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by

Joseph Connolly, III

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**Certifies that this is the approved version of the following capstone:**

**Predictors of Prolonged Opioid Use following Lumbar Fusion**

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**PREDICTORS OF PROLONGED OPIOID USE FOLLOWING  
LUMBAR FUSION**

**by**

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**Capstone**

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## **Dedication**

In memory of Harris Robert Prager, MD, Lt Col, USAF, MC, FS  
Obstetrician, gynecologist, flight surgeon.

1966-2009

## **Acknowledgements**

Teaching a 50-year-old neurologist regression and the use of SAS is akin to trying to teach a pig how to sing. I am grateful to Dr. Kuo for her attempts and expectation of success with this pursuit. As a consequence, I have evaluated this data first with a linear model and then, at her suggestion, with quantile regression, which was quite interesting and a method I have now used successfully in another project. Finally, in this capstone I have used logistic regression to evaluate this data set. Karen Pierson, MA provided the life blood of usable data for this project. She astutely relayed the possible and less possible reality of working with Clinformatics Data Mart. Karen used great creativity and SAS expertise to accurately create and extract a multitude of usable variables.

I have always been interested in epidemiology and have wanted to explore vexing patient-centered care issues. Listening to a seminar lecture by Jacques Baillargeon, PhD on his testosterone study using pharmacy claims data provided the idea for using pharmacy opioid pain reliever data. Taking his Translational Epidemiology I class (the best organized course I have ever taken) gave me the self-efficacy to proceed. I aspire to be able to give advice as comprehensively and concisely as Jacques does.

Finally, it was the encouragement of Christine Arcari, PhD to change my capstone to this project, and her insistence at multiple points that I would be able to get the data and that it would happen, that kept me on track. This is definitely the capstone of my MPH experience.

# **PREDICTORS OF PROLONGED OPIOID USE FOLLOWING LUMBAR FUSION**

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The University of Texas Medical Branch, 2014

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The United States has the highest rate of lumbar fusion in the world.<sup>1</sup> The lumbar fusion rate increased 2.4 times between 1998 and 2008.<sup>2</sup> Rates of opioid pain reliever (OPR) use at 24 months post-lumbar fusion have been reported in up to 30% to 67% of patients. Currently, the number of OPR-related deaths in the US exceeds deaths from motor vehicle accidents.<sup>3</sup> The objective of this study is to assess predictors of prolonged opioid use after lumbar fusion.

We designed a retrospective cohort of patients who underwent lumbar fusion in 2009. We used claims data from Clinformatics Data Mart. The cohort consisted of 630 non-workers compensation (WC) adults, age 23-62 years, who underwent lumbar fusion for degenerative indications and were enrolled in the commercial health plan for a minimum of 12 months prior to surgery and 24 months following lumbar fusion. Those excluded had ICD-9 codes indicating lumbar spine tumors, fracture, infection, inflammation, a major traumatic accident, or who were pregnant at the time of surgery.

Variables indicating lumbar fusion type included posterior, anterior, circumferential (360), and outpatient minimally invasive (OPMI). The variables for indication included degenerative, post-laminectomy, and repeat fusion. In addition, we examined days of OPRs used in the year prior to fusion (divided into quartiles),

Elixhauser Comorbidity Index, and diagnosis of smoking, depression, and obesity. The primary outcome variable was excessive OPR use (>364 days dispensed) in two years post-fusion. Logistic regression was used to assess the independent contributions of each of the aforementioned independent variables in predicting the binary outcome variable.

Risk for having >364 days of OPRs dispensed post-lumbar fusion was observed for pre-fusion OPR use of 25-86 days dispensed odds ratio (OR) 3.5 (95% CI 1.6-8.3); pre-fusion OPR use of 87-266 days dispensed OR 12.4 (95% CI 5.6-27.2); pre-fusion OPR use (>266 days dispensed) OR 119.8 (95% CI 50.0-287.3); and smoking OR 1.74 (95% CI 1.04-2.92). There was no significant statistical association between fusion type or indication for lumbar fusion, with the binary outcome excessive post-fusion OPR use. These findings demonstrate need for rigorous development of evidence-based policy concerning OPR use following lumbar fusion.

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## List of Abbreviations

360	Both anterior and posterior approaches used
AD	Administrative Data
BMP	Bone Morphogenic Protein
CI	Confidence Interval
CDM	Clinformatics Data Mart
DDD	Degenerative Disc Disease
LOS	Length of Stay
MAO	Minimal Acceptable Outcome
MCID	Minimal Clinically Important Difference
OPMI	Outpatient Minimally Invasive
OPR	Opioid Pain Reliever
OR	Odds Ratio
PCD	Pharmacy Claims Data
PFCD	Physicians and Facility Claims Data
RTW	Return to Work
SAS	Statistical Analytic Software
SD	Standard Deviation
TDC	Thesis and Dissertation Coordinator
TDR	Total Disc Replacement
UTMB	University of Texas Medical Branch
WC	Workers Compensation

## **Chapter 1 Introduction**

### **SPECIFIC AIMS**

#### **Specific Aim 1**

To assess whether excessive opioid use following lumbar fusion surgery varies by lumbar fusion surgery type and surgical indication.

#### **Specific Aim 2**

To assess clinical and behavioral predictors of excessive opioid use following lumbar fusion.

### **SIGNIFICANCE**

There is confusion regarding the indication, risks, and benefit of lumbar fusion (defined as the surgical immobilization of adjacent lumbar vertebrae), yet its utilization continues to increase.<sup>1,2,4-9,10-12</sup> Deyo, et al. have clearly pointed out the increased risks of complex spinal fusion to the elderly, showing that the fusions result in about twice the life threatening complications and re-hospitalization compared with simple decompression.<sup>13</sup> Furthermore, patients with work-related injuries and conditions that are covered by workers compensation (WC) insurance are reported to have worse outcomes from lumbar fusion than do non-WC patients, when matched with known predictors of outcome by propensity score.<sup>14</sup> Multiple authors have observed the disappointing nature of lumbar fusion in the WC population in terms of return to work, re-operation rates, and the demonstrated risk for long-term OPR dependence in this population.<sup>10,15-17</sup> The non-

WC under-age-65 adult population has unknown rates of OPR dependence after surgery. Nevertheless, the rate of lumbar fusions in the US has been reported to have increased from 46 to 80 per 100,000 population per year between 2001-2010.<sup>18</sup>

The vast majority of the best studies on lumbar fusion outcomes rely on standardized, self-reported assessments on pain, functionality, and well-being, without objective measure.<sup>9</sup> The purpose of this study is to use an objective outcome measure (days of OPRs dispensed following lumbar fusion) to assess what has been the most rapidly expanding hospital-based surgery in the US over the last two decades.<sup>2</sup> The results of this study can be used to counsel patients considering lumbar fusion on the potential risk for opioid dependence by diagnostic indication and surgery as well as some other factors previously shown to affect outcomes from lumbar fusion, including medical comorbidities, depression, obesity, and smoking.<sup>18-24</sup> Likewise, the results can be used by third-party payers of medical care in concert with other outcomes research to help guide decisions on paying for lumbar fusion.

