

# TIME TO LISTEN:

## WHAT THE EXPERTS HAVE TO SAY ABOUT SAFE OPIOID PRESCRIBING AND ADDICTION TREATMENT



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### TARGET AUDIENCE

Physicians, dentists, physician assistants, nurse practitioners, nurses, and pharmacists.

### LEARNING OBJECTIVES

- Recognize the growing burden of the opioid epidemic and the role of all stakeholders in addressing the opioid epidemic in their community.
- Apply knowledge of acute and chronic pain pathways and underlying mechanisms to clinical assessment and appropriate management of pain.
- Upon evaluation of your current clinical workflow for opioid prescribing, incorporate two best practice strategies to optimize safe and competent prescribing and minimize potential for abuse and diversion.
- Educate patients about their pain to optimize safe and effective, multimodal treatment plans.
- Integrate in practice, concepts from novel programs in the community to address opioid overdose and treat patients with opioid use disorder.

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## INTRODUCTION

In December 2018, the Opioid Healthcare Provider/Advocacy Working Group convened for a two-day advisory board meeting with representatives from the primary care, pain management, oral surgery, orthopedic surgery, addiction, and physician assistant healthcare provider community, and the DEA Educational Foundation. The purpose of this meeting was to address the opioid epidemic and create actionable steps to promote appropriate and responsible prescribing for individuals with acute and chronic pain to curb the impact of the growing crisis facing our communities.

The data and trends illustrating the impact of opioids on the United States are staggering. From July 2016 through September 2017, the Centers for Disease Control and Prevention (CDC) reported:<sup>1</sup>

- A 30% increase in overdoses among men and a 24% increase among women.
- All ages were affected—a 31% increase among individuals aged 25 to 34 years, a 36% increase among those aged 35 to 54 years, and a 32% increase among those over 55.
- The Midwest experienced an astounding 70% increase in opioid overdoses.
- From rural to urban settings, communities witnessed the growing and deadly impact of opioids.

The panel of faculty experts gathered to provide insight on the challenges, consequences, and opportunities for the development of education to help meet the pain management needs of patients amid rising concerns of addiction and diversion.

## PART 1: UNDERSTANDING THE PAIN LANDSCAPE

Fueled by the rise in opioid misuse and abuse, the United States is currently facing the worst drug overdose crisis in our nation's history. In 2017, the United States had 70,237 drug overdose deaths, of which 47,600 (67.8%) were from opioid overdoses. Between 1999 and 2015, it was estimated that the annual number of opioid-related deaths quadrupled in the United States.<sup>2</sup> The risks brought on our communities by the opioid epidemic are devastating—addiction, overdose, progression to heroin, neonatal opioid withdrawal syndrome, and increased incidence of infectious disease transmission (eg, HIV, hepatitis C) through injection drug use of prescription or illicit opioids.<sup>3,4</sup>

The growing burden caused by opioid use disorder (OUD) in our communities and the role of all stakeholders in addressing the opioid epidemic are highlighted in a September 2018 report by McKinsey and Company, which suggests that the opioid crisis may worsen, and that bolder and broader actions must be taken.<sup>5</sup> Themes fall under prevention-focused (eg, improve prescribing practices, collaborate with law enforcement, address risk factors), treatment-focused (eg, increase availability of

naloxone, expand capacity of medication-assisted treatment [MAT]), and how to control foundational enablers (eg, promote coordinated opioid strategy, leverage analytics to support and improve interventions).

### *The role of the US Drug Enforcement Administration*

The US Drug Enforcement Administration (DEA) enforces the provisions of the Controlled Substances Act, which classifies drugs into one of five schedules based on their medical utility as well as the potential for abuse, misuse, and physical and psychological dependence.<sup>6</sup> Over the past decade, the rise in prescription drug abuse has led to increased law enforcement scrutiny of healthcare providers who must register for a DEA license to prescribe controlled substances. The regulation of prescription controlled substances has been described as a volatile “clash” of cultures between law enforcement and medicine.<sup>7</sup> The former aims to improve public safety through criminalizing illegal drug activity; the latter interacts at the patient level with the goal of improving individual health and well-being through a continuing relationship.<sup>7</sup>

When used appropriately, prescription opioids are powerful and effective tools in pain management.<sup>8</sup> However, many primary care providers (PCPs) report concerns about opioid prescribing and insufficient pain management training. Results of a survey by Jamison et al showed that 89% of PCPs were concerned about misuse, 84% were stressed about managing chronic pain, and 54% reported that they did not feel sufficiently trained and lacked confidence in prescribing opioids.<sup>9</sup> With the exception of federal prescribers who are required to be trained, it is estimated that fewer than one-fifth of the over one million prescribers licensed to prescribe controlled substances have training on how to prescribe opioids safely.<sup>10</sup>

### *Cross collaboration*

The DEA should partner with the prescribing community by engaging in a more open dialogue to take advantage of opportunities to decrease diversion and expand continuing education initiatives to ensure that prescribers are aware of the potential for abuse and misuse of prescription opioids.<sup>10</sup> A study by Pitt et al shows how a combination of different approaches is necessary to make a substantial impact on deaths from opioids.<sup>11</sup> This study analyzed the effects of 11 policy interventions (acute pain prescribing, prescribing for transitioning pain, chronic pain prescribing, drug rescheduling, prescription drug monitoring programs [PDMPs], drug reformulation, excess opioid disposal, naloxone availability, MAT, and psychosocial treatment). Increases in life years and quality-adjusted life years and decreases in deaths were projected with increasing naloxone availability, expanding MAT, and increasing psychosocial treatment. The results of this study illustrate the benefits of a cross-collaborative, multimodal model to stem deaths from OUDs.

