The Impact of the Federal Schedule II Prescribing Mandate on Opioid Prescribing Practices within a Dental School Setting

by

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Abstract

Introduction:

Opioid analgesic drugs prescribed for pain have the potential for misuse and addiction. In 2011, dentists prescribed 12% of the total prescriptions written in the United States for immediate release opioids, particularly hydrocodone and oxycodone. In October 2014, a federal mandate reclassified hydrocodone combination products as Schedule II drugs requiring a written prescription. Reclassification assumed a subsequent change in provider prescribing habits. The aim of this study was to evaluate the opioid prescribing practices and the impact of the federal mandate on prescribing at the Graduate Endodontic Clinic, Oregon Health & Sciences University (OHSU) School of Dentistry.

Materials and Methods:

A retrospective electronic health records (axiUm®) review (OHSU IRB # 00018567) was conducted of opioid prescribing practices from November 2010 to August 2018. Data collected on the date of the prescribing visit were patient age, gender, tooth location, Common Dental Terminology (CDT) code, pulpal and periapical diagnosis, pain level, type of opioid, opioid prescribing rates (number of tablets, dose and frequency), prescribing dental provider code, and day of the week prescribed. CDT codes were grouped into procedure groups (problem focused exam, root canal therapy, root canal retreatment, apicoectomy, pulpal debridement and other). Data were described using counts and percentages (prescription rate). Associations between the data sets were determined by chi-square analysis, and mean differences by ANOVA. Logistic regression analysis and multivariable analysis were used to determine significance in the data before and after the mandate.

Results:

The total number of patients meeting the inclusion criteria was 4,851. The majority of patients seen were not prescribed opioids (92%). Overall, opioid prescribing rates (prescriptions per completed endodontic procedures) before and after the mandate differed significantly ($P < 0.001$); 7.5% before (228/3021) versus 4.0% after (192/4820). The odds ratio for prescribing an opioid was 1.75 times higher before the mandate compared to after. The prescription rate decreased significantly after the mandate and from year to year ($P < 0.001$) with an increasing trend in prescribing between 2011 and 2014 and a decrease in rate each year after the mandate. Hydrocodone with acetaminophen was the

most prescribed opioid (392/509). The number of tablets prescribed did not differ before versus after the mandate ($P = 0.56$). There was a significant trend due to age ($P = 0.0013$) with peak percentages in 30 year-olds. Females were more likely to receive an opioid prescription ($P = 0.0236$). Among procedure groups, patients who underwent apicoectomies were the most likely to receive an opioid prescription ($P < 0.0001$) and problem focused exams rarely received a prescription. Before the mandate, prescription percentages increased during the week (Monday 6%, Wednesday 7.2%, Thursday 8.2%, Friday 8.2%; $P = 0.0015$) while after the mandate the percentage decreased or stayed flat (Monday 4.8%, Tuesday 4.1%, Wednesday 3.6%, Thursday 3.6%, Friday 3.8%). There were no correlations between receiving an opioid prescription and either pulpal diagnosis ($P = 0.4024$ chi-square) or periapical diagnosis ($P = 0.8476$ chi-square). There was no correlation between receiving an opioid prescription and the pain level reported (chi-square $P = 0.2857$); 49.4% of patients received a prescription in the absence of pain (25.7%) or when experiencing only mild pain (23.7%), compared to 33% of patients with severe pain receiving a prescription.

Conclusion:

An overall reduction in opioid prescribing rates occurred after the federal mandate. Among graduate endodontic providers in the dental healthcare setting at OHSU, the prescribing rate reduction was coincident with the federal mandate of 2014. Lack of correlation with prescribing practice and pain level highlights the need for prescribing protocols that are evidence-based rather than habitual.

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Chapter 1. Literature Review and Purpose of the Study

1.1. Opioid analgesics

Opium extracted from the poppy seed has been utilized since early civilization for pain management. In the early 1800's the active ingredient in the poppy seed, morphine, was isolated (1). Since then, synthetic opioids with similar analgesic effects have been developed, such as oxycodone and hydrocodone, which are used in operating rooms, and for post-surgery analgesia and the management of chronic pain. However, prescription opioids analgesics have also been associated with abuse, misuse and addiction.

Opioids have strong analgesic properties. The interaction of the opioid with anti-nociceptive receptors is responsible for elimination of the perception of pain. There are 3 types of receptors: mu, delta, and kappa. The actions of these receptors give the effect of analgesia (2). The mu and delta receptors facilitate the inhibition of adenylate cyclase and the activation of the inward potassium channels. Kappa and delta receptors have demonstrated the capability of inhibiting the voltage dependent calcium channels (1). The major effects of the agonists on the 3 receptors are as follows: mu receptors agonists give the effects of analgesia, respiratory depression, miosis, reduced gastrointestinal motility, nausea, vomiting, and euphoria. Delta receptor agonists give supra-spinal analgesia. Kappa receptor agonists have the effect of analgesia at the spinal level, miosis (weak), respiratory depression (weak) and dysphoria (1). There are two categories of opioid analgesics, immediate release and extended release or long acting. The immediate release opioids have an effect time between 4 and 6 hours whereas the extended release opioids can be effective for 12 to 24 hours (3, 4).

In the hospital setting opioids are commonly used in anesthesia, surgical and post-surgical care, following trauma and for burn care, palliative care, cancer and terminal illness. In outpatient settings, opioids are prescribed in emergency departments, physician's offices, rehabilitation facilities, and for hospice care. It has been estimated that roughly 100 million Americans deal with pain each year and 9-12 million live with chronic pain for which they receive opioid prescriptions from their primary care physician (5). Patients may have multiple providers from whom they are obtaining opioid prescriptions (6). In a cohort study of 169 million patients who received prescriptions written for opioids for chronic pain management from 2003-2014, the vast majority of opioids being prescribed were immediate release (96%) (7). The frequency with which these drugs have been prescribed to manage outpatient chronic non-cancer pain is considered to have been a major contributory factor to the ongoing nationwide "opioid crisis" in the United States (U.S.) (4, 8).

It is not uncommon for the dental office setting to be where people are first prescribed opioid analgesics. Earlier this decade, 12 percent of all the immediate release opioid analgesics were reported to be written by dentists (9, 10). For young adults, surgery to remove impacted wisdom teeth is commonly the first exposure to opioid containing medications used for intravenous sedation and post-operative pain management (11). In a retrospective study of Tennessee Medicaid children and adolescent patients from 1999-2014, 1,306,503 opioid prescriptions were written for children aged 2-17 years, of which 31% were for dental procedures (12). A review of the Truven Health MarketScan database found that of 70,942 patients aged from 13-30 years who had wisdom teeth extractions, 56,686 filled prescriptions for opioid analgesics. Importantly, after controlling for patient characteristics, a filled perioperative opioid prescription was associated with an adjusted odds ratio of 2.60 for persistent opioid use (13). Even if usage of opioids for the management of pain is limited to short term, taking an opioid prescription for only 5 days significantly increases the chance of developing a long-term opioid dependence. This in turn leads to an increased risk of eventually developing an addiction and the possibility of an overdose (14).

1.2. Addiction to opioids

Throughout the history of opioid use there has been documentation of their potential for abuse and addiction (1). Nonetheless, an article published in 1980 in the New England Journal of Medicine reported that in patients without a history of addiction who were treated in a hospital setting for pain with narcotics, addiction rarely occurred (15). Further, a 1986 case series that followed 38 patients with chronic pain treated similarly, reported an absence of addictive properties by oxycodone (16). In 1996, advertising and marketing by Purdue Pharma (Stamford, CT), claimed that a new synthetic opioid, OxyContin (Purdue Pharma, Stamford, CT), had a very low addictive property due to its extended release properties. It has been suggested that these studies gave the pharmaceutical industry the ammunition they needed to advertise new products as no longer holding the same addictive characteristics as their predecessors (17). Subsequently, a survey from the U.S. Centers for Disease Control and Prevention showed that, from 1999 through 2011, hydrocodone consumption had more than doubled, and oxycodone consumption had increased by nearly 500% (18). Further, an analysis of the 2015 National Survey on Drug Use and Health estimated that 91.8 million U.S civilians used prescription opioids, of which 12.5% subjects reported misuse with 63.4% of these subjects reporting the misuse was to relieve physical pain (19). Correspondingly, the number of overdoses leading to reported hospitalizations and deaths increased dramatically; in 2014 it was less than 30,000, in 2015 it was less than 35,000, but by 2016 opioid related overdose deaths were 42,249. In 2017 overdose deaths reached 49,068 (20).

In 2016 the Oregon Health Authority reported that an average of three Oregonians die every week from prescription opioid overdose (21). An analysis of prescription drug monitoring programs (PDMP) data in Oregon from October 2011-October 2014 found significant differences in opioid prescription profiles and opioid-related hospitalization and mortality among patients receiving opioid prescriptions from nurse practitioners, naturopathic physicians, or medical clinicians in Oregon. However, these differences were considered to be attributable to differences in patient mix between provider types rather than discipline-specific prescribing practices (6). Noteworthy was that patients of Nurse Practitioners or Naturopathic physicians were also more likely to have four or more prescribers.

1.3. Federal Schedule II prescribing mandate on opioid prescribing practices

Ironically, and in contradistinction to the above, while overdose deaths have increased there has been an overall reduction in the rates of opioid prescribing between 2006 and 2017 according to the recent CDC Surveillance Report (22). This trend could be attributable in part to the U.S. federal government's involvement with the opioid crisis and subsequent changes that came into effect on October 6th 2014 (23), at which time hydrocodone combination products were reclassified from Schedule III to Schedule II controlled substances. In addition, refills would no longer be permitted for hydrocodone combination products, and Schedule II drug prescriptions could no longer be called-in or faxed to the pharmacy. The mandate decreed that patients would need a hard copy of the prescription as part of the order. Between 2006 and 2017, the annual prescribing rate per 100 persons decreased from 72.4 to 58.5 for all opioids, which is an overall relative reduction of 19.2% (22). Still, according to the CDC, 56,935,332 persons, or 17.4% of the population, filled at least one prescription for an opioid and a total of 191,146,822 opioid prescriptions were dispensed by retail pharmacies.

1.4. Oregon Health & Science University (OHSU) Graduate Endodontic Clinic (GEC)

The GEC is a referral-based clinic that provides endodontic services to patients referred by predoctoral students and dentists in the dental school, and general dentists in clinics throughout Oregon and southwest Washington. The GEC also provides educational opportunities for predoctoral dental students and trainee dental assistants who rotate through the clinic. Starting in 2010, electronic health records (EHRs) for patients were phased into use in the GEC and have been continuously maintained with the proprietary dental patient management system axiUm® (Exan, Henry Schein Company, Coquitlam, BC). The patient population of the GEC includes patients enrolled in Medicaid dental benefits plans, patients covered by private insurance plans and those who self-pay. The dental provider enters all prescriptions written into the axiUm® patient EHR.

With the heightened awareness of the impact the opioid crisis has on the community at large, and the potential role of dentistry in its development, it is timely to evaluate the impact of federal policy decisions on opioid prescribing patterns in an educational setting in Oregon where future dental professionals are trained. No data could be found that evaluated the impact of the Federal Schedule II Prescribing Mandate implemented in 2014 on opioid prescribing practices in a university-based endodontic graduate clinic by screening electronic health records (EHRs).

1.5. Purpose and aims of the study

The overall purpose of this study was to evaluate the impact of the Federal Schedule II Prescribing Mandate on opioid prescribing practices in the GEC following its implementation in October 2014 by conducting a retrospective review of EHRs from patients who attended the GEC and were treated by graduate endodontic residents between 2010 and 2018.

The specific aims were to obtain and compare EHR data recorded during time frames of equivalent duration before and after the mandate about:

(1) Opioid prescribing practices according to:

1. Date (by year, month, day of week)
2. Unique dental provider
3. Patient factors (age, gender)
4. Endodontic procedures associated with a prescription
5. Quadrant of the mouth
6. All factors (multivariate analysis)

(2) Opioid prescriptions provided according to:

1. Medication prescribed
2. Number of tablets prescribed
3. Prescriptions per person
4. Diagnoses associated with a prescription (pulpal, periapical)

(3) Associations between pain levels and opioid dosage

The null hypothesis was that there would be no difference between before and after the mandate.

Chapter 2. Materials and Methods

The study was reviewed and declared exempt by the OHSU Institutional Review Board (IRB# 00018567). A de-identified EHR database review was conducted of opioid prescriptions written by graduate endodontic residents for patients attending the GEC who received treatment as defined by the Code on Dental Procedures and Nomenclature Current Dental Terminology (CDT).

Dental Informatics at the School of Dentistry prescreened EHRs for eligibility. Baseline data were obtained on the number of patients who attended the GEC during the study periods. Baseline frequency data on completed codes were obtained for all patients seen/treated by residents in the Graduate Endodontic Clinic at OHSU School of Dentistry. The axiUm® database was queried for all prescriptions written for any and all opioid drugs within the GEC since the inception of EHRs.

2.1. Pilot study

A pilot study was conducted to: (i) verify that the EHR documentation contained information that would be reproducible and not open to interpretation. (ii) identify the starting date for EHRs eligible for inclusion in the study, and (iii) identify inclusion and exclusion criteria to determine eligible EHRs.

Twenty EHRs selected at random were reviewed throughout the span of the 9 years starting in January 2010 when EHRs were first phased into use in the GEC up until August 2018, the assigned terminal end point of data collection. There were at least 2 EHRs reviewed for each year of data. Four EHRs were reviewed in 2010 to determine if the documentation during the transition from paper records to EHRs was complete. There were some missing data in all EHRs; however, the vast majority was present with the exception of the initial data in 2010 being more likely to be incomplete than subsequent EHRs. For this reason, and to make the time frames equivalent in length, the start date for reviewing EHRs was set at November of 2010, 10 months after the introduction of EHRs to the GEC.

2.1.2. Inclusion and exclusion criteria

Based on the results of the pilot study the inclusion and exclusion criteria were established as:

Inclusion criteria: The EHRs of all patients for whom opioid prescriptions were written and who received treatment as defined by CDT code were included [D0140, D3320, D3221, D3310, D3320, D3332, D3333, D3346, D3347, D3348, D3410, D4321, D3425, D3426, D3427, D3450, D3470 and D3920] (Table 1).

Exclusion criteria. Cases where prescriptions were written for patients receiving treatments coded for D3355, D3356, D3357 (pulpal regeneration procedure codes), and D3351, D3347, D3348 (apexification/recalcification procedures codes) were excluded from the study. D3355, D3356 and D3357 are dental codes recently added to the CDT list in 2011 for pulpal regeneration, and were not in use throughout the entire study period. All six of these codes are utilized more frequently in patients less than age 18. All patients less than 18 years or greater than 89 were excluded from the study.

2.2. EHR data extraction

The following data were extracted from eligible de-identified EHRs:

1. Date of treatment (by year, month, day of week)
2. Prescribing dental provider code
3. Patient demographic data (age, gender)
4. Endodontic procedure associated with prescription
5. Tooth type (quadrant of mouth)
6. Opioid medication prescribed
7. Number of tablets (dosage and frequency)
8. Prescriptions per person
9. Pre-operative diagnosis (pulpal and periapical)
10. Pain level [no pain, mild (1-4), moderate (5-6) and severe (7-10)]

Data were retrieved for the period from November 2010 through August 2018. The "before mandate" period ran from November 12th 2010 - October 6th 2014. The "after mandate" period ran from October 7th 2014– August 31st 2018. Each period covered 1,424 days (47 months) either side of implementation of the Federal Schedule II Prescribing Mandate.

2.3 Statistical analysis

The data were described by counts and percentages or means and standard deviations, as appropriate. The primary outcome variable was whether an opioid prescription was issued as a result of a particular procedure on an individual tooth. The prescription rate was calculated as the number of prescriptions divided by the number of procedures (times 100, to yield a percentage).

