2016

The Utility of Health Care Performance Indicators in Evaluating Low Back Surgery

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This is to certify that the doctoral dissertation by

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Walden University
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Abstract

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Abstract

Low back syndrome affects 20% of people, and it is estimated that 30% of patients are unable to return to work after surgery. The monitoring of health care outcomes could improve the delivery of health services. The health performance conceptual framework, derived from the Donabedian model, was used to evaluate the functional outcome, clinical recovery, response to surgery, and physician performance of the surgical management of lumbar spine degeneration. A quantitative study (n=685) was undertaken using an administrative database in a repeated-measures design. The clinical and functional outcome improvements were analyzed using *t* tests. Surgical complexity on health outcome was examined with ANOVA. Predictors of patient satisfaction was explored using Pearson's correlation and regression analyses. The results demonstrated highly significant improvements in functional (mean change 30%; ODI=16.79 ± *SD* 19.92) and clinical recovery (mean change 50%; modified-JOA=6.983 ± *SD* 2.613) with surgery at 3 months; a >50% positive response to surgery; and a > 90% patient satisfaction, sustained over a 2 year period. Complexity of surgery did not impact health performance. Strong correlations between the health performance metrics were detected up to 6-months from surgery. Poor clinical recovery and persistent functional disability were predictive of patient dissatisfaction. The social change implications for health policy are that a constellation of health performance metrics could predict the potential for functional and clinical recovery based on presurgery disability while avoiding medical expenditures for procedures with no health benefit; aid in health quality monitoring, peer comparisons, revision of practice guidelines, and cost benefit analysis by payers.

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Dedication

This dissertation is dedicated to my wife, Nalini, who encouraged me in my pursuit of higher education. Valid research involves personal satisfaction in the acquisition of knowledge. The processing of data yields information; the understanding of information yields knowledge; the transmission of knowledge results in wisdom.

“Et tenebras ignorantiae deducet me in lucem scientiam
Et præ timore mortis per inmortalitatem sapientiae deducet me”

“From the darkness of ignorance, lead me to the light of knowledge;
And from the fear of death, lead me to immortality of wisdom.”

Acknowledgments

I would like to thank Dr. Clarence J. Schumaker Jr., as chair, for his excellent supervision, guidance, motivation, and support during the dissertation process. I am especially grateful to Dr. Robert Hoye, who has mentored and guided me for most of my PhD program at Walden University and has served as my committee member. I would like to thank Dr. Mary Lou Gutierrez, as URR, for her constructive criticism and suggestions to improve this dissertation. I would like to thank Union Hospital Neuroscience for access to the administrative database upon which this study was based.

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Chapter 1: Introduction to the Study

Introduction

The technological advances in health care in the treatment of many diseases has resulted in mortality reduction and improved quality of life (Arias, 2004; Murphy, Xu, & Kockanek, 2013). In developed countries, attention has been directed to the escalating health care costs associated with cardiovascular disorders, cancer, and degenerative conditions (McGinnis, Williams-Russo, & Knickman, 2009). Spinal degeneration presents as chronic debilitating low back pain resulting in functional disability, affecting activities of daily living and restricting the ability to work (Long, 2008). Low back pain is a common health condition affecting at least 20% of the general population, an annual prevalence up to 40%, and a lifetime prevalence of 60% (Long, 2008). Low back pain is often persistent and frequently episodic, with up to 75% recurrence within the year (Long, 2008). The determination of clinical quality is based on broad scientific or biological principles, clinical studies, and professional consensus, and is linked primarily to patient outcomes (McGlynn, 2014).

The trend towards consumerism of health care over the past 30 years has culminated into the evolution of health care as a commercial enterprise in the United States (Robinson, 2005; Zeckhauser & Sommers, 2013). Health consumerism has been legislated and implemented as the Affordable Care Act ("Health Care in America: Shock treatment," 2015). Consequently, if health care is considered a commodity (Robinson, 2005), it may be generalized as goods and services (Centers for Medicare & Medicaid Services, 2014; "DocAdviser: Patient Review," 2014; "Medicare," 1990). Customer satisfaction, which is considered paramount to the viability and marketing of goods and services, represents a transcendental component of quality (Deming, 1994; Garvin, 1988, 1991). As a consumer of health services (Deming, 1994), satisfaction with health care is defined primarily from the perspective of the patient (Hershberger & Brickner, 2014). Information on patient satisfaction is derived primarily from patient surveys ("CGCAHPS: Improve Delivery of Patient-Centered Care," 2014; Center for Medicare and Medicaid Services, 2012; "DocAdviser: Patient Review," 2014). These surveys on patient satisfaction are used to judge a medical practices' quality and physician effectiveness instead of patient outcome, which underpins clinical quality ("Health Care in America: Shock treatment," 2015; Hershberger & Brickner, 2014; McGlynn, 2014).

There are no standardized methods to define health care quality, as observed by Donabedian (1988, 2005). Health care quality is dependent on the type of health care system, the location of the observer within the system, and the observer's responsibilities within the system (Donabedian, 1980, 1988, 2005). In contrast, healthcare quality has been defined by the Institute of Medicine (1990) as "the extent to which health services provided to individuals and patient populations improve desired health outcomes which encompasses safety, efficacy, patient orientation, efficiency, timeliness and equitability" (Chassin & Galvin, 1998; Lohr & Schroeder, 1990), but is considered to be too vague for specific application (Pelletier & Beaudin, 2009). The data generated by health system performance measurement and reporting are critical to inform various stakeholders in health care systems to achieve better outcomes and improve quality (Smith, Mossialos, Papanicolas, & Leatherman, 2009). Due to the impending fiscal restraint to curb health care costs, the Center for Medicare and Medicaid Services is starting to link clinical outcome and quality metrics to hospital and physician reimbursements (Center for Medicare and Medicaid Services, 2012; "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014; Lindenauer et al., 2007; US Department of Health and Human Services, n.d.). However, patient-centric satisfaction scores serve only as a proxy for quality (Gill & White, 2009; Godil et al., 2013).

Although spinal disorders have been recognized for at least 3,500 years, surgery for lumbar disc herniation was first performed in 1909 (Chedid & Chedid, 2003). The technological advances over the past 100 years have resulted in even more complex spinal procedures being performed on patients. Surgeons seek the best remuneration for their services to overcome the tendency by commercial insurers and federal programs to decrease reimbursements for standard procedures (Deyo et al., 2010; Resnick et al., 2005a, 2005b). The introduction of evidence-based guidelines for degenerative spinal conditions was motivated by the greater morbidity associated with such complex procedures (Resnick et al., 2005a). These guidelineshave been recently updated to aid physicians in choosing appropriate modalities of treatment for spinal degenerative conditions (Ghogawala et al., 2014; Kaiser et al., 2014).

Functional outcome in spinal surgery from the patient’s perspective is becoming more important to judge the effectiveness of treatment, in addition to clinical recovery (Boden, 2014; Dyrda, 2014; McCormick, Werner, & Shimer, 2013). In the past, health performance metrics have been used primarily in clinical research studies. These have not been universally applied to routine clinical practice (Ghogawala et al., 2014; Kaiser et al., 2014). Spinal surgeons are now focusing their attention to the measurement and reporting of their health performance (Boden, 2014; Godil et al., 2014). The data generated from health performance metrics may justify the therapeutic paradigms employed in their practice (Smith et al., 2009).

In this retrospective, quantitative, cohort study, I evaluated the health performance of a community based neurosurgery spine practice using functional outcome, clinical recovery, and levels of patient satisfaction in patients undergoing elective spine surgery for lumbar degenerative conditions. The findings of this study will help to identify those surgical procedures that provide health beneficence, associated with a good clinical recovery and functional outcome. The constant and routine monitoring of all patients' individual satisfaction could help guide the physician to improve the quality of service to patients (Donabedian, 1988, 2005). The continuous data collection with a yearly analysis of health performance data by medical practitioners could guide patient decision making on the suitability of a particular intervention by the physician, based on the patients' individual level of disability and suffering, and by using evidence-based clinical outcome metrics.

Background of the Study

Although health care may be analyzed from two major perspectives, that is, a community-based approach and an individualized approach, the implementation of health services involves a spectrum of different combinations of approaches in many countries (Fuchs, 2013; Gottret & Schieber, 2006). The community-based approach (Type I-Organization for Economic Co-operation and Development [OECD]) is conceptualized by the social policies of utilitarianism and social justice (Almgren, 2007; Smith, 2008; Teutsch & Rechel, 2012). In this approach, there is equitable distribution of health resources according to need and the institutions that provide impartial care to all persons in the community are clearly defined (Nordhaug, 2011; Teutsch & Rechel, 2012). In contrast, the individualized approach focuses on the provision of high tech, high cost health services directed to the particular needs of a patient (Nordhaug, 2011). Consequently, patients with the financial resources, privileged benefits, or government-subsidized individuals expect the costly services (Lipsitz, 2012). Therefore, the key dimensions in assessing patient satisfaction are individual gratification and personal beneficence (Hawthorne, 2006).

In 1969, Donabedian theorized on defining quality of health care using three major concepts or dimensions: structure, process, and outcome (Donabedian, 1988, 2005; Larson & Muller, 2002). Dagger, Sweeney and Johnson, in 2007, summarized the adaptation of the Donabedian model that has grounded many health quality processes. Brook and Williams (1975) emphasized the role of technical proficiency, diagnostic, and therapeutic measures on patient-physician interaction. Ware Jr., Davies-Avery, and Stewart (1978) and Ware Jr., Snyder, Russell-Wright, and Davies (1983) explored patient-physician interaction, technical skills, and environmental factors as dimensions of patient satisfaction and added a fourth dimension, that is, administration of health care, also advocated by McDougall and Levesque (1994). Wiggers (1990) realized the combination of technical skills and interpersonal relationship in determining service quality while Doran and Smith (2004) proposed a model in which outcome was fundamental to quality of care.

Behavioral factors of empathy, assurance, responsiveness, and reliability were the core aspects of quality while the physical or environmental aspects were considered as being peripheral (Doran & Smith, 2004). Choi, Lee and Lee (2005) proposed a four dimensional system, comprised of physician concern, staff concern, convenience of care, and tangibles, similar to the four dimensional system described by Ware Jr et al (1983). In 2006, Zineldin speculated that there could be five dimensions of quality, viz., technical, process, infrastructure, interaction, and atmosphere. In 2006, the World Health Organization (WHO) outlined a universal framework to aid in decision-making in order to improve health care quality across health care systems (as cited in Bengoa et al., 2006). Contemporaneously, experts from the OECD countries proposed a conceptual framework in 2005 to measure health system performance as the Health Care Quality Indicators Project (HCQI; Arah, Westert, Hurst, & Klazinga, 2006; Kelley & Hurst, 2006).

While Donabedian postulated that patient satisfaction should be one of the important indicators of quality (Donabedian, 1988; Nelson, 1990), the expected positive effects on outcome have not been realized despite the appropriate improvements in structure and process (Chesanow, 2014). Some of the factors implicated were patient compliance with treatment, patients' medical risk factors, medical comorbidities, and the socioeconomic status of patients (Chesanow, 2014; Larson & Muller, 2002). The increasing attention on chronic disease, degenerative conditions, and the consumerism of health care consumption has been placing more attention to patient satisfaction as a component of health performance.

Since the rise of health care consumerism in 1995, patient satisfaction has been elevated as a key element in quantifying health care aimed at improving hospital facilities, patient amenities, and ease of access, rather than the quality of care (Boyer, Francois, Doutre, Weil, & Labarere, 2006; Hood, 1995). While patient satisfaction may represent the end result of totality of care associated with good clinical outcomes, efficient health care process, and a favorable patient-physician interpersonal relationship, it is still highly subjective (Heidegger, Sall, & Nuebling, 2006). The emotional aspect of patient satisfaction hampers a clear definition to ground a conceptual framework due its personalized components (Gill & White, 2009) and its dependency on the interrelationship between the patient and the health care provider (Crowe et al., 2002; Urden, 2002). A new conceptualization of health performance comprises of the dimensions of healthcare quality and patient satisfaction (Smith et al., 2009). Health performance was used as a structural framework in this dissertation.

Surgeons exercise wide discretion in the planning of spine operations, aided by the wide range of treatment options available for the management of spinal degenerative conditions and the ability to tailor and design specific procedures (Deyo et al., 2010). They are incentivized by financial reward based on productivity and by the practice of coding and billing fusion procedures per segment using the International Statistical Classification of Diseases and Related Health Problems (ICD) 9 code (Agrawal, Taitsman, & Cassel, 2013; Deyo et al., 2010). All available options, some of which may not be evidenced-based, are presented to the patient irrespective of cost (Agrawal et al., 2013; Deyo et al., 2010; Teutsch & Rechel, 2012). The patient makes the choice for the best treatment by exercising his/her autonomy despite the fact that other people's money is being used to pay for these services (Beauchamp & Childress, 2009; Cartwright, 2008).

The professional ethos of a health care business model is to maximize profit and reduce cost aided by financial incentives to the medical practitioner to increase services and health resource utilization (Fuchs, 2013; Janecka, 2009; Moses III et al., 2013; Woolf & Aron, 2013). This business model is influenced by the individual demands and needs of the patients and the physicians' ability to tailor procedures (Deyo et al., 2010; Teutsch & Rechel, 2012). Deyo et al. (2010) explored several possible causes for the escalation in invasive spinal surgery despite the fact that the numbers of patients have not radically changed. Some of the factors implicated were the advent of newer and more expensive medical implants, conflicts of interest that can arise when medical opinion leaders are associated with device manufacturers, and financial incentives to hospitals and surgeons (Deyo et al., 2010). The Center for Medicare and Medicaid Services is linking clinical outcome, service costs, and quality metrics to hospital and physician reimbursements to curb escalating health care costs (Center for Medicare and Medicaid Services, 2012; " Data Analysis Support and Tracking," 2014, "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014; Lindenauer et al., 2007; US Department of Health and Human Services, n.d.).

Quality metrics following treatment for degenerative low back pain have primarily focused on improvements in functional outcome (Fairbank, Couper, Davies, &

O'Brein, 1980; Ghogawala et al., 2014). This focus comprises two broad categories: generic health status and disease specific instruments relevant to specialty care, such as spine surgery (Cox et al., 1999; Fujiwara, Kobayashi, Saiki, & Kitagawa, 2003; Ghogawala et al., 2014; Lurie, 2000; Thornes, Ikonomou, & Grotle, 2011). The short-form 36 (SF-36) abstracted from the Medical Outcomes Study has become the mainstay instrument to evaluate the general health status or health-related quality of life for low back pain patients (HRQoL; McHorney, Ware Jr, Rogers, Raczek, & Rachel Lu, 1992; Ware Jr & Sherbourne, 1992). A panel of experts from the North American Spine Society, American Association of Neurological Surgeons, and the Congress of Neurological Surgeons has recommended the SF-36 as the preferred metric of general health outcome following spine surgery (Ghogawala et al., 2014).

While physiological evaluations of range of motion and muscle motor strength have been considered objective, they have not been strongly associated with functional outcomes of pain relief, activities of daily living, return to work, and social functioning. Therefore, an international group of back pain researchers convened a panel to propose six dimensions of outcome in order to standardize the reporting of outcome for interventions relating low back pain pathology: pain symptoms, function, psychological well-being, disability, social restriction, and satisfaction of care that could be applicable to clinical care, quality improvement, and research (Deyo et al., 1998). In 1986, the Japanese Orthopedic Association (JOA) introduced a scoring system examining the effects of treatment for degenerative low back disorders (Inoue et al., 1986). The JOA also has been adopted internationally (Fujiwara et al., 2003). The Macnab criteria and the modified Macnab criteria reflect the physicians' evaluation of patient satisfaction following low back surgery (Macnab, 1971).

More recently, attention has been directed to the measurement of patient satisfaction following surgical procedures and its relationship to quality of care rendered (Godil et al., 2013). The combination of functional outcome, clinical recovery, and levels of patient satisfaction can be used as a metric for health performance of a health delivery system (Smith et al., 2009). In addition, the constellation of several metrics may serve to quantify physician effectiveness and serve as a vanguard against patients' individual noncompliance with medical management (Hershberger & Brickner, 2014; Kaplan, 2014).

Problem Statement

Low back pain is a common health condition affecting at least 20% of the general population, an annual prevalence up to 40%, and a lifetime prevalence of 60% such that low back pain is often persistent and frequently episodic with up to 75% recurrence within the year (Long, 2008). Functional disability, restrictions on daily activity, and poor work productivity associated with low back pain are influenced by a myriad of prognostic factors. These may be work-related, psychosocial, demographic, habits, pain and function, general medical health, and litigation (Long, 2008). Although resolved in most patients, low back pain may become chronic and debilitating, such that 5% of patients may require surgery despite conservative management (Atlas, Keller, Robson, Deyo, & Singer, 2000; Thornes et al., 2011). The physician has had wide discretion in designing specific surgical procedures to meet the individual demands (Deyo et al., 2010). In the past, health care quality has been judged clinically but the tendency toward health care consumerism ("Health Care in America: Shock treatment," 2015) is placing more importance to patient satisfaction as a quality measure (Center for Medicare and Medicaid Services, 2012; "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014; Teutsch & Rechel, 2012).

There are a large number of questionnaires rating low back pain and disability (Cox et al., 1999; Kopec, 2000; McCormick et al., 2013; Mirza et al., 2006). These surveys are geared primarily towards research studies (Atlas et al., 2000; Saban, Penckofer, Androwich, & Bryant, 2007). The questionnaires are not routinely used in clinical practice since they are too numerous and too long and onerous to fill out by both patients and physicians (Fitzpatrick 2009; Thornes et al., 2011). Furthermore, patient satisfaction questionnaires have not been validated by objective clinical metrics in the assessment of the quality of low back spine surgery. In addition, they have not been used for an ongoing general medical practice audit or to evaluate the clinical efficacy of patient interventions in the general population (Azad et al., 2016; Copay et al., 2010).

Consequently, this retrospective, quantitative study is important to examine the health performance of a community based neurosurgical service that provides surgical options for the management of lumbar degenerative disease by examining both quality of care and patient satisfaction. The knowledge gained will be useful in determining the beneficence of such invasive and costly procedures to patients suffering from debilitating low back pain and neurological dysfunction (Beauchamp & Childress, 2009; Godil et al., 2014; Parker et al., 2014). This knowledge may also help to guide patient decision to undergo surgery based on the level of disability and health performance scores of the medical practice. Patient satisfaction could be improved by closing the gap between patient expectations of service and clinical and functional outcome (Nakhai & Neves, 2009; Parasuraman, Zeithami, & Berry, 1988). Furthermore, results of this study could allow for valid comparisons of the health performance equivalence of the treatment paradigm employed in this practice with peers (Copay et al., 2010; McCormick et al., 2013).

Purpose of Study

The purpose of this quantitative study was to evaluate the health performance of the surgical management of lumbar spine degenerative pathology. The high prevalence of degenerative conditions afflicting the spine, presenting as long back pain, is particularly relevant to this study (Manek & MacGregor, 2005). The intent of the study was to compare the changes in functional outcome, clinical recovery, and levels of patient satisfaction over a 2-year period following surgery performed between 2008 and 2014. The independent variable was surgical intervention. The dependant variables were the Oswetry Disability Index (ODI; Fairbank et al., 1980), which measured overall functional outcome; the modified Japanese Orthopedic Association Score (JOA; Fujiwara et al., 2003; Haro, Maekawa, & Hamada, 2008; Inoue et al., 1986), which quantified the clinical status; and the spine surgery outcome score, which quantified specifically the functional response to surgery (Deyo et al., 1998). In addition, in this study, I explored the impact of the complexity of surgery on key outcome measures (Deyo et al., 2010). Known factors that affect the postoperative period such as diabetes and smoking were incoporated as a covariates (Aalto et al., 2012; Appaduray & Lo, 2013). Smoking affects both the immediate postoperative period and long-term deleterious effects on pain response and fusion (Bydon et al., 2014; Bydon et al., 2015; Kalfas, 2001; Nakajima & Al'Absi, 2014).

Research Questions and Hypotheses

I examined the health performance of the surgical management of degenerative spinal conditions in a community based neurosurgical practice. The duration of the study was a 6-year period between 2008 and 2014. Performance measures were collected preoperatively and at defined intervals postoperatively, which are discussed in Chapter 3. The data collection period for each patient spanned 2 years.

Research Question 1: Is there a statistically significant difference in the ODI and the modified JOA prior to and after low back surgery for spinal degenerative conditions, controlling for the effect of smoking and diabetes?

Null Hypothesis: There is no statistically significant change in the ODI and modified JOA following surgery when compared to the preoperative measures over the 2-year period.

Research Hypothesis: There is a statistically significant change in the ODI and modified JOA following surgery when compared to the preoperative measures over the 2-year period.

Research Question 2: Is there a statistically significant difference in the ODI, the modified JOA, and the spine surgery outcome score for the complexity level of the surgical procedure?

Null Hypothesis: There is no statistically significant difference in the ODI, the modified JOA, and the spine surgery outcome score for the complexity level of the surgical procedure.

Research Hypothesis: There is a statistically significant difference in the ODI, the modified JOA, and the spine surgery outcome score for the complexity level of the surgical procedure.

Research Question 3: Is there a statistically significant relationship between patient-reported outcome measures (ODI, Spine Surgery Outcome Score), clinical evaluations (the modified JOA), and levels of patient satisfaction?

Null Hypothesis: There is no statistically significant relationship between patient-reported outcome measures (ODI, Spine Surgery Outcome Score), clinical evaluations (the modified JOA), and levels of patient satisfaction?

Research Hypothesis: There is a statistically significant relationship patient-reported outcome measures (ODI, Spine Surgery Outcome Score), clinical evaluations (the modified JOA), and levels of patient satisfaction?

Conceptual Framework for the Study

In this study, I examined the beneficence of a treatment paradigm for lumbar degenerative pathology involving varying complexity of surgery and evaluated it specifically at the patient-physician interaction perspective, congruent with the medical care quality conceptual framework proposed by Donabedian in 2005. The Donabedian model has three components: structure, which examines the medical and health care facilities, health care resources of funding and financing, the allocation of human resources and personnel, and organizational structure of health care facility; process which involves the patient's action in accessing health care and the provision of health care by the medical practitioner; and outcomes, which refers to the effect of the medical care on the patient and the community by examining the improvements in health quality of life and patient satisfaction.

Nature of Study

This was a retrospective quantitative study of a patient cohort from a community-based neurosurgical practice in Indiana. It was an observational study without active interventions using repeated measurements over a 2-year period, evaluating the beneficence (Beauchamp & Childress, 2009) of spine surgery for degenerative conditions (independent variable), consistent with a repeated-measures design (Creswell, 2009). A quantitative data analysis of the dependent variables was performed to examine the relationship of the ODI (Fairbank et al., 1980), the spine surgery outcome score (Deyo et al., 1998), levels of patient satisfaction (Deyo et al., 1998), and the clinical recovery, as measured by the modified JOA Score (Inoue et al., 1986) as determinants of health performance. Descriptive data included clinical, demographic, behavioral, and outcome metrics, while analytical data was generated using *t* tests, correlations, ANOVA, and regression analysis.

Definitions

Variables

The definition of the independent and dependent variables used in this study are as follows:

Clinical Recovery: This is calculated using the formula: recovery rate (%) = (postoperative JOA - preoperative JOA)/(maximum score - preoperative JOA) X 100. A recovery rate of >75% was excellent, 50 to 75 as good, 25 to 50 as fair and <25% as poor (Watanabe et al., 2005).

Complexity of surgery: The complexity of surgery has ranged from decompression, simple fusions, and complex fusions reflecting increasing invasiveness, risks, cost, and morbidity (Deyo et al., 2010).

Diabetes: Glucose intolerance requiring diet, oral medications, and/or insulin for control, as reported by patient during the history-taking process, and/or confirmed with fasting blood glucose >150mg/dl on blood tests.

Levels of patient satisfaction: This is a dimension of the spine surgery outcome score quantifying the patients' subjective contentment with the treatment provided for low back pain and sciatica (Deyo et al., 1998).

Low back surgery: These patients underwent spinal surgery specifically for lumbar degenerative spine pathology using various standard neurosurgical techniques (Greenberg, 2006; Park & Chung, 1999; Park et al., 2002; Resnick et al., 2005a, 2005b; "Surgical treatment for spine pain," 2014).

Modified Japanese Orthopedic Association Score: The JOA is scoring system has been used extensively in Japan and based on the physician's assessment (history and clinical examination) of patient physical status (Fujiwara et al., 2003; Inoue et al., 1986). It has specific application to measure surgical outcomes following surgical interventions to (Haro et al., 2008).

Oswestry Disability Index: The ODI is a dependent variable and is based on a disease specific patient reported survey and has been used extensively to evaluate the degree of disability suffered by the patient due to his/her low back condition (Fairbank et al., 1980).

Physician performance rating: This is a dimension of the spine surgery outcome score derived from the spine surgery outcome score where the patient adjudicates the quality of care.

Smoking: Consumption of tobacco products by inhalation or chewing, as reported by patient during the history-taking process.

Spine Surgery Outcome Score: This is a patient-reported outcome measure based on the core set of six dimensions proposed for clinical use and quality improvement low back pain (Deyo et al., 1998).

Terms

Acceptability of health care: Acceptability is conformity of patients and his/her families to their realistic expectations, wishes and desires of a healthcare experience, which could have an effect on future utilization of the health care resource (Kelley & Hurst, 2006).

Appropriateness of health care: This examines the relevance of medical care to the clinical needs using the latest evidence-based information and represents a dimension of health performance (Kelley & Hurst, 2006).

Beneficence: This is implicit in all medical and health care professionals to improve the welfare of patients and communities (Beauchamp & Childress, 2009).

Health Care Quality Indicators Project: Representatives from 23 countries participated in the project to propose a conceptual framework to define health care quality and identify metrics for quantification (Kelley & Hurst, 2006).

Health consumerism: This involves the empowerment of the patient to make his/her own health care decisions based on individual choices rather than collective paradigms (Robinson, 2005).

Lumbar disc herniation: Protrusion of the intervertebral disc into the spinal canal greater than 50% beyond the disc space, which may be sequestrated, free fragment, or migrated. A disc bulge is displacement of disc material less than 50% of the disc space (Greenberg, 2006).

Lumbar degenerative spine disease: This is the commonest cause of low back pain related to the aging of the spine as the intervertebral disc breaks down causing wear and tear of the facet joints resulting in spinal osteo-artheritis. The complications can cause disc herniation, bone spurs, spinal stenosis and nerve compression, and microinstability of the spine due to laxity of the facet joints and spinal instability causing spondylolisthesis (Greenberg, 2006).

Macnab criteria: This is the physicians assessment of the patients' back and/or leg pain after surgery that is categorized as excellent, no pain, no restriction of activity; good, occasional back or leg pain of sufficient severity to interfere with the patient's ability to do their normal work or their capacity to enjoy him or herself in his or her leisure hours; fair, improved functional capacity, but handicapped by intermittent pain of sufficient severity to curtail or modify work or leisure activities; and poor, no improvement or insufficient improvement to enable increase in activities, further operative intervention required (Macnab, 1971).

Neurogenic claudication: This is caused by compression of the lumbar-sacral nerve roots in the lumbar spine, most often due to lumbar stenosis. It manifests as low back pain with radiation of pain to the legs resulting in cramps that worsens when walking (Greenberg, 2006).

Sciatic leg pain: Sciatica is defined by radiating leg pain in the distribution of a nerve root in the lumbar-sacral spine, which may be associated with weakness and or numbness. A herniated lumbar disc most commonly causes nerve root compression (Greenberg, 2006; Peul et al., 2007).

Spinal fusion surgery: This is a form of treatment of symptomatic lumbar disc degeneration, lumbar stenosis, spondylolisthesis, scoliosis, chronic axial low back pain, radiculopathy, and spinal instability (Greenberg, 2006; Resnick et al., 2005a).

Spinal instrumentation: This involves the use of metallic and synthetic material to provide immediate stabilization of the spine until biological bone fusion can occur (Greenberg, 2006).

Therapeutic paradigms: Clinical protocols (Narotam, Morrison, & Nathoo, 2009) for treating or managing a disease or illness based on a shared understanding among scientists and physicians working in a discipline (Narotam, Morrison, Schmidt, & Nathoo, 2014).

Assumptions

It was expected that all patients had returned for their regular post procedure follow-up visits at the specified time intervals of 2 weeks, 6 weeks, 3 months, 6 months, 1 year, and 2 years and that the surveys had been completed by the patients and entered into the computerized database. Loss to follow up was mitigated by a large sample size and the use of repeated measures. Other threats to internal validity involved the instrumentation, that is, the gradual introduction of dependent variables into the dataset based on clinical needs of the practice, modifications in the survey questions according to clinical need and clinical quality requirements, and the lack of prospective clinical studies to support of one of the instruments used in the study (Creswell, 2009; Deyo et al., 1998). This was overcome by the uniform application of a constellation of instruments over 4 years of the 6-year study period and a year-to-year analysis of the dependent variables. Since the study involved a repeated-measures design, patients could have become familiar with the questions, and patients' survey responses may have reflected their potential for secondary personal gain. This introduces bias, that is, litigation, need to narcotic medication, and social security disability application, which was construed as threats to internal validity (Creswell, 2009).

Scope and Delimitation

In this quantitative retrospective study, I examined the health performance of a community-based neurosurgical practice that provides health care to the general population, specifically in the surgical management of lumbar spinal degenerative conditions. I used a survey design employing disease-specific patient reported outcome questionnaires and disease-specific physician reported outcome surveys to assess both the quality of care and patient satisfaction. In addition, I explored the beneficence of surgery for low back degenerative conditions, the equivalence of outcome according to complexity of surgery, and the ability to inform patients and the expectation of functional outcome of surgery at various time periods, including up to 2 years to enable physicians and patients to make informed choices about their health care options. Delimitations of the study included the use of the spine surgery outcome score as one the instruments in the study representing one of the dependent variables, and patient satisfaction was incorporated into the spine surgery outcome score that was extracted out for proper interpretation of results.

This study involved a community based neurosurgical spine practice, which used functional outcome as a measure of quality and a physician performance rating to evaluate health performance of a practice (Smith et al., 2009). The major focus was on the outcome component of the Donabedian conceptual model (Donabedian, 1980, 1988, 2005). Indeed, the Donabedian model of evaluating the quality of care is specifically directed to physician-patient interaction and not the administrative aspects of quality control (Donabedian, 2005). The structure and process were already in place by the hospital system and thus its quality has been judged independently (Donabedian, 2005).

The use of random anonymous surveys of patient satisfaction to judge a medical practice quality and physician effectiveness does not represent an accurate picture of the health performance of the medical practice ("CGCAHPS: Improve Delivery of Patient-Centered Care," 2014; Center for Medicare and Medicaid Services, 2012; "DocAdviser:

Patient Review," 2014; Hershberger & Brickner, 2014). The surveys are limited by small samples size that are not representative of the entire practice and therefore cannot be generalized. In contrast, I have included all surveys of all the patients to overcome the potential unreliability of medical experts' judgment of quality based on small unrepresentative samples (Ghogawala et al., 2014; Resnick, et al., 2014). In addition, the instruments used in judging functional outcome as a measure of service quality has been established in the spine community as a valid measure to allow for comparisons of treatment paradigms or clinical protocols and for regulatory approvals of medical devices (Cox et al., 1999; Fujiwara et al., 2003; Ghogawala et al., 2014; Lurie, 2000; Thornes et al., 2011) Therefore the results of this study will be generalizable to the disease specific condition of lumbar spine degenerative pathology (Ghogawala et al., 2014), and be analogous to individual cases (Aldrich et al., 2008; Hodgson & Knudsen, 2008; Narotam et al., 2014).