## Attitudes toward chronic pain

Primary care providers commonly treat patients with chronic, non-cancer pain and account for nearly 50% of opiates dispensed.<sup>12</sup> Opioid prescribing continues to be a contentious issue for many PCPs who may have negative attitudes regarding patients with chronic pain.<sup>13</sup> The following factors contribute to the development of negative attitudes:

- Difficult patient interactions<sup>14</sup>
- Concerns about opioid prescribing, including addiction
- Diversion and regulatory scrutiny<sup>15</sup>
- Psychiatric comorbidities among these patients<sup>15</sup>
- Concerns about the time-consuming nature of care for these patients<sup>15</sup>
- Compliance issues<sup>16</sup>

These concerns may result in physician reluctance to prescribe opioids where appropriate, leading to suboptimal access to pain treatment.<sup>9,13</sup> Still, it is possible to manage pain and use medications safely, even in patients with addictions.<sup>17</sup> The results of a survey by Mendiola et al reflected negative attitudes toward chronic pain, with physicians reporting a lower regard for patients with substance use disorders than other medical conditions with behavioral components. More than half (54%) of respondents stated that they prefer not to work with patients with substance use disorder who have pain.<sup>18</sup> Negative attitudes toward chronic pain must be overcome in order to combat the opioid epidemic.

## CDC Guideline for Prescribing Opioids for Chronic Pain

The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain provides recommendations for PCPs who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.<sup>8</sup> Based on a systematic review of best available evidence, 12 recommendations are given in three key areas—determining opioid needs; opioid selection, dosage, and duration of therapy; and assessing risk and addressing harm (**Table 1**).

“The ongoing opioid crisis lies at the intersection of two substantial public health challenges — reducing the burden of suffering from pain and containing the rising toll of the harms that can result from the use of opioid medications.”<sup>19</sup>

An overarching criticism of the CDC guideline is the lack of emphasis that optimal pain management begins with identifying the cause of pain and the biopsychosocial mechanisms that contribute to its severity and associated disability.<sup>20</sup> As a result, the CDC guideline may not adequately address the entire spectrum of pain management needs. The CDC guideline is voluntary rather than prescriptive, and clinicians should consider the circumstances and unique needs of each patient when providing care.<sup>8</sup> The CDC guideline also recommends the use of non-opioid treatments in managing chronic pain when possible;<sup>8</sup> however, multimodal pain management, including non-pharmacological modalities, may be unavailable or unaffordable. In a 2017 report, the President’s Commission on Combating Drug Addiction and the Opioid Crisis noted that the CDC guideline has resulted in practical challenges resulting from administrative and documentation burdens, difficulty accessing alternative forms of pain control, a lack of information on how to taper current levels of prescribing, and concerns that the pain management needs for all populations are not being adequately addressed.<sup>10</sup>

Although the CDC guideline does not endorse a maximum limit on opioid medicines or involuntary tapering, the lack of explicit guidelines has led to misinterpretation by legislators, pharmacy chains, insurers, and others who have used the guidelines to justify restrictions on opioid treatment. An editorial published in *Pain Practice* noted that the CDC guideline set up unrealistic expectations that can make prescribers reluctant to prescribe opioids the patient might urgently need.<sup>21</sup> Furthermore,

**Table 1. 2016 CDC Guideline for Prescribing Opioids for Chronic Pain<sup>8</sup>**

### Determining need for opioids

- Opioids are not first-line or routine therapy for chronic pain.
- Establish and measure goals for pain and function.
- Discuss benefits and risks of opioid therapy and availability of nonopioid therapies.

### Opioid selection, dosage, and duration of therapy

- Use immediate-release opioids when starting treatment.
- Start low and go slow.
- Reassess pain and function when doses reach >50 mg of morphine equivalents a day and avoid increasing doses to >90 mg a day.
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed.

### Assessing risk and addressing harm

- Evaluate risk factors for opioid-related harms.
- Check PDMP for high dosages and prescriptions from other providers.
- Use urine drug testing to identify prescribed substances and undisclosed use.
- Avoid concurrent benzodiazepine and opioid prescribing.
- Arrange treatment for OUD if needed.

OUD = opioid use disorder; PDMP = prescription drug monitoring program.

unintended harms may result from overly aggressive adoption of the CDC guideline, including withdrawal reactions, uncontrolled pain, anxiety for patients, and loss of trust in their physicians.<sup>22</sup> In severe cases, some patients may turn to street drugs, increasing their risk of overdose, or resort to suicide.<sup>23</sup>

### Pain overview

Pain is a complex biologic and psychologic phenomenon that is often poorly understood and inadequately managed by primary care providers because of insufficient education and training.<sup>24</sup> A mechanism-based approach can be applied to the clinical assessment and management of pain.<sup>25</sup> Pain mechanisms include predominantly neuropathic, predominantly nociceptive, and a new classification of predominantly nociplastic pain.<sup>26</sup> Neuropathic pain is caused by a lesion or disease of the somatosensory nervous system. Nociceptive pain arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors. Nociplastic pain arises from altered nociceptors despite no clear evidence of active tissue damage causing the activation of peripheral nociceptors, or evidence for disease or lesion of the somatosensory system causing the pain. It is important to recognize that patients may benefit from tailored and targeted treatments prescribed based on specific types of pain. For example, neuropathic pain often responds to antidepressants or anticonvulsants. Additionally, pain can be characterized by duration (eg, acute, chronic), which also affects treatment selection.

Acute pain involves primarily nociceptive processing areas in the central nervous system (CNS) and is not associated with changes in the CNS.<sup>27</sup> Acute pain typically occurs as a normal response to surgery, acute illness, trauma, or other injury and is self-limiting, generally lasting from hours to days or a month after the precipitating event. The duration of acute pain is consistent with the time required for normal healing to occur.<sup>28</sup> Acute nociceptive pain responds well to analgesics such as acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs).

Chronic pain is defined as pain that lasts 3 months or more and is typically associated with changes in the CNS known as central sensitization.<sup>27</sup> Chronic pain is often associated with alterations in brain centers involved with emotions, reward and executive function as well as central sensitization of nociceptive pathways across several CNS areas. For those with central pain syndromes (eg, fibromyalgia), centrally acting neuroactive compounds, such as certain antidepressant medications and anticonvulsants, may provide better relief than opioids.<sup>29</sup>

Development of central sensitization may occur over time with long-term opioid use and produce pain response to non-painful stimulus, which could lead to spontaneous pain (hyperalgesia and allodynia).

