http://dx.doi.org/10.2106/JBJS.19.00437

April 21, 2020

In response to: "Ethics of Opioid Prescriber Regulations: Physicians, Patients, and Pain."

Daniel B.C. Reid
Orthopaedic Surgeon
Department of Orthopaedics, Warren Alpert Medical School of Brown University

Other Contributors:

Kalpit N. Shah
Orthopaedic Surgeon
Department of Orthopaedics, Warren Alpert Medical School of Brown University

Edward Akelman
Orthopaedic Surgeon
Department of Orthopaedics, Warren Alpert Medical School of Brown University

Alan H. Daniels
Orthopaedic Surgeon
Department of Orthopaedics, Warren Alpert Medical School of Brown University

Dear Editor,

We read the recent article "Ethics of Opioid Prescriber Regulations: Physicians, Patients, and Pain." by Lajam et. al. with great interest. Given the rapid expansion of local, statewide, and national regulations, a thoughtful review of the practical and ethical implications of opioid-related policies was certainly needed. In particular, we commend the authors' examination of the primary tenets of medical ethics; namely beneficence, nonmaleficence, autonomy, justice, and utilitarianism. The authors explore the ethical implications of opioid prescription limits, drug monitoring programs, mandatory prescriber education, expanded naloxone use, opioid disposal, and pain/satisfaction scores. While the authors' generally present appropriately nuanced arguments for each type of regulation, their reasoning remains largely theoretical. As orthopedic providers in one of the first states to implement regulations mandating strict opioid prescribing limitations, we have substantial experience navigating such laws. We have published our experience on this topic (1–6) and would like to offer our thoughts on the matter.

We respectfully disagree with the authors' conclusion that opioid prescribing limits are not ethically sound

and may have negative ethical implications. The authors state that because surgeons are bound by the moral duties of beneficence (a duty to do good) and nonmaleficence (a duty to do no harm), appropriate treatment of postoperative pain is necessary to assist in recovery from painful treatments and permit function for patients with chronic pain. While we certainly agree that appropriate perioperative pain control is in the best interest of patients, the authors provide no peer-reviewed evidence that unrestricted access to opioids in the postoperative period results in enhanced pain control, rehabilitation, or recovery. Furthermore, the authors fail to explore the ways in which physicians can appropriately control perioperative pain within the framework of modern opioid prescribing regulations. We will discuss the evidence-based literature which supports the beneficence, nonmaleficence, and utilitarianism of most opioid limiting legislation.

First of all, the majority of patients we treat, even following extensile procedures, experience pain which is adequately managed within the framework of existing opioid restricting laws (6, 7, 8). The orthopedic literature has generally failed to associate increased perioperative opioid use with better pain control or improved patient satisfaction (7, 9, 10, 11). Previous studies evaluating the of effect of opioid limiting laws on spine surgery patients found no effect on 90-day postoperative emergency department visits, hospital readmissions, or reoperations, indirectly suggesting that postoperative pain control is not a major issue (4, 5). Such findings should not be surprising, given the known discrepancy between perioperative opioid use in the United States and European countries (12–15).

Second, while it is true that most opioid prescribing laws do not specifically exempt postoperative patients, most do provide legal exemptions under which surgical patients may reasonably fall. In our state, for example, any patients with a prior opioid prescription documented within 30 days falls withing the “chronic use” category for which no opioid restrictions apply. Thus, in conjunction with a robust prescription drug monitoring program and the ability to electronically prescribe opioid pain medications (with use of secure two factor authentication), surgeons can easily tailor postoperative prescribing starting at the first refill. When evaluating prescription patterns following implementation of a statewide opioid limiting law in Rhode Island, we found an absolute decrease in the mean number of opioid pills filled in the 30-day postoperative period, regardless of procedures, specialty, or number of refills required (1–6).

