EDITORIAL AND COMMENT

Opportunities to Improve Decision-Making About Opioid Prescribing

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As morbidity and mortality associated with prescription opioids continue to rise, there is an urgent need for strategies to ensure that these opioid pain relievers (OPRs) are prescribed only where the benefits outweigh potential harms. Over the past 15 years, OPRs have flooded the licit and illicit markets, a result of well-intentioned prescribers attempting to reduce patients' pain as well as a small number of physicians who illegally prescribe OPRs with no medical justification.

Unfortunately, many OPR prescriptions do little to help the patient, and some cause harm. Despite widespread use of OPRs for chronic pain, evidence supporting their long-term use outside of cancer, AIDS, and palliative therapy is weak to nonexistent. For example, recent systematic reviews have concluded that "the current literature does not support that opioids are more effective than other groups of analgesics" for treatment of lower back pain[1] and that chronic OPR therapy "is associated with increased risk for overdose, opioid abuse and dependence, fractures, myocardial infarction, and use of medications to treat sexual dysfunction."[2] After systematically reviewing the medical literature, the American Academy of Neurology recently concluded that "[t]he risks for chronic opioid therapy for some chronic conditions such as headache, fibromyalgia, and chronic low back pain likely outweigh the benefits."[3] Similarly, the Centers for Disease Control and Prevention (CDC) recently conducted an exhaustive review and concluded that "[n]onpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain."[4]

The dramatic increase in OPR prescribing has been accompanied by a rise in OPR-related harms—including almost 19,000 OPR-related fatalities in 2014 alone. In response to this public health crisis, states have implemented laws, regulations, and policies intended to improve prescribing decisions and curb clearly illicit prescribing. For example, about a quarter of the states have passed "pill mill" laws, which impose regulatory requirements on pain management clinics to ensure they are operated in a professional manner that meets patients' needs and the prevailing standard of care. Forty-nine states have established Prescription Drug Monitoring Programs (PDMPs), which collect information about dispensing of controlled substances and make those data available to physicians and other authorized users. While a small but growing evidence base suggests that these policies are having at least some positive effect,[5,6] it is also clear that they are insufficient to markedly reduce poorly managed pain and OPR-related harms.

In this issue of the *Journal of General Internal Medicine*, Richard Deyo and colleagues report the results of a retrospective cohort study that examined the association between variations in initial opioid prescribing practices and the likelihood of subsequent long-term use of OPRs.[7] Using a rigorous approach that linked data from Oregon's PDMP, vital records, and hospital discharge registry, they found that 5% of opioid-naïve individuals who filled an opioid prescription between October 1, 2012 and September 30, 2013 proceeded to long-term OPR use, defined as filling at least six opioid prescriptions during the year following the initial opioid prescription fill.

The article contributes considerably to the literature by confirming what many had suspected: the number of prescription fills and the amount of morphine milligram equivalents (MME) dispensed in the initial month of OPR therapy are significantly associated with progression to long-term use. Further, long-term use was associated with a higher risk of opioid-related hospitalization.

While this study contains several notable insights and expands the knowledge base regarding the significance of opioid prescribing practices on the transition to long-term OPR use, it has some limitations related to the use of PDMP data. As the authors note, the Oregon PDMP, like most, does not track the prescriber's practice area or the condition a prescription was intended to treat. The authors were therefore required to use less precise indicators to attempt to determine whether the prescriber intended initiation of long-term OPR therapy. The

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PDMP also did not track patients' gender, race, ethnicity or method of payment, making it impossible to determine whether the results vary by these measures.

PDMP data have other limitations as well. Most notably, and as the authors acknowledge, the study uses number of prescription fills (derived from PDMP data) as a proxy for ingestion of the prescribed drug, and assumes that medications are actually being taken by the person to whom they were prescribed. While these assumptions are necessary given the limitations of the available data, they are unlikely to hold for an unknown number of cases. In fact, surveys consistently show that most nonmedical OPR users obtained the medication from a friend or family member.[8]

In addition, and as the authors note, the Oregon PDMP only tracks prescriptions filled in the state. This necessarily means that PDMP data provide incomplete or incorrect information regarding patients who are Oregon residents but fill some or all prescriptions in another state, as well as residents of other states who fill some prescriptions in Oregon. Some of these patients might erroneously appear to be opioid naïve when they are not, or appear not to have transitioned to long-term OPR use when they have.