High-impact chronic pain has been identified as a subset within the chronic pain population who also have at least one major activity restriction, such as being unable to work outside the home, go to school, or do household chores. A study of high-impact chronic pain by Pitcher et al revealed that pain-related disability affects a substantial portion of the chronic pain population experiencing progressive deterioration in mental and physical health outcomes along with substantially higher healthcare usage.<sup>30</sup> Multimodal treatment approaches are particularly important to reduce the impact of disability in patients with high-impact chronic pain.

### The opioid landscape

In a position statement on opioids, the International Association for the Study of Pain (IASP) identified opioids as indispensable for the treatment of severe short-lived pain during acute painful events and at the end of life, with no other oral medication currently offering immediate and effective relief of severe pain.<sup>31</sup> Opioid analgesics belong to a broad class of medications that include full agonists, partial agonists, mixed agonist-antagonists, and antagonists.<sup>32</sup> Opioids bind to opioid receptors (mu, delta, kappa, and opioid-receptor like-1 [ORL-1]) distributed widely throughout the central and peripheral nervous system and in the gastrointestinal tract, immune cells, pituitary gland, and skin.<sup>33</sup>

### Non-pharmacological options for pain management

There are many nonpharmacological treatments that can be beneficial and should be explored and considered for the management of pain. These techniques may be used in conjunction with pharmacological treatments and include active interventions, noninvasive and integrative therapies, invasive interventions, and psychological approaches (**Table 2**).

### Evaluation of risk

One approach to improve safe opioid prescribing practices has focused on screening, identifying, and monitoring patients who may be at risk of opioid-related harms prior to the prescription of opioids. An assortment of screening and risk assessment tools are available to identify patients at risk of opioid-related harm.<sup>36</sup> These tools are generally used for the following purposes: 1) to assess risks for patients who are being considered for long-term

**Table 2. Non-Pharmacologic Options for Managing Pain<sup>34,35</sup>**

Active Interventions	Noninvasive and Integrative Therapies	Invasive Interventions	Psychological Approaches
Physical therapy	Heat and cold	Dry needling	Cognitive behavioral therapy
Exercise	Massage	Trigger point injections	Fear avoidance therapy
Pilates	Ultrasound	Intra-articular steroid injections	Stress reduction
Yoga	Electrical stimulation	Epidural steroid injections	Relaxation/guided imagery
Tai chi	Paraffin treatment	Nerve blocks	Art/music therapy
Qigong	Infrared light therapy	Implantable devices	Biofeedback
Feldenkrais	Spinal traction/ decompression		Hypnosis
Postural re-training	Spinal manipulation		
	Acupuncture		



**Table 3. Tools for Evaluating Addiction Risk<sup>36-40</sup>**

Tool	# of Items	Administered By	Comments
<b>Patients considered for long-term opioid therapy</b>			
<b>ORT</b>	5	Patient	Predicts aberrant or drug-related behaviors
<b>SOAPP</b>	24, 14, 5	Patient	Evaluates risk of long-term opioid therapy in those with chronic pain
<b>DIRE</b>	8	Clinician	Determines risk of long-term opioid use in those with chronic pain; evaluates regimen efficacy
<b>Characterize misuse once opioid treatment begins</b>			
<b>PMQ</b>	26	Patient	Evaluates risk of opioid misuse in those with chronic pain
<b>COMM</b>	17	Patient	Identifies aberrant behaviors; for those with chronic pain who are already on opioids
<b>PDUQ</b>	31	Clinician	Evaluates and predicts opioid misuse in those with chronic pain
<b>Not specific to pain populations</b>			
<b>CAGE-AID</b>	4	Clinician	Screens for substance dependence; modified CAGE questionnaire
<b>RAFFT</b>	5	Patient	Can be used for alcohol, marijuana, or other drug use
<b>DAST</b>	28	Patient	Screens for risky/illicit drug use in adults
<b>SBIRT</b>	Varies	Clinician	Designed to provide universal screening; secondary prevention to detect risky or hazardous substance use before the onset of problems; early intervention; and treatment

CAGE-AID = CAGE Adapted to Include Drugs; COMM = Current Opioid Misuse Measure; DAST = Drug Abuse Screening Test; DIRE = Diagnosis, Intractability, Risk, and Efficacy; ORT = Opioid Risk Tool; PDUQ = Prescription Drug Use Questionnaire; RAFFT = Relax, Alone, Friends, Family, Trouble; SBIRT = Screening, Brief Intervention, and Referral to Treatment; SOAPP = Screener and Opioid Assessment for Patients with Pain.

opioid therapy; 2) to screen for misuse once opioid treatments have begun; and 3) to screen for substance use not limited to opioid misuse (**Table 3**).

The management of pain is complex and difficult and is impacted by a variety of factors that reflect co-morbidities, individual variability in the response to pain and its treatment. A holistic approach to pain management addresses the whole patient and incorporates physical, psychological, biological, spiritual, social, and cultural components that influence the patient's experience.<sup>37</sup> These integral components play a significant role in areas of everyday life and influence the experience of pain. Consideration of the components that influence the patient's pain experience will help to formulate a treatment plan that best meets individual needs.

## PART 2: IMPLEMENTING NEW PRACTICES

Primary care providers should perform a comprehensive assessment that includes a history and physical examination with screening for substance use to determine an appropriate treatment plan that safely meets the patient's needs.<sup>38</sup> A comprehensive assessment can be performed efficiently with standardized processes; however, multiple visits may be needed to complete the entire assessment. One possible method to consider is a four-step approach, which follows the SOAP (Subjective–Objective–Assessment–Plan) format (**Table 4**).