Finally, while the authors’ discussion of the ethical considerations of opioid limiting regulations focuses largely on theory, in the face of a national opioid crisis resulting in profound national morbidity and mortality, the ethical concept of utilitarianism (does an action benefits the majority of society?) must be strongly considered. Perhaps the best way to examine such an ethical imperative is to evaluate the impact of such regulations in the real world. To our knowledge, every major study that has examined the implementation of opioid limiting regulations (whether governmental or institutional) has noted

substantial reductions in opioid prescribing, regardless of specialty (1-6, 16-22). In an anonymous survey of surgeons from every orthopaedic subspecialty at our institution (unpublished, N=77), we found that 87.7% (64/73) of surgeons believed opioid limiting regulations are “ethically sound.” Likewise, while 58.5% (45/77) of surgeons stated that they were initially concerned about the possibility of poor postoperative pain control prior to implementation of aforementioned legislation, only 19.5% (15/77) of surgeons now (3 years post-implementation) describe postoperative pain control as a significant problem for their patients. Some 81.3% (61/75) of surgeons surveyed stated that opioid limiting legislation “helps patient care,” with only 18.7% (14/75) stating this it “hurts patient care.”

In conclusion, while a number of theoretical ethical concerns have been raised by the authors in this important and timely article, the majority of applicable real world studies to date have found opioid limiting regulations to be safe, effective, and individualizable for postoperative care. Orthopaedic surgeons can adequately maintain the ethical principles of beneficence, nonmaleficence, and utilitarianism while caring for their patients within a legal framework of opioid limiting legislation.

References

1. Shah KN, Ruddell JH, Reid DBC, et al. Opioid-Limiting Regulation: Effect on Patients Undergoing Knee and Shoulder Arthroscopy. Arthrosc J Arthrosc Relat Surg. 2020;36(3):824-831. doi:10.1016/j.arthro.2019.09.045
2. Reid DBC, Shah KN, Shapiro BH, et al. Opioid-Limiting Legislation Associated With Reduced Postoperative Prescribing After Surgery for Traumatic Orthopaedic Injuries. J Orthop Trauma. 2020;34(4):e114-e120. doi:10.1097/BOT.0000000000001673
3. Reid DBC, Shapiro B, Shah KN, et al. Has a Prescription-limiting Law in Rhode Island Helped to Reduce Opioid Use After Total Joint Arthroplasty? Clin Orthop Relat Res. July 2019:1. doi:10.1097/CORR.0000000000000885
4. Reid DBC, Patel SA, Shah KN, et al. Opioid-limiting legislation associated with decreased 30-day opioid utilization following anterior cervical decompression and fusion. Spine J. September 2019. doi:10.1016/j.spinee.2019.08.014
5. Reid DBC, Shah KN, Ruddell JH, et al. Effect of narcotic prescription limiting legislation on opioid utilization following lumbar spine surgery. Spine J. 2019;19(4):717-725. doi:10.1016/j.spinee.2018.09.007
6. Reid DBC, Shah KN, Shapiro BH, Ruddell JH, Akelman E, Daniels AH. Mandatory Prescription Limits and Opioid Utilization Following Orthopaedic Surgery. J Bone Jt Surg. 2019;101(10):e43. doi:10.2106/JBJS.18.00943
7. Etcheson JI, Gwam CU, George NE, Caughran AT, Mont MA, Delanois RE. Does the Amount of Opioid Consumed Influence How Patients Rate Their Experience of Care After Total Knee Arthroplasty? J Arthroplasty. 2018;33(11):3407-3411. doi:10.1016/j.arth.2018.06.028
8. Holte AJ, Carender CN, Noiseux NO, Otero JE, Brown TS. Restrictive Opioid Prescribing Protocols Following Total Hip Arthroplasty and Total Knee Arthroplasty Are Safe and Effective. J Arthroplasty. 2019;34(7):S135-S139. doi:10.1016/j.arth.2019.02.022
9. Adalbert JR, Ilyas AM. Implementing Prescribing Guidelines for Upper Extremity Orthopedic Procedures: A Prospective Analysis of Postoperative Opioid Consumption and Satisfaction. HAND. August 2019:155894471986712. doi:10.1177/1558944719867122
10. Hills JM, Carlile CR, Archer KR, et al. Duration and Dosage of Opioids after Spine Surgery. Spine (Phila Pa 1976). February 2020:1. doi:10.1097/BRS.0000000000003446
11. Nota SPFT, Spit SA, Voskuyl T, Bot AGJ, Hageman MGJS, Ring D. Opioid Use, Satisfaction, and Pain Intensity After Orthopedic Surgery. Psychosomatics. 2015;56(5):479-485. doi:10.1016/j.psym.2014.09.003
12. Lindenhovious ALC, Helmerhorts GTT, Schnellen AC, Vrahas M, Ring D, Kloen P. Differences in Prescription of Narcotic Pain Medication After Operative Treatment of Hip and Ankle Fractures in the United States and the Netherlands. J Trauma Inj Infect Crit Care. 2009;67(1):160-164. doi:10.1097/TA.0b013e31818c12ee

