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ORIGINAL RESEARCH

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Impact of state legislation and institutional protocols on opioid prescribing practices following pediatric tonsillectomy

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Abstract

Objectives: Tonsillectomy is a common pediatric surgery, and pain is an important consideration in recovery. Due to the opioid epidemic, individual states, medical societies, and institutions have all taken steps to limit postoperative opioids, yet few studies have examined the effect of these interventions on pediatric otolaryngology practices. The primary aim of this study was to characterize opioid prescribing practices following North Carolina state opioid legislation and targeted institutional changes.

Methods: This single center retrospective cohort study included 1552 pediatric tonsillectomy patient records from 2014 to 2021. The primary outcome was number of oxycodone doses per prescription. This outcome was assessed over three time periods: (1) Before 2018 North Carolina opioid legislation. (2) Following legislation, before institutional changes. (3) After institutional opioid-specific protocols.

Results: The mean (± standard deviation) number of doses per prescription in Periods 1, 2, and 3 was: 58 ± 53, range 4–493; 28 ± 36, range 3–488; and 23 ± 17, range 1–139, respectively. In the adjusted model, Periods 2 and 3 had lower doses by −41% (95% CI −49%, −32%) and −40% (95% CI −55%, −19%) compared to Period 1. After 2018 North Carolina legislation, dosage decreased by −9% (95% CI −13%, −5%) per year. Despite interventions, ongoing variability in prescription regimens remained in all periods.

Conclusion: Legislative and institution specific opioid interventions was associated with a 40% decrease in oxycodone doses per prescription following pediatric tonsillectomy. While variability in opioid practices decreased post-interventions, it was not eliminated.

Level of evidence: 3

KEYWORDS
analgesia, opioids, pediatric pain, pediatric tonsillectomy

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1 | INTRODUCTION

Tonsillectomy is a common surgical procedure in children with over a half million procedures performed annually in the United States.[1] Postsurgical tonsillectomy pain is common, expected, and often severe. Multiple recent clinical practice guidelines include recommendations for non-opioid medication regimens including acetaminophen and non-steroidal anti-inflammatories following tonsillectomy in children.[2–5] Yet there continue to be conflicting recommendations on the use of postoperative opioids,[3,4] and opioid prescribing data remains limited in children after tonsillectomy. In general, the literature has described trends in national claims data[6–8] with fewer studies focused on dosing regimens and variability.

The opioid epidemic continues to represent a significant public health challenge.[9] Similar to adults, children and adolescents are known to be at high risk of opioid related harms following surgery including misuse and diversion.[10–13] In addition to clinical practice guidelines proposed by medical societies, many states and federal legislatures have instituted regulations to curtail opioid prescribing in effort to reduce prescription related overdoses.[14] These policies as a successful tool to change post-operative opioid prescribing practices has been highlighted in multiple adult studies.[14–18] In 2018, the state of North Carolina passed the Strengthen Opioid Misuse Prevention (STOP) Act[19] which states "a practitioner shall not prescribe more than a seven-day supply of any targeted controlled substance for post-operative acute pain relief." Hospital systems have also implemented surgery-specific standardization protocols to reduce variability associated with post-surgical opioid prescribing.[20–23] Our institution introduced comprehensive recommendations to reduce opioid overprescribing across pediatric surgical specialties in early 2020.

The purpose of this study is twofold. First, we examined the change in opioid prescribing practices for pediatric tonsillectomy at our center before and after the implementation of statewide legislation, and subsequently, our internal institutional standardization protocols. At our institution, all children receive an oxycodone prescription following tonsillectomy at discharge. Therefore, the primary outcome of this study was defined as the number of doses per prescription over time. Second, we sought to determine whether changes in number of oxycodone doses were associated with post-tonsillectomy adverse events, defined as a return visit to the Emergency Department for a surgery-related complication within 30 days.

2 | MATERIALS AND METHODS

2.1 | Study environment

Duke Children's Hospital and Health Center (DCH) is contained within Duke University Health System (DUHS) and provides full service pediatric tertiary care. DCH is a Level 1 trauma center and is verified as a Level I Children's Surgery Center by the American College of Surgeons Children's Surgery Verification Quality Improvement Program. This study was approved by the DUHS Institutional Review Board (IRB); the requirement for written informed consent was waived by the IRB. This manuscript adheres to the applicable STROBE guidelines.

2.2 | Study cohort

DUHS electronic health records data are stored in queryable database, modeled to the PCORnet Common Data Model.[24] We abstracted electronic health record data for children less than 18 years of age who underwent tonsillectomy or adenotonsillectomy within DUHS from January 8, 2014 (the date of DUHS start of integrated EPIC-based system) to December 31, 2021. To identify eligible children, we used Current Procedure Terminology 2020 codes for tonsillectomy: 42,820, 42,821, 42,825, and 42,826. Oxycodone (solution or tablet) was the sole opioid prescribed to the cohort. We abstracted additional data about the patient including age, sex, race/ethnicity, obesity at time of procedure, documented history of asthma, obstructive sleep apnea, and trisomy 21 diagnosis, county (local to DUHS or not), tonsillectomy procedure location (hospital based or ambulatory center), American Society of Anesthesiology physical status risk classification (ASA-PS), date of surgery, tonsillectomy indication, insurance status, and tonsillectomy encounter type (same day surgery versus inpatient/emergency), length of stay, prescription for ibuprofen and corticosteroids, and use of intraoperative adjuvant analgesics.