Limitations

Since this was a retrospective study, there were incomplete data fields in the dependent variables due to early discharge of patients for simple spine procedures, incomplete follow-up visits, and loss to follow-up before the 2-year scheduled visit. The physician could have introduced bias in his or her survey responses in the modified JOA since all patients in the study had undergone surgery as the treatment modality for lumbar spinal degenerative conditions. External validity was affected since this study involved a purposeful sample of patients with lumbar degenerative pathology who had undergone surgery, consequently limiting generalization to the normal population. This was overcome by a large sample size that included all patients who underwent surgery for their spinal degenerative conditions. The community-based setting is representative of a subset of the general population in the Mid-West geographic area in the United States. The use of standardized instruments allowed for valid comparisons of treatment paradigms among medical institutions treating similar conditions. The inability of the medical and scientific community of accurately defining health care quality by providing standardized instruments to measure health quality, and offering variable definitions of patient satisfaction (Gill & White, 2009; Godil et al., 2013), together with a lack of quantification of subjective measures impacted the interpretation of the results of this study. This was overcome by using definitions advanced by the Health Quality Indicators Project (Kelley & Hurst, 2006) for this dissertation.

Significance

The United States spends 17% of its GDP on health care, 50% more than many of the other OECD countries without any advantage in the major health outcome measures (Teutsch & Rechel, 2012). Currently, commercial insurers and government payers use patient reported outcome measures that may not have any relationship to the patients' clinical outcome to restrict reimbursements to hospitals and physicians (Center for Medicare and Medicaid Services, 2012; "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014; Lindenauer et al., 2007; US Department of Health and Human Services, n.d.). As the fiscal restraints bear down on the medical profession, it behooves all medical practices to gather clinical outcome, quality, and patient-satisfaction metrics (Boden, 2014).

The implications of this study are to help identify low back surgical procedures that have a good functional outcome and clinical recovery for patients and to reject procedures that do not have demonstrable benefit using both the patient-reported outcome metrics, that is, ODI, spine surgery outcome score, and the physician-reported outcome, that is, modified JOA Score as guidelines. For example, a patient with an ODI of 60 to 80 would more likely have benefitted from lumbar fusion than a patient with an ODI of 30 since the neurosurgical practice could report a mean 6-month ODI of 40.7 ± 21.4 (Mazellan, Battles, & Narotam, 2014). The constant and routine monitoring of all patients' individual satisfactions helps guide the physician to improve the quality of service (Donabedian, 1988, 2005). The continuous data collection with an annualized analysis guides patient decision making on the suitability of a particular intervention by the physician. The continuous tracking of the health performance of a medical practice could help to mitigate against frivolous medical malpractice litigation with the accurate tracking of patients' functional outcome and satisfaction of health services provided (Rovit, Simon, Drew, Murali, & Robb, 2007). In addition, health performance metrics could protect physicians from highly selective medical peer review examinations (Kaiser et al., 2014) and potentially limit financial penalties that are predicated by the selective and flawed patient satisfaction surveys ("CGCAHPS: Improve Delivery of Patient-Centered Care," 2014; "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014).

Summary and Transition

In this chapter, I have provided a conceptual overview of health performance contextualized to the health care system in the United States. A brief description of health care systems and the technological advances in the management of lumbar spine degenerative conditions changes was presented. I also provided an overview of the attempts to quantify health care quality and patient satisfaction. The emergence of patient reported outcome measures as a proxy for health quality and the devolution of patient satisfaction from health quality was operationalized as health performance. The use of disease-specific outcome measures is more relevant to specialty surgical services.

Chapter 2 is a critical literature review of health quality, in which I address the controversy in definitional issues and the quantification of health quality, as well as patient satisfaction as measures of health performance from a historical perspective. I also examine the utility of surgery to treat spinal degenerative disorders and charted the evolution of disease-specific functional outcome measures relevant to spine surgery.

Chapter 2: Literature Review

Introduction

The purpose of this quantitative study was to evaluate the health performance of the surgical management of lumbar spine degenerative pathology. Low back pain is a common health condition affecting at least 20% of the general population, while 60% of people will suffer from low back at some time in their life (Long, 2008). In general, 5% of patients may require surgery despite conservative management for chronic and debilitating pain (Atlas et al., 2000; Thornes et al., 2011). The main goal of surgical intervention for degenerative spinal pathology is to relieve pain, reduce functional disability, and enhance the quality of life by restoring function (McCormick et al., 2013). Uncertainty in functional outcome prediction is affected by the lack of implementation of clinical protocols and treatment paradigms that are supported by evidenced-based medicine (Kaiser et al., 2014). This limits valid peer comparisons of treatment efficacy, which is further complicated by the use of nonstandard instruments to measure functional outcome, and that standard instruments are not uniformly applied across institutions (Copay et al., 2010; Deyo et al., 1998; Du Bois, Szpalski, & Donceel, 2012). The purpose of this quantitative study is to evaluate the health performance of the surgical management of lumbar spine degenerative pathology in a subpopulation of patients in Indiana by comparing the changes in functional outcome and patient satisfaction. In addition, I explored the impact of complex of surgeries on health performance and the influence of confounding factors such as diabetes and smoking on functional outcome.

The scientific advances in modern medicine over the past 150 years has yielded a greater understanding of disease mechanisms, efficacy of various treatment modalities inter alia, and, together with the technological inventions, has resulted in significant extensions of life expectancy at birth from the 39 in 1850 to the 76 in 2001, and by 2013, to 78.7 years (Arias, 2004; Murphy et al., 2013). Morbidity for many of the diseases and disorders that have plagued humans over the years has also improved. While clinical quality is linked to patient outcome, the quality of health care is being defined from the perspective of the patient as a consumer of goods and services (Deming, 1994; Hershberger & Brickner, 2014; McGlynn, 2014). Health consumerism uses patient satisfaction as a quality measure (Center for Medicare and Medicaid Services, 2012; "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014; Teutsch & Rechel, 2012). In addition to clinical quality metrics, health care providers and hospitals are being penalized financially for unsatisfactory patient satisfaction scores, consistent with trend towards consumerism in U.S. health care (Center for Medicare and Medicaid Services, 2012; "Health Care in America: Shock treatment," 2015; "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014; Lindenauer et al., 2007; US Department of Health and Human Services, n.d.).

The notion that health quality can be accurately defined, reliably measured, and consistent with a broad philosophical definition has not been supported by quantifiable contemporary research (Chassin & Galvin, 1998; Fiscella, Burnstin, & Nerenz, 2014; Godil et al., 2013; Hershberger & Brickner, 2014; McGlynn, 2014). The lack of standard outcome metrics in health care has hampered efforts in improving quality in health care, aggravated by the failure to apply uniform, evidence-based clinical practice. A major disincentive is the ever-present threat of medical malpractice lawsuits limiting collection of systemic quality related data points from physicians. Resistance by physicians to engage in performance measurements and the exertion of external controls on physician behavior detracts from their perceived authoritarian position can, at times, turn to resentment of the hospital executive branch (Nembhard, Alexander, Hoff, & Ramanujam, 2009).

The complication rates, clinical outcomes, and radiological efficacies for spine surgery have been well documented (Ghogawala et al., 2014a; Ghogawala et al., 2014b; Groff et al., 2014; Mummaneni et al., 2014; Resnick et al., 2014a; Resnick et al., 2014b). However, the comparative reporting of functional outcome has been deficient since standardized instruments to measure health performance are not uniformly or consistently applied across institutions or surgical procedures, nor are they routinely implemented outside clinical research studies (Copay et al., 2010; Ghogawala et al., 2014; "Health Care in America: Shock treatment," 2015; McCormick et al., 2013). The lack of a clear definition of health care quality that has been scientifically verified has resulted in patient satisfaction being used as a proxy for health care quality in patients undergoing spinal surgery for degenerative conditions (Godil et al., 2013). In the literature review, I examine the concepts that define the quality of goods and services with a special focus on health care quality and the conceptualization and reporting of health performance in the modern era, as applicable to low back surgery. In addition, this review provides an overview of the pathology of lumbar spine degeneration, its medical and surgical management, and clinical and functional outcomes.

Literature Search Strategy

The literature search was performed using the following key terms: *health care quality, functional outcome in spine surgery, outcome measure for low back pain, patient satisfaction, spinal stenosis, consumerism in health care, quality of life in spine surgery, lumbar disc surgery, spine surgery for lumbar degenerative disease*, *Oswestry disability index, modified JOA,* inter alia using PubMed, Proquest, Google Scholar, and Google for the period between 2000 and 2014. The subscription journals, *Journal of the Medical Association of America* and *Journal of Neurosurgery* between 2010 and 2015 were also sourced. Seminal or landmark publications were sourced to 1974. The articles selected for this review focused on the determination of health quality and were particularly aligned towards the analysis of the health performance of surgery for lumbar spinal degenerative conditions.

Theoretical Foundation

Quality of Goods and Services

In the philosophy of the scientific management school, analysis of workers' tasks is used to maximize productivity using vertical control by company executives and managers (Taylor, 1911). Managers control the workflow by assessing the best way to perform an element of work, by selecting the best worker for each job, by educating and training the worker, by ensuring that the work follows prescribed scientific principles, and by dividing tasks into smaller self-contained work units (Borkowski, 2008). They are responsible, with the worker, for the final output (Johnson, 2009). The drive towards efficiency and productivity viewed workers as machines, regulated by managers who had to develop precise procedures to achieve the organizations goals. The vertical mechanistic and hierarchical system of control ensured that decisions were made at the top, executive level with managers rigorously implementing these goals, while workers followed orders according to strict protocols (Daft, 2012). This structure is suitable for industrial production where the product parameters and tolerances have already been scientifically determined, impacting product bases and manufacturing quality (Garvin, 1988).

In the late 1980s Motorola developed the six-sigma philosophy to improve service quality (Nakhai & Neves, 2009). Since customers are key to survival, selected metrics were needed to quantify all components of the organization. Reliance on facts rather than opinions should drive decisions, and the involvement of all personnel is essential in the quality process. There should be a continuous pursuit of quality improvement and customer satisfaction (Smith, 2014). In practice, the structured framework of the six-sigma dogma involves define, measure, analyze, improve, and control (DMAIC), with its associated tools (Smith, 2014). Following its success in the business world, it has been expanded to other service sectors, including health care (Nakhai & Neves, 2009; Smith, 2014).

There were five definitions of quality for goods and service as proposed by Garvin in 1988: Transcendent quality is a subjective awareness of a missing component that is poorly defined and thus cannot be objectively measured or quantified. In product-based quality, the key differentiator is the physical content of the product defined by atomic or molecular composition, whilst manufacturing quality refers to the process by which design or technical standards are met. Value-based quality reflects the balance between performance and cost user-based quality is aimed towards the needs and wants of the customer, consumer, or client (Garvin, 1988). Although this list was expanded into eight criteria to evaluate the quality of tangible goods, that is, aesthetics, features, conformance, performance, reliability, durability, serviceability, and perceived quality, it was not adequate to examine quality of services (Garvin, 1991). In 2005, the evaluation of quality of services was expanded into eight dimensions: time, timeliness, completeness, courtesy, consistency, accessibility and convenience, accuracy, and responsiveness (Evans & Lindsay, 2005). While up to 85% of quality can be addressed by systemic factors with careful attention to the process, individual behavior, often unpredictable, can still affect final quality (Deming, 1994). More recently, there has been focus on the end-user in determining quality of goods and services (Nakhai & Neves, 2009).

Previous studies in marketing have contributed to the understanding of the nature of service quality and its role in customer satisfaction (Nakhai & Neves, 2009). Service quality is more difficult to evaluate than product quality since there is a divergence between the actual service provided and customer expectations, since quality evaluations involve both outcome and delivery of service (Ghobadian, Speller, & Jones, 1994; Grønroos, 1984; Nakhai & Neves, 2009). Parasuraman et al. (1988) introduced service quality model (SERVQUAL) by incorporating the dimensions of tangibles, reliability, responsiveness, assurance, and empathy to evaluate customer perceptions of service quality. They defined the gap model, in a survey-based quantitative tool, as differences between customer expectations and customer perceptions (Nakhai & Neves, 2009; Parasuraman et al., 1988).

Health Performance Measurement and Reporting

In the modern era of medicine, concerns on the quality of care can be traced to the Flexner Report (1910), which called for the regulation of professional medical education (Larson & Muller, 2002). In 1960, Andersen, a medical sociologist, proposed a behavioral model to evaluate the use of health care services by individuals. Over the years, it has been modified to analyze clinicians' response to payment incentives based on quality of care (as cited in McDonald et al., 2007). The deeper understanding of disease processes and its natural history, together with the technological and therapeutic advances in medical care, has resulted in significant reductions in morbidity and mortality from illness. Since 1970, attention has shifted towards quality assessment and quality assurance involving facilities, medical staff qualifications and competence, and delivery of medical services, with the emergence of disease specific outcome metrics (Larson & Muller, 2002).

Much of the current conceptualization of health care quality can be traced to the philosophical expositions of Donabedian. The assessment of health quality comprised of three major dimensions: structure, process, and outcome (Donabedian, 1980, 1988, 2005). The Donabedian model has emerged as the dominant philosophical framework, enjoying over 4,000 citations to date (Bengoa et al., 2006; Center for Medicare and

Medicaid Services, 2012; Dagger, Sweeney, & Johnson, 2007; "Donabedian," 2014; El Haj, Lamrini, & Rasi, 2013; Gill & White, 2009; Kelley & Hurst, 2006; Kunkel, Rosenqvist, & Westerling, 2007; Larson & Muller, 2002; McDonald et al., 2007; "Medicare," 1990; "Outcomes Research," 2006; Institute of Medicine, 1999). The WHO, including OECD countries, has adopted this model of quality (Arah et al., 2006; Bengoa et al., 2006; Kelley & Hurst, 2006). While Donabedian (2005) admitted that while some aspects of quality may be easier to measure, several components remain elusive to reliable and valid quantification. For example, patient satisfaction was a reflection of the interpersonal aspects of patient physician relationship and the patients' judgment of the overall quality of care (Donabedian, 1980). In an extensive review of 3,000 publications, van Campen, Sixma, Friele, Kerssens and Peters (1995) concluded that, while several nonstandard different scales were used by many researchers, only a handful were rigorous enough to measure quality of care (SERVQUAL) and patients' judgment of quality of hospital services (Meterko et al., 1990; Parasuraman et al., 1988).

Over the past 40 years, several instruments have been developed to measure patient satisfaction in order to plan, administer, and evaluate health care programs (Gill & White, 2009; Hulka, Zyzanski, Cassell, & Thompson, 1970; Larsen et al., 1979, Ware Jr & Snyder, 1975). Patient satisfaction is affected by the confluence of patient expectation and patient outcome. Patient satisfaction is higher when patients' expectations were met due to clinical and technical competence, aided by friendliness, good bedside manner, and professional behavior (Korsch, Gozzi, & Francis, 1968; Larsen & Rootman, 1976; Wilson & McNamara, 1982). Perception of a good clinical outcome can boost patient satisfaction while good patient-physician interaction, with counseling, can improve patient compliance (Kincey, Bradshaw, & Ley, 1975; Stimson & Webb, 1975).

In 1980s, several philosophical theories on patient satisfaction emerged, some inclusive in health quality, while others divergent of health care quality (Gill & White, 2009; Heidegger et al., 2006). The relativism of patient satisfaction was outlined in the discrepancy and transgression theories, which is based on the orientation of patient expectations and the provision of care (Fox & Storms, 1981). The impact of patients' personal beliefs and values, together with patients' expectations, was postulated in the expectant-value theory of Linder-Pelz in 1983. This theory was expanded from 1983 to 1993 into a psychological model comprising of six factors: cognition and affect, multidimensional factors, dynamic processes, attitudes, iterations, and individual differences (Pascoe, 1983; Strasser, Aharony, & Greenberger, 1993). The effect of the subjective response to medical care, influenced by personal preferences and individual expectations on patient satisfaction, has grounded the determinants and components theory, as theorized by Ware Jr (1983). Since patients' expectations were socially influenced, in which illness and treatment could adversely affect patient's personal perception of himself or herself, multiple models were needed to evaluate patient satisfaction (Fitzpatrick & Hopkins, 1983). Although a favorable patient physician emotional connection affects patient satisfaction, it is the clinical outcome that has the strongest impact (Hall, Roter, & Katz, 1988). Hulka (1970) emphasized the continuity of care as being critical to patient satisfaction. Building upon the prior research, Woolley, Kane, Hughes and Wright (1978) concluded that there were four key variables that impacted patient satisfaction: satisfaction with clinical outcome, continuity of care, expectation of patient, and physician-patient relationship. These concepts were further substantiated by studies on continuity of care, administrative components such as admissions and billing, and personal services such as food and housekeeping (Carey & Posavas, 1982; Hays, 1987; Nelson-Wernick, Currey, Taylor, Woodbury, & Cantor, 1981).

While the Donabedian model (Donabedian, 1980, 1988, 2005) concluded that patient satisfaction is the key end-point in determining quality, Gill and White (2009) revealed several flaws in this approach because assessments on patient satisfaction have not had a valid psychometric basis. Over the past 10 years, the divergence between patient satisfaction and health quality has become more pronounced (Gill & White, 2009; Gotlieb, Grewal, & Brown, 1994). They can no longer be intermingled since there is no consensus on how to measure the former and the personalized perceptions of the latter (Lee, Khong, & Ghista, 2006; O'Conner & Shewchuck, 2003). While patient satisfaction is being used as a proxy for healthcare quality or used as part of a multidimensional construct for healthcare quality, it causes confusion to providers, payers, and patients (Brown, 2007; Dagger et al., 2007; Taylor, 1999; Turris, 2005). Therefore, patient satisfaction should be considered separate from healthcare quality (Cleary & Edgeman-Levitan, 1997).

Measures to evaluate patient satisfaction are restricted in their predictive ability since the exact definition of patient satisfaction lacks reliability and validity (Gilbert & Veloutsou, 2006; Hawthorne, Sansoni, Hayes, Marosszeky, & Sansoni, 2011; Sitzia, 1999). This has limited valid comparisons between different scales (Nguyen et al., 1983). Even using the meta-analysis of several patient satisfaction studies, there is no conceptual model on patient satisfaction that is scientifically grounded (Crowe et al., 2002; Gill & White, 2009; Pascoe, 1983; Sitzia, 1999; van Campen et al., 1995). Physician effectiveness is increasing being quantified by patient behavior over which they have no control, whilst social factors and noncompliant patient behavior accounts for over 50% of the differences in health outcomes (Kaplan, 2014; Hershberger & Brickner, 2014). The combination of disease-specific health care quality metrics and patient satisfaction could represent valid measures of health performance (Smith et al., 2009).

Conceptual Framework

Since the 1970's, focus has shifted towards quality assessment and quality assurance especially with the health care facilities, medical staff qualifications and competence, delivery of medical services, and, the emergence of disease specific outcome metrics (Larson & Muller, 2002). The sociologically based Anderson Behavior Framework is too generalized and dependent on the vagaries of human behavior prediction (McDonald et al., 2007). Similarly, the Relational Coordination Framework focuses on the understanding of the dynamics of teamwork and collaboration (McDonald et al., 2007). The Organizational Design Framework examines the interrelationship and intra-relationship of bureaucratic structures (McDonald et al., 2007), which would be more suitable for institutionalized national health care systems.

Over the years, there have been several philosophical conceptualizations of health care quality but a well-defined quantifiable framework that has withstood the rigors of scientific analysis has yet to be established. For example, the Institute of Medicine (1990) declared that: "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Chassin & Galvin, 1998; Lohr & Schroeder, 1990). While may be representative of the transcendent component of quality (Garvin, 1988), the lack of specific proposals to measure desired health outcomes, or proposals to determine likelihood ratios, or specifications on the instruments that can quantify perceived quality, brings into question this definition of quality. Indeed current assessments of quality have coalesced primarily on the end-user experience or patient perceptions reflected in patient satisfaction, thereby serving as a proxy for quality (US Department of Health and Human Services, 2014; "CGCAHPS: Improve Delivery of Patient-Centered Care," 2014; Center for Medicare and Medicaid Services, 2012; "DocAdviser: Patient Review," 2014; Godil et al., 2013; "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014; US Department of Health and Human Services, n.d.). In the social science arena, health quality is principally defined by access to health care and the effectiveness of health care. These definitions are applicable to the patient as an end-user of health care. (Campbell, Roland, & Buetow, 2000).

In 2005, the OECD sought out a conceptual framework for the Health Quality Indicators Project to establish a set of indicators, which would reflect on the quality of health care. The international panel operationalized health care quality into various dimensions to enable decision makers around the world to implement changes that would be applicable to their particular health priorities and health systems (Kelley & Hurst, 2006). The major dimensions, applicable to an institutionalized, bureaucratic, nationalized universal health care system, were safety, responsiveness, accessibility, equity, and efficiency (Bengoa et al., 2006; Kelley & Hurst, 2006). In contrast, in the consumer driven US health care model the minor dimensions of acceptability, appropriateness, competence, continuity, timeliness would be applicable (Almgren, 2007; Janecka, 2009; Lipsitz, 2012; Nordhaug, 2011; Teutsch & Rechel, 2012; Woolf & Aron, 2013). Consequently, this study, which is based in the US, is amenable to the Donabedian conceptual framework (Donabedian, 1980, 1988, 2005; McDonald et al., 2007). The Donabedian Model has been operationalized for this study as follows:

(a) *Structure or amenities*: The study location is in the United States. The health care delivery model involves a small office based physician practice. The hospital owns the facility and provides the amenities and recourses (McDonald et al., 2007);

(b) *Process or technical*: The facility is in close proximity to the hospital. It is integrated into the allied health care services. The electronic medical record is fully integrated electronically with the hospital. The patients have full access to health services in the medical practice since it is a hospital owned not for profit facility;

(c) *Outcomes:* Patient reported surveys and objective clinical evaluations had been introduced at Union Hospital Neuroscience as part of the health quality initiative introduced at Union Hospital, Terre Haute, Indiana since February 2008 (Mazellan et al., 2014). In addition to clinical quality, these surveys are used to monitor functional outcome.

Despite the appropriate improvements in structure and process, the expected positive effects on outcome have not been realized as there are many other factors not accounted for in the Donabedian model (Hershberger & Brickner, 2014; McGinnis, Williams-Russo, & Knickman, 2009). Medicine and health care are not exact sciences. Human diseases are inherently complex, and, the pathophysiological processes and treatments are not yet fully understood. Illnesses manifest differently in people (Nembhard et al., 2009). Since it is becoming apparent that patient satisfaction may not be an indicator of health quality but a subjective behavioral interaction between physician and patient, it needs to be examined separately (Gill & White, 2009; Godil et al., 2013). Thus, for this dissertation, I have modified the Donabedian conceptual framework (Donabedian, 1980, 1988, 2005) into a Health Performance conceptual framework using the definitions advanced by the Health Quality Indicators Project (Kelley & Hurst, 2006).

Literature Review

Spine Surgery

Interest in the treatment of spinal disorders can be traced ancient civilizations inhabiting the Levant, as early as 1550 BC in Egyptian texts and later by Greek, Roman and Arabic writings (Chedid & Chedid, 2003; Knoeller & Seifried, 2000). Early treatment of spinal disorders focused on trauma in ancient Egyptian times, while Hippocrates (460-377 BC) was first credited with the analysis of spinal disorders. Galen described the anatomical deformities afflicting the spine (Chedid & Chedid, 2003). As Europe plunged into the Dark Ages, ancient medical knowledge was translated into Arabic. The Turkish physician Serefeddin Sabuncuoglu epitomized the advances in medicine, including neurosurgery, by the 15th century (Chedid & Chedid, 2003; Knoeller & Seifried, 2000; Naderi, Acar, & Arda, 2002).

During the renaissance period, treatment of spinal injuries evolved with the use of suspension or traction until 1814 when the first surgery was performed even though Paulus of Aegina proposed the idea was as early as the 7th century (Chedid & Chedid, 2003; Knoeller & Seifried, 2000). Infectious disease, until the advent of antibiotics, presenting one of the greatest threats to mankind, was first fought with spinal surgery for tuberculosis by Sir Percival Pott (1713-1788), a disease that still carries his name (Chedid & Chedid, 2003; Knoeller & Seifried, 2000). In the 19th century significant advances were made in the management of spinal infections. The understanding of biomechanics of the spine was revolutionized by the discovery of x-ray imaging by Rontgen in 1895 (Chedid & Chedid, 2003).

The realization of the neurogenic causes of sciatic leg pain occurred in 1764 by Domenico Cotugna and neurologists Lasegue, Dejerine, and Sicard. The understanding of lumbar disc disease, its pathology and the management of spinal degenerative disorders did not occur until the early 20th Century with the introduction of myelography in the 1930's (Chedid & Chedid, 2003). Oppenheimer and Kruse, using the trans-dural approach, performed the first surgery for lumbar disc herniation in 1909. The extra-dural approach by Love [1937], aided by the introduction of micro-surgical techniques by Caspar and Yasargil [1977] remains the preferred choice (Chedid & Chedid, 2003).

In the mid 20th century, interest in spinal instrumentation arose to stabilize the spine with the introduction of spinal fixation by: Holdsworth and Hardy (1953);

Harrington rods (1958); trans-pedicular screws by Boucher (1959); and the Luque system (Chedid & Chedid, 2003). The Cotrel-Dubousset system in the 1970’s, Texas Scottish Rite and the Miami-Moss systems in the 1990’s represented a major advance in the management of the unstable spine and to augment the treatment of lumbar degenerative conditions, concomitant with the advances in neuroradiology imaging such as CT scan and MRI (Chedid & Chedid, 2003). The surgical approaches to the spine are variable and predicated by the clinical and neuro-imaging criteria and the need to perform stabilization procedures, in various combinations (Chedid & Chedid, 2003). In contrast to spinal fusion procedures, spinal arthroplasty with the implantation of artificial disc, which serves to preserve spinal motion, was investigated in the late 20th century but had not shown any beneficence over lumbar fusion procedures (Chedid & Chedid, 2003; Rao & Cao, 2014; Rohlmann et al., 2013; Siepe et al., 2014; Thavaneswaran & Vandepeer, 2014).

While clinical outcomes for the management of lumbar degenerative spinal disorders are well documented, functional outcomes vary according to regional differences, scope of professional practice and patient population (Du Bois et al., 2012). In addition, clinical protocols and treatment paradigms are not universally applied using evidenced based medicine leading to uncertainty in functional outcome prediction (Du Bois et al., 2012; Kaiser et al., 2014). This is complicated by the use of non-standard instruments to measure functional outcome or standard instruments are not uniformly applied to allow for valid peer comparisons (Copay et al., 2010; Deyo et al., 1998;

"Health Care in America: Shock treatment," 2015; McCormick et al., 2013; Zanoli, 2005).

This quantitative repeated-measures cohort study evaluated health performance of low back surgery using standardized instrument, such as, ODI and modified JOA, to measure functional outcome and clinical outcome respectively. The surgical outcome score specifically addressed the overall performance of the low back surgery (Deyo et al., 1998), from which the satisfaction with care has been extracted as the patient satisfaction score. In addition, this study explored the interaction amongst the various instruments measuring health performance to determine any predictive capability (Dyke & Kleidon, 2010).

Beneficence of spine surgery. Low back pain is common problem afflicting almost 20% of people with 60% lifetime prevalence, and at times, being persistent and episodic (Long, 2008). Although resolving in most patients, low back pain may become chronic and debilitating, 5% of patients may require surgery (Atlas et al., 2000; Thornes et al., 2011). In properly selected patients, surgery is beneficial over the prolonged and costlier medical management of degenerative spine disease (Parker et al., 2014). Although clinical outcomes may be similar a 1 year, pain relief and recovery was superior with surgery than prolonged conservative management, favorable clinical outcomes are reported for 85-90% of patients undergoing discectomy, and 66% of patients show significant functional improvement [mean ODI change >20} with lumbar disc surgery (Lubelski et al., 2014; Peul et al., 2007; Solberg, Johnsen, Nygaard, & Grotle, 2013).

The clinical outcomes following lumbar spine surgery are well documented, yet, functional outcomes have not been uniformly reported outside of clinical trials (Atlas et al., 2000; Azimi, Mohammadi, Benzel, Shahzadi, & Azhari, 2014; Du Bois et al., 2012; Fujiwara et al., 2003; Godil et al., 2014; Haro et al., 2008; Lubelski et al., 2014; Mekhail, Constandi, Abraham, & Samuel, 2012; Omoto, Bederman, Yee, Kreder, & Finkelstein, 2010; Peul et al., 2007; Roitberg et al., 2013; Saban et al., 2007; Slatis et al., 2011; Solberg et al., 2013; Soroceau, Ching, Abdu, & McGuie, 2012; Thornes et al., 2011; Weinstein et al., 2009). While there is drive towards less invasive procedures in spine surgery, inappropriate treatment paradigms can lead to costlier repeat surgeries without functional benefit or improved quality of life to patients (Whitmore, 2014). This study examined the health care benefits in patients undergoing low back surgery for spinal degenerative disorders.

Health performance and quality in low back pain. Over the past 25 years, there has been a significant growth and expansion of various health performance measures using different clinical outcome measures to determine health care quality (Smith et al., 2009). The explosive growth in patients' reported outcome measures [PROM] have yielded over a thousand different instruments by 2002 and over three thousand by 2007 to evaluate patient satisfaction (Fitzpatrick, 2009). Quality metrics, following treatment for degenerative low back pain, have primarily focused on improvements in functional outcome (Fairbank et al., 1980; Ghogawala et al., 2014). These can be divided into the broad categories of generic health status and disease specific instruments relevant to specialty care, such as spine surgery (Cox et al., 1999; Fujiwara et al., 2003; Ghogawala et al., 2014; Lurie, 2000; Thornes et al., 2011).

General health status. In 1981, Bergner et al. introduced the Sickness Impact Profile [SIP], which consisted of 12 categories containing 136 items. The SIP evaluates and quantifies general mental and physical health, together with function at work and within society (Bergner, Robbitt, Carter, & Gilson, 1981). The SIP has been extensively studied in patients with low back pain and other musculoskeletal disorders in contrast to the Nottingham Health Profile [NHP], which consists of 38 items grouped into 6 categories (Hunt, McEwen, & McKenna, 1985; Lurie, 2000). The Duke Health Profile [DUKE], introduced in 1990, comprised of 17 questions that examines health and dysfunction (Parkerson Jr, 1990).

By 1992, the short-form 36 [SF-36], abstracted from the Medical Outcomes Study, became the mainstay instrument to evaluate the general health status or health-related quality of life [HRQoL] for low back pain patients (McHorney et al., 1992; Ware Jr, & Sherbourne, 1992). This has been adopted in many countries (Fujiwara et al., 2003). In 2005, Zanoli performed an extensive review evaluating functional outcomes in spine surgery and concluded that *the* health related quality of life instrument for spine pathology was the SF-36, and was superior to the visual analogue scale in determining outcome. Consequently, although VAS has been used in many research studies, its omission as an instrument would not impact this study. More recently, the American Association of Neurological Surgeons, based on an extensive review of the literature and using the evidence-based standards of care criteria, recommended the SF-36 as a general health outcome measure for clinical studies (Ghogawala et al., 2014; Kaiser et al., 2014). In this study, the SF-36 was not implemented as part of the routine survey due to its complexity, length and being onerous for the patient to complete at each office visit. Instead, this study focuses on disease outcome measures as routine monitoring of health performance.

Disease-specific functional outcome measures. In 1980, Fairbank et al. introduced the Oswestry Disability Index [ODI] that comprised 10 items to evaluate the impact of pain on daily physical activities. The Roland-Morris Disability Questionnaire (RMDQ), on the other hand, is a derivative of the SIP with 24 specific references to back pain as a cause of the patients suffering (Fujiwara et al., 2003; Roland & Morris, 1983a, 1983b). Over the years several instruments have been introduced: Million Visual Analog Scale; Low Back Outcome Score; Clinical Back Pain Questionnaire or the Aberdeen Low Back Pain Scale; Low Back Pain Rating Scale; and the Quebec Back Pain Disability Scale; North American Spine Society Lumbar Spine Questionnaire; and the Resumption of Activities of Daily Living (Daltroy, Cats-Baril, Katz, Fossel, & Liang, 1996; Greenough & Fraser, 1992; Kopec et al., 1995; Manniche et al., 1994; Millon, Hall, Nilsen, Baker, & Jayson, 1982; Ruta, Garratt, Wardlaw, & Russell, 1994; Williams & Myers, 1998). The ODI and the RMDQ have become the most widespread (Fujiwara et al., 2003; Kopec, 2000). In 2014, in an extensive evidenced-based review by the American Association of Neurological surgeons, the ODI has emerged as the dominant disease-specific outcome measure to evaluate low back pain (Ghogawala et al., 2014; Kaiser et al., 2014).