Associations between groups were initially determined by chi-square analysis and mean differences by ANOVA. The primary binary outcome was the presence or absence of an opioid prescription associated with the dental procedure recorded in the patient's chart. Initial data analysis used logistic regression to determine whether there was a difference in prescription percentage before and after the mandate, and also due to the other variables of interest. After each of the variables were considered one at a time, those significant were included in a multivariable logistic regression. Variables not remaining significant were removed in order to describe all of the factors which jointly were associated with prescription percentage. All analyses were performed using SAS software (SAS 9.4, JMP Pro 14.1, SAS Institute Inc., Cary NC). Significance was declared at the alpha < 0.05 level.

Chapter 3. Results

Of the 4851 unique individuals eligible for the study the vast majority (92.2%) were not prescribed opioids during the study period (Table 2). Of the 380 prescribed an opioid prescription, 50.8% of the patients were seen for a single procedure. There were 21 individuals who were not patients of record in the GEC but were patients of record in the School of Dentistry and were treated by the resident at OHSU and prescribed an opioid.

There are three main sections in the report of the results.

1. Opioid prescribing practices
2. Opioid prescriptions
3. Associations between pain levels and opioid dosage

3.1. Opioid prescribing practices

This section describes the cases in terms of the number of procedures and the number of prescriptions. The subsections describe the differences across time, between providers, according to age, gender, endodontic procedures and quadrants of the mouth. These one-variable-at-a time differences are then combined into a single multivariable model to describe joint differences.

3.1.1. Date of treatment

3.1.1.1. Year

The primary aim of the study was to assess whether the prescription rate changed after the implementation of the federal mandate in 2014. Table 3 shows the number of procedures performed during each year, before and after the federal mandate. It should be noted that the number of procedures changed across time (Figure 1). 2010 and 2018 were only partial years and 2014 was split between the months before and after the mandate was issued. Generally speaking, the number of procedures performed during the study period was greater after 2014. Overall, before the mandate 7.5% of the cases were associated with an opioid prescription (228 prescriptions out of 3021 procedures) and after the mandate the percentage was 4.0% (192 out of

4820). There were 420 unique procedures which resulted in the total of 509 prescriptions written for opioid analgesics.

Since the number of procedures varied during the study period, it was important to calculate the number of prescriptions as a rate per procedure. Figure 2 shows the prescription percentages per year before and after the federal mandate. A logistic regression analysis showed a significant decrease after the mandate ($P < 0.001$) and also significant year to year differences ($P < 0.001$). Figure 2 shows the 95% confidence intervals on the estimates, with wider limits evidenced in years with fewer procedures. Between 2011 and 2014 there was an increasing trend in prescription rate. The prescription rate decreased each year after the mandate.

In an academic clinic, there are variations in the patients seen from month to month. Figure 3 shows the number of procedures for each month during the study period with a smoothed line derived from a model that includes the yearly and monthly averages. The average number of procedures was smoothed by modeling the yearly increase and the monthly averages. Within a year, the number of procedures increased and peaked in April. The summer months, especially July, were lower, as were the months of November and December (Table 4). The logistic regression results show that the prescription rate before the mandate was significantly higher than after mandate ($P < 0.001$). There were no significant monthly differences within each subgroup ($P = 0.117$), nor across the before and after study periods (interaction $P = 0.406$) (Figures 4 and 5).

3.1.1.2. Year and Month

The month by month prescription percentage during each month of the study period is shown in Figure 6. The before versus after mandate is represented by a break in the line. The numerical estimates are shown in the Appendix (Table 22).

3.1.1.3. Day of the week

Ignoring the three procedures done on the weekend, the number of procedures varied greatly according to day of the week (Table 5) (Figure 7). On Tuesdays patients are not normally scheduled for treatment in the GEC except for emergencies. After the mandate, there were larger number of procedures performed on Monday or Friday. The logistic regression results showed a significant day of the week difference (P = 0.0015) and that these differences were not consistent across the study period (interaction P < 0.001). The different daily prescription averages are shown in Figure 8. Generally, before the mandate, prescription percentages seemed to increase during the week while after the mandate the percentages either decreased or were flat.

3.1.2 Dental providers

Thirty unique providers were included in this study. In Table 6 they are ordered according to when they first provided patient care. In the table, the number of procedures is counted as well as whether they were accompanied by an opioid prescription, and the prescription percentage was calculated. The information is presented in Figure 9 on a per month basis; the study period is shown on the horizontal axis and each provider's monthly practice is represented by a colored dot. The size of the dot is proportional to the number of procedures performed during the month and the color of dot represents the percentage of procedures that were accompanied by a prescription. The date of the federal mandate is represented by a vertical line. Providers at the bottom of the figure practiced solely before the mandate. These pre-mandate providers issued opioid prescriptions approximately 8% of the time. Providers in the middle practiced both before and after the mandate was issued and these providers issued prescriptions slightly less than 8% of the time. Providers at the top-right practiced after the mandate and these providers prescribed opioids 2.5% of the time. The figure highlights that there are more large-red dots in the left side of the figure (representing a higher prescription likelihood) and more large blue dots on the right side of the figure (representing a lower prescription likelihood). Since there are few providers who practiced during the change, it is problematic whether the change across time can be attributed to the effect of the mandate or the effect of differing providers.

3.1.3. Patient demographics – age and gender

The average age was 45.6 years (SD 17.0, range = 18 to 95). There were more procedures completed in patients 40 years and older (Table 7 and Figure 10). The logistic regression results showed that the prescribing percentage peaked in patients in their 40s (P < 0.001) and that this was consistent between whether the patient was seen before or after the mandate ($P > 0.4$) (Figure 11).

Females comprised 57.5% of patients who received opioid prescriptions. Logistic regression results show there was a difference between before and after the mandate ($P < 0.001$) and gender ($P < 0.025$) with females more likely to receive a prescription (Table 8) (Figures 12 and 13).

3.1.4. Endodontic procedures associated with prescription

The CDT procedure codes were grouped into six categories; 1) limited oral evaluation, 2) RCT, 3) retreatment RCT, 4) apicoectomy, 5) pulpal debridement, and 6) other. The number of procedures by procedure group and prescription percentage by procedure group are shown in Figures 14 and 15. The logistic regression analysis showed a significant difference in prescription percentage before and after the mandate ($P <0.001$) and between procedure groups ($P < 0.001$) (Table 9). Within procedure groups, there was no significant difference between before and after the mandate, with the exception being an increase in the number of RCT after the mandate ($P < 0.001$) (Figure 14)

3.1.5. Quadrant of the mouth

Each procedure was associated with a tooth number which was indicated in the chart record. These tooth numbers were classified into quadrants. Procedures without tooth numbers were labeled as “whole mouth” for the purposes of analyses (Figures 16 and 17). Logistic regression results showed no significant associations between quadrants and prescription percentages before and after the mandate (Table 10).

3.1.6. Opioid prescribing practices: Multivariable analysis of prescription percentage

In all of the above analyses a single factor was considered, along with the before versus after mandate differences. This screening of factors identified potential predictors to be included in a multivariable logistic regression. A multivariable logistic regression was considered with the following potential predictors: mandate (before versus after), year within mandate, month, day of the week, age (decades), gender, procedure group, and quadrant. Month ($P = 0.1580$) and quadrant (P = 0.0641) were not significant after the other effects were accounted for. After adjusting for all other factors, there was clear indication that the prescription percentage decreased after the mandate (P = 0.0033) and that both before and after the mandate there were significant year to year differences (P < .0001) (Table 11). In the graduate endodontic clinic, there was a significant day of the week effect (P = 0.0250) due to the higher prescription percentage on Tuesday (Figure 18). There was a significant trend due to age (P = 0.0013) with the peak percentage occurring in 30-year olds. Females were more likely to receive an opioid prescription (P = 0.0236). By far, cases of root end surgery (apicoectomy) were more likely to receive a prescription and the cases of a limited problem-focused exam rarely received an opioid prescription (P < 0 .0001).

The odd-ratios and estimated prescription proportions derived from the full model are shown in Table 12. The odds of an opioid prescription were 1.75 times more likely before the mandate compared to after the mandate (95% CI = 1.36 to 2.25). Before the mandate, 3.9% of all cases were associated with an opioid prescription (95% CI = 2.6 to 5.5%) and after the mandate this had decreased to 2.2% (95% CI = 1.5 to 3.4%).

3.2. Opioid prescriptions

In this section, the prescriptions are described and any differences associated with the federal mandate are described. A number of additional characteristics were recorded for prescriptions and not for the procedures. These characteristics were: medication prescribed (by generic name), dosage, number of tablets, written at an emergency appointment, written or phone prescription, pain levels, pulpal diagnosis and periapical diagnosis. Since the prescription percentage could not be calculated using these data, only an association with the federal mandate is reported.

3.2.1. Medications prescribed

A total of 509 prescriptions were written for 380 individuals during the study period. Table 13 shows each drug and dose combination with its morphine milligram equivalents (MME). Hydrocodone with acetaminophen was the most prescribed medication (n = 392, or 77%). The number of prescriptions is shown in the first set of columns and the number of tablets in the second set of columns. The last column shows the total MME per prescription (MME/p) prescribed, which was calculated by multiplying the MME times the number of prescribed tablets. Only 6.7% of all prescriptions were phoned in; none were faxed. A total of 25 prescriptions were phoned in before the mandate and 9 prescriptions were phoned in after the mandate. Before the mandate 72% (18/25) of the phoned in medications were for hydrocodone with acetaminophen, 8% (2/25) for oxycodone with acetaminophen, 16% (4/25) for tramadol and 4% (1/25) for codeine with acetaminophen. After the mandate 88.9% (8/9) were for tramadol and 11.1% (1/9) were for codeine with acetaminophen. There was a significant association between medication prescribed and the mandate (chi-square; P = 0.0234); tramadol was significantly more likely to be prescribed after the mandate (3.7% of prescriptions before versus 11.0% after) (Table 14).

3.2.2. Number of tablets prescribed

Between 3 and 40 tablets were prescribed across all the occasions. The number of tablets varied according to the opioid prescribed (ANOVA; P = 0.0008) (Table 15), but did not vary depending upon whether the prescription was issued before or after the mandate (P = 0.56). A post hoc comparison of the means, using Tukey's HSD, indicated that oxycodone and hydrocodone prescriptions were issued with fewer tablets than Tramadol.

3.2.3. Prescriptions per person

The number of prescriptions per patient is shown in Table 16. The substantial majority of patients only ever received a single prescription. There was no significant difference in the number of prescriptions depending upon the mandate (chi-square; P = 0.86).

3.2.4. Diagnoses associated with prescription (pulpal and periapical)

No associations were found between the mandate and either the pulpal diagnosis (chi-square; P = 0.4024) (Table 17) or periapical diagnosis (chi-square; P = 0.8476) (Table 18).

3.3. Associations between pain levels and opioid dosage

In this section, the associations between pain levels and opioid dosage are described.

3.3.1. Pain levels and opioid prescription

Pain at the time of the prescription was recorded either on a 0 to 10 scale or was described in the EHR as “none”, “mild”, “moderate”, or “severe”. For the purpose of analysis, the four text-descriptions were used. Numerical pain levels were not documented 38.5% of the time (196/509); on those occasions pain was categorized by using the subjective descriptions described by the patient to the provider. Only 33% of all the prescriptions were associated with severe pain (Table 19). There was no significant difference between the pain levels reported before and after the mandate (chi-square; $P = 0.2857$) (Table 20).

3.3.2. MME/prescription (MME/p)

Multiplying the prescription MME times the number of tablets yielded an estimate of the total MME per prescription. Before the mandate, the average was 77.0 MME/p (median = 60, SD = 32.1, range = 27 to 225) and the average after the mandate was 75.3 MME/p (median = 69, SD = 32.1, range = 15 to 210). As Figure 19 shows, the per prescription pattern of opioid dosage was not significantly different (t-test; $P = 0.59$).

3.3.3. Pain levels and opioid dosage (MME/p)

The total MME/p was associated with the pain level at the time of the prescription (ANOVA; $P < 0.0001$) (Figure 20). Those reporting severe pain received an average of 86.6 MME/p, moderate pain received an average of 80.1 MME/p, mild pain an average of 66.4 MME/p, and no pain an average of 71.7 MME/p.

There was a significant association between the procedure performed and the pain level recorded (chi-square; $P < .0001$) (Table 21, Figure 21). As Figure 21 shows, severe pain was more commonly associated with the limited oral evaluation, an endodontic retreatment, and possibly, a pulpal debridement (though the sample is small). Root end surgery was associated with no or mild pain at the time of a prescription. A two-way ANOVA using procedure group and pain level indicated a significant difference in total MME/p depending upon procedure group ($P = 0.0449$) and pain level ($P < 0.0001$) (Figure 22).

Chapter 4. Discussion

The purpose of this study was to evaluate the impact of the Federal Schedule II prescribing mandate on opioid prescribing practices in the GEC following its implementation in October 2014. After adjusting for all other factors, the data clearly showed that the prescription percentage decreased from 3.9% before the mandate to 2.2% after the mandate ($P = 0.0033$). The odds of an opioid prescription were 1.75 times more likely before the mandate compared to after the mandate (95% CI = 1.36 to 2.25). The null hypothesis was rejected.

It is important to note the existence of additional potential variables that were not evaluated and which could have contributed to the reduction in opioid prescriptions after the mandate. For example, over the period there were 30 different providers participating as part of a 2-year residency program, making the question "is there a before versus after difference" confounded by "are providers different?". Other potential confounders are the staffing changes that occurred after the mandate, the timing of which correlates with the steepest reduction in prescribing rates (Figure 4). A challenge to documenting MME/day occurred because of the many different prescription signatura with the prescribed opioids attributable in part to having 30 different providers variably prescribe MME/day. Fortunately, there were adequate data to allow calculation of the MME/prescription which was used for analyses. Future studies would ideally identify the MME actually taken by the patient.

Being a retrospective study, the quality of the data retrieved was dependent upon the accuracy of documentation in the EHR by providers. It should be noted that on occasion, the chart reviewer was required to "interpret" the information given. For example, just over one third of providers did not document numerical pain levels; on those occasions, to allow data analysis, pain was categorized by using the subjective descriptions described by the patient to the provider. Mild pain was attributed if the patient stated something along the lines of "my tooth feels better but it is still a little tender" or "my tooth just doesn't feel quite right and I have not needed to take any medication for pain relief." Examples of moderate pain attributes were "My tooth hurts to chew on and I have avoided that side when I eat. I take the ibuprofen and acetaminophen and the pain goes down to a level where it doesn't bother me but when the 6 hours are up the tooth starts to throb again." Severe pain attributes examples were "I cannot eat, sleep, or do anything, the tooth is throbbing. Nothing I do makes the tooth feel better. It just hurts all the time." The need for interpretation of these statements point to a further limitation of the study in that only one person reviewed and extracted data from the EHRs. It is noteworthy that the rationale for providing a prescription was not always consistently documented in the EHR. As a consequence, steps have been taken to ensure this is included in the documentation in the future; a GEC policy has been implemented requiring all opioid prescriptions to be reviewed and approved by faculty. In addition, documentation will be required of the rationale for opioid prescription and confirmation of the failure to achieve success with nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen regimen i.e. ensuring that opioids are rescue medications.

The major strength of the study is the comprehensive analysis of longitudinal data retrieved from EHRs recorded over an almost 8 years period. Beyond addressing the central question of the impact of the mandate of prescription rates, these detailed longitudinal data allowed additional sub-analyses to evaluate opioid prescribing practices, the types of opioid prescriptions provided, and associations between pain levels and opioid dosage (MME/p).

