

Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

Draft Report Overview

The Comprehensive Addiction and Recovery Act (CARA) of 2016 led to the creation of the Pain Management Best Practices Inter-Agency Task Force (Task Force), whose mission is to determine whether gaps in or inconsistencies between best practices for acute and chronic pain management exist and to propose updates and recommendations to those best practices. The Task Force consists of 29 experts who have significant experience across the disciplines of pain management, patient advocacy, substance use disorders, mental health, and minority health. This draft report describes preliminary recommendations of the Task Force that will be finalized and submitted to Congress in 2019, following a 90-day public comment period. Initial key concepts:

- **Balanced** pain management should be based on a biopsychosocial model of care.
- **Individualized**, patient-centered care is vital to addressing the public health pain crisis.
- Ensure better and **safer opioid** stewardship through **risk assessment** based on patients' medical, social, and family history to ensure safe and appropriate prescribing.
- **Multidisciplinary** approach to chronic pain that focuses on the patient's medical condition, comorbidities, and various aspects of care including:
 - **Medications.** Different classes depending on patient medical conditions and history.
 - **Restorative movement therapies.** Physical and occupational therapy, massage therapy, aqua therapy.
 - **Interventional procedures.** Different types of minimally invasive procedures can be important for both acute and chronic pain.
 - **Complementary and integrative health.** Acupuncture, yoga, tai chi, meditation.
 - **Behavioral health/psychological interventions.** Coping skills, cognitive behavioral therapy.
- **Multi-modal approach** to acute pain in the surgical, injury, burn and trauma setting.
- **Perioperative surgical home and acute pain guidelines** to provide a framework for improved patient experience and outcomes.
- **Addressing drug shortages** that might affect acute and chronic pain care.
- **Access to care** is vital through improved health care coverage for various treatment modalities and an enlarged workforce of pain specialists and behavioral health clinicians to help guide and support appropriately trained primary care clinicians.
- **Stigma** is a major barrier to treatment, so it is important to provide empathy and a non-judgmental approach to improve treatment and outcomes.

- **Education** through societal awareness, provider education and training, and patient education are needed to understand choices and promote therapeutic alliances between patients and providers.
- **Innovative** solutions to pain management such as telemedicine, tele-mentoring, mobile apps for behavioral and psychological skills, newer medicines, and medical devices should be utilized as part of the overall approach to pain management.
- **Research** is required to develop a better understanding of the mechanisms of pain, preventive measures, the use of innovative medical devices and medications to prevent the acute-to-chronic pain transition, and methods to improve outcomes of chronic pain conditions.
- **Special populations** are highlighted, including pediatric, women, older adults, American Indians/Alaskan Natives, active duty soldiers/veterans, sickle cell disease (as an example of a chronic relapsing condition).

Sections:

[1. Introduction](#)

[2. Clinical Best Practices](#)

[2.1 Approaches to Pain Management](#)

[2.1.1 Acute Pain](#)

[2.2 Medication](#)

[2.2.1 Risk Assessment](#)

[2.2.2 Overdose Prevention Education and Naloxone](#)

[2.3 Restorative Therapies](#)

[2.4 Interventional Procedures](#)

[2.4.1 Perioperative Management of Chronic Pain Patients](#)

[2.5 Behavioral Health Approaches](#)

[2.5.1 Access to Psychological Interventions](#)

[2.5.2 Chronic Pain Patients With Mental Health and Substance Use Comorbidities](#)

[2.6 Complementary and Integrative Health](#)

[2.7 Special Populations](#)

[2.7.1 Unique Issues Related to Pediatric Pain Management](#)

[2.7.2 Older Adults](#)

[2.7.3 Unique Issues Related to Pain Management in Women](#)

[2.7.4 Pregnancy](#)

[2.7.5 Chronic Relapsing Pain Conditions](#)

[2.7.6 Sickle Cell Disease](#)

[2.7.7 Health Disparities in Racial and Ethnic Populations, Including African-Americans, Latinos, American Indians, and Alaska Natives](#)

[2.7.8 Military Personnel and Veterans](#)

[3. Cross-Cutting Clinical and Policy Best Practices](#)

[3.1 Stigma](#)

[3.2 Education](#)

[3.2.1 Public Education](#)

[3.2.2 Patient Education](#)

[3.2.3 Provider Education](#)

[3.3 Access to Pain Care](#)

[3.3.1 Medication Shortage](#)

[3.3.2 Insurance Coverage for Complex Management Situations](#)

[3.3.3 Workforce](#)

[3.3.4 Research](#)

[4. Review of the CDC Guideline](#)

[Acronyms](#)

[References](#)

1. Introduction

The experience of pain has been recognized as a national public health problem with profound physical, emotional, and societal costs.¹ Today, chronic pain affects an estimated 50 million U.S. adults, and as many as 19.6 million of those adults experience high-impact chronic pain that interferes with daily life or work activities.² Pain management stakeholders have been working to improve care for those suffering from acute and chronic pain in an era challenged by the opioid crisis.³

At the same time, our nation is facing an opioid crisis that has seen an unprecedented rise of overdose deaths associated with prescription opioids, heroin, and synthetic opioids in the past two decades.⁴ The practice of pain management and the opioid crisis have influenced one another as they each have

evolved in response to different influences and pressures. It is imperative to strike a balance between ensuring that patients with painful conditions can work with their health care providers to develop an integrative pain treatment plan that optimizes function, quality of life (QoL), and productivity while also ending the devastating effects of opioid misuse.

“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.”

-- Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use; National Academies of Sciences, Engineering, and Medicine, 2017.