The JOA score was developed in 1986 by select members of the Japanese Orthopedic Association, and used extensively for clinical research in Japan (Fujiwara et al., 2003; Inoue et al., 1986). It has specific application to measure surgical outcomes (Haro et al., 2008). While the ODI quantifies the degree of disability from the patients' perspective, the modified JOA score provides a more objective and clinical evaluation [history and clinical examination] of the patient's disability from the physicians' perspective. The JOA correlates well to the ODI, the Roland Morris Disability Questionnaire, and subscales of the SF-36 (Fujiwara et al., 2003). The modified JOA has been simplified to remove the category "activities of daily living" which is better captured by the ODI (Tajima et al., 1989; Vialle et al., 2007). In contrast to the ODI and the JOA, the *modified* JOA score is not widely adopted as an outcome measure except for very few clinical studies (Ghogawala et al., 2014).

Spine fusion involves the use bone grafts, which are incorporated by creeping substitution with the deposition of new bone and remodeling. Systemic factors that affect this healing process include smoking and diabetes (Kalfas, 2001). Smoking has shown to have a significant deleterious effect on the clinical outcome following spine surgery due to its impact on fusion rates, especially in 2-level complex fusion of the spine (Bydon et al., 2014). Even in simple spinal surgery such as laminectomy, smoking has shown to be a significant predictor for the need for repeat surgeries (Bydon et al., 2015). Smokers are at a significantly high risk in the post-operative complications related to their associated chronic obstructive pulmonary disease (Armaghani et al., 2014; Tang et al., 2014). Chronic smoking affects endogenous pain regulation with increased pain sensitivity

(Nakajima & Al'Absi, 2014). The recommendation to stop smoking prior to lumbar spine surgery and in the post–operative period can increase the need for narcotic pain medication (Morasco, Duckart, Carr, Deyo, & Dobscha, 2010; Skurtveit, Furu, Selmer, Handal, & Tverdal, 2010; Steinmiller et al., 2012; Woodside, 2000) since withdrawal of nicotine can result in increased sensitivity to painful stimuli (Baiamonte et al., 2014).

Although there is some suggestion that health related quality of life using the SF-12 may not be affected by smoking (Appaduray & Lo, 2013; Stienen, Smoll, Hildebrandt, Schaller, & Gautschi, 2014), many researchers have demonstrated the deleterious impact of smoking: on functional outcome, the quality of life, and pain scores (Aalto et al., 2012; Cobo Soriano et al., 2010; Sanden, Forsth, & Michaelsson, 2011). While post-operative complications are more frequent in diabetics (Appaduray & Lo, 2013; Golinvaux, Varthi, Bohl, Basques, & Grauer, 2014; Tang et al., 2014), in the long term, diabetes does not affect re-operations or fusion rates (C. H. Kim et al., 2015). Indeed, successful surgery, associated with increased patient mobility, can promote glycemic control in diabetics (H. J. Kim et al., 2015).

The technological advances over the past 100 years have resulted in even more complex spinal procedures being performed on patients (Deyo et al., 2010; Resnick et al., 2005a, 2005b). Health care decisions in spinal surgery are highly variable, often dependent on physician preference and competency (Deyo et al., 2010). Surgeons exercise wide discretion in the planning of spine operations, aided by the wide range of treatment options available for the management of spinal degenerative conditions. In the absence of evidence-based medicine all available options are presented to the patient irrespective of cost [*informed consent*], granting patients' the autonomy of choice (Beauchamp & Childress, 2009; Teutsch & Rechel, 2012). Although varying beneficence is seen with increasing complexity of spinal surgery, especially for return to work, randomized controlled studies for complex fusion have demonstrated early benefits over a four-year period when compared to non-surgical management (Du Bois et al., 2012; Weinstein et al., 2009). The complexity of surgery has been stratified, ranging from decompression to complex fusions reflecting increasing invasiveness, risks, cost, and morbidity (Deyo et al., 2010). The greater morbidity associated with complex procedures has resulted in the publication of evidence-based guidelines for degenerative spinal conditions (Ghogawala et al., 2014; Kaiser et al., 2014).

In 1998, Deyo and an international group of back pain researchers considered reliability, validity, responsiveness, and practicality to develop a core set of survey questions to measure the surgical outcome following low back surgery for spinal degenerative conditions. The six domains, abstracted from the SF-36, SF-12, Euro-Qol, American Association of Orthopedic Surgeons Lumbar Cluster, North American Spine Society Lumbar Spine Questionnaire, involved pain symptoms, function, well-being, disability, social activities and satisfaction with care (Deyo et al., 1998). While Deyo et al. made the scientific justification for the implementation of these measures, to the best of my knowledge, clinical validation of the proposal has not appeared in the published literature.

Customer satisfaction, a poorly defined transcendental component of quality, is paramount to the viability and marketing goods and services (Deming, 1994; Garvin, 1988, 1991). Analogous to the health care sector, patient satisfaction is the end result of totality of care that results from clinical and technical competence, representing clinical quality (Korsch et al., 1968; Larsen & Rootman, 1976; Wilson & McNamara, 1982). In addition, good clinical outcomes, efficient health care processes and quality, friendliness, good bedside manner, professional behavior and warm patient-physician inter-personal relationship, represents the confluence of patient expectation and patient outcome (Heidegger et al., 2006). While the Donabedian model [1980, 1988, 2005] concludes that patient satisfaction is the key end-point in determining quality, Gill and White (2009) reveal several flaws in this approach, since the assessments of patient satisfaction have not had valid psychometric bases. The emotional aspect of patient satisfaction, its subjective personalized components, and its dependency on inter-relationship between patient and health care providers hampers a clear definition, or to ground a conceptual framework (Crowe et al., 2002; Urden, 2002).

Since 1995, health care consumerism has resulted in patient satisfaction as being a key element in quantifying health care delivery, aimed at improving hospital facilities, patient amenities, and ease of access of health services, rather than in the improvement of quality of care (Boyer et al., 2006; Hood, 1995). Despite the appropriate improvements in health structure and process, the expected positive effects on outcome have not been realized due to poor patient compliance with treatment, patients' medical risk factors and co-morbidities, and socioeconomic status of patients (Chesanow, 2014; Larson & Muller, 2002). The increasing prevalence of chronic disease, degenerative conditions and the increasing consumerism of health care consumption have placed more attention on patient satisfaction as a component of health performance.

The propensity to use random anonymous surveys of patient satisfaction to judge medical practice quality and physician effectiveness is a perspective, purely from the patient's point of view ("CGCAHPS: Improve Delivery of Patient-Centered Care," 2014; Center for Medicare and Medicaid Services, 2012; "DocAdviser: Patient Review," 2014; Hershberger & Brickner, 2014). In addition, the Center for Medicare and Medicaid Services is linking patient experience and satisfaction with health services as proxies for quality to restrict hospital and physician re-imbursements (Center for Medicare and Medicaid Services, 2012; "Hospital Consumer Assessment of Healthcare Providers and Systems," 2014; Lindenauer et al., 2007; US Department of Health and Human Services, n.d.). While the generic health status measures and disease specific outcome measures may be a reflection on patient satisfaction (Haro et al., 2008), Godil et al. (2013) have demonstrated that patient satisfaction is not a valid proxy for quality of care or the effectiveness of surgical intervention.

Summary and Conclusions

Medical care accounts for only 10% of variance in health outcomes whilst social factors and non-compliant patient behavior is attributable to over 50% of the differences in health outcomes (Kaplan, 2014). The belief promulgated by the Institute of Medicine that health quality can be accurately defined, and reliable measured (Chassin & Galvin, 1998), has not been supported by quantifiable contemporary research (Fiscella et al., 2014; Godil et al., 2013; Hershberger & Brickner, 2014; McGlynn, 2014). In addition, the quantification of health performance has been hampered by the lack of a scientifically validated conceptual model (McDonald et al., 2007), uncertainties related to the complete understanding of disease and treatment effects, unpredictability of human behavior, and, the lack of standardized health performance metrics.

Since the clinical outcomes for the management of diseases are increasingly well known, focus has shifted onto the health care experience by the patient. The patient satisafaction instruments currently in use do not have theoretical or conceptual frameworks, lack a clear and agreed definition, are highly subjective and are prone to the emotional perception of the patient. Physician effectiveness is increasing being quantified by patient behavior over which doctors have no control (Hershberger & Brickner, 2014). While clinical quality of health services are paramount, the rising tide of health care consumerism representative of the end–user experience, patient satisfaction is serving as proxy for health care quality (Gill & White, 2009; Godil et al., 2013).

Health care decisions in spinal surgery are highly variable, depending on physician preference and technical competency, and influenced by insurance payer mix. Surgeons exercise wide discretion in the planning of spine operations for spinal degenerative conditions (Deyo et al., 2010). While clinical outcomes for the management of lumbar degenerative spinal disorders are well documented, functional outcomes vary according to regional differences, scope of professional practice and patient population (Copay et al., 2010; Du Bois et al., 2012). In addition, clinical protocols and treatment paradigms based on evidenced based medicine are not universally implemented (Kaiser et al., 2014) often leading to uncertainty in functional outcome prediction (Du Bois et al., 2012). This is complicated by the use of non-standard instruments to measure functional outcome or standard instruments are not uniformly applied, impeding valid peer comparisons (Deyo et al., 1998).

This quantitative repeated-measures cohort study uses several metrics to evaluate the health performance of a community-based neurosurgery in treating lumbar spinal degenerative conditions. Patient-reported outcome measures, such as, standardized ODI are disease specific measures of functional outcome that have been applied in research studies but not routinely used as a health performance measure (Ghogawala et al., 2014). Although the spine surgery outcome score is a derivative of the core set of outcome measures proposed by Deyo et al., (1998) it has not been validated in a scientific study nor has it been accepted by professional organizations (Ghogawala et al., 2014). While clinical recovery can be quantified by the JOA and be considered a standard instrument (Fujiwara et al., 2003; Haro et al., 2008), in contrast to the ODI, is not uniformly applied to spine research (Ghogawala et al., 2014). While patient satisfaction represents the increasing consumerism in health care, all metrics need to be corroborated as valid measures of health performance to determine their predictive utility in guiding both patients and physicians in their health care decisions.

Chapter 3: Research Method

Introduction

The purpose of this quantitative study was to evaluate the health performance of the surgical management of lumbar spine degenerative pathology. I compared the changes in functional outcome in a subpopulation of patients in Indiana who underwent surgery and the extent of patient satisfaction with clinical care. In addition, I explored the impact of a complex of surgeries on health performance and the influence of confounding factors such as diabetes and smoking on functional outcome. In this chapter, I examine the rationale for the research design and the relationship between the variables, guided by the conceptual model. A detailed description of the population and sampling strategies is presented, including the power analysis and justification for the sample size. A description of the instruments and their operationalization as variables for this study is provided. The threats to validity were explored while ethical issues were examined.

Research Design and Rationale

The research design involved a retrospective cohort study using a secondary dataset obtained from a subpopulation of patients undergoing neurosurgical management in a community-based practice in Indiana. This was a fixed cohort since all patients had degenerative spine conditions and had undergone surgery. The repeated-measures design of the dependent variable at fixed intervals spanned a 2-year period. The independent variable was spinal surgery for lumbar degenerative spine pathology using standard neurosurgical techniques (Greenberg, 2006; Park & Chung, 1999; Park et al., 2002; Resnick et al., 2005a, 2005b; "Surgical treatment for spine pain," 2014). The dependent variables of the ODI (Appendix A), modified JOA (Appendix B), and Spine Surgery Outcome Score (Appendix C) are scalar, while the patient satisfaction score was categorical, justifying a quantitative design. The categorical covariates were smoking and diabetes. The primary end-point of the study was to track the changes in health performance measures, when compared to preoperatively, in patients who had undergone low back surgery over a 2-year follow-up period.

In this study, I used a survey design since the dependent variables of ODI, surgery satisfaction outcome score, and levels of patient satisfaction were based on questionnaires. The ODI questionnaire evaluated the degree of disability suffered by the patient due to his/her low back condition (Fairbank et al., 1980). The modified JOA is scoring system is based on the physician's assessment (history and clinical examination) of patient physical status to measure surgical outcomes (Haro et al., 2008; Fujiwara et al., 2003; Inoue et al., 1986) using a standard questionnaire. The spine surgery outcome questionnaire was based on the core set of six dimensions proposed for clinical use and quality improvement low back pain (Deyo et al., 1998). The physician performance rating reflected the level and degree of patient satisfaction reflecting the patients' subjective contentment with the treatment provided for low back pain and sciatica (Deyo et al., 1998).

Surgeons exercise wide discretion in the planning of spine operations and may be associated with greater morbidity for complex procedures based on reflecting increasing invasiveness, risks, cost, and morbidity (Deyo et al., 2010; Resnick et al., 2005a, 2005b). An effective treatment paradigm should have similar outcomes for varying complexity of surgery. The secondary endpoint explores the ability of patient-reported outcome measures and clinical recovery to predict patient satsifaction. In this study, I examined the relationship between the patient-reported outcome and physician-reported recovery to acertain their utility in evaluating health performance.

Methodology

Population

The study population comprised of patients who reside in western Indiana and southern Illinois. They had been referred to Union Hospital Neuroscience in Terre Haute, Indiana by their primary care physicians for specialist neurosurgical care or had been admitted to hospital from the emergency room. A subpopulation of patients with lumbar spine degenerative pathology who had undergone surgery was sampled for this study. The study sample involved 686 patients.

Study Sample

The sampling strategy involved a single stage process, without stratification. A randomized study was not applicable to this study since all patients had undergone surgery, representing a purposeful sample of a patient cohort. The demographic, clinical, radiological, functional outcome, and quality data had been collected into a computerized databank at Union Hospital Neuroscience since February 25, 2008. This secondary databank included all patients with degenerative lumbar pathology who had undergone surgery, and, had been sequentially entered into the database.

In the repeated-measures design, the *t* test (2-tailed) for dependent means sought an effect of 20% reduction in functional disability following surgery and used an effect size of 0.20, with α at 0.05 and power at 0.95. The power analysis was performed using G*Power 3.1.3, which yielded a minimum sample size 327 (Faul, Erdfelder, Lang, & Buchner, 2009; see Table 1). The sample size for this study was 685, large enough to detect a very small difference in the dependent variables from the preoperative status.

Table 1

G Power Analysis to Compute Sample Size*

t tests Difference between two dependent means (matched pairs)		
Input	Tail(s)	Two
	Effect size dz	0.20
	α err prob	0.05
	Power (1-β err prob)	0.95
Output	Noncentrality parameter δ	3.6166283
	Critical t	1.9672675
	Df	326
	Total sample size	327
	Actual power	0.9501171

Data Source

Union Hospital Neuroscience, as part of the Union Hospital Medical Group (Physician directory, 2015), provides neurosurgical services to Vigo county and surrounding areas, drawing from a population of approximately 250,000 persons. In 2008, an electronic medical record system with integrated health performance metrics had been introduced. On a weekly basis, the advanced nurse practitioner extracted the information from the integrated electronic medical record into a separate statistical databases (SPSS) that had been established to monitor functional outcome of patients undergoing surgery for degenerative conditions involving the cervical spine and lumbar spine as part of the health outcomes and quality monitoring at Union Hospital.

The original lumbar database contained individual cases with the following variables: last name, first name, age, sex, diabetes, smoker, smoke, preoperative work status, primary clinical diagnosis 1 at initial visit, secondary clinical diagnosis 2, primary clinical pathology 1 at initial visit, secondary clinical pathology 2 at initial visit, surgery date, surgery type, number of levels, interbody device, fusion material, typhoon, interbody material, DuraGen, internal bone stimulator, external bone stimulator, preoperative ODI, preoperative smoker, preoperative weight, preoperative claudication, preoperative leg pain, preoperative modified JOA, 2-week ODI, 2-week spine surgery outcome score, 2-week patient satisfaction score, 2-week smoker, 6-week ODI, 6-week spine surgery outcome score, 6-week patient satisfaction score, 6-week weight, 6-week smoker, 6-week modified JOA, 3-month ODI, 3-month spine surgery outcome score, 3-month modified JOA, 3-month patient satisfaction score, 3-month fusion grade, 3-month instability, 3-month junctional instability, 3-month weight, 3-monthsmoker, 3-month work status, 6-month ODI, 6-month spine surgery outcome score, 6-month modified JOA, 6-month patient satisfaction score, 6-month fusion grade, 6-month instability, 6-month junctional instability, 6-month weight, 6-monthsmoker, 6-month work status, 1-year ODI, 1-year spine surgery outcome score, 1-year modified JOA, 1-year patient satisfaction score, 1-year fusion grade, 1-year instability, 1-year junctional instability, 1-year weight, 1-year smoker, 1-year work status, 2-year ODI, 2-year spine surgery outcome score, 2-year modified JOA, 2-year patient satisfaction score, 2-year fusion grade, 2-year instability, 2-year junctional instability, 2-year weight, 2-year smoker, 2-year work status, postoperative infection, code orange, reoperation, confounder, lost to follow up, notes, last-visit time, last-visit ODI, last-visit spine surgery outcome score, last-visit modified JOA, last-visit patient satisfaction score, last-visit fusion grade, last-visit instability, last-visit junctional instability, last-visit weight, last-visit smoker, last-visit work status, last-visit worker classification, bone growth stimulator, and comments. Patient identifiers, such as last name and first name, had been removed as stipulated in the data use agreement (see Appendix D).

The following clinical and demographic data was extracted from the original database for this study: age, sex, primary clinical diagnosis 1 at initial visit, secondary clinical diagnosis 2, primary clinical pathology 1 at initial visit, secondary clinical pathology 2 at initial visit, preoperative smoker, preoperative weight, preoperative claudication, preoperative leg pain, surgery type, and number of levels. The dependent variables for repeated-measures included preoperative ODI, preoperative modified JOA, 2-week ODI, 2-week spine surgery outcome score, 2-week patient satisfaction score, 6-week ODI, 6-week spine surgery outcome score, 6-week patient satisfaction score, 6-week weight, 6-week modified JOA, 3-month ODI, 3-month spine surgery outcome score, 3-month modified JOA, 3-month patient satisfaction score, 6-month ODI, 6-month spine surgery outcome score, 6-month modified JOA, 6-month patient satisfaction score, 1-year ODI, 1-year spine surgery outcome score, 1-year modified JOA, 1-year patient satisfaction score, 2-year ODI, 2-year spine surgery outcome score, 2-year modified JOA, and 2-year patient satisfaction score. The data for the covariates included history of diabetes, smoker, 2-week smoker, 6-week smoker, 3-monthsmoker, 6-monthsmoker, 1-year smoker, and 2-year smoker.

Quality reports were generated and submitted to the hospital quality department for review. The analyses from the database served for research purposes and to respond to peer-review queries (Mazellan et al., 2014). The dataset was housed on password-protected computer at Union Hospital Neuroscience, Terre Haute, Indiana. Permission to access the database has been obtained from Union Hospital. The database was anonymized by removing specific patient identifiers, such as name, prior to electronic transfer from Union Hospital Neuroscience for this study.

Instrumentation and Operationalization of Constructs

The published instruments used in the study were based on patient surveys and clinical analysis (Creswell, 2009). The patient reported outcome metrics were Oswestry Disability Index (intact), spine surgery outcome score (indigenous), and patient satisfaction score (generic). The clinical analysis used the modified JOA (intact). In this study, the Donabedian conceptual framework was operationalized as a Health Performance framework (see Figure 1).

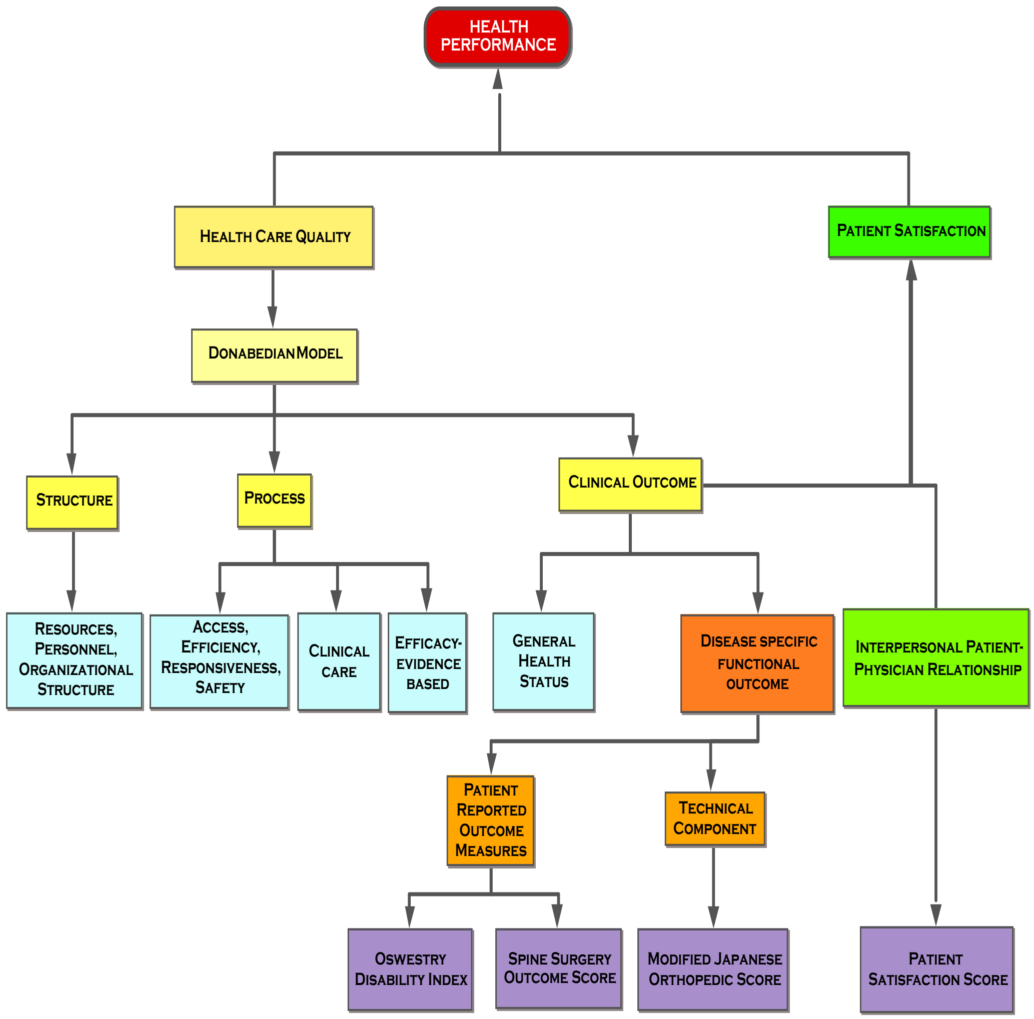


Figure 1. Conceptual framework of health performance.

The operationalization of the dependent variables (purple) used in this study, incorporates the Donabedian model (yellow) for health quality and patient satisfaction as a measure on health performance (Red; Smith et al., 2009).

Published instruments. In this study, I used the instruments, such as, patient-reported outcome measures, physician-reported clinical recovery surveys, patient satisfaction scores, and complexity of surgery analysis. The rational for these modalities is described below.

ODI. In 1980, Fairbank et al. introduced the ODI that comprised 10 items to evaluate the impact of pain on daily physical activities and the degree of disability suffered by the patient from his/her low back condition using a standardized questionnaire. The responses are then computed as percentage disability. It has been used extensively over the past 30 years, primarily as a research tool, and has emerged as the most valid and responsive measure of treatment effect (Godil et al., 2014). In 2014, in an extensive evidenced-based review by the American Association of Neurological surgeons, the ODI has become the dominant disease specific outcome measure to evaluate low back pain (Ghogawala et al., 2014; Kaiser et al., 2014). The ODI survey had been implemented at Union Hospital Neuroscience on a routine basis since February 25, 2008. Every patient low back symptoms fills it out with at every office visit, the scores are recorded and then scanned into the electronic medical record (EMR) (see Appendix A).

Modified JOA. Select members of the Japanese Orthopedic Association developed the JOA score in 1986 (Inoue et al., 1986). It is a scoring system that uses the history and physical examination of the patient to quantify the effects of treatment for degenerative low back disorders. The modified JOA removes the category “activities of daily living,” which is better captured by the ODI (Tajima et al., 1989; Vialle et al., 2007). Since it has specific application to measure surgical outcomes, the modified JOA would be an appropriate instrument to monitor clinical recovery in this study (Haro et al., 2008). The modified JOA is scored as integers (see Appendix B). In this study, it allows for the clinical corroboration of the ODI by examining the relationship between patient-reported and physician-reported outcome measures in patients undergoing increasing complexity of surgery. Although the modified JOA correlates to the ODI, the Roland Morris Disability Questionnaire, and subscales of the SF-36, has not been widely adopted as an outcome measure except for very few clinical studies (Costanzo, Cellocco, Di Francesco, & Rossi, 2005; Fujiwara et al., 2003; Ghogawala et al., 2014).

Spine surgery outcome survey. In 1998, Deyo et al., collaborated with an international group of back pain researchers to consider the reliability, validity, responsiveness, and practicality of a core set of survey questions to measure the surgical outcome after low back surgery for spinal degenerative conditions. In this study, the spine surgery outcome score used some of the components of the standardized outcome measure for low back pain (Deyo et al., 1998) but focused on the patients' surgical experience based on the dimensions of level of function, time restriction of daily activity, restriction of activity type, impact on quality of life, evaluation of treatment, and care by the health care provider. The spine surgery outcome score was recorded as integers and computed as percentage improvement from pre-operative status (Appendix C). The relationship between the spine surgery outcome and the subjective ODI and the objective JOA was explored in this study. While Deyo et al. (1998) made the scientific justification for the implementation of these measures, to the best of my knowledge, clinical validation of the proposal has not appeared in the published literature.

Patient satisfaction. The patients' satisfaction with care is one of the core dimensions proposed by Deyo, together with a diverse group on international researchers, in 1998, to measure the surgical outcome after low back surgery for spinal degenerative conditions. The typology of patient experience may be categorized as excellent, very good, good, fair, and poor (Deyo et al., 1998). In this study, all patients had undergone surgery, making it a suitable instrument to evaluate the treatment and care by the health care provider. For the purposes of this study, the patient experience or physician performance rating had been recorded categorically [ordinal variable] as excellent, very good, good, fair, and poor on the spine surgery outcome questionnaire (*see Appendix C – Dimension E*). Although patient satisfaction is not a direct measure of clinical outcome it is being used as metric for quality improvement, and as proxy for quality of care in spine surgery (Deyo et al., 1998; Godil et al., 2013). To the best of my knowledge, clinical validation of the proposal, using this stratification, has not appeared in clinical studies of spine surgery for degenerative conditions in the published literature (McCormick et al., 2013).

Complexity of surgery. Surgeons exercise wide discretion spine operations, aided by the technological advances over the past 30 years, resulting in even more complex spinal procedures for degenerative conditions (Deyo et al., 2010; Resnick et al., 2005a, 2005b). Following the analysis of 37 598 Medicare patients undergoing surgery for lumbar stenosis between the years 2002 and 2007, complexity of surgery may be categorized into decompressions, simple fusions, and complex fusions [3 levels] reflecting increasing invasiveness, risks, cost, and morbidity (Deyo et al., 2010). In this study, the complexity of surgery was stratified [ordinal variable] into 4 levels: simple spine [decompression]; simple fusion [facet fixation, interlaminar fixation, interspinous fixation]; complex fusion [pedical fixation and interbody fusions], complicated fusion [combination of pedical and facet fixation or hybrid].

Data Analysis

Analysis of the secondary database was performed using SPSS IBM version 21 for MAC. The study examined the 2-year health performance of the surgical management of degenerative spinal conditions in a community based neurosurgical practice on patients who underwent surgery between 2008 and 2014 by comparing the changes in functional outcome and patient satisfaction over a 2-year period in a quantitative, retrospective repeated-measures study to determine if: there statistically significant difference in the ODI and the modified JOA prior to and after low back surgery for spinal degenerative conditions, controlling for the effect of smoking and diabetes; there are statistically significant difference in the ODI, the modified Japanese Orthopedic Association Score and the spine surgery outcome score for the complexity level of the surgical procedure; and if there is a statistically significant relationship between patient-reported outcome measures (ODI, the modified JOA) and patient satisfaction.

The independent variable was surgical intervention. The dependant variables were the Oswetry Disability index, which measured overall functional outcome; the modified Japanese Orthopedic Score, which measured the clinical recovery; the spine surgery outcome score, which quantified the response to surgery, together with the confounding influence of diabetes and smoking. This study explored the impact of complex of surgeries on health performance on health performance and the relationship between clinical quality and patient satisfaction.

Statistical analysis. The clinical, demographic, and outcome metrics were analyzed using frequency tables to generate tables and graphs. The clinical and outcome improvements in the patients undergoing lumbar spine surgery for degenerative conditions were analyzed using *t* tests for correlated samples, while paired *t* tests were performed to compare the outcome metrics from pre-surgery to the defined time periods after surgery since each patient served as their own control (Field, 2009). Pearson's correlation between the dependent variables was undertaken using parametric statistics. The effect of each of the patient reported outcome metrics on patient satisfaction was examined using ANOVA. The effect of the modified Japanese Orthopedic Score on patient satisfaction was examined using ANOVA (*see Table 2*). Linear, non-linear and multiple regression analysis quantified the influence of the variables on each other and determined if patient reported and clinical outcome measures were predictive of patient satisfaction.

Table 2

Classification of Variables and Statistical Tests

	Independent variable	Dependent variable	Statistical analysis
Research Question 1			
Is there a statistically significant difference in the Oswestry Disability Index and the modified Japanese Orthopedic Score prior to and after low back surgery for spinal degenerative conditions, controlling for the effect of smoking and diabetes?	Nominal • surgical procedure	Scalar • Oswestry Disability Index • Modified Japanese Orthopedic Score	• Paired sample t test
	Covariates (Nominal) • smoking • diabetes	Scalar • Oswestry Disability Index • Modified Japanese Orthopedic Score • Spine Surgery Outcome Score	• Independent samples t test • Analysis of covariance (ANCOVA) • Logistic regression
	Nominal • smoking • diabetes	Ordinal • Levels of patient satisfaction	• Cross tabulation • Chi-square
Research Question 2			
Is there a statistically significant difference in the Oswestry Disability Index, the modified Japanese Orthopedic Score and the spine surgery outcome score for the complexity level of the surgical procedure?	Ordinal • Complexity of Surgery	Scalar • Oswestry Disability Index • Modified Japanese Orthopedic Association Score • Spine Surgery Outcome Score	• One-way analysis of variance (ANOVA) • Correlation • Regression
Research Question 3			
Is there a statistically significant relationship between outcome measures (Oswestry Disability Index, the modified Japanese Orthopedic Score) and levels of patient satisfaction?	Nominal • Surgery	Scalar • Oswestry Disability Index • Modified Japanese Orthopedic Association Score • Spine surgery outcome score Ordinal • Levels of Patient Satisfaction	• Correlation • Regression • Multinomial logistic regression

Threats to Validity

This cohort study involved a purposeful sample, involving a sub-population of patients, all undergoing surgical intervention for lumbar spine degenerative conditions and may not be generalizable to the population at large, representing a threat to external validity. The results of this study, conducted in a community based neurosurgical practice involving lumbar degenerative pathology, may not readily translate to larger academic centers where more complex procedures may be performed. However, this study included a range of spinal procedures from simple decompressions to complicated hybrid surgeries, which may have relevance to larger institutions.

A potential threat to internal validity is the retrospective design of the study such that data fields may be missing or the accessed information may not be consistent. This has been overcome by weekly updating of the database against the medical record and patient survey responses that have been digitally scanned into the EMR (Physician Directory, 2015). The repeated-measures design spanning 2-years represents a threat to validity since all patients may not have return for scheduled follow-up visits, re-located, referred to other providers, or in cases of simple spine surgery been discharged following their 3-month visit. This was overcome by the large sample size and analysis of data points from the last visit.

Familiarity with the instruments could influence survey responses possible motivated by secondary gain such as litigation, social security disability, and narcotic pain medication since the questionnaire involves surveys of pain and functional outcome. The impact of these influences on functional outcome was corroborated with the correlational analysis of the more objective physician evaluation captured by the modified JOA score, and, by the repeated-measures design of the study. Although the ODI was introduced at the beginning of the study, other instruments such as the surgical outcome score were introduced 6-months later and the modified JOA was introduced in October 2009. This was mitigated by a large sample size of 685 cases.