2.3 | Exposures and outcome

The primary exposure was date of surgery. Prior to 2018, there were no legislative or institutional restrictions on opioid practices; prescriptions were at the sole discretion of the surgeon. The STOP Act, introduced in 2017 and enacted on January 1, 2018, required that all postoperative opioid prescriptions be limited to a seven-day supply for adults and children. There were no specific legislative recommendations on type, amount, or age considerations in opioid prescribing. In March 2020, an interdisciplinary team at DCH composed of pediatric anesthesiologists and subspecialty pediatric surgeons implemented recommendations for discharge opioid prescribing for postoperative pain for multiple pediatric surgeries. For tonsillectomy, the oxycodone prescription given at discharge was recommended to be 20 doses or less at a dosing regimen of 0.05 mg/kg, which would allow up to one dose every 6 h as needed for 5 days. This protocol was agreed upon by the pediatric otolaryngologists at our institution based on their collective experience and did not change following the publication of updated clinical practice guidelines by the American Academy of Otolaryngology – Head and Neck Surgeons (AAO-HNS) in 2021. Surgical trainees were given focused opioid education at the beginning of the academic year. Our perioperative nurses and surgeons also provided families with clear instructions that acetaminophen and non-steroidal inflammatory drugs (NSAIDs) should be

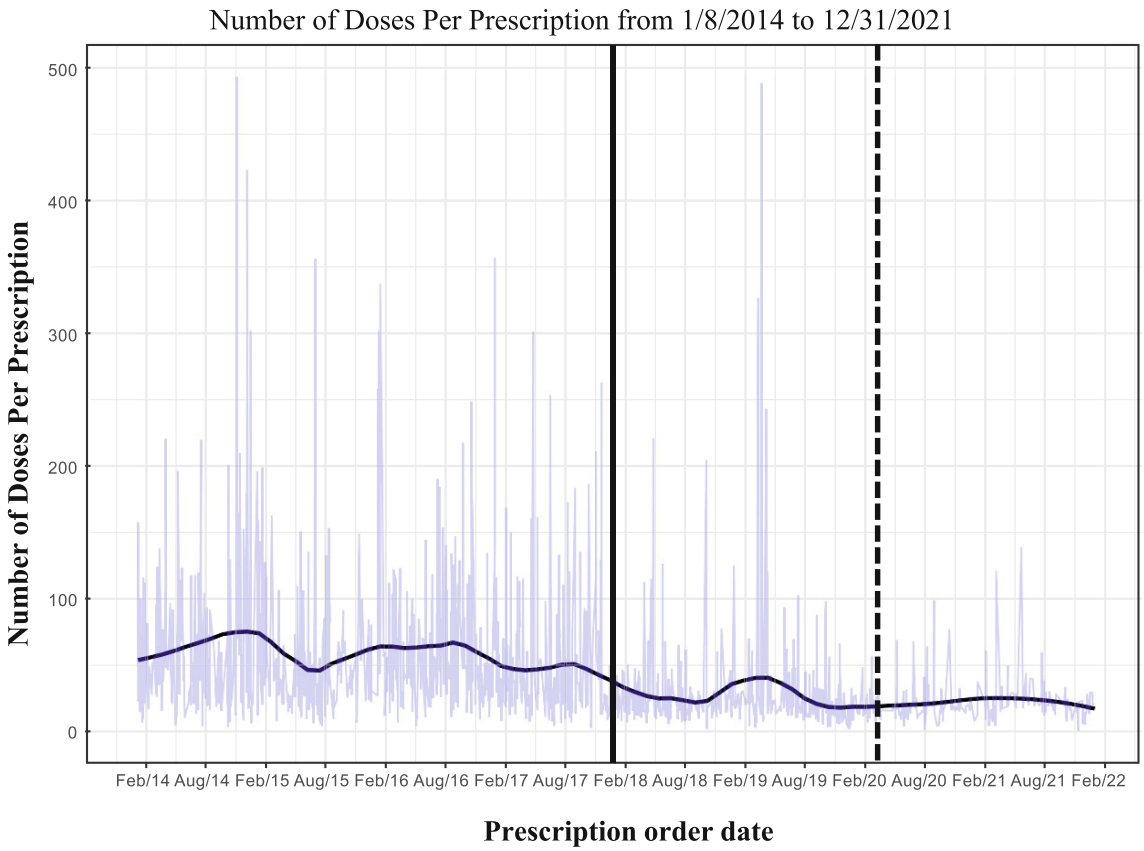

FIGURE 1 Number of doses per prescription from January 8, 2014 to December 31, 2021. Visual representation of the number of doses for all prescriptions over time. Solid black vertical line represents the implementation of the Strengthen Opioid Misuse Prevention (STOP) Act on January 1, 2018. The dashed black vertical line represents the implementation of Duke Children's institutional opioid protocol for pediatric tonsillectomy on March 1, 2020.

used as the primary pain management modality, given on a staggered schedule, with opioids as needed only as a rescue for severe pain.[2,5] Patients were given follow up information to reach their surgical team during and after normal business hours for questions or concerns.

Patients were stratified into three time periods: (1) Pre-STOP Act (January 8, 2014 to January 1, 2018) "Period 1". (2) Post-STOP Act but prior to institutional changes (January 1, 2018 to February 29, 2020) "Period 2". (3) Post institutional changes (after March 1, 2020) "Period 3." Given that oxycodone was the only opioid prescribed to this cohort as well as the wide range of ages and weights of patients included in the analysis, we elected to use number of doses per prescription as the primary outcome instead of average daily oral morphine milligram equivalents. If the child received a prescription for oxycodone tablets, 1 pill was considered 1 dose. If the child received an oxycodone solution, number of doses per prescription was calculated by weight (kg), volume (mL) and dosing regimen (mg/kg) as written for the prescription.

Secondary outcomes were adverse post-tonsillectomy events, defined as a visit to the Emergency Department due to a surgery-related complication within the first 30 days of surgery. All patients who met this criterion underwent a manual review of the medical record to confirm the surgery-related complication (i.e., poorly controlled pain, dehydration, poor intake by mouth, bleeding, gastrointestinal complaints [constipation, nausea, vomiting], respiratory issues, and fever.) Other reasons for returns to the Emergency Department within 30 days of the operation that were unequivocally unrelated to surgery (i.e., car accident, broken bones, fall, joint pain) were excluded.

2.4 | Statistical analysis

We characterized the study population by time period ("Period"), including mean oxycodone dose per prescription with standard deviation (SD). We first assessed whether there was a change in the opioid doses per prescription before and after the policy changes by the Kruskal–Wallis test. To assess the variability between dosing regimens in each Period, we calculated the median oxycodone dose per prescription with interquartile range. We identified extreme outliers by assessing the 95th percentile of the entire cohort. We also calculated standardized

TABLE 1 Demographic and baseline cohort characteristics based on date of surgery.