4.1. Opioid prescribing practices

Opioid prescribing practices were evaluated in terms of the number of procedures and the number of prescriptions across time, between providers, according to patient age and gender, by endodontic procedures and according to quadrants of the mouth. In addition to the reduction in prescription percentages after the mandate, there were significant year to year differences. The increasing trend observed from 2011 to 2014 until the mandate was implemented was followed by a decrease each year after the mandate (Figure 2). Overall, there was a significant trend associated with the age of the patients ($P = 0.0013$) with the peak percentage rate of opioid prescriptions occurring for patients in their 30s and 40s. In contrast, the rates for patients in their 70s and older were consistently lower than other age groups. Interestingly, gender played a role only after the mandate with females being more likely to receive an opioid prescription than males ($P = 0.0236$).

The only procedure to have a significant reduction in the rate of opioid prescription after the mandate was NS-RCT (from 7.6% to 4.2%). By far, cases of root end surgery were much more likely to receive a prescription, and patients presenting for a limited problem-focused exam rarely received an opioid prescription ($P < 0.0001$); these trends did not change with the implementation of the mandate. While the multivariate analysis showed the highest odds ratio for prescribing opioids occurred on Tuesdays, despite the relatively low number of endodontic procedures performed on this particular day, this finding can be explained by only emergency patients being seen on this day and who were consequently more likely to be experiencing pain.

The study showed that a substantial majority of patients (92.2%) attending the graduate endodontic clinic were never prescribed opioids over the duration of the study period. Similarly, a recent study describing a 2014-2017 longitudinal analysis of opioid prescribing by dentists in Manitoba, Canada, reported that the overall contribution of dentists to opioid overuse is limited; dentist prescriptions accounted for only 3.8% of all opioid prescriptions and 0.58% of total MME (24).

The EHRs of patients who did not receive an opioid prescription were not reviewed. It would be illuminating to evaluate the pain management protocols adopted and analgesics prescribed for this group of patients in a future longitudinal study. Endodontic therapy has typically utilized opioid analgesics as a rescue medication for post-operative flare-ups, and not as the primary source of analgesics. The use of a flexible prescription plan has been advocated for pain management to maximize analgesic effect while minimizing the side effects. In this plan, the maximum daily amount of the non-steroidal anti-inflammatory is taken before adding an opioid analgesic (25). In a recent overview of systematic reviews that had evaluated the risks and benefits of analgesics in dental pain, it was concluded that opioid medications, or their combinations, should not be utilized as the first line of defense in the management of acute dental pain. Opioids and their combinations were not the most effective or longest lasting analgesic in relieving acute dental pain. The authors' recommendation based upon the current literature for the management of acute dental pain was the use of nonsteroidal anti-inflammatory drugs, with or without acetaminophen (26).

Tooth pain initiated by reversible pulpitis is generally mild to moderate with non-lingering symptoms. Symptoms resolve with definitive dental treatment supplemented with ibuprofen or acetaminophen if needed. Irreversible pulpitis with symptomatic apical periodontitis can be progressively more painful, though the progression can also be pain free (27). As an emergency treatment to relieve pain, extirpation of coronal pulp tissue will resolve the majority of the symptoms; the completion of an emergency pulpotomy eliminated tooth pain in 96% of the patients who presented for a dental emergency appointment with irreversible pulpitis (28). In cases where root canal therapy is necessary, a recent systematic review and meta-analysis showed that taking ibuprofen and acetaminophen within hours of initiating root canal therapy adequately relieves pain of endodontic origin (29). The utilization of anti-inflammatories is typically the first line of analgesia (30). Ibuprofen, naproxen, and steroids would be utilized prior to prescribing opioids. The combination of ibuprofen with acetaminophen is an effective regimen for mild to moderate pain management due to their synergistic analgesic effect (31).

If the disease process is left unattended, severe pain can develop that may not be manageable with NSAIDs. However, in situations when severe pain occurs pre-operatively or post-treatment that requires an emergency appointment, it is not uncommon for a prescription to be written for an opioid analgesic. In patients with the pre-operative diagnosis of pulpal necrosis and symptomatic apical periodontitis associated with pain levels of moderate to severe, the post-operative effectiveness of ibuprofen and combined ibuprofen with acetaminophen were compared. Nearly 20% of both groups of patients required the escape medication provided (5mg hydrocodone with 500mg acetaminophen) (32).

4.2. Opioid Prescriptions

The types of opioid prescriptions provided in the GEC were evaluated with regard to the specific medication prescribed, the number and dosage of tablets, the number of prescriptions each patient received, and the pulpal and periapical diagnosis at the time of dispensing the prescription. Hydrocodone with acetaminophen was by far the most prescribed opioid medication (392 of the total 509 prescriptions, or 77%).

Tramadol was more common after the mandate (3.7% of all prescriptions before versus 11.0% after) (Table 14). Tramadol is a centrally acting analgesic with a structure related to codeine and morphine. It was first synthesized in 1962 and became available in the United States in 1995 (33). Analgesic properties of tramadol are due to the actions on the μ opioid receptors (which have a lower affinity than morphine) and the blockage of norepinephrine and serotonin reuptake. In 2014, tramadol was added to the list of Schedule IV medications. A written prescription is not necessary for Schedule IV medication and they can be phoned into a pharmacy. Increased tramadol prescribing after the mandate is potentially attributable to its status as a Schedule IV medication and to the ability to phone the medication into the patient's pharmacy. However, tramadol, being an opioid, has abuse potential. The DEA reports that 43 million prescriptions were dispensed in 2016 and that there were 5,712 single substance exposures with 3 associated deaths (34).

No prescribing changes were seen for the Schedule III drug codeine plus acetaminophen (Table 14). Although the number of tablets varied according to the opioid prescribed (ANOVA; P = 0.0008) (Table 15), there were no significant differences between before and after the mandate in the number of tablets dispensed for each type of opioid (P = 0.56). Not unexpectedly, there were no associations between the mandate and either the pulpal diagnosis (chi-square; P = 0.4024) (Table 17) or periapical diagnosis of patients attending the GEC (chi-square; P = 0.8476) (Table 18). Similarly, and as expected, there were no significant differences between the pain levels reported before and after the mandate (chi-square; P = 0.2857) (Table 20).

In the present study, hydrocodone in combination was the most prescribed opioid (77%). Similarly, an evaluation of insurance claims for all prescriptions written by dentists from 2010-2015 found that 63% of all the opioid prescriptions amongst dental providers was hydrocodone in combination (35). A surgical visit was associated with 68% of the prescriptions for opioids (35). The authors reported the mean number of tablets prescribed was 18 for non-surgical treatment, 20 for surgical appointments, 16 for pre-surgical appointments and 16 for post-surgical appointments. A separate survey conducted in 2013 of oral surgeons in the United States, found that only 2 of the 384 respondents reported not prescribing narcotics for impacted wisdom teeth extractions, with a mean number of tablets prescribed as 20 (36). The average number of tablets prescribed for the most commonly prescribed opioid (hydrocodone with acetaminophen) was 13.8 ± 4.8.

As is a common limitation with similar studies, while the EHR provided information on dosage and number of tablets, whether the patient filled the prescriptions and the number of tablets taken was unknown in this study. A nationwide survey of oral surgeons found the average number of tablets prescribed following third molar extraction numbered 20 (37), which would potentially cover a longer period than the expected duration of post-operative pain. Similarly, of the 33,348 dental providers in the United States who prescribed opioids to Medicare Part D beneficiaries in 2014, 56.9% prescribed a mean opioid days per claim greater than the recommended duration of 3 days for acute pain (38). The extra unused tablets become a potential source for diversion and misuse. A survey at Midwestern University Dental School found that 18.9% of patients seen during an admitting or emergency dental clinic appointment stated that they had taken prescription medications for pain relief, and 15% stated that they used prescription pain medication from a diverted source (39). Friends or family members with leftover or unfilled prescriptions following dental procedures are a potential source of opioids available for abuse. For example, following third molar extractions 54% of the filled opioids were left unused because by 3-4 days post-surgery the majority of patients were no longer experiencing pain (11). In the analysis of the 2015 National Survey on Drug Use and Health, 40.8% of adults self-prescribing pain medication reported that friends or relatives were their source (19).

In March 2018 the ADA adopted an interim policy regarding opioids and their use within the profession (40). The policy supports a requirement for mandatory continuing education on the prescribing of opioids and other controlled substances, and limiting the duration of opioid prescribing to no longer than 7 days for treatment of acute pain (thus reflecting the recommendations from the CDC). The ADA advocated that dentists register with prescription drug monitoring programs (PDMP), state-based electronic databases that track the prescribing and dispensing of controlled substances, to help deter misuse and abuse of prescriptions (40). The Oregon Health Authority has established guidelines for dental prescribing of opioids for acute dental pain. The current guidelines recommend prescribing in small dosages (in most cases not to exceed 3 days or 10 tablets) and stipulate the dental providers' responsibility to inform the patient how to secure medication against diversion and how to dispose of leftover medication (41).

4.3. Associations between pain levels and opioid dosage (MME/p)

Analyses of associations between pain levels and opioid dosage found that the average MME/p prescription before the mandate (77.0 MME/p) was almost identical to after the mandate (average = 75.3 MME/p). Curiously, 49% (248) of all the procedures that resulted in a prescription had no pain or mild pain. Further, documentation of "no pain" in the EHRs was associated with patients receiving an average of 71.7 MME/p while "mild pain" received an average of 66.4 MME/p. These groups included patients who received a prescription for opioids and had presented on that day for scheduled root end surgery. It is reasonable to query if providing an opioid prescription was due to the perception that since the patient was having a "surgical" procedure they would need a stronger analgesic. The use of a flexible prescription plan in which the maximum daily amount of a non-steroidal anti-inflammatory medication is taken before adding an opioid analgesic is an evidence based approach to pain management (25). The adoption of this flexible pain management protocol or one similar to the University of Minnesota prescribing protocol, could possibly reduce the prescriptions rate even further. The University of Minnesota protocol calls for a NSAID alone or in combination with acetaminophen, as the first-line pain treatment for acute dental pain with opioids prescribed based on established indications and professional clinical judgement (42).

4.4. Future directions

The 2018 CDC annual surveillance report of drug related risks and outcomes study reported that while drug overdose deaths in 2016 reached a new record high, through 2017 there was a continuing trend for reduced opioid prescribing and high-dose prescribing (22). However, as the prescribing of opioids have decreased, the abuse of synthetic opioids such as fentanyl has increased. The need for access to treatment for individuals with substance abuse disorder, whether from abuse of opioids, heroin, or fentanyl, continues to outpace supply.

Development of medications associated with the opioid receptors that are responsible for analgesia without the addiction potential could provide an alternative to the current opioid options. The benefits of a mu receptor drug with anti-nociceptive properties but without the additive properties has shown promise in an animal model (43). Drug development of opioid alternatives will require judicious skepticism and impartial human clinical trials are needed in light of the false claims with the historical introduction of non-additive drugs such as Oxycontin.

Within the OHSU School of Dentistry, the GEC is the first to have conducted a retrospective analysis of its opioid prescribing practices. Analyses of other clinical units would provide institutional information about prescribing practices and the impact of the federal mandate. Given the limitations of the study, future studies should look to minimize variables by creating a standardized protocol for prescribing medications based on symptoms. These studies should ideally be prospective with protocols that are reproducible and that minimize the various signatura (sig). Patients ideally would be asked whether the opioid prescription was filled or not, whether OTC medications alone provided pain relief, and would document in a pain diary the use of the opioid stating the number of tablets taken and the VAS recorded at time of taking the medication; this would allow MME to be calculated instead of MME/p. In addition, with more stringent opioid prescribing protocols in place, and documentation of the rationale for the prescription, a greater understanding of the relationship between different opioids in their efficacy to control pulpal and periapical pain may be feasible.

Chapter 5. Summary and Conclusions

The research from this study showing a decline in opioid prescribing in the GEC is encouraging. It is feasible that these changes might be attributable in part to the impact of the Federal Mandate in 2014. The age group that received an opioid prescription at the highest rate was 30-year-olds. Females were more likely to be prescribed an opioid, and root end surgery was the most common procedure associated with a prescription. There was no correlation between pain level and receiving an opioid prescription. There were no changes before and after the mandate in the most prescribed opioid, with hydrocodone with acetaminophen continuing to be the main rescue medication utilized in the GEC. There was an increase in the prescribing rate of tramadol after the mandate compared to before, with 30% of the prescriptions for tramadol phoned in to the pharmacy after the mandate.

As healthcare providers it is important to continue to review policies and audit health care records as a quality assurance mechanism. In reviewing the data associated with this study, new policies have been implemented in the GEC aimed at 1) the reduction of unwarranted prescriptions, 2) the management of dental pain with a flexible prescription plan in which NSAIDS, or NSAIDS and acetaminophen are used as first line pain management strategies followed by the addition of an opioid prescription as a rescue medication, 3) increasing patients' awareness of the risks associated with opioid analgesics to include addiction and diversion, and 4) documentation in the patients' EHR of the rationale for opioid prescription and confirmation of failure to achieve success with non-opioid medications.

Within the limitations of the study, it can be concluded that an overall reduction in opioid prescribing rates occurred in the GEC after implementation of the federal mandate. Among graduate endodontic providers in the dental healthcare setting at OHSU, the prescribing rate reduction was coincident with the federal mandate of 2014. Lack of correlation with prescribing practice and pain level highlights the need for prescribing protocols that are evidence-based rather than habitual.

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Table 1.CDT procedure codes using in this study

Procedure Groups	CDT	Description
RCT	D3310	RCT - anterior
	D3320	RCT - bicuspid
	D3330	RCT - molar
Re-tx RCT	D3346	Re-tx RCT - anterior
	D3347	Re-tx RCT - bicuspid
	D3348	Re-tx RCT - molar
Apicoectomy	D3410	Apicoectomy - anterior
	D3421	Apicoectomy - biscupid
	D3425	Apicoectomy - molar
	D3426	Apicoectomy - addl roots
Pulpal Debridement	D3221	Pulpal Debridement
Other	D3331	Root canal obstruction
	D3332	Incomplete endo therapy
	D3427	Periradicular surgery w/o apicoectomy
	D3450	Root amputation - per root
	D3470	Intentional reimplantation
	D3920	Hemisection, incl root removal
	D3999B	Exploratory surgery
	D3999C	External resorption repair
	D7140	Non-surgical Extraction
	D7210	Surgical Extraction
Limited oral eval-prob focused	D0140	Limited oral eval-prob focused

Table 2. Number of Procedures By Number of Prescriptions

Number of Procedures	Number of Prescriptions								Total	Percent
	0	1	2	3	4	5	6	7		
0	0	18	2	1	0	0	0	0	21	0.43
1	2345	101	17	2	0	0	1	0	2466	50.83
2	1729	120	25	9	1	1	0	0	1885	38.86
3	297	38	11	0	5	1	0	1	353	7.28
4	65	11	2	1	0	1	0	0	80	1.65
5	17	6	2	0	0	0	0	0	25	0.52
6	12	2	0	0	1	0	0	0	15	0.31
7	2	0	0	0	0	0	0	0	2	0.04
8	2	0	0	0	0	0	0	0	2	0.04
9	1	0	0	0	0	0	0	0	1	0.02
11	1	0	0	0	0	0	0	0	1	0.02
Total	4471	296	59	13	7	3	1	1	4851	

Percent	92.17	6.10	1.22	0.27	0.14	0.06	0.02	0.02

Table 3. Prescription Percentage by Year

		Count		%
Mandate	Year	Procedures	Prescriptions	Prescriptions
Before	2010	92	7	7.6
	2011	812	42	5.2
	2012	784	56	7.1
	2013	782	79	10.1
	2014	551	44	8.0
After	2014	227	22	9.7
	2015	1016	71	7.0
	2016	1084	45	4.2
	2017	1477	33	2.2
	2018	1016	21	2.1

Logistic regression results: Before vs after, P<0.001, Year P<0.001.