This report is the product of the Pain Management Best Practices Inter-Agency Task Force (Task Force). The practice of pain management began to undergo significant changes in the 1990s, when pain experts recognized that inadequate assessment and treatment of pain became a public health issue.¹ Recommendations for improving the quality of pain care⁵ were followed by initiatives that recognized patients’ reported pain scores as “The 5th Vital Sign.”⁶ Hospital administrators and regulators began to focus on pain scores, encouraging and incentivizing clinicians to aggressively treat pain to lower pain scores. In addition, increasing administrative burdens (e.g., required quality measures, electronic health records [EHRs], data management and government regulation requirements) common across all medical disciplines and settings led to a lack of sufficient time for health care professionals to spend with patients to conduct assessment of pain and determine optimal treatment plans. The administrative burden of using the EHR contributes significantly to physician burnout, likely affecting their capacity to manage the complexity of pain care.^{7,8,9} As the mandate for improved pain management has increased, there was and remains a need for greater education and greater time and resources to respond to the greater needs of patients with painful conditions.^{3,10}

The emergence of standards recommending the improvement of pain scores, and greater use of opioids, along with aggressive marketing of new opioid formulations, in addition to limited time and resources, and limited coverage for non-opioid therapies, there resulted a liberalization of opioid prescribing.^{3,11} Prescription opioids can be used to treat acute and chronic pain and are often prescribed following surgery or injury as well as for a subset of patients with medical conditions such as complex cancer or inflammatory, neurological, and musculoskeletal conditions. However, multidisciplinary, multimodal approaches to acute and chronic pain are often not supported in time and resources, leaving clinicians with few options to treat often challenging and complex underlying conditions. As medical and policymaking organizations began to urge caution about the use of opioids for pain, the federal government has developed a multifaceted approach to the opioid epidemic, including the U.S. Department of Health & Human Services (HHS) 5-Point Strategy to Combat the Opioid Crisis.¹² In addition, there are various efforts across federal, state, and local governments as well as the community, private, and academic sectors, including the Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand issued in 2018 by President Donald J. Trump.

The significant public awareness and the pressure for both federal and state regulatory agencies and other stakeholders to address the opioid crisis has in part contributed to health care providers limiting the number of opioid prescriptions they write. Regulatory oversight has also led to fears of prescribing among some clinicians, with some refusing to prescribe opioids even to established patients on a stable opioid regimen.¹³ This increased vigilance and targeting of the misuse of prescription opioids and the tightening of their availability have in some situations led to unintended consequences, such as patient abandonment and forced tapering, with established patients with pain possibly transitioning to illicit drugs, including illicit fentanyl and heroin – this would be a separate group of patients distinguished from those with substance use disorders (evidenced by Task Force public comments). The Centers for Disease Control and Prevention (CDC) has recently noted that the opioid crisis is quickly moving to a fentanyl crisis.¹⁴ This has coincided with an increase in the demand of the illicit drug market for synthetic opioids as well as other substances,^{15,16} and with a four-fold increase in the heroin death rate since 2010.¹⁷ Nationwide, nearly half of all opioid overdose deaths in 2017 involved illicitly manufactured fentanyl. Fentanyl is an opioid used for pain and anesthesia and is 50 times more potent than morphine. Illicit fentanyl (manufactured abroad and distinct from medical use in the United States), with an even more potent synthetic form, has sometimes been mixed with other opioids (prescription and illicit opioids, cocaine, and other illegal substances), including heroin, resulting in sentinel outcomes because of its concentrated effect and low costs.

Public comments submitted to the Task Force show growing consideration of suicide resulting from unrelieved pain and in some cases lack of access to treatment. According to a recent CDC report using data from the National Violent Death Reporting System, the percentage of people who died by suicide who also had evidence of chronic pain increased from 7.4% in 2003 to 10.2% in 2014.¹⁸ Numbers from this data set beyond 2014 are not yet available. This finding leads to the rising concern that a recent trend of health care professionals opting out of treating pain has contributed to an existing shortage of pain management specialists¹ and is leaving some patients without adequate access to care.

Comprehensive pain management can be a challenge for various reasons. In the current environment, patients with chronic pain, particularly those being treated with opioids, can be stigmatized, a tendency exacerbated when their pain condition is complicated by common mental health co-morbidities such as anxiety and depression or by addiction. Opioids can have addictive properties in certain at-risk populations; risk assessment and periodic reevaluation and monitoring are required for all patients in these populations and should be a part of the complex care management they need, particularly when there is an intersection of chronic pain, opioids, mental health, and addiction. There is strong evidence that because of awareness and education about these issues, opioid misuse has since been decreasing, from 12.8 million individuals in 2015 to 11.4 million individuals in 2017.¹⁹

HHS is advancing a comprehensive overview that addresses all issues in the practice of acute and chronic pain management, an effort that is coordinated with the 5-Point Strategy to Combat the Opioid Crisis to recalibrate the role opioid medications play in pain care to reduce opioid harm and improve

the QoL for patients living with pain.¹² This work includes execution of mandates set forth by the Comprehensive Addiction and Recovery Act (CARA), which establishes “an interagency task force, convened by the Department of Health and Human Services, in conjunction with the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the White House Office of National Drug Control Policy.”²⁰ The CARA legislation instructs the Task Force to “[d]etermine whether there are gaps in or inconsistencies between best practices for pain management” and “propose updates to best practices and recommendations on addressing gaps or inconsistencies.”²⁰

The Task Force recognizes that comprehensive pain management often requires the work of various health care professionals, including physicians, dentists, nurses, pharmacists, physical therapists, occupational therapists, behavioral health specialists, psychologists, and integrative health practitioners. The complexity of some pain conditions requires multidisciplinary coordination among health care professionals; in addition to the direct consequences of acute and chronic pain, the experience of pain can exacerbate other health issues, such as delayed recovery from surgery or an activation of behavioral and emotional disorders. Achieving excellence in patient-centered care depends on a strong patient-clinician relationship defined by mutual trust and respect and, in the case of chronic pain, empathy and compassion on the part of the health care provider.²¹ As required by congressional legislation, HHS has convened the Task Force, which consists of 29 members with expertise in pain management, patient advocacy, substance use disorders (SUDs), mental health, state medical boards, minority health, and veteran service organizations as well as other organizational representatives. The Task Force includes representatives from federal agencies, including HHS, the VA, DoD, and the Office of National Drug Control Policy.

