

Risk Management and Mitigating Risk Opportunities for Opioid Prescribing

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All clinicians are ethically obliged to prescribe responsibly and cautiously to diminish the potential for opioid diversion and to help minimize the growth of the current opioid abuse epidemic. Podiatric physicians should establish procedures to better control and limit opioid prescription and develop analgesic regimens to treat pain. The main purpose and goal of this review is to present data congruent with clinical, medical, and legal reports for allowing an appreciation of the possibility of the risk assumed when ordering and prescribing opioids within the podiatric medical profession. First, the concept and process of risk management, illustrated using a root cause analysis approach, is introduced, and application of these principles specifically to opioid prescribing is presented. Then, several examples found in both the medical and legal literature documenting the reasons for opioid prescription risk are presented. Finally, mitigating strategies for safe opioid prescribing are offered so that mitigation of opioid harm can be possible and realized by the lower-extremity specialist. Risk management strategies and tools to mitigate opioid harm, lessen opioid adverse effects, and reduce opioid deaths are presented narratively and graphically. (*J Am Podiatr Med Assoc* 113(5), 2023)

The seasoned astute podiatric physician prescriber will remember the national push in 1996 for identification of pain as a primary medical disorder and the approval of oxycodone hydrochloride, popularly known by its brand name OxyContin (Purdue Pharma, Stamford, Connecticut), as a “minimally addictive pain reliever” by the Food and Drug Administration (FDA) in the same year.¹⁻⁵ On July 17, 2020, relying on public data, including up-to-date government studies and new reports in the medical literature, Mann⁵ revealed that prescriptions for half of all Americans for at least one opioid were being written each year. Patients are still receiving more than twice the volume of opioids considered normal before the prescribing boom in the late 1990s.^{1,2,5,6} The opioid epidemic is considered to have occurred in three waves. The first wave began in 1991 when deaths involving opioids began to rise sharply, with a spurt in the prescription of opioids or opioid combination medications for treating pain.^{2,7} This increase was influenced by reassurances from pharmaceutical companies and medical societies or associations, emphasizing the low risk of addiction to such medications.^{2,7-9} Bachtell⁸ reported that dozens of opioid manufacturers, distributors, pharmacies, and doctors

turned a blind eye to the opioid crisis swamping the United States.

Van Zee⁹ used the “Oxycontin Marketing Plans from 1996–2001” to validly argue that the manufacturers of OxyContin pursued an “aggressive” marketing campaign to promote the use of opioids by emphasizing the greater benefits of opioid-based products over others without disclosing the involved risks. Ellenbogen and Segal¹⁰ published their findings in a report examining the differences in opioid prescriptions among general physicians, nurses, and physician assistants. They conducted a serial cross-sectional analysis of the data regarding the prescription claims during 2013–2016 collected from the public domain of the Centers for Medicare and Medicaid Services (CMS).¹⁰ The analysis demonstrated relatively higher rates of opioid prescriptions among nurses and physician assistants.¹⁰ The factor contributing to this high rate among midlevel health-care professionals may be understood by a piece of recent news reporting that Purdue Pharma told pharmaceutical representatives “that midlevel providers are critical to our success” and referred to them as “high-value Oxycontin prescribers” in a 2015–2016 training session.¹¹ From all of these findings, a valid argument can be made that the opioid oligopoly got so enmeshed in greater profiteering that it forgot to abide by the most important

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aspect of health care—the ethical responsibility to do no harm and to stand as a community leader.

The art of prescribing involves many subtle influences and ethical issues, yet the consequences are wholly borne by the patient. All clinicians are ethically obliged to prescribe responsibly and cautiously to diminish the potential for opioid diversion and help minimize the growth of the current opioid abuse epidemic. Lower-extremity practices should establish procedures to better control and limit opioid prescription and develop analgesic regimens to treat pain. Opioid analgesics should be prescribed by balancing their beneficial and adverse effects.¹² Although the ramifications of prescribing opioids are both social and economic, the specific act itself involves two parties: the practitioner and the patient. The role of the lower-extremity specialist is to responsibly provide pain management in a safe environment, mitigating and avoiding medication prescribing errors while adhering to both state and federal regulations such as the Centers for Disease Control and Prevention (CDC) guidelines to assist physicians in effectively managing pain amid the opioid crisis.¹³

The main purpose and goal of this review is to present data congruent with clinical, medical, and legal reports for allowing an appreciation of the possibility of the risk assumed when ordering and prescribing opioids within the podiatric medicine profession. First, the concept and process of risk management is introduced, and the application of these principles specifically to opioid prescribing is presented. Then, to enrich the podiatric physician's body of knowledge, several examples found in both the medical and legal literature documenting the reasons for opioid prescription risk are presented. Finally, mitigating strategies for safe opioid prescribing are described so that mitigation of opioid harm can be possible and realized by the podiatric physician.