Providers should assess the patient's pain including location, intensity, quality, etc; the effects of the pain on function and quality of life; comorbidities (eg, depression, anxiety); psychosocial history, including family history of substance abuse and psychiatric disorders, history of trauma/sexual abuse;

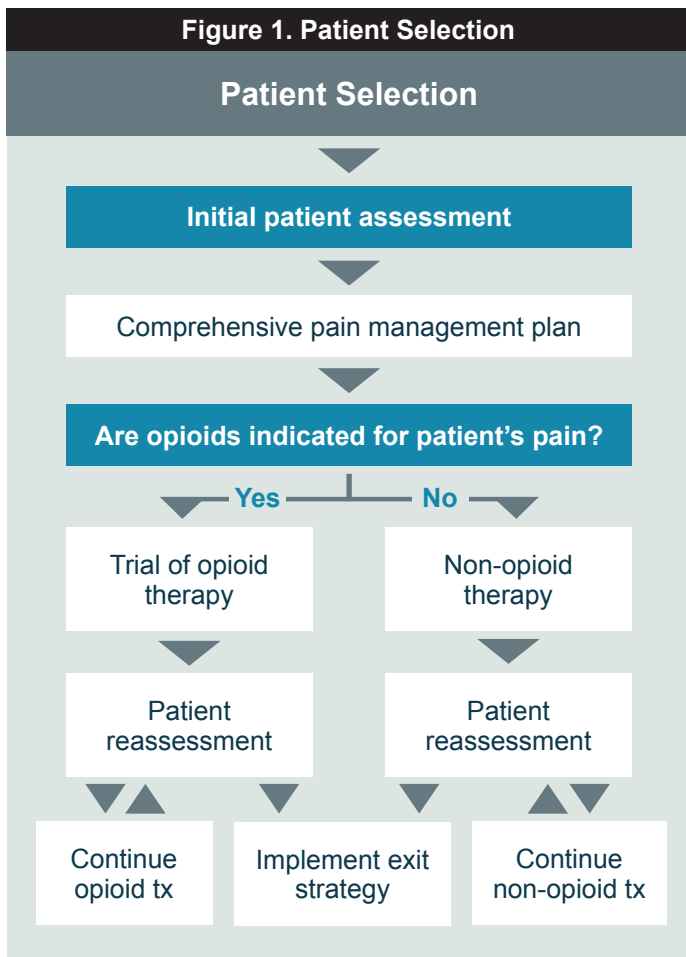
**Table 4. The Four-Step Approach<sup>38</sup>**

<b>Step 1</b>	History, Physical + Screen	Subjective–Objective
<b>Step 2</b>	Screen and full SBIRT if screen is positive	
<b>Step 3</b>	Diagnosis	Assessment–Plan
<b>Step 4</b>	Document	

SBIRT = Screening, Brief Intervention, and Referral to Treatment

mental health and functional status; medication and substance use history; past and current substance use disorders; and past pain management and coping strategies as well as maladaptive pain-related thought patterns.<sup>38</sup> The patient history should include psychosocial stressors, family history, and pre-adolescent history. This comprehensive history and physical, and risk assessment at the initial evaluation are necessary to determine the appropriate pain management strategy (**Figure 1**).

The risk of abuse should be evaluated using risk stratification and assessment tools (**Table 3**). The presence of risk factors (eg, personal or family history of OUD, history of sexual trauma or abuse, psychiatric disorder) may influence the choice of medication, follow-up, monitoring, and tapering protocols after surgical procedures. Urine drug testing (UDT) is an important component of risk management and should be completed in initial screening and annually during follow-up.<sup>32</sup> UDT is an effective and cost-efficient method that facilitates objective assessment of treatment compliance. Although UDT is generally reliable, false positives can occur and confirmatory testing may be necessary.<sup>40</sup>



**Table 5** shows several common nonopioid and opioid medications that can be considered for the management of acute and chronic pain.<sup>35</sup> Medication selection is based on the severity of pain and injury.<sup>8,41</sup>

A benefit-to-harm evaluation is necessary to assess the risk of pain versus the risk of opioid treatment for pain management.

Pain is associated with decreased quality of life, reduced physical functioning, increased disability, and increased social costs (eg, work absenteeism, increased utilization of medical resources).<sup>19</sup> Comorbidities associated with chronic pain include depression, sleep disturbances, and impaired memory, cognition, and attention.

The benefits of opioid treatment in the management of severe pain include analgesia (pain control) and improved function.<sup>8</sup> Providers should be wary of overprescribing medication and consider the risks of treatment as part the benefit-to-harm evaluation. The potential risks of opioid treatment are considerable and include overdose; life-threatening respiratory depression; abuse, misuse, and addiction by patient or household contacts; physical dependence and tolerance; interactions with other medications and substances; and risk of neonatal withdrawal syndrome.<sup>42,43</sup>

The need for a change in opioid prescribing has been increasingly recognized to address overprescribing and the risk of abuse. The frequent prescribing of opioids for the treatment of dental pain was highlighted in a study by Mutlu et al, which surveyed 384 randomly selected oral and maxillofacial surgeons and found that the average number of tablets prescribed was 20, with 22% of oral surgeons prescribing more than 20 tablets and 11% prescribing more than 30 for postoperative pain following oral surgery.<sup>44</sup> Yet, Lahey et al examined 105 patients of 8 oral surgeons to determine the number of opioids actually used by patients following third molar surgery and found that only 38.4% of all prescribed opioids were consumed during the study period.<sup>49</sup> Nonopioid analgesics should be the primary agents for managing postoperative dental pain. In a study of published systematic reviews, Moore examined the benefits and harms of analgesic medications used for the management of acute dental pain.<sup>45</sup> Their findings supported the use of NSAIDs and acetaminophen to provide effective acute pain management.

**Table 5. Medications Used for Pain Management<sup>35</sup>**

Class	Mechanism of Action	
<b>Acetaminophen</b>	Inhibits COX-3 with decreased CNS prostaglandin E2	First-line therapy for the treatment of osteoarthritis and musculoskeletal pain
<b>NSAIDs</b>	Inhibit COX-1 and COX-2, which decreases pain and inflammation	First-line therapy for musculoskeletal pain and acute and chronic low back pain
<b>Opioids</b>	Act by binding to opioid receptors (mu, delta, kappa, and ORL-1) in the brain	Used for moderate or severe, pain that has an adverse influence on function or quality of life if the potential therapeutic benefits outweigh potential harms, and other treatment modalities have been ineffective
<b>TCAs</b>	Inhibit reuptake of serotonin and norepinephrine	First-line therapy for neuropathic pain
<b>SSRIs</b>	Selectively inhibit reuptake of serotonin	Can be effective for neuropathic pain
<b>Anticonvulsants</b>	Various; most common is enhancement of GABA action coupled with inhibition of sodium channel activity, calcium channels, and glutamate receptors	Adjuvant therapy for chronic pain, cancer pain, trigeminal neuralgia, postherpetic neuralgia, migraine headache, and neuropathic pain
<b>Muscle relaxants</b>	Unknown for many; baclofen, a GABA derivative, acts primarily at the spinal cord level	Use for acute or exacerbation of chronic low back or neck pain with muscle spasms, for short term use only (<7 days)

COX = cyclooxygenase; GABA = gamma-aminobutyric acid; NSAIDs = nonsteroidal anti-inflammatory drugs; ORL-1 = opioid-receptor like-1; SSRIs = selective serotonin reuptake inhibitors; TCAs = tricyclic antidepressants.