In 2018, the Task Force convened two public meetings that included extensive public comment and critical patient testimonials from various different patient groups. There were numerous subcommittee meeting deliberations and discussions that included various special population presentations, including the Indian Health Services (IHS), the Defense Health Agency, the VA, state health officials, private and industry experts, and integrative pain experts. The Task Force reviewed extensive public comments, patient testimonials, and existing best practices; considered relevant medical and scientific literature; and requested information from government and nongovernment experts in pain management and related disciplines. Task Force discussion and analysis resulted in the identification of gaps, inconsistencies, updates, and recommendations for acute and chronic pain management best practices described in this report, consistent with the CARA legislation. In the context of this report, the term “gap” includes gaps across existing best practices, inconsistencies among existing best practices, the identification of needed updates to best practices, or a need to reemphasize vital best practices. Gaps and recommendations in the report span five major interdisciplinary treatment modalities: medication, restorative therapies, interventional procedures, behavioral health approaches, and complementary and integrative health. This report also provides gaps and recommendations for special populations confronting unique challenges in pain management as well as gaps and recommendations for critical topics that are broadly relevant across treatment modalities, including stigma, education, and access to care. The report reviews various clinical practice guidelines (CPGs), with 2018 public comments from

key stakeholders, patients, family members, as well as the CDC guideline.

2. Clinical Best Practices

CPGs are designed to provide evidence-based information and assist in clinical decision making to optimize patient care and outcomes. In pain management, a critical part of providing comprehensive care is performance of a thorough initial evaluation, including assessment of both the medical and the probable biopsychosocial factors causing or contributing to the pain, with a treatment plan to address the causes of pain and to manage pain that persists despite treatment. Quality pain management and CPGs can alter opioid prescribing both by offering alternatives to opioids and by clearly stating when they may be appropriate and how to consider risk assessment and benefit analysis with ongoing nonopioid treatment modalities.³ Several recent CPGs for chronic pain management agree on specific recommendations for mitigating opioid-related risk through risk assessment, including screening for risks such as depression, active or prior history of SUDs, family history of SUD, and childhood trauma, among other issues, prior to initiating opioids; medication dosing thresholds; consideration of drug-drug interactions, with specific medications and drug-disease interactions; risk assessment and mitigation (e.g., patient-provider treatment agreements); drug screening/testing; prescription drug monitoring programs; and access to nonpharmacologic treatments. CPGs that only promote and prioritize minimizing opioid administration run the risk of undertreating pain, especially when the cause of the pain is uncertain or cannot be reduced by nonopioid approaches.

To continue improving quality of pain care in the current environment of opioid-related risks, experts have noted several key challenges associated with CPGs. First, there is the need to increase the use of CPGs, as indicated in specific patient groups delineated by their underlying diagnosis or cause of pain (e.g., arthritis, postoperative, neuropathic), comorbidities, demographics, and settings (e.g., hospital, perioperative, primary care, emergency department [ED]). Second, there must be improved access to effective pain management treatments through adoption of CPGs in medical practice and clinical health systems.²² Third, CPGs for pain management should be more incorporated into the routine training of clinicians,²³ with special attention to residency training to meet the needs of patients treated in each specialty.^{3,10} Finally, there needs to be adequate reimbursement for quality care.

Pain management experts have also identified specific research gaps that are impeding the improvement of pain management guidelines as well as other needs, including synthesizing and tailoring recommendations across guidelines, diagnoses, and populations. In addition, there are gaps and inconsistencies within and between pain management and opioid prescribing guidelines.²⁴⁻²⁶ This finding is also the result of demographic and other variances, because clinical best practices (CBPs) are developed in different regions and states around the country. A recent review of clinical opioid prescribing guidelines by Barth et al.²⁷ notes several needs — including the development of postoperative pain management guidelines for different surgical procedures, with the understanding of patient variability in physiology, drug metabolism and other medical underlying disease processes. This further emphasizes the need for an individualized patient-centered approach. In light of these

gaps, there are potential limitations to evidence-based clinical recommendations that should be considered by pain management providers.²⁸

A systematic review of CPGs for neuropathic pain²⁹ identified shortcomings across four evaluation domains: 1) stakeholder involvement (i.e., the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users); 2) the rigor of development (i.e., the process used to gather and synthesize the evidence and the methods used to formulate the recommendations); 3) applicability (i.e., likely barriers and facilitators to implementation of the guideline, strategies to improve its uptake, and resource implications of applying it); and 4) editorial independence (i.e., bias in the formulation of the recommendations), not to mention the knowledge and skill set of the clinician. Identified inconsistencies across guidelines for some painful conditions, such as fibromyalgia, have demonstrated a need for a consensus in guideline development.³⁰ A review of state-level guidelines for opioid prescriptions found that a minority of states had guidelines specific to EDs.³¹ Pain guidelines from the World Health Organization are facing a lack of adoption, potentially because they lack incorporation of contemporary pain management practices.³²