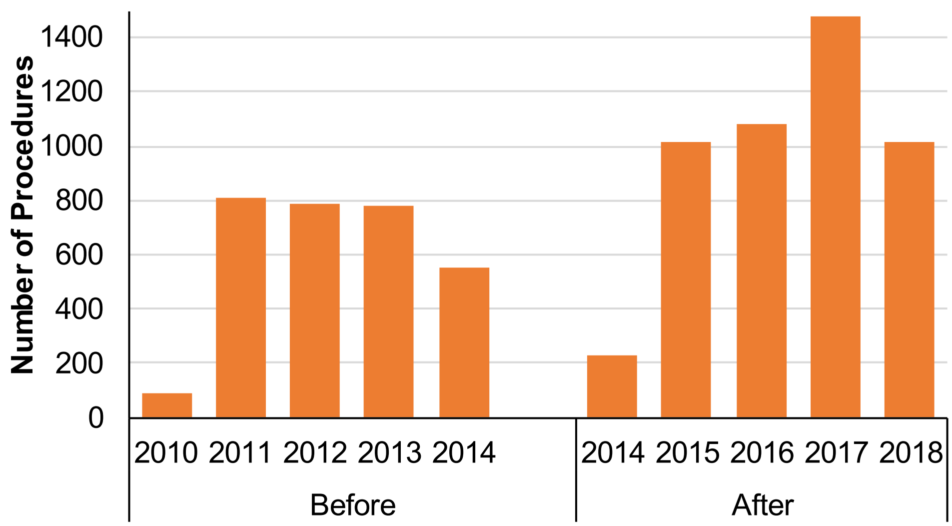


Figure 1. Number of Procedures by Year

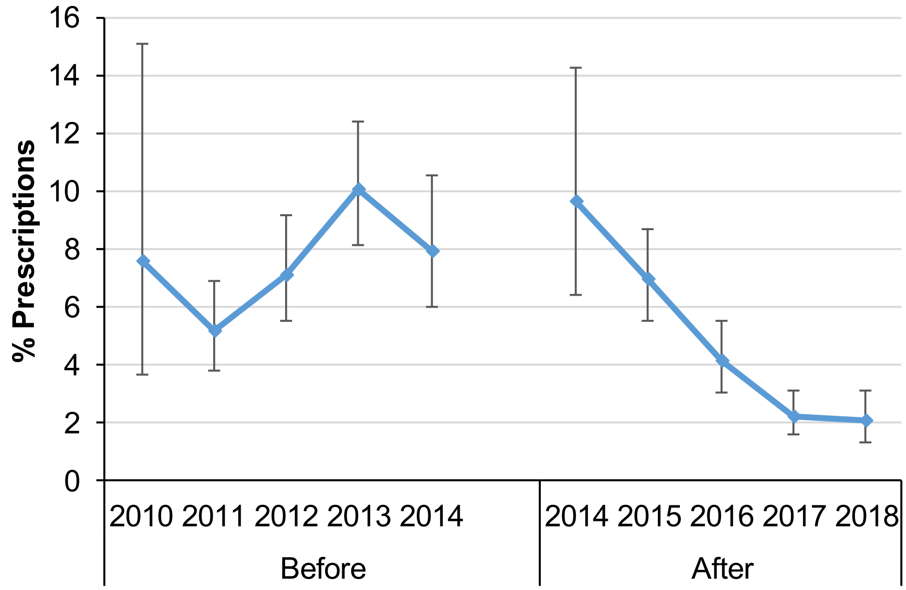


Figure 2. Prescription Percentage by Year

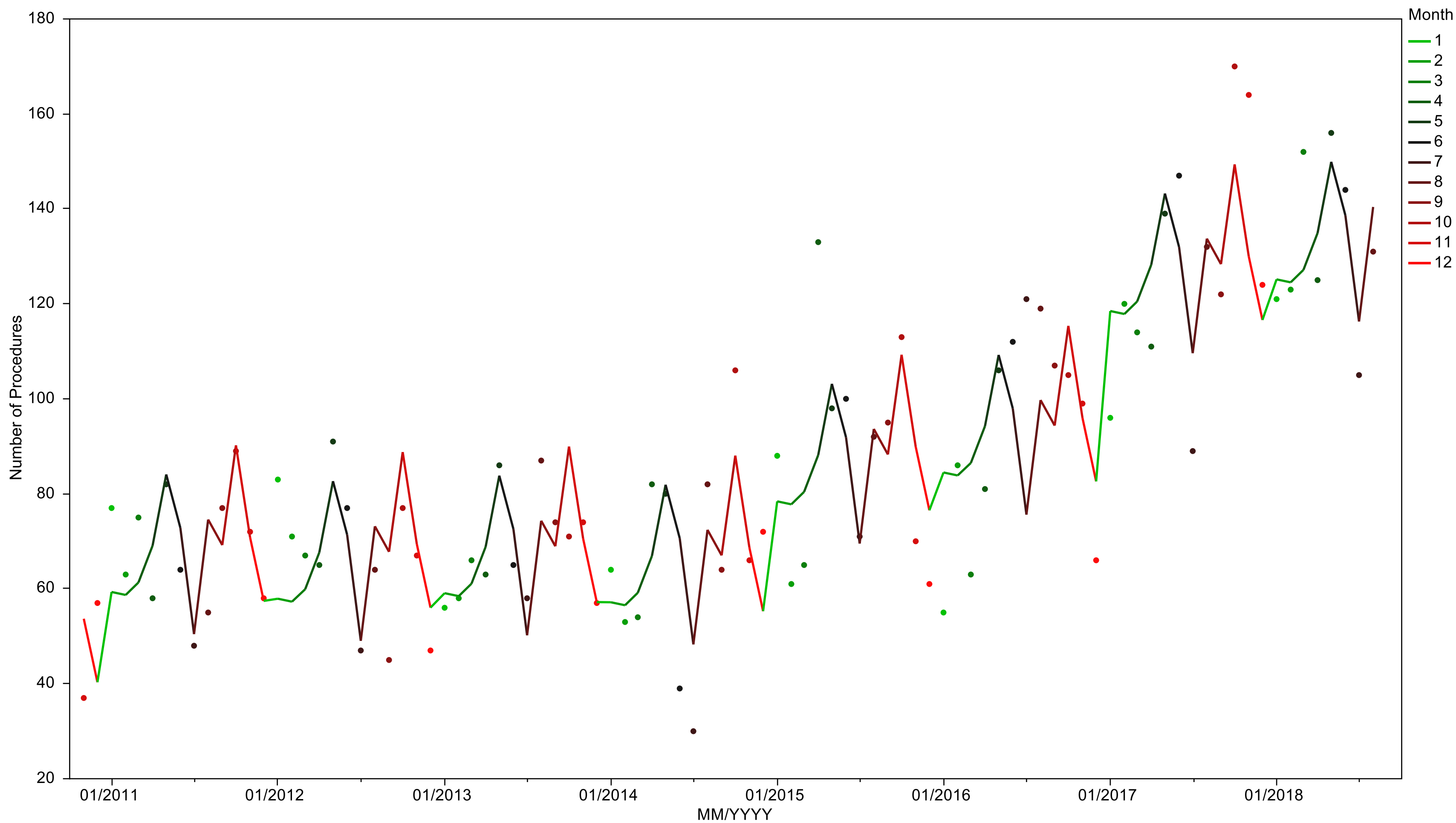


Figure 3. Number of Procedures by Month and Year

Table 4. Prescription Percentage by Month

Mandate	Month	Count: Procedures	Count: Prescriptions	% Prescriptions
Before	1	278	16	5.8
	2	243	8	3.3
	3	256	19	7.4
	4	267	19	7.1
	5	332	29	8.7
	6	240	22	9.2
	7	177	10	5.6
	8	278	22	7.9
	9	250	18	7.2
	10	244	24	9.8
	11	242	20	8.3
	12	214	21	9.8
After	1	352	16	4.5
	2	379	12	3.2
	3	381	12	3.1
	4	433	25	5.8
	5	482	15	3.1
	6	486	24	4.9
	7	367	16	4.4
	8	459	12	2.6
	9	314	12	3.8
	10	466	21	4.5
	11	391	11	2.8
	12	310	16	5.2

Logistic regression results: Before vs after P<0.001, Monthly difference P=0.117, interaction P=0.406

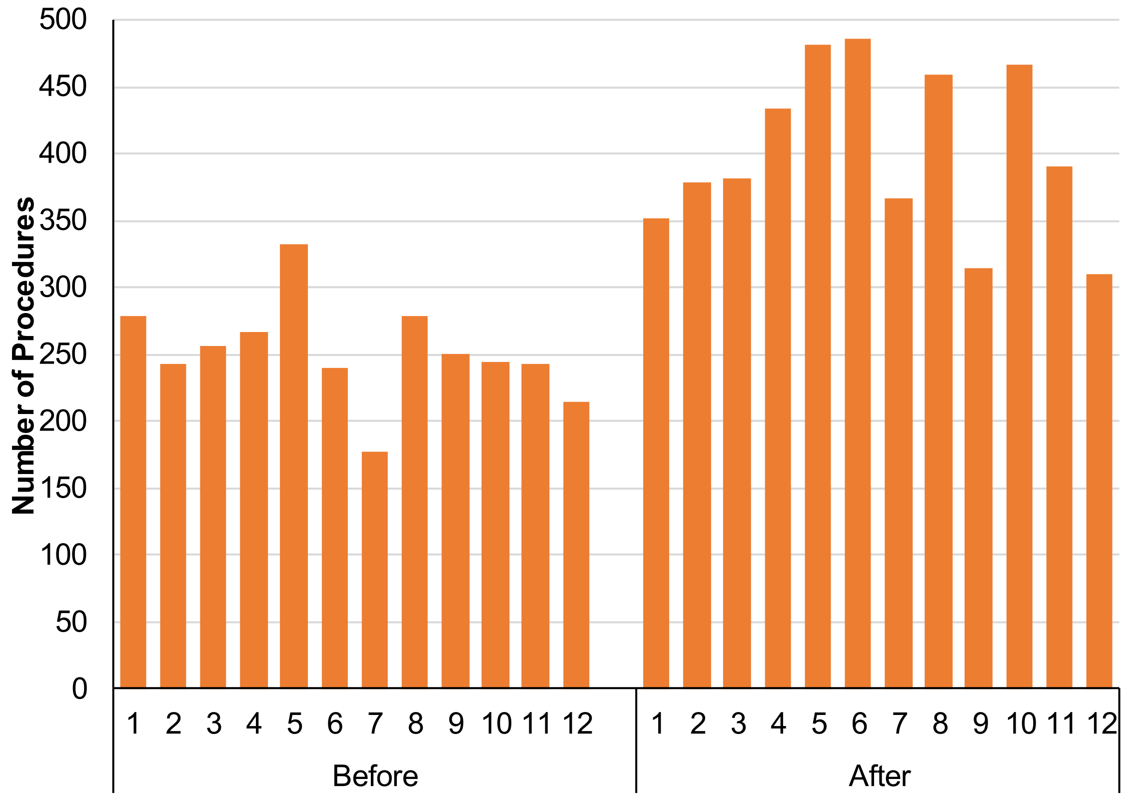


Figure 4.Number of Procedures by Month

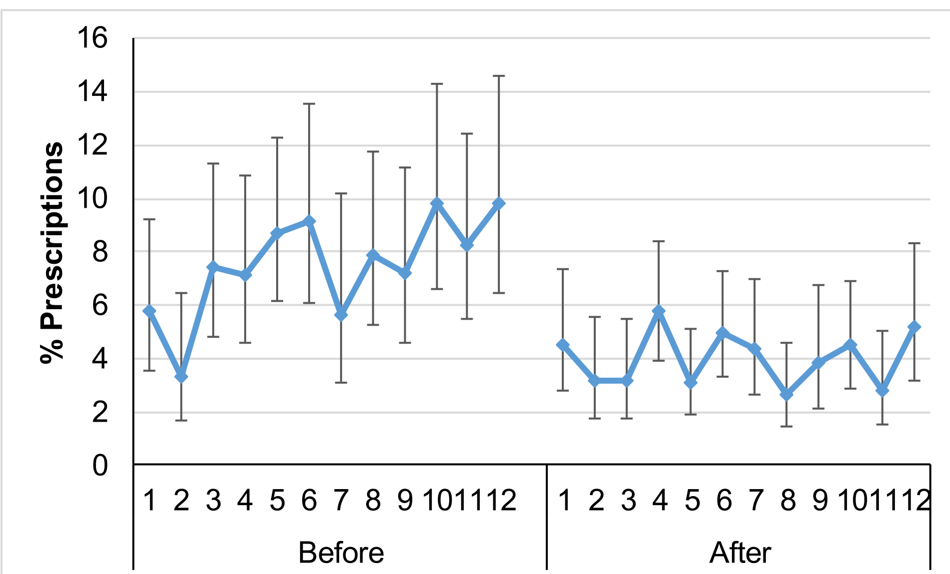


Figure 5. Prescription Percentage by Month

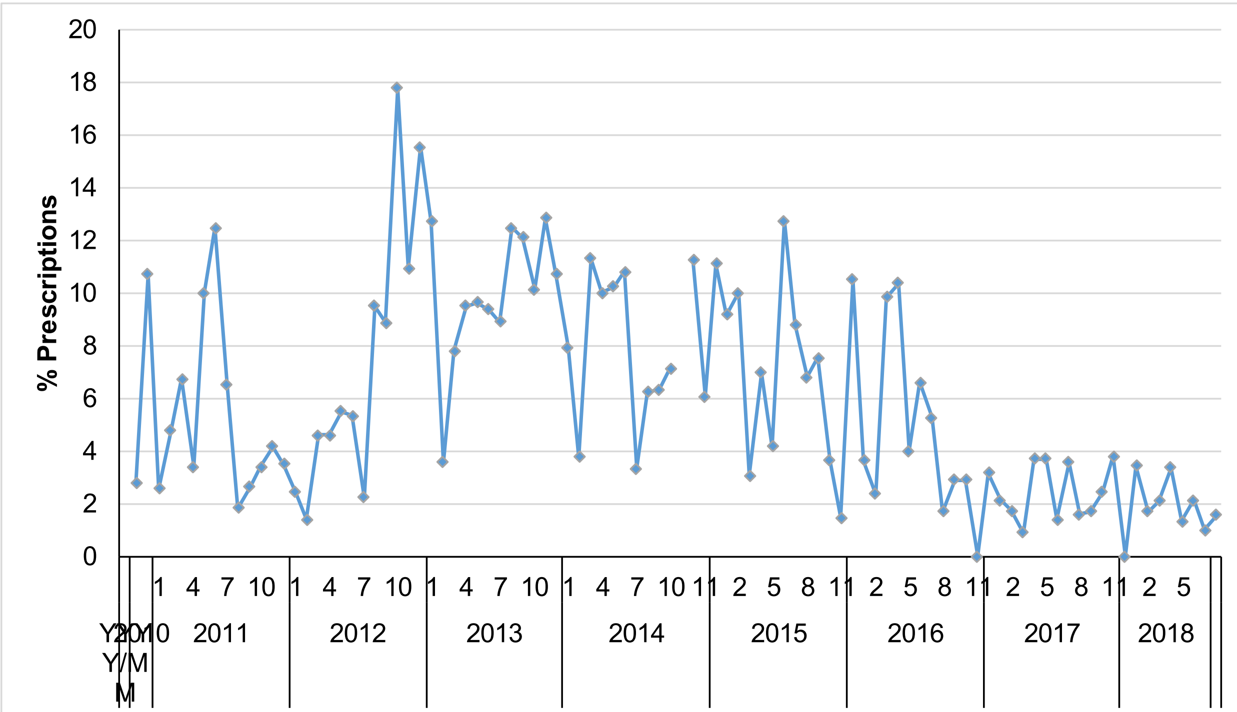


Figure 6. Prescription Percentage by year and month

Table 5. Prescribing Percentage by Day of the Week

Mandate	Day of Week	Count		% Prescriptions
		Procedures	Prescriptions	
Before	MON	865	52	6.0
	TUE	8	6	
	WED	625	45	7.2
	THU	719	59	8.2
	FRI	804	66	8.2
After	MON	1299	62	4.8
	TUE	245	10	4.1
	WED	867	31	3.6
	THU	1048	38	3.6
	FRI	1359	51	3.8

Logistic regression results: Before vs After P<0.001, Day P=0.0015, interaction P<0.001.