## Chapter 2 Background and Literature Review

The CDC notes that from 2006-2009, the death rate from OPR overdoses/100,000 population more than doubled, as did the OPR sales in kg/10,000 population, and admissions for treatment of OPR use almost quadrupled.<sup>25</sup> In 2008 in the US, OPR overdose (poisoning) deaths exceeded deaths from motor vehicle accidents, at 14,800 OPR deaths for the year with a rate of 12 OPR poisoning deaths per 100,000 population per year.<sup>25,26</sup> For the 2009 year, Inocencio and Carroll estimated the total cost to the US for OPR overdoses at \$20.4 billion.<sup>27</sup> Studies of OPR utilization, misuse, and unintentional OPR poisoning deaths frequently show lumbar spine pain (clearly including post-fusion) is the number one diagnosis (and majority diagnosis) leading to the prescription of OPRs.<sup>3,28-31</sup> Some studies have shown increased dosage and duration of OPRs after lumbar surgery.<sup>15,31</sup> In a study of direct costs in OPR abuse, back pain was the most common pain diagnosis to accompany the diagnosis of OPR abuse, with a prevalence of 19%.<sup>32</sup>

Rajaei, et al. reported that lumbar fusions performed in the US between 1998 and 2008 increased from a rate of 64.5 fusions/100,000 population/year to 135/100,000, with an average hospital cost increase from \$24,676 to \$81,960 per patient.<sup>2</sup> Cherkin, et al. revealed that the US has the highest rate of lumbar spine surgery in the world, five times the rate in the UK.<sup>1</sup> Hospital costs in the US for spinal (cervical through lumbar) fusion rose from \$10 billion in 2001 to \$46.8 billion in 2010.<sup>18</sup> Some studies have shown OPR use rates between 30-70% at two years post-lumbar fusion.<sup>16,33-35</sup>

Hydrocodone is the most commonly prescribed opioid in the US.<sup>36</sup> Ninety-nine percent of the world's hydrocodone is sold in this country.<sup>37</sup> The most common hydrocodone preparation is a combination with acetaminophen. Below is a table constructed using hydrocodone 5 mg/acetaminophen 300 mg with the recognizable trade name Vicodin<sup>R</sup> as an example of what various numbers of days of OPRs dispensed

(various data points from our study) would look like if the patients were dispensed Vicodin<sup>R</sup>.

<b>Days OPR Dispensed</b>	<b>Number of Vicodin<sup>R</sup> 5/300 Pills</b>	<b>Study Milestone</b>
0-24	0-192	1 <sup>st</sup> Quartile of pre-fusion OPR use in 1 year
25-86	200-688	2 <sup>nd</sup> Quartile of pre-fusion OPR use in 1 year
87-266	696-2,128	3 <sup>rd</sup> Quartile of pre-fusion OPR use in 1 year
267-1168	2,136-9,344	4 <sup>th</sup> Quartile of pre-fusion OPR use in 1 year
86	688	Median OPR use 1 year pre-fusion
173	1,384	Mean OPR use 1 year pre-fusion
365-1902	2,920-15,216	Excess OPR use 2 years post-fusion
161	1,288	Median OPR use 2 years post-fusion
384	3,072	Mean OPR use 2 years post-fusion
265	2,120	Median OPR use 2 years post-fusion OPMI
524	4,192	Mean OPR use 2 years post-fusion OPMI

Table 1: Days of Opioid Pain Relievers Dispensed, with Vicodin<sup>R</sup> as an Example

The fusion (attempted immobilization, called arthrodesis) of adjacent lumbar vertebrae can be performed in a variety of ways. The lumbar spine is closest to the skin posteriorly. However, the paraspinal muscles are traumatized by the posterior approach and, if a disc is to be decompressed, the spinal canal and nerve roots are between the surgeon and the intervertebral disc. In addition, fusions performed using this approach have higher rates of non-union (lack of fusion/immobilization, called pseudoarthrosis) than other approaches. The anterior approach to the lumbar spine allows good visualization of the vertebral body, has higher rates of fusion, and poses less risk to the spinal nerve roots, but there is risk of damage to the abdominal viscera and great vessels (aorta, vena cava, iliac vessels, and so forth). The posterior lateral approach does not risk

the anterior structures, but it increases risk to the lumbar spinal nerve roots and dural vessels and has higher rates of fusion does than the posterior approach. The lateral approach to lumbar fusion is blocked at L5-S1 (the most common level fused) by the iliac crest.<sup>38,39</sup>

In addition to direction of approach, there are many ways in which a lumbar fusion can be performed. The surgery (fusion) can be open or minimally invasive (operating through tubes, using scopes, or fluoroscopy, without a conventional-sized incision). A vast array of hardware including screws, rods, wires, and cages can be utilized or not used at all. Bone grafts can come from various sites on the patient (spine, hip, or rib) or from cadavers. Recombinant bone morphogenic protein (BMP) can be used to stimulate bone growth at the desired fusion site. The literature is rife with controversy over the merits of each of these variables and their combinations.<sup>38,39,40</sup>

The literature is sparse concerning how direction of approach or technique of lumbar fusion affects duration of post-fusion OPR use. There are a few studies that directly compare minimally invasive types of lumbar fusion to open types and show shorter duration of OPR use following a minimally invasive fusion than following an open fusion.<sup>41-44</sup> Unfortunately, these studies track OPR use for only six months at most.<sup>41-44</sup> In a study of re-do fusions, Stewart and Sachs found that anterior fusion (vs posterior fusion) was correlated with a successful outcome, defined as returning to work, not needing OPR, and being satisfied with the surgery at 24 months post-lumbar fusion.<sup>40</sup> Otherwise, there are not studies that compare OPR use duration by surgical approach to lumbar fusion.

While there are a variety of indications for lumbar fusion, there is little to no controversy over some indications for fusion such as spine tumors, fractures, or infection when each causes instability.<sup>45</sup> Most lumbar fusions are performed for a myriad of diagnoses that can be grouped as degenerative. These include degenerative or herniated discs, spondylosis, spondylolisthesis, and spinal stenosis. Classically, these anatomic and



radiologic observations become indications when coupled with neurogenic pain and weakness in the form of radiculopathy and/or claudication that has not responded to conservative therapy and time (at least four weeks) though many fusions are performed for the anatomic substrate and disabling back pain without the accompanying radiculopathy or neurogenic claudication. Ultimately, from a patient's perspective, the fusion is performed because of disabling pain. Since anatomic/radiologic diagnoses can completely overlap (spondylosis and degenerative disc) or coexist (spinal stenosis with any of the other diagnoses), there is a lot of ambiguity over degenerative indications.<sup>39,45,46</sup> Glassman, et al. demonstrated this ambiguity when they showed 19 non-controversial degenerative cases to 32 spine surgeons and there was only moderate agreement on surgical indication.<sup>47</sup>

People who have undergone lumbar surgery (fusion or decompression of nerve roots) for degenerative diagnoses may not experience relief from pain or, after an interval, may have recurrence or even a worsening of pain. Thus recurrent, unrelieved, or worsening pain after lumbar surgery is also considered an indication for lumbar fusion. Persistent pain after a lumbar laminectomy (removal of the posterior bony arch of the spinal canal), called Post-Laminectomy Syndrome, is frequently considered to have a worse outcome from fusion than degenerative diagnoses although there are studies where it does fairly well.<sup>48,49</sup> Common reasons for a repeat fusion at the same lumbar level include problems with hardware (instrumentation) or a failure of the lumbar segments to fuse (pseudoarthrosis or non-union). A study of 2,345 fusions followed over 11 years found a 20% repeat fusion rate, of which 65% were for problems with the hardware or incomplete fusion.<sup>50</sup> Glassman, et al. in a study comparing various indications, noted only 35% of the repeat fusion patients for non-union (pseudoarthrosis) were judged to have a good outcome (10-point improvement on the Oswestry Disability Index).<sup>48</sup>