	Period 1, $N = 837$ Before January 1, 2018	Period 2, $N = 483$ January 1, 2018 to March 1, 2020	Period 3, $N = 202$ After March 1, 2020	Total cohort, $N = 1522$ January 1, 2014 to December 31, 2021	SMD
Number of oxycodone doses					0.58
Mean (SD)	58 (53)	28 (36)	23 (16)	43.6 (47.4)	
Median (IQR)	44 (25, 70)	20 (14, 28)	19 (15, 25)	28 (17.8, 51.7)	
Range	(3, 493)	(3, 488)	(1, 139)	(1, 492.6)	
Age (years)					0.17
Mean (SD)	6.2 (4.3)	7 (4.2)	7.4 (4.8)	6.6 (4.3)	
Medium (IQR)	5 (3, 8)	6 (4, 9)	6 (3, 11)	5 (3, 9)	
Range	(0, 17)	(1, 17)	(0, 17)	(0, 17)	
Sex					0.07
Male	460 (55.0%)	239 (49.5%)	104 (51.5%)	803 (52.8%)	
Female	377 (45.0%)	244 (50.5%)	98 (48.5%)	719 (47.2%)	
Race/ethnicity					0.06
Hispanic	175 (20.9%)	99 (20.5%)	43 (21.3%)	317 (20.8%)	
Black	251 (30.0%)	127 (26.3%)	56 (27.7%)	434 (28.5%)	
White	326 (38.9%)	204 (42.2%)	83 (41.1%)	613 (40.3%)	
Other/unknown	85 (10.2%)	53 (11.0%)	20 (9.9%)	158 (10.4%)	
Patient county					0.36
Local	289 (34.5%)	100 (20.7%)	25 (12.4%)	414 (27.2%)	
Non-local	548 (65.5%)	383 (79.3%)	177 (87.6%)	1108 (72.8%)	
Surgery location					0.17
Hospital based	767 (91.6%)	402 (83.2%)	174 (86.1%)	1343 (88.2%)	
Ambulatory	70 (8.4%)	81 (16.8%)	28 (13.9%)	179 (11.8%)	
Adjuvant medication					
Corticosteroid	806 (96.3%)	477 (98.8%)	200 (99.0%)	1483 (97.4%)	0.12
Ibuprofen	767 (91.6%)	449 (93.0%)	193 (95.5%)	1409 (92.6%)	0.11
Insurance status					0.08
Public	518 (61.9%)	303 (62.7%)	115 (56.9%)	936 (61.5%)	
Private/self-pay	319 (38.1%)	180 (37.3%)	87 (43.1%)	586 (38.5%)	
Surgical indication					0.15
SDB/OSA	787 (94.1%)	475 (98.3%)	196 (97.0%)	1458 (95.9%)	
Recurrent tonsillitis	49 (5.9%)	8 (1.7%)	6 (3.0%)	63 (4.1%)	
Length of stay					0.12
Mean (SD)	0.7 (1.9)	0.4 (1.1)	0.6 (1.0)	0.6 (1.6)	
Median (IQR)	0 (0, 1)	0 (0, 1)	0.5 (0, 1)	0 (0, 1)	
Range	(0, 43)	(0, 17)	(0, 10)	(0, 43)	
Prior year's encounter count					
Mean (SD)	10.9 (10.5)	10.5 (13.3)	12.8 (12.5)	11 (11.7)	0.12
Median (IQR)	8 (4, 14)	7 (4, 12)	9 (5, 14.8)	8 (4, 13)	
Range	(0, 72)	(0, 172)	(1, 90)	(0, 172)	
Encounter type					0.15
Outpatient	765 (91.4%)	467 (96.7%)	194 (96.0%)	1426 (93.7%)	
Inpatient/emergency	72 (8.6%)	16 (3.3%)	8 (4.0%)	96 (6.3%)	
ASA PS					0.33
1	87 (10.4%)	84 (17.4%)	25 (12.4%)	196 (12.9%)	
2	494 (59.0%)	333 (68.9%)	148 (73.3%)	975 (64.1%)	
≥3	256 (30.5%)	66 (13.7%)	29 (14.4%)	349 (22.9%)	

TABLE 1 (Continued)

	Period 1, $N = 837$ Before January 1, 2018	Period 2, $N = 483$ January 1, 2018 to March 1, 2020	Period 3, $N = 202$ After March 1, 2020	Total cohort, $N = 1522$ January 1, 2014 to December 31, 2021	SMD
Comorbidities					
Asthma	213 (25.4%)	120 (24.8%)	54 (26.7%)	387 (25.4%)	0.03
Obesity	79 (9.4%)	71 (14.7%)	39 (19.3%)	189 (12.4%)	0.19
Obstructive sleep apnea	318 (38.0%)	160 (33.1%)	77 (38.1%)	555 (36.5%)	0.07
Trisomy 21	49 (5.9%)	14 (2.9%)	11 (5.4%)	74 (4.9%)	0.10

Abbreviations: ASA, American Society of Anesthesiologists physical status risk classification; IQR, interquartile range; SD, standard deviation; SDB/OSA, sleep disordered breathing/obstructive sleep apnea; SMD, standard mean difference.