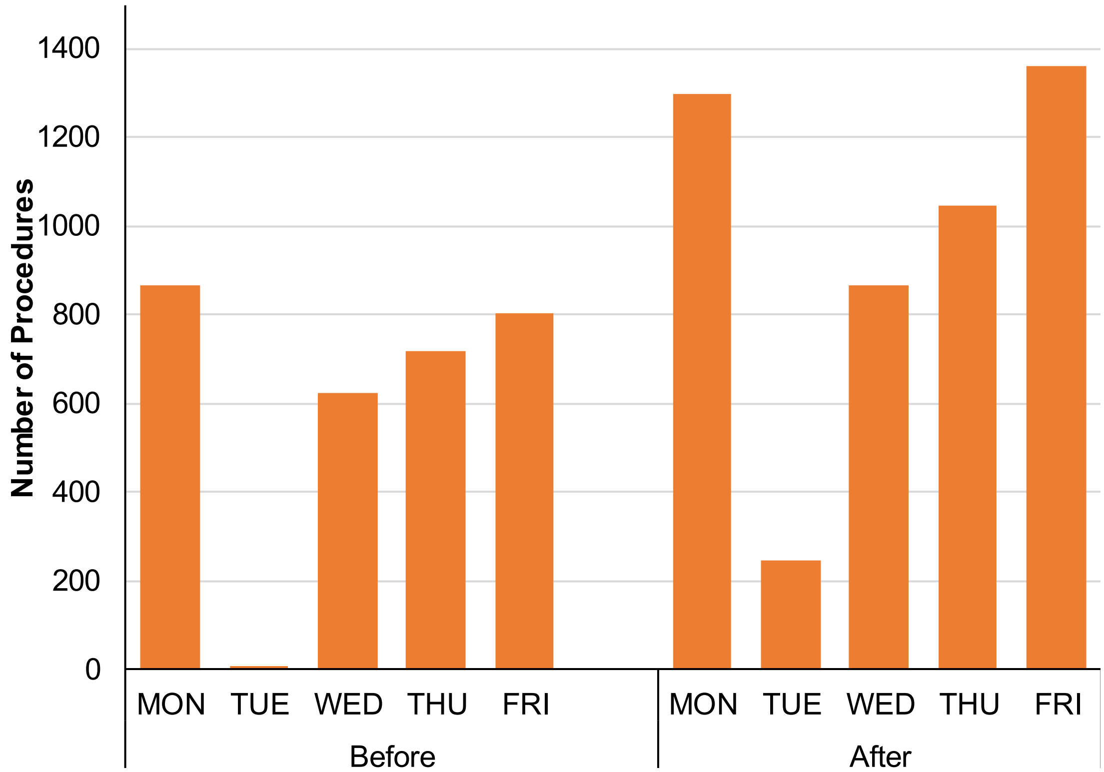


Figure 7. Number of Procedures by Day of the Week

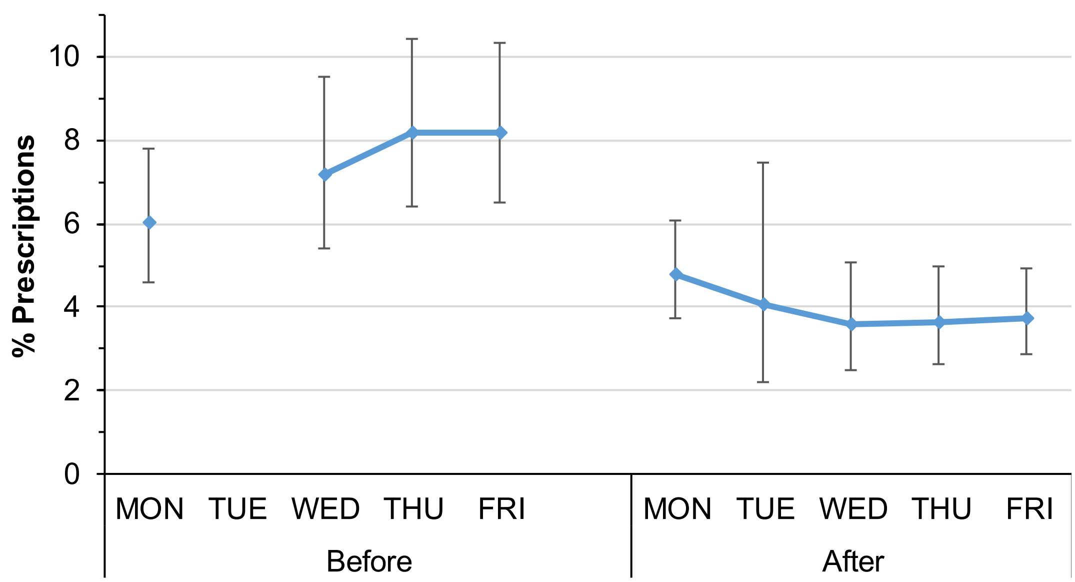


Figure 8. Prescribing Percentage by Day of the Week

Table 6. Prescriptions Written Per Provider

Providers	ID	Count: Procedures	Count: Prescriptions	% Prescriptions
		Before the mandate		
1	16	100	7	7.0
2	20	83	6	7.2
3	18	99	15	15.2
4	19	231	15	6.5
5	21	218	8	3.7
6	17	216	4	1.9
7	24	280	7	2.5
8	22	240	25	10.4
9	23	281	20	7.1
10	25	241	38	15.8
11	26	301	39	13.0
12	27	240	15	6.3
Before		2530	199	7.9
		During the mandate		
13	6	358	29	8.1
14	2	279	15	5.4
15	4	274	21	7.7
16	3	225	24	10.7
17	7	272	30	11.0
18	1	340	14	4.1
During		1748	133	7.6
		After the mandate		
19	5	418	16	3.8
20	8	427	11	2.6
21	9	364	15	4.1
22	10	513	7	1.4
23	12	424	13	3.1
24	11	443	13	2.9
25	13	217	8	3.7
26	14	336	1	0.3
27	15	296	4	1.4
28	29	10	0	0.0
29	28	11	0	0.0
30	30	15	0	0.0
After		3474	88	2.5

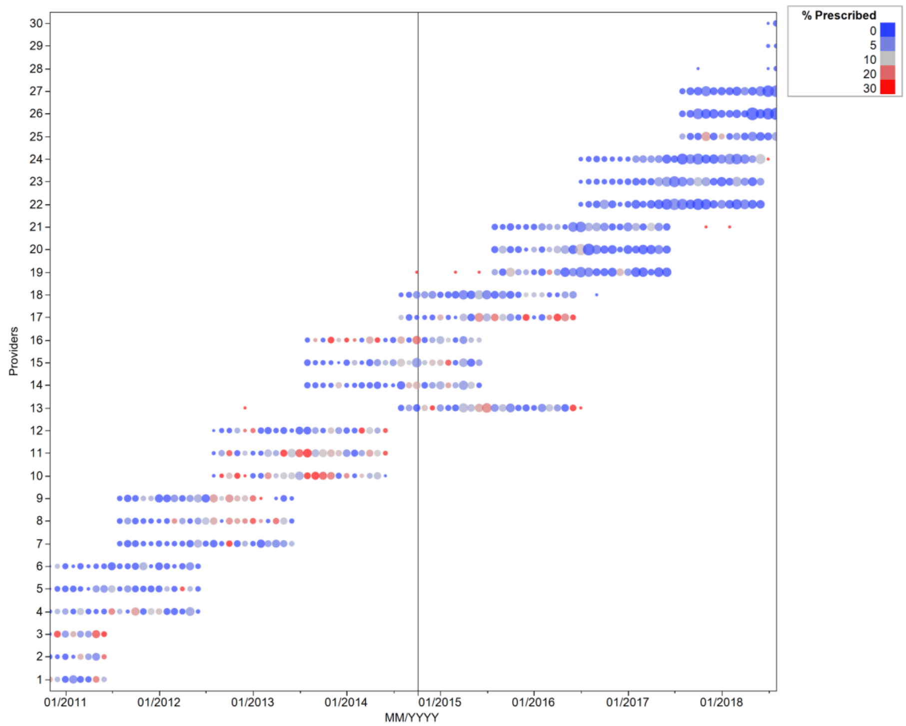


Figure 9. Prescriptions Written Per Provider across Time

Table 7. Prescription Percentage by Age

		Count		%
Mandate	Age	Procedures	Prescriptions	Prescriptions
Before	20s or under	690	43	6.2
	30s	608	37	6.1
	40s	469	30	6.4
	50s	479	28	5.8
	60s	471	29	6.2
	70s and up	252	9	3.6
After	20s or under	1011	17	1.7
	30s	1025	36	3.5
	40s	813	32	3.9
	50s	771	25	3.2
	60s	707	20	2.8
	70s and up	439	8	1.8

Logistic regression results: Before vs After P<0.001, Age quadratic trend <0.001, interaction P=0.411.

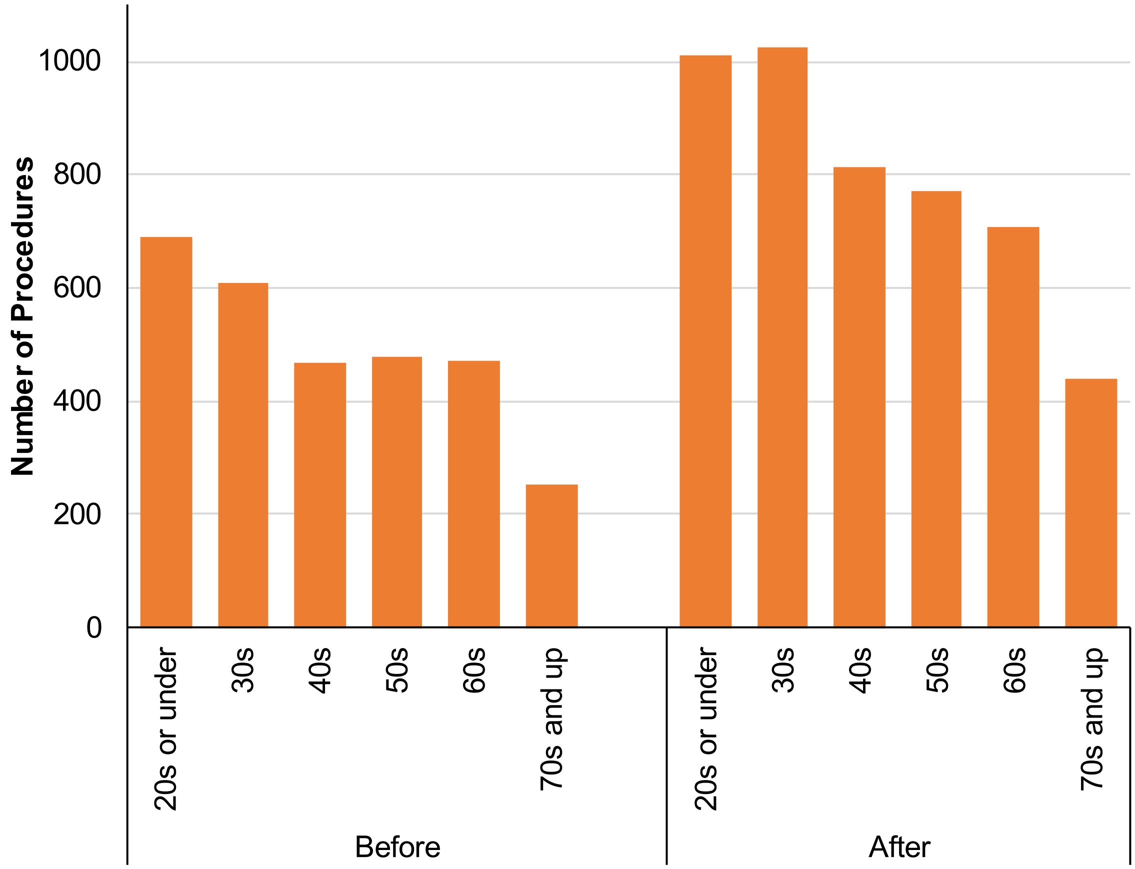


Figure 10. Number of Procedures by Age

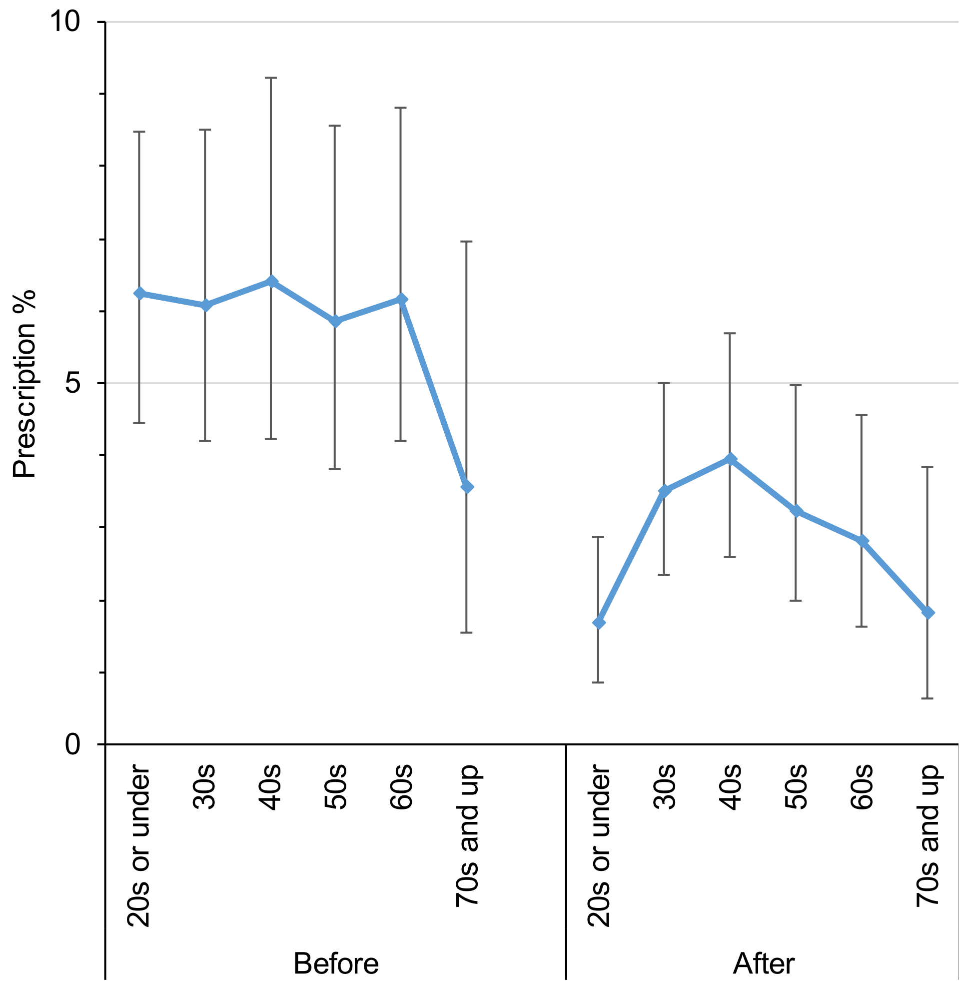


Figure 11 Prescription Percentage by Age

Table 8. Prescription Percentage by Gender

Mandate	Gender	Count: Procedures	Count: Prescriptions	% Prescriptions
Before	F	1728	101	5.8
	M	1241	75	6.0
After	F	2753	97	3.5
	M	2011	41	2.0

Logistic regression results: Before vs After $P<0.001$, Gender $P<0.025$, interaction $P=0.018$.