13. Helmerhorst GTT, Lindenhovius ALC, Vrahas M, Ring D, Kloen P. Satisfaction with pain relief after operative treatment of an ankle fracture. Injury. 2012;43(11):1958-1961. doi:10.1016/j.injury.2012.08.018
14. Meyer A, LeClair C, McDonald J V. Prescription Opioid Prescribing in Western Europe and the United States. R I Med J (2013). 2020;103(2):45-48. http://www.ncbi.nlm.nih.gov/pubmed/32122101. Accessed April 19, 2020.
15. Chapman CR, Stevens DA, Lipman AG. Quality of Postoperative Pain Management in American Versus European Institutions. J Pain Palliat Care Pharmacother. 2013;27(4):350-358. doi:10.3109/15360288.2013.846955
16. Premkumar A, Lovecchio FC, Stepan JG, et al. Characterization of opioid consumption and disposal patterns after total knee arthroplasty. Bone Joint J. 2019;101-B(7_Supple_C):98-103. doi:10.1302/0301-620X.101B7.BJJ-2018-1518.R1
17. Earp BE, Silver JA, Mora AN, Blazar PE. Implementing a Postoperative Opioid-Prescribing Protocol Significantly Reduces the Total Morphine Milligram Equivalents Prescribed. J Bone Jt Surg. 2018;100(19):1698-1703. doi:10.2106/JBJS.17.01307
18. Hill M V., Stucke RS, McMahon ML, Beeman JL, Barth RJ. An Educational Intervention Decreases Opioid Prescribing After General Surgical Operations. Ann Surg. 2018;267(3):468-472. doi:10.1097/SLA.0000000000002198
19. Stanek JJ, Renslow MA, Kalliainen LK. The Effect of an Educational Program on Opioid Prescription Patterns in Hand Surgery: A Quality Improvement Program. J Hand Surg Am. 2015;40(2):341-346. doi:10.1016/j.jhsa.2014.10.054
20. Lovecchio F, Premkumar A, Stepan JG, Albert TJ. Fighting Back: Institutional Strategies to Combat the Opioid Epidemic: A Systematic Review. HSS J ®. 2019;15(1):66-71. doi:10.1007/s11420-018-09662-y
21. Lovecchio F, Stepan JG, Premkumar A, et al. An institutional intervention to modify opioid prescribing practices after lumbar spine surgery. J Neurosurg Spine. 2019;30(4):483-490. doi:10.3171/2018.8.SPINE18386
22. Kahlenberg CA, Stepan JG, Premkumar A, Lovecchio FD, Cross MB. Institutional Guidelines Can Decrease the Amount of Opioids Prescribed After Total Joint Replacement. HSS J ®. 2019;15(1):27-30. doi:10.1007/s11420-018-9632-6

Conflict of Interest: None Declared