Although various instruments have been used to gauge health performance for low back surgery, both standardized and non-standardized, they have not been applied in a uniform way (Copay et al., 2010; McCormick et al., 2013). In this highly powered study, statistical validity was enhanced by a large sample size, usage of an effect size of at least 20% in the dependent variable to reach statistical significance. The constellation of health performance measures used in study represents a unique combination, but not yet translatable for general adoption. The corroboration of these metrics was one of the goals of this study. The combination of health performance metrics therefore would need validation by prospective clinical studies.

Ethical Procedures

This was a retrospective observational research study using an archival administrative database originating from Union Hospital Neuroscience, Terre Haute, Indiana. This study did not involve any intervention or experimentation. Permission to use the dataset had been obtained from the CEO at Union Hospital Neuroscience, Terre Haute, Indiana (*see Appendix D*). The data had been anonymized by removal of patient name, hospital numbers, medical record numbers and other identifying variables prior to transfer. Upon transfer, the dataset was sequestered in a password-protected computer.

All cases in the database were analyzed to ensure accuracy in the reporting of the information. The database was secured for 5-years for audit after which it will be shredded. I had completed the Collaborative IRB Training Initiative (CITI) on July 6, 2005 and NIH training in 2015 (*see Appendix E*).

The surgeon and/or the nurse practitioner compiled the data for the modified JOA, one of the instruments used in the study required clinical patient evaluation, prior to entry into the EMR. The potential conflict of interest was overcome by the fact that the medical assistant and licensed practical nurse had entered all patients survey data into the EMR. The survey documents had been electronically scanned into the EMR since 2009 and the patients' records were sealed upon final signature. A licensed nurse practitioner, who is the custodian of the database, had entered the information into the computerized database. The IRB approval number for this study is 09-03-15-0140019.

Summary and Transition

This was a retrospective quantitative correlational study, using secondary data. The study sample was a non-randomized, purposive sample of patients who had undergone surgery for lumbar spinal degenerative conditions, sequentially collected. In this repeated-measures study, spanning 2-years, *t* tests, correlations, ANOVA and multi-nominal regression analysis was performed to examine the relationship between the independent and dependent variables. The results of the study and analysis are detailed in chapter 4.

Chapter 4: Results

The purpose of this research study was to evaluate the health performance of the management of lumbar spine degenerative pathology by analyzing the changes in functional and clinical disability in a subpopulation of patients who had undergone spinal surgery and their satisfaction with clinical care over a 2-year period. In addition, I examined the impact of complexity of surgeries on health performance, the influence of confounding factors such as diabetes and smoking on functional and clinical outcome, and the relationship between patient-reported outcome measures and patient satisfaction as determinants of quality of medical care. The descriptive data analysis provides a demographic and clinical overview of the study population. The statistical analysis explores the key research questions of the study.

Clinical and Demographic Data

Over a 6-year period between 2008 and 2014, of the 686 patients entered into the database, 685 patients had undergone lumbar spine surgery for degenerative pathology at Union Hospital Neuroscience, Terre Haute, Indiana. One patient with a spinal tumor, erroneously entered into the database, was excluded from the analysis. The mean age of the study population was 46.6 ± *SD* 12.6 with a mean weight of 206.3 ± *SD* 50.0 lbs. (see Figure 3). Male and female patients were evenly distributed in the study sample. Almost half of the patients were smokers (45.5%), while preoperative diabetes was recorded in 13.15% of patients.

The histogram demonstrates the age distribution (upper diagram) and weight (lower diagram) of patients in the study sample. The majority of patients were middle aged, distributed around 40 to 60 years. Prior to surgery, the most frequent patients' weight was distributed around 200 lbs.

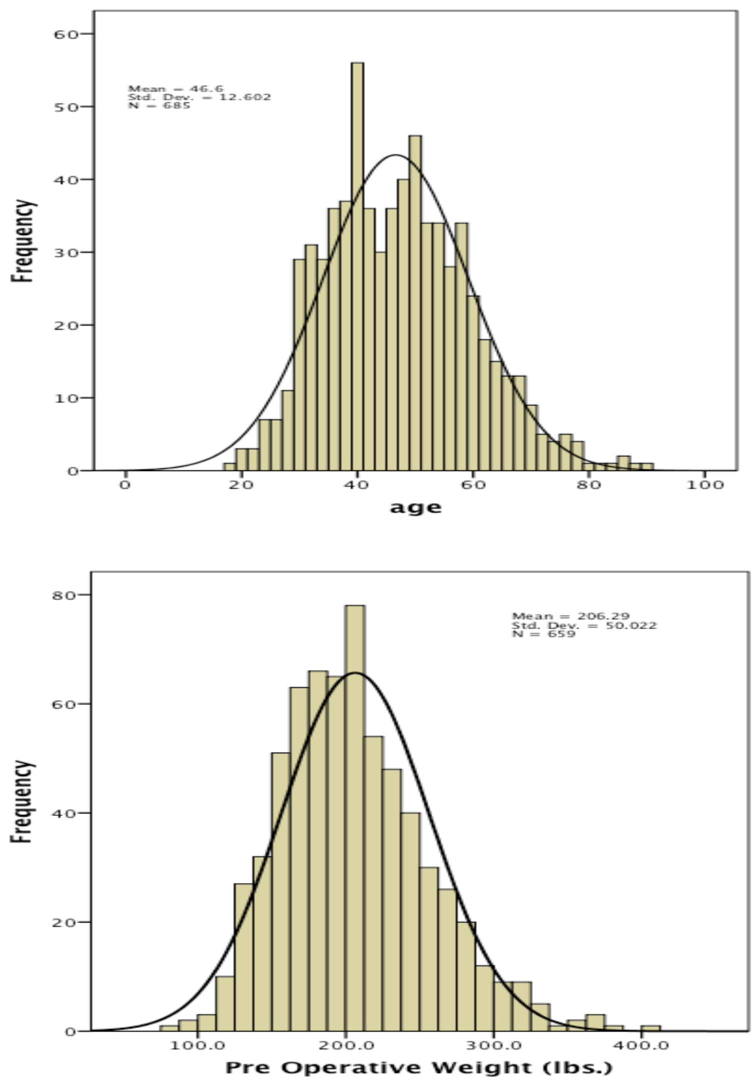


Figure 3. Distribution of age and weight.

Table 3

Clinical and Demographic Data

		n	%
Sex	Male	342	49.9
	Female	343	50.1
Clinical diagnosis (Primary)	Radiculopathy	592	86.4
	Neurogenic claudication	33	4.8
	Chronic axial low back pain	14	2.0
	Failed back syndrome	43	6.3
	Other	3	0.4
Clinical diagnosis (Secondary)	Radiculopathy	45	6.6
	Neurogenic claudication	392	57.2
	Chronic axial low back pain	47	6.9
	Failed back syndrome	28	4.1
	Other	3	0.4
Primary clinical pathology	Herniated lumbar disc	234	34.2
	Lumbar stenosis	370	54.0
	Spondylolysis &/or spondylolisthesis	68	9.9
	Lumbar degenerative disc disease	13	1.9
Secondary clinical pathology	Herniated lumbar disc	95	13.9
	Lumbar stenosis	51	7.5
	Spondylolysis &/or spondylolisthesis	4	0.6
	Clinical instability	42	6.1
Preoperative	Leg pain	669	97.7
	Claudication	624	91.1
	Smoking	312	45.5
	Diabetes	90	13.1
	Weight (Mean *SD*)	206.3±50.0	
	ODI (Mean *SD*)	56.9±16.1	
	Modified JOA (Mean *SD*)	11.2±1.7	

The majority of patients presented with leg pain (97.7%) and neurogenic claudication (91.1%), suggesting nerve impingement. The commonest pathology was lumbar stenosis (54.0%) followed by lumbar disc herniation (34.2%). Almost 7% of patients underwent surgery for just chronic axial low back pain or clinical instability (6.1%) related to lumbar degenerative disc disease (1.9%; see Table 3). Prior to surgery, 32.7% of patients (*n* = 225) were considered crippled (ODI 60-80%) while 36 (5%) patients rated their disability between 80 and 100%. Severe disability (ODI 40-60%) in daily function was seen in 271 patients (39%), moderate disability (ODI 20-40%) in 13.4% (*n* = 97), while only 10 patients had minimal restrictions (ODI 0-20%) in activities of daily living related to their degenerative lumbar pathology (see Figure 4). In this patient population, a mean ODI of 56.9 ± *SD* 16.1 reflects an overall severe disability.

The histogram demonstrates a severe to critical functional disability in a majority of patients.

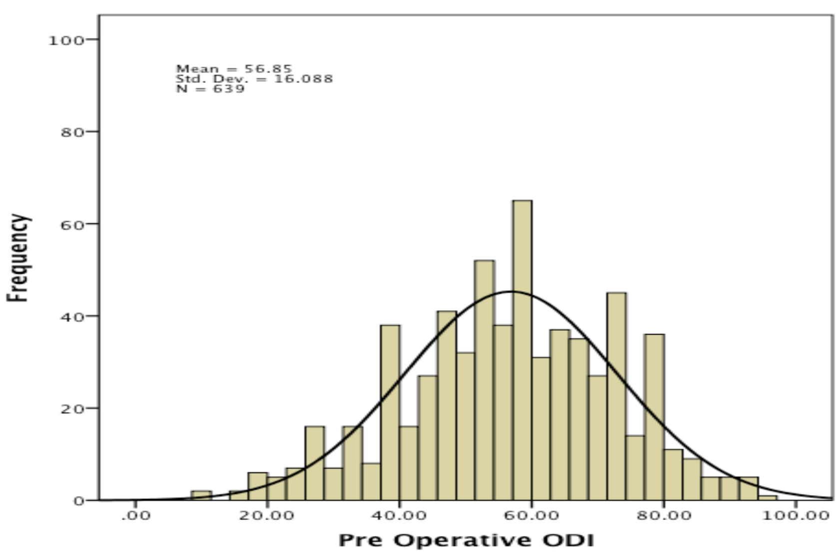


Figure 4. Distribution of preoperative ODI.

Similarly, at least 34% of patients (n = 145) had severe neurological dysfunction (modified JOA <11.0) due to their lumbar degenerative pathology prior to surgery. Moderate impact on clinical dysfunction (modified JOA 11.0-14.0) was seen in 61% (n = 261) of patients. The lumbar degenerative pathology presented with an almost 50% reduction in normal clinical capabilities of the patient as measured by the modified JOA (mean 11.2 ± *SD* 1.7, normal score 21). Most of the patients' clinical dysfunction was centered on 10 to 12 and a right skewness of 0.555 was detected (see Figure 5).

The histogram demonstrates a significant clinical dysfunction in a majority of patients prior to surgery.

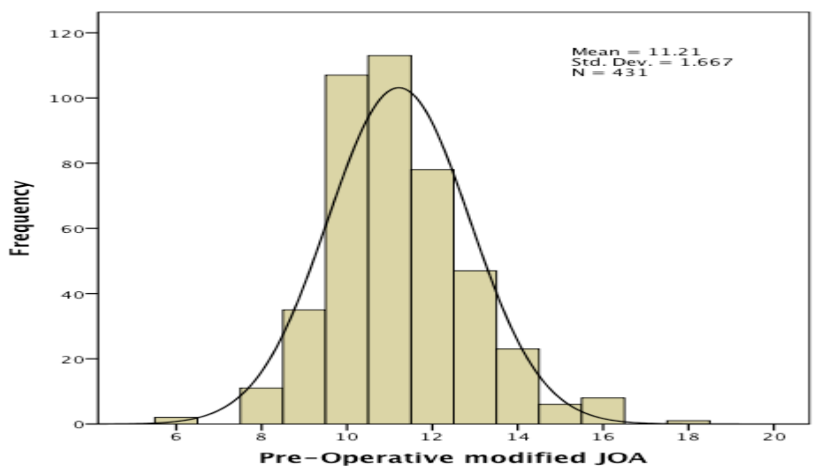


Figure 5. Distribution of preoperative modified JOA.

Surgery

In addition to spinal decompression, the majority of patients had undergone spinal fixation with varying degrees of complexity as described below. Simple decompressions accounted for only 18.4% of patients. While different methods of simpler fixation techniques were used, trans-facet arthrodesis accounted for 45.5% of the surgeries. The complex surgeries involved pedicle fixation with vertebral interbody stabilization and fusion in 195 patients (28.5%). Complicated fusions involved a combination of pedicle and trans-facet fixation (see Table 4).

Table 4

Description of Types of Surgical Procedures Performed

	Surgical Procedure	*N*	%
Type	Micro-discectomy	101	14.7
	Decompressive laminectomy	25	3.6
	Trans-facet fixation	311	45.5
	Inter-laminar fixation	19	2.8
	Inter-spinous fixation	4	0.6
	Pedicle fixation	195	28.5
	Hybrid (pedicle & trans-facet) Fixation	25	3.6
	Other	5	0.7
Number of spinal levels	One	287	41.9
	Two	196	28.6
	Three	108	15.8
	Four	61	8.9
	Five and greater	16	2.3
Complexity of surgery	Simple spine	128	18.7
	Simple fusion	337	49.2
	Complex fusion	195	28.5
	Complicated fusion	25	3.6

Surgical outcome. The spine surgery outcome questionnaire, which measured six dimensions pain symptoms, function, psychological well-being, disability, social restriction, and satisfaction of care, quantified the patients' response specifically to low back surgery for degenerative pathology (Deyo et al., 1998). The spine surgery outcome score was recorded, which was the percentage improvement from patients' perception of their preoperative condition, as described in Table 5 below. An overall positive response of 41.66 ± *SD* 26.68 % was detected as early as 2 weeks after surgery for their lumbar degenerative condition. Over the 2-year study period, a greater 50% positive response rate was sustained (see Figure 6).

Table 5

Patients Response to Lumbar Spine Surgery

Spine surgery outcome score

Interval	*n*	Range	Mean %	Std. Error	Std. Deviation	Skewness	Std. Error
2 weeks	509	150	41.66	1.183	26.682	-.534	.108
6 weeks	497	140.0	52.637	1.1964	26.6718	-.789	.110
3 months	502	150	52.55	1.370	30.700	-.887	.109
6 months	390	150	50.63	1.625	32.086	-.754	.124
1 year	252	150	52.82	2.154	34.190	-.813	.153
2 years	72	145	52.92	4.107	34.851	-.837	.283

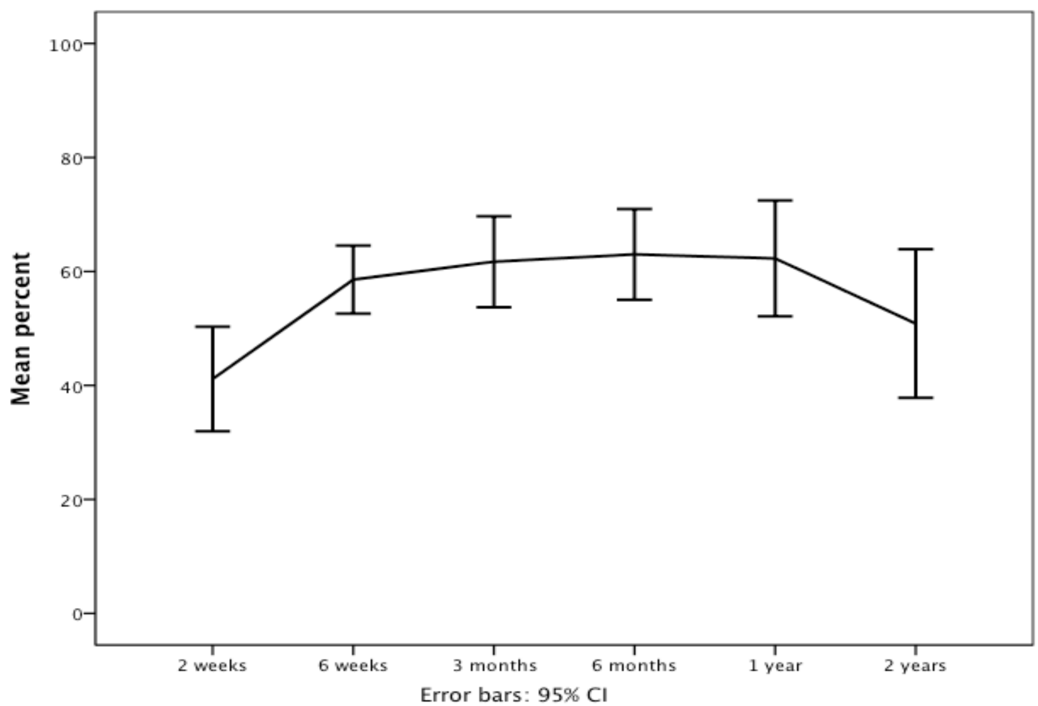


Figure 6. Response to lumbar spine surgery.

Patient satisfaction. In this study, the typology of patient experience had been categorized as excellent, very good, good, fair, and poor, as proposed by Deyo et al. (1998). Over the 2-year study, a consistently high mean patient satisfaction score between 4 (*very good*) and 5 (*excellent*) was recorded (see Table 6). Figure 7 illustrates the physician performance rating at the various time intervals following surgery.

Table 6

Patient Satisfaction With Surgery

Time interval	*n*	Mean			Skewness
			Std. error	Std. deviation	
2 weeks	471	4.28	.047	1.015	-1.550
6 weeks	472	4.32	.043	.933	-1.396
3 months	483	4.22	.049	1.069	-1.493
6 months	380	4.18	.055	1.066	-1.380
1 year	241	4.24	.072	1.111	-1.702
2 years	72	4.21	.144	1.221	-1.653

The montage demonstrates high levels of patient satisfaction over the 2-year study period. The majority of patients reported *good*, *very good*, or *excellent* care. The category of *no response* may have represented reluctance by the patient to adjudicate their satisfaction with care and had been scored a zero in the database.

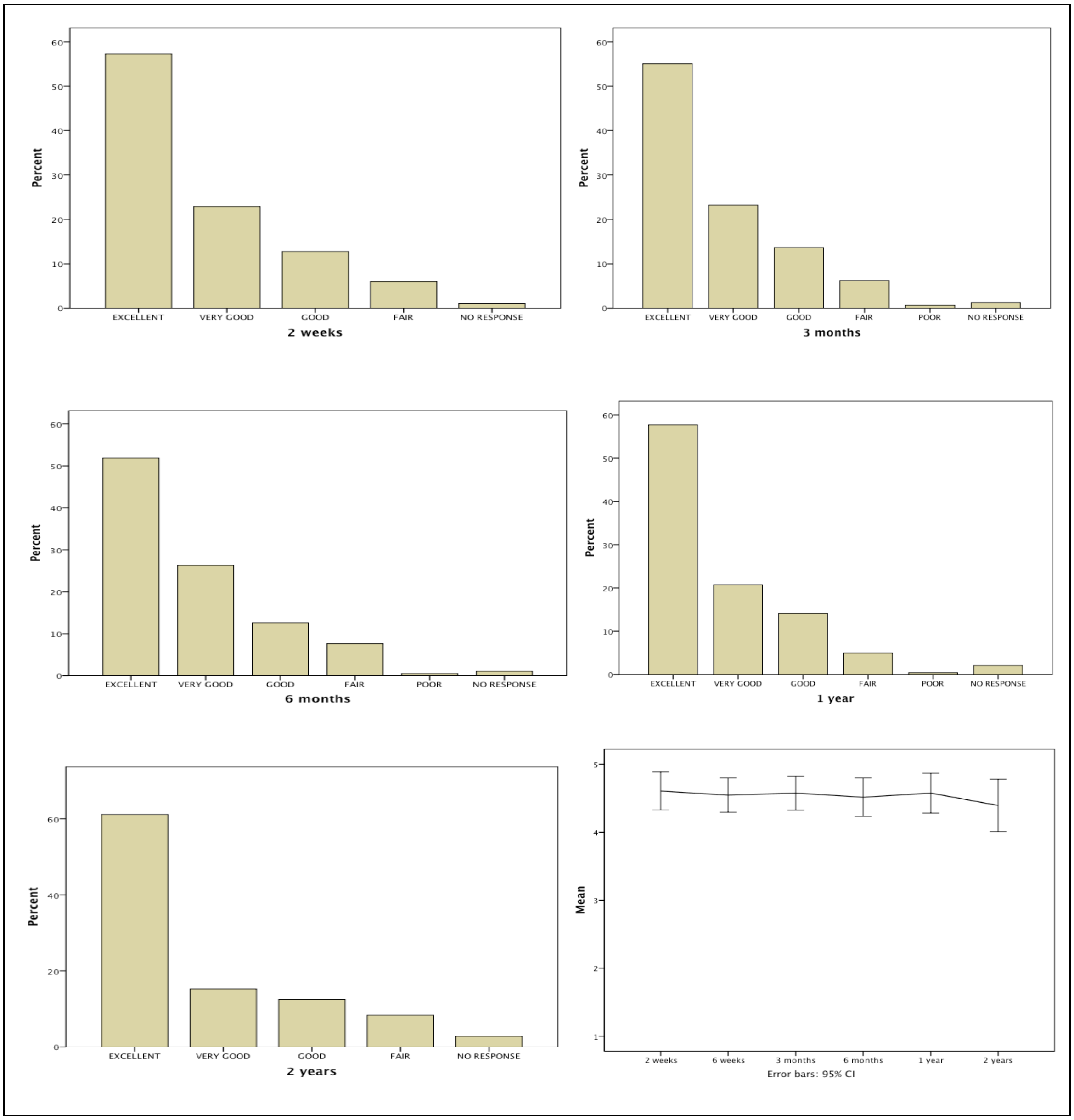


Figure 7. Quality of care.

Research Questions and Hypothesis

Statistical analysis of the secondary database was performed using IBM SPSS version 21 for Mac OS (Armonk, NY). The independent variable was surgical intervention. The dependant variables were the ODI, which measured overall functional outcome; the modified JOA, which measured the clinical recovery; the spine surgery outcome score, which quantified the functional response to surgery, together with the confounding influence of diabetes and smoking. The functional outcome improvement and clinical recovery was analyzed using *t* tests for correlated samples, while paired *t* tests were used to compare the outcome metrics from presurgery to the defined time periods after surgery since each patient served as their own control (Field, 2009). Pearson's correlations between the dependent variables were performed using parametric statistics. The effect of each of the patient reported outcome metrics on patient satisfaction was examined using ANOVA. The effect of the modified Japanese Orthopedic Score on levels of patient satisfaction was evaluated using ANOVA (see Table 2). Linear and multiple regression analysis quantified the influence of the variables on each other determined if patient-reported and physician-reported measures are predictive of physician performance rating. Multinomial logistic regression analysis evaluated the relationship of functional outcome and clinical recovery with degrees of patient satisfaction. Bivariate logistic regression analysis computed the influence of functional outcome measures, clinical evaluations, and patient response to surgery on patient dissatisfaction. The statistical tests were computed at each time interval, that is, 2 weeks, 6 weeks, 3months, 6 months, 1 year, and 2 years following surgery with major emphasis at the 3-month and 6-month window.

Research Question 1

Is there a statistically significant difference in the ODI and the modified JOA prior to and after low back surgery for spinal degenerative conditions, controlling for the effect of smoking and diabetes?

Functional outcome (t test). The ODI, which is comprised of 10 items to evaluate the impact of low back pain on daily physical activities, was used to quantify the functional disability, measured as a percentage (Fairbank et al., 1980). There was significant reduction of 16.79 ± *SD* 19.92, p< .001) in functional disability following surgery from a mean ODI of 57.58 ± *SD* 16.0 to a mean of 41.00 ± *SD* 20.52 at the three month time interval after surgery (see Tables 7 and 8).

Table 7

Descriptive Data of ODI

	Mean	*n*	Std. Deviation	Std. Error Mean
Pre-OP ODI	57.5794	550	16.00609	.68250
2 week ODI	54.69292	550	19.632901	.837150
Pre-OP ODI	57.1560	540	15.79242	.67960
6 week ODI	42.3203	540	20.66981	.88949
Pre-OP ODI	57.7974	518	15.12664	.66463
3 month ODI	41.0000	518	20.52488	.90181
Pre-OP ODI	58.1969	388	15.15350	.76930
6 month ODI	42.5101	388	20.50225	1.04084
Pre-OP ODI	58.1086	239	14.48110	.93670
I year ODI	41.7525	239	21.57854	1.39580
Pre-OP ODI	56.3149	73	16.50545	1.93182
2 year ODI	41.9316	73	21.29248	2.49210

Table 8

Differences in ODI Over 2 Years When Compared to Preoperative Status

Interval	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. deviation	Std. error mean	95% Confidence interval of the difference				
				Lower	Upper			
2 weeks post Op	2.88	19.62	.836	1.242	4.53	3.449	549	.001
6 weeks post Op	14.83	19.96	.859	13.148	16.52	17.270	539	.000
3 months post Op	16.79	19.92	.875	15.077	18.51	19.188	517	.000
6 months post Op	15.68	20.00	1.015	13.690	17.68	15.449	387	.000
1 year post Op	16.35	22.94	1.484	13.432	19.27	11.021	238	.000
2 years post Op	14.38	24.33	2.848	8.705	20.06	5.050	72	.000

A significant reduction in functional disability is seen over the two years, as measured by the Oswestry Disability Index (ODI).

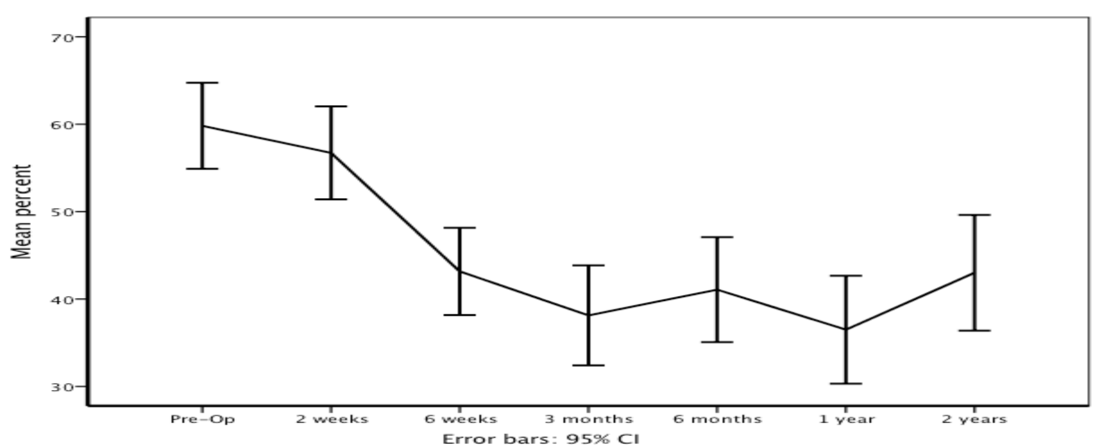


Figure 8. Changes in functional outcome following lumbar spine surgery.

The null hypothesis stated that there in no difference in functional outcome following lumbar spine surgery for lumbar degenerative pathology. The results of this study demonstrated a highly significant reduction (p<. 001) in functional disability by the six week post-operative period (*see Table 8*), thereby rejecting the null hypothesis and accepting the research hypothesis. The improvement in functional outcome was sustained over the two year study period following surgery, as illustrated in Figure 8 above.

Clinical recovery (t test). The modified JOA score (integers), a specific measure for surgical outcomes for spinal degenerative conditions (Inoue et al., 1986; Tajima et al., 1989; Vialle et al., 2007), quantified the clinical changes from the pre-operative baseline score. There was a 50% (mean change = 6.983 ± *SD* 2.613) improvement in the modified JOA from a baseline of 11.28 ± *SD* 1.667 to 18.13 ± *SD* 2.408, p<. 001, at the three month evaluation (*see Table 9*).

Table 9

Descriptive Data of Changes in the Modified JOA

Interval		Mean	n	Std. Deviation	Std. Error Mean	Recovery Rate
Pre-Op		11.53	19	2.144	.492	
	6 week	15.79	19	4.341	.996	46%
Pre-Op		11.28	351	1.677	.090	
	3 months	18.26	351	2.416	.129	72%
Pre-Op		11.16	255	1.672	.105	
	6 months	17.85	255	2.465	.154	68%
Pre-Op		11.31	150	1.655	.135	
	1 year	18.15	150	2.586	.211	71%
Pre-Op		11.46	35	1.771	.299	
	2 year	18.34	35	2.722	.460	72%

Table 10

Differences in the Modified JOA over Two Years when Compared to Pre-Operative Status

Time Interval	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. deviation	Std. error mean	95% Confidence interval of the difference				
				Lower	Upper			
6 weeks post-Op	-4.263	3.899	.895	-6.143	-2.384	-4.766	18	.000
3 months post-Op	-6.983	2.613	.139	-7.257	-6.709	-50.065	350	.000
6 months post-Op	-6.686	2.697	.169	-7.019	-6.354	-39.596	254	.000
1 year post-Op	-6.833	2.796	.228	-7.284	-6.382	-29.932	149	.000
2 years post-Op	-6.886	2.654	.449	-7.798	-5.974	-15.347	34	.000

A significant improvement in clinical dysfunction is seen over the two year study period, as measured on the modified JOA score.

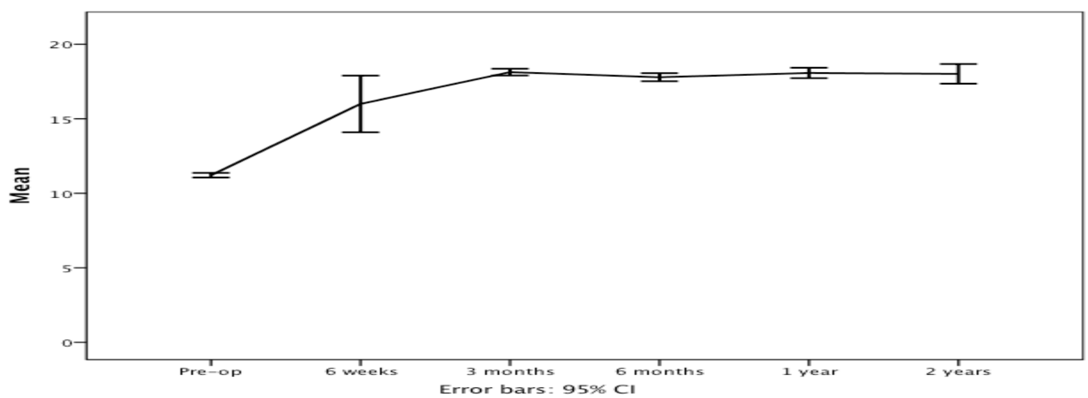


Figure 9. Changes in clinical outcome following lumbar spine surgery

The null hypothesis stated that there in no impact of surgery on clinical recovery following lumbar spine surgery for lumbar degenerative pathology. The results of this study demonstrated a highly significant clinical recovery by the six week post-operative period (*see Table 10*). This clinical recovery was sustained at similar levels over the entire study period (*see Figure 9*). Therefore, the null hypothesis is rejected and the research hypothesis has been accepted.

Influence of smoking and diabetes (*t* test). Patients who were smokers prior to surgery presented with a significantly higher ODI score when compared to non-smokers, 58.63 ± *SD* 15.10 and 55.09 ± *SD* 16.85, $p<0.01$, respectively. Even if patients continued to smoke, as documented on the follow-up visits, their functional outcome was significantly reduced at all time intervals except at the six month and two year visit. However, logistic regression analysis (bivariate) revealed that persistent smoking only accounted for one to four percent of the variation in the ODI (*see Table 11*). The null hypothesis stated that there in no effect of smoking on functional outcome following lumbar spine surgery for lumbar degenerative pathology. The results of this study demonstrated that, although smokers had significantly lower functional outcome at all time intervals, smoking only had a limited affect on functional outcome, thereby accepting the null hypothesis (*see Figure 10*).