Risk Management Principles

General risk identification involves brainstorming, as in the process of root cause analysis. A business, eg, a podiatric medical practice, gathers its employees together so that they can review all of the various sources of risk. One paramount risk that the podiatric physician may encounter is the harm that may result when prescribing opioid medications. The next step is to arrange all of the identified risks in order of their priority. Because it is impossible to mitigate all of the existing risks, prioritization

ensures that risks that can affect a provider's practice, such as prescribing opioid agents, are significantly dealt with more urgently and effectively to prevent them from being repeated.

The next step is assessing these risks; in many cases, problem resolution involves identifying the problem and then finding an appropriate solution. However, before figuring out how best to handle risks, the podiatric physician should locate the cause of the risks by asking the simple question, "What caused such a risk and how could it influence the art of podiatric medicine as in prescribing opioid products?" Once the lower-extremity provider entity is set on assessing remedies to mitigate identified risks and prevent their recurrence, they need to ask the following questions: "What measures can be taken to prevent the identified risk from recurring? Furthermore, what is the best thing to do if it does recur?" Overprescribing of opioids has been implicated in the opioid crisis and may be a real risk for the opioid-prescribing lower-extremity specialist. Therefore, a multilevel collaborative health-care team approach using an opioid stewardship program can provide the necessary framework to change the current opioid analgesic culture and practice.¹⁴⁻¹⁶ An opioid stewardship program can address opioid prescribing and treatment for opioid use disorder, using both educational initiatives and information technology to assist with appropriate opioid prescribing and, thus, serving as a helpful tool to curtail the opioid crisis.¹⁶

An identifiable risk behavior during opioid prescribing detailed in the orthopedic and podiatric medical literature is overprescribing of opioid dosing units, which may result in overuse, misuse, or diversion. Sabatino et al¹⁷ accepted the premise that postoperative pain management in orthopedic surgery accounts for a substantial portion of opioid medications and that understanding the prescribing habits and patient utilization of opioid analgesics after surgical procedures is critical to establishing appropriate opioid-prescribing protocols. These investigators performed a review of prescribing data of procedures by gathering data from a telephone survey to determine the number of opioid "pills" prescribed postoperatively and the number of the unused "pills."¹⁷ They concluded that prescribing patterns vary widely, and a large amount of opioid medication remains unused after elective orthopedic surgical procedures.¹⁷

Furthermore, Ranases et al,¹⁸ used an anonymous online survey distributed by e-mail to the orthopedic societies of all 50 states and several large private practices to assess practicing orthopedic surgeons'

opioid-prescribing practices. These authors acknowledge that orthopedic surgeons are the fifth highest prescribers of opioids in patients aged 30 to 39 years and the third highest prescribers in patients older than 40 years.^{18,19} First, these data determined that orthopedic surgeons rarely prescribe refills, tend to prescribe fewer opioids to teenagers than to adults, and prescribe fairly uniformly for patients who are treated nonsurgically or undergo minor or arthroscopic surgery. Last, their data revealed that their study participants exhibited considerable variation in prescribing opioids for fractures and major procedures.¹⁹ Saini et al²⁰ conducted a level II, prospective, observational cohort study to prospectively determine and assess opioid consumption patterns after outpatient orthopedic foot and ankle procedures. They selected patients undergoing outpatient orthopedic foot and ankle procedures who met their inclusion criteria and had the following prospective information collected: patient demographics, preoperative health history, patient-reported outcomes, anesthesia type, procedure type, opioid prescription, and consumption details.²⁰ During this study, postoperative opioid utilization was reported for 988 patients. Overall, patients consumed a median of 20 “pills,” whereas the median number of “pills” prescribed was 40.²⁰ This investigation found that patients who underwent orthopedic foot and ankle procedures were overprescribed narcotic medication by nearly twice the amount that was actually consumed.²⁰ The assertion of Saini et al that 20 dosage units is most appropriate for many foot and ankle procedures bears out when examining the investigational results of Gupta et al²¹ that found patients who received regional anesthesia for outpatient foot and ankle surgeries consumed a mean of 22.5 “pills,” with a confidence interval from 18 to 27 “pills.” Moreover, Merrill et al,²² to determine opioid consumption after foot and ankle surgery, conducted a survey of patients during their first postoperative visit. The mean number of opioids consumed by patients was determined to be 27.2 dosage units.²² They found no significant difference in opioid use between bony and nonbony procedures.²²