From the patient's perspective, the reason to have a lumbar fusion is disabling pain, with corresponding anatomic/radiologic degenerative change. Thus it makes sense

to evaluate pain and disability as outcome measures of lumbar fusion. The Oswestry Disability Index (ODI) is a standardized/validated questionnaire for evaluating lumbar back pain and self-care/activities of daily living functionality scored up to 100%, with increasing percentage corresponding to increasing disability.<sup>51</sup> The ODI is the most commonly used outcome measure in lumbar surgery studies.<sup>51</sup> Validated self-reported scales like the ODI and others, as opposed to objective measurements, are currently the gold standard in clinical spine research.<sup>52</sup>

There are studies that clearly show differences in outcome from lumbar fusion measured by ODI, based on diagnostic indication.<sup>49,53,54</sup> There are not any studies that demonstrate a difference of duration of OPR use post-lumbar fusion by diagnostic indication for the lumbar fusion surgery.

Published studies that correlated pre-fusion OPR use with outcome generally have found pre-fusion OPR use leads to poorer outcomes from lumbar fusion measured a variety of ways. Albert, et al. noted that preoperative daily OPR use was significantly associated ( $p=0.04$ ) with the fusion outcome being classified as a functional failure.<sup>55</sup> Smith, et al. compared the characteristics of 279 patients who had lumbar fusion for scoliosis in two age categories (ages 18-45 and 46-85) to identify the preoperative features of those who had the best and worst outcome. For both age categories, there was a higher percentage using OPRs pre-fusion (33% for the young category and 66% for the old) in the worst outcome group based on ODI. The patients in the best outcome group had 5% OPR use for the young category and 18% OPR use in the old category.<sup>56</sup>

Moore, et al. noted an association between the use of OPRs at the time of surgery and at 24 months post-fusion.<sup>57</sup> Interestingly, a study of length of stay (LOS), with shorter LOS being the more desirable outcome after a minimally invasive fusion technique, found that less pre-fusion OPR use was associated with a LOS of >24 hours (compared with <24 hours). The same study found that pre-fusion Oxycontin<sup>R</sup> use (suggesting chronicity of OPR use) had an odds ratio of 7 ( $p=0.032$ ) for LOS >48 hours

(a less desirable outcome).<sup>58</sup> While this study, which was just looking at the very short-term outcome of LOS after a minimally invasive fusion, found some benefit to OPR use, Oxycontin<sup>R</sup> use (suggesting chronic OPR use) predicted the poorest outcome. To date, no published studies have reported the extent to which OPR use before lumbar fusion surgery is associated with prolonged OPR use post-surgery.

Other factors associated with worse outcomes from lumbar fusion include smoking, depression and other mental health issues, and obesity. Smoking has been associated with worse outcomes from lumbar fusion measured with a variety of outcomes.<sup>19,22,56,59</sup> While it has not been evaluated as a predictor of duration of OPR use after lumbar fusion, it has been associated with deaths from OPR overdoses and increased OPR use after other types of surgery.<sup>29,60</sup> Depression and other mental health issues have also been associated with poorer outcomes from lumbar fusion and OPR overdoses.<sup>19,23,24</sup> Obesity has been associated with poorer outcomes from lumbar fusion using different outcome measures, and chronic OPR use before bariatric surgery has been associated with chronic OPR use and increased dosage after bariatric surgery.<sup>18,20,21,61</sup> However, none of these have been studied as predictors of extended OPR use following a lumbar fusion.

The following studies include duration of OPR use as an outcome. Adogwa, et al., in a study of revision lumbar fusion in patients 65 years or older, reported a median time of OPR use of four months, but noted 33% were still using OPRs at 24 months.<sup>52</sup> When comparing an open and minimally invasive lumbar fusion type in a study of 30 (apparently non-WC) patients, Adogwa, et al. reported 100 percent of the minimally invasive patients used OPRs less than two months, and 100 percent of the open fusion patients used OPRs less than six months.<sup>41</sup> Schwender, et al. reported a two- to four-week mean OPR use time period following minimally invasive transforaminal lumbar interbody fusion.<sup>42</sup> A systematic review of lumbar fusion vs total disc replacement

(TDR) noted rates of OPR use following fusion (two different studies) of 59 percent (n=52) and 43 percent (n=148) at two years.<sup>33</sup>

In a retrospective study of WC patients in Australia, Harris and coworkers found that 24 months after lumbar fusion, 69.9% of 92 patients were still taking OPRs.<sup>16</sup> Nguyen, et al., in a retrospective cohort study of WC lumbar fusion (n=75) in Ohio, showed 76% of fusion patients still OPR dependent at 90 days.<sup>15</sup> Both of these studies demonstrated a poor social/vocational outcome, with 36% of the patients in the Australian study returning to work and 26% of fusion patients in the Ohio study returning to work.<sup>16,15</sup>

To summarize the literature on OPR use following lumbar fusion, it appears that after open fusion more than 30% of patients may be on OPRs for longer than two years. Patients seem to have markedly shorter duration of OPR use after minimally invasive lumbar fusions.<sup>41-44</sup> (Again, note that the longest duration follow-up with OPR duration data is only six months.) Finally, several studies of only WC patients have long-term (24-month) OPR usage >65%.

In a study of reoperation of the lumbar spine (adult, elderly, WC, and non-WC population), mainly fusion, Stewart and Sachs found that continued pain at 24 months was, not surprisingly, correlated ( $p < 0.05$ ) with the OPR use (not returning to work and not being satisfied). In addition, they considered the surgery a failure if persistent OPRs were used even on a monthly or occasional basis when evaluated at 24 or more months.<sup>40</sup> In a study of anterior and posterior fusion combined (360) patients with degenerative disc disease, Moore, et al. found that 48% were on OPRs preoperatively and only 19% were on long-term (average follow-up, three years) OPRs after surgery. They considered patients on OPRs for longer than six weeks postoperatively to be a complication.<sup>57</sup>

Carragee and Cheng tested the concept of minimum clinically important difference (MCID) against what patients wanted by surveying 165 patients with DDD and isthmic spondylolisthesis. The survey responses, preoperatively to lumbar fusion, had

a high inter-rater agreement with  $\kappa=0.73-0.90$  for various outcome measures. Based on strongly desired outcomes from patients, expressed as would not plan to have surgery for worse outcomes, Carragee and Cheng propose a patient-centered minimal acceptable outcome (MAO). The MAO includes an ODI improvement of at least 20 points, decrease of pain to 3/10 on visual analog scale, returning to work, and not using OPRs. In this study of preoperative expectations of lumbar fusion, 90% of patients indicated that OPR dependence would be an unsuccessful outcome from lumbar fusion.<sup>62</sup>

Our study will attempt to address the following gaps in the literature. It is clear from the above that the WC population has a significant risk for extended duration OPR use after lumbar fusion. Previous studies have demonstrated that following lumbar fusion surgery, the WC population has poorer responses, in comparison to the non-WC population, on the following outcomes: RTW, OPR use, ODI, and similar scales.<sup>10,14,63</sup> What is unclear is what the risk is for becoming a long-duration OPR user after lumbar fusion in the non-WC working age population. It is unclear whether other factors (duration of pre-fusion OPR use, medical comorbidities, depression, obesity, or smoking) predispose a person to becoming an excessive OPR user after lumbar fusion surgery. It is unclear whether the direction of surgical approach to lumbar fusion (posterior vs anterior vs 360) may predispose a patient to become a long-term OPR user after lumbar fusion. Minimally invasive lumbar fusions appear to incur much less OPR use after fusion, but to date there are no multi-year studies of OPR use after minimally invasive lumbar fusions.<sup>41-44</sup> This study may inform clinical and policy decision making on the relevance of indication and type of lumbar fusion to duration of OPR use after fusion. Moreover, our findings may help physicians understand the extent to which behavioral and clinical factors affect the risk of excessive OPR use among patients undergoing lumbar fusion surgery.