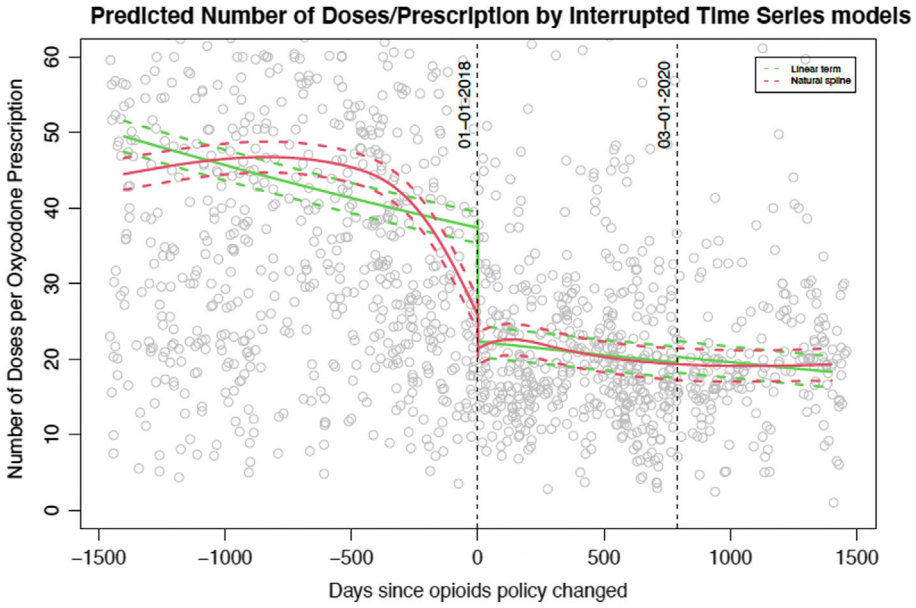

FIGURE 2 Predicted number of doses by interrupted time series models. Fitted model for the change in opioid prescription dosage before and after the STOP Act. Model showed as a linear fit (green) and natural spline (red). There is a gradual reduction in opioid dosage leading up to the STOP Act with a meaningful decrease as the STOP Act goes into effect.

mean differences (SMDs) of oxycodone dose, demographic, and clinical factors to assess the similarity of children across Periods. An SMD is a measure of the ratio of the average difference to its variability. Typically, an SMD >0.10 indicates that two groups are imbalanced. A visual representation of the number of doses for each oxycodone prescription was created to highlight this variability across time (Figure 1).

We next performed two multivariable analyses. We first assessed the impact of the legislative change on dosage, using an interrupted time series design. We regressed log of dosage—to account for skewness—onto an indicator for pre/post the policies, a time variable and interaction between the two. The indicator variable estimates the raw change in opioid dose at the time of policy; the time variable reflects the overall trend in dosage change and the interaction term is the change in that trend after the policy change. The model was adjusted for individual level covariates. Next, we assessed whether dosage was associated with post discharge Emergency Department visits for surgery-related complications. We used a time-to-event Cox Model, regressing time to Emergency Department visit onto log dosage and individual factors to estimate hazard ratios and 95% confidence interval (CI) that estimated the effect of an increase of dosage on risk of Emergency Department visit. Finally, we used Chi-square and Fisher exact tests when appropriate to evaluate differences in complication-specific Emergency Department visits. For all analyses, we calculated effect estimates with 95% CIs. All analyses were conducted in R 4.1.2.

3 | RESULTS

3.1 | Cohort

The total cohort included records of 1522 children. Periods 1, 2, and 3 included 837, 483, and 202 patients respectively.

TABLE 2 Interrupted time series model (association between period and number of dose/prescription).

Variables	Unadjusted relative rates (95% CI)	Adjusted relative rates (95% CI)
Tonsillectomy date		
Period 1 (reference group)[a]		
Period 2[b]	0.60 (0.52, 0.69)*	0.59 (0.51, 0.68)*
Period 3[c]	0.62 (0.46, 0.84)*	0.60 (0.45, 0.81)*
Time: years between tonsillectomy to STOP Act	0.93 (0.89, 0.97)*	0.92 (0.88, 0.96)*
Trend: years after STOP Act	1.01 (0.92, 1.11)	1.02 (0.93, 1.13)
Age (years)		1.02 (1.01, 1.03)*
Sex		
Male (reference group)		
Female		1.08 (1.01, 1.16)*
Race		
White (reference group)		
Hispanic		0.91 (0.82, 1.02)
Black		0.95 (0.87, 1.04)
Other/unknown		0.93 (0.82, 1.05)
Surgery location		
Hospital based (reference group)		
Ambulatory based		0.91 (0.81, 1.03)
Patient county		
Non-local (reference group)		
Local		0.79 (0.73, 0.87)*
Asthma		
No (reference group)		
Yes		1.03 (0.94, 1.11)
Surgical indication		
SDB/OSA (reference group)		
Tonsillitis		1.06 (0.88, 1.28)
Length of stay (days)		1.01 (0.98, 1.03)
Prior year's encounter count		1.00 (0.99, 1.00)
Encounter type		
Outpatient		
Inpatient/emergency		0.93 (0.79, 1.10)
Insurance status		
Public (reference group)		
Private		1.06 (0.97, 1.15)
ASA-PS		
2 (reference group)		
1		1.03 (0.92, 1.16)
≥3		0.99 (0.90, 1.09)

Note: Age, length of stay, and prior year's encounter count were centered (Age = Age − mean [Age], etc.).
Abbreviations: ASA, American Society of Anesthesiologists physical status risk classification; SDB/OSA, sleep disordered breathing/obstructive sleep apnea.
[a]Period 1: before January 1, 2018.
[b]Period 2: January 1, 2018 to March 1, 2020: after North Carolina legislation, prior to institutional changes.
[c]Period 3: After March 1, 2020: after institutional changes.
*$p < .05$.

TABLE 3 Adjusted and unadjusted[a] Cox model examining opioid prescription dose, demographic and clinical factors associated with surgical complication-related Emergency Department visits within 30 days.

Variable	Adjusted hazard ratio (95% CI)
Log10 (number of doses per prescription)[b]	2.14 (1.21, 3.77)*
Age (years)	0.98 (0.92, 1.03)
Sex	
Male (reference group)	
Female	0.68 (0.44, 1.05)
Race	
White (reference group)	
Hispanic	1.46 (0.78, 2.73)
Black	1.20 (0.67, 2.16)
Other/unknown	1.41 (0.68, 2.91)
Surgery location	
Hospital based (reference group)	
Ambulatory based	0.65 (0.28, 1.52)
Geography	
Non-local (reference group)	
Local	1.64 (1.05, 2.56)*
Asthma	
No (reference group)	
Yes	1.45 (0.93, 2.28)
Surgical indication	
SDB/OSA (reference group)	
Tonsillitis	1.08 (0.38, 3.02)
Length of stay (days)	0.72 (0.50, 1.04)
Prior year's encounter count	1.00 (0.98, 1.02)
Encounter type	
Outpatient (reference group)	
Inpatient/emergency	1.51 (0.55, 4.12)
Insurance status	
Public (reference group)	
Private	0.73 (0.44, 1.23)
ASA-PS	
2 (reference group)	
1	1.28 (0.64, 2.56)
≥3	1.11 (0.66, 1.86)

Abbreviations: ASA, American Society of Anesthesiologists physical status classification system; SDB/OSA, sleep disordered breathing/obstructive sleep apnea.