The 20 dosage units of Saini et al²⁰ are most appropriate for many foot and ankle procedures, a declaration fortified by the findings of Gupta et al²¹ and Merrill et al,²² bears out compared with other medical disciplines. By studying the cross-sectional survey by Madsen et al²³ of a national sample of American College Obstetricians and Gynecologists Fellows and Junior Fellows who are part of the Collaborative Ambulatory Research

Network.²⁰⁻²³ They used a sequential mixed-methods approach that determines that obstetrician-gynecologists reported prescribing a median of 26 opioid “pills” across all indications combined.²³ On the other hand, a positive outlook has been presented by Brooks et al,²⁴ who concluded in their 2021 published report that although postoperative opioid-prescribing practice variation exists in foot and ankle surgery, compared with the orthopedic community, podiatric foot and ankle surgeons prescribe approximately 25% fewer opioids at the time of surgery than orthopedic foot and ankle surgeons. Currently, this is but one report, and more opioid-prescribing risk management educational initiatives are needed.

Finally, the podiatric physician must develop preventive mechanisms for identified risks in the context of prescribing opioids. The proactive narrative can be as simple as the following: “Here are the ideas that were found to be useful in mitigating risks and are now developed into several tasks and then into contingency plans deployable in the future. Therefore, if risks occur, then the plans can be activated.”

Risk management is an important process when prescribing any medication, especially opioids, because it empowers a prescriber with the necessary tools to adequately identify and deal with potential risks of opioid use. Once a risk has been identified, mitigating it is easy. In addition, risk management provides the opioid prescriber with a basis for undertaking sound decision-making. For the podiatric pain prescriber, assessment and management of risks is the best way to prepare for the potential eventualities in the path of progress and growth. When prescribers evaluate their plan for handling potential threats and develop structures to address them, the process improves their odds for successful opioid prescribing. In addition, progressive opioid-prescribing risk management ensures that high-priority risks are dealt with as aggressively as possible. Moreover, the management process will have the necessary information to make informed decisions and ensure that the profession remains viable.

Opioids and Medical Malpractice

Lowes²⁵ reported that a medical liability insurer found that prescription painkillers are the basis of more medical malpractice claims involving drug errors than from any other drug class. The company analyzed more than 10,000 closed malpractice

claims from 2012 through 2016. Twenty-four percent of medication-related claims involved opioids, although these drugs accounted for only approximately 5% of the prescription drugs dispensed in 2016, according to published data from IQVIA (Overland Park, Kansas).²⁵ Claims often involve overdose as well as allegations that patients developed addiction to painkillers. More than one-third of opioid-related malpractice claims involve errors or failures during the follow-up phase of prescribing. Physicians commonly renewed prescriptions without appropriately monitoring them. Furthermore, an effective legal service internet advertisement summarizes that both the CDC and the FDA have reviewed medical malpractice claims for opioid prescriptions and assert that none of the prescribing physicians had followed the necessary steps recommended by both agencies' intended published guidelines.²⁶ There was little attention to assessing and educating patients before prescribing opioids. Doctors who bypass these crucial steps increase the likelihood of a patient developing an opioid addiction.²⁶

Hazi²⁷ offers and defines three of the most common claims in opioid medical malpractice litigation:

1. Lack of medical necessity: Plaintiffs' attorneys allege that their clients were prescribed medically unnecessary opioids, either because no treatment was indicated or because an alternative (nonopioid) treatment option was available.²⁷
2. Overprescription of opioids: Claims alleging overprescription of opioid medications are common as well. This includes claims of unnecessarily relying on opioid medications for treatment of pain and other conditions, overdosing individuals under inpatient and outpatient care, and failing to reduce a prescription when indicated.²⁷
3. Failure to monitor: Once patients have been prescribed opioid medications, failure to monitor them adequately for signs of dependency (investigating refilling prescriptions without assessing adequately) can also be the basis for a medical malpractice claim.²⁷