## Chapter 3 Data and Methods

### STUDY DESIGN

In this study, we used administrative claims data from Clinformatics Data Mart (CDM) to conduct a retrospective cohort study of one of the largest commercial insurance companies in the US. These data have been validated in a number of previous studies.<sup>64-67</sup> The study cohort (which included three diagnostic groups and four fusion types, defined below) were followed from 12 months prior to lumbar fusion surgery (index) date to 24 months following the operation or index date.

### STUDY POPULATION/SAMPLE

The study population was constructed relying heavily on the methods and codes (ICD-9 and CPT codes for diagnoses and definition of lumbar fusion cases) of Deyo, et al. from their 2005 paper in *Spine*.<sup>46</sup> In addition, The methodology of Nguyen, et al. was utilized in separating the fusions into posterior (including posterior-lateral), anterior, and 360 (circumferential or anterior and posterior).<sup>15</sup>

We identified patients who were members of the US commercial health plan under study and who underwent lumbar fusion surgery in 2009, using the following surgery CPT and ICD-9 codes: posterior lumbar fusion (ICD-9 code=81.08; CPT=22612, 22614, 22630, 22632, 22840, 22842 and 22851), anterior lumbar fusion (ICD-9 code=81.04, 81.05, 81.06, 81.07; CPT= 22558, 22585 and 22851), and 360 anterior and posterior lumbar fusion (one of any of the above listed anterior codes and one of any of the above posterior codes). Outpatient minimally invasive (OPMI) fusions were identified by an outpatient location for the fusion procedure. There were not codes to specifically identify most minimally invasive lumbar fusion techniques in 2009.

To be eligible for inclusion in the study, patients were required to have been enrolled in the commercial insurance plan from 12 months prior to surgery and for 24 months following surgery. The study cohort was also required to have been between the ages of 21 through 63 on the date of surgery (index date). The age range was chosen to study working age adults to include the follow-up period. The exclusion criteria, except for the exclusion of the Medicare/Social Security retirement age population, were taken from Deyo, et al.'s methods, which have been used in other studies of lumbar surgery using large databases.<sup>68,13,49</sup> The exclusion criteria were chosen to study degenerative diagnoses, which are the largest diagnostic indication for lumbar fusion.<sup>46</sup> Excluded were those who received Social Security disability benefits or WC benefits based on health insurance type (commercial excluding state or federal sponsorship), or who had any of the following diagnoses in the 12 months prior to surgery: lumbar spine tumor (ICD-9=140-239.9), fracture (ICD-9=733.1, 733.10, 733.13, 733.95, 733.8, 733.81-733.82, 805-806.9, 839-839.59), infection (ICD-9=324.1, 730-730.99), or inflammation (ICD-9=720.0-720.9). Also excluded were those who had suffered a major traumatic accident (ICD-9= E800-E849.9) or who were pregnant (ICD-9=630-676) at the time of surgery.

## **DATA SOURCE**

The CDM database provides de-identified patient longitudinal data. We used data from the following files: (1) administrative data (AD), (2) pharmacy claims data (PCD), and (3) physician and facility claims data (PFCD).

## **DATA MANAGEMENT AND COLLECTION**

All data management and analysis was conducted on a personal computer by the primary investigator PI at the University of Texas Medical Branch (UTMB), which

maintains a complete database of all CDM files. Data were linked across datasets and anonymized by CDM. These data have served as the basis for numerous peer-reviewed publications. All data abstraction, data management, and data analysis was conducted in full compliance with HIPPA regulations.

## VARIABLES

Definitions of variables are found in Table 1. Variables are also described in the paragraphs below.

**Age**—in years.

**Gender**—male or female, as recorded by the subject’s health insurance.

**Indication**—diagnosis recorded on billing for the surgical procedure. The exclusion criteria were designed to incorporate primarily degenerative conditions: disc abnormalities (degeneration, herniation), spondylosis, spinal stenosis, spondylolysis, and spondylolisthesis. The first diagnostic category in this study was **degenerative**, which encompassed the above diagnoses. The second diagnostic category was **post-laminectomy**, with an underlying degenerative diagnosis. The third category was **redo/revision/repeat lumbar fusion** with an underlying degenerative diagnosis. All diagnostic categories were degenerative in nature.<sup>39,46,18</sup>

**Elixhauser Comorbidity Index**—a standardized validated index of comorbidities used in studies of large claims-based data sets. Elixhauser Comorbidity Index is a total of diagnostic groups reported as integers with a possible range of 0-30.<sup>69,70,71</sup>

**Total days of OPRs dispensed.** Insurance data on medication dispensed has been used in studies of exposure to medication, compliance, and persistence of medication use.<sup>72-74</sup>



**Total days of OPRs dispensed in the 12 months prior to fusion and total days of OPRs dispensed in the 24 months after fusion** was collected. Days of OPRs dispensed in the year pre-fusion were grouped by quartiles of pre-fusion OPR use. The first quartile of pre-fusion OPR use was 0-24 days of OPRs dispensed. The second quartile of pre-fusion OPR use was 25-86 days dispensed of OPRs dispensed. The third quartile was 87-266 days of pre-fusion OPRs dispensed. The fourth quartile of pre-fusion OPR use was >266 days dispensed.

**Excessive OPRs dispensed** for this study was defined as 365 or more days dispensed in the two-year, post-fusion period. In our study, the PI conducted an informal focus group on 8/30/2013 with 12 primary care physicians. All agreed, when asked whether they would consider either 180 or 365 days of OPR use post-fusion excessive, that both were excessive.

Svendsen, et al. performed a study to determine definitions of persistent OPR use from a prescription database used defined daily dosages, a World Health Organization phrase for the most frequent total daily dose of a medication, for its most frequent use. The wide definition of persistent OPR use was >180 daily dose equivalents in a year.<sup>75</sup> The days of medication dispensed used in our study is not exactly the same as defined daily dosages but in most cases is very similar. Given the variability of the measure, it seems safe to assume that most physicians, patients, and the public can agree that greater than 365 days of OPRs dispensed in a two-year period after spinal fusion is excessive. Using 365 or more days of OPRs dispensed post-fusion as excessive is balanced between the ideal of using OPRs less than six weeks and the reality that over 30% of fusion patients are taking OPRs at 24 months post-fusion.

