**Predictive Modelling of Long-Term Surgical Outcomes for Lumbar Degenerative Disorders and Complex Spinal Deformity.**

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| **University:** University of California, San Francisco | |
| **PI and Co-PI name(s):** Sigurd Berven MD | **Proposed Budget:** <br> **(includes 10% indirects)**: $40,000 |
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**Need and Industrial Relevance**:

The management of spinal disorders is characterized by significant variability in surgical approaches to care, expected clinical outcomes, and expected rates of complication. The end result of care is determined by factors including procedure-specific and patient-specific factors.  Predictive modelling can be useful in empowering informed choice for patients, and in guiding evidence-based treatment recommendations.  While predictive models have been developed with high levels of accuracy and AUC values, based upon known datasets, the accuracy of predictive modelling in prospective studies has been more limited.  Outcomes of interest include complications, readmission, reoperation, health status change, costs and value of care.  Durability of outcome of care over time is an important consideration in estimating the cost-effectiveness of surgical care.  Many studies in cost-effectiveness for degenerative disorders, and for deformity, are limited by length of follow-up and inadequate measurement of costs. With a better understanding of expected outcomes, complications, and cost, the appropriateness of a given surgical procedure in a particular patient can be determined. Appropriate surgery is surgery in which the expected and observed benefits of surgery exceed the expected and observed complications of care.  The purpose of this study is to develop predictive models for appropriateness of surgery for lumbar degenerative conditions and for complex deformity of the spine.

**Project Aims (including Hypotheses)**:

The purpose of this study is to follow on our previous work regarding the cost-effectiveness of surgery for degenerative pathology and deformity, and to identify predictor variables for the outcomes of clinical improvement, readmission, revision surgery, cost-effectiveness, and appropriateness of surgery.  A predictive model will be based upon patient specific and diagnosis specific variables. This model and other established models (SPORT calculator, Spine Sage, NSQIP Calculator) will then be compared.  In parallel, we will apply a multidisciplinary conference prediction of complications to determine the accuracy of computerized predictive models with the wisdom of a crowd of clinicians.

The specific outcomes for the predictive model include expected complications, readmission, reoperation, and appropriateness of surgery based upon observed outcomes and complications.

**Methods**:

Retrospective analysis of clinical outcomes and complications of patients treated with surgery for lumbar degenerative pathology and complex multilevel fusion. We will identify patient-specific and procedure specific variables and determine how these independent variables predict the outcomes using a multivariate regression. We have studied the predictor variables, outcomes, and cost components of over 500 cases of single level fusion for lumbar degenerative pathology, and 120 cases of multilevel fusion for deformity. Currently, we have clinical outcomes for over 70% of the deformity cases, and 30% of the single level fusion cases. The patient predictor variables of interest and disease and procedure specific variables are listed below.

Patients will have clinical and radiographic data evaluated 1 year after surgery; including health status change (ODI, SRS-22, EQ5-D), medical and surgical complications, re-operations, readmissions, and cost effectiveness. A multivariate regression will be used to identify variables that are independent predictors of outcomes. A predictive model will be based upon the predictor variables, and subsequently tested on an independent cohort.

A subset of patients for whom data is complete will be presented to a multidisciplinary conference including fellowship trained spine surgeons (Neurosurgery and Orthopaedic Surgery), anesthesia staff, intensive care specialists, and non-operative spine specialists. A questionnaire will be completed by each member of the conference. The accuracy of the multidisciplinary conference participants in predicting observed complications will be compared to our predictive model developed during this study and against established computer models (SPORT Calculator, NSQIP Calculator and the Spine Sage program) using paired analysis of observed and expected outcomes. The appropriateness of surgery will be rated using the Rand/UCLA criteria preoperatively, and compared to the observed clinical improvement and complications for each case.

1) Patient variables:

   a. Age, gender, work status, educational level, smoking status, pain medication usage, insurance

   b. Comorbidities: Frailty, Mental status, BMI, Bone Health, Nutrition status, Blood Sugar Control, Infection history/risk, Cardiovascular disease, Liver Disease, Renal Disorders, Inflammatory Arthropathy

2) Disease-specific and Procedure Specific variables:

   a. Pre-operative and Post-operative Radiographic Parameters: Pelvic Incidence (PI), Lumbar lordosis (LL), PI-LL mismatch, Pelvic tilt (PT), Sagittal vertical axis (SVA)

   b. Diagnosis

   c. Surgical Approach

      i. Levels fused

    ii.  Circumferential vs Posterolateral fusion

   iii.  Use of cement augmentation

**Milestones**:
- Obtain IRB Approval – Oct 30th, 2017
- Finish collecting all data – July 31, 2018
- Finish data analysis – August 31, 2018

**Deliverables (must include)**:

*Quarterly presentation updates:*
- *December 2017 – conference call*
- *Spring 2018 – Spring Symposium @ UT (conference call option for non-UT teams)*
- *June 2018 – conference call*
- *September 2018 – Fall Symposium @ UCSF (conference call option for non-UCSF teams)*

*Final written report including results* – November 2, 2018

*Specific work product (e*.g. protocols, material, device, database)

The specific work product will be a series of predictive models with independent variables including patient-specific and procedure specific consideration, and outcome variables to include complication, readmission, reoperation, value of surgery, and appropriateness of surgery.

**General Budget Outline**:

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| Personnel (Research Associate) | $ 34,000 |
| Supplies | $ 1,800 |
| DataBase | $ 200 |
| Total Direct | $ 36,000 |
| Indirects (10%) | $ 4,000 |
| Total | $ 40,000 |

| **Start Date**: | **End Date**: |
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| October 10th, 2017 | September 30th, 2018 |

Please limit this document to 2-3 pages and email it to PuiYee.Law2@ucsf.edu by September 8th.