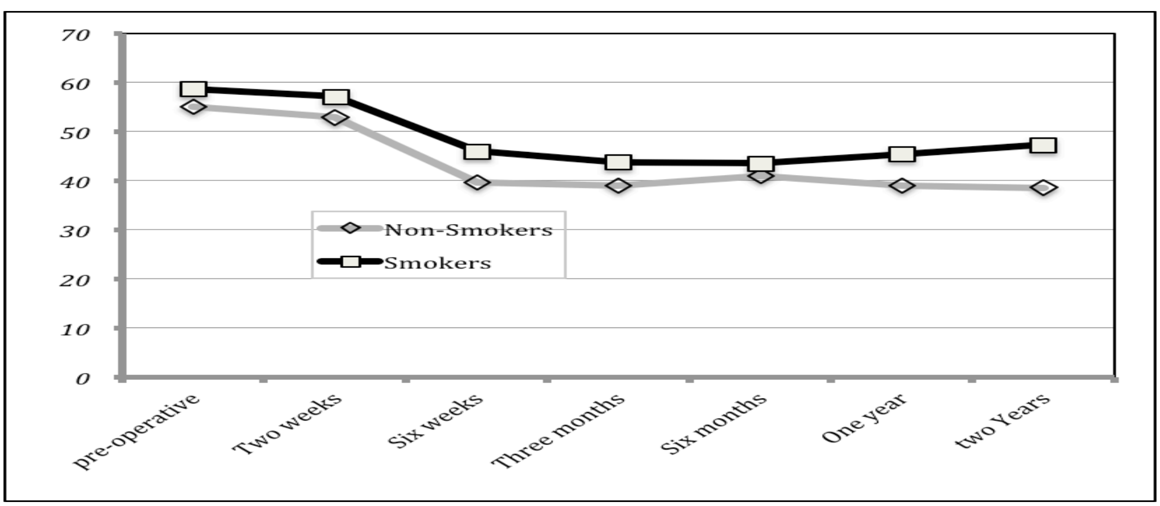


Figure 10. Differences in functional disability (ODI) for smoking

Table 11

Comparison of Functional Disability Between Smokers and Nonsmokers

				ODI				
Time Interval	Smoker	n	Mean	Std. deviation	Std. error mean	*t*-test (2-tailed) p	Mean difference	Logistic regression R^2
Pre-OP	No	326	55.0957	16.85277	.93339	<0.01	3.537	0.008
	Yes	309	58.6333	15.10881	.85951			
2 weeks	No	325	52.93722	19.272782	1.069062	<. 05	4.15	0.011
	Yes	246	57.09224	19.649329	1.252795			
6 weeks	No	307	39.7286	20.01094	1.14208	<. 001	6.23	0.017
	Yes	250	45.9620	20.61461	1.30378			
3 months	No	299	39.0680	20.20357	1.16840	<. 01	4.72	0.013
	Yes	235	43.7925	20.07513	1.30956			
6 months	No	223	41.4042	21.32373	1.42794	0.312	2.06	0.003
	Yes	181	43.4710	19.21973	1.42859			
1 year	No	140	38.9639	20.84703	1.76190	<. 05	6.38	0.022
	Yes	116	45.3526	21.38680	1.98571			
2 years	No	55	38.5962	20.15853	2.71818	<. 05	8.69	0.039
	Yes	28	47.2936	21.64309	4.09016			

In contrast to functional outcome, smoking had no significant effect on the clinical recovery. Although statistical significance reached at the 3-month time interval was the mean difference of 0.537 is deemed not to be clinically relevant. The null hypothesis stated that there in no effect of smoking on clinical recovery following lumbar spine surgery for lumbar degenerative pathology. The results of this study demonstrate that smoking has no significant effect on clinical outcome, thereby retaining the null hypothesis (*see Table 12*). The diagnosis of diabetes at the prior to surgery had no significant impact on functional outcome or clinical recovery at any of the time periods, up to two years following surgery (*see Tables 13 and 14*). The null hypothesis stated that the diagnosis of diabetes has no effect on functional outcome and/or clinical recovery following lumbar spine surgery for lumbar degenerative pathology. The results of this study demonstrate that diabetes does not influence either functional outcome or clinical recovery, thereby retaining the null hypothesis.

Table 12

Comparison of Clinical Outcome Between Smokers and Non-smokers

Modified JOA						
Interval	Smoker	n	Mean	Std. deviation	Std. error mean	Sig. (2-tailed) p
Pre-Op	No	205	11.30	1.699	.119	0.337
	Yes	224	11.14	1.637	.109	
6 weeks	No	12	15.75	4.070	1.175	0.761
	Yes	8	16.38	4.955	1.752	
3 months	No	218	17.85	2.669	.181	<. 05
	Yes	215	18.39	2.081	.142	
6 months	No	161	17.79	2.689	.212	0.98
	Yes	165	17.78	2.306	.180	
1 year	No	109	18.18	2.636	.252	0.624
	Yes	104	18.01	2.529	.248	
2 years	No	39	18.31	2.546	.408	0.317
	Yes	29	17.62	3.064	.569	

Table 13

Comparison of Functional Disability for Diabetes

ODI						
Post operative Interval	Diabetes	n	Mean	Std. Deviation	Std. Error Mean	*t*-test (2-tailed) p
Pre Op	No	553	56.6901	16.07914	.68375	>. 05
	Yes	83	57.8828	16.41737	1.80204	
2 weeks	No	496	54.30427	19.494829	.875344	
	Yes	80	57.68663	18.714476	2.092342	
6 weeks	No	489	41.8624	20.58197	.93075	
	Yes	78	44.7582	20.43769	2.31411	
3 months	No	473	40.9847	20.31662	.93416	
	Yes	74	41.8936	20.30709	2.36065	
6 months	No	356	41.8773	20.52136	1.08763	
	Yes	53	45.5128	18.83881	2.58771	
1 year	No	225	41.9075	21.39212	1.42614	
	Yes	35	41.4411	21.07009	3.56150	
2 years	No	68	41.5696	20.99136	2.54558	
	Yes	15	41.3520	21.49996	5.55126	

Table 14

Comparison of Clinical Outcome for Diabetes

				Modified JOA		
Interval	Diabetes	N	Mean	Std. deviation	Std. error mean	Sig. (2-tailed) p
Pre-Op	No	368	11.19	1.704	.089	>. 05
	Yes	61	11.39	1.417	.181	
6 weeks	No	17	15.71	4.511	1.094	
	Yes	3	17.67	3.215	1.856	
3 months	No	373	18.13	2.386	.124	
	Yes	60	18.05	2.554	.330	
6 months	No	283	17.78	2.493	.148	
	Yes	43	17.84	2.563	.391	
1 year	No	184	18.01	2.652	.196	
	Yes	30	18.50	2.224	.406	
2 years	No	54	17.72	2.845	.387	
	Yes	14	19.14	2.248	.601	

Research Question 2

Is there a statistically significant difference in the ODI, the modified JOA and the spine surgery outcome score for the complexity level of the surgical procedure?

Clinical and demographic data. The type surgical procedures were classified into increasing levels of complexity according to invasiveness, risks, cost, and morbidity, as proposed by Deyo et al., in 2010 (*see Table 5*). The distribution of the clinical and demographic factors prior to surgery have been summarized in Tables 15 a and 15 b below. While higher patient age was associated with increaing complexity of surgery $F(3,681) = 9.702$, $p<0.001$, there was no significant variance in preoperative weight. Smokers were evenly represented in all categories of surgery. While intergroup differences were seen for diagnosis and pathology, they do not have clinical relevance since the majority of patients presented with either radiculopathy (86%) and or neurogenic claudication (76%). Indeed, patients with just lumbar disc degeneration (n=13) and or clinical instability (n=42) underwent fusion procedures (92%). Fusion procedures were more likely in patients with claudication symptoms (81%) and radicular pain (68%). However, patients with spondylolisthesis or spondylolysis required major spinal surgery (91%) either as complex fusion or complicated fusion. While patients with higher functional disability had undergone increasing complex spinal procedures, $F(3,635) = 3.56$, $p<0.05$, no significant differentiation was detected on the clinical evaluation, $F(3,427) = 0.816$, $p>0,05$. The means plot is illustrated in Figure 11 below.

Table 15 a

Clinical and Demographic Data According to Complexity of Surgery

Categorical variables			Simple spine	Simple fusion	Complex fusion	Complicated fusion	Pearson's chi-square
		n (%)	128 (18.7)	337 (49.2)	195 (28.5)	25 (3.6)	
Sex	Male	342 (49.9)	56 (16.4)	187 (54.7)	91 (26.6)	8 (2.3)	.017
	Female	343 (50.1)	72 (10.5)	150 (43.7)	104 (30.3)	17 (5.0)	
Smoker		325 (48)	62 (9.2)	153 (22.5)	97 (14.3)	14 (2.1)	.677
Diabetes		90 (13.2)	11 (1.6)	58 (8.5)	18 (2.6)	3 (0.4)	.022
Leg pain		669 (99)	126 (18.6)	328 (48.5)	190 (29.4)	25 (3.7)	.305
Claudication		624 (93.6)	108 (16.2)	317 (50.8)	175 (26.2)	24 (3.6)	.006
Clinical diagnosis	Radiculopathy	592 (86.4)	126 (18.4)	295 (43.1)	148 (21.6)	23 (3.4)	.000
Secondary diagnosis	Neurogenic claudication	392 (76.1)	88 (17.1)	210 (40.8)	80 (15.5)	14 (2.7)	.000
	Chronic axial LBP	47 (9.1)	2 (0.4)	15 (2.9)	30 (5.8)	0	
	Failed back syndrome	28 (5.4)	1 (0.2)	12 (2.3)	14 (2.7)	1 (0.2)	
	Other	3 (0.6)	0	3	0	0	
	Radiculopathy	45 (8.7)	1 (0.2)	18 (3.5)	25 (4.9)	1 (0.2)	
Clinical pathology	Herniated lumbar disc	234 (34.2)	106 (15.5)	66 (9.6)	59 (8.6)	3 (0.4)	.000
	Lumbar stenosis	349 (50.9)	21 (3.1)	248 (36.2)	61 (17.5)	19 (5.4)	
	Lateral recess syndrome	21 (3.2)	1 (0.1)	14 (2.0)	5 (0.7)	1 (0.1)	
	Spondylolysis spondylolisthesis	68 (9.9)	0	6 (0.9)	60 (8.8)	2 (0.3)	
	Lumbar degenerative disc disease	13 (1.9)	0	2 (0.4)	10 (1.5)	0	
Secondary pathology	Clinical instability	42 (10.9)	4 (1.0)	29 (7.5)	8 (2.1)	1 (0.3)	.000

Table 15 b

Clinical and Demographic Data According to Complexity of Surgery

Scalar variable	Complexity of surgery	*n*	Mean	Std. deviation	Std. Error	95% confidence Interval for mean Lower bound	95% confidence Interval for mean Upper bound
Age	Simple spine	128	43.86	14.613	1.292	41.30	46.42
	Simple fusion	337	48.73	12.528	.682	47.39	50.08
	Complex fusion	195	44.04	10.682	.765	42.53	45.54
	Complicated fusion	25	51.80	9.552	1.910	47.86	55.74
	Total	685	46.60	12.602	.482	45.65	47.54
Weight	Simple spine	122	201.545	49.7511	4.5043	192.628	210.462
	Simple fusion	321	210.089	50.1097	2.7968	204.586	215.591
	Complex fusion	191	205.209	49.3600	3.5716	198.164	212.254
	Complicated fusion	25	189.000	52.2319	10.4464	167.440	210.560
	Total	659	206.293	50.0225	1.9486	202.467	210.119
ODI	Simple spine	120	53.1870	17.40245	1.58862	50.0414	56.3326
	Simple fusion	307	57.1479	15.75612	.89925	55.3784	58.9174
	Complex fusion	187	57.9356	15.52982	1.13565	55.6951	60.1760
	Complicated fusion	25	62.7644	15.18579	3.03716	56.4960	69.0328
	Total	639	56.8543	16.08803	.63643	55.6045	58.1041
Modified JOA	Simple spine	77	11.34	1.683	.192	10.96	11.72
	Simple fusion	197	11.19	1.555	.111	10.97	11.41
	Complex fusion	132	11.27	1.906	.166	10.94	11.59
	Complicated fusion	25	10.76	.970	.194	10.36	11.16
	Total	431	11.21	1.667	.080	11.06	11.37

Montage demonstrating the significant variances in age, weight, functional disability, and clinical dysfunction associated with higher complexity of surgery.

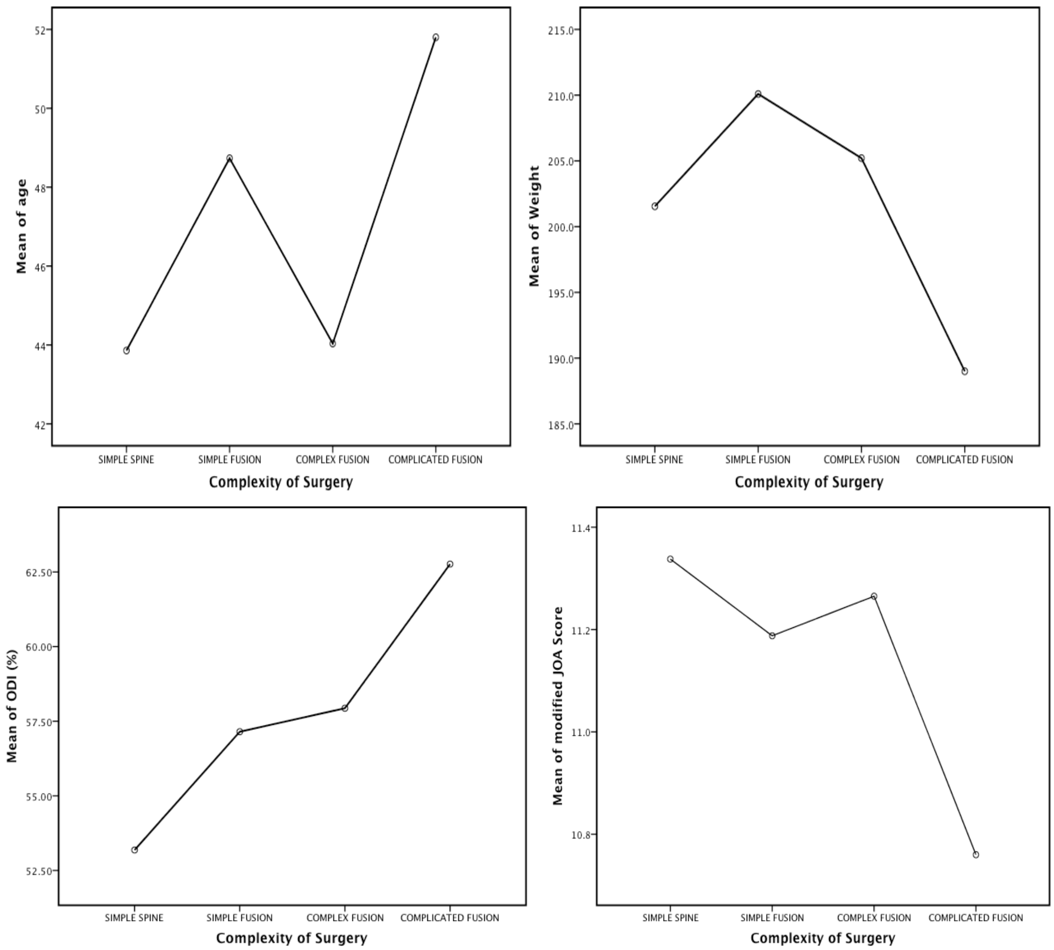


Figure 11. Means plot according to complexity of surgery

Health performance and complexity of surgery (ANOVA). At two weeks, patient who underwent more complex surgeries reported on moderate to severe functional disability when compared to patients undergoing more simple surgeries, F(3,575) = 22.02, p<. 001, (see Table 16). The inflection point was between just spinal decompression and/or discectomies, and, fusion procedures, Bonferroni *post hoc* test; mean difference 13.83 ± *SE* 2.05, *CI* = 8.4-19.27, p<. 001. Similarly, the positive response to surgery was lower with increasing complexity of the surgical procedures, $F(3,505) = 3.799$, $p < .05$. The significant difference jump was seen between simple spinal procedure and complex fusions, Bonferroni *post hoc* test; mean difference 11.22 ± *SE* 3.38, *CI* = 2.26-20.18, $p < 0.01$, (*see Figure 12*). Interestingly, although patients who underwent increasingly complex procedures reported higher levels of patient satisfaction, it did not reach statistical significance.

Patients who had undergone simple spinal procedures had, by 6 weeks, returned to only mild functional disability with a mean ODI = 31.52 ± *SD* 21.57, when compared to the spinal fusions, who still reported moderate disability with a mean ODI ≈ 44-52, $F(3,566) = 14.555$, $p < .001$, (see Table 17). The highest difference was detected between simple spine and complicated spinal fusions, Bonferroni *post hoc* test; mean difference 20.61 ± *SE* 4.55, *CI* = 8.56-32.66, $p < .01$, (see Figure 13). Similarly, patients who had simple spinal decompressions and/or discectomies had returned to almost normal clinical function, mean modified JOA ≈19-21 ± *SD* 2.40, when compared to fusion procedures in whom an almost 50% clinical dysfunction was detected, even accounting for a small sample size, $F(2,17) = 14.082$, $p < .001$. No significant differences were detected in patients' response to surgery or with their levels of satisfaction with medical care.

Table 16

Descriptive Data for Health Performance According to Complexity of Surgery (2 Weeks)

Outcome measure	Complexity of surgery	N	Mean	Std. deviation	Std. error	95% confidence interval for mean	
						Lower bound	Upper bound
ODI	Simple spine	115	42.44609	19.308972	1.800571	38.87917	46.01300
	Simple fusion	280	56.28261	18.502793	1.105753	54.10593	58.45929
	Complex fusion	163	59.26049	18.022965	1.411668	56.47285	62.04813
	Complicated fusion	21	62.71743	18.641293	4.067864	54.23201	71.20284
Spine surgery outcome score	Simple spine	107	48.75	23.081	2.231	44.32	53.17
	Simple fusion	238	41.14	26.615	1.725	37.74	44.54
	Complex fusion	143	37.52	27.609	2.309	32.96	42.09
	Complicated fusion	21	39.52	32.477	7.087	24.74	54.31
Level of patient satisfaction	Simple spine	92	4.26	1.068	.111	4.04	4.48
	Simple fusion	220	4.26	.984	.066	4.13	4.39
	Complex fusion	138	4.29	1.062	.090	4.11	4.47
	Complicated fusion	21	4.62	.740	.161	4.28	4.96

The montage illustrates the significant variances in the ODI, the Spine Surgery Outcome Score and patient satisfaction scores.

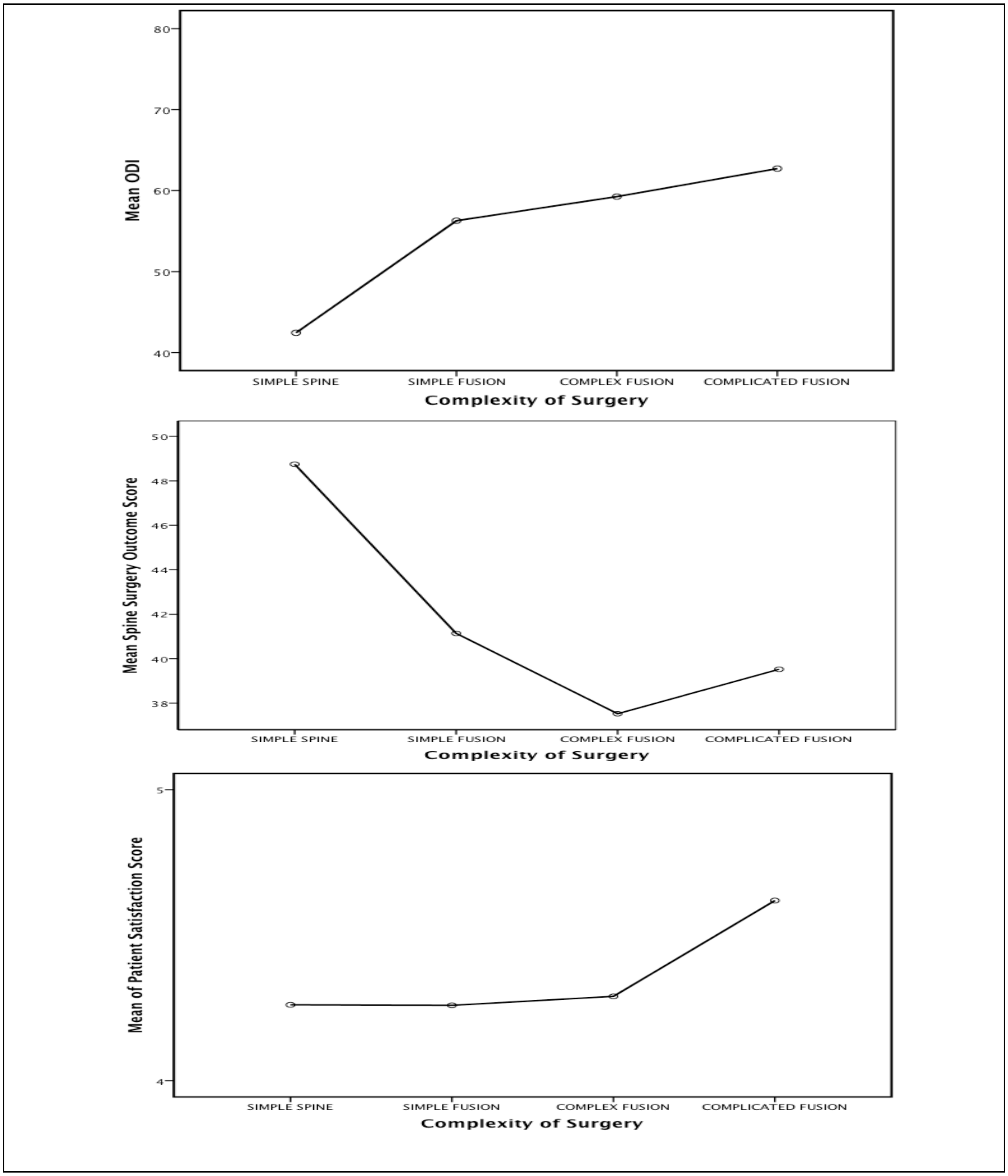


Figure 12. Means plot of complexity of surgery at the two weeks post-operative interval.

The montage demonstrates the significant variances seen in the functional outcome (ODI) and the clinical outcome (modified JOA).

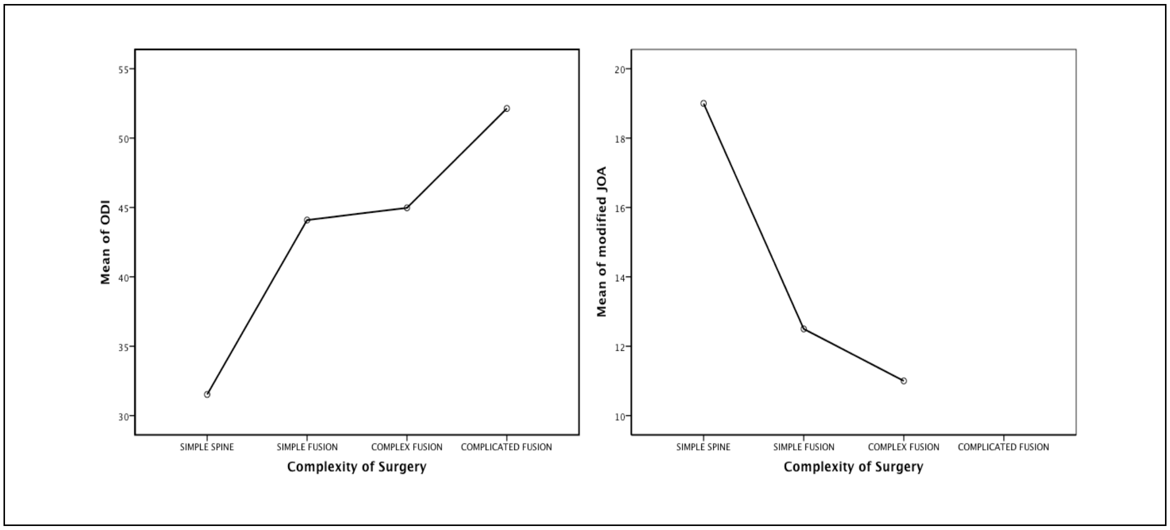


Figure 13. Means plot of complexity of surgery at 6 weeks post-operative.

Table 17

Descriptive Data for Health Performance According to Complexity of Surgery (6 Weeks)

Outcome measure	Complexity of surgery	*n*	Mean	Std. deviation	Std. error	95% confidence interval for mean	
						Lower bound	Upper bound
ODI	Simple spine	112	31.5234	21.57157	2.03832	27.4843	35.5625
	Simple fusion	275	44.0937	19.20284	1.15797	41.8141	46.3734
	Complex fusion	160	44.9729	19.99738	1.58093	41.8505	48.0952
	Complicated fusion	23	52.1357	18.31294	3.81851	44.2165	60.0548
Spine surgery outcome score	Simple spine	102	57.549	27.7341	2.7461	52.102	62.997
	Simple fusion	231	49.613	26.4589	1.7409	46.182	53.043
	Complex fusion	142	54.366	25.7295	2.1592	50.098	58.635
	Complicated fusion	22	50.455	27.3387	5.8286	38.333	62.576
Level of patient satisfaction	Simple spine	93	4.30	.964	.100	4.10	4.50
	Simple fusion	217	4.27	.930	.063	4.15	4.40
	Complex fusion	141	4.43	.896	.075	4.28	4.57
	Complicated fusion	21	4.14	1.062	.232	3.66	4.63
Modified JOA	Simple spine	11	19.00	2.408	.726	17.38	20.62
	Simple fusion	8	12.50	3.295	1.165	9.75	15.25
	Complex fusion	1	11.00	.	.	.	.
	Complicated fusion	0	.	.	.	.	.

At the end of the global period at three months from surgery, there was a reduction on functional disability of patients undergoing fusion procedures when compared to the 6 week visit. Although a significant variance in ODI was detected, F(3,546) = 3.109, p<. 05, *post hoc* analysis revealed that there was a tendency for complicated fusion to have increased disability but did not reach statistical significance, Bonferroni *post hoc* test; mean difference 12.07 ± *SE* 4.71, *CI* = -0.4147-24.57, p= .74. In contrast, clinical assessment of patients at this time interval revealed that fusion patients had sufficiently recovered from their neurological dysfunction, which was comparable to simple spine surgeries (*see Table 18*). However, the patients' response to surgery (spine surgery outcome score) and levels of satisfaction did not show any distinction for the complexity of surgery.

Table 18

Descriptive Data for Health Performance According to Complexity of Surgery (Three months)

Outcome measure	Complexity level	*n*	Mean	Std. deviation	Std. error	95% confidence interval for mean	
						Lower bound	Upper bound
ODI	Simple spine	79	35.1415	20.90648	2.35216	30.4587	39.8243
	Simple fusion	277	41.6531	20.80499	1.25005	39.1922	44.1139
	Complex fusion	170	41.6201	19.39639	1.48764	38.6833	44.5568
	Complicated fusion	24	47.2213	16.99315	3.46871	40.0457	54.3968
Modified JOA	Simple spine	66	17.71	2.778	.342	17.03	18.39
	Simple fusion	209	18.07	2.419	.167	17.74	18.40
	Complex fusion	139	18.50	2.048	.174	18.16	18.85
	Complicated fusion	21	17.62	3.008	.656	16.25	18.99
Spine surgery outcome score	Simple spine	73	55.37	32.290	3.779	47.84	62.90
	Simple fusion	247	49.41	32.132	2.045	45.39	53.44
	Complex fusion	159	56.04	27.067	2.147	51.80	60.28
	Complicated fusion	23	53.26	31.931	6.658	39.45	67.07
Level of patient satisfaction	Simple spine	70	4.24	1.042	.125	3.99	4.49
	Simple fusion	238	4.10	1.150	.075	3.95	4.25
	Complex fusion	153	4.35	.975	.079	4.19	4.50
	Complicated fusion	22	4.59	.666	.142	4.30	4.89

By the 6 months, no significant differences in both functional (ODI) and clinical outcome (modified JOA) could be detected. However, the sample size for simple spinal surgeries was markedly less since many patients had been discharged at their three month visit. The response to surgery was not affected by the complexity of the surgical procedure. Paradoxically, patients who underwent the more invasive complicated fusions, mean = 4.75 ± *SD* 0.0444 and 4.06 ± *SD* 1.114, $F(3,376) = 3.198$, $p < .05$, exhibited the highest satisfaction score, when compared to the simple fusion procedures, Bonferroni *post hoc* test; mean difference 0.689 ± *SE* 0.248, *CI* = 0.3-1.35, $p < .05$, albeit from a small sample size, (*see Figure 14*).

Significant variance was seen in patient satisfaction scores between simple fusions and complicated fusions.

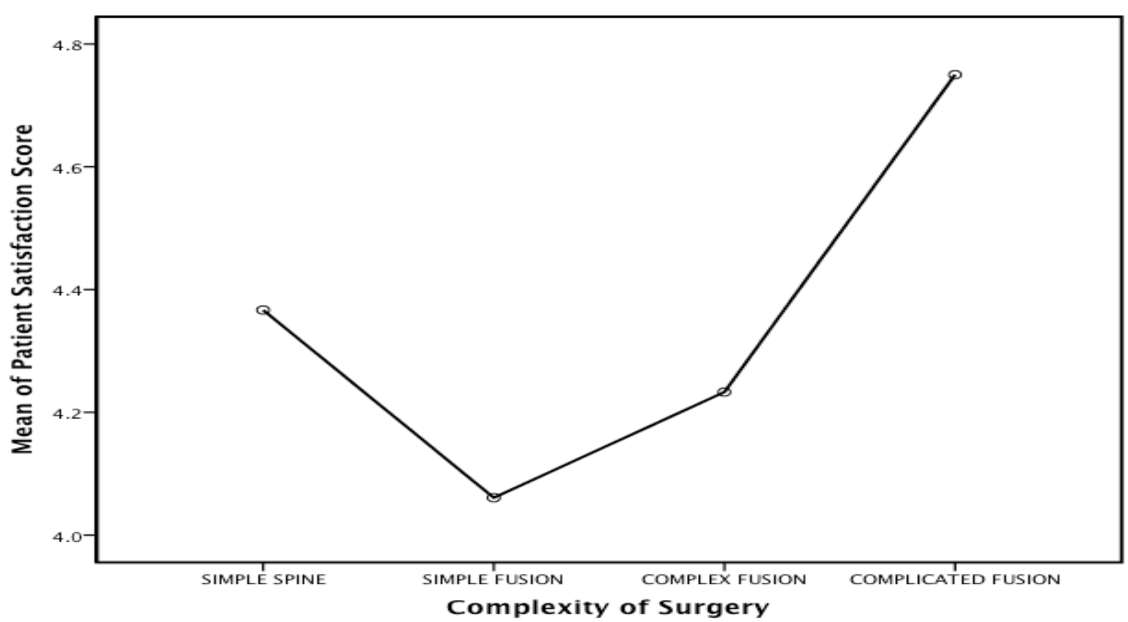


Figure 14. Means plot of complexity of surgery at 6 months post-operative.

The analysis of the late post-operative period was limited by much smaller sample sizes when compared to the earlier periods especially for simple spine (n=11) and complicated spine procedures (n=16). At although patients undergoing more complex procedures reported higher levels of functional disability (ODI) and clinical dysfunction (modified JOA), the variance did not reach statistical significance, Bonferroni *post hoc* test; mean difference 7.87 ± *SE* 8.36, *CI* = -30.11-14.36, p=1.00. Similarly, patients who underwent simple spinal procedures had a higher positive response to surgery (spine surgery outcome score) but it did not reach statistical significance. The levels of satisfaction were also similar, irrespective of the complexity of surgery.

Complexity of surgery had no impact on functional outcome, clinical outcome, response to surgery, and levels of satisfaction at the two year time frame. *Post hoc* analysis revealed that complexity of surgery was not predictive of the degree of patient satisfaction (multinomial regression analysis) at any of the follow-up visits. In addition, complexity of surgery had no impact on the patient's satisfaction or dissatisfaction with the health care provider at any of post-operative time intervals (Pearson's chi-square test).