<b>Variable Name</b>	<b>Data Source</b>	<b>Definition</b>	<b>Operational Definition</b>
<b>Demographic</b>			
Age	AD	Age in years	Age in years at time of fusion
Gender	AD	Female or male	Female or male
<b>Fusion Type</b>		Surgical approach: posterior, anterior, 360, or OPMI	
Posterior	PFCD	Posterior approach to lumbar spine for fusion, including posterior lateral and interbody fusions	ICD-9 code= 81.08; CPT= 22612, 22614, 22630, 22632, 22840, 22842 and 22851
Anterior	PFCD	Anterior approach to lumbar spine (through abdomen)	ICD-9 code= 81.04, 81.05, 81.06, 81.07; CPT= 22558, 22585 and 22851
360	PFCD	Spinal fusion both anteriorly and posteriorly, also known as circumferential	(Algorithm must include both anterior and posterior codes)
OPMI	PFCD	Minimally invasive lumbar fusion, using scopes, tubes, fluoroscopy, without a conventional-sized incision	Fusion performed in an outpatient setting; if performed in outpatient setting, excluded from posterior, anterior and 360 groups
<b>Indication</b>		Diagnosis justifying fusion	Diagnosis from billing at time of fusion
Degenerative	PFCD	Disc herniation and degeneration Spinal stenosis Possible instability	ICD-9: 722.10, 722.73, 721.3, 722.52, 722.93. ICD-9: 721.42, 724.02. ICD-9: 724.6, 738.4, 756.11, 756.12
Post-laminectomy	PFCD	Previous lumbar laminectomy at same level	ICD-9: 722.83
Repeat fusion	PFCD	Previous lumbar fusion	ICD-9: 724.9, 733.82, 996.4, 996.44, 996.60, 996.63, 996.67, 996.70, 996.78, V45.4, V54.0,

Table 2: Table of Variables and Definitions

<b>Comorbidity</b>		<b>Other medical conditions</b>	
Elixhauser index	PFCD	Number of comorbid diagnostic groups	Total number of Elixhauser comorbidity groups extracted from the database using SAS code from the University of Manitoba
Depression, dysthymia, adjustment disorder, PTSD	PFCD	Depression, major (initial, recurrent), dysthymia, adjustment disorder, or PTSD with depressed or anxious mood	ICD-9=300.4, 300.5, 296.2, 296.3, 309.0, 309.1, 309.28, 309.81, 309.82, 309.83, 309.89, and 311
Obesity	PFCD	Obesity and morbid obesity	ICD-9=278.0, 278.00, 278.01, 278.02
Smoking	PFCD	Smoking/tobacco abuse	ICD-9= 305.1
<b>OPR Use</b>			
Days OPRs dispensed pre-fusion	PCD		Days of opioid pain relievers dispensed in the 365 days prior to the date of fusion
Days OPRs dispensed post-fusion	PCD		Days of opioid pain relievers dispensed in 730 days after the date of fusion

Table 2 continued: Table of Variables and Definitions

## **STATISTICAL ANALYSIS**

We examined the distribution of study factors using descriptive statistics including percentages, 95% confidence intervals (CI), contingency tables, one-way ANOVAs, and chi-square statistics. We then used logistic regression to assess the independent contributions of multiple independent variables (age, gender, fusion type, indication, Elixhauser group number, obesity, depression, and smoking) to predict the binary outcome of 365 or more days of OPRs dispensed in the two years following lumbar fusion. Statistical analysis was performed using SAS 9.2 (copyright (c) 2002-2008 by SAS Institute Inc., Cary, NC, USA).

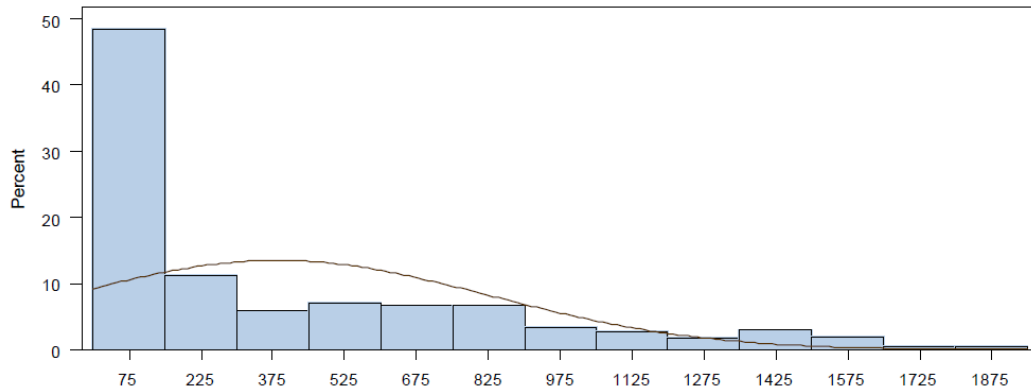
## Chapter 4 Results

Table 3 shows the distribution of patient characteristics by fusion type. Overall, the mean patient age was 49.6 years (SD of 8.8 years). Fifty-six percent were female, 44% were male, 61% had degenerative diagnoses, 2% had Post-Laminectomy Syndrome, and 37% had repeat fusion. The mean Elixhauser score was 2.53 (SD 1.81) diagnostic groups; 31% were depressed, 20% were coded as obese, and 26% were coded as smokers. The mean days of OPRs dispensed in the year prior to fusion was 173 (SD 204). In the two-year, post-fusion follow-up period, the mean number of days of OPRs dispensed was 385 (SD 443). Both variables for days of dispensed, pre- and post-fusion, were skewed (Figure 1 and 2). Finally, in the two-year, post-fusion follow-up period, 38% were dispensed at least a 365-day supply of OPRs.

	<b>Posterior Fusion (n=382)</b>	<b>Anterior Fusion (n=119)</b>	<b>360 Fusion (n=58)</b>	<b>OPMI Fusion (n=71)</b>	<b>p-Value</b>
<b>Demographics</b>					
Age in years	49.9 (8.75)	49.5 (8.60)	48.1 (8.12)	49.0 (9.62)	0.4375
Female	56% (51-61)	54% (45-63)	53% (41-66)	56% (45-68)	0.9493
Male	44% (39-49)	46% (37-55)	47% (34-59)	44% (32-55)	
<b>Indication</b>					0.0463
Degenerative % (95% CI)	64% (59-69)	63% (54-72)	47% (34-59)	54% (42-65)	
Post-laminectomy	2% (1-4)	1% (0-3)	7% (0-13)	3% (0-7)	
Re-fusion	34% (29-38)	36% (28-45)	47% (34-59)	44% (32-55)	
<b>Comorbidity</b>					
Elixhauser groups	2.51 (1.83)	2.45 (1.79)	2.29 (1.81)	2.94 (1.72)	0.9659
Depression	32% (27-36)	30% (22-39)	19% (9-29)	40% (28-51)	0.0943
Obesity	19% (15-23)	23% (15-30)	17% (8-27)	21% (12-32)	0.7624
Smoking	24% (20-28)	25% (17-33)	31% (19-43)	32% (22-43)	0.3547
<b>OPR Use Pre-Fusion</b>					0.2066
Quartile 1: 0-24 days	25% (21-29)	31% (23-39)	17% (8-27)	24% (14-34)	
Quartile 2: 25-86 days	26% (22-30)	24% (16-31)	26% (15-37)	23% (13-32)	
Quartile 3: 87-266 days	26% (21-30)	26% (18-34)	26% (15-37)	17% (8-26)	
Quartile 4: >266 days	24% (19-28)	19% (12-26)	31% (19-43)	37% (25-49)	
<b>OPR Use Post-Fusion</b>					
Dispensed $\geq$ 365 days OPR post	37% (0.32-0.41)	31% (0.23-0.39)	47% (0.34-0.59)	46% (0.35-0.58)	0.0836

Continuous variables reported as mean (SD), categorical variables as percentage (95% CI), p-values based on F value from ANOVA for means, and chi-square for percentages.