[a]Unadjusted hazard ratio (95% CI): 2.02 (1.15, 3.54).

[b]Number of doses. Log of number of doses per prescription was used to account for the skewness of the dosage per prescription data.

*$p < .05$.

Demographic data are in Table 1. Mean age for all patients was 6.6 ± 4.3 years, range 0–17 years. There were similar numbers of males (47%) and females (53%). The majority of patients underwent tonsillectomy for sleep disordered breathing or obstructive sleep apnea (96%). There is a larger proportion of patients in Period 1 with ASA PS ≥3 (31% vs. 14% in Periods 2 and 3). This is not explained by common comorbid medical conditions that present in children undergoing pediatric tonsillectomy including diagnoses of obesity, obstructive sleep apnea, asthma, and Trisomy 21. There is a slightly larger proportion of patients in Periods 2 and 3 who received corticosteroids and ibuprofen, but no difference between groups for the use of intraoperative adjuvant analgesic medications (i.e., dexmedetomidine).

3.2 | Outcomes

Mean (±SD) number of oxycodone doses per prescription by Periods 1, 2, and 3 were: 58 ± 53 (range 4–493); 28 ± 36 (range 3–488); and 23 ± 17 (range 1–139), respectively. Figure 1 is a visual representation of the number of doses for every opioid prescription in the cohort plotted over time. The dashed lines divide the cohort into the three time periods. Median (Q1, Q3) number of doses by Periods 1, 2, 3 were 44 (25, 70); 20 (14, 28); and 19 (15, 25), respectively. There is significant variability in the number of doses per prescription, particularly in Period 1, which is supported by SMD >0.1 between groups. While the variability decreases in Periods 2 and 3, the upper quartile (25%) of prescriptions in Periods 2 and 3 were greater than 28 and 25 doses of oxycodone, respectively. The percentage of prescriptions that were less than or equal to 20 doses was 15%, 53%, and 59% in Periods 1, 2, and 3 respectively. The percentage of outlier prescriptions (>95th percentile = number of doses > 123) was 8%, 2%, and 0.4% in Periods 1, 2, and 3 respectively. Figure 2 shows a visual representation of the results of the interrupted time series analysis. After the implementation of STOP Act, there was a decrease in the number of doses by −9% (95% CI −13%, −5%) per year in Periods 2 and 3 (Table 2).

Table 3 summarizes the hazard ratios for clinical factors and adverse outcomes. The rate of Emergency Department encounters and the reasons patients had a return visit is shown in Table 4. The overall Emergency Department encounter rate was 6% of the study group, with 8% (68/837), 4% (19/483), and 3% (5/202) in Periods 1, 2, and 3 respectively. When all types of surgery-related complications to the Emergency Department were examined, there were no differences in the reasons patients returned despite the significantly higher event rate in Period 1. The higher number of doses in the prescription was associated with a higher likelihood of a return visit to the Emergency Department, where every 10-fold increase in dosage has an adjusted HR = 2.1 (95% CI: 1.2, 3.8). However, it is not clear from our manual review of these patients' electronic health records whether these return visits were specifically opioid related.

TABLE 4 Surgery related reason for emergency department visits within 30 days of tonsillectomy.

Outcome	Time Period 1 Prior to January 1, 2018	Time Period 2 Between January 1, 2018 to March 1, 2020	Time Period 3 After March 1, 2020	*p* value
Pain	19	4	0	.182
Dehydration/poor feeding	14	1	0	
GI (nausea/vomiting/constipation)	6	1	1	
Bleeding	16	7	3	
Respiratory issues	2	4	1	
Fever	8	5	0	
Other	3	0	0	
Total	68	22	5	

Abbreviation: GI, gastrointestinal.

4 | DISCUSSION

While clinical guidelines strongly recommend the scheduled use of non-opioid adjuvants for post-tonsillectomy pain in children,[2–5] the use of as needed postoperative opioids remains highly variable in clinical practice.[7,25–27] This may be, in part, due to conflicting published recommendations. The most recent guidelines from the American Academy of Otolaryngology-Head and Neck Surgeons (AAO-HNS) in 2021 suggest no postoperative opioids for pediatric patients between 5 and 12 years of age after routine adenotonsillectomy.[4] Yet recommendations from an expert surgical panel, also published in 2021, list pediatric adenotonsillectomy as a procedure in which "opioid-free postoperative analgesia may be possible for some patients under some circumstances."[3] Practical applications of national guidelines through The National Tonsil Surgery Registry in Sweden showed that half the departments surveyed prescribed rescue medications, including opioids, while the other half did not.[25] Literature has shown that children often receive more opioid doses than are needed to treat postoperative pain and that these left-over medications are routinely left undisposed of with the potential for misuse and diversion.[28–32] However, the risk of over-prescribing medications must be carefully balanced by the risks of the undertreatment of post-tonsillectomy pain which include poor oral intake, dehydration, and prolonged recovery time.[33] It is the ongoing challenge to find this delicate balance, which has resulted in the continuation of a wide range of practices with varying analgesic regimens.[7,26,27]

Our study highlights three new findings. First, there was a significant change in the number of doses per oxycodone prescription following pediatric tonsillectomy after the passage of state legislation from an average of 58 doses to 28 doses per prescription. Average number of doses was further lowered to 23 doses following institutional practice recommendations and continued to decrease yearly. This is a strength of our study as much of the current literature around opioids following pediatric tonsillectomy only analyze the categorical outcome of whether a child received a prescription, not the quantity of or variation in the prescription itself. Second, as the number of oxycodone doses decreased, there was no increase in returns to the Emergency Department for pain complaints. Finally, despite state legislation and focused institutional interventions to change prescribing practices, we found ongoing variability in discharge oxycodone regimens and less than 60% of prescriptions were consistent with the institutional intervention.