2.1 Approaches to Pain Management

A multimodal approach to pain management consists of using more than one treatment modality from one or more medical disciplines to be incorporated into a pain treatment plan. Such modalities allow for different approaches to address the pain condition (acute and chronic) from a variety of mechanisms, often allowing for a synergistic approach that addresses the different aspects of the pain condition, including addressing improved symptoms and functionality. Multidisciplinary approaches incorporate various disciplines to address different components of chronic, often complex pain conditions including biopsychosocial effects of the medical condition on the patient.^{33–35} The efficacy of such a coordinated, integrated approach has been documented in the scientific literature to reduce pain severity, improve mood and overall QoL, and increase function.^{34,36–41} HHS has developed a National Pain Strategy that “recommends a population-based, biopsychosocial approach to pain care that is grounded in scientific evidence, integrated, multimodal, and interdisciplinary, while tailored to an individual patient’s needs.”⁴² Recent CPGs developed by the VA and DoD integrate the biopsychosocial model of pain,²⁶ and the Veterans Health Administration (VHA) has identified biopsychosocial care plans as an essential element to effective pain management.⁴³ The biopsychosocial approach is applied clinically across pain experiences, including chronic pain,⁴⁴ and specifically to musculoskeletal pain,⁴⁵ low-back pain,^{46,47} and HIV-related pain.⁴⁸ Specialty interdisciplinary pain medicine team consultation, collaborative care, and (when indicated) mental health and addiction services should be readily available in the course of treatment of pain to help ensure the best patient outcomes.

Gaps and Recommendations

Gap 1: Current inconsistencies and fragmentation of pain care limit best practices and patient

outcomes. A coherent policy for pain management within health systems is needed.

- **Recommendation 1a:** Encourage coordinated and collaborative care that allows for best practices and improved patient outcomes whenever possible. One of many examples is the collaborative stepped model of pain care, as adopted by the VA and DoD health systems.

2.1.1 Acute Pain

Acute pain is a ubiquitous human experience⁴⁹ that is classified as a physiologic response to noxious stimuli that is sudden in onset and time limited.⁵⁰ Acute pain can occur after an injury, burn, or trauma or following surgery in the perioperative period. Acute pain and chronic pain are often interlinked, with nearly all cases of chronic pain beginning as acute pain.⁵¹ Acute pain flares may recur periodically in common and complex chronic medical problems, including as examples, but not limited to arthritis,⁵² neuropathies,⁵³ spinal conditions, low-back pain,⁵⁴ sickle cell disease (SCD),⁵⁵ migraine,⁵⁶ multiple sclerosis (MS),⁵⁷ trigeminal pain or neuralgia,⁵⁸ and complex regional pain syndrome (CRPS).⁵⁹ As with acute pain flares in these and other conditions, it is important to perform a thorough evaluation — one that leads to a presumed diagnosis or differential diagnosis — that facilitates both diagnostic and therapeutic plans. The optimal management of acute pain should include establishing a diagnosis and overall treatment plan with continuity of care.⁶⁰ It is vital to consider a risk-benefit analysis with a risk assessment approach to provide the best possible patient-centered outcome while mitigating unnecessary opioid exposure. To avoid the side effects associated with the prescription of opioids (e.g., nausea, vomiting, constipation, sedation, opioid use disorder [OUD], addiction), it is important to acknowledge the benefits of multimodal, nonopioid approaches in acute pain management in conjunction with possible opioid therapy.⁶¹ Reevaluation of patient is critical in this setting because the use of medications to control acute pain should be for the shortest time necessary while also ensuring that the patient is able to mobilize and function to optimize outcome following surgery or injury. Although opioids are effective in treating acute pain, patients can be at risk of becoming new chronic opioid users in the postsurgical setting. As one large study illustrated, among a population of opioid-naïve patients who were given a course of opioids to treat pain following surgery, about 6% became new chronic users. Patients who were at higher risk for becoming chronic opioid users were patients with tobacco use, alcohol and substance abuse disorders, anxiety, depression, other pain disorders, and comorbid conditions.⁶² This finding further underscores the value and importance of initial clinician-patient time together as well as appropriate follow-up time to better assess risk and provide appropriate treatment for these complex pain conditions.

Gaps and Recommendations

Gap 1: Multimodal, nonopioid therapies are underutilized in the perioperative setting.

- **Recommendation 1a:** Use procedure-specific, multimodal regimens and therapies when indicated in the perioperative period, including various nonopioid medications, ultrasound-guided nerve blocks, analgesia techniques (e.g., lidocaine and ketamine infusions), and psychological and integrative therapies to mitigate opioid exposure.
- **Recommendation 1b:** Use multidisciplinary and multimodal approaches for perioperative pain control (e.g., joint camps, Enhanced Recovery After Surgery [ERAS], Perioperative Surgical Home [PSH]). Key components may include preoperative psychology screening and monitoring; preoperative and postoperative consultation and planning for managing pain of moderate to severe complexity; preventive analgesia with preemptive analgesic nonopioid medications; and regional anesthesia techniques, such as continuous catheter-based local anesthetic infusion.
- **Recommendation 1c:** Develop appropriate reimbursement and authorization policies to allow for a multimodal approach to acute pain in the perioperative setting and the peri-injury setting, including preoperative consultation to determine a multimodal plan for the perioperative setting.

Gap 2: Guidelines for the use of multimodal clinical management of the acute pain associated with common categories of surgical interventions and trauma care are needed.

