to analyze the value of our protocol with regards to both the family and health care system. Using both historical controls from our initial retrospective review as well as a hypothetical cost analysis using national controls (discharge 5.6 days following surgery), we will document the cost savings from expedited discharge. To document the value realized by the family, we will look at return to work following spinal fusion and correlate to the time of actual discharge. Hospital charges will be recovered from hospital billing records as has been previously performed in our institution (see above retrospective study)

* 1. Subject Selection and Withdrawal
     1. Inclusion Criteria

Subjects must meet ALL of the following

* + Signed Informed Consent
  + Male and Females between ages of 10-18, both inclusive
  + Scheduled for posterior spinal fusion with pedicle screw and/or hybrid instrumentation
    1. Exclusion Criteria

Subjects will be excluded if they meet ANY of the following

* + Male and Females under the age of 10 and 19 years and older
  + Patients who have spinal deformities with neuromuscular involvement
  + Patients undergoing anterior or circumferential spinal fusion
  + Prior spinal surgery
    1. Ethical Considerations

As all patients within the CHOA system are currently managed under the AD pathway, this will be considered the standard of care. No comparative group will be analyzed other than historical controls.

* + 1. Subject Recruitment Plans and Consent Process

Investigators will identify patients who have been diagnosed with AIS and are candidates for PSF treatment. The investigators will inform the patient and if patient is interested the investigator will discuss the study with the patient and refer the patient to the coordinator. All patients will complete the informed consent process with study staff and be asked to sign the IRB approved consent form before any study-related procedures will occur.

* + 1. Randomization Method and Blinding

All patients will be offered by a post-operative protocol aimed to accelerate discharge. No randomization or blinding will occur in this protocol.

* + 1. Risks and Benefits

There are specific risks for PSF. This procedure will be according to the investigators standard of care and investigators will review all risks thoroughly prior to any treatment and patients will be asked to sign a separate surgical consent form.

As in all clinical studies, confidentiality of protected health information may be breached due to study-related activities beyond those of routine clinical care. This risk will be minimized by not collecting personally identifying information on study forms, using a unique study ID number on study forms, and allowing only those people authorized to be part of this study to have access study forms.

Subjects might not receive any direct health benefits from participation in this study. The information gained from this study might benefit other patients in the future. Study results will be published to contribute to the AIS literature.

* + 1. Early Withdrawal of Subjects

Subjects will be encouraged to complete all protocol requested study activities. Subjects may withdraw from the study at anytime for any reason. Likewise, the Principal Investigator may withdraw subjects who they deem is not in their best interest to continue and subjects who are not compliant with protocol.

The reason for early withdrawal will be recorded on the Early Withdrawal Form and in the subject’s medical record. If the subject is willing, final data will be collected prior to the subject withdrawing from the study. Subjects who withdraw from the study will be continued to be followed by their study doctor’s usual standard of care without affect on their postoperative course.

1. Study Procedures
   1. Screening for eligibility

Investigators will identify patients who have been diagnosed with AIS and are candidates for PSF treatment. The investigators will inform the patient and if patient is interested the investigator will discuss the study with the patient and refer the patient to the coordinator. All patients will complete the informed consent process with study staff and be asked to sign the IRB approved consent form before any study-related procedures will occur.

* 1. Schedule of Measurements

Subjects will be evaluated and data collected pre-operatively, intra-operatively, and post-operatively. With an enrollment period of one year and patient participation period of two years, this study will last up to three years.

Prior to the surgical procedure, spine and other medical history will be collected on study forms. Subjects will complete the following surveys: [This was not in the previous plan but all forms should be collected pre-op. We need a baseline to find differences]

All surgical procedures will be performed under the investigator’s standard of care. Details of the surgery will be collected on study forms to include operative time, blood loss, and ASA status.

In-patient hospital admission data collection will include length of stay, readmission, financial information, patient satisfaction, SF-12, SRS 22, and safety.

Post-operative follow-up will be completed at 1 month, 6 months, 12 months, and 24 months. At these follow-up visits, study forms will collect data on subject satisfaction, subject quality of life return to work/school, and safety as outlined in Table 1. Moreover, subjects will complete the SF-12 and SRS 22 surveys. The PEDSQL is designed to quickly evaluate the health related quality-of-life in children. It evaluates the physical, emotional, social and school function of a child who is either healthy or has an acute or chronic health condition. Patient satisfaction will be evaluated by a short questionnaire designed to evaluate the happiness of the patient and family with regards to the perioperative period. Subjects will also complete return to school forms and return to work for parents will be documented whenever possible.

