

Opioid Medication Management

Clinician Beware!

IN this issue, the excellent report by Fitzgibbon *et al.*¹ presents summary data of malpractice claims about opioid medication management for chronic pain between 2005 and 2009. The investigators examined 8,962 closed claims from 35 liability insurance companies and determined that 295 claims involved chronic pain management. Of these, 17% (51) directly related to medication management, mostly for prescribing opioids for chronic low-back pain. Unfortunately, death was the most common outcome involved in these claims. The authors note that compared with a previous review by their same group,² the number of claims related to medication management had increased from 2 to 8%. The primary reasons for medication management claims, which may surprise some readers, included (1) failure by the prescribing physician to communicate a care plan, (2) inadequate monitoring and documentation of care, (3) inappropriately high-prescribed doses of opioids, or (4) unethical or illegal clinical practices.

The authors point out that the increase in claims is most probably related to the increased availability of prescription opioids. The recent rapid increase in opioid prescription and the corresponding increase in opioid abuse have been well documented by both regulatory agencies and the lay press. Now, opioids are some of the most commonly prescribed drugs. Although often touted as safe, it has become clear that substantial societal problems have accompanied our liberalized prescribing practices. For example, deaths due to prescription of drug overdose now outnumber deaths due to automobile accidents in several states.³ Poisoning deaths nearly doubled from 1996 to 2004, due for the most part to the increase in deaths from prescription opioids.⁴ Similar to the findings of Fitzgibbon *et al.*, the leading drugs involved in this type of overdose death were methadone and oxycodone.⁵ The economic burden of prescription opioid abuse has been estimated to be several billion dollars per year.⁶

Concern has been raised that because of the high prevalence of psychiatric disease in populations with chronic pain, opioids disproportionately wind up in the hands of patients with depression, anxiety, and substance abuse disorders. Indeed, Fitzgibbon *et al.* found that the use of long-acting

opioids and psychiatric comorbidity increased the likelihood of death. Importantly, it became clear in this analysis that several patient factors were often present in eventually those adversely affected by the prescription drugs; physicians frequently failed to recognize signs of medication misuse and patient addiction, for example, positive illicit drug screens, obtaining opioids from multiple providers, selling medications, and others, often resulting in death particularly among young male patients. These results challenge us to determine how we are going to provide opioid analgesics to those who will benefit from treatment while limiting exposure of those who might harm themselves or others with these medications.

This timely review spells out the need for a multidisciplinary assessment of persons with chronic pain and the importance of the use of screening tools for potential misuse of opioids.⁷ Prescription opioid precautions should include careful patient selection including assessment of pain, mood, function, and misuse risk factors, a treatment plan accompanied with a patient–physician treatment agreement, and an appropriate level of monitoring of the patient during opioid therapy based on the level of risk to assess efficacy, adverse effects, and aberrant drug-taking behavior. Unfortunately, documentation of patient evaluation, formulation of treatment plans, and follow-up on treatment plans are absent from the medical records of many patients managed with opioids.⁸ Implementation of these procedures takes time and requires thorough documentation but results in reduced opioid misuse. For those patients with high-risk chronic pain who have a history of abuse but for whom a trial of opioid therapy is still to be undertaken, structural interventions including frequent urine screen monitoring, self-report compliance checklists, and individual and group substance abuse counseling, can result in improved compliance with prescription opioids. Special diligence when prescribing opioids for chronic noncancer pain may be indicated in light of the relative paucity of long-term outcome data demonstrating broad efficacy of these drugs

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* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184399.htm>. Accessed November 5, 2009.

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and the specific absence of evidence for long-term safety and efficacy in patients with serious psychiatric and substance abuse histories.

The Food and Drug Administration has recently called for risk evaluation and mitigation strategies* to be in place by all pharmaceutical companies who manufacture opioids to help reduce deaths resulting from misuse of opioids. Physicians will likely be required to document training for substance abuse, similar to online programs developed by insurance companies (*e.g.*, CRICO, "Chronic Pain: Assessment, Treatment, and Risk").† Although it is yet to be determined, future opioid prescription may require (1) evidence of training in opioid management and substance abuse, (2) documentation of a thorough patient evaluation, including medical, psychiatric, and addiction history, an assessment of pain level and function, and a urine drug test, (3) a written treatment plan, which includes a carefully planned trial of opioid or adjunctive medications, a treatment agreement that outlines the responsibilities and commitments of physician and patient, and patient education, and (4) continuous monitoring of the patient during treatment, which includes assessing therapy efficacy (pain level, function, and quality of life), drug-related adverse effects, and aberrant behaviors. Thus, the casual prescribing of opioid analgesics especially to patients we now understand to be at elevated risk for treatment failure, abuse, and self-injury will become more clearly discouraged. Whether risk evaluation and mitigation strategies measures alter the overall availability of opioids for chronic pain remains to be seen.

New opioid formulations using advanced technologies are being specifically designed to alleviate some of the worries surrounding opioid-related risks such as addiction and abuse. Most of these involve strategies to reduce the extraction of opioid from the prescription preparation or reduce the ability of the patient to artificially accelerate the rate of drug delivery. How these new "abuse-deterrent" drugs will be integrated into practice, and to what degree they can be expected to reduce the problem of abuse and addiction, are unknown. Although the introduction of these new formulations may eventually prove to have a significant effect on the landscape of opioid prescription and the way pain is medically managed, it is highly likely that these formulations will be adjuncts to, not a substitute for, current safe opioid-prescribing practices.

† www.rmfcme.com. Accessed November 5, 2009.

The authors need to be congratulated for presenting these data. Although the study has limitations in terms of the number of medication management cases identified, and the use of expert opinion rather than fully transparent objective standards as review criteria, the major points seem very clear. Prescription opioid abuse is a significant public health issue that must be addressed and so is the undertreatment of chronic pain. Some might suggest that prescription opioids will continue to be abused at some level by those with an addiction disorder regardless of restrictions on prescribing, and that abusers will always find a way around an abuse-deterrent formulation. Nevertheless, an improved understanding of who might benefit from opioid management is essential in improving outcomes and overall safety. Continued advances in potential misuse assessment, compliance interventions, and opioid formulations can help mitigate risk for those with legitimate need for pain control, but only if used rationally in the context of good clinical practice. Even an incremental benefit in deterring abuse has the potential to advance public health and will likely reduce the number of claims due to prescription opioids.

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