Table 3: Descriptive Statistics of Variables by Fusion Type



Days of Opioid Pain Relievers Dispensed Two Years Post-Fusion

Figure 1: Histogram of Distribution of Days of OPRs Dispensed Post-Fusion

Note that with opioid pain medications, the number of days of medication dispensed does not clearly equal the number of days of medication used; this could be either many more or less days used. For example, the common combination pain reliever hydrocodone 5mg with acetaminophen 300 mg (Vicodin<sup>R</sup>) is commonly prescribed one to two pills by mouth every 4-6 hours with a maximum of eight pills a day (Epocrates<sup>TM</sup>). If 40 pills were dispensed, this would be considered five days of medication dispensed; however, it may last many more days for a patient tapering off of the medicine. On the other hand, a patient taking 70 mg of long-acting oxycodone (Oxycontin<sup>R</sup>) every 12 hours may receive a prescription for sixty-two 60 mg pills and sixty-two 10 mg pills, which would be 31 days of medication of each size of pill, counting as 62 days of opioid pain medication, but would be used in one month. Additionally, patients may be prescribed several different OPRs concurrently with a myriad of combinations and rationales.

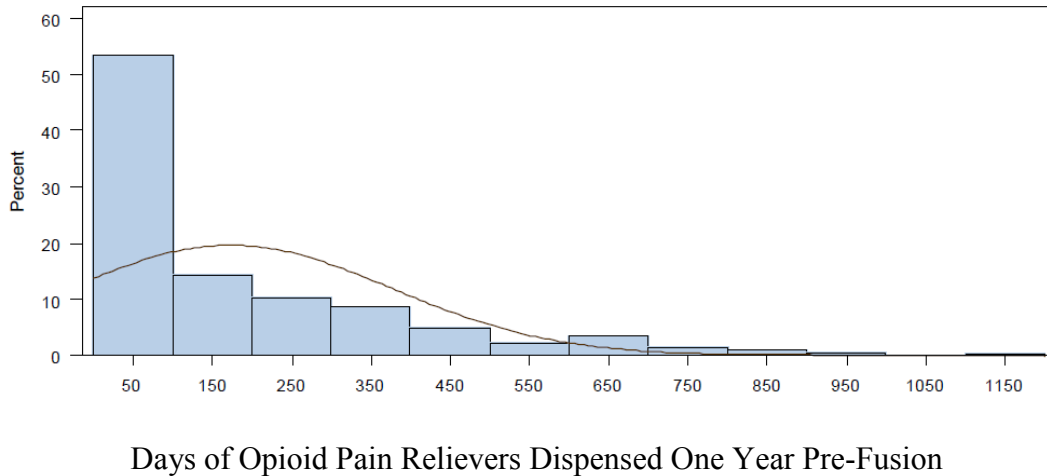


Figure 2: Histogram Distribution of Days of OPR Use One Year Pre-Fusion

***SPECIFIC AIM 1***

**To assess whether opioid dependence/prolonged opioid use varies by lumbar fusion type and surgical indication.** Our analyses show that after adjusting for covariates (age, gender, Elixhauser comorbidity, depression, obesity, smoking, and indication), the type of lumbar fusion was not predictive of the binary outcome, increased OPR use (>364 days dispensed post-fusion). In comparison to the referent (posterior fusion), neither anterior fusion (p=0.28) nor 360 fusion (p=0.41) nor OPMI fusion (p=0.85) reached statistical significance. Likewise, after adjusting for covariates, diagnostic category (degenerative, post-laminectomy, and repeat fusion) was not predictive of this outcome. Specifically, in comparison to the referent (degenerative), neither post-laminectomy (p=0.16) nor re-fusion (p=0.07) reached statistical significance.

***SPECIFIC AIM 2***

**To assess clinical and behavioral predictors (pre-fusion OPR use, Elixhauser Comorbidity Index, depression, obesity, and smoking) of duration of OPR use**



**following lumbar fusion.** The number of days of OPRs used in the year prior to the lumbar fusion was the most significant predictor of the number of days of OPRs used in the two-year, post-fusion follow-up period. Figure 1 and Figure 2 show the similarity in the distribution of days of OPRs used pre- and post-fusion.

In comparison to the referent (first quartile, 0-24 days OPRs dispensed), patients in the second quartile of pre-fusion OPR (25-86 days dispensed) use were found to have an odds ratio (OR) of 3.5 ( $p < 0.0001$ ) for excessive OPR use post-fusion ( $> 364$  days dispensed). Patients in the third quartile (87-266 days) of pre-fusion OPR use had an OR of 12.4 ( $p = 0.0356$ ) for having excessive OPR use post-fusion. Finally, the fourth quartile of pre-fusion OPR use,  $> 266$  days dispensed, had an OR of 119.8 ( $p < 0.0001$ ) for having excessive OPR use post-fusion. The only other predictor variable to meet statistical significance was tobacco use, with an OR of 1.74 ( $p = 0.0346$ ) for having excessive ( $> 364$  days) OPRs dispensed post-fusion.

Variable	% Dispensed >365 Days OPR	OR Estimate	95% CI	p-Value
<b>Demographics</b>				
Age		0.98	0.96-1.01	0.1903
Male	36%	1.0	reference	
Female	39%	1.14	0.72-1.79	0.5830
<b>Fusion Type</b>				
Post-fusion	37%	1.0	reference	
Anterior fusion	31%	0.81	0.45-1.46	0.2887
360 fusion	47%	1.32	0.62-2.79	0.4131
OPMI fusion	46%	1.10	0.52-2.31	0.8501
<b>Indication</b>				
Degenerative	35%	1.0	reference	
Post-laminectomy	33%	0.36	0.07-1.87	0.1604
Re-fusion	43%	1.35	0.86-2.13	0.0744
<b>Comorbidity</b>				
Elixhauser groups		1.14	0.99-1.31	0.0516
Depression	54%	1.49	0.91-2.42	0.1070
Obesity	37%	0.93	0.51-1.69	0.8013
Smoking	46%	1.74	1.04-2.92	0.0346*
<b>OPR Use Pre-fusion</b>				
Quartile 1: 0-24 days	5%	1.0	reference	
Quartile 2: 25-86 days	17%	3.5	1.6-8.3	<0.0001*
Quartile 3: 87-266 days	42%	12.4	5.6-27.2	0.0356*
Quartile 4: >266 days	88%	119.8	50.0-287.3	<0.0001*

Table 4: Odds Ratio Estimates for Risk of Being Dispensed Opioid Pain Relievers for 365 Days or More in Two-Year, Post-Fusion Follow-Up Period

## Chapter 5 Discussion

The Centers for Disease Control and Prevention reports that one American dies every 19 minutes from unintentional overdose.<sup>76</sup> Approximately 73 percent of these deaths are from OPRs and are responsible for more deaths than heroin and cocaine combined.<sup>76</sup> Opioid pain relievers are frequently prescribed for back pain, particularly following lumbar fusion surgery.<sup>28,29</sup> To date, however, little information is available on the risks such patients face for excessive OPR use following surgery. In particular, it is not clear whether such risks vary by type of surgery, indication for surgery, duration of prior opioid use, or other clinical and behavioral factors.