- **Recommendation 2a:** Develop acute pain management guidelines for common surgical procedures and trauma management, carefully considering how these guidelines can serve both to improve clinical outcomes and to avoid unintended negative consequences.
- **Recommendation 2b:** Emphasize the following in guidelines, which provide an initial pathway to facilitate clinical decision making:
 - Individualized treatment as the primary goal of acute pain management, accounting for patient variability with regard to factors such as comorbidities, severity of conditions, surgical variability, geographic considerations, and community/hospital resources.
 - Improved pain control, faster recovery, improved rehabilitation with earlier mobilization, less risk for blood clots and pulmonary embolus, and mitigation of excess opioid exposure.

To reflect multidisciplinary approaches and the biopsychosocial model for management of acute and chronic pain, the following sections are organized by five major approaches to pain management: medication, restorative therapies, interventional procedures, behavioral health approaches, and complementary and integrative health. The following section focuses on special populations that face unique challenges in acute and chronic pain management.




2.2 Medication

Effective pain management, particularly for chronic pain, is best achieved using a patient-centered, multidisciplinary, multimodal, integrated approach that may include pharmacotherapy.^{42,46,63} In general, two broad categories of medications are used for pain management: opioids and a variety of nonopioid classes of medications.^{64,65}

In response to the public health crisis resulting from the current opioid epidemic, there is a surge of interest in nonopioid pharmacotherapies for chronic pain.⁶⁶⁻⁶⁸ Nonopioid medications that are commonly used include acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), antidepressants (e.g., serotonin-norepinephrine reuptake inhibitors [SNRIs] and tricyclic antidepressants [TCAs]), anticonvulsants, musculoskeletal agents, and anxiolytics.⁶⁸⁻⁷¹ Nonopioid modalities, including these medications, can mitigate and minimize opioid exposure. Each medication has its own risks and benefits as well as mechanism of action. Different medications can complement one another, and their effects can be synergistic when used in combination. A risk-benefit analysis is always recommended based on the individual patient's medical, clinical, and biopsychosocial circumstances.

The following paragraphs briefly describe nonopioid medications, which can be considered singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions. This list is not inclusive or exhaustive but instead describes examples of common nonopioid medications. As a general rule, caution should be taken, particularly for over-the-counter medicine, to ensure that patients are aware of the individual side effects and risks of these medications. Over-the-counter medications can be present in or components of common cold and cough medicine; therefore, it is necessary to ensure that patients are aware of and discuss their medications with their doctor and/or their pharmacist.

Acetaminophen can be effective for mild to moderate pain. Risks of acetaminophen can include dose-dependent liver toxicity, especially when taken at high doses or by those with liver disease.⁷² This risk further illustrates why patients should be aware of the presence of acetaminophen in both over-the-counter and prescribed combination medications.

NSAIDs such as [aspirin](#) , [ibuprofen](#) , and [naproxen](#)  can provide significant pain relief for inflammation, such as arthritis, bone fractures or tumors, muscle pains, headache, and acute pain caused by injury or surgery. Nonselective NSAIDs (those that inhibit the activity of both cyclooxygenase [COX]-1 and COX-2 enzymes) can be associated with gastritis, gastric ulcers, and gastrointestinal bleeding. Conversely, COX-2 inhibitors have less gastrointestinal adverse effects. The use of certain NSAIDs may be associated with renal insufficiency, hypertension, and cardiac-related events.

Anticonvulsants are medications originally developed to treat seizures but are also commonly used to treat different pain syndromes, including postherpetic neuralgia, peripheral neuropathy, and migraine.^{73,74} They are often used as part of a multimodal approach for the treatment of pain in the perioperative period. Some of these agents can be effective in treating the neuropathic components of pain syndromes. Anticonvulsants, which include gabapentinoids, may cause significant sedation and have recently been associated with a possible risk of misuse.⁷⁵

Antidepressants are commonly used in various chronic pain conditions.^{73,76} Tricyclic antidepressants are effective medications for a variety of chronic pain conditions, including neuropathic pain. As with other medications, they can have risks and adverse effects, including dry mouth, dizziness, sedation,

memory impairment, orthostatic hypotension, and cardiac conduction abnormalities. Trials with different TCAs (e.g., desipramine, nortriptyline, amitriptyline) should be initiated at a low dose and gradually titrated to optimal effect. SNRIs, such as venlafaxine and duloxetine, are effective for a variety of chronic pain conditions, including musculoskeletal pain, fibromyalgia, and neuropathic pain conditions, but with markedly fewer adverse effects (e.g., lower risk of drowsiness, memory impairment, and cardiac conduction abnormalities) than TCAs. There have been some reports of withdrawal reactions when these medications are suddenly stopped.⁷⁷ Although selective serotonin reuptake inhibitors, such as fluoxetine, sertraline, citalopram, and paroxetine, are effective antidepressants, they have less analgesic effect compared with other antidepressant classes. Overall, the analgesic actions of antidepressants occur even in patients who are not clinically depressed, and their analgesic effect typically occurs sooner and at lower doses than are required for the treatment of depression.

Musculoskeletal agents commonly used for pain treatment include baclofen, tizanidine, and cyclobenzaprine (a TCA). Carisoprodol is metabolized to meprobamate, which is both sedating and possibly addictive, and so the use of carisoprodol is not recommended, particularly because alternatives are available.⁷⁸

Anxiolytics, including benzodiazepines, are often prescribed for anxiety and stress associated with chronic pain. Benzodiazepines do not have independent analgesic effects but can have indirect pain-relieving effects because of other mechanisms of action⁷⁹. Caution must be used with benzodiazepines because of the potential for substance use disorder. Co-prescription of benzodiazepines and opioids is associated with enhanced risks of overdose, respiratory depression, and death.⁸⁰⁻⁸² Combining opioids and benzodiazepines can be unsafe because both types of drugs sedate users and suppress breathing — the cause of overdose fatality — in addition to impairing cognitive function.⁸³

The following paragraphs briefly describe opioid medications, which can be considered singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions.