In the pediatric literature, three recent investigations into effects of legislative policies on post-operative opioid prescribing in children[34–36]; however, none of these studies address the effect of legislation on variation in prescriptions. The first, published in 2021, retrospectively analyzed over 4300 pediatric urology patients in the state of Pennsylvania in which opioid consents have been required for minors since 2016.[34] Following this mandate, opioid prescriptions in this population decreased dramatically from 45% to 3% ($p < .001$) with no increase in Emergency Department visits or additional opioid prescriptions. The second study, from West Virginia, which enacted a law in 2018 limiting the quantity of opioids prescribed, retrospectively reviewed over 10,000 pediatric trauma patients and showed more modest but still statistically significant decreases in the percentage of patients receiving a prescription (46%–37%, $p < .001$).[35] Finally, the most recent publication compared 360 pediatric tonsillectomy patients 1 year before and after legislation requiring signed opioid consents in the state of Vermont.[36] This study reports large decreases in the percentage of patients receiving an opioid prescription (50% pre vs. 15% post, $p < .001$).

In addition to legislation, multiple studies have shown that the implementation of institutional protocols, including electronic health record order sets can reduce variability in opioid prescriptions. Two publications reported this specifically for pediatric tonsillectomy.[37,38] It has been well described that high variation in perioperative prescribing is a major contributor to the supply side of the opioid pool.[9] Limiting variability associated with prescribing is particularly important at a large academic tertiary care center in which relatively inexperienced trainees are often responsible for postsurgical prescribing. At our institution, second year otolaryngology residents rotate on the pediatric service for three to four consecutive months and write for greater than 95% of opioid prescriptions. This is often their first experience with writing weight-based dosing prescriptions in liquid

formulations. Despite opioid focused education at the beginning of the academic year, this trainee model with perpetual rotation of residents on the pediatric ENT service may account for the temporally associated variability with spikes every 3–4 months seen in Figure 1 and relatively low compliance with institutional recommendations.

This finding of continued opioid prescribing variability in a single center despite legislation and targeted institutional interventions highlights the need for continued and concerted efforts to maintain changes in behaviors associated with medical practice. While our institution was able to decrease the mean number of doses and the number of extreme outliers prescribed to patients in Period 3, the variation in take home oxycodone dosing regimens, as noted above, was *not* eliminated. Recent implementation science studies and associated commentaries have highlighted this resistance to change in perioperative care despite evidence-based recommendations and guidelines.[39–41] While significant resources are used to develop clinical practice guidelines, it is well-established that (1) recommendations alone may not be sufficient to result in sustained change in practice,[40] (2) there continue to be lengthy "evidence to practice gaps,"[42,43] and (3) the effectiveness of clinical practice guidelines on health outcomes is understudied.[44] Best practice guidelines may also have untoward and unexpected outcomes,[45] which can result in dramatic overhauls in subsequent recommendations. An example of this is currently unfolding as the CDC recently updated their 2016 clinical practice guideline for prescribing opioids for pain,[46] now providing clinicians with more flexibility and eliminating dose and length of treatment caps. It is too early to evaluate the effect of the 2021 AAO-HNS opioid guidelines and whether surgeons will receive more postoperative pain complaints from pediatric tonsillectomy patients. Regardless, this study supports the idea that behavioral changes in practice may begin with legislation, government supported clinical practice guidelines, society recommendations, or institutionally driven protocols, but the implementation of lasting change requires an active commitment to the process to be effective in the real world.

We do recognize our study limitations. First, this retrospective analysis examines opioid prescriptions and short-term outcomes (Emergency Department visit) only, and we do not have data on (1) the numbers of consumed and unused leftover oxycodone doses, (2) pain scores and patient/family perception of pain management, and (3) long term patient outcomes as suggested by The National Academy of Medicine.[47] Additionally, DCH is a teaching hospital and tertiary care center so our results may not be generalizable to other clinical environments. Furthermore, for our adverse events analysis, we did not account for type of tonsillectomy performed (intracapsular vs. extracapsular), surgical technique, or variations in the dosing regimens of NSAIDs and corticosteroids, which may influence postoperative pain control.[48–50] Nonetheless, despite these notable limitations, this study adds to the current information about the role of state legislation and institutional practice changes in opioid prescribing for a common and painful pediatric surgery. It also illustrates the need for more evidence-based prescribing of post-discharge opioids for pediatric tonsillectomy, as well as perioperative regimens that provide better and longer-duration analgesia, thereby reducing patient needs for post-discharge opioids.

5 | CONCLUSION

In this retrospective cohort study, we found that the mean number of doses per oxycodone prescription decreased following the introduction of state legislation and institutional guidelines in pediatric patients undergoing tonsillectomy. Following these interventions, variability in prescription regimens also decreased but was not eliminated. This decreased number of doses per prescription was not associated with an increase in return visits to the Emergency Department for pain.

AUTHOR CONTRIBUTIONS

Lisa Einhorn: This author helped design the study, collect, and analyze the data, write and approve the final manuscript. Congwen Zhao: This author helped analyze the data; critically revise the manuscript for important intellectual content; and edit, read, and approve the final manuscript. Benjamin Goldstein: This author helped analyze the data; critically revise the manuscript for important intellectual content; and edit, read, and approve the final manuscript. Sudha Raman: This author helped design the study; critically revise the manuscript for important intellectual content; write and approve the final manuscript. Jeffrey Cheng: This author helped design the study; edit, read and approve the final manuscript.

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CONFLICT OF INTEREST STATEMENT

None.