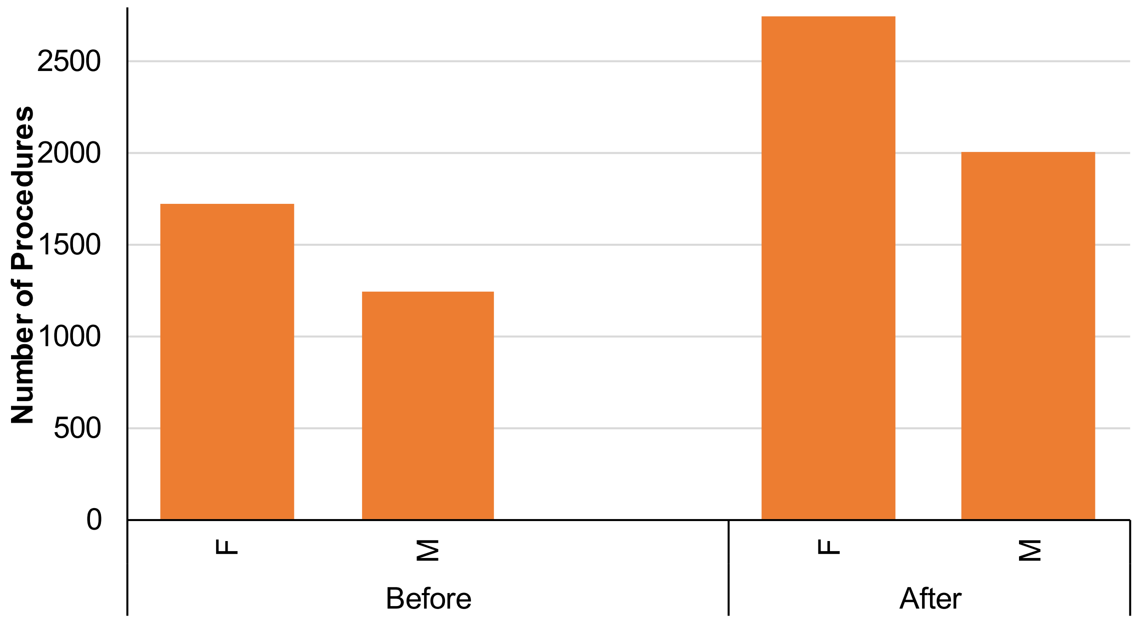


Figure 12. Number of Procedures by Gender

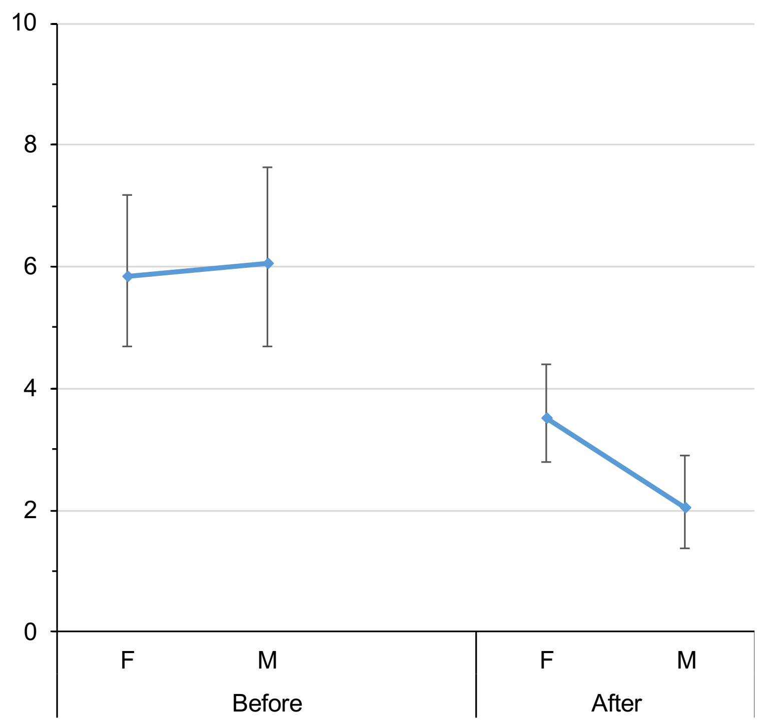


Figure 13. Prescription Percentage by Gender

Table 9. Prescription Percentage by Procedure Group

Mandate	Procedure Groups	Count		%
		Procedures	Prescriptions	Prescriptions
Before	Limited oral eval	1186	32	2.7
	RCT	1139	86	7.6
	Re-tx RCT	436	22	5.0
	Apicoectomy	174	66	37.9
	Pulpal Debridement	37	8	21.6
	Other	49	14	28.6
After	Limited oral eval	2228	33	1.5
	RCT	1781	75	4.2
	Re-tx RCT	470	22	4.7
	Apicoectomy	148	47	31.8
	Pulpal Debridement	137	7	5.1
	Other	56	8	14.3

Logistic regression results: Before vs After $P<0.001$, Procedure groups $P<0.001$, interaction $P=0.153$.

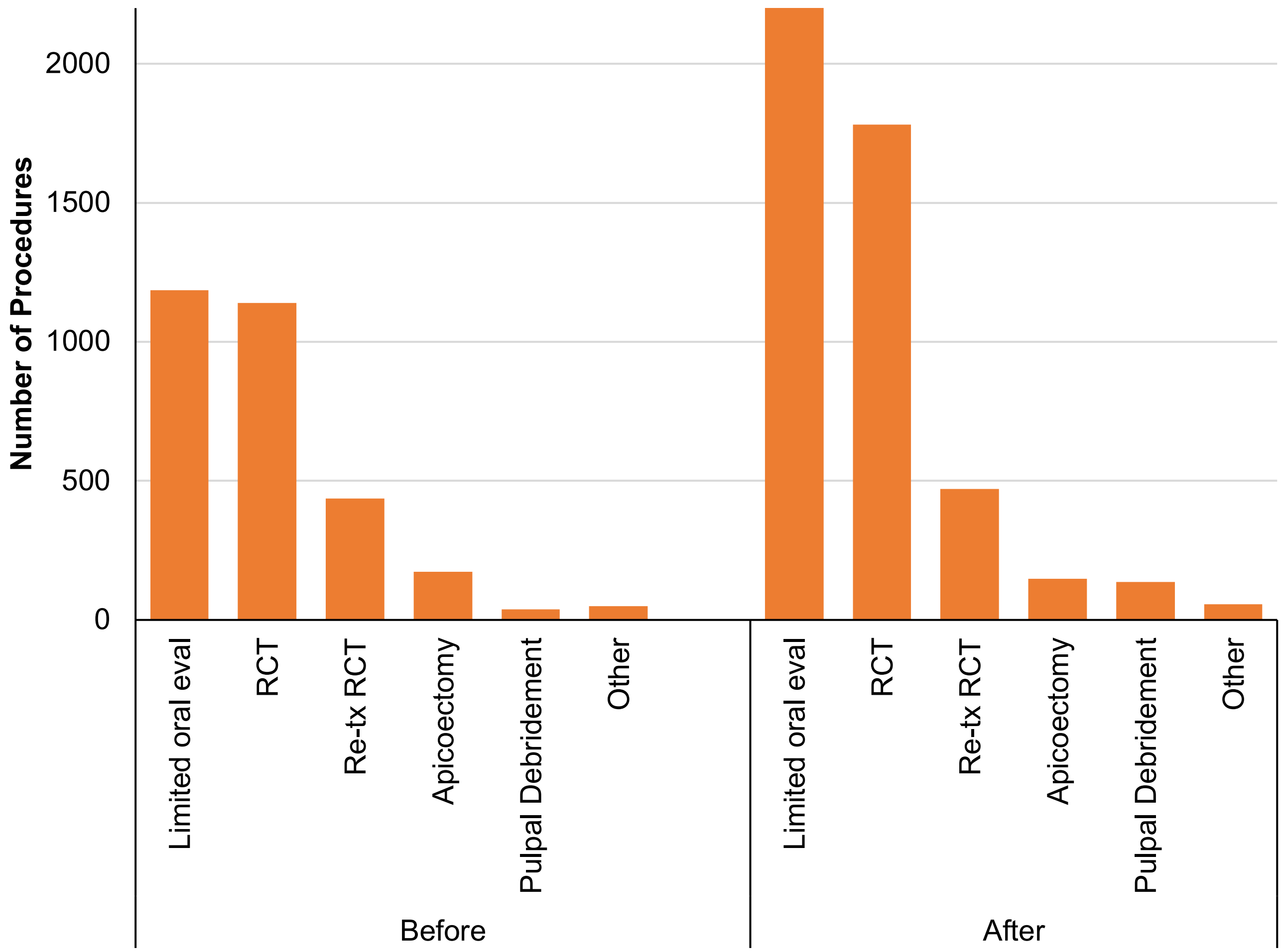


Figure 14. Number of Procedures by Procedure Group

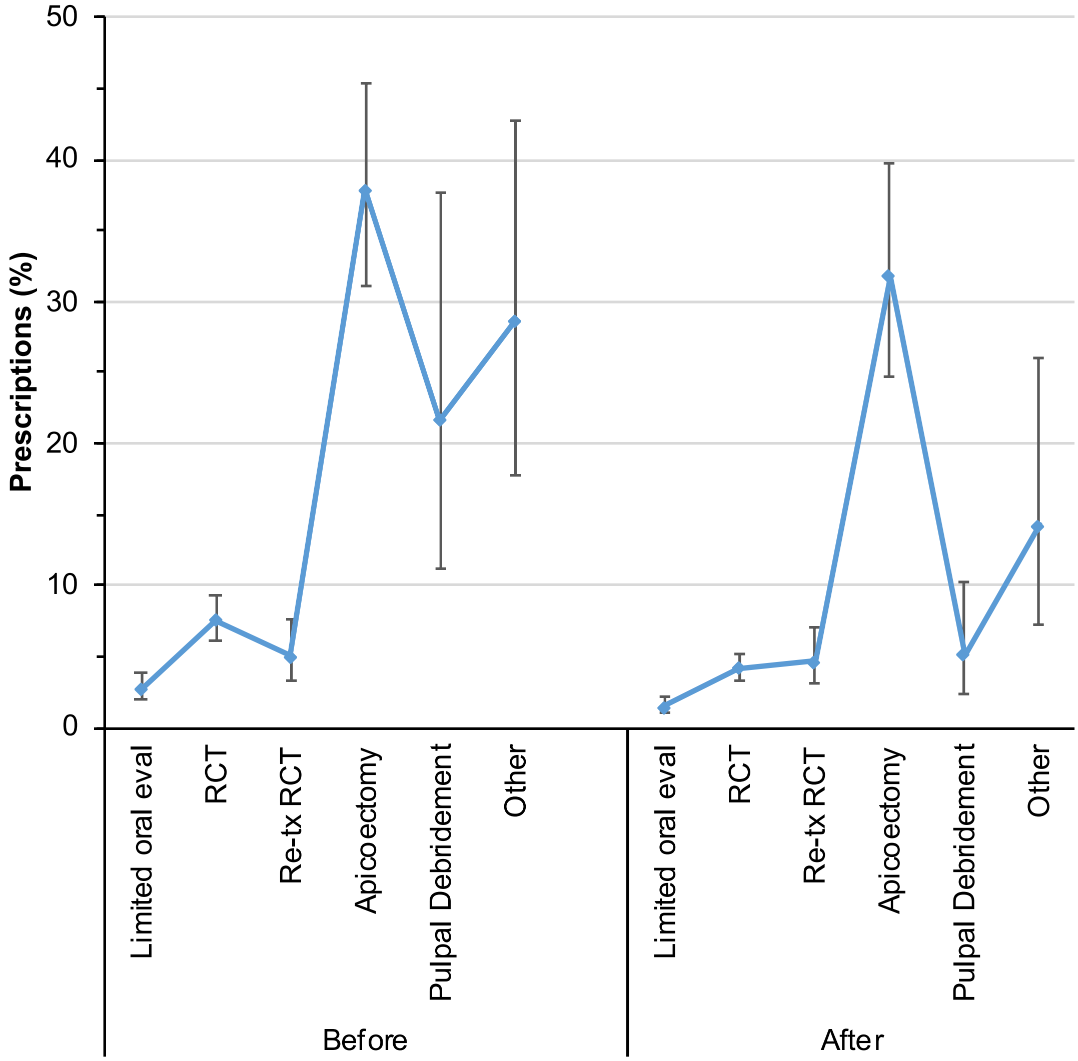


Figure 15. Prescription Percentage by Procedure Group

Table 10. Prescription Percentage by Quadrant

		Count		%
Mandate	Quadrant	Procedures	Prescriptions	Prescriptions
Before	Anterior Mandibular	82	2	2.4
	Anterior Maxillary	310	45	14.5
	Posterior Mandibular	677	79	11.7
	Posterior Maxillary	797	102	12.8
	whole mouth	1155	0	0.0
After	Anterior Mandibular	160	15	9.4
	Anterior Maxillary	436	28	6.4
	Posterior Mandibular	945	87	9.2
	Posterior Maxillary	1083	61	5.6
	whole mouth	2196	1	0.0

Logistic regression results: Before vs After P=967, Quadrants P=0.144, interaction P=0.004.