Opioids are broad-spectrum analgesics that provide pain relief for a wide variety of conditions. Administration of opioid medication can include short- versus long-acting formulations⁸⁴ and different delivery modalities, such as oral, intravenous, per-rectum, transdermal patches⁸⁵ and lozenge formulation. Opioids bind to opioid receptors in the brain, spinal cord, and other sites, activating analgesic and reward pathways.⁸⁶ It is important to point out that different opioid medications vary in the ratio of their analgesic potency and their potential for respiratory depression, the major cause of opioid overdose death.⁸⁷ For example, synthetic fentanyl and fentanyl analogues (e.g., carfentanyl) are particularly potent for respiratory depression. Illicit fentanyl-related overdoses are now a leading cause of overdose deaths in the United States, often because of its use in combination with illicitly obtained heroin, cocaine, diverted prescription opioids, and other drugs of abuse. Common prescription opioid medications that can be considered for management of acute and chronic pain include hydromorphone,

hydrocodone, codeine, oxycodone, methadone, and morphine.⁸⁸⁻⁹¹ Although effective for moderate to severe acute pain, the effectiveness of opioids beyond 3 months requires more evidence.⁹² A recent study concluded that treatment with opioids alone was not superior to treatment with trials of various combinations of nonopioid medications for improving pain-related function over 12 months, and the authors concluded that the results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.⁹³ There are challenges to completing long-term studies of any therapy for moderate to severe pain, particularly patient drop-out from intolerable pain.⁹⁴ Opioid medications can be associated with significant side effects, including constipation, sedation, nausea, vomiting, irritability, pruritis, and respiratory depression.⁹⁵⁻⁹⁷ Opioid medications can be associated with OUD⁹⁸ and can be diverted.⁹⁹ Buprenorphine is another medication that is FDA approved for pain management. Because buprenorphine is a partial agonist at the mu opioid receptor, it has a reduced potency for respiratory depression and is thus safer than full agonists such as morphine, hydrocodone, and oxycodone.^{100,101} In addition, buprenorphine acts as an antagonist at the kappa receptor, an effect shown to reduce anxiety, depression, and the unpleasantness of opioid withdrawal. Oral buprenorphine is widely used for treating patients with OUD but can also be effective and is approved for treatment of pain. There has been a noted challenge, however, by physicians in getting authorization for buprenorphine for pain.

As outlined in recent guidelines, including the VA/DoD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain, the CDC guideline, and the American Society of Interventional Pain Physicians guidelines, risk assessment, close follow-up, and pain reevaluation are important aspects of the treatment plan prior to and throughout the duration of opioid therapy for pain management.^{26,102,103} Initiation of opioid therapy, when the benefits are deemed by the patient and the clinician to outweigh the risks, should be administered at the lowest dose of medication required to optimally control the pain or improve function and QoL and for the shortest period necessary.^{26,42,102} Similarly, assessing for tolerance and consideration of adjunctive therapies, opioid rotation, tapering, and discontinuation based on periodic reevaluation with risk assessment should be considered.^{26,102,104} Periodic reevaluation with continued risk assessment and accurate dose adjustment is critical because patients vary widely in the dose required for analgesic efficacy.^{105,106} Comprehensive risk assessments consider patient functionality, QoL, and potential comorbidities.^{26,42,102}

The idea of a ceiling dose of opioids has been put forward, but establishing such a ceiling is difficult, and the precise level for such a ceiling has not been established.¹⁰⁷ The risk of overdose increases with the dose, but the therapeutic window is highly variable. For example, the CDC guideline identified a dose limit of 90 morphine milligram equivalents (MMEs) per day. More recent data evaluated the risk of death related to opioid dose in 2.2 million North Carolinians and found that the overall death rate was only 0.022% per year.¹⁰⁸ The researchers noted that:

“Dose-dependent opioid overdose risk among patients increased gradually and did not show evidence of a distinct risk threshold. Much of the risk at higher doses appears to be associated with co-prescribed benzodiazepines. It is critical to account for overlapping prescriptions, and justifies taking a person-time approach to MME calculation with intent-to-treat principles.”

ADDITIONAL CONSIDERATIONS

The following paragraphs briefly describe additional considerations relevant to medications used for pain management.

Synthetic opioids other than methadone (a category that includes prescribed fentanyl as well as illicit fentanyl) are now the leading opioid involved in overdose deaths in the United States.^{[88-90](#)} The source of illicit fentanyl has been identified as international and rarely from diverted fentanyl pharmaceuticals. These sources come through the U.S. Postal Service and other means. The illicit fentanyl analog used is not necessarily the same compound used during surgeries, nor in the transdermal fentanyl patches provided for moderate to severe pain. The illicit form that has been seen is an analog called carfentanil, which is 100 times more potent than regular fentanyl. The availability of naloxone as well as patient and family education about naloxone can mitigate the risks of fentanyl-related overdose.^{[109](#)}