The null hypothesis states that there is no statistically significant difference in the ODI, the modified JOA and the spine surgery outcome score for the complexity level of the surgical procedure. The results of this study demonstrates that there are significant differences in functional outcome, clinical recovery, and response to surgery, but not on levels of satisfaction in the early post-operative period (two weeks and six week) following surgery, thereby rejected the null hypothesis and accepting the research hypothesis. However, after the three month period, in medium to long term, complexity of surgery had no impact on health performance metrics, thereby accepting the null hypothesis.

Research Question 3

Is there a statistically significant relationship between patient-reported outcome measures (ODI, Spine Surgery Outcome Score), clinical evaluations (the modified JOA) and patient satisfaction?

Relationship between PROM and clinical assessment (Pearson's correlation). Prior to surgery, only a mild but significant correlation between functional disability (ODI) and clinical dysfunction (modified JOA) was detected, n=426, $r = -0.334$, $p < .001$. At the two week post-operative time interval, a mild but significant correlation between ODI and levels of satisfaction was seen. [The modified JOA was not recorded at this time interval. The moderate correlation between the spine surgery outcome score and levels of satisfaction could be related to the fact that patient satisfaction is one of the dimensions of the spine surgery outcome score and as such account for up to 20% of its value]. The response to surgery, at the six week interval, revealed highly significant moderate to strong correlations between functional outcome, clinical outcome, and response to surgery (*see Table 19*). Only a mild correlation was seen between the response to surgery and levels of satisfaction with the medical provider.

Table 19

Relationship between Patient Reported Outcome Measure and Clinical Outcome

Time interval	*n*		ODI	Modified JOA	Spine surgery outcome score	Pearson's correlation
				r		
2 weeks	579	ODI		-0.334		P<0.001
	509	Spine surgery outcome score	-0.587			P<0.001
	471	Level of patient	-0.136			P<0.01
		satisfaction			0.449	P<0.001
6 weeks	570	ODI		-0.680		P<0.01
	20	Modified JOA			0.570	P<0.01
	497	Spine surgery outcome score	-0.655			P<0.001
	472	Level of patient	-0.226			P<0.001
		satisfaction		0.895		P<0.001
					0.471	P<0.001
3 months	550	ODI		-0.524		P<0.001
	435	Modified JOA			0.579	P<0.001
	502	Spine surgery outcome score	-0.720			P<0.001
	483	Level of patient	-0.289			P<0.001
		satisfaction		0.292		P<0.001
					0.600	P<0.001
6 months	411	ODI		-0.554		P<0.001
	327	Modified JOA			0.594	P<0.001
	390	Spine surgery outcome score	-0.772			P<0.001
	380	Level of patient	-0.275			P<0.001
		satisfaction		0.256		P<0.001
					0.515	P<0.001
1 year	260	ODI		-.0.588		P<0.001
	214	Modified JOA			0.544	P<0.001
	252	Spine surgery outcome score	-0.729			P<0.001
	241	Level of patient	-0.304			P<0.001
		satisfaction		0.270		P<0.001
					0.547	P<0.001
2 years	83	ODI		-0.755		P<0.001
	68	Modified JOA			0.673	P<0.001
	72	Spine surgery outcome score	-0.684			P<0.001
	72	Level of patient	-0.231			P<0.001
		satisfaction		0.325		P<0.001
					0.663	P<0.001

At the end of the global period, such as three months post surgery, moderate correlations between functional outcome, clinical outcome and response to surgery was revealed. However, patient satisfaction with care was poorly correlated with either functional outcome or clinical evaluations. The results at the six month, one year and two year post-operative intervals are similar to those of the three month visit. A divergence exists between patient satisfaction scores and both, functional outcomes and clinical recovery.

Prediction of levels of patient satisfaction (linear regression analysis). The ability to predict levels of patient satisfaction using functional outcome, clinical outcome and the response to surgery at the various time intervals were examined post surgery using multiple linear regression analysis. At two weeks, the surgical outcome score accounted for only 20% of the patient satisfaction score, $R^2 = 0.201$, while ODI accounted for 2.4%, partial correlation of 0.176. The proximity of R-square and Adjusted R-square, R^2 change = 0.025, is suggestive of the generalizability of the sample to the population. Therefore, the regression equation derived is, $p < .001$:

Level of Patient Satisfaction = 2.82 + 0.02(spine surgery outcome score) + 0.10(ODI)

At six weeks, clinical recovery accounted for 80% of the patient satisfaction score, $R^2 = 0.80$, adjusted $R^2 = 0.78$, $p < .001$, while ODI and spine surgery outcome score did not feature. This analysis is limited by the small sample size, $F(1,11) = 40.10$, $p < .001$. When the modified JOA is removed from the analysis, the spine surgery outcome score accounts for 22% of the level of patient satisfaction, $R^2 = 0.222$, adjusted $R^2 = 0.220$, while the addition of ODI increases the predictive value only to 24%. At the three month interval, which is the end of the global period, a full analysis of the variables could be performed (n=402). The spine surgery outcome score accounted for 36% of the patient satisfaction score, R^2 =0.359, adjusted R^2 = 0.357, yet ODI only contributes to 4%. Clinical outcome had no influence on patient satisfaction scores. At the 6 month, the spine surgery outcome score contributed 27% of the level of patient satisfaction, R^2 =0.269, adjusted R^2 = 0.267, with ODI influencing only 2%. Clinical recovery has no impact on patient satisfaction scores. These findings were sustained at one year, R^2 =303, adjusted R^2 = 0.300, with ODI contributing 2%. At two years, the spine surgery outcome score influenced 52% of the level of patient satisfaction score with clinical recovery contributing only 9%, R^2 =0.522, adjusted R^2 = 0.514.

Functional outcome, clinical dysfunction and degrees of patient satisfaction (multinomial regression analysis). In this study, the degree of patient satisfaction had been initially categorized into 5 levels, however a "no response" was included as the 6th category for the multinomial logistic regression analysis. During the early two week post-operative period, the ODI was a significant predictor for a "fair' outcome or when a "patient declined to respond", B = -4.557 and B=-8.232 respectively, X^2 (5) = 23.56, p<. 001. By six weeks, the ODI significantly predicted a "Good" or "Fair" degree of patient satisfaction, X^2 (6) = 40.37, p<. 001, (*see Table 20*). At the three month visit, both functional outcome and clinical recovery, X^2 (5) = 16.286, p<. 01 and X^2 (5) = 14.61, p<. 05 respectively, were significant predictors of the degree of patient satisfaction, X^2 (10) = 52.499, p<. 05. The specific effects, as described in table 21, revealed that it was clinical recovery that had a significant effect on the degree of patient satisfaction. In contrast, functional disability, as measured by the ODI, had no significant effect despite the moderate correlation seen with the levels of patient satisfaction.

Although at the 6 month interval, functional outcome and not clinical recovery X^2 (6) = 21.305, p<. 01 and X^2 (6) = 10.372, p=. 110 respectively, was the significant predictor of patient satisfaction, X^2 (12) = 49.209, p<. 001, the parameter estimates revealed that it was *clinical recovery* that had a significant effect on the degree of patient satisfaction (*see Table 22*). Although the ODI was a significant predictor in the model, the level of functional disability did not predicate the degrees of patient satisfaction in this study. Both functional and clinical outcome, X^2 (6) = 24.209, p<. 001 and X^2 (6) = 14.52, p<. 05 respectively, were the significant predictors of the degrees of patient satisfaction, X^2 (12) = 45.579, p<. 001, at one year after surgery.

Good clinical recovery yielded and excellent outcome, whilst patients who experienced functional disability expressed some degree of dissatisfaction by failing to adjudicate the quality of care (*see Table 23*). This effect disappeared by the two year visit when neither functional outcome nor clinical recovery, X^2 (4) = 4.053, p=. 072 and X^2 (4) = 2.607, p=. 626 respectively, could predict the degree of patient satisfaction in this regression model, X^2 (8) = 19.512, p<. 05. Analysis of the parameter estimates confirmed no predictive outcome metrics for degrees of patient satisfaction, despite the moderate correlations between the variables (*see Table 18 above*).

Table 20

Multinomial Regression Analysis of Patient Satisfaction, Early Post Surgery

Parameter Estimates

Degree of patient satisfaction		B	Std. error	Wald	df	Sig.	Exp(B)	95% confidence interval for exp(B)	
								Lower bound	Upper bound
Two Weeks									
Excellent	Intercept	.422	.317	1.775	1	.183			
	ODI	.009	.006	2.260	1	.133	1.009	.997	1.020
Very good	Intercept	-.701	.396	3.125	1	.077			
	ODI	.012	.007	3.111	1	.078	1.012	.999	1.026
Good	Intercept	-1.085	.466	5.424	1	.020			
	ODI	.008	.008	1.054	1	.304	1.008	.992	1.025
Fair	Intercept	-4.557	.930	24.006	1	.000			
	ODI	.053	.014	14.560	1	.000	1.054	1.026	1.083
No Response	Intercept	-8.232	2.632	9.785	1	.002			
	ODI	.081	.036	5.047	1	.025	1.084	1.010	1.163
Six Weeks									
Excellent	Intercept	.831	.255	10.646	1	.001			
	ODI	.004	.006	.515	1	.473	1.004	.993	1.016
Very good	Intercept	-.270	.304	.788	1	.375			
	ODI	.013	.007	3.515	1	.061	1.013	.999	1.026
Good	Intercept	-2.216	.465	22.693	1	.000			
	ODI	.036	.009	15.688	1	.000	1.036	1.018	1.055
Fair	Intercept	-4.198	.789	28.317	1	.000			
	ODI	.057	.014	17.699	1	.000	1.059	1.031	1.087
Poor	Intercept	-2.756	1.072	6.605	1	.010			
	ODI	-.022	.030	.516	1	.473	.979	.922	1.038
No response	Intercept	-9.303	4.700	3.918	1	.048			
	ODI	.088	.070	1.586	1	.208	1.092	.952	1.252

Bolded variable reflect statistically significant categories

Table 21

Multinomial Regression Analysis of Patient Satisfaction at 3 Months.

Parameter Estimates

Degree of patient satisfaction	Outcome metric	B	Std. error	Wald	df	Sig.	Exp(B)	95% confidence interval for exp(B)	
								Lower bound	Upper bound
Excellent	Intercept	.136	3.791	.001	1	.971			
	Modified JOA	.373	.163	5.251	1	.022	1.453	1.056	2.000
	ODI	-.051	.032	2.600	1	.107	.950	.892	1.011
Very good	Intercept	-2.680	3.920	.467	1	.494			
	Modified JOA	.443	.169	6.843	1	.009	1.558	1.118	2.172
	ODI	-.036	.032	1.266	1	.261	.964	.905	1.027
Good	Intercept	-.126	3.877	.001	1	.974			
	Modified JOA	.257	.166	2.389	1	.122	1.293	.933	1.791
	ODI	-.029	.032	.788	1	.375	.972	.912	1.035
Fair	Intercept	-.877	4.113	.045	1	.831			
	Modified JOA	.202	.176	1.320	1	.251	1.224	.867	1.728
	ODI	-.015	.034	.182	1	.670	.986	.922	1.054
Poor	Intercept	-20.968	10.335	4.116	1	.042			
	Modified JOA	.906	.383	5.585	1	.018	2.474	1.167	5.244
	ODI	.058	.089	.419	1	.517	1.059	.890	1.261

Bolded variable reflect statistically significant categories

Table 22

Multinomial Regression Analysis of Patient Satisfaction at 6 Months

Parameter Estimates

Degree of satisfaction	Outcome metric	B	Std. error	Wald	df	Sig.	Exp(B)	95% confidence interval for exp(B)	
								Lower bound	Upper bound
Excellent	Intercept	-3.416	2.339	2.134	1	.144			
	ODI	.001	.017	.001	1	.972	1.001	.967	1.035
	Modified JOA	.334	.109	9.388	1	.002	1.397	1.128	1.730
Very good	Intercept	-2.816	2.448	1.322	1	.250			
	ODI	.000	.018	.000	1	.985	1.000	.965	1.036
	Modified JOA	.261	.114	5.224	1	.022	1.298	1.038	1.624
Good	Intercept	-3.986	2.565	2.415	1	.120			
	ODI	.032	.019	2.647	1	.104	1.032	.994	1.072
	Modified JOA	.209	.118	3.144	1	.076	1.232	.978	1.553
Fair	Intercept	-6.209	3.022	4.222	1	.040			
	ODI	.036	.022	2.761	1	.097	1.037	.994	1.082
	Modified JOA	.288	.139	4.292	1	.038	1.333	1.016	1.750
Poor	Intercept	-11.821	9.408	1.579	1	.209			
	ODI	.136	.090	2.278	1	.131	1.146	.960	1.367
	Modified JOA	.074	.291	.065	1	.799	1.077	.609	1.904
No response	Intercept	-10.410	5.498	3.585	1	.058			
	ODI	.095	.048	3.851	1	.050	1.099	1.000	1.209
	Modified JOA	.223	.212	1.115	1	.291	1.250	.826	1.893

Bolded variable reflect statistically significant categories

Table 23

Multinomial Regression Analysis of Patient Satisfaction at 1 Year

Parameter Estimates

Degree of patient satisfaction	Outcome metric	B	Std. error	Wald	df	Sig.	Exp(B)	95% confidence interval for exp(B)	
								Lower bound	Upper bound
Excellent	Intercept	-4.627	2.579	3.219	1	.073			
	ODI	.015	.016	.839	1	.360	1.015	.983	1.048
	Modified JOA	.330	.121	7.397	1	.007	1.391	1.097	1.764
Very good	Intercept	-1.887	2.754	.469	1	.493			
	ODI	.006	.018	.124	1	.725	1.006	.971	1.043
	Modified JOA	.140	.129	1.172	1	.279	1.150	.893	1.481
Good	Intercept	-4.784	2.867	2.784	1	.095			
	ODI	.054	.020	7.291	1	.007	1.055	1.015	1.098
	Modified JOA	.161	.130	1.533	1	.216	1.175	.910	1.516
Fair	Intercept	-2.071	3.572	.336	1	.562			
	ODI	.018	.025	.544	1	.461	1.018	.970	1.069
	Modified JOA	.044	.165	.073	1	.787	1.045	.757	1.444
Poor	Intercept	-22.747	12.994	3.064	1	.080			
	ODI	.152	.091	2.780	1	.095	1.164	.974	1.392
	Modified JOA	.645	.544	1.407	1	.236	1.906	.657	5.532
No response	Intercept	-21.648	8.081	7.176	1	.007			
	ODI	.152	.057	7.166	1	.007	1.164	1.042	1.301
	Modified JOA	.645	.337	3.660	1	.056	1.906	.984	3.690

Bolded variable reflect statistically significant categories

The null hypothesis states that is no statistically significant relationship between patient-reported outcome measures (ODI, spine surgery outcome score), physician-reported outcomes measures (modified JOA) and, the extent of patient satisfaction. The results of this study demonstrate that a highly significant relationship exist between patient-reported outcome measures (ODI, Spine Surgery Outcome Score), clinical recovery (the modified JOA) and degrees of patient satisfaction, thereby rejecting the null hypothesis and accepting the research hypothesis. However, these effects are variable according to the time intervals following surgery, predominantly at the three month and six months follow-up visits but recede by the two year time interval.

Posthoc Analysis of Study Variables

Clinical and Functional Outcome According to Surgical Procedure

Prior to surgery, patients with a herniated lumbar disc presented with severe functional disability while patients with stenosis were more likely crippled by their disability (mean ODI = 51.09 SD ± 17.29 vs. mean ODI = 61.18 SD ± 16.81, $p < .05$). Over the six months following surgery, significant reduction in functional disability was seen for all sub-groups (*see Table 24*). Patients who underwent micro-discectomy had a 45% reduction (-22.82 points) in functional disability. In contrast, patients undergoing lumbar decompressive laminectomy demonstrated only a 12.15-point reduction (20%) in ODI from baseline. Good clinical recovery (50-75%) was seen for surgical types as measured by the modified JOA.

Patient Satisfaction According to Clinical Pathology

In this study, over a two year period, the physician performance was rated high, ranging between 80-93% at different time intervals for the various pathological conditions that had been treated (*see Tables 6 & 25*). However, no significant differences in the ratings were detected between the various conditions (ANOVA). While the majority of patients were satisfied (>90%) with their functional improvement, clinical outcome and medical care, a small percentage expressed dissatisfaction (rated the physician performance as “Fair”, “Poor”, or “Declined to respond”) (*see Figure 7*).

Table 24

Functional Outcome & Clinical Recovery Comparison for Surgical Procedures

Functional Outcome (ODI)						
Index Procedure			ODI Change			
	n	Baseline	3 months	6 months	1 year	2 years
Facet Fusion	283	56.97	-15.93	-14.12	-16.03	-17.03
Pedicle Fusion	187	57.94	-16.32	-15.95	-15.34	-14.18
Micro-discectomy	94	51.09	-20.82	-22.82		
Lumbar Laminectomy	25	61.18	-12.03	-12.15		
Clinical Outcome (Modified JOA)						
	n	Baseline	Clinical Recovery Rate			
Facet Fusion	174	11.17	71%	66%	70%	75%
Pedicle Fusion	132	11.27	74%	69%	67%	62%
Micro-discectomy	57	11.26	72%	68%		
Lumbar Laminectomy	20	11.55	50%	58%		

Table 25

Levels of Patient Satisfaction as a Function of Lumbar Pathology

	Three Months	Six months	One Year	Two Years
Clinical Pathology	Mean Level (± *SD*) of levels of patient satisfaction (%)			
Herniated Lumbar Disc	4.22 ± 1.09 (84.4)	4.01 ± 1.12 (80.2)	4.33 ± 1.11 (86.6)	4.35 ± 1.22 (87)
Lumbar Stenosis	4.18 ± 1.08 (83.6)	4.22 ± 1.06 (84.4)	4.20 ± 1.11 (84)	4.13 ± 1.30 (82.6)
Spondylolisthesis Spondylolysis	4.42 ± 0.88 (88.4)	4.31 ± 1.00 (86.2)	4.19 ± 1.21 (83.8)	4.25 ± 0.86 (85)
Lumbar Disc Degeneration	4.67 ± 0.70 (93.4)	4.63 ± 0.74 (92.6)	4.40 ± 0.89 (88)	4.0 (80)
	Number of patients (%)			
Satisfied	444 (91.9)	345 (90.8)	223 (92.5)	64 (88.9)
Dissatisfied	39 (8.1)	35 (9.2)	18 (7.5)	8 (11.1)

Relationship Between Clinical Recovery and Functional Outcome

The relationship between functional outcome and clinical recovery was examined using linear regression since the subjective symptoms (history taking) overlaps with some of the dimensions reported in the ODI (*see Appendix B*). The pre-operative clinical dysfunction accounted for 33% of the functional disability experienced by the patient, R^2 =0.334, adjusted R^2 = 0.111, F-change (1,423) = 53.107, p<. 001. While at the six week visit, clinical dysfunction contributed to 46% of the functional disability, at the three month interval, clinical dysfunction contributed only 27% towards the functional disability experienced by the patient, R^2 =0.270, adjusted R^2 = 0.269, F-change (1,423) = 156.76, p<. 001. These relationships were similar at the six month interval (30%) and at one year (34%). However, at two years, clinical dysfunction influenced 57% of the functional disability, R^2 =0.570, adjusted R^2 = 0.563, F-change (1,64) = 84.83, p<. 001.

Relationship Between Spine Surgery Outcome and Patient Satisfaction

The level of patient satisfaction is a key dimension of the spine surgery outcome score, contributing almost 20% of its score (see *dimension G of Appendix C*). Linear regression analysis confirmed these findings with the level of patient satisfaction significantly accounting for between 20% at two weeks and 52% at two years of the spine surgery outcome score. Therefore, *post-hoc* analysis was performed to examine the relationships between the various outcome metrics by excluding the spine surgery outcome score. The degree of patient satisfaction was dichotomized into “satisfied” (rating scores of “excellent”, “very good”, and “good”) and “dissatisfied” (rating scores of “fair”, “poor”, and declined to respond) to analyze the predictive utility of functional and clinical outcome metrics.

Relationship Between Patient Satisfaction, Functional Outcome and Clinical Dysfunction

The differences in functional outcome and clinical recovery were compared using *t* test at the various time intervals. The analysis revealed that functional outcome, as measured by ODI, was significantly higher in patients who were deemed to be dissatisfied with care up to one year following surgery (*see Table 26*). However, by two years, there was no difference in ODI between satisfied and dissatisfied patients. Although differences in clinical recovery were significant up to the six month interval, these differences receded at the outcomes one year and two year visits.

The relationship between levels of patient satisfaction, functional outcome, and clinical recovery was examined using multiple linear regression. Two weeks following spine surgery, functional disability accounted for just 2% of levels of patient satisfaction, R^2 =0.019, adjusted R^2 = 0.016, F-change (1,465) = 8.779, p<. 01, and just 5% at six weeks. At the end of the global period at three months, functional disability contributed to 9%, which increased by only 2% with the entry of the modified JOA. Similarly, at 6 months, functional disability (ODI) influenced the level of patient satisfaction by only 9%, R^2 =0.091, adjusted R^2 = 0.088, F-change (1,304) = 30.549, p<. 001, while clinical evaluations had no effect. Even at the one year interval (11%), and the two year interval 8%, functional disability and clinical evaluations has no appreciable influence on the levels of patients’ satisfaction with care.

The predictive capacity of functional outcome metrics and clinical recovery patient dissatisfaction was analyzed using logistic regression. The patients' functional disability at two weeks and six weeks post-surgery was a significant predictor if the patient was satisfied with the medical provider, B = -2.577, SE ± 0.181; Wald =203.591, (1), p<. 001 with a 93.6% predictive capacity and B = -2.764, SE ± 0.195; Wald =201.167, (1), p<. 001 with a 94.1% predictive capacity, respectively. Higher ODI scores were associated with increasing dissatisfaction with care at two weeks and six weeks after surgery, Exp (B) = 0.076 & 0.063 respectively. While the ODI was a significant predictor of patient dissatisfaction, B = -2.518, SE ± 0.190; Wald =175.973, (1); p<. 001 with a 92.5% predictive capacity, Exp (B) = 0.081, the degree of clinical recovery did not affect patients' satisfaction with care at the end of the global period at three months. Similar results were obtained at the 6 month, 1 year and 2 year time interval where there was an increasing likelihood of a dissatisfied patient with higher the functional disability at a 90% predictive capacity.

Table 26

Differences in Functional and Clinical Outcome According to Patient Dissatisfaction

Time interval	Outcome score	Satisfied	N	Mean	Std. deviation	Std. error mean	t test
2 weeks	ODI	Yes	434	54.54271	19.617292	.941660	P<0.001
		No	33	68.04364	14.856828	2.586242	
6 weeks	ODI	Yes	444	42.2482	20.51549	.97362	P<0.01
		No	28	55.6982	18.45204	3.48711	
3 months	ODI	Yes	432	40.5494	19.59453	.94274	P<0.001
		No	39	55.9490	17.12515	2.74222	
	Modified JOA	Yes	381	18.31	2.282	.117	P<0.001
		No	30	16.10	2.940	.537	
6 months	ODI	Yes	338	40.7509	20.27340	1.10273	P<0.001
		No	34	54.7638	16.00206	2.74433	
	Modified JOA	Yes	283	18.00	2.390	.142	P<0.01
		No	29	16.69	2.804	.521	
1 year	ODI	Yes	216	40.2392	21.16778	1.44028	P<0.01
		No	17	54.3665	18.13118	4.39746	
	Modified JOA	Yes	182	18.24	2.531	.188	ns
		No	15	17.27	2.404	.621	
2 years	ODI	Yes	62	39.6194	21.18229	2.69015	ns
		No	8	36.9650	14.12598	4.99429	
	Modified JOA	Yes	60	18.05	2.746	.354	
		No	7	17.71	3.450	1.304	

Bolded variable reflect statistically significant categories

Summary

This chapter has examined the research data, addressing each of the research questions. The descriptive analysis has provided an overview of the clinical and demographic data of the study sample, the types of surgical procedures, response to surgery, clinical and functional outcome metrics, and quality of care. The statistical tools employed included *t* tests, ANOVA, correlations, linear regression, logistic regression and multinomial regression analysis to answer each of the research questions. Furthermore, in the repeated-measures design, these analyses were computed prior to surgery and for each on the six post-operative time intervals spanning two years. The results revealed that patients undergoing spine surgery for a variety of lumbar degenerative conditions demonstrated significant reductions in functional disability, recovery from clinical dysfunction and reported high levels of satisfaction with the medical provider. However, patients who were smokers and continued to smoke had higher functional disability than non-smokers while the diagnosis of diabetes had no effect. This study demonstrates that the complexity of surgery has an effect in the early post-operative period it does not persist beyond six weeks. Although a significant relationship between the outcome variables was detected, functional and clinical outcome metrics accounted for a small percentage of the levels and degrees of patient satisfaction at varying time intervals. The patients' dissatisfaction with the health care provider was more strongly associated with higher levels of functional disability than a poor clinical outcome. Chapter 5 presents a discussion of the study findings, clinical management recommendations aimed at health care practitioners, social changes issues, suggestions for future research, and conclusions.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

Low back pain syndrome is a common health burden throughout the world, causing limitation in daily activities and absence from work. In 2010, low back pain syndrome was deemed the sixth highest global disease burden of the 291 conditions evaluated, with an estimated prevalence of > 9%. In every country examined by the Global Burden of Disease Collaborators in 2013, the leading causes of years living with disability could be attributed to low back pain syndrome and depression (Vos et al., 2015). Low back pain syndrome has the highest years of living with disability than any other condition since it is associated with the higher life expectancy and aging population in the developed world, and the number of people living with low back pain may become higher as more low and middle-income countries become more prosperous with rising living standards (Hoy et al., 2014).

The epidemiological factors of increasing age and prosperity places demands on effective medical and surgical strategies to treat low back pain resulting from degenerative conditions afflicting the lumbar spine. This is evident in the increasing demand for spine surgery with the concomitant rise in resource utilization for degenerative conditions afflicting the spine, often a result of the natural history of aging and activity (Deyo et al., 2010). In the United States, the medical cost for nonoperative management of lumbar disorders due to various degenerative conditions ranges between $6,000 and $8,000 per quality-adjusted life year, and $50,000 to $65,000 for surgical management (Parker et al., 2014). The Spine Patient Outcomes Research (SPORT) study further delineated the costs as approximately $70,000 for disc surgery, $78,000 for decompression for stenosis, and $116,000 for fusion operations (Weinstein et al., 2009).

The use of standardized disease specific patient reported outcome measures allows for valid comparisons of treatment paradigms between different health care providers (Godil et al., 2014; Kaiser et al., 2014). Performance measurements provide useful information to various stakeholders, such as, payers, regulators, government organizations, purchaser organizations, and inter alia to make health care decisions. The purpose of this quantitative study was to evaluate the health performance of the surgical management of lumbar spine degenerative pathology in a subpopulation of patients from Indiana. I compared the changes in functional outcome and clinical recovery from a preoperative baseline to various time intervals over a 2-year period and examined the extent of patient satisfaction with clinical care delivered by the health care provider. I explored the impact of a complexity of surgeries on health performance and the influence of confounding factors such as diabetes and smoking on functional outcome and clinical recovery. In addition, I explored the interaction between the vaious components of a disease-specific constellation of outcome metrics as a guide to quantify health performance.

The advances in information technology and computational ability allow for the accumulation of large data volumes that can improve predictive capability (Smith et al., 2009). The results revealed that patients (N = 685) undergoing spine surgery for a variety of lumbar degenerative conditions demonstrated a 29% reduction in functional disability, a 58% recovery from clinical dysfunction, and reported high levels of satisfaction (greater than 90%) with the medical provider. However, history of smoking and persistent smoking has a deleterious impact in functional recovery (9% reduction), while the diagnosis of diabetes had no effect. This study demonstrates that simple spine operations recovered quicker in the early postoperative period than fusion procedures, but this difference did not persist beyond 6 weeks. Although moderate correlations between the outcome variables were detected, functional and clinical outcome metrics accounted for a small percentage of the levels and degrees of patient satisfaction at the various time intervals. Higher levels of functional disability, rather than a poor clinical outcome, were strongly predictive (>90%) of patients' dissatisfaction with the health care provider.

Interpretation of Findings

Type of Study

In the neurosurgical literature, the philosophical foundation evaluating the efficacy of treatment interventions has been randomized clinical trials, which are considered as the gold standard (Simon, Koyama, Zacharia, Schirmer, & Cheng, 2015). Motivated by the publication of the guidelines for the management on severe traumatic brain injury, Resnick et al. (2005) applied these criteria to spinal procedures. These authors proposed that randomized clinical trials represent Class I evidence for effectiveness of treatment and be considered as standards of care. Nonrandomized cohort studies, case controlled studies, and poorly designed randomized controlled studies represent Class II evidence, which provide the basis of recommendations of treatment. Class III evidence is from case series, comparative studies with the use of historical controls, case reports, and expert opinions (Resnick et al., 2005a). As such, decisions based on Class III evidence are optional. This study does not meet the standards of care Level I evidence and may be categorized as Class II evidence, since it is as nonrandomized cohort study, and therefore would represent a management recommendation. Ghogawala et al. and Resnick et al., in 2014, together with other collaborators, updated the guidelines for the lumbar fusion surgery. Based on these revised criteria, this study is still congruous with Level II evidence and as such is still a management recommendation.

However, the implementation of Level I evidence provided by randomized clinical trials is often delayed and has had a variable impact on true clinical practice (Simon et al., 2015). Despite these recommendations and aided by the paucity of Level I evidence for management of spinal disorders, many spine interventions and/or surgeries are considered optional treatments (Resnick et al., 2005a; Resnick et al., 2005b, 2005c, 2005d, 2005e, 2005f). Spine surgeons tend to exercise wide discretion in the planning of spine operations aided by the wide range of treatment options available for the management of spinal degenerative conditions and the ability to tailor and design specific procedures incentivized by market-driven policies (Deyo et al., 2010; Eck et al., 2014; Groff et al., 2014; Mummaneni et al., 2014; Resnick et al., 2014)

The evaluation of the efficacy of clinical protocols and treatment paradigms involves the evaluation of all patients against well-established outcome metrics. This may offer a better representation of the clinical scenario, in contrast to randomized clinical trials, which have strict inclusion and exclusion criteria (Marshall & Eisenberg, 1987; Marshall et al., 1979; Narotam et al., 2008; Narotam et al., 2009; Narotam et al., 2014).

Similarly, in other areas of general medicine, for example, in the management of hypertension, evidence-based clinical management protocols are being called for to apply to the general population instead of the individualized approach (Frieden, 2014).

An administrative database has distinct advantages in its ability to identify complications and outcomes, whilst a longitudinal database monitors these parameters at different time intervals (Veeravagu, Cole, Azad, & Ratliff, 2015), and observational cohorts are important for comparative analysis of disease processes in the general population (Tosteson et al., 2011). Similarly, I used a repeated measures analysis of a without exclusion bias into a prospectively assembled, longitudinal administered spine registry. Although the analysis in this study is retrospective, the registry was specifically designed to monitor health outcomes and quality of care.

In contrast to small and medium study cohorts, this study has large sample size of 685 patients, conducted over 6 years, is comparable to other large published studies that have examined aspects of health performance (Bydon et al., 2015; Du Bois et al., 2012; Mazur et al., 2015; Solberg et al., 2013; Weinstein et al., 2009; Weinstein et al., 2007). The 2-year observation period of functional outcome in this study is comparable (Azimi et al., 2014; Omoto et al., 2010; Parker et al., 2014) and does exceed the minimum 3-month follow-up period and the recommended minimum 1-year follow-up interval for lumbar fusions (McGirt, 2015). Consequently, the results of this study analysis with highly statistically significant results and up to a 2-year follow-up period would approach the Level I evidence of randomized controlled study (Veeravagu et al., 2015) and lend credence to a real world scenario facing community-based spine surgeons (Tosteson et al., 2011).