As an example of this shift in pain management protocols, the Virginia Commonwealth University (VCU) Department of Oral and Maxillofacial Surgery has issued a set of pain management guidelines to assist in curbing the use of opioids for the treatment of dental pain.

Similarly, to address the need for guidance for reducing opioid use for acute pain, the Orthopaedic Trauma Association (OTA) recently released their *Clinical Practice Guidelines for Pain Management in Acute Musculoskeletal Injury*. The new guidelines address pain management for musculoskeletal injury based on different levels of injury sustained—major musculoskeletal injury or surgery, minor musculoskeletal injury or surgery, and non-operative injuries.<sup>47</sup> Their recommendations include pain medication strategies, cognitive strategies, physical modalities, and system tools (**Table 7**). Pain management should be discussed and patient expectations should be managed at each visit. For opioid tolerant patients, coordination between acute pain service for inpatient management and the patient's prescriber for outpatient management is especially important to maintain a single prescriber.<sup>47</sup>

Patients should receive regular follow-up to determine whether treatment goals are being met and whether opioid rotation, tapering, or discontinuation is needed.<sup>48</sup> Opioid rotation involves changing from an existing opioid regimen to another opioid with the goal of improving therapeutic outcomes or to avoid adverse events attributed to the existing drug.<sup>28</sup> The CDC has published a pocket guide for tapering or discontinuing opioids in patients with chronic pain to assist with implementation in clinical practice.<sup>48</sup> It is advised to go slow (generally no more than 10% decrease per week) with the goal of maximizing pain treatment and minimizing opioid withdrawal symptoms.

Motivational interviewing is a useful technique that can be integrated with behavioral treatment for use in a range of clinical settings, including opioid tapering and OUDs.<sup>49,50</sup> This technique engages the patient to establish a connection, focus on a particular goal or agenda, evokes the patient's own motivation for change, and plans a specific course of action. Motivational interviewing has been shown to improve treatment engagement and outcomes, increase medication adherence, and decrease illicit drug use. A randomized controlled study by Sullivan et al

**Table 6. VCU OMFN New Pain Management Protocol<sup>46</sup>**

Pain Severity	Recommended Treatment
Mild	Ibuprofen (200-400 mg) q4-6 hours prn for pain
Mild to Moderate	Step 1: Ibuprofen (400-600 mg) q6 hours: fixed intervals for 24 hours Step 2: Ibuprofen (400 mg) q4-6 hours prn for pain
Moderate to Severe	Step 1: Ibuprofen (400-600 mg) with APAP (500 mg) q6 hours: fixed interval for 24 hours Step 2: Ibuprofen (400 mg) with APAP (500 mg) q6 hours prn for pain
Severe	Step 1: Ibuprofen (400-600 mg) with APAP (500 mg) q6 hours for 24 hours Step 2: Ibuprofen (400-600 mg) with APAP (650 mg) prn for pain OR (5mg) hydrocodone q6 hours PRN: 3-day supply.
<b>If NSAIDs are Contraindicated:</b>	
Mild	APAP (650-1000 mg) q6 hours prn for pain
Moderate	Step 1: APAP (650-1000 mg) q4-6 hours prn for pain Step 2: Hydrocodone (5 mg) q6 hours: 3-day supply
Severe	Step 1: APAP (650-1000 mg) q6 hours: prn for pain Step 2: Hydrocodone (5 mg) q6 hours: 3-day supply

APAP = acetaminophen

**Table 7: OTA Clinical Practice Guidelines for Pain Management in Acute Musculoskeletal Injury<sup>47</sup>**

Category	Recommendation
Pain Medication Strategies	<ul style="list-style-type: none"> <li>Use multimodal analgesia (MMA). MMA may include NSAIDs, acetaminophen, gabapentinoids, immediate-release (IR) opioids</li> <li>Prescribe lowest effective IR opioid dose for shortest period possible</li> <li>Do not use extended-release opioids</li> <li>Consider local or regional block anesthesia as part of post-op multimodal regimen</li> </ul>
Cognitive Strategies	<ul style="list-style-type: none"> <li>Discuss alleviation of pain, expected recovery course, patient experience at all encounters</li> <li>Connect patients with pain that is greater or more persistent than expected and patients with substantial symptoms of depression, anxiety or post-traumatic stress, or less effective coping strategies to psychosocial interventions and resources</li> <li>Consider strategies for optimal mindset such as aromatherapy, music therapy, or approaches based on cognitive behavioral therapy</li> </ul>
Physical Strategies	<ul style="list-style-type: none"> <li>Use immobilization, ice, and elevation appropriately</li> <li>Consider use of transcutaneous electrical stimulation (TENS) units</li> <li>Consider use of cryotherapy units</li> </ul>
System Strategies	<ul style="list-style-type: none"> <li>Query state and regional PDMP before prescribing opioids</li> <li>Develop and support implementation of clinical decision support in the EMR</li> <li>Support opioid education for prescribers and patients</li> <li>Implement pain medication prescribing strategy or policy</li> </ul>