Interaction of multiple medications prescribed to patients (polypharmacy) can have significant clinical and symptomatic effect. **Poison centers** are available 24/7 to health care professionals and the public to answer questions about medication interactions and adverse effects and to assess the need to use emergency health care resources.^{[110,111](#)} Poison center engagement is associated with significant reductions in unnecessary use of emergency medical services, EDs, and hospital resources, resulting in significant cost savings for the U.S. health care system.^{[112,113](#)} Increased awareness by providers of the complex and variable interactions of medications prescribed to patients as well as any homeopathic, supplemental, or other over-the-counter remedies they may be using is needed.^{[114](#)}

Abuse-deterrent technologies are being developed with the goal of preventing alterations of prescription opioid formulations and the extraction of the active ingredient by users.^{[115,116](#)} For example, some abuse-deterrent formulations (ADFs) have a hardened tablet surface that prevents crushing, while others turn into a gooey substance upon crushing; both formulations are designed to limit the potential for injecting the core substance.^{[117](#)} ADFs also include adding a pharmaceutical or chemical compound to the opioid to decrease the user’s response to the abused substance or provide an adverse reaction when the medication is altered.^{[116](#)} To address misuse of prescription opioids, the FDA released guidance in 2015 for the development of opioids formulated to meaningfully deter abuse.^{[115](#)} A challenge to the development of opioid ADFs is the need to maintain the same safety and efficacy profile as the opioid without the ADF for FDA approval.^{[116,118,119](#)}

Gaps and Recommendations

Gap 1: Clinical policies tend to treat the large population of patients with multiple conditions causing chronic pain with simple medication rules. Guidelines for medication use for specific populations of patients (e.g., different ages, genders, medical conditions, comorbidities) with chronic pain need to be developed for each specialty group and setting.

- **Recommendation 1a:** Develop condition-specific treatment algorithms that guide physicians to have a more individualized approach for common pain syndromes and conditions. A multidisciplinary approach that integrates the biopsychosocial model is recommended.
- **Recommendation 1b:** Primary care and non-pain specialists should have timely, early consultation with the pain medicine team and other specialists for the assessment of patients with complex pain to prevent complications and loss of function and to improve QoL.
- **Recommendation 1c:** Develop a collaborative, multimodal treatment plan among the referring physician, the pain medicine team, and the patient.
- **Recommendation 1d:** Pharmacies should collaborate with area physicians and other health care providers to develop more effective and patient-friendly delivery systems to meet the needs of their patients.

Gap 2: Opioids are often used early in pain treatment. There has been minimal pain education in medical school and residency programs, and little guidance for primary care providers (PCPs) on appropriate pain treatment approaches.

- **Recommendation 2a:** Use of nonopioid medications (e.g., oral and IV acetaminophen, oral and IV NSAIDs, long-acting local anesthetics, dexmedetomidine), with nonpharmacologic treatments, should be used as first-line therapy whenever possible in the in-patient and out-patient settings.
- **Recommendation 2b:** If an opioid is being considered, physicians and other health care providers should use evidence-informed guidelines.
- **Recommendation 2c:** The type, dose, and duration of opioid therapy should be determined by treating clinicians according to the individual patient's need and pain condition.
- **Recommendation 2d:** Opioid therapy should be initiated only with ongoing nonopioid treatments when the benefits outweigh the risks; the patient is experiencing severe acute or chronic pain that interferes with function; and the patient is willing to continue to engage with the team on a comprehensive multidisciplinary treatment plan, as clinically indicated, with established clear and measurable treatment goals, along with close follow-up and regular risk assessment and reevaluation.
- **Recommendation 2e:** The Centers for Medicare & Medicaid Services (CMS) and payors should provide reimbursement that aligns with the medication guidelines the Task Force has described.

Gap 3: There is often a lack of understanding and education regarding the clinical indication and effective use of nonopioid medications as part of a multimodal and multidisciplinary approach to acute and chronic pain management. Chronic pain is often ineffectively managed, which can in part be the result of a variety of factors, including physician training, patient access, and other barriers to care:

- **Recommendation 3a:** Physicians and other health care providers should understand the use of nonopioid medication and their mechanism-based pharmacology for managing different components of pain syndromes.
- **Recommendation 3b:** For neuropathic pain, consider antineuropathic medication, including TCAs; anticonvulsants (e.g., gabapentin, pregabalin, carbamazepine, oxcarbazepine); SNRIs (e.g., duloxetine, venlafaxine); and topical analgesics, such as lidocaine and capsaicin. Regardless of the route of medication, education regarding the side effects and risks and benefits is vital in terms of understanding clinical indications and patient outcomes.
- **Recommendation 3c:** For non-neuropathic, noncancer pain, use NSAIDs and acetaminophen as first-line classes of medications following standard dosing schedules. Further classes of medication depend on the patient's response and can include (depending on specific pain syndromes) an indication for muscle relaxants (e.g., tizanidine, baclofen) and topical agents in addition to other multimodal approaches. Additional consideration should be given to SNRIs indicated for chronic musculoskeletal pain.

Gap 4: Barriers, such as lack of coverage and reimbursement and understanding of proper usage, limit access to buprenorphine treatment for chronic pain:

- **Recommendation 4a:** Make buprenorphine treatment for chronic pain available for specific groups of patients, and include oral buprenorphine for third-party payors with hospital formularies.
- **Recommendation 4b:** Provide coverage and reimbursement for buprenorphine treatment approaches.

Gap 5: There is currently inadequate education for patients regarding safe medication storage and appropriate disposal of excess medications targeted at reducing outstanding supplies of opioids that may be misused by others or inadvertently accessed by children and other vulnerable members of the household.