Clinical and Demographic Factors

The consequence on increased life expectancy and advancing age yields a higher global burden of disease for low back pain syndrome due to spinal degenerative disorders (Hoy et al., 2014). In this study, the mean patient age of 46 years is in the similar range of other large clinical series, that is, 46 years (Solberg et al., 2013), 52.7 years (Du Bois et al., 2012); medium sized studies, that is, 55.2 years (Omoto et al., 2010), 59.8 years (Azimi et al., 2014); smaller studies, that is, 62 years (Slatis et al., 2011). While few studies have published patients' weight, the mean preoperative weight in this study of 206 pounds is higher than that of the medium sized study of Azimi et al. (2014; $N = 168$) who reported a mean weight of 173 lbs. The deleterious effect of smoking on spinal disorders has been well described (Armaghani et al., 2014; Bydon et al., 2014; Bydon et al., 2015; Nakajima & Al'Absi, 2014; Tang et al., 2014). A high incidence of preoperative smokers of 45% was found in this study, similar to other mid-western states such as Tennessee (40%; Parker et al., 2014) and Spain (37%; Soriano et al., 2010) but higher than Oslo in Norway (24%; Thornes et al., 2011) or Cleveland (22%; Lubelski et al., 2014).

Health care decisions in spinal surgery are variable depending on physician preference and competency, aided by the advances in medicine and technology (Deyo et al., 2010; Resnick et al., 2005a). In this study, the surgeon had used the patients' history, physical examination, and neurological imaging studies to plan and execute the surgical procedure, which involved a variety of techniques, ranging in complexity (see Table 4). As such, over 90% of patients had some degree of nerve impingement, either due to lumbar stenosis or lumbar disc herniation, resulting in moderate to severe disability in 90% of patients in this study, while less than 10% required fusion surgery for mechanical low back pain or lumbar disc degeneration, consistent with published neurosurgical guidelines (Greenberg, 2006; Resnick et al., 2005a).

In this observational cohort study, I specifically examined the patients' functional and clinical response to surgery and not the effect of nonoperative treatment modalities. In contrast to pathology-specific outcome studies for lumbar disc operations (Lubelski et al., 2014; Peul et al., 2007; Solberg et al., 2013), spinal stenosis (Atlas et al., 2000; Azimi et al., 2014; Slatis at el., 2011; Thornes et al., 2011) or spondylolisthesis (Weinstein et al., 2009), I examined the health performance of lumbar spine surgery as has been reported by several clinical studies that have published their results on outcomes (Copay et al., 2010; Du Bois et al., 2012; Omoto et al., 2010; Parker et al., 2014; Saban et al., 2007; Slover, Abdu, Hanscom, & Weinstein, 2006; Soroceau, et al. 2012; Zanoli, 2005).

Health Performance

There has been a significant growth and expansion of various health performance measures using various clinical outcome measures to determine health care quality over the past 25 years (Smith et al., 2009). The explosive growth in patients reported outcome measures has yielded over a thousand different instruments by 2002 and over 3,000 by 2007 to evaluate patient satisfaction (Fitzpatrick, 2009). A key challenge is to choose the performance metrics that are valid for the clinical scenario, easy to measure on a repeated basis, are reproducable, are universally applicable for comparative analysis, and are reliable. Six diminsions of health perfromance measures, that is, population health, individual healht outcomes, clinical quality and appropirateness of care, responsiveness of the healht care system, equity, and productivity have been proposed (Smith et al., 2009). Although the American Association of Neurological Surgeons has recommended the SF-36 as a general health outcome measure for clinical studies (Ghogawala et al., 2014; Kaiser et al., 2014), in this study, the SF-36 questionnaire was not implemented due to its complexity, length, and being onerous for the patient to complete at each office visit. The constellation of health performance measures used in study represents a unique combination of health outcomes, as measured by the disease-specific ODI and the modified JOA; the responsiveness of health systems, as measured by the spine surgery outcome score; and, patient satisfaction.

Quality of health care. While there are no standardized methods to define health care quality, the determination of quality is dependent on the health care system and the role of the physician responsibilities within the system (Donabedian, 1980, 1988). In contrast, the Institute of Medicine (1990) philosophized healthcare quality vaguely as to the extent that health services strive to produce health outcomes desired by individuals and societies incorporating the dimensions of safety, efficacy, patient orientation, efficiency, timeliness and equitability (Lohr & Schroeder, 1990). In the evaluation of the health performance of spine surgery, outcome measures have have not been uniformly applied. This study has used a constellation of disease-specific outcome measures to evaluate health performance using both patient-reported and physician-reported instruments.

Functional outcome. In 1980, Fairbank et al. introduced the ODI that comprised 10 items to evaluate the impact of pain on daily physical activities. The ODI has now superceded the Ronald-Morris disability questionnarie to evaluate functional outcome (Ghogawala et al., Resnick, et al., 2014). Indeed, patients with lumbar degenerative pathology responded well spinal rehabilitation with a 15-point reduction in ODI (Gatchel & Mayer, 2010). However, patients who do not respond to conservative treatments and who have been carefully selected for surgery do have a good clinical response (Slatis et al., 2011; Weinstein et al., 2006; Weinstein et al., 2008; Weinstein et al., 2009;), which may even be superior and cost effective to just medical management (Parker et al., 2014). While a good clinical outcome is a given, there is an increasing focus on the functional outcome from the patients' perspective (Ghogawala et al.; Resnick, et al., 2014).

In this study, the majority of patients selected for surgery had presented with crippling (32.7%) or severe disability (39%). The mean ODI of 56.9 ± *SD* 16.1 in this study is comparable to other small and large published studies as described below (see Table 26), and from the National Spine Network Outcomes Database of over 14,700 patients (mean ODI =57.3; Walsh, Hanscom, Lurie, & Weinstein, 2003). The significant reduction in functional disability in patients from this study is equivalent to published data over the past 12 years, as illustrated in Table 27. While several studies have reported at inconsistent intervals, Whitmore et al. (2015) suggested that the optimal functional benefit following surgery occurs at the 3- month interval and there is limited gain thereafter out to 1year after surgery. This observation is consistent with the findings in this study where the functional improvement did not appreciably change over the 2-year period.

Table 27

Comparative Analysis of Functional Outcome Following Lumbar Surgery

Year	Author	N	ODI					
			Baseline	Spine rehabilitation (Nonoperative control)				
				6 weeks	3 months	6 months	1 year	2 years
2010	*(Gatchel & Mayer, 2010)**	*1,180*	*41.97*				*-15.63*	
				Surgery				
2003	(Walsh et al., 2003)	970	52.3					
2006	(Slover et al., 2006)	3482			-11.2		-12.1	
2007	(Saban, 2007)	57	51.31		-27.42			
2008	(Copay et al., 2008)	454	52.50				-14.9	
2010	(Omoto et al., 2010)	144	41.8				-18.3	-17.9
2013	(Roitberg et al., 2013)	85	30.83					
2016	**This Study**	**685**	**57.7**	**-14.83**	**-16.79**	**-15.68**	**-16.35**	**-14.38**

* *non-surgical historical control*

The critical threshold to measure treatment efficacy has been conceptualized as the “minimum clinically important difference” (MCID). A 30% reduction from baseline has been proposed as a MCID measure (Jaeschke, 1989). In this study, the MCID occurred at 17.31-point reduction in ODI, representing an overall 29% reduction in ODI just shy of the suggested 30% threshold. However, the 30% threshold has been challenged for the ODI when objective and independent criteria are used (Gatchel &

Mayer, 2010). For spine surgery, was determined as 12.8 points for the ODI, based on a study of 454 patients (Copay et al., 2008).

In this study of 685 patients, the change in ODI exceeds the MCID threshold as early as six weeks and sustained over the entire two year study period. In addition, the mean change in the ODI in this study is consistent with the FDA recommendations for lumbar fusion efficacy (Fairbank, & Pynsent, 2000). One has to also consider the efficacy of surgery over the non-operative spinal rehabilitation (Gatchel & Mayer, 2010). Although this study was not a randomized controlled study for surgery, the 16 point reduction in functional disability is higher than conservative management in carefully selected patients. A corollary would be that spinal rehabilitation should produce an at least 15 point reduction in the ODI before considering the patient for surgery.

Clinical recovery. The Japanese Orthopedic Score (JOA) was developed to evaluate the management of low back pain (Inoue et al., 1986). Since the activities of daily living is better quantified by the ODI, in the modified JOA, symptoms account for 9 points, clinical signs 6 points and bladder function 6 points for a total of 21 points (Haro et al., 2008; Tajima et al., 1989; Vialle et al., 2007). The modified JOA is not a patient-reported outcome measure but rather a surgeon's assesment of the patients physical condition (Haro et al., 2008), which allows for quantification of their clinical status. Fujiwara et al. (2003) have demonstrated that the JOA correlated with the eight sub-scales of the SF-36, is a valid measure to quantify the patients physical or clinical status, and has suffiecient psychometric properties of reliability and construct validity for patient application. Despite these advantages, the modified JOA has not been advocated to adjudicate clinical outcome (Ghogawala et al., Resnick, et al., 2014), yet, in contrast, this study had routinely used the modified JOA to quantify patients clinical assessment to allow for valid peer comparisons. In this study, a 50% (seven point) improvement in the clinical status of the 351 patients, in whom the survey information was available, was detected at the three month time interval. The clinical response was sustained over the two year study period.

Although there are few publications on the use of the full JOA score (Azimi et al., 2014; Chen, Zhou, Liu, Yuan, & Li, 2009; Haro, 2008; Watanabe et al., 2005; Yorimitsu, Chiba, Toyama, & Hirabayashi, 2001), none were found on the utility of the *modified* JOA for lumbar pathology. In order to allow valid comparisons, Watanabe et al. (2005) introduced the concept of the recovery rate whereby the recovery rate of >75% was rated as excellent, 50 to 75 as good, 25 to 50 as fair and <25% as poor, based upon the formula: recovery rate (%) = (postoperative JOA - preoperative JOA)/(maximum score - preoperative JOA) X 100. In a small patient study (34 patients) involving endoscopic lumbar disc surgery, a greater than 90% clinical receovry rate can be achieved (Hanaoka, 2005). In an 18 patient study, a recovery rate ranging between 59 and 67% following decompression for lumbar stenosis at two years post-operatively has been reported (Watanabe et al., 2005). In a long term 10 year study, a good clinical recovery rate of 73.5% for lumbar disc surgery has been reported (Yorimitsu et al., 2001). These results are comparable to a 117 patient study where a clinical recovery rate of 78% was achieved (Azimi, Mohammadi, & Montazeri, 2012).

In this study, 94 patients had undergone micro-discectomy procedures in whom a good clinical recovery rate of 72% at three months and 68% at six months was obtained (see Table 25). Longer term calculations were not possiible since many of these patiients had been discharged at the 3 month visit. In a small 43 patient study of lumbar fusion for recurrent disc herniation, Chen et al. (2009) reported an excellent recovery rate of 86% at a two to four year post-operative time interval. In this study, fusion procedures yeilded clinical recovery rates ranging between 62 and 75% over the two year study period (*see Table 25*). In this study, the clinical recovery rate was fair at two weeks (46%) but good at the three month (72%), six month (68%), one year (71%), and 72% at two years for a diverse range of pathology and surgical complexity. This would be the first study to validate the clinical application of the modified JOA to monitor the response to lumbar surgery.

Several outcome studies on lumbar surgery have not used the modified JOA but relied on patient-reported outcome mesures, more specifically the physical component summary of the SF-36 (Copay et al., 2010; Gatchel & Mayer, 2010; Godil et al., 2013; Walsh et al., 2003). Therefore there is no objective corroboration of the patients symptoms since the ODI can be manipulated by patient behavior such as litigation, narcotic dependence, disability, psychological factors, inter alia (Bianchini et al., 2014; Carleton, Kachur, Abrams, & Asmundson, 2009). The strong correlation between the physical component of the SF-36 and the JOA (Fujiwara et al., 2003) would obviate its need for routine clinical practice and health performance monitoring but could be retained for research studies (Weinstein et al., 2009; Weinstein et al., 2008). In summary, this study supports the use of the ODI as a patient-reported outcome measure, and, the modified JOA as a clinical outcome measure to quantify the quality of health care for lumbar degenerative pathology.

Smoking. The deleterious effect of smoking on fusion rates has a significant impact on spine surgery outcomes ranging from simple spinal surgery such as laminectomy to complex fusion of the spine, often requiring repeat surgeries (Bydon et al., 2014; Bydon et al., 2015). Chronic smoking affects endogenous pain regulation with increased pain sensitivity (Nakajima & Al'Absi, 2014), which could have an impact on functional outcome. However, the impact of smoking on functional outcome has not been well publicized (Soriano et al., 2010). While smoking can affect the Visual Analog Scale for leg pain, it did not influence the ODI in a study by Soriano et al. (2010). In a small subset of patients in a report by Omoto et al. (2010), ten patients who were smokers had a 7.4 point difference at 1 year and 20.1 point difference at two years in ODI, when compared to the non-smoker group of 134 patients.

This study is one of the largest that has examined the role of smoking (N=685), periodically, on functional outcome for lumbar spine surgery over two years. While significant differences were seen in functional outcome at all time intervals (see Table 11) ranging from 2-9 points, smoking per se did not significantly affect the functional outcome as measured by the ODI. Slover, Abdu, Hanson and Weinstein, in 2006, using linear regression analysis, demonstrated a small but significant influence of smoking on ODI (B co-efficient -1.60) in a 3482 patient observational study. However, in their study, other factors such as education (B co-efficient 1.45), employment status (B co-efficient

3.30), litigation (B co-efficient -2.77), and acute medical disorders (B co-efficient 8.06) had a much greater impact at the three months follow-up visit. One may conclude that although smoking affects functional disability, it does not influence significantly the functional or clinical recovery from surgery. Therefore, smokers should not be denied spine surgery but be informed on the deleterious effect of smoking on pain, fusion and re-operation.

Patient response to surgery. In 2008 an expert panel considered reliability, validity, responsiveness, and practicality, and proposed a standardized outcome measure for low back pain, a derivative of other scoring instruments such the modified Oswestry, SF-36, Roland Morris Disability Scale, National Health Interview Survey, and typology of patient experience, inter alia (Deyo et al., 1998). The spine surgery outcome score used some of the components of the standardized outcome measure for low back pain but focused on, the patients surgical experience based on the dimensions of level of function, time restriction of daily activity, restriction of activity type, impact on quality of life, evaluation of treatment and care by the health care provider. To the best of our knowledge, this study is the first clinical application of the instrument as an outcome metric. In this study, by the six week post-operative period, over 50% improvement in the patient's perception of their recovery from their pre-operative status could be appreciated. It is important to note that unsatisfactory responses garnered negative scores on the questionnaire (see Appendix C).

A key dimension (D) of the spine surgery outcome score is a measure of patient expectation. Although this dimension was captured as a component of the score, it deserves separate analysis, which would present an opportunity for future research. The gap between patient expectation and actual functional and clinical outcome could be a source for patient dissatisfaction (Nakhai & Neves, 2009; Parasuraman et al., 1988). Dimension E of the spine surgery outcome score is the physician performance rating score, which has been analyzed separately and is the basis of the determination of patient satisfaction.

Patient Satisfaction. The philosophical basis of consumer satisfaction with medical services is based on many factors related to the patients lifestyle, previous experience with health care providers, expectations of outcome, individual personal and social values, and, community attitudes towards health care (Carr-Hill, 1992). In the context of health consumerism, patient satisfaction represents the end-point of patient's experience and perception of the health service (Chow, Mayer, Darzi, & Athanasiou, 2009) and, as such, is an intensely subjective measurement that lacks clear definition (Locker & Hunt, 1978). Therefore, different people define patient satisfaction differently, and, patients' response is variable at different times (Locker & Hunt, 1978). For example, Atlas et al. (2000) reported only 63% of patients were satisfied with their spinal situation but did not report on the satisfaction with care patient received. There are four components of patient satisfaction: background patient expectations, patient-physician interaction, patient management (action) and outcome (Chow et al., 2009). This study has focused on patient the two components of patient management, and, clinical and functional outcome, as a consequence of surgical management of a defined pathology such as lumbar spine degenerative conditions. The components of background and interaction need to be examined separately in future research (Hawthorne et al., 2011).

Chow, Mayer, Darzi, and Athanasiou, in 2009, raised significant methodological issues with patient satisfaction questionnaires. While open questionnaires receive direct patient input as a qualitative measure, closed questionnaires require a direct response that can be quantified. Majority of the scales, sourced from consumer surveys of goods and services involve a Likert-type scale that categorizes responses from "very satisfied" to "very dissatisfied" some using a five point scale or even a three point scale (Chow et al., 2009; Copay et al., 2010; Zanoli, 2005). The five point Likert scale for patient satisfaction has been dichotomized into two responses: "satisfied" or "dissatisfied.

Patients undergoing low back surgery for degenerative disease have reported overall, high patient satisfaction rates. In a 422 patient study, Copay et al. (2010) reported 85% patient satisfaction score with their provider at their three-month visit. Similarly, in this study, at the three month follow-up visit, almost 92% (n=444) of patients had expressed satisfaction with the medical provider (see Table 25).

While patient satisfaction rates as low as 70% have been reported (Thornes et al., 2011), Azimi et al. (2014) were able to demonstrate an 89% (N=168) patient satisfaction for the management of lumbar stenosis at the two years (success being defined as "complete relief" or a "great deal of relief" from leg pain). Results from this study (n=370) are congruent with those of Azimi et al. (2014), above and those of Weinstein et al. (2008) who, in a randomized cohort study, evaluated the benefits of surgery over conservative management. These authors demonstrated a significantly higher patient satisfaction with care ranging between 90% at 6 weeks and 83% at two years in the surgical management of lumbar stenosis (Weinstein et al., 2008).

In 2007, Weinstein et al., in a multi-center study involving 13 major centers of over 300 patients, reported on the outcome of the management of spondylolisthesis (decompression and fusion) comparing the effects of surgery over non-operative management. These authors reported patient satisfaction rates of 90% consistently over the two year study period (Weinstein et al., 2007). In this single center, single provider study (n=68), comparable rates of patient satisfaction levels ranging from 84-88% were detected.

Complexity of Surgery

In the management of lumbar degenerative conditions, there are numerous factors that influence the decision for surgery, including the patients' demographics, clinical presentation, neuroimaging studies, which have to be individualized to the patient. In this study patient population, a range of clinical conditions with varying degrees of disease severity were treated, except those requiring major deformity correction (*see Table 3 & 4*). The type of procedure is dependent on the surgical skills and proficiencies, facilities, insurance reimbursements, technical difficulties, severity of disease, medical and behavioral risk factors, inter alia (Mirza et al., 2006). In addition, surgeons have wide discretion in planning and execution of surgical procedures (Deyo et al., 2010), making peer comparisons of the efficacy of various procedures challenging (Mirza et al., 2006).

In 2006, Deyo's group proposed a conceptual model using a complicated system of quantifying disease severity on neuroimaging using nine subscales was proposed, together with three dimensions of surgical invasiveness in order to standardized reporting of adverse events in spine surgery (Mirza et al., 2006). This system is too complicated for general use and, to the best of our knowledge, has not been further reported upon. In 2010, a simplified the classification of surgical cases into simple spine, simple fusion, and complex fusion was proposed (Deyo et al., 2010). This study added a new category, complicated fusion, which involved a hybrid construct involving pedicle and facet fixation.

In this study, while fusion procedures were performed on patients with spinal instability and higher levels of functional disability, reflecting more severity of disease when compared to simple spine procedures. Increasing severity of spinal degeneration is associated with advancing age requiring more complex procedures, as has been reflected in this study (Deyo et al., 2010; Hoy et al., 2014; Vos et al., 2015). The majority of patients in this study, presented radicular signs and/or neurogenic claudication suggesting significant nerve root compression (*see Table 16a*). There were no differences in the clinical presentation or levels of clinical dysfunction in subgroup analysis. Although the deleterious effect of smoking on lumbar fusion has been well established (Bydon et al., 2014), smokers were not denied fusion procedures in this study.

In this study, patients undergoing simple spine procedures recovered some their functional incapacity as early as two weeks from surgery and most at the six week time period when compared to the more invasive fusion procedures. While complexity of surgery did not impact functional recovery in the late post-operative period, many patients undergoing lumbar micro-discectomy or lumbar laminectomy were not seen after the three to six month time interval. Although this might represent a study limitation, Whitmore et al. (2015) demonstrated that the greatest gain in functional recovery occurs within first three months following surgery for lumbar disc herniation with a variance of only 1-2 points on ODI at six months and one year.

Health performance according to index procedure. Although the case classification by complexity of surgery has been proposed for a cost benefit analysis by Deyo et al., (2010), it has not been implemented by other researchers to allow for meaningful analysis. Since there are no published reports on the utility of this classification system, in this study, the health performance metrics were analyzed for individual surgical procedures (*see Tables 24 & 25*). If one uses the historical control of spinal rehabilitation, it stands to reason that patients who fail conservative management, the MCID should be around a 15-point reduction in ODI (Gatchel & Mayer, 2010). The results of this study reveal that the MCID has been achieved and is comparable to many published studies as delineated in Table 28 below. Comparative analysis using the published literature on functional outcome for spinal procedures, together with the results of this study suggest that the MCID should be a minimum of a 15 point reduction in ODI. A corollary would be that if spinal rehabilitation over an 8 to 12 week period does not produce a 10 to15 point reduction in functional disability, then surgery could be an option, predicated upon the clinical and neuro-imaging criteria.

Table 28

Comparative Analysis of Functional Outcome Related to Index Procedure

Year	Authors	N	Baseline ODI	Change in ODI				
				Six weeks	Three months	Six$^+$ months	One year	Two years
Spine rehabilitation *(Nonoperative control)*								
2010	(Gatchel & Mayer, 2010)	*1,180*	*41.97*				*-15.63*	
Simple spine surgery								
2016	**This Study**	**120**	**53.16**	**-21.64**	**-18.02**	**-17.79**	**-13.09**	
Micro-discectomy for herniated lumbar disc								
2006	(Weinstein et al., 2006)	198	51.7		-26		-30.6	-31.4
2013	(Solberg et al., 2013)	692	46				-28	
2015	(Whitmore et al., 2015)	148			-27.9	-29.4	-29.9	
2016	**This study**	**94**	**51.09**	**-22.01**	**-20.82**	**-22.82**		
Decompressive laminectomy for lumbar stenosis								
2008	(Weinstein et al., 2008)	116	42.7	-6.5	-7.6	-14.6	-14.9	-16.4
2010	(Omoto et al., 2010)	94					-21.6	-19.7
2011	(Slatis et al., 2011)	94	34			-13	-17	-14
2015	(den Boogert et al., 2015)	175					-20.3	
2016	**This Study**	**22**	**61.18**	**-22.81**	**-12.08**	**-12.55**	**-33.63**	
Simple fusion surgery								
Inter-laminar fixation								
2016	**This study**	**17**	**59.73**	**-12.8**	**-11.15**	**-9.01**	**-24.51**	
Facet fusion								
2016	**This Study**	**307**	**57.14**	**-13.05**	**-15.49**	**-13.84**	**-16.38**	**-17.07**
Anterior Inter-body fusion								
2015	(Flouzat-Lachaniette et al., 2015)	47	51			-26		
Complex fusion surgery								
2007	(Weinstein, et al., 2007)	385	45.0		-20.8		-25.4	-24.2
2010	(Omoto et al., 2010)	50					-10.9	-13.7
2016	**This Study**	**187**	**57.93**	**-13.14**	**-16.31**	**-15.95**	**-15.33**	**-14.18**
Complicated fusion surgery								
2016	**This Study**	**25**	**62.76**	**-10.63**	**-15.54**	**-19.21**	**-14.79**	**-28.17**

The clinical recovery rate for patients undergoing lumbar disc surgery in this study ranged between 72% at three months and 69% at one year, equivalent to a long-term 10 year study where a 73.5% rate was reported (Yorimitsu et al., 2001). However, for complex spine surgery such as pedicle fixation, the three month recovery rate of 74% gradually declined to 62% at two years in this study involving 132 patients. Chen et al. (2009) reported on and average clinical recovery rate of 86% in a 43 patient study. In patients undergoing decompressive laminectomy, the clinical recovery rates in this study (n=20) ranged between 50% at three months to 78% at one year, comparable to the 59 to 68% rates reported by Watanabe et al. (2005) at two years.

Predictors of Patient Dissatisfaction

Although considerable effort has been invested into the quantification of patient satisfaction by means of survey instruments, the determination of patient satisfaction remains elusive, has been unpredictable and reflected more on the perception of quality that the patient received (Gill & White, 2009). In many studies, a Likert-type scale which has categorized responses from "very satisfied" to "very dissatisfied" used a five or three point scale (Chow et al., 2009; Copay et al., 2010; Zanoli, 2005) or been dichotomized into two responses: "very satisfied or somewhat satisfied with care" in some studies (Weinstein et al., 2009; Weinstein et al., 2008; Weinstein et al., 2007; Weinstein et al., 2006). This non-specific approach does not allow for a direct adjudication on the disease-specific evaluation or patient satisfaction, in contrast to this study, where physician performance rating was recorded.

Indeed, patient satisfaction is a commonly reported measure in controlled clinical trials and observational studies, in which satisfaction scores ranged between 64% and 90%, often unrelated to the efficacy of treatment or the adherence to clinical evidence based guidelines (Haldeman, 2012). Health care payers are more focused on quality or care rather than quantity and ushered in patient satisfaction as a proxy for health care quality (Truumees, 2013) that breeds into the consumerism of health care. Consequently, physicians, by reporting of high patient satisfaction scores, expect higher remuneration from payers for promoting and performing certain operations (Haldeman, 2012). Haldeman, in his commentary in 2012, challenged authors to report more on patient dissatisfaction, identify risk factors that prevented patients to reach pre-treatment goals among others. One of the major short comings of randomized controlled trials that report on patient satisfaction is that they do not reflect upon the patients that general spine surgeons see in their practices (Truumees, 2013). This study population is reflective of a community based clinical general neurosurgery practice performing a range of spinal surgeries for degenerative pathologies, the results of which could generalizable to the wider community.

This study uses a unique constellation of both patient-reported, and, physician-reported instruments to quantify and predict health performance. In this study, the moderate to strong correlations between the ODI, modified JOA and the spine surgery outcome score reflects on the close relation of the components. For example, the subjective questions in the modified JOA would elicit similar responses to the ODI. Unique to this study is the relationship of functional and clinical outcome where the ODI accounted for only between 30-60% of the variation in the modified JOA at various time intervals following surgery. These findings suggest that both the ODI and the modified JOA are essential components of any quantification of health performance for spinal surgery involving degenerative conditions, in contrast to the numerous studies using only patient-reported outcome metrics (*see Tables 27 & 28*).

In the spine surgery outcome questionnaire, questions A, B, and C are a derivative of the ODI (Deyo et al., 1998). However, the patient satisfaction, defined as physician performance rating for this study, correlated mildly with the ODI or with the modified JOA. Yet, the moderate correlation of patient satisfaction with the spine surgery outcome score is due to the fact that it is a derivative of that instrument, which was verified in this study such that patient satisfaction accounted for between 20-50% of the spine surgery outcome score. Similar to the study of Godil et al. (2013), who were unable to demonstrate the relationship between patient-reported outcome measures and patient satisfaction, in this study the patient-reported outcome metric (ODI) and the physician-reported outcome metric (modified JOA) did not account appreciable to the level of patient satisfaction.

In response to the challenges presented by Haldeman (2012) and by Truumees (2013), results of this study demonstrate that in the small group of patients (*see table 25*) who were dissatisfied reported significantly higher functional disability, while physicians recorded lower modified JOA scores, albeit only up to one year from surgery. This study is the first demonstrate that it is functional outcome, as measured by the ODI, that is the significant determinant of patient dissatisfaction following spine surgery with a >90%

predictive capacity. This is not surprising since around 30% of patients undergoing low back surgery are unable to return to work after one year (Du Bois et al., 2012). This finding could be reflective of the gap between patient expectation and functional outcome. In order to close the gap, the functional assessment of the patient using the ODI is key during counseling. The health performance of the Union Hospital Neuroscience spine practice reveals a MCID of 15 points for functional improvement for lumbar fusion surgery for patients that report severe disability prior to surgery. The implications for this study are to advise against fusion procedures for patients with ODI less than 40. The patients can expect a 15-22 point reduction in ODI, a clinical recovery rate of 70% and a satisfaction of 90% with care for lumbar spine surgery involving degenerative pathology using various individualized surgical techniques.

Health Performance Model for Low Back Surgery

Over the past 40 years, the theoretical framework of Donabedian based on structure, process and outcome has been used to determine health care quality (Donabedian, 1980, 1988, 2005). The structure component of the model is fulfilled since the study was conducted in a small office based physician US practice, owned by the hospital that provides the amenities and recourses (McDonald et al., 2007). The proximity of the facility to the hospital with a fully integrated allied medical health services, electronic medical records, and full access to various health services in a non-profit entity fulfills the process component. A major shortcoming of the outcome component has been its reliance on patient satisfaction as its instrument. However, patient satisfaction is a poor defined concept, difficult to measure, and rarely standardized, especially in spine surgery (Chow et al., 2009; Godil et al., 2013; Haldeman, 2012; Truumees, 2013). Smith et al., in 2009, introduced a more contemporary approach using performance measurement to improve health care systems.

Using the health performance model (*see Figure 1*), the outcome component of health care quality, has two key dimensions, such as general health status and disease-specific outcome measures. The SF-36 has been established as the most important metric of general health status applicable to outcome assessment of low back surgery for spinal degenerative conditions (Ghogawala et al., Resnick, et al., 2014; Zanoli, 2005). While the SF-36 may be suitable for clinical trials and other research application, it was not implemented as part of the routine survey due to its complexity, length and being onerous for the patient to complete 36 questions at each office visit in addition to the ODI and the spine surgery outcome score. It is more important for the sickness impact profile that quantifies the general health status, of which the SF-36 is a derivative, to be performed by the primary care physician in an integrated health care system, while specialty services can focus on disease specific conditions, as has been in this study.

In the assessment of spine surgery outcomes, Copay et al. (2010) have reported primarily on patient-reported outcome measure such as the ODI, physical component summary of the SF-36, numerical back and leg pain scales, and patient satisfaction scores but without the clinical corroboration of the modified JOA, similar to other authors as summarized in Tables 27 and 28. On the other hand, since the JOA has shown correlation with the SF-36 and the ODI (Fujiwara et al., 2003), other investigators have used the JOA solely as an outcome metric for clinical recovery following low back surgery (Chen et al., 2009; Watanabe et al., 2005; Yorimitsu et al., 2001). Unique to this study, the disease-specific outcome dimension uses the combination of the ODI and the modified JOA to measure functional outcome and clinical recovery respectively

Limitation of Study

The retrospective design of this survey study was prone to missing or inconsistent data as a result of the early discharge of patients for lumbar disc operations and decompressions for stenosis while fusion patients were followed-up longer. In addition, all patients may not return for scheduled follow-up visits, re-locate, referred to other providers. The database had been corroborated against the medical record and the digitally scanned into patient survey responses on a weekly basis by the administrator. These limitations are overcome by the large patient sample using a repeated-measures design with sufficient cases at the key three month visit for all patients, six month data for most patients, and, one and two year data for fusion procedures. These factors allow for valid comparisons with published historical data.

The inability of the medical and scientific community of accurately define health care quality, provide standardized instruments to measure health quality, the variable definitions of patient satisfaction (Gill & White, 2009; Godil et al., 2013) and lack of quantification does impact the interpretation of the results of this study. Since this study is based on patient-reported and physician-reported survey questionnaires, the reliability and validity of these instruments can be called into question (*see Table 29*). Although the ODI used to gauge the patients functional status has emerged as the dominant instrument for research studies (Ghogawala et al., Resnick, et al., 2014), it still prone to exaggerated responses motivated by secondary gain such as litigation, narcotic dependence, social security disability applications, psychological factors, narcotic pain medication dependence, inter alia (Bianchini et al., 2014; Carleton et al., 2009), aggravated by familiarity with the instruments and the observation that the physician attributes clinical value on these responses. Similarly, when physicians complete their responses in the modified JOA, the subjective component may be over-estimated. These factors were mitigated by the repeated-measures design os this study. Although the ODI is used universally to measure functional status, the modified JOA has not achieved such widespread adoption. The results of this study suggest that these instruments need to be applied in combination so that the deficits of the ODI can be corroborated by objective clinical examination contained in the modified JOA.