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REFERENCES

1. Hall MJ, Schwartzman A, Zhang J, Liu X. Ambulatory surgery data from hospitals and ambulatory surgery centers: United States, 2010. *Natl Health Stat Rep*. 2017;102:1-15.
2. Mitchell RB, Archer SM, Ishman SL, et al. Clinical practice guideline: tonsillectomy in children (update). *Otolaryngol Head Neck Surg*. 2019; 160(1_suppl):S1-S42. doi:10.1177/0194599818801757
3. Kelley-Quon LI, Kirkpatrick MG, Ricca RL, et al. Guidelines for opioid prescribing in children and adolescents after surgery: an expert panel

opinion. *JAMA Surg*. 2021;156(1):76-90. doi:10.1001/jamasurg.2020.5045
4. Anne S, Mims JW, Tunkel DE, et al. Clinical practice guideline: opioid prescribing for analgesia after common otolaryngology operations. *Otolaryngol Head Neck Surg*. 2021;164(2_suppl):S1-S42. doi:10.1177/0194599821996297
5. Ericsson E, Brattwall M, Lundeberg S. Swedish guidelines for the treatment of pain in tonsil surgery in pediatric patients up to 18 years. *Int J Pediatr Otorhinolaryngol*. 2015;79(4):443-450. doi:10.1016/j.ijporl.2015.01.016
6. Qian ZJ, Alyono JC, Jin MC, Cooperman SP, Cheng AG, Balakrishnan K. Opioid prescribing patterns following pediatric tonsillectomy in the United States, 2009–2017. *Laryngoscope*. 2021;131(5):E1722-E1729. doi:10.1002/lary.29159
7. Chua KP, Harbaugh CM, Brummett CM, et al. Association of perioperative opioid prescriptions with risk of complications after tonsillectomy in children. *JAMA Otolaryngol Head Neck Surg*. 2019;145(10):911-918. doi:10.1001/jamaoto.2019.2107
8. Chua KP, Shrime MG, Conti RM. Effect of FDA investigation on opioid prescribing to children after tonsillectomy/adenoidectomy. *Pediatrics*. 2017;140(6). doi:10.1542/peds.2017-1765
9. Kharasch ED, Clark JD, Adams JM. Opioids and public health: the prescription opioid ecosystem and need for improved management. *Anesthesiology*. 2022;136(1):10-30. doi:10.1097/ALN.0000000000004065
10. Harbaugh CM, Lee JS, Hu HM, et al. Persistent opioid use among pediatric patients after surgery. *Pediatrics*. 2018;141(1). doi:10.1542/peds.2017-2439
11. Hudgins JD, Porter JJ, Monuteaux MC, Bourgeois FT. Prescription opioid use and misuse among adolescents and young adults in the United States: a national survey study. *PLoS Med*. 2019;16(11):e1002922. doi:10.1371/journal.pmed.1002922
12. Sung HE, Richter L, Vaughan R, Johnson PB, Thom B. Nonmedical use of prescription opioids among teenagers in the United States: trends and correlates. *J Adolesc Health*. 2005;37(1):44-51. doi:10.1016/j.jadohealth.2005.02.013
13. Brown KW, Carlisle K, Raman SR, et al. Children and the opioid epidemic: age-stratified exposures and harms. *Health Aff (Millwood)*. 2020;39(10):1737-1742. doi:10.1377/hlthaff.2020.00724
14. Xie Y, Joseph AW, Rudy SF, et al. Change in postoperative opioid prescribing patterns for oculoplastic and orbital procedures associated with state opioid legislation. *JAMA Ophthalmol*. 2021;139(2):157-162. doi:10.1001/jamaophthalmol.2020.5446
15. McDowell CM, Bradian AK, Cheesman QT, et al. The effect of state legislation on opioid prescriptions following arthroscopic rotator cuff repair. *Orthopedics*. 2021;44(1):e80-e84. doi:10.3928/01477447-20200928-01
16. Benfield CP, Doe KK, Protzuk OA, Thacker LR, Golladay GJ. Effect of state legislation on discharge opioid prescriptions after total hip and knee arthroplasties. *Arthroplast Today*. 2020;6(4):856-859. doi:10.1016/j.artd.2020.08.003
17. Cunningham DJ, Ryan SP, George SZ, Lewis BD. Opioid legislation and narcotic filling in total hip arthroplasty: descriptive study of time and state-level trends in the United States. *Subst Abuse Treat Prev Policy*. 2021;16(1):75. doi:10.1186/s13011-021-00410-w
18. Guidry C, Dema B, Allen C, Stewart D. Impact of state legislation in Tennessee on opioid prescribing practices of orthopedic surgeons. *J Opioid Manag*. 2022;18(2):143-149. doi:10.5055/jom.2022.0704
19. Strengthen Opioid Misuse Prevention (STOP) Act Overview. Accessed September 27, 2022. https://www.ncleg.gov/DocumentSites/Committees/NCCFTF/Presentations/2017-2018/STOP%20Act%20Overview%20CFTF%209-26-2017.pdf.
20. Chen EY, Betancourt L, Li L, Trucks E, Marcantonio A, Tornetta P. Standardized, patient-specific, postoperative opioid prescribing after inpatient orthopaedic surgery. *J Am Acad Orthop Surg*. 2020;28(7):e304-e318. doi:10.5435/JAAOS-D-19-00030
21. Overton HN, Hanna MN, Bruhn WE, et al. Opioid-prescribing guidelines for common surgical procedures: an expert panel consensus. *J Am Coll Surg*. 2018;227(4):411-418. doi:10.1016/j.jamcollsurg.2018.07.659
22. Jones K, Engler L, Fonte E, Farid I, Bigham MT. Opioid reduction through postoperative pain management in pediatric orthopedic surgery. *Pediatrics*. 2021;148(6). doi:10.1542/peds.2020-001487
23. Chang MT, Lalakea ML, Shepard K, Saste M, Munoz A, Amoils M. Implementation of a standardized perioperative pain management protocol to reduce opioid prescriptions in otolaryngologic surgery. *Otolaryngol Head Neck Surg*. 2022;167(4):657-663. doi:10.1177/01945998211071116
24. Hurst JH, Liu Y, Maxson PJ, Permar SR, Boulware LE, Goldstein BA. Development of an electronic health records datamart to support clinical and population health research. *J Clin Transl Sci*. 2020;5(1):e13. doi:10.1017/cts.2020.499
25. Alm F, Jaensson M, Lundeberg S, Ericsson E. Adherence to Swedish guidelines for pain treatment in relation to pediatric tonsil surgery: a survey of the multidisciplinary team. *Int J Pediatr Otorhinolaryngol*. 2017;101:123-131. doi:10.1016/j.ijporl.2017.07.040
26. Franz AM, Dahl JP, Huang H, Verma ST, Martin LD, Low DK. The development of an opioid sparing anesthesia protocol for pediatric ambulatory tonsillectomy and adenotonsillectomy surgery-a quality improvement project. *Paediatr Anaesth*. 2019;29(7):682-689. doi:10.1111/pan.13662
27. George JA, Park PS, Hunsberger J, et al. An analysis of 34,218 pediatric outpatient controlled substance prescriptions. *Anesth Analg*. 2016;122(3):807-813. doi:10.1213/ANE.0000000000001081
28. Renny MH, Yin HS, Jent V, Hadland SE, Cerdá M. Temporal trends in opioid prescribing practices in children, adolescents, and younger adults in the US from 2006 to 2018. *JAMA Pediatr*. 2021;175(10):1043-1052. doi:10.1001/jamapediatrics.2021.1832
29. Cartmill RS, Yang DY, Walker BJ, et al. Opioid prescribing to preteen children undergoing ambulatory surgery in the United States. *Surgery*. 2021;170(3):925-931. doi:10.1016/j.surg.2021.03.043
30. Stone AL, Qu'd D, Luckett T, et al. Leftover Opioid Analgesics and Disposal Following Ambulatory Pediatric Surgeries in the Context of a Restrictive Opioid-Prescribing Policy. *Anesth Analg*. 2022;134(1):133-140. doi:10.1213/ANE.0000000000005503
31. Monitto CL, Hsu A, Gao S, et al. Opioid prescribing for the treatment of acute pain in children on hospital discharge. *Anesth Analg*. 2017;125(6):2113-2122. doi:10.1213/ANE.0000000000002586
32. Horton JD, Munawar S, Corrigan C, White D, Cina RA. Inconsistent and excessive opioid prescribing after common pediatric surgical operations. *J Pediatr Surg*. 2019;54(7):1427-1431. doi:10.1016/j.jpedsurg.2018.07.002
33. Salonen A, Kokki H, Nuutinen J. The effect of ketoprofen on recovery after tonsillectomy in children: a 3-week follow-up study. *Int J Pediatr Otorhinolaryngol*. 2002;62(2):143-150. doi:10.1016/s0165-5876(01)00610-3
34. Villanueva J, Grajales V, Colaco M, et al. Government mandated consent dramatically reduces pediatric urologist opioid utilization for outpatient and minor emergency surgeries. *J Urol*. 2021;205(1):264-270. doi:10.1097/JU.0000000000001320
35. Shackleford TL, Ray JJ, Bronikowski DM, Lancaster JD, Grant DR. Effect of state legislation on opioid prescribing practices after surgery at a pediatric hospital. *Acad Pediatr*. 2022;22(1):137-142. doi:10.1016/j.acap.2021.09.017
36. Gerges D, Wershoven N, Hubbell R, Herrington H. Opioid prescribing practices for pediatric tonsillectomy before and after policy interventions. *Laryngosc Investig Otolaryngol*. 2022;7(2):621-626. doi:10.1002/lio2.737
37. Agamawi YM, Cass LM, Mouzourakis M, Pannu JS, Brinkmeier JV. Pediatric post-tonsillectomy opioid prescribing practices. *Laryngoscope*. 2021;131(6):1386-1391. doi:10.1002/lary.29157