To their credit, Deyo and colleagues conducted a subanalysis that excluded patients with addresses outside of Oregon, which may have improved the likelihood of restricting that analysis to opioid-naïve patients. However, that subanalysis also excluded many other opioid recipients, making it difficult to determine whether and to what extent that possibility occurred. This is a promising area for future research.

This article helpfully highlights the importance of initial prescribing decisions, particularly for opioid-naïve patients, and the role they may play in long-term OPR use. Interventions to improve such decisions are urgently needed. Most medical schools currently devote an extremely small amount of time to pain management and addiction treatment, and physicians consistently rate their knowledge and competence in these areas as fair or poor.[9] Much of the pain management education physicians receive after medical school is via industry-funded CME, which may encourage OPR therapy over other interventions.

These are solvable problems. States can and should require medical schools to adopt curricula based on the best available evidence—including the recently released CDC Guideline for Prescribing Opioids for Chronic Pain—and of sufficient breadth and depth to significantly improve knowledge and practice.[4] Likewise, licensing boards can require that clinicians receive relevant CME, based on the best available evidence, and, ideally, not funded or influenced by OPR manufacturers.

Practicing clinicians should familiarize themselves with current evidence and adapt their practice accordingly. Professional associations that have not modified their guidelines and educational materials to shift emphasis from pain as the "fifth vital sign" and acknowledge that, in some cases, complete elimination of pain may not be a reasonable clinical goal, should quickly do so. Insurance mechanisms should be modified to disincentivize use of methadone for pain (an outsize driver of overdose mortality), reduce prior authorization and other utilization controls for physical therapy and other non-OPR treatment, and fully comply with the Mental Health Parity and Addiction Equity Act. Reimbursement for patient counseling and other supportive services should be increased. Finally, we recommend that state regulatory boards be more proactive in identifying, counseling and—where appropriate—sanctioning prescribers who objectively fail to meet the standard of care for OPR prescribing and pain management.

We understand that every patient is different, there is no "one size fits all" model of patient care, and physicians and other healthcare professionals must be permitted and empowered to craft treatment plans tailored to an individual's needs and goals. However, we also believe that if the medical community does not move quickly and effectively to reduce OPR prescribing that the best available evidence suggests is more likely to harm than help patients, states will increasingly constrain their authority and autonomy in this area. Such changes are already underway. For example, at least seven states now impose strict time or duration limits on most initial opioid prescriptions, and similar legislation has been introduced in several more. If the tsunami of OPR-related deaths continues, the medical community should expect to see an expansion of these and similar prescribing restrictions.

Deyo and colleagues have conducted a very well-conceived study that confirmed the association between characteristics of initial OPR prescribing and subsequent long-term use for some individuals. In this editorial, we have highlighted actions that state governments and other stakeholders can take to help prescribers navigate and effectuate the sometimes complex decisions involved in prescribing OPRs to opioid-naïve patients.

When viewed in the broader context of OPR-related morbidity and mortality, the current study addresses one piece of a much larger puzzle. To design and implement effective interventions that improve pain treatment while reducing OPR-related harm, better data and better use of existing data are needed.[10] For example, the research done by Deyo and colleagues could be greatly enriched if more detailed patient characteristics and the diagnosis for which OPRs were prescribed were known. Linkages between states' PDMP and other relevant data are needed to better understand OPR prescribing and usage behaviors that cross jurisdictional boundaries. More and

higher quality data about the effects of prescribing decisions on patient outcomes are urgently needed. And, of course, changes in prescribing must be paired with other evidence-based interventions, such as increased access to effective addiction treatment and the opioid antagonist naloxone. Until these and other data are used to develop and implement a suite of innovative interventions that draw on the best available evidence, the OPR epidemic will continue to destroy lives and devastate families and communities.

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