As the nation's opioid epidemic continues, physicians are increasingly facing scrutiny regarding their prescription practices. In fact, opioid-related medical malpractice claims have become so prevalent that some insurers are now writing policies specifically covering opioid lawsuits.²⁷

Berman and Li²⁸ report that the US news media has reported on an increasing number of opioid-related criminal cases against physicians from a variety of

clinical specialties. The most commonly convicted crime in these cases is drug trafficking, followed by fraud, money laundering, and manslaughter.²⁸ They report that the annual number of criminal cases against physicians charged with opioid-related offenses reported in the US news media increased from 0 in 1995 to 42 in 2019.¹⁷ Moreover, of the 372 physician defendants in these criminal cases, 90.1% were male, 27.4% were 65 years and older, and 23.4% were charged in Florida. Finally, drug trafficking was the most convicted crime (accounting for 54.2% of all convicted cases), followed by fraud (19.1%), money laundering (11.0%), and manslaughter (5.6%).²⁸

Kim and Sibai²⁹ reported that the overall risk of Drug Enforcement Agency action as a percentage of total physicians is small but not insignificant; however, the overall rates of Drug Enforcement Agency prosecution have increased. Also, new risk factors include the type of degree of the physician (osteopath versus allopath) and being in private practice, with a subtle trend toward foreign graduates being at higher risk.²⁹ Finally, they proclaim that more subtle charges have been added involving interpretation of the medical purpose of opioids and standard of care for their use.²⁹

Mitigating Opioid-Prescribing Risk

Thorough and diligent documentation and opioid monitoring by the opioid prescriber are the most effective foundations for building a defense in an opioid medical malpractice case. Overprescribing opioids can cause the death of the patient, especially through overdose. The appropriate kind of civil action to file is a wrongful death lawsuit, not a personal injury lawsuit. One tool that will assist the podiatric physician with both documentation and monitoring is the opioid stewardship program, which may be described as coordinated interventions designed to improve, monitor, and evaluate the use of opioids to support and protect patients.^{30,31}

A multimodal analgesic approach is likely to produce superior analgesia over an opioid-based approach because multimodal analgesics target a variety of pain pathways.^{30,31} An essential duty of the podiatric physician who prescribes opioids is to recognize and reduce risks of opioid harm.^{30,31} Therapeutic success depends on proper candidate selection, assessment before administration of opioid therapy, and close patient monitoring.^{30,31} Pain management specialists can enhance a patient's

ability to function and improve their quality of life.^{30,31}

Pollock et al³² offer and describe a systematic strategy for appropriate prescribing of opioid analgesics to minimize poor-quality and erroneous prescribing and can thus be another self-directed tool for risk mitigation. This eight-step approach to prescribing suggests that the physician should 1) evaluate and clearly define the patient's problem; 2) specify the therapeutic objective; 3) select the appropriate drug therapy; 4) initiate therapy with appropriate details and consider nonpharmacologic therapies; 5) give information, instructions, and warnings; 6) evaluate therapy regularly (eg, monitor treatment results, consider discontinuation of the drug), 7) consider drug cost when prescribing; and 8) use computers and other tools to reduce prescribing errors.³² These eight steps, along with ongoing self-directed learning, compose a systematic approach to efficient and practical prescribing for the podiatric physician.³² The CDC recommends the following strategies for opioid prescribers: assess, check, discuss, and observe to detect signs of harm related to long-term opioid therapy.³³ Thus, this CDC recommendation can assist the podiatric physician with mitigating opioid harm as a risk reduction strategy.

1. Assess: Evaluate for risk factors, such as a history of substance use disorder or respiratory conditions, which could increase the patient's risk of harm from opioid therapy.³³

2. Check: Use drug testing and check the prescription drug monitoring program to ensure that the patient is not taking too high of an opioid dosage or combining opioids with other drugs, which could raise their risk of drug interactions.³³

3. Discuss: Ask the patient about their concerns to determine whether they are experiencing any ill effects, such as nausea or oversedation.³³

