PSNet
PATIENT SAFETY NETWORK

Patient Safety and Opioid Medications

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Opioid medications confer significant risks of harm, including overdose death and abuse potential. Recent years have seen increasingly frequent reports of harms, to the point that in 2016 opioids became a focus in patient safety. This year, the Centers for Disease Control and Prevention (CDC) reported a 200% increase in opioid overdose deaths between 2000 and 2014 in the United States. Moreover, an analysis of new prescriptions of long-acting opioids for chronic noncancer pain showed a significantly increased risk of all-cause mortality, not just deaths from overdose.

How Is This a Patient Safety Issue?

Patient safety problems refer to preventable harms caused by medical care, as opposed to underlying disease. Beginning in the 1990s, the use of opioid medications began to rise, for a number of reasons. One was a well-intentioned, and increasingly patient-centered, focus on relieving pain. Another was the enactment of policies designed to prompt clinicians and health care organizations to focus on pain control. Such policies include The Joint Commission's Pain Management Standards, which helped cultivate the idea of pain as a "fifth vital sign," and the inclusion of pain-related questions on the HCAHPS [Hospital Consumer Assessment of Healthcare Providers and Systems] survey, whose results can affect hospital reimbursement. Although neither of these policies explicitly promotes opioid use, the focus on pain may have contributed to increases in prescribing. Advertising campaigns for a growing array of opioid medications (often marketed with attributes such as less addiction potential or being tamper-resistant) may also have contributed to more liberal prescriptions of opioids for acute and chronic pain over the past 10–15 years. Crucially, little evidence supports substantial benefits from chronic opioid use for noncancer related pain.

Regardless of the specific reason for the large surge in opioid use, it seems clear that the health care system as a whole encouraged increasing use of opioids and overlooked the risk of misuse. In this sense, the opioid epidemic is iatrogenic, and thus falls within the scope of patient safety. (It might even be seen as an unanticipated consequence of an improvement intervention—in that way parallel to the risks of

information technology-related errors or those of increased handoffs in the face of residency duty-hours reductions.) Because most opioids misused by patients originate from prescription medications, it is important, at a minimum, to better educate and monitor patients on opioids as part of a broad safety strategy. Numerous studies in 2016 highlight current unsafe opioid use practices and strategies to enhance the safety of opioid use.

High-risk Prescribing Practices Are Common

A number of studies published in 2016 demonstrated the prevalence of potentially inappropriate opioid prescribing across multiple care settings. Jena and colleagues reported that Medicare beneficiaries (age 65 and older) are often discharged from the hospital with new opioid prescriptions, and they often remain on opioid medications for extended periods (90 days) after discharge. Another 2016 report found that prescription of opioids following dental extraction increased from 2000–2010, despite the lack of evidence regarding the benefit of using opioids in this setting. Similarly, the number of opioid prescriptions following low-risk surgical procedures increased between 2004 and 2012, as documented in a study this year.

Clearly, systematic efforts are needed to prescribe safer, nonopioid pain medications across multiple health care settings. In 2016, the *New York Times* reported on an emergency room (ER) in New Jersey that has made concerted efforts to offer alternatives to opioids for certain causes of acute pain. Before reaching for opioids, staff in this ER try regimens such as ultrasound-guided nerve blocks using local anesthetics, injections of anti-inflammatory medications and muscle relaxants at "trigger points," nitrous oxide ("laughing gas"), as well alternative therapies, such as "energy healing" and a wandering harpist. Although not all of these approaches are likely to prove efficacious, some may become standard of care, the way the use of ketorolac (Toradol), a nonopioid anti-inflammatory, has become first-line treatment for the intense pain of kidney stones, replacing meperidine (Demerol) or other opioids.

Recent literature also indicates that the manner in which opioids are prescribed and used by patients is often unsafe. For instance, LaRochelle and colleagues demonstrated that more than 90% of patients who experienced a nonfatal opioid overdose continued to be prescribed opioids afterwards. This safety gap demonstrates the need to put a safe pain control regimen in place following an overdose, incorporating nonpharmacologic approaches and nonopioid medications.

