

A Protocol for Addressing Acute Pain and Prescribing Opioids

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Physicians across the country are re-examining their role in the prescription opioid abuse problem. In response to growing public awareness about the dangers of opioids, the Minnesota Medical Association formed a Prescription Opioid Management Advisory Task Force. As part of its work, the task force partnered with the Institute for Clinical Systems Improvement (ICSI) to develop a protocol for prescribing opioids for acute pain. This article describes the development of the new ICSI Acute Pain Assessment and Appropriate Opioid Prescribing Protocol and highlights key aspects of the protocol, which emphasizes shared decision-making and careful, conservative prescribing.

Many were shocked to learn of the recent heroin overdose death of actor Philip Seymour Hoffman, who after 20 years of sobriety again started abusing drugs. Another noteworthy actor, Heath Ledger, died in a similar incident six years earlier. According to the New York City medical examiner's office, Ledger died "as the result of acute intoxication by the combined effects of oxycodone, hydrocodone, diazepam, temazepam, alprazolam and doxylamine."¹

The tragic reality is that for every Hoffman or Ledger, there are thousands of others, as the medical and recreational use of opioids has exploded over the last decade. Between 2001 and 2012, the number of prescriptions for opioids in the United States rose 33%, from 181.7 million to 240.9 million, and total sales of opioids rose 110%, from \$3.97 billion to \$8.34 billion.² Americans, who comprise 5% of the world's population, now consume 80% of the world's opioid supply.³

Although most people take prescription medications responsibly, an estimated 52 million (20% of those ages 12 years and

older) have used prescription drugs for nonmedical reasons at least once in their lifetime.⁴ Every day, 2,500 youths (ages 12 to 17 years) abuse a prescription pain reliever for the first time. The problem is evident in U.S. emergency rooms, where the number of cases related to nonheroin opioid abuse increased from 299,498 in 2004 to 885,348 in 2011.² It is also evident in addiction treatment facilities. Minnesota's own Hazelden saw the portion of patients treated for painkiller or heroin addiction rise from 15% in 2001 to 41% in 2011.²

Dilemma for Physicians

Physicians often find themselves feeling conflicted about opioids. They have both a desire and an ethical responsibility to relieve suffering. They know many patients' acute pain episodes can be appropriately managed with opioid therapy. However, they also know prescriptions for opioids written by well-meaning physicians like themselves have started many patients down the road to drug dependence. How does that happen?

Part of the problem is that physicians have relied on a thin evidence base regarding the use of opioids for pain. The literature supporting chronic opioid therapy for noncancer pain is very weak. In fact, some of the most vocal proponents now admit that their justification for prescribing opioids for this population was a small case series report suggesting that the use of opioids in this situation was safe and carried an addiction risk of <1%.⁵

From this, expert panels and specialty groups developed guidelines and position statements encouraging providers to take an aggressive stance and prescribe opioids for all pain. The Joint Commission promoted pain as the "fifth vital sign" in response to what was viewed as inadequate pain management in the past. As a result, in the last 20 years, we've seen a fourfold increase in opioid prescriptions in the United States.⁴ And we underestimated the risks of opioids including abuse, misuse, addiction, diversion and unintentional overdose.



Health Community Takes Action

Late in 2012, in response to growing public awareness about the dangers of opioids, the Minnesota Medical Association (MMA) formed a group to assess what physicians could do about the problem in Minnesota. The Prescription Opioid Management Advisory Task Force began its work by identifying these four objectives:

- 1 Raise awareness among Minnesota physicians about the nature and extent of the problems associated with prescription opioid addiction, abuse and diversion
- 2 Examine specific strategies for improving physician management of opioid prescribing (eg, education, use of the Minnesota Prescription Monitoring Program, controlled-substance contracts)
- 3 Facilitate MMA participation in multidisciplinary, communitywide conversations/coalitions aimed at addressing prescription opioid addiction, abuse and diversion
- 4 Identify and disseminate resources and tools to physicians for opioid prescribing best practices.

To help achieve these objectives, the task force partnered with the Institute for Clinical Systems Improvement (ICSI), which produces evidence-based clinical guidelines and protocols. ICSI brought together a workgroup, whose members had expertise in pain management, addiction management, primary care, specialty care, emergency medicine, pharmacy, physical therapy, dentistry and hospital medicine (Table 1). Several MMA task force members were among them. The workgroup reviewed clinical evidence, best practices from specialty societies, the work of local and national experts, guidelines from other states and ICSI's own Chronic Pain Guideline.

Acknowledging that the process of assessing pain and appropriately prescribing opioids is complex, workgroup members decided they needed to identify certain values and drivers to guide their efforts. They took the following considerations

into account during each step in the process:

- Patient safety. The group considered that opioids have known side effects and that those effects may be particularly adverse in patients with specific comorbid conditions. The workgroup also considered the potential for misuse, addiction and diversion. The group held that safe prescribing requires careful assessment of patient risk and history of opioid use from available sources including patient self-reports, medical records and a prescription-monitoring program.
- The need for supportive pain management. The group considered that patients expect their physician to help them determine the best course of treatment to manage their acute pain.
- Community safety and population health. The group acknowledged that easy access to opioids in the home and elsewhere may contribute to inappropriate use, addiction and related crime.