Other data collection mentioned that needs to be put in here: comorbidities and need for unscheduled outpatient office visits

* 1. Visit schedule

The schedule of study activities and data collection are shown in Table 1.

**Table 1: Study Activities and Data Collection**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Enrollment | Surgery | In-Patient Admission | 6 weeks | 6 Month | 12 Month | 24 Month |
| Informed Consent | X |  |  |  |  |  |  |
| Medical History | X | X |  |  |  |  |  |
| Operative Data |  | X |  |  |  |  |  |
| Length of Hospital Stay |  |  | X |  |  |  |  |
| Patient Satisfaction | X |  | X | X | X | X | X |
| SRS 22 | X |  | X | X | X | X | X |
| PEDSQL | X |  | X | X | X | X | X |
| Return to School/Work |  |  |  | X | X | X | X |
| Financial Data |  |  | X |  |  |  |  |
| Safety Data |  |  | X | X | X | X | X |

* 1. Safety and adverse events
  2. Safety and compliance monitoring
     1. Data Monitoring, Data Safety and Monitoring
     2. Definition of adverse events

1. Statistical Plan
   1. Sample Size Determination, Power
   2. Interim Monitoring
   3. Analysis Plan
   4. Statistical Methods
2. Cited References

1. Carreon, L.Y., et al., *Non-neurologic complications following surgery for adolescent idiopathic scoliosis.* J Bone Joint Surg Am, 2007. **89**(11): p. 2427-32.

2. Daffner, S.D., C.F. Beimesch, and J.C. Wang, *Geographic and demographic variability of cost and surgical treatment of idiopathic scoliosis.* Spine (Phila Pa 1976), 2010. **35**(11): p. 1165-9.

3. Kamerlink, J.R., et al., *Hospital cost analysis of adolescent idiopathic scoliosis correction surgery in 125 consecutive cases.* J Bone Joint Surg Am, 2010. **92**(5): p. 1097-104.

4. Auerbach, J.D., et al., *Perioperative outcomes and complications related to teaching residents and fellows in scoliosis surgery.* Spine (Phila Pa 1976), 2008. **33**(10): p. 1113-8.

5. Rampersaud, Y.R., et al., *Intraoperative adverse events and related postoperative complications in spine surgery: implications for enhancing patient safety founded on evidence-based protocols.* Spine (Phila Pa 1976), 2006. **31**(13): p. 1503-10.

6. Fu, K.M., et al., *Morbidity and mortality associated with spinal surgery in children: a review of the Scoliosis Research Society morbidity and mortality database.* J Neurosurg Pediatr, 2011. **7**(1): p. 37-41.

7. Smith, J.S., et al., *Rates of infection after spine surgery based on 108,419 procedures: a report from the Scoliosis Research Society Morbidity and Mortality Committee.* Spine (Phila Pa 1976), 2011. **36**(7): p. 556-63.

8. Reames, D.L., et al., *Complications in the surgical treatment of 19,360 cases of pediatric scoliosis: a review of the Scoliosis Research Society Morbidity and Mortality database.* Spine (Phila Pa 1976), 2011. **36**(18): p. 1484-91.

9. Patil, C.G., et al., *Inpatient complications, mortality, and discharge disposition after surgical correction of idiopathic scoliosis: a national perspective.* Spine J, 2008. **8**(6): p. 904-10.

10. Sanders, J.O., et al., *Variation in care among spinal deformity surgeons: results of a survey of the Shriners hospitals for children.* Spine (Phila Pa 1976), 2007. **32**(13): p. 1444-9.

11. Murphy, N.A., et al., *Spinal surgery in children with idiopathic and neuromuscular scoliosis. What's the difference?* J Pediatr Orthop, 2006. **26**(2): p. 216-20.

12. Shan L, Skaggs DL, Lee C, Kissinger C, Myung KS. I*ntensive Care Unit Versus Hospital Floor: A Comparative Study of Postoperative Management of Adolescent Idiopathic Scoliosis Patients*  J Bone Joint Surg. In press

13. Fletcher ND, Shourbaji N, Mitchel PM, Oswald TS, Devito DP, Bruce RW. *Clinical and economic implications of accelerated discharge following posterior spinal fusion for adolescent idiopathic scoliosis*. Accepted for presentation, Pediatric Orthopaedic Society of North America annual meeting 2013, Toronto, Canada.