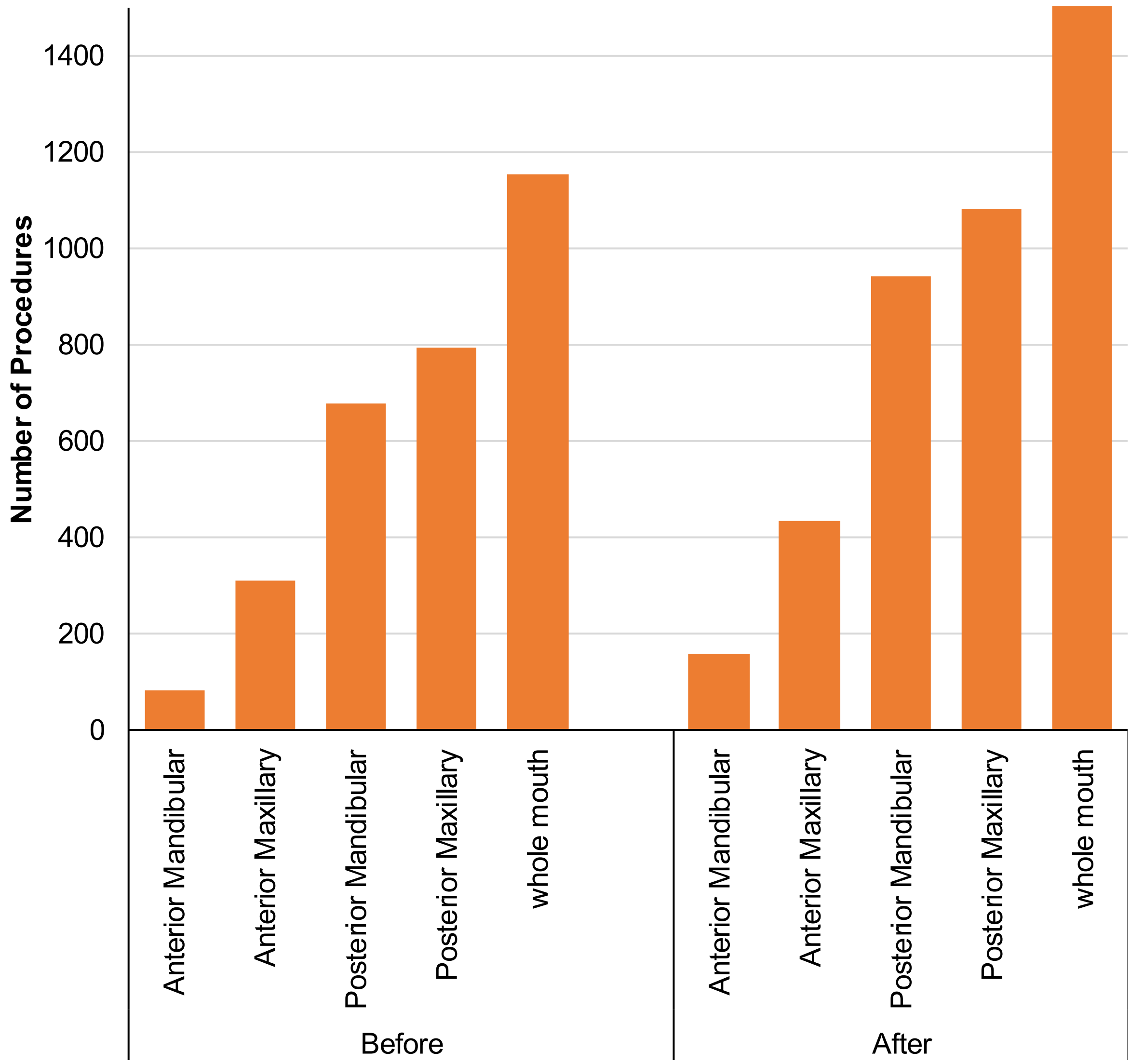


Figure 16. Number of Procedures by Quadrant

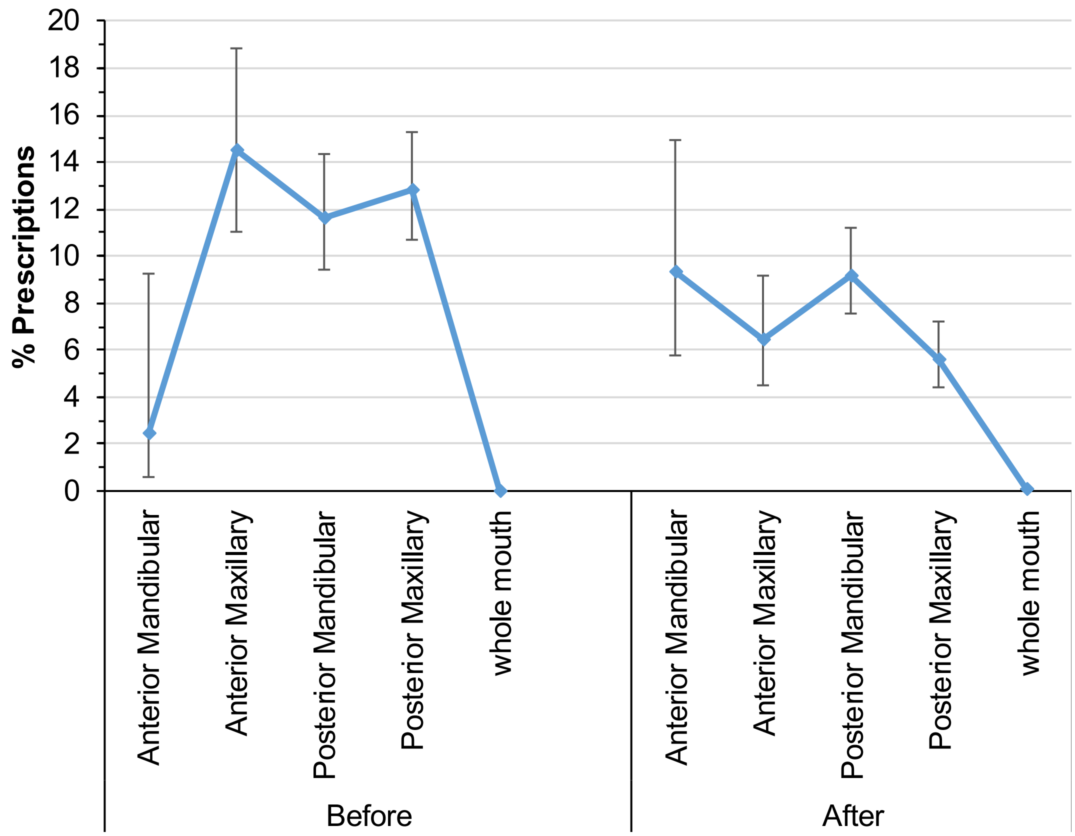


Figure 17. Prescription Percentage by Quadrant

Table 11. Significant effects in the full model of Prescription Percentage

Effect	df	Chi-Square	P-value
Mandate	1	8.63	0.0033
Year (Mandate)	8	55.94	<.0001
Day of Week	4	11.14	0.0250
Age	5	19.86	0.0013
Gender	1	5.13	0.0236
Grouped Procedures	5	287.80	<.0001

Table 12. Odds-ratios and Estimated Prescription Proportions in the Full Model

Effect		Odds-ratio			Prescription proportion		
		estimate	95% CI		estimate	95% CI	
Mandate	Before	1.75	1.36	2.25	0.0387	0.0255	0.0584
	After	Ref			0.0225	0.0149	0.0339
Year	2010	0.59	0.18	1.56	0.0310	0.0110	0.0842
	2011	0.54	0.32	0.92	0.0287	0.0169	0.0484
	2012	0.75	0.45	1.26	0.0392	0.0238	0.0641
	2013	1.11	0.69	1.82	0.0569	0.0354	0.0903
	2014B	Ref			0.0515	0.0302	0.0864
	2015	0.67	0.37	1.29	0.0463	0.0286	0.0743
	2016	0.30	0.16	0.61	0.0215	0.0127	0.0361
	2017	0.19	0.09	0.38	0.0133	0.0076	0.0231
	2018	0.15	0.07	0.34	0.0110	0.0057	0.0211
	2014A	Ref			0.0676	0.0356	0.1246
Weekday	Mon	1.08	0.78	1.50	0.0279	0.0179	0.0434
	Tue	2.76	1.38	5.21	0.0686	0.0347	0.1312
	Wed	0.87	0.59	1.27	0.0227	0.0139	0.0366
	Thu	1.10	0.78	1.55	0.0284	0.0179	0.0448
	Fri	Ref			0.0260	0.0165	0.0406
Age	under 30	3.00	1.70	5.56	0.0386	0.0241	0.0614
	30s	3.47	1.99	6.37	0.0443	0.0281	0.0692
	40s	3.25	1.84	6.01	0.0417	0.0261	0.0659
	50s	2.70	1.51	5.05	0.0349	0.0216	0.0561
	60s	2.39	1.33	4.48	0.0310	0.0190	0.0503
	70+	Ref			0.0132	0.0069	0.0252
Gender	F	1.34	1.04	1.73	0.0366	0.0241	0.0554
	M	Ref			0.0276	0.0178	0.0425
Procedure	Apicoectomy	>999.99	420.77	>999.99	0.3657	0.3012	0.4353
	Pulpal Debridement	97.61	14.25	>999.99	0.0287	0.0106	0.0751
	RCT	183.75	41.30	>999.99	0.0527	0.0425	0.0651
	Re-tx RCT	155.93	33.98	>999.99	0.0451	0.0321	0.0629
	other	306.59	53.33	>999.99	0.0849	0.0402	0.1706
	Limited exam	Ref			0.0003	0.0000	0.0022

Notes: Post hoc tests indicated that Tuesday was significantly higher than the other week days. Apicoectomy was significantly higher and Limited exam was significantly lower than the other procedure groups.

Figure 18. Estimated Prescription Percentages (and 95% CIs) in the Full Model

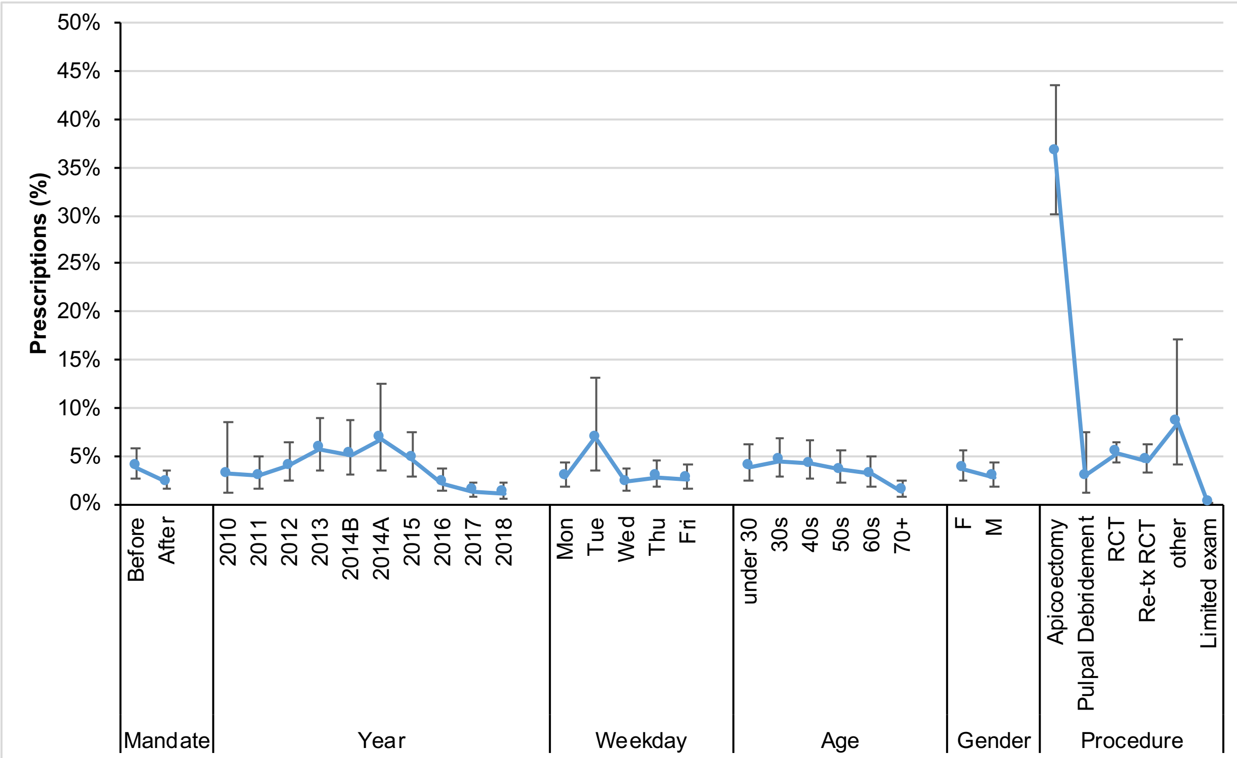


Table 13. Prescriptions Before and After the Federal Mandate

			Prescriptions		Tablets		
			Mandate		Mandate		Total
Drug Description	Dose	MME	Before	After	Before	After	MME
Codeine	15mg	2.25	0	1	0	30	68
	30mg	4.5	0	1	0	20	90
Codeine + acetaminophen	15mg + 300mg	2.25	4	3	70	41	250
	30mg + 300mg	4.5	5	3	66	52	531
	30mg + 325mg	4.5	2	0	24	0	108
Hydrocodone	5mg	5	2	2	27	20	235
Hydrocodone + acetaminophen	2.5mg + 325mg	2.5	1	0	12	0	30
	2.5mg + 500mg	2.5	1	0	12	0	30
	5mg + 300mg	5	15	13	288	151	2195
	5mg + 325mg	5	113	145	1551	2005	17780
	5mg + 500mg	5	74	0	961	0	4805
	7.5mg + 300mg	7.5	2	3	28	52	600
	7.5mg + 325mg	7.5	2	7	38	111	1118
	7.5mg + 500mg	7.5	3	0	44	0	330
	10mg + 300mg	10	1	2	10	22	320
	10mg + 325mg	10	0	2	0	33	330
	10mg + 650mg	10	4	0	45	0	450
Meperidine	50mg	5	1	0	25	0	125
Oxycodone	5mg	7.5	3	6	32	61	698
Oxycodone + acetaminophen	5mg + 325mg	7.5	25	20	390	262	4890
	5mg + 500mg	7.5	2	0	30	0	225
	7.5mg + 325mg	11.25	0	1	0	12	135
	10mg + 325mg	15	3	1	47	10	855
Tramadol	50mg	5	9	26	150	437	2935
	100mg	10	1	0	15	0	150
Total			273	236	3865	3319	39281

Table 14. Number of Opioid Prescriptions Before and After the Mandate

	Mandate		
Opioid	Before	After	Total
Codeine	11	8	19
Hydrocodone	218	174	392
Meperidine	1	0	1
Oxycodone	33	28	61
Tramadol	10	26	36
Total	273	236	509

Table 15. Number of Tablets by Opioid

Opioid	Number	Mean	Std Dev
Codeine	19	15.95^{AB}	7.10
Hydrocodone	392	13.80^{B}	4.76
Meperidine	1	25.00^{AB}	.
Oxycodone	61	13.84^{B}	4.57
Tramadol	36	16.72^{A}	6.14

ANOVA P = 0.0008. Means connected by the same letter were not significantly different (P < 0.05)

Table 16. Number of Prescriptions Before and After the Mandate

	Number of Prescriptions per Person							
Mandate	1	2	3	4	5	6	7	Total
Before	167	29	7	4	1	1	0	209
After	141	24	6	3	2	0	1	177
Total	308	53	13	7	3	1	1	386

Note that 6 individuals with prescriptions during both study periods were counted twice.

Table 17. Pulpal diagnoses Before and After the Mandate

Pulpal diagnosis	Before	After	Total
Normal	4	1	5
Previously Initiated	75	75	150
Previously Treated	122	92	214
AIP	2	1	3
RP	0	1	1
SIP	31	38	69
Necrotic	38	27	65
Missing Data	1	1	2
Total	273	236	509

Table 18. Periapical diagnoses Before and After the Mandate

Periapical diagnosis	Before	After	Total
Normal	10	11	21
AAA	30	26	56
AAP	42	32	74
CAA	24	17	41
SAP	166	150	316
Missing Data	1	0	1
Total	273	236	509

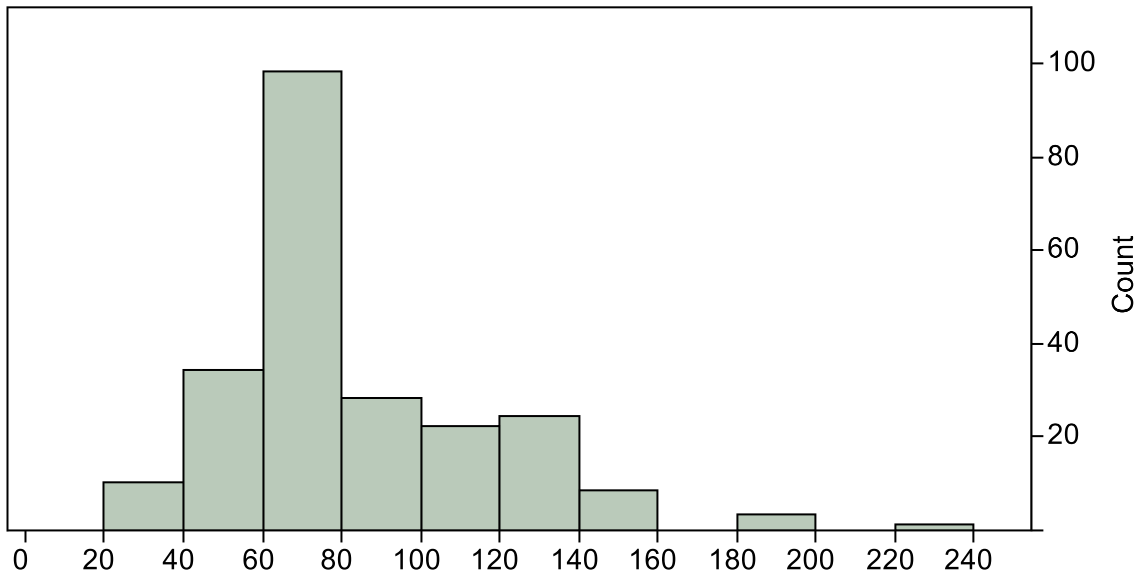
Table 19. Correspondence of the numerical and text description of pain