4. Observe: Look for slurred speech or abnormal gait.³³

Podiatric physicians may study and use strategies to assist them in mitigating the potential harm from opioid use, misuse, and the possibility of precipitating opioid use disorder. A multimodal analgesic approach has produced superior analgesia over the use of an opioid-based approach because multimodal analgesic agents target a variety of pain pathways.^{30,31} Podiatric physicians may want to develop an opioid formulary.^{30,31} It is imperative that the podiatric physician realizes that therapeutic success depends on proper candidate selection, assessment before administration of opioid therapy, and close patient monitoring.^{30,31} Further dangerous drug combinations indeed occur for legitimate reasons by clinicians without recognition of the possible dangerous effects of opioids, and a good tool to mitigate these interactions is knowledge of opioid pharmacokinetics, pharmacodynamics, and pharmacogenomics.^{30,31} Pain management specialists can empower a patient's ability to function and improve their quality of life.^{30,31} The podiatric physician should embrace the influence of electronic records and the data they provide, such as oversight and adherence to regulatory changes and evolving state laws that can influence opioid prescribing.^{30,31} It is paramount that an open dialog can be fostered so that expectations of opioid therapy can be appreciated by all of the parties.^{30,31} To further a safe patient environment, the opioid-prescribing lower-extremity specialist may use a variety of key mitigating strategies to reduce opioid overdose and deaths as described in Table 1.

Drug therapy is a vast territory, and the prescribing provider cannot be expected to be familiar with more than a small fraction of medication agents, but it is necessary and possible for them to know a small part of these medication agents of which they need to do their daily work (200–300 medication agents), replacing the older ones with newer ones.³⁴ Furthermore, Dukes and Swartz³⁴ assert that indeed it is feasible for a prescriber to learn and remember

Table 1. Strategies to Mitigate and Reduce Opioid Deaths

Ensure the medical necessity of opioid medications
Use opioid agreements
Screen and risk stratify patients
Use prescription drug monitoring programs
Titrate opioid prescriptions/orders slowly
Reduce opioid dose when switching between opioid agents
Be cautious when rotating opioids with methadone
Require that the patient secures their opioid prescriptions to avoid accidental ingestion by children or pets or theft of the prescription
Realize that prescribing opioid medications to patients who may die of their effects can expose prescribers to criminal charges

sufficiently about the drugs, which they use, to use them properly. Moreover, Dukes and Swartz's report that there is no doubt that some physicians make little effort to acquit themselves of the duty to keep abreast of events of adverse effects.³⁴ Dukes and Swartz³⁴ state that major drug contraindications described in the literature have been overlooked by providers. They suggest that prescribing providers should have readily available resources of knowledge of all of the significant risks associated with the drugs they use from day to day, including adverse drug interactions, drug-drug interactions, or other frequent and severe contraindications.³⁴ Therefore, exercising an ignorance defense as it applies to opioid pharmacology, pharmacodynamics, pharmacokinetics, and even pharmacogenomics may not be a successful risk management strategy if an opioid medication error occurs to shield the opioid prescriber from a malpractice lawsuit.

Kay³⁵ declared that now providers bear much of the burden and blame for the US opioid addiction epidemic. Thus, targeting prescribers is much easier than facing hard truths about poverty, disparities, and social inequity.³⁵ The podiatric prescriber must appreciate that management of chronic pain is complex and requires multidisciplinary approaches. Opioids are just one tool in a provider's armamentarium for helping patients.³⁵ Finally, the prescribing of opioid analgesics as a highly individualized, patient-centered approach may be more beneficial than broad, all-encompassing policies.³⁵

Conclusions

Given, the dramatic effect that the opioid crisis has had on the world, there is a need for lower-extremity specialists to acknowledge and commit to adopting an opioid-prescribing risk-mitigating strategy to foster a safe opioid-prescribing environment. Federal, state, and practice advocacy organizations have published best practice guidelines to provide a pathway to prevent opioid overdose with the following strategies: 1) improve opioid-prescribing practices, 2) reduce exposure to opioids, 3) prevent misuse of opioids, and 4) treat opioid use disorder. Historically, medication errors to include adverse events are being monitored by local, state, and federal agencies; therefore, it can be inferred that prescribing a medication, including opioids, can be considered a risk assumed by podiatric physicians as they practice their art. The goal of this review was to present data congruent with clinical, medical, and legal reports for the appreciation of risk assumed when ordering and prescribing opioids as

well as strategies and tools to mitigate such risk to foster a safe patient environment. Risk management strategies and tools to mitigate opioid harm, lessen opioid adverse effects, and reduce opioid deaths were presented narratively and graphically.

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