**Budget Instructions and Guidelines**

***Personnel***

* Staff eligible for salary support include study coordinator, research nurse or assistant, statistician, research lab tech.
* Investigators are not eligible for salary support
* Salary support for clinical staff should be expressed in a per subject cost.

Example: total hourly rate x time required per subject x number of subjects.

Scenario: If you are budgeting for a coordinators salary and that coordinators hourly rate including fringe is $25.00 per hour. You then estimate the time the coordinator will spend working on each subject enrolled, for example 2.5 hours per patient.

$25 x 2.5 hours per pt x 50 patients = $3,125 = total amount requested for coordinator.

* Include fringe benefits where appropriate. For example, Children’s Healthcare fringe benefit rate is 22%.

***Consultant***

* Salary support for statistician should be expressed in a per hour cost.

Example: $100 per hour x 10 hours of statistical support required = $1,000.

* Other: non-Children’s employee providing a service not available through Children’s.
* Children’s employees cannot be paid as consultants or contract employees.

***Equipment***

* Computer equipment is not funded

***Supplies***

* Itemize all supplies by category.

***Patient Expenses***

* + Costs of all research procedures (for example: laboratory tests, MRI’s, EKG’s, ECHO’s, Chest X-ray)
  + Patient costs must include Children’s technical fee and professional fee if applicable (for example: if you are requesting an EKG, there is a technical fee from Children’s and a professional fee from Sibley Heart Center Cardiology for interpretation)
  + Pharmacy expenses
  + Compensation/Reimbursement for patient/parent (parking, time and travel compensation). Breakdown as per patient costs.

**Sample Budget**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Children’s Personnel**  **Name** | **Role on**  **Project** | **# of Subjects** | **Time**  **per Subject** | **Hourly**  **Rate** | **Base**  **Salary** | **Fringe**  **(CHOA**  **Rate 22%)** | **Total Salary Requested** |
| Jane Smith | Coordinator | 50 | 2 hours | 25.00 | $2,500 | $550 | $3,050 |
| John Doe | Data Manager | 50 | 3 hours | 20.00 | $3,000 | $660 | $3,660 |
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| **Total Children’s Salary Requested** | | | | | | | **$6,710** |

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| --- | --- | --- | --- | --- | --- | --- |
| **Consultant/Non-Children’s Personnel Costs** | | | | | | |
| Name | Role on  Project |  |  |  |  | Total Salary Requested |
| John Doe | statistician |  |  |  |  | $1,000 |
|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |
| **Total Consultant/Non-Children’s Personnel Costs** | | | | | | $1,000 |

|  |  |
| --- | --- |
| **Equipment (itemize):**  None | 0 |
| **Supplies (itemize by category):**  Optical Disks 10 @ $25 = $250  Questionnaires and Surveys $850  Office Supplies $200  Specimen Shipping Supplies $500  UPS Charges $300 | $2,100 |
| **Patient Expenses (Itemize by category)**  Patient reimbursement 50 pts @ $25 =$1,250  Blood Draw and Specimen Processing 50 @ $23 $1,150 | $2,400 |
| **Total Budget Requested** | **$12,210** |

**Budget**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Children’s Personnel**  **Name** | Role on  Project | # of Subjects | Time  per Subject | Hourly  Rate | Base  Salary | Fringe  (CHOA 22%) | Total Salary Requested |
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| **Total Children’s Salary Requested** | | | | | | |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Consultant/Non-Children’s Personnel Costs** | | | | | | |  |
| **Name** | Role on  Project | # of Subjects | Time  per Subject | Hourly  Rate | Base  Salary | Fringe  (Emory Non-Fed 27.75%) | Total Salary Requested |
|  | Coordinator | 248 | 6.0 hrs | 25.00 | $37,200 | $10,230 | $47,430 |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **Total Consultant/Non-Children’s Personnel Costs** | | | | | | | $47,430 |

|  |  |
| --- | --- |
| **Equipment (itemize):**  None | 0 |
| **Supplies (itemize by category):**  Office supplies= $200  Study forms and questionnaires=$500  Mail supplies=$100 | $900 |
| **Patient Expenses (Itemize by category):** |  |
| **Total Budget Requested** | **$48,330** |