**Table 8: OTA Recommendations for Pain Medication Taper Following Musculoskeletal Injury Procedure<sup>47</sup>**

	Opioid	Non-Opioid
Inpatient	<ul style="list-style-type: none"> <li>Moderate pain: OXY/APAP 5mg/325mg 1 tab po q4 hrs PRN</li> <li>Severe pain: OXY/APAP 5mg/325 mg 2 tabs po q6 hrs PRN</li> <li>Hydromorphone 1mg IV q3 hrs PRN for severe breakthrough pain</li> </ul>	<ul style="list-style-type: none"> <li>Ketorolac 15mg IV q6 hrs x 5 doses followed by ibuprofen 600mg po q8 hrs</li> <li>Gabapentin 100mg 1 tab po TID</li> <li>Scheduled APAP 500mg po q12 hrs</li> </ul>
Week 1 at discharge	<ul style="list-style-type: none"> <li>OXY/APAP 5mg/325 mg 1 tab po q4 hrs PRN. Dispense #42 (1 time Rx, no refills)</li> </ul>	<ul style="list-style-type: none"> <li>Ibuprofen 600mg po q8 hrs x 7 days (Rx given)</li> <li>Gabapentin 100mg 1 tab po TID x 7 days (Rx given)</li> <li>Scheduled APAP 500mg po q12 hrs x 7 days (can increase as combined opioid analgesic decreases)</li> </ul>
	<ul style="list-style-type: none"> <li>Hydrocodone/APAP 5mg/325mg or tramadol 50mg (only if necessary, 3 Rx Max)</li> </ul>	<ul style="list-style-type: none"> <li>NSAIDs PRN as directed</li> <li>Gabapentin if necessary (up to 1800 mg/day)</li> </ul>
Week 2	<ul style="list-style-type: none"> <li>1 tab po q4 hrs PRN Dispense #42</li> </ul>	<ul style="list-style-type: none"> <li>Scheduled APAP 500mg po q12 hrs (can increase as combined opioid analgesic decreases)</li> </ul>
Week 3	<ul style="list-style-type: none"> <li>1 tab po q6 hrs PRN Dispense #28</li> </ul>	<ul style="list-style-type: none"> <li>Scheduled APAP 1000mg po q12 hrs (can increase as combined opioid analgesic decreases)</li> </ul>
Week 4	<ul style="list-style-type: none"> <li>1 tab po q8 hrs PRN Dispense #21</li> </ul>	<ul style="list-style-type: none"> <li>Scheduled APAP 1000mg po q8 hrs (can increase as combined opioid analgesic decreases)</li> </ul>
Week 5+		<ul style="list-style-type: none"> <li>NSAIDs PRN as directed</li> <li>APAP PRN as directed</li> <li>Gabapentin if necessary (then wean)</li> </ul>

OXY = oxycodone

**Table 9: OTA Recommendations for Pain Medication Taper Following Musculoskeletal Injury Procedure: Discharge<sup>47</sup>**

	Opioid	Non-Opioid
Week 1	<ul style="list-style-type: none"> <li>Hydrocodone/APAP 5mg/325mg or tramadol 50mg</li> <li>1 tab po q6 hrs PRN, Dispense #28</li> <li>1 time Rx, No refills</li> </ul>	<ul style="list-style-type: none"> <li>Ibuprofen 600mg po q8 hrs x 7 days (Rx given)</li> <li>Gabapentin 100mg 1 tab po TID x 7 days (Rx given)</li> <li>Scheduled APA 500mg po q12 hrs x 7 days (can increase as combined opioid analgesic decreases)</li> </ul>
Week 2	<ul style="list-style-type: none"> <li>Hydrocodone/APAP 5mg/325mg or tramadol 50mg</li> <li>Only if necessary, 2 Rx Max</li> <li>1 tab po q8 hrs PRN Dispense #21</li> </ul>	<ul style="list-style-type: none"> <li>NSAIDs PRN as directed</li> <li>Gabapentin if necessary (up to 1800 mg/day)</li> <li>Scheduled APAP 1000mg po q8 hrs (can increase as combined opioid analgesic decreases)</li> </ul>
Week 3	<ul style="list-style-type: none"> <li>1 tab po q12 hrs PRN Dispense #14</li> </ul>	<ul style="list-style-type: none"> <li>NSAIDs PRN as directed</li> <li>Gabapentin if necessary (up to 1800 mg/day)</li> <li>Scheduled APAP 1000mg po q8 hrs (can increase as combined opioid analgesic decreases)</li> </ul>
Week 4		<ul style="list-style-type: none"> <li>NSAIDs PRN as directed</li> <li>APAP PRN as directed</li> </ul>

**Table 10. OTA Recommendations for Pain Medication Taper Following Non-Operative Musculoskeletal Injury<sup>47</sup>**

Injury Category	Opioid	Non-Opioid
Minor Injury (e.g. Small bone fracture, sprain, laceration, etc.)	<ul style="list-style-type: none"> <li>Tramadol 50mg</li> <li>Only if necessary, 2 Rx Max</li> <li>1 tab po q6 hrs PRN, Dispense #20, then #10</li> </ul>	<ul style="list-style-type: none"> <li>NSAIDs PRN as directed</li> <li>Scheduled APAP 1000mg po q8 hrs, then PRN as directed</li> </ul>
Major Injury (e.g. Large bone fracture, rupture, etc.)	<ul style="list-style-type: none"> <li>Hydrocodone/APAP 5mg/325mg or tramadol 50mg</li> <li>Only if necessary, 2 Rx Max</li> <li>1 tab po q6 hrs PRN</li> <li>Dispense #20, then #10</li> </ul>	<ul style="list-style-type: none"> <li>NSAIDs PRN as directed</li> <li>Scheduled APAP 1000mg po q12 hrs, then PRN as directed</li> </ul>



compared tapering support intervention that included motivational interviewing versus usual care. Study results showed reductions in opioid doses and pain severity ratings for both groups, and improvements in pain interference and pain self-efficacy in the motivational interviewing group.<sup>51</sup>

**Table 11** describes guiding principles to promote optimal communication between providers and patients experiencing chronic pain.<sup>38,52</sup> These principles can be helpful to facilitate difficult conversations with challenging patients and enable tailored pain management to maximize patient outcomes.

In a survey by Kroll et al, pain medicine physicians reported higher rates of burnout (defined by exhaustion, cynicism, and inefficacy) compared with other specialties (61% vs 38%).<sup>53</sup> The authors noted that occupational fatigue due to burnout puts physicians at risk for alcohol use, interpersonal difficulties, and suicidal ideation, and increases the risk for medical error. To avoid burnout, clinicians who treat patients with chronic pain should practice self-care and set healthy boundaries (eg, appropriate prescription refills, visit expectations, time limitations) with patients.<sup>35</sup>

Programs that integrate behavioral health in primary care clinics (counselor, psychologist, psychiatrist, community mental health) have succeeded in expanding access, improving retention, and reducing relapse in the treatment of OUD.<sup>53</sup> A 2017 meta-analysis conducted by Lagisetty et al analyzed 35 studies in primary care locations in eight countries.<sup>54</sup> The authors determined that a multidisciplinary approach between primary care and specialty addiction services improves success, along with a united care team including nurses and pharmacists.