- Prevention of inappropriate or overuse of opioids. The group wanted the protocol to offer clinical guidance for the appropriate use of opioid and nonopioid therapies.
- Informed patients and shared decision-making. Members felt patients needed to be included in decision-making about opioid use and that they needed information about the risks and benefits of opioid use. The group felt this would support culture change over time and help reset patients' expectations of physicians and about opioid prescriptions.

After multiple revisions, a public comment period and final review by ICSI's Committee for Evidence Based Practice, the new Acute Pain Assessment and Opioid Prescribing Protocol was formally approved and published on the ICSI website in January 2014. It is available at www.icsi.org (search "acute pain protocol").

TABLE 1

Members of the Protocol Development Work Group

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The Protocol

The new protocol, summarized in Table 2, guides physicians through the following steps:

Target population

Patients must be adult (18 years of age and older) outpatients who do not have cancer but who have 1) acute or subacute pain, 2) chronic pain but are experiencing unrelated acute pain or 3) an acute exacerbation of chronic pain.

It is not intended to be used with patients who have active cancer and/or are receiving palliative or hospice care. Nor is it intended for patients with nontraumatic dental pain. Those patients should be referred to a dental provider and should never be prescribed opioids, as they may mask an abscess and thus increase the potential for adverse outcomes.

Assess the Patient's Pain

Physicians are to begin with a brief assessment of pain and administer emergent use of opioids if the situation dictates (ie, the patient is experiencing overwhelming pain). A more thorough assessment of pain that covers its etiology and nature should be done in most cases. The assessment should include a review of appropriate diagnostics and the patient's medication history including past and current opioid use. The physician should consider querying a prescription monitoring program.

Evaluate Treatment Options and Risks

The physician should explore treatment options and work with the patient to create a plan to manage pain and optimize function. The goal is to use appropriate therapies and use pain medications conservatively.

Common conditions that are almost never indicated for opioids include but are not limited to fibromyalgia, headache, uncomplicated neck and back pain or musculoskeletal pain, and pain—such as sore throat pain—that is related to a self-limiting illness.

TABLE 2

Acute Pain Assessment and Appropriate Opioid Prescribing Protocol Summary

If after a doing a thorough assessment to determine the etiology, type and anticipated duration of a patient's acute pain, carefully assessing the possible risks (ABCDPQRS) and evaluating all other possible therapies, you determine that opioids will offer significant treatment value, take into consideration these recommendations before prescribing them:

- Avoid prescribing more than a three-day supply (or 20 pills) of low-dose, short-acting opioids, unless circumstances clearly warrant additional opioid therapy (Tramadol is an atypical opioid and should be managed appropriately)
- Never prescribe long-acting/extended-release preparations for acute pain
- Maximize appropriate nonopioid therapies
- Review side effects with your patient
- Review safe driving, work, storage and disposal concerns with your patient
- Use shared decision-making with your patient; the patient must be educated about opioid risks and benefits to make an informed decision
- Use additional caution when prescribing opioids for the elderly and other patients with known risks for complications
- Ensure some method of follow up with the patient's primary care provider within three to five days to re-evaluate pain and response to treatment

Source: ICSI Acute Pain Assessment and Appropriate Opioid Prescribing Protocol

Chronic pain patients who are using opioids and who present with acute pain will need to be managed according to their pain management plan and/or in collaboration with the prescribing provider. Additional information about managing the chronic pain patient can be found in the ICSI Assessment and Management of Chronic Pain Guideline (www.icsi.org/_asset/bw798b/ChronicPain.pdf).

Risks and benefits should always be carefully explored when considering treatment of pain. There is no way to calculate the absolute risk of misuse, abuse, addiction or overdose in any individual patient. However, knowing about a factor such as a history of drug abuse can help a physician make a general assessment of relative risks/benefits. And factors such as the patient's condition should be considered when determining potential benefit.

The mnemonic "ABCDPQRS" provides an easy way for clinicians to remember what to cover when assessing opioid risk:

- **Alcohol use.** Assessing the patient for alcohol use is essential, as no amount of alcohol is safe for a patient on opioids. For patients with a positive screen for misuse of drugs or alcohol, the Screen-

ing, Brief Intervention, and Referral to Treatment (SBIRT) model is recommended. Use of SBIRT has been shown to reduce alcohol consumption and alcohol-related harm.⁶