38. Luk LJ, Mosen D, MacArthur CJ, Grosz AH. Implementation of a pediatric posttonsillectomy pain protocol in a large group practice. *Otolaryngol Head Neck Surg*. 2016;154(4):720-724. doi:10.1177/0194599815627810
39. Weigel WA, Williams BL, Hanson NA, et al. Quantitative neuromuscular monitoring in clinical practice: a professional practice change initiative. *Anesthesiology*. 2022;136(6):901-915. doi:10.1097/ALN.0000000000004174
40. Lane-Fall MB. What anesthesiology has to learn from implementation science and quality improvement. *Anesthesiology*. 2022;136(6):875-876. doi:10.1097/ALN.0000000000004206
41. Ong SY, Walker A. Using Kotter's 8 steps of change to tackle overfasting of children attending day surgery. *Paediatr Anaesth*. 2022;32(11):1238-1245. doi:10.1111/pan.14499
42. Lane-Fall MB, Cobb BT, Cené CW, Beidas RS. Implementation science in perioperative care. *Anesthesiol Clin*. 2018;36(1):1-15. doi:10.1016/j.anclin.2017.10.004
43. Balas EA, Boren SA. Managing clinical knowledge for health care improvement. *Yearb Med Inform*. 2000;1:65-70.
44. Kredo T, Bernhardsson S, Machingaidze S, et al. Guide to clinical practice guidelines: the current state of play. *Int J Qual Health Care*. 2016;28(1):122-128. doi:10.1093/intqhc/mzv115
45. Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *BMJ*. 1999;318(7182):527-530. doi:10.1136/bmj.318.7182.527
46. Dowell DRK, Jones CM, Baldwin GT, Chou R. CDC clinical practice guideline for prescribing opioids for pain—United States, 2022. *MMWR Recomm Rep*. 2022;71(RR-3):1-95. doi:10.15585/mmwr.rr7103a1
47. National Academies of Sciences Engineering and Medicine. *Framing, opioid prescribing guidelines for acute pain: developing the evidence*. National Academies Press; 2020. doi:10.17226/25555
48. Palme CE, Tomasevic P, Pohl DV. Evaluating the effects of oral prednisolone on recovery after tonsillectomy: a prospective, double-blind, randomized trial. *Laryngoscope*. 2000;110(12):2000-2004. doi:10.1097/00005537-200012000-00003
49. Park SK, Kim J, Kim JM, Yeon JY, Shim WS, Lee DW. Effects of oral prednisolone on recovery after tonsillectomy. *Laryngoscope*. 2015;125(1):111-117. doi:10.1002/lary.24958
50. Kelly LE, Sommer DD, Ramakrishna J, et al. Morphine or ibuprofen for post-tonsillectomy analgesia: a randomized trial. *Pediatrics*. 2015;135(2):307-313. doi:10.1542/peds.2014-1906

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