Mitigating Risk Associated With Opioid Use

Several recent studies examined approaches to mitigate harms associated with opioid medication use. A survey of opioid-using ambulatory patients found that more than 20% had shared their medications with someone else, and nearly half had never received information on safe storage or disposal of these medications. Addressing these gaps could mitigate some of the risks associated with opioid use. An observational study of outpatients using opioids compared those given a naloxone prescription (a medication that rapidly reverses the pharmacologic effects of opioids) to those not given naloxone. Individuals who received a naloxone prescription were less likely to have opioid-related emergency department visits. Greater use of naloxone could thus prevent overdoses in home and community settings. Some communities, including Baltimore, are promoting the distribution of naloxone in an effort to prevent opioid-related harm and death. The Agency for Healthcare Research and Quality has several efforts

underway to broaden the evidence base for opioid safety, including a program announcement for safe medication use research (PA-16-421) and an initiative that will implement medication-assisted treatment (MAT) for opioid use disorder in primary care practice in rural US (PA-16-001).

Health Care Policies to Address Opioid Misuse

Two policy evaluations published this year examined state regulation of opioid medications. The first examined state-level prescription drug monitoring programs and found that states with more complete and timely opioid monitoring achieved greater overdose reductions than those with less comprehensive programs. In contrast, an analysis of chronic opioid use among disabled Medicare beneficiaries did not find reductions in high-risk opioid prescribing practices (including high opioid doses and receipt of opioids from four or more prescribers) or rates of nonfatal overdose before and after adoption of stringent prescription drug monitoring programs. These mixed results suggest that larger, longer-term studies are needed to assess the effect of state-level policies.

Another analysis examined the effect of the US Drug Enforcement Agency's rescheduling of hydrocodone, which led to more restrictions on prescribing and tighter monitoring. The authors identified a steep decline in hydrocodone prescriptions and in overall dispensing of this opioid class. While a modest increase in other opioid medication prescriptions was seen, this effect did not approach the sharp drop in hydrocodone products. This study suggests that policies (in this case federal policies) to restrict opioid access can reduce dispensing.

Guidance for Clinicians

The opioid safety studies discussed suggest that health system and policy actions could enhance the safety of opioid use. While patient safety leaders pursue strategies addressing these targets, individual clinicians can also enhance opioid safety. In 2016, the CDC published a new guideline for opioid prescribing and monitoring in the setting of noncancer, nonpalliative chronic pain. This guideline recommends using opioids for chronic pain only if nonopioid medications and nonpharmacologic approaches are not effective. Importantly, the new guideline favors immediate-release medications rather than long-acting formulations. For acute pain, CDC recommends limiting duration of therapy, generally to one week or less. The guidelines also suggest minimizing concurrent use of opioids and other sedating medications and dispensing naloxone to prevent overdoses. In late 2016, the Surgeon General also issued opioid prescribing guidelines and launched a new website to serve as a resource. Best practices for patient–clinician communication around chronic opioid use are also available to assist in improving prescribing practices in a patient-centered manner.

Summary

Articles drawing attention to the epidemic of opioid use and the resulting harm have appeared at an increasing rate in recent years, but reached a peak in 2016. The attention came not just from public health officials and clinical researchers with an interest in this area, but also from groups focused on quality improvement and patient safety, such as the Institute for Healthcare Improvement. A burgeoning literature demonstrates the severe and growing harms associated with opioid misuse and the risks inherent in current opioid prescription and use practices. This year also saw the emergence of some promising

approaches to enhancing opioid safety, including widespread naloxone prescribing and targeting the reflexive use of opioids after minor procedures or even during episodes of acute pain when nonopioid alternatives exist. New policy approaches restrict access to these high-risk medications, but their effectiveness remains unclear. Of course, there is also a risk that aggressive policies to restrict opioid use will lead to new harms associated with undertreated pain. Future efforts should examine clinic, health system, state, and federal policy approaches to address opioid use as a patient safety problem and work to ensure that these approaches lead to the maximum benefit and least harm.