This study, conducted on one of the largest commercially insured populations in the US, showed no significant statistical association between lumbar fusion type or diagnostic indication with the outcome of excessive OPR use (defined as 365 or more days of OPRs dispensed) in the two-year, post-fusion follow-up period. There was, however, a strong statistically significant association between the number of days of OPRs dispensed in the year *prior to* lumbar fusion and the outcome of number of days of OPR use in the two-year, post-fusion follow-up period. These findings are consistent with those of Nguyen, et al., who reported no statistically significant benefit of one type of lumbar fusion over another in their study of 750 WC lumbar fusion patients using return to work (RTW) as the outcome measure.<sup>15</sup> We did not observe a statistically significant benefit of one lumbar fusion approach over another. This finding is counter-intuitive given that multiple smaller studies of open vs minimally invasive techniques showed less OPR use with the minimally invasive fusions.<sup>41-44</sup> Additionally, the various approaches to lumbar fusion surgery have varying rates of fusion (arthrodesis, or fusion forming) which are felt to affect outcome.<sup>38,39,40</sup> Other studies have reported varying rates of

success based on surgical indication.<sup>48,49,54</sup> We did not observe such variation in our study.

In our study, relative to patients in the lowest quartile of pre-fusion OPR use (0-24 days), those who were in the second quartile of pre-fusion OPR use (25-86 days dispensed) had 3.5 times the risk of excessive post-fusion OPR use (365 or more days dispensed); those in the third quartile of pre-fusion OPR use (87-266 days dispensed) had 12.4 times the risk of excessive OPR use; and those in the final quartile of pre-fusion OPR use (>266 days dispensed) had 120 times the risk

Our findings suggest that clinicians should closely monitor the use of opioids in the treatment of back pain. In our study, indication and approach to lumbar fusion were not associated with excessive opioid use, but pre-fusion OPR use duration is exceedingly statistically relevant to the outcome of post-fusion excessive OPR use.<sup>10</sup> The results from our study do not support the notion that lumbar fusion surgery decreases OPR use, but that OPR use before surgery predicts OPR use after surgery. The results of this study do not support the notion of treating a long-term OPR user's back pain with lumbar fusion so they can become pain free and discontinue their OPRs. The results of this study suggest that patients considered for lumbar fusion for degenerative diagnoses should be stratified by duration of OPR use.

To our knowledge, our study is the first study to show an association between pre-fusion OPR use duration and postoperative OPR use duration. In our study, pre-fusion OPR use was the strongest predictor of our undesirable outcome of excessive post-fusion OPR use. Nguyen, et al. compared pre-fusion with post-fusion OPR dose and found that the morphine equivalents per day increased by 41% post-fusion with at least a 90-day follow-up period in his WC population. Increasing OPR dose was related to decreased RTW rate.<sup>15</sup> Nguyen, et al. did not explore pre-fusion OPR duration or dose as a predictor of post-fusion OPR usage.<sup>15</sup> Moore, et al. noted but did not quantify that pre-fusion OPR use was associated with chronic (at least 24 months) OPR use.<sup>57</sup>

Our finding of 38% of patients (aggregate of the four fusion types) having 365 or more days of OPRs dispensed in the 24-month post-fusion period is not dissimilar to recent lumbar fusion studies published. It should be pointed out that those studies, unlike ours, did not exclude elderly and WC patients. Adogwa, et al., in a study on elderly revision fusion, found 33% of the patients continued OPR use at 24 months post-fusion. It was postulated that pre-fusion OPR use may affect post-fusion OPR use, but the researchers did not have pre-fusion OPR data.<sup>52</sup> In Zigler and Delamarter's study comparing patients with 360 fusion and those with total disk replacement surgery, the authors noted OPR use at 24 months post-procedure at 42.5% and 44.6%, respectively, compared to 76% and 84%, respectively, of patients using OPRs prior to their lumbar surgeries.<sup>34</sup> Our study shows a similar ratio to studies of open (as opposed to minimally invasive) fusion techniques, where the post-fusion OPR-dependent percentage of patients is very roughly half (+/- 10%) of the pre-fusion percentage of OPR-dependent subjects.<sup>33,35</sup>

Studies of minimally invasive lumbar fusion types that evaluate post-fusion OPR use suggest that there is relatively rapid weaning from OPRs with minimally invasive lumbar fusions. In a study of 49 minimally invasive transforaminal interbody lumbar fusions, the researchers noted the mean for OPR discontinuation was by four weeks.<sup>42</sup> A later study of the same procedure (with 149 patients) noted that all patients were on OPRs pre-fusion, but at six months post-fusion, only 31% continued use of OPRs.<sup>43</sup> Adogwa, et al., in a study of a minimally invasive fusion type, demonstrated all patients were off OPRs at two months.<sup>41</sup> A study comparing open and a minimally invasive lumbar fusion noted that the post-fusion patients who had the minimally invasive procedure used about half the morphine equivalents of the open fusion group while in the hospital.<sup>44</sup> In our study, 46% of the outpatient minimally invasive fusion patients were dispensed 365 or more days of OPRs post-fusion.

More specifically, for the outpatient minimally invasive surgery cohort, the median days of OPR dispensed (for two years) post-fusion was 265 and the mean was 524 days of OPR dispensed. To compare, the one-year pre-fusion OPR use for this cohort was a median of 141 days of OPR dispensed with a mean of 241 days of OPR dispensed. The difference between our findings of post-fusion OPR use for minimally invasive lumbar fusion and other published studies on minimally invasive lumbar fusion suggests the need for more long-term follow-up data on the outcomes of minimally invasive lumbar fusion types and OPR usage. Our study had a significantly longer follow-up period (two years) than the longest published follow-up with OPR duration (six months). It is possible that patients initially do well after minimally invasive fusion, which is captured by the other studies, and then some have a pain relapse over time, which was captured by our study with the longer follow-up period.

We note that the patients in our OPMI cohort had the highest percentage of patients that were diagnosed with smoking ( $p=0.3$ , from Table 3), which had an OR of 1.7 ( $p=0.035$ , from Table 4) for the excessive post-fusion OPR use outcome, the highest mean Elixhauser comorbidity score ( $p=0.96$ , Table 3), the highest percentage with depression ( $p=0.09$ , Table 3), and the highest percentage in the fourth quartile of pre-fusion OPR use ( $p=0.20$ , Table 3) OR of 120 ( $p<0.0001$ , Table 4) for excessive post-fusion OPR use, of the four fusion type cohorts. In addition, the OPMI cohort had the second highest percentage of the diagnosis of repeat fusion ( $p=0.046$ , Table 3) and diagnosis of obesity ( $p=0.76$ , Table 3). It appears that the pain acuity and comorbidity of the OPMI patients was greater than that of the other cohorts. We attempted to address this by adjusting for age, comorbidity, smoking, depression, and indication.