Pain	VAS	N
None	0	130
Mild		78
	1	8
	2	12
	3	22
Moderate		49
	4	16
	5	9
	6	15
Severe		72
	7	15
	8	37
	9	16
	10	27
Missing Data		3

Table 20. Pain levels Before and After the Mandate

Pain	Before	After	Total	%
None	73	57	130	25.7
Mild	66	54	120	23.7
Moderate	50	39	89	17.6
Severe	81	86	167	33.0
Missing	3	0	3	
Total	273	236	509	

Before



After

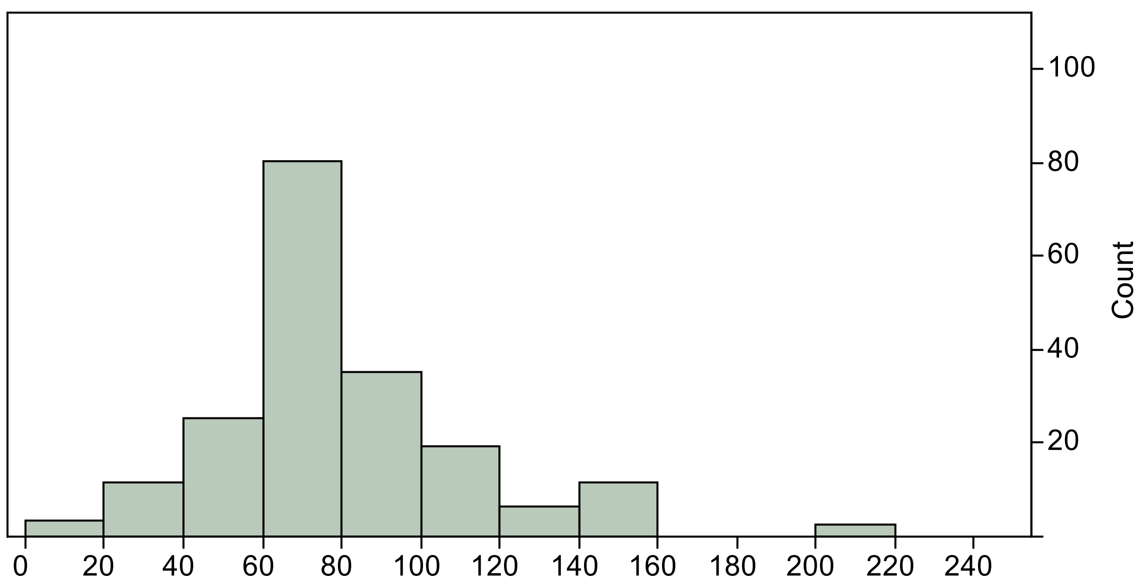


Figure 19. Total MME/p per Person Before and After the Mandate

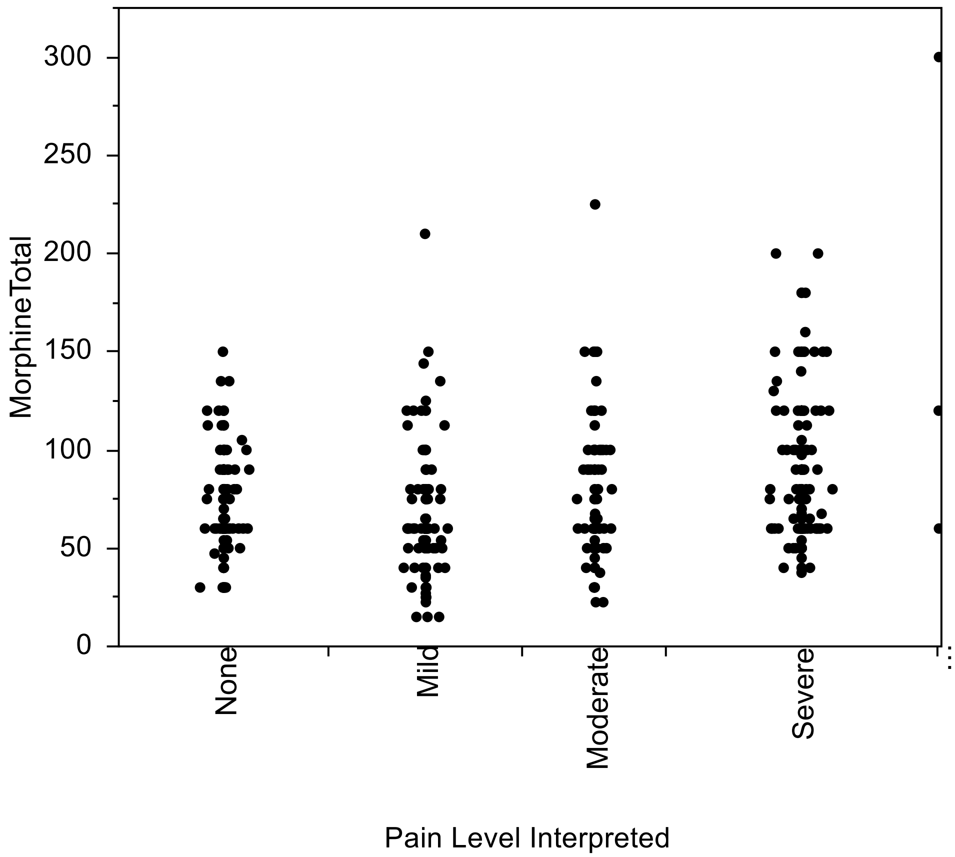


Figure 20. Total MME/p for each Pain Level Group

Table 21. Prescriptions by pain level and procedure

Procedure Groups	Pain								
	None		Mild		Moderate		Severe		Total
Limited oral eval-prob focused	6	9%	11	16%	20	30%	30	45%	67
RCT	39	18%	48	23%	43	20%	81	38%	211
Re-tx RCT	10	16%	17	27%	4	6%	33	52%	64
Apicoectomy	63	52%	33	27%	15	12%	11	9%	122
Pulpal Debridement	2	11%	4	21%	4	21%	9	47%	19
Other	8	38%	7	33%	3	14%	3	14%	21
Total	128	25%	120	24%	89	18%	167	33%	504

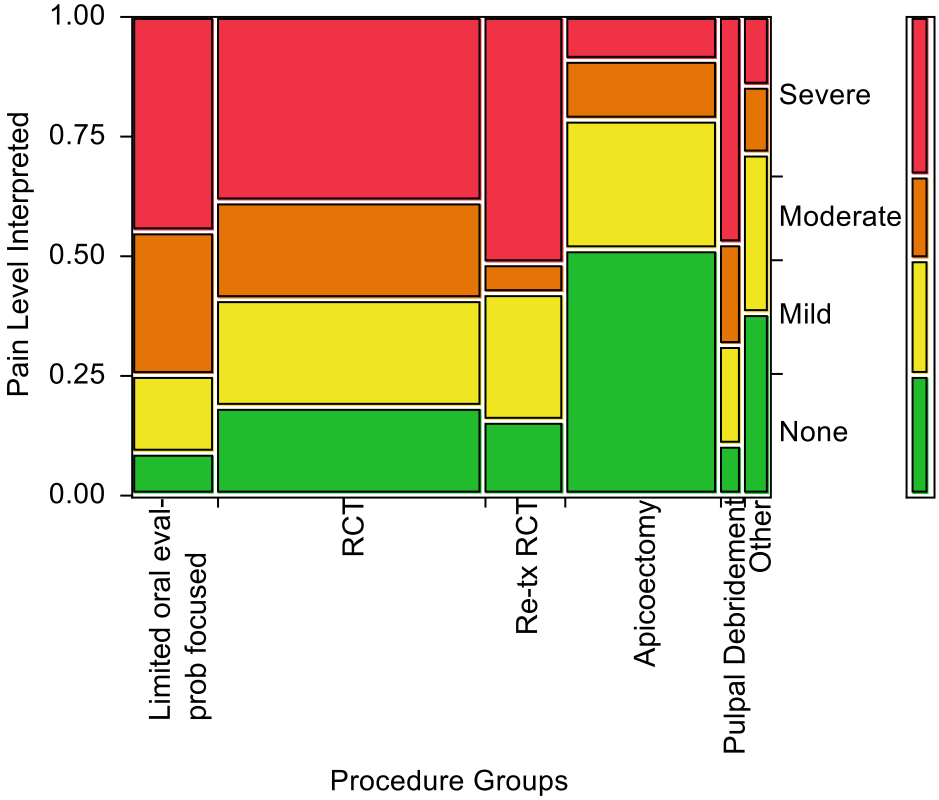


Figure 21. Pain Level by Procedure Group

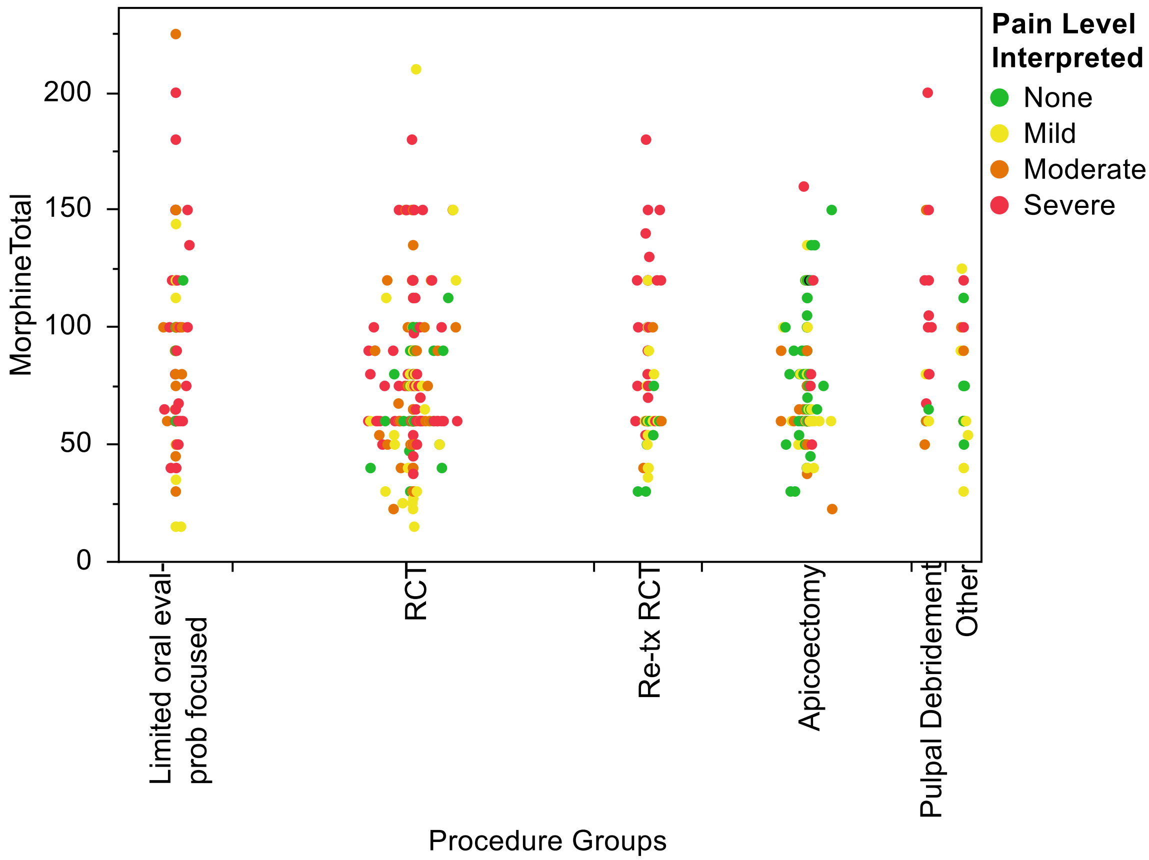


Figure 22. Total MME/p by Procedure and Pain Level

Appendix:

Table 22. Prescribing Percentages by year and month

Mandate	YYYY/MM		Count		%
			Procedures	Prescriptions	Prescriptions
Before	2010	11	36	1	2.8
		12	56	6	10.7
	2011	1	78	2	2.6
		2	63	3	4.8
		3	74	5	6.8
		4	59	2	3.4
		5	80	8	10.0
		6	64	8	12.5
		7	46	3	6.5
		8	55	1	1.8
		9	76	2	2.6
		10	88	3	3.4
		11	72	3	4.2
		12	57	2	3.5
	2012	1	82	2	2.4
		2	71	1	1.4
		3	65	3	4.6
		4	65	3	4.6
		5	91	5	5.5
		6	75	4	5.3
		7	45	1	2.2
		8	63	6	9.5
		9	45	4	8.9
		10	73	13	17.8
		11	64	7	10.9
		12	45	7	15.6
	2013	1	55	7	12.7
		2	56	2	3.6
		3	64	5	7.8
		4	63	6	9.5
		5	83	8	9.6
		6	64	6	9.4
		7	56	5	8.9
		8	80	10	12.5
		9	66	8	12.1
		10	69	7	10.1
		11	70	9	12.9
		12	56	6	10.7
	2014	1	63	5	7.9

		Count		%
Mandate	YYYY/MM	Procedures	Prescriptions	Prescriptions
	2	53	2	3.8
	3	53	6	11.3
	4	80	8	10.0
	5	78	8	10.3
	6	37	4	10.8
	7	30	1	3.3
	8	80	5	6.3
	9	63	4	6.3
	10	14	1	7.1
After				
	10	89	10	11.2
	11	66	4	6.1
	2015 12	72	8	11.1
	1	87	8	9.2
	2	60	6	10.0
	3	65	2	3.1
	4	129	9	7.0
	5	96	4	4.2
	6	94	12	12.8
	7	68	6	8.8
	8	88	6	6.8
	9	93	7	7.5
	10	110	4	3.6
	11	69	1	1.4
	2016 12	57	6	10.5
	1	55	2	3.6
	2	85	2	2.4
	3	61	6	9.8
	4	77	8	10.4
	5	100	4	4.0
	6	106	7	6.6
	7	114	6	5.3
	8	118	2	1.7
	9	104	3	2.9
	10	103	3	2.9
	11	98	0	0.0
	2017 12	63	2	3.2
	1	94	2	2.1
	2	115	2	1.7
	3	113	1	0.9
	4	108	4	3.7
	5	135	5	3.7
	6	145	2	1.4

		Count		%
Mandate	YYYY/MM	Procedures	Prescriptions	Prescriptions
	7	84	3	3.6
	8	126	2	1.6
	9	117	2	1.7
	10	164	4	2.4
	11	158	6	3.8
	2018 12	118	0	0.0
	1	116	4	3.4
	2	119	2	1.7
	3	142	3	2.1
	4	119	4	3.4
	5	151	2	1.3
	6	141	3	2.1
	7	101	1	1.0
	8	127	2	1.6

The Oregon Health & Science University School of Dentistry

Master of Science in Endodontology Data Sheet

Name Andrew M. Broadsword — Degree Sought MS
Major Endodontics — Date of Graduation 2019

Exact Title of Thesis:

The Impact of the Federal Schedule II Prescribing Mandate on Opioid Prescribing Practices within a Dental School Setting

Special Field of the Thesis:

Opioid Prescribing Practices

Total Number of Pages 69 — Number of Illustrations 21

Previous Degrees

Degree	Name of University	Year
DMD	Oregon Health & Science University	2013
BS	Portland State University	2009

Christine Sedgley
Chair, Thesis Committee

Brief Summary of Thesis:

An overall reduction in opioid prescribing rates occurred after the federal mandate. Among graduate endodontic providers in the dental healthcare setting at OHSU, the prescribing rate reduction was coincident with the federal mandate of 2014. Lack of correlation with prescribing practice and pain level highlights the need for prescribing protocols that are evidence-based rather than habitual.