### PART 3: IMPROVING PATIENT EDUCATION AND CHANGING PERSPECTIVES

A key priority in pain management is engaging and educating patients about their pain to optimize safe and effective multimodal treatment plans.<sup>20</sup> Providers should utilize patient-centered strategies to help patients develop a greater understanding of their underlying disease process and pain triggers and educate them on how to seek appropriate professional care.

Patient engagement may include discussions between the patient and provider about treatment goals, expectations and risks, signs of dependence, and documented contracts or agreements outlining the responsibilities of both participants in the treatment process.<sup>55</sup> Goals should focus on improvement in pain and function and should be realistic, specific, and measurable.<sup>28,56</sup> Patients should receive information about pain management options and potential treatment outcomes, including the benefits and risks of non-opioid pharmacotherapy, nonpharmacological therapies, and opioid therapy. Providers should assist patients with the evaluation of pain management options based on the patient's values and preferences to enable a joint decision between the patient and physician on initiation of opioid therapy.<sup>57</sup> A written, formalized contract can help establish and document a common understanding between the patient and provider.<sup>58</sup> To minimize the risk of OUD and overdose, patients should also be educated about the signs and symptoms of opioid dependence and withdrawal; and safe storage and disposal of medication.

**Table 11. Principles of Communication with Patients Experiencing Chronic Pain<sup>38,52</sup>**

#### Establish Trust

- Slow down and take time to listen to your patient.
- Recognize your patient's uniqueness.
- Listen reflectively.
- Show empathy; use empathic statements and consider your nonverbal communication (eg, body language).

#### Consider Effect on Quality of Life

- Engage in patient-centered collaboration.
- Set reasonable long-term and short-term goals.
- Plan attainable incremental steps toward each goal but allow patients to hold steady on a taper to build trust and readiness.
- Recognize and appreciate your patient's situation.
- Take the time needed to address concerns and be supportive.

#### Explore Options

- Explore all feasible options to manage chronic pain and improve quality of life.
- Empathize with the patient while presenting the benefits of recommended options.

#### Example: Motivational Interviewing

OARS:

- **O**pen questions
- **A**ffirmations
- **R**eflective listening
- **S**ummarizing

**Table 12. FDA-Approved Medications to Treat Opioid Use Disorders<sup>32,69</sup>**

Medication	Opioid Receptor Pharmacology	Formulation	Restriction
<b>Methadone</b>	Full agonist	Oral tablet or liquid	Dispensed for opioid dependence only from federally licensed treatment facilities
<b>Buprenorphine</b>	Partial agonist	Oral tablet, buccal film, or extended-release implant	Prescribed with appropriate waiver
<b>Buprenorphine-naloxone</b>	Mixed agonist-antagonist	Oral tablet or buccal film	Prescribed with appropriate waiver
<b>Naltrexone</b>	Antagonist	Oral tablet or extended-release injectable	None noted

### Medication storage and disposal

Safe storage and disposal of opioids is essential to minimize diversion. Medications should be stored in their original packaging inside a locked cabinet, a lockbox, or other secure location.<sup>13</sup> The FDA recommends consumers follow instructions for safe disposal provided on the medication label.<sup>59</sup> If there are no disposal instructions on the label, options for discarding unused or expired medications include:

1. Medication take-back programs: Permanent DEA-registered collection sites including select retail/hospital/clinic pharmacies and law enforcement facilities, and periodic events such as national prescription drug take-back events.
2. Disposal in household trash: To dispose medication in household trash, mix (do not crush tablets or capsules) with an unpalatable substance such as dirt, cat litter, or used coffee grounds. Seal the mixture in a plastic bag and throw in the trash. Delete personal information from the prescription label before disposing.
3. Disposal in a drug deactivation and disposal pouch: There are now safe and effective ways to deactivate and dispose of drugs at home. Medications can be placed in a drug disposal pouch, that utilizes activated carbon to deactivate the drugs, and can be disposed of in the household trash.

While the FDA has endorsed flushing of opioids down the toilet, many organizations strongly recommend against flushing of opioids due to growing concerns about the impact of medications on aquatic life.

### Naloxone administration

Naloxone is an FDA-approved medication that rapidly reverses the effects of opioids, such as respiratory depression, which is the cause of death in the majority of overdoses.<sup>35,60</sup> Wider naloxone administration and education has been identified as a priority area in the Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy.<sup>60</sup> In December 2018, the Department of Health and Human Services released a recommendation for co-prescribing naloxone with opioids to patients at high risk of opioid overdose.<sup>61</sup> In 2014, the FDA approved a subcutaneous/intramuscular autoinjector form that could be administered by an individual. In 2017, they approved a nasal spray form of naloxone. Allison L. Pitt and her Stanford colleagues point out that none of the current treatment and policy proposals can substantially reduce opioid-induced deaths in the long term, but of the current interventions, naloxone could have the most impact. Studies have shown the public health

benefits of community-based overdose education and naloxone distribution (OEND) programs that provide naloxone and train at-risk individuals and their friends, family members or caregivers on overdose prevention and response.<sup>62</sup> Such programs have led to significant reductions in opioid-related overdose death rates.<sup>63-65</sup>

### Medication-assisted treatment

Medication-assisted treatment (MAT) involves the use of medications combined with behavioral therapies for the treatment of substance use disorders, including OUD. Pharmacotherapies used to treat OUD include methadone, buprenorphine, buprenorphine-naloxone, and naltrexone (**Table 12**). Studies have shown that MAT is effective for the treatment of OUDs, with success rates ranging from 50% to 66% as measured by mortality reduction and opioid use suppression.<sup>66,67</sup> In one study, patients who continued to receive MAT at 18 months were more than twice as likely to report avoidance of non-medical use of opioids compared with those who were not receiving MAT (80% vs 36.6%).<sup>68</sup>