In our study, being coded as smoker in the medical billing had an OR of 1.74 for being dispensed  $>364$  days of OPRs. Smoking has previously been noted to be a predictor of poor outcomes from lumbar fusion, using Oswestry Disability Index, non-union (fusion), and patient satisfaction as outcome measures.<sup>19,22,56,59</sup>

Smoking has been associated with death from OPR poisoning in WC patients and especially in those with back conditions. Franklin, et al. studied poisoning deaths of WC patients from OPRs in Washington State between 1996 and 2002. Among those who died from OPR poisoning, 69% were smokers and 62% were being treated for low back pain (this study did not address surgical status).<sup>29</sup>

Policy seems to be the most effective way to deal with smoking at this point. Cheng, et al., in a study of payer policy, noted that Cigna does not cover fusion unless the patient has been a non-smoker for six weeks.<sup>77</sup> The Washington State Department of Labor and Industries (workers comp) considers continued smoking to be a relative contraindication to lumbar fusion.<sup>78</sup> As smoking is associated with worse outcomes from lumbar fusion, whether measured by ODI, satisfaction, non-union, or duration of OPR use, and is associated with death from OPR poisoning, it is evidence based to include current smoking status in guidelines and payer policies for lumbar fusion with degenerative indications and repeat fusions.

## **LIMITATIONS**

Limitations of this study are primarily the nature of the data being used, that is, insurance claims data. For example, the diagnostic categories of smoking, obesity, and depression are based on the provider coding for these conditions rather than us asking the patient whether he/she smokes, measuring the subject's BMI, or performing a psychometric assessment as could be done in a prospective clinical trial. In most cases for these diagnoses, we suspect that these diagnostic categories are under reported. Not having a non-surgical control group precludes observations on whether overall fusion increases or decreases OPR use. There are a myriad of diagnoses and variations that this study has not taken into account.

Likewise, there are many variations in the way a lumbar fusion can be performed, beyond what was studied here, including the source of the bone graft for the fusion, the use of bone morphogenic protein, and a wide variety of instrumentation that is frequently used. Some of the variations in surgical technique can be determined from coding; some cannot. For all types of minimally invasive fusions in 2009, there was only one CPT code for one minimally invasive lumbar fusion type that was not found in our data set. Clearly, fusions done on an outpatient basis are non-invasive; however, there were likely some in the other groups as well that, due to a lack of precision of coding, could not be taken into account. In subsequent years, new codes have been approved, so re-evaluation of OPR use long term after minimally invasive fusion should be undertaken.

Possible reasons for missing values for OPR dispensing (from insurance data) include not actually having the medication prescribed or dispensed, being covered also by other insurance not in the database, being eligible to receive prescription medication from a VA or military facility free of charge, and paying cash for the medications.

This study used days of OPRs dispensed over a two-year period, but it did not measure number of months without an OPR being dispensed or the morphine equivalents per day dispensed. Due to the mandatory follow-up period for inclusion, this study does not take into account those who died from OPR use (now responsible for more deaths per year than motor vehicle accidents and suicides combined), traumatic deaths related to or occurring while the patient was under the influence of OPR, or those who lost insurance as a consequence of a downward socio-economic spiral from OPR abuse.<sup>3,79,80</sup>

## **STRENGTHS**

The strengths of this study are its sample size—the sample comes from approximately 2% of the US population—and that it is generalizable to working age



adults with commercial insurance, not involved with a WC claim. Furthermore, this study represents real world patients and health care delivery across a broad geographic region.

## **FUTURE DIRECTIONS**

When studying lumbar fusion using claims data, one can evaluate pre- and post-fusion OPR usage relatively simply if the set includes pharmacy data. This is an objective measure that can be generalized to pain relief and well-being after fusion and should be included in most studies of lumbar fusion, just as comorbidity scores such as the Elixhauser or Charlson are. This methodology should be refined and repeated in other data sets, particularly databases which reflect systems of health care delivery, such as comparing commercial insurance, with closed systems such as staff model Health Maintenance Organization, the Veterans Affairs, and the Department of Defense. Comparing rates of fusions in populations and rates of OPR dependence after fusion by style of health care delivery system could lead to improvement in the delivery of spine care to populations and help to address our OPR use and death epidemic.

Patients, clinicians, payers, and policy makers should ponder the rationality of continuing to go forward with lumbar fusion surgeries on patients who have had more than 266 days of opioid pain relievers dispensed in the previous year. These patients face a risk 120 times greater risk of a poor outcome compared to patients dispensed less than 24 days of OPRs. This is especially true since a 24-day supply of OPRs can be up to 192 hydrocodone and acetaminophen pills and can last substantially longer than 24 days. There are a body of literature and guidelines forming which suggest that OPRs are not rational therapy for low back pain and that getting patients off OPRs is the rational path to pursue.<sup>10,81-84</sup>

Finally, the PI reviewed five pages of a Google search and a PubMed search on patient education materials for lumbar fusion. One of the complications of lumbar fusion

listed was pain of uncertain duration and incomplete resolution of pain. None of the patient education materials listed risk of chronic OPR use or dependence. Based on this and other studies, patients should be informed that they run a significant risk of taking OPRs for more than one year post-lumbar fusion.

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## Vita

Colonel Joseph Connolly, III is a Resident in Aerospace Medicine at the US Air Force School of Aerospace Medicine. He served as Commander, 354th Medical Operations Squadron (MDOS), Eielson AFB, AK from June 2009-June 2012 and Deputy Commander 354 Medical Group (MDG) from July 2010-June 2012. The 354 MDOS consists of 110 military and civilian personnel generating 31,000 patient visits a year. In 2012, the 354 MDG was rated Outstanding on the Health Services Inspection overall and on Aerospace Elements.

Col Connolly is certified in Neurology by the American Board of Psychiatry and Neurology, and was a fellow of the American Association of Neuromuscular and Electrodiagnostic Medicine\*. Before entering the Air Force, Dr Connolly served on the Board of Governors of the Washington Osteopathic Medical Association and practiced at the Everett Clinic, where he was a pioneer of “drop-in group medical appointments.” While at Ramstein AB, Germany, Dr Connolly served as the USAFE NASA Medical Support Coordinator and 86 CRG Expeditionary Medical Flight Commander. Dr Connolly served as the Chief of Aerospace Medicine at Aviano AB, Italy, which was chosen as the 2008 USAF Team Aerospace by the Air Force Medical Service. Col Connolly has deployed to South America and Africa in support of a variety of humanitarian, theater security cooperation, and Global War on Terrorism missions, including counter-narcotics support, peacekeeping force insertions, multinational and joint service exercises, Medical Civic Action Projects, and POW and American citizen repatriation/evacuation.

## **EDUCATION**

1985 Bachelor of Science degree, Biology, Biola University, La Mirada, CA  
1986 Army Medical Department Officer Basic Course, Fort Ord, CA  
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## **FLIGHT INFORMATION**

Rating: Flight Surgeon  
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Aircraft flown: F-16D, C-12U, C-130E, C-130H, KC-135R, KC-10A, C-17A, C-26B

## **MAJOR AWARDS AND DECORATIONS**

Meritorious Service Medal with second oak leaf cluster  
Joint Service Achievement Medal  
Air Force Achievement Medal

\*Through 2007

This capstone was typed by Joseph Connolly, III, with editorial assistance from Laurie Bowers Connolly.

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