- **Benzodiazepines and similar drugs.** Benzodiazepines can cause over-sedation in combination with opioids.⁷
- **Clearance and metabolism of the drug.** Many opioids require renal clearance of active metabolites. Be aware that potential renal or hepatic impairment will accentuate the side effects of opioids.⁸
- **Delirium, dementia and risk of falls.** Opioids will further compromise patients with these concerns. Opioids should be prescribed judiciously in the elderly because of these risks.⁹
- **Psychiatric comorbidities.** Many mental health disorders are correlated with increased opioid misuse, opioid-related accidents and accidental opioid overdose death. Physicians should take a thorough personal and family history to learn about any psychiatric conditions a patient may have and any substance abuse and sexual abuse in order to iden-

tify individuals who may need closer assessment and monitoring.¹⁰

- **Query the Minnesota Prescription Monitoring Program.** This statewide database can provide a better picture of a patient's history with certain prescriptions.
- **Respiratory insufficiency and sleep apnea.** Patients with hypoxia, hypercapnea and other conditions or medications that affect their ability to breathe will be at increased risk of respiratory insufficiency and respiratory arrest if they use opioids.
- **Safe driving, work, storage and disposal.** Opioids are a controlled substance. Patients need to be counseled about the dangers of driving or working while taking these drugs and reminded to safely store and dispose of them to prevent diversion.¹¹

Consider the Side Effects

Physicians and patients alike need to be aware that numerous biochemical and physiologic changes can occur in patients taking opioids. Opioids change the chemistry of the brain and its response to pain. Following opioid exposure, homeostatic adaptations within the central nervous system may contribute to the development of tolerance, cause increased neuropathic pain, lead to the release of excitatory neuropeptides that cause peripheral nociceptive stimulation and result in opioid-induced hyperalgesia, defined as a state of nociceptive sensitization caused by exposure to opioids. This increased sensitization to painful stimuli may clinically manifest as apparent opioid tolerance, worsening pain or abnormal pain symptoms such as allodynia.¹²⁻¹⁶

Among the other numerous side effects associated with opioids are:

- Constipation, anorexia, bloating, nausea/vomiting and abdominal cramping¹⁷
- Respiratory concerns including decreased central drive, suppressed gag reflex, reduced frequency of respirations, altered breathing rhythm, inhibition of brain stem arousal centers, and blunted response to hypoxia and hypercapnia¹⁸

What Physicians Can Do about the Opioid Abuse Problem

- Become familiar with the ICSI prescribing protocol and use the risk assessment mnemonic in your practice.
- Have the latest information on opioids and other therapies that may better support patients through the acute phase of an injury.
- Use tools such as the Opioid Prescription Patient Agreement and Scripting Support for Saying No to a Patient in appropriate circumstances.
- Discuss with colleagues how to help a patient in pain.
- Encourage your organization to develop policies on appropriate opioid administration for acute pain, including prescription limitations that support the clinician and promote patient and community safety.
- Collaborate with dental organizations, specialty groups and patient groups within your community to create a standardized approach to pain management and opioid prescribing.
- An increased percentage of sleep time spent in light sleep and a decreased percentage of time spent in deep sleep¹⁹
- Bladder effects including decreased detrusor muscle tone and force of contraction, decreased sensation of fullness and urge to void, and inhibition of voiding reflex²⁰
- Immune system changes including diminished cellular immune responses, natural-killer cell activity, cytokine expression and phagocytic activity²⁰
- Endocrine system changes including inhibition of adrenocorticotrophic hormone ACTH and cortisol secretion, causing a decreased glucocorticoid response; inhibition of LH- and gonadotropin-releasing hormone secretion, resulting in lower steroid hormone levels; inhibition of estradiol and testosterone

secretion, resulting in hypogonadism, menstrual irregularities, sexual dysfunction, infertility and osteoporosis; inhibition of insulin secretion, leading to hyperglycemia and worsening diabetes.²¹

Shared Decision-Making

The patient and his or her physician should engage in a thoughtful discussion about the benefits and risks of all treatment options. This discussion should be coupled with education about pain management, the side effects of opioids and potential adverse effects of treatment. Decisions should support patient safety while improving function and be made collaboratively.

Prescribe Conservatively

If after thorough assessment, evaluation and exploration of all other options for pain management, the physician and patient together agree that opioids are needed for the patient's acute pain, the physician should prescribe no more than three days (or 20 pills) of low-dose, short-acting opioids. Patients with acute tissue damage and inflammation should experience a decrease in pain during this period. If not, their primary care physician or treating physician should re-evaluate them for ongoing or unrecognized issues. Use of a controlled-substance contract sends a message about the patient's responsibility in opting to use an opioid medication (a sample is included in the protocol).

Conclusion

Physicians alone cannot solve our society's opioid abuse problem. But as prescribers of these highly addictive drugs, they can do a lot to help prevent their inappropriate use, misuse and other untoward effects. They can first become more knowledgeable about the indications for and against prescribing opioids. In addition, they need to carefully assess the risks and benefits of these drugs for each patient before prescribing them. Finally, physicians need to involve the patient in the decision about whether to take these drugs and make sure

they prescribe the lowest effective dose for the shortest duration needed to manage acute pain. This protocol is one attempt to ensure that physicians are doing what they can to prevent abuse and harm while ensuring proper treatment of pain. **MM**

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