A major limitation of this study instruments is the use of the spine surgery outcome score, which was derived from the standardized outcome measure for low back pain (Deyo et al., 1998). To the best of our knowledge, this instrument has not been tested in prospective controlled studies or any other publication to date. This study is the first to measure health performance using this instrument. In addition, the spine surgery outcome score was used to evaluate patient satisfaction, not using the Likert scale of “very satisfied” to “very dissatisfied” (Chow et al., 2009) but a typological response as “physician performance rating”. Since health care performance is mulit-dimentional, a composite of indicators is necessary (Goddard & Jacobs, 2009). While it has been suggested that these measure should not have significant collinearity (Goddard & Jacobs, 2009), results of this study suggest that collinearity is important for corroboration of the instruments, as demonstrated in the significant correlations between the instruments. These factors are important to ensure the clinical credibility of the constellation of instruments used to measure the health performance of low back surgery.

Table 29

Critical Assessment of the Instruments Used to Evaluate Health Performance

Measure (Chow et al., 2009)	Instrument				
	ODI	JOA	Spine surgery outcome score	Physician performance rating	Patient satisfaction
Appropriate	yes	yes	maybe	yes	No[4]
Acceptable	yes	yes	yes	yes	yes
Feasible	yes	yes	yes	yes	yes
Interpretability	excellent	excellent	uncertain	good	poor
Precision	good	excellent	marginal	Very good	poor
Reliable[1]	yes	yes	no	yes	no
Validity[1]	yes	yes	no	yes	no
Citations on Google scholar	>2379	>144	1[2]	1[2]	>1000[3]

[1](Ghogawala et al., 2014); [2](Deyo et al., 1998); [3](Williams, 1994); and [4] (Godil et al., 2013).

Since this is a retrospective study, it may not meet the class I level of evidence when compared to prospective randomized clinical trials (Ghogawala et al., Resnick, et al., 2014). The conduct and interpretations of this study would be generalizable due to the large sample size, the analysis of a range of spinal procedures from simple decompressions to complicated hybrid surgeries, the highly statistically significant results, and the proximity of the R^2 to the adjusted R^2 in the regression analysis. While this study was conducted in a community based neurosurgical practice involving lumbar degenerative pathology, it may not readily translate to larger academic centers where more complex procedures are being performed, yet, the results of this study are comparable to those reported in large multicenter controlled studies (see table 27 & 28) (Goddard & Jacobs, 2009; Weinstein et al., 2008; Weinstein et al., 2007; Weinstein et al., 2006). The community-based setting of this study in the Mid-West geographic area in the United States, the use of an administrative longitudinal database, specifically designed to monitor health outcomes and quality of care, that included *all* patients (Veeravagu et al., 2015), is representative of patients seen typically a general neurosurgery practice (Truumees, 2013).

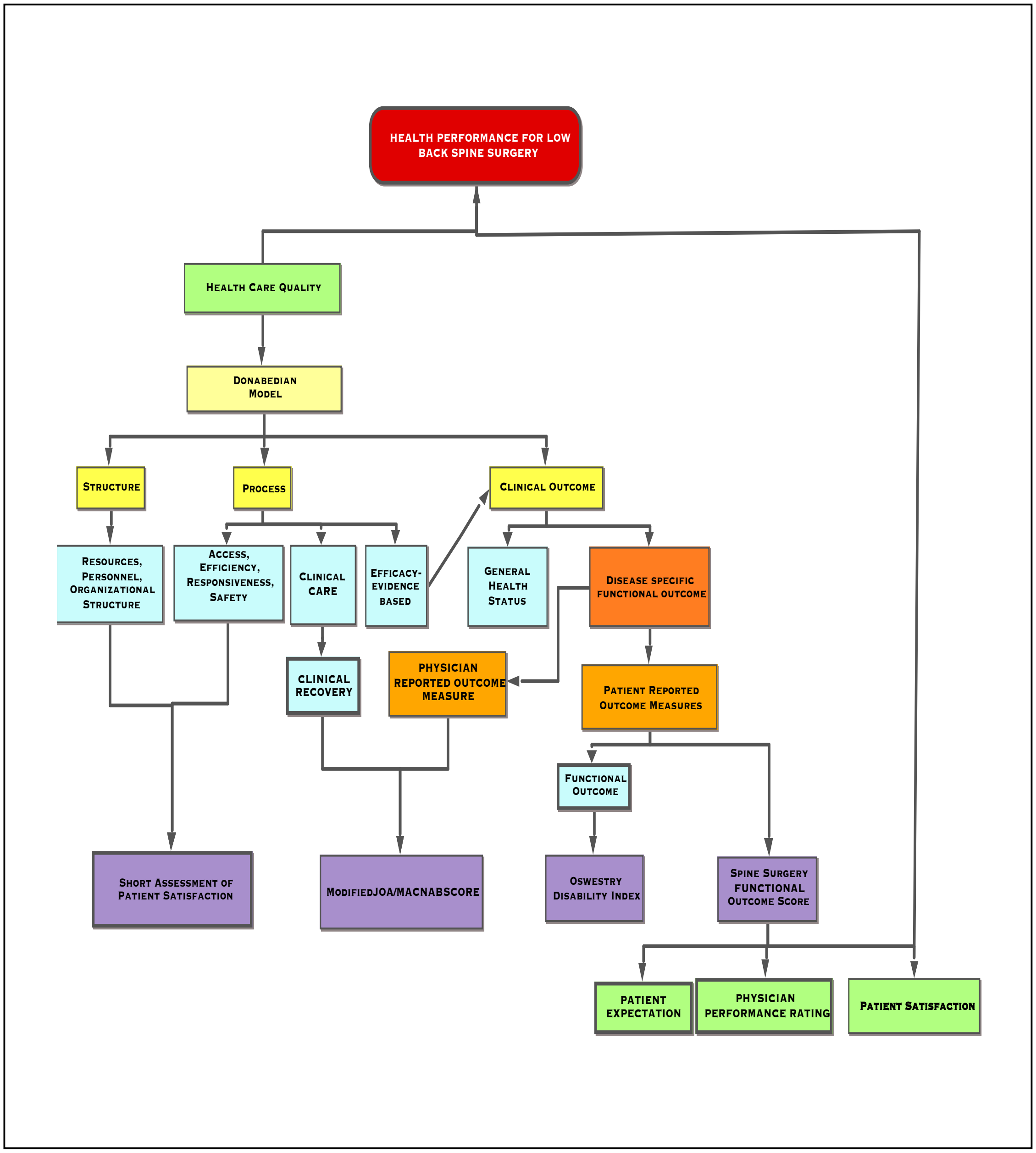
The beneficence of spine surgery in patients who fail medical management has been well established with class I randomized controlled trials (Weinstein et al., 2009; Weinstein et al., 2007; Weinstein et al., 2006; Weinstein et al., 2008). In addition, the MCID for non-surgical management has also been well established (Gatchel & Mayer, 2010). With reference to these historical controls, the results of this large study of 685 patients are comparable with regard to functional outcome, clinical recovery, and patient satisfaction (*see tables 27 & 28*).

Recommendations

The use of integrated health performance metrics directly into the neurosurgical EMR for all clinic visits involving degenerative spinal conditions, including lumbar and cervical spine regions, was introduced at Union Hospital Neuroscience in February 2008, from which the specific data had been transferred to a statistical database on a weekly basis. In 2013, researchers at the Stanford University of Medicine, built a spine registry measuring functional outcome and quality of life integrated into the EMR (Azad et al., 2016). Similar to our study, the collection of health quality metrics did not impact workflow in their clinic. Therefore, on the basis of the unique constellation of both patient-reported and physician-reported outcome metrics modification of the health performance conceptual model is justified for future research (*see Figure 15*). The publication arising from this dissertation could guide the adoption of this constellation of instruments at other institutions, thereby allowing for valid comparisons of health performance for low back surgery.

This study is the first to examine the utility of the spine surgery outcome score, derived from the proposed standardized outcome measure for low back pain by Deyo and collaborators (1998). Although the first three dimensions are congruent with the ODI and parts of the modified JOA, as confirmed in this study by the moderate correlations between these instruments, the dimensions of patient expectation were not examined independently. In this study, the typology of the patient experience was useful to quantify patient satisfaction, as the physician performance rating and to, for the first time, identify the key instrument for patient dissatisfaction.

Since around 30% of patients undergoing low back surgery are unable to return to work after one year (Du Bois et al., 2012), the modified JOA has to include an added dimension related to work capacity (Macnab, 1971) (*see Appendix F*). The spine surgery outcome score should be modified to include the consumer driven Likert style dimension of satisfaction (*see Appendix G*). In order to fulfill the *structure* and *process* components for health performance a modification of the short assessment of patient satisfaction, as proposed by Hawthorne et al. (2011) needs to be introduced. On the basis of this study, these new instruments have been proposed to the Union Hospital Neuroscience, which



could be subject to further study.

Figure 15: Conceptual framework of health performance for low back surgery.

Implications

The development of health policy (Smith et al., 2009) for low back surgery for spinal degenerative conditions have been met in this study with the use of a clear conceptual framework, well defined instruments consistent with a health performance conceptual framework, reliable and valid indicators of functional outcome and clinical recovery that were statistically sound, credible results with peers, utility of information to guide physician-patient decision making process, opportunity to improve health care quality and patient satisfaction, frequent monitoring of health performance data. Such information can enhance health decision-making by various stakeholders such as patients, physicians, regulatory bodies, government agencies, commercial and government insurers, quality control systems in hospitals, and professional associations to promote evidence based guidelines (Kaiser et al., 2005a; Smith et al., 2009).

Recommendations for Social Change

Social change is an evolutionary process by which societies respond to changes on the natural and social environment (Elwell, 2013), using the mechanisms of selection, variation and transmission based on the information presented to a system or a society (Cartwright, 2008; Fuentes, 2009; Richardson & Boyd, R:, 2005; Richardson & Boyd, 2000). Therefore, social change cannot be described as positive or negative, good or bad, progressive or retrogressive pre-emptively, unless it has survival benefits. Since social change is relativistic to the observer, the attribute of "positive social change" is arbitrary and its impact can only be determined retrospectively or analyzed historically. In health care, information plays a pivotal role in a health system to improve its performance in delivering high quality care to its population (Smith et al., 2009). In this study, the integration of specific health performance indicators directly into the EMR has taken advantage of the revolution in information technology in health care.

The analysis of global health trends yields that, although low back and neck pain syndromes rank 4th after ischemic hearth disease, lower respiratory infections, and cerebrovascular disease, its prevalence is increasing throughout the world ("Disease squeeze", 2016; Vos et al, 2015). These trends would place increasing demands on societies' health care demands in the allocation of health resources. The impact of this study on positive social change affects many stake holders involved in the provision of health services to the general population, as described below:

1. *Health care benefits*: Conservative management of low back pathology should result in ODI reductions of 15-points (Gatchel & Mayer, 2010). The beneficence of low back surgery for patients that do not respond to spinal rehabilitation has been well established (Weinstein et al., 2007; Weinstein et al., 2006; Weinstein et al., 2008). As has been demonstrated in this study, the ODI is an important guide to aid in the decision-making process. Therefore, patients who do not respond to conservative management by a 10-15 point reduction in ODI might be considered for surgery, in addition to the clinical, demographic, neuro-imaging, neurophysiological testing, inter alia. The continuous health performance of a medical practitioner could guide patient decision making on the suitability of a

particular surgical intervention, based on the patients' individual propensity for clinical and functional recovery.

2. *Patient care benefits:* The positive health value for patients would be to identify low back surgical procedures that would have a good clinical recovery and functional outcome, and to avoid procedures that do not have demonstrable benefit. For example, based on the results of this study, a patient with an ODI of > 50 would more likely benefit from lumbar fusion procedures at Union Hospital Neuroscience with an at least 15 point reduction in disability (30%) at six months from surgery, consistent with the a minimally clinical important difference in published data (see Table 28) yet fusion procedures may not be beneficially to patients with an ODI of <40. A functional recovery of least 22 points can be expected for simple disc operations within three months. Patients should expect a clinical recovery rate of 60-80%. The patient care benefits would enable patients and physicians to choose the best treatment options for their low back syndrome based on their presurgery disability and predict their potential for functional clinical recovery. Therefore, patient would be empowered to make health care decisions based on health performance metrics and choose their health care provider appropriately, who would guide specific type of spinal surgery.
3. *Health provider benefits:* The constant and routine monitoring of all patients' individual satisfaction on a prospective basis could help guide the physician to improve the quality of service to patients. Subsequent reductions in ODI or in modified JOA scores may be a signal for further testing. As described in this

study, the combination of physician performance ratings of “fair”, “poor” or “no response”, and, increasing ODI scores would signify patient dissatisfaction, would be cause of concern to the health provider, requiring further inquiry as to its causes. Examination of the spine surgery outcome survey would reveal the gap between patient expectations and actual outcome. Corrective action can be undertaken within the practice to prevent escalation of a declining physician patient relationship and breakdown of the patient-physician sanctum (Teutsch, 2012). Therefore, transfer of care to another health provider may be necessary. The patient signs the patient-reported outcome measure survey documents that track the patients’ clinical recovery, functional recovery, and response to surgery before being digitally scanned into the EMR. Favorable responses may provide limited protection against frivolous lawsuits (Rovit et al., 2007). The documentations of good quality care of health care and high patient satisfaction scores recorded by individual health providers could counter unsatisfactory reviews by the National Research Corporation ("CGCAHPS: Improve Delivery of Patient-Centered Care," 2014) since poor CGCAHPS grades can motivate hospital and practice administrators to reduce physician remuneration between 10-20%. In response to selective peer review case analyses generated by PEPPER (*Data Analysis Support and Tracking*, 2014), the patient and physician reported outcome metrics with high patient satisfaction score would provide counter to the report by external reviewers, which has been classified as unreliable Class V evidence (Kaiser et al., 2014).

4. *Health policy benefits:* The continuous monitoring of clinical and functional outcome, the response to surgery, and patient satisfaction on *all* patients would allow for yearly analyses the health performance of a medical practice, which could be vital component of institutional health quality and monitoring. The results of this study would advocate for implementation of a standardized or uniform constellation of clinical and functional outcome metrics, which would allow for valid peer reviewed comparisons of health performance across health providers and institutions. The publication resulting from this study could guide professional organizations such as the North American Spine Society or the American Association of Neurological Surgeons to issue updated practice guidelines and establishes "standards of care" paradigms to guide physicians (Ghogawala et al., Resnick et al., 2014; Kaiser et al., 2014).
5. *Commercial insurers and government payers:* The cost benefit analysis of the complexity surgical strategies for the management of low back degenerative conditions in terms of both clinical recovery, functional outcome and patient satisfaction would factor into hospital and provider reimbursement rates.

Conclusions

Globally, low back pain syndrome is a common health condition with an estimated prevalence of >9% worldwide limiting daily activities and absence from work even after spine surgery. In carefully selected patients who have failed medical management surgical has proven beneficial. The results of this study are aligned with the health performance conceptual framework by measuring individual disease-specific health outcomes, and the responsiveness of the health system by measuring response to surgery, and, patient satisfaction. In this study, patients who opted for surgery had presented with severe functional disability and clinical dysfunction. Following the surgical procedure that had been individualized to each patient, significant reduction in functional disability and recovery from clinical dysfunction occurred as early as six weeks and persisted up to two years for fusion procedures in this highly powered study of 685 patients. The level of patient satisfaction exceeded 90% for all types surgical procedures. Although patient who underwent simple disc operations recovered faster, there were no other differences for the complexity of surgery. While patient-reported or physician-reported outcome metrics were not predictive for levels of patient satisfaction, results of this study reveal that persistent high functional disability scores are predictive of patient dissatisfaction. The implications of study could affect patient-care decisions, quality of health care service, support institutional health quality and monitoring, recommendations to professional organizations, and accountability to commercial and government payers. The implementation of a constellation instruments for low back surgery would allow for a more comprehensive measurement of health performance resulting in improvement of health systems.

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Appendix A: ODI Questionnaire

Oswestry Disability Questionnaire

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking **one box in each section** for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement **which most clearly describes your problem.**

Section 1: Pain Intensity

☐ I have no pain at the moment
☐ The pain is very mild at the moment
☐ The pain is moderate at the moment
☐ The pain is fairly severe at the moment
☐ The pain is very severe at the moment
☐ The pain is the worst imaginable at the moment

Section 2: Personal Care (eg. washing, dressing)

☐ I can look after myself normally without causing extra pain
☐ I can look after myself normally but it causes extra pain
☐ It is painful to look after myself and I am slow and careful
☐ I need some help but can manage most of my personal care
☐ I need help every day in most aspects of self-care
☐ I do not get dressed, wash with difficulty and stay in bed

Section 3: Lifting

☐ I can lift heavy weights without extra pain
☐ I can lift heavy weights but it gives me extra pain
☐ Pain prevents me lifting heavy weights off the floor but I can manage if they are conveniently placed eg. on a table
☐ Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
☐ I can only lift very light weights
☐ I cannot lift or carry anything

Section 4: Walking*

☐ Pain does not prevent me walking any distance
☐ Pain prevents me from walking more than 2 kilometres
☐ Pain prevents me from walking more than 1 kilometre
☐ Pain prevents me from walking more than 500 metres
☐ I can only walk using a stick or crutches
☐ I am in bed most of the time

Section 5: Sitting

☐ I can sit in any chair as long as I like
☐ I can only sit in my favourite chair as long as I like
☐ Pain prevents me sitting more than one hour
☐ Pain prevents me from sitting more than 30 minutes
☐ Pain prevents me from sitting more than 10 minutes
☐ Pain prevents me from sitting at all

Section 6: Standing

☐ I can stand as long as I want without extra pain
☐ I can stand as long as I want but it gives me extra pain
☐ Pain prevents me from standing for more than 1 hour
☐ Pain prevents me from standing for more than 30 minutes
☐ Pain prevents me from standing for more than 10 minutes
☐ Pain prevents me from standing at all

Section 7: Sleeping

☐ My sleep is never disturbed by pain
☐ My sleep is occasionally disturbed by pain
☐ Because of pain I have less than 6 hours sleep
☐ Because of pain I have less than 4 hours sleep
☐ Because of pain I have less than 2 hours sleep
☐ Pain prevents me from sleeping at all

Section 8: Sex Life (if applicable)

☐ My sex life is normal and causes no extra pain
☐ My sex life is normal but causes some extra pain
☐ My sex life is nearly normal but is very painful
☐ My sex life is severely restricted by pain
☐ My sex life is nearly absent because of pain
☐ Pain prevents any sex life at all

Section 9: Social Life

☐ My social life is normal and gives me no extra pain
☐ My social life is normal but increases the degree of pain
☐ Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
☐ Pain has restricted my social life and I do not go out as often
☐ Pain has restricted my social life to my home
☐ I have no social life because of pain

Section 10: Travelling

☐ I can travel anywhere without pain
☐ I can travel anywhere but it gives me extra pain
☐ Pain is bad but I manage journeys over two hours
☐ Pain restricts me to journeys of less than one hour
☐ Pain restricts me to short necessary journeys under 30 minutes
☐ Pain prevents me from travelling except to receive treatment

Appendix B: Modified JOA Questionnaire

Modified JOA for assessment of treatment of low-back pain

***SUBJECTIVE SYMPTOMS* (9)**

Low-back pain

☐None	3
☐Occasional mild pain	2
☐Frequent mild or occasional severe pain	1
☐Frequent or continuous severe pain	0

Leg pain &/or tingling

☐None	3
☐Occasional minimal symptoms	2
☐Frequent minimal or occasional severe symptoms	1
☐Frequent or continuous severe symptoms	0

Gait

☐Normal	3
☐Able to walk 500m/yds but w/pain, tingling, &/or muscle weakness	2
☐Unable to walk 500m/yds owing to leg pain, tingling, &/or muscle weakness	1
☐Unable to walk 100 m/yds owing to leg pain, tingling, &/or muscle weakness	0

***CLINICAL SIGNS* (6)**

Straight leg-raising test (including tight hamstrings)

☐Normal	2
☐30–70°	1
☐<30°	0

Sensory disturbance

☐None	2
☐Slight disturbance (objective)	1
☐Marked disturbance	0

Motor disturbance (manual muscle testing)

☐Normal (Grade 5)	2
☐Slight weakness (Grade 4)	1
☐Marked weakness (Grade 3)	0

URINARY BLADDER FUNCTION

☐Normal	6
☐Mild dysuria	3
☐Severe dysuria	0

Appendix C: Spine Surgery Outcome Questionnaire

SPINE SURGERY OUTCOME QUESTIONAIRE

NAME: ___________________________________ Date _____/______/_______

Date of Surgery: ☐ 2-weeks ☐ 6 weeks ☐ 3months ☐ 6 months ☐ 1 year
☐ 2 years

A. Are you **functioning** better or worse than before your spine surgery?

2. ☐ Much better
1. ☐ Slightly better
0. ☐ Same
-1. ☐ Slightly worse
-2. ☐ Much worse

B. During the past four weeks how much of the time have you ***cut down*** on the amount of time you spent on work.

2. ☐ None of the time
1. ☐ A little of the time
0. ☐ Some of the time
-1. ☐ Most of the time
-2. ☐ All of the time

C. During the past four weeks how much of the time were you limited in the kind of work you did.

5. ☐ None of the time
4. ☐ A little of the time
3. ☐ Some of the time
2. ☐ Most of the time
1. ☐ All of the time

D. How much did your spine operation change the **quality of your life?**

6. ☐ More improvement than I ever dreamed possible
5. ☐ A great improvement
4. ☐ Moderate improvement
3. ☐ Little improvement
0. ☐ No improvement
-3. ☐ A little worse
-4. ☐ Moderately worse
-5. ☐ Much worse

E. How would you rate the overall **treatment**?

5. ☐ Excellent
4. ☐ Very good
3. ☐ Good
2. ☐ Fair
-2. ☐ Poor

Total Score = /20 X 5 = ________ %

Appendix D: Data Use Permission

UNION HOSPITAL

August 26, 2015

Pradeep K. Narotam, M.D.
2461 Oakcrest Lane
Terre Haute, IN 47803

Re: Permission to Access Union Hospital Neuroscience Lumbar Spine Database

Dear Dr. Narotam:

This notification serves to formally grant you, subject to the terms and provisions of this letter, unrestricted access to your patient records and data sets contained in the above mentioned database. Such access shall specifically include access to the following data sets:

age, sex, primary clinical diagnosis 1 at initial visit, secondary clinical diagnosis 2, primary clinical pathology 1 at initial visit, secondary clinical pathology 2 at initial visit, preoperative smoker, preoperative weight, preoperative claudication, preoperative leg pain, surgery type, and number of levels. The dependent variables for repeated-measures include: preoperative ODI, preoperative modified JOA, 2-week ODI, 2-week spine surgery outcome score, 2-week patient satisfaction score, 6-week ODI, 6-week spine surgery outcome score, 6-week patient satisfaction score, 6-week weight, 6-week modified JOA, 3-month ODI, 3-month spine surgery outcome score, 3-month modified JOA, 3-month patient satisfaction score, 6-month ODI, 6-month spine surgery outcome score, 6-month modified JOA, 6-month patient satisfaction score, 1-year ODI, 1-year spine surgery outcome score, 1-year modified JOA, 1-year patient satisfaction score, 2-year ODI, 2-year spine surgery outcome score, 2-year modified JOA, 2-year patient satisfaction score, The data for the covariates include history of diabetes, smoker, 2-week smoker, 6-week smoker, 3-month smoker, 6-month smoker, 1-year smoker, 2-year smoker. Other variables that may be used [post-hoc] are 3-month fusion grade, 3-month instability, 3-month junctional instability, 3-month weight, 3-month work status, 6-month fusion grade, 6-month instability, 6-month junctional instability, 6-month weight, 6-month work status, 1-year fusion grade, 1-year instability, 1-year junctional instability, 1-year weight, 1-year work status, 2-year fusion grade, 2-year instability, 2-year junctional instability, 2-year weight, and 2-year work status.

A NEW DAWN IN HEALTHCARE

1606 N. 7th Street • Terre Haute, IN 47804 • Ph: 812.238.7000 • www.myunionhospital.org

This access is granted for your sole exclusive use in working on your dissertation titled, "The Utility of Health Care Performance Indictors in Evaluating Low Back Surgery" towards your Doctorate in Philosophy in Health Policy & Management in the Department of Health Sciences at Walden University. Any and all information used for such dissertation must be anonymized and any protected health information de-identified.

Access is specifically conditioned upon:

(a) Your responsibility to see that no patient names, patient identifiers or identifiable protected health information will be disclosed or part of the dissertation or released to any party.

(b) Use or disclose the data sets only as permitted by this letter or as required by law.

(c) Use appropriate safeguards to prevent use or disclosure of the data sets other than as permitted by this letter or required by law.

(d) Report any use or disclosure of the data sets of which you become aware that is not permitted by this letter or required by law.

(e) Require any of your subcontractors or agents that receive or have access to the data sets agree to the same restrictions and conditions on the use and/or disclosure of the data sets that apply under this letter.

For access you must agree to indemnify and hold Union Hospital, Inc., its directors, officers and agents harmless from any and all losses and damages attributable to a breach of the terms of this agreement or any impermissible release of protected health information.

Sincerely

Steven M. Holman
President & CEO

By signing this letter, I understand and agree to the above-referenced terms and provisions pertaining to my access to the Union Hospital Neuroscience Lumbar Spine Database and the use of such information.

____
Pradeep K. Narotam, M.D.

Date: 02/28/2015

Appendix E: Protecting Human Research Participants Training

Creighton
UNIVERSITY

Research Compliance Office

Human Subject Research Education
Certificate of Completion

This is to certify that the person listed below has demonstrated successful completion of the required Creighton University Human Subjects Research Education Program.

Requirements for certification in the education program include:

1) Verification of receipt of the Creighton University Institutional Review Board *"Investigators' Manual for the Use of Human Subjects in Research".*
2) Attendance at a Creighton University Institutional Review Board On-Site Human Subjects Research Education Seminar.
3) Completion of the CITI Web-Based Course in the Protection of Human Research Subjects.
4) Attendance at a Creighton University Institutional Review Board Health Insurance Portability and Accountability Act (HIPAA) Education Seminar.

A description of each of these components can be found on the attached pages.

The Creighton University Human Subjects Research Education Program was developed to instruct research staff in the basic principles and special requirements associated with research involving human subjects.

A copy of this certificate is retained on file in the Creighton University Research Compliance Office.

Name: **Pradeep K. Narotam, M.D.**

Date of Completion: 07-13-2005

Certified by: Kathleen Diaz Taggart
Kathleen Diaz Taggart
Research Compliance Officer

Location: 1912 California Street Mail: 2500 California Plaza Omaha, Nebraska 68178
http://www.creighton.edu/researchcompliance phone: 402.280.2360 fax: 402.280.4766 hotline: 402.280.3200

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Pradeep Narotam** successfully completed the NIH Web-based training course “Protecting Human Research Participants”.

Date of completion: 07/15/2015

Certification Number: 1791154

Appendix F: JOA/MacNab

JOA/MACNAB for assessment of treatment of low-back pain

Name: ________________________________ **Surgery Type:** ______________________

Time ☐**Pre-op** ☐**3-months** ☐**6-months** ☐**1-year** ☐**2-years**

***SUBJECTIVE SYMPTOMS* (9)**	
Low-back pain	
☐None	3
☐Occasional mild pain	2
☐Frequent mild or occasional severe pain	1
☐Frequent or continuous severe pain	0
Leg pain, numbness &/or tingling	
☐None	3
☐Occasional minimal symptoms	2
☐Frequent minimal or occasional severe symptoms	1
☐Frequent or continuous severe symptoms	0
Gait	
☐Normal	3
☐Able to walk 500yds but w/pain, tingling, &/or muscle weakness	2
☐Unable to walk 500yds owing to leg pain tingling, &/or muscle weakness	1
☐Unable to walk 100 m/yds owing to leg pain, tingling, &/or muscle weakness	0
***CLINICAL SIGNS* (9)**	
Straight leg-raising test (including tight hamstrings)	
☐Normal	2
☐30–70˚	1
☐<30˚	0
Sensory disturbance	
☐None	2
☐Slight disturbance (objective)	1
☐Marked disturbance	0
Motor disturbance (manual muscle testing)	
☐Normal (Grade 5)	5
☐Slight weakness (Grade 4)	4
☐Marked weakness (Grade 3)	3
☐Locomotion Aides (walker, cane)	1
☐Wheelchair	0
URINARY BLADDER FUNCTION (6)	
☐Normal	6
☐Mild dysuria	3
☐Severe dysuria	0
MODIFIED MACNAB (4)	
☐No pain, no restriction of mobility, able to work/normal activity	4
☐Occasional non radicular pain, modified work	3
☐Reduction in functional capacity, disabled, unable to work	2
☐Neurological involvement	0

Appendix G: Spine Surgery Functional Outcome Questionnaire

SPINE SURGERY FUNCTIONAL OUTCOME QUESTIONAIRE

NAME: ___________________________________ Date _____/______/_______

Date of Surgery: ☐ 2-weeks ☐ 6 weeks ☐ 3months ☐ 6 months ☐ 1 year ☐ 2-year

A. Are you **functioning** better or worse than before your spine surgery?

2. ☐ Much better
1. ☐ Slightly better
0. ☐ Same
-1. ☐ Slightly worse
-2. ☐ Much worse

B. During the past four weeks how much of the time have you ***cut down*** on the amount of time you spent on work.

2. ☐ None of the time
1. ☐ A little of the time
0. ☐ Some of the time
-1. ☐ Most of the time
-2. ☐ All of the time

C. During the past four weeks how much of the time were you limited in the kind of work you did.

5. ☐ None of the time
4. ☐ A little of the time
3. ☐ Some of the time
2. ☐ Most of the time
-1. ☐ All of the time

D. How much did your spine operation change the **quality of your life?**

6. ☐ More improvement than I ever dreamed possible
5. ☐ A great improvement
4. ☐ Moderate improvement
3. ☐ Little improvement
0. ☐ No improvement
-3. ☐ A little worse
-4. ☐ Moderately worse

E. How would you rate the overall **treatment** of your arm or leg pain related to your spine?

5. ☐ Excellent
4. ☐ Very good
3. ☐ Good
2. ☐ Fair
-2. ☐ Poor

G. How satisfied are you with your overall medical care by Dr. Narotam for your spine problem?

5. ☐ Very Satisfied
4. ☐ Somewhat satisfied
0. ☐ Neither satisfied or dissatisfied
-1. ☐ Somewhat dissatisfied
-2. ☐ Very dissatisfied

Patient Signature: ____

Appendix H: Short Assessment of Patient Satisfaction

SPINE SURGERY SHORT ASSESSMENT OF PATIENT SATISFACTION

NAME: ___________________________________ Date _____/______/_______

A. How satisfied are you with the care and attention you received by our office staff during your visit?

3. ☐ Very Satisfied
2. ☐ Somewhat satisfied
1. ☐ Neither satisfied or dissatisfied
-1. ☐ Somewhat dissatisfied
-2. ☐ Very dissatisfied

B. Dr. Narotam and/or Regina Battles –NP was attentive in listening to your medical problems.

3. ☐ Strongly agree
2. ☐ Agree
1. ☐ Not sure
-1. ☐ Disagree
-2. ☐ Strongly Disagree

C. Dr. Narotam and/or Regina Battles –NP was careful to check everything when examining you

3. ☐ Strongly agree
2. ☐ Agree
1. ☐ Not sure
-1. ☐ Disagree
-2. ☐ Strongly Disagree

D. How satisfied are you with the explanations Dr. Narotam and/or Regina Battles –NP gave you about your tests?

3. ☐ Very Satisfied
2. ☐ Somewhat satisfied
1. ☐ Neither satisfied or dissatisfied
-1. ☐ Somewhat dissatisfied
-2. ☐ Very dissatisfied

E. How satisfied are you with the choices or options given to you by Dr. Narotam and/or Regina Battles –NP affecting you health care?

3. ☐ Very Satisfied
2. ☐ Somewhat satisfied
1. ☐ Neither satisfied or dissatisfied
-1. ☐ Somewhat dissatisfied
-2. ☐ Very dissatisfied

F. How would you rate the overall **care & treatment** you received in our office?

5. ☐ Excellent
4. ☐ Very good
3. ☐ Good
2. ☐ Fair
-2. ☐ Poor

Patient Signature: ____