### Buprenorphine prescribing

Under the Drug Addiction Treatment Act of 2000, healthcare providers must qualify for and obtain a waiver to prescribe buprenorphine for OUD (**Table 13**).<sup>70</sup> Despite only requiring eight hours of training to receive a prescribing waiver, just 4% (or 37,448) of all active physicians in the United States have applied for a waiver.<sup>71,72</sup> A study by Andilla et al found that 60% of rural counties lacked a single physician authorized to prescribe buprenorphine, demonstrating current barriers to treatment access for patients, particularly in rural and underserved areas.<sup>73</sup> Several barriers to buprenorphine treatment have been identified, including federal limits on the number of patients a physician may treat with buprenorphine; federal limits on nurse practitioners' and physician assistants' prescribing; inadequate integration of buprenorphine into primary care treatment; and stigma against maintenance treatment for opioid addiction.<sup>74</sup> Addressing these barriers to increase the number of prescribers approved to prescribe buprenorphine will expand access to treatment and improve outcomes for patients with OUD.

### Destigmatizing language

Focus on supply has a limited efficacy<sup>76</sup> and can be counterproductive in reinforcing shame and stigma. The public perception of individuals who use opioids is overwhelmingly negative, leading to an aversion to confront potential

**Table 13. Requirements To Obtain a Waiver To Provide Buprenorphine Treatment<sup>75</sup>**

- Active, valid state medical license/state-controlled substance license
- Register with DEA to prescribe controlled substances
- Complete 8 hours MAT training
- Complete SAMHSA waiver notification
- Be capable to refer patients to counseling services

**Table 14. Non-Stigmatizing Language Versus Stigmatizing Language<sup>81</sup>**

Non-Stigmatizing Language	Stigmatizing Language
<ul style="list-style-type: none"> <li>• Person with a substance use disorder</li> </ul>	<ul style="list-style-type: none"> <li>• Substance abuser or drug abuser</li> <li>• Alcoholic</li> <li>• Addict</li> <li>• User</li> <li>• Abuser</li> <li>• Drunk</li> <li>• Junkie</li> </ul>
<ul style="list-style-type: none"> <li>• Substance use disorder or addiction</li> <li>• Use, misuse</li> <li>• Risky, unhealthy, or heavy use</li> <li>• Relapse</li> </ul>	<ul style="list-style-type: none"> <li>• Drug habit</li> <li>• Abuse</li> <li>• Problem</li> </ul>
<ul style="list-style-type: none"> <li>• Person in recovery</li> <li>• Abstinent</li> <li>• Not drinking or taking drugs</li> </ul>	<ul style="list-style-type: none"> <li>• Clean</li> </ul>
<ul style="list-style-type: none"> <li>• Treatment or medication for addiction</li> <li>• Medication for Addiction Treatment or Medication-Assisted Recovery</li> <li>• Long-term Recovery</li> <li>• Pharmacotherapy</li> <li>• Positive, negative (toxicology screen results)</li> </ul>	<ul style="list-style-type: none"> <li>• Substitution or replacement therapy</li> <li>• Medication-Assisted Treatment</li> <li>• Clean, dirty</li> </ul>

See pages 13-16 for a complete list of references.

addiction.<sup>77-79</sup> High levels of stigma associated with opioid use are common not only in the general public but also found among key groups involved in responding to the opioid epidemic, including first responders, public safety officers, and healthcare providers.<sup>80</sup> Stigma is a key barrier that prevents patients from seeking care.<sup>81</sup> As a consequence, only 10% of individuals with substance use disorder get treatment;<sup>10</sup> women, communities of color, and residents of rural areas often face additional barriers to accessing services and are even less likely to receive treatment.<sup>82</sup> Thus, it is important that providers aim to reduce stigma and minimize barriers to treatment. To this end, a nationwide public education campaign is being promoted to combat the opioid crisis and reduce this stigma by emphasizing that addiction is not a moral failing, but rather a chronic brain disease with evidence-based treatment options.<sup>10,62</sup> A report published by the Johns Hopkins School of Public Health and the Clinton Foundation recommends to combat stigma by avoiding stigmatizing language and including information about treatment barriers and treatment effectiveness when communicating with the public about opioid use disorders (**Table 14**).<sup>74,81</sup> This includes replacing dehumanizing terms (eg, “substance abuser,” “addict,” or “junkie”) with non-stigmatizing language (eg, “person with a substance use disorder”).

High levels of social stigma have been linked to greater support for punitive policies and lower support for public health-oriented policies that affect individuals with OUDs.<sup>79</sup>

#### FACULTY PANEL INSIGHTS

The overall consensus among the faculty panel was that a collaborative patient-centered approach is needed to guide optimal pain management. Providers need to educate patients about their pain in order to optimize safe and effective multi-disciplinary treatment plans. The faculty panel highlighted the importance of understanding the complex biopsychosocial aspects of pain. Best practices include the careful integration of multimodal approaches including non-pharmacologic and non-opioid interventions. Providers need to understand and manage patient expectations. Pharmacovigilance is needed to apply an evidence-based approach to chronic pain management and improve prescribing practices. More education is needed to reduce stigma and increase treatment access. Concepts from successful novel programs should be integrated into clinical practice.

“When a clinician changes the treatment approach with a patient who tests positive for an illicit drug, that response is not about punishing the patient, but about changing the treatment plan on the basis of a new risk and addressing a newly identified problem.”<sup>83</sup>

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Mr. Alden has no disclosures to report.

Dr. Abubaker has no disclosures to report.

Ms. Judd has disclosed that she serves on the speakers bureau of Alkermes; Neurocrine Biosciences, Inc.; Otsuka America Pharmaceutical, Inc.; and Sunovion Pharmaceuticals Inc. She also serves on the advisory board of ACADIA Pharmaceuticals Inc.; and Neurocrine Biosciences, Inc.

Dr. Mir has disclosed that he is a consultant for OrthoGrid Systems, Inc.; Smith & Nephew; StabilizOrtho; Trice Medical; and Zimmer Biomet.

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# TIME TO LISTEN:

## WHAT THE EXPERTS HAVE TO SAY ABOUT SAFE OPIOID PRESCRIBING AND ADDICTION TREATMENT



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