- **Recommendation 5a:** Increase public awareness of poison center services as a resource that provides educational outreach programs and materials; referral to treatment facilities; links to take-back facilities; and resources for safe drug storage, labeling, and disposal.
- **Recommendation 5b:** The US Drug Enforcement Administration (DEA) should increase opportunities for safe drug disposal and drug disposal sites (i.e., pharmacies, police departments, fire departments).
- **Recommendation 5c:** Adopt neutralization technologies that may make safe disposal more readily available.
- **Recommendation 5d:** Include partial fills of C-2 drug classes.
- **Recommendation 5e:** Educate veterinarians on the importance of safe storage and disposal of

opioid medications in their practice. In addition, educate pet owners about the importance of safe storage and disposal of opioid pain medication prescribed for their pets.

2.2.1 Risk Assessment

The selection of the most appropriate medication-based treatment approach for an individual with pain involves a careful analysis of risk and benefit. Risks of side effects and toxicity — and costs — must be balanced against the benefits of the treatment, including improved function with improved QoL, activities of daily living (ADLs), maintaining work, as well as with improvement in medical condition. Clinicians evaluating pain, whether acute or chronic, must conduct a thorough history, physical exam, and risk assessment, especially when considering medications such as opioids in the treatment plan. Identifying patients at risk of SUD will minimize potential adverse consequences and facilitate treatment or referral for treatment of active SUDs.

2.2.1.1 Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are state-managed electronic databases of controlled substances dispensed (typically schedule II – IV), with the majority of the data being reported by community-based pharmacies.^{[120](#)} PDMPs allow prescribers and pharmacists (and in some states, insurers, researchers, and medical licensing boards) to access the data, monitor use by patients, monitor prescribing practices by practitioners, and check population-level drug use trends. Forty-nine states and most of Missouri (so, almost all 50 states) and the District of Columbia have operational PDMPs.^{[121,122](#)}

Prescribers may be required to use PDMP data at the point of care, allowing them to identify patients with multiple provider episodes or potentially overlapping prescriptions that place them at risk. PDMPs can support safe prescribing and dispensing practices and help curb opioid prescription by detecting patterns that can alert clinicians to the potential that patients are at risk of SUD. PDMPs can alert clinicians to provide potentially lifesaving information and interventions. The information found in the PDMP can prompt the clinician to take action to improve patient safety by having a conversation about safety concerns and understanding the patient’s goals and needs. Providers who identify uncertain medication behavior can respond clinically, making referrals to mental health or substance abuse treatment.^{[123,124](#)} McAllister et al.^{[125](#)} found that all prescribers who were surveyed indicated that accessing PDMP data altered their prescribing patterns. Caution is needed when using PDMPs as a tool to aid in the proper dispensing of medications. However, PDMPs are not to be used as tools to stop dispensing medications appropriately to those in need. For example, it is also important for pharmacists to know that doctors often work as teams and to ensure that “doctor shopping” is a conclusion made after the pharmacist has made contact with the provider.

PDMPs can assist in determining whether a patient is obtaining medications from multiple providers and filling prescriptions at multiple pharmacies, especially when prescriptions are filled in quick succession or on the same day. As a tool to help inform clinical decisions, PDMPs’ potential utility was highlighted in CDC’s Guideline for Prescribing Opioids for Chronic Pain.^{[126](#)} Clinicians should review

PDMP data when starting patients on opioid therapy for chronic pain and periodically during opioid therapy for chronic pain.¹²⁶

Prescribers are more likely to use PDMPs that present data in real time, are used by all prescribers, are technically easy to use without time constraints, and actively identify potential problems such as multiple prescribers or multiple prescriptions.¹²⁷ Requiring PDMP checks also has a positive effect. Buchmueller and Carey¹²⁸ found stronger effects when providers are required to access the PDMP, and PDMPs significantly reduced measures of misuse in Medicare Part D. In contrast, they found that PDMPs without such provisions had no effect. PDMPs can also bolster provider confidence. For example, in one study, ED providers report feeling more comfortable prescribing controlled substances when they receive information from a PDMP.¹²⁵

Baehren et al.¹²⁹ found that when PDMP data were used in an ED, 41% of cases had altered prescribing after the clinician reviewed PDMP data, with 61% of the patients receiving fewer or no opioid pain medications than had been originally planned by the physician prior to reviewing the PDMP data and 39% receiving more opioid medication than previously planned because the physician was able to confirm that the patient did not have a recent history of controlled substance use. The effective use of PDMP data is beneficial to both health care professionals and patients.

The need to modernize and enhance functionality of PDMPs is widely acknowledged.¹³⁰⁻¹³³ For example, Colorado favors the integration of automatic queries and responses that obviate time-consuming manual data entry and also recommends that PDMPs be optimized with improvements, links to ED registration, and data population in EHRs.¹³⁴ EHRs should work to integrate PDMPs in their system design at minimal to no additional cost to providers (to eliminate barriers to accessing PDMP data), especially when these data points are mandated. States should individually provide links to their PDMPs from major, certified EHR platforms. Maryland also recommends enhanced user interfaces and interstate data sharing for PDMPs.¹³¹ Provider PDMP adoption has been shown to fall when interoperability is low and use is not mandated.¹³⁵ Accessing PDMP data also affects the VA and IHS. VA physicians noted that incomplete or unavailable data was a significant barrier to increasing PDMP use.¹³⁶ In 2016, HHS issued a policy requiring IHS prescribers to query the PDMP before prescribing opioids and pharmacists to report their dispensing activity to the PDMP; it also directed IHS to ensure that memoranda of understanding were signed with the appropriate state offices.^{42,137} Linkage to and use of PDMPs varies across IHS service areas.

Gaps and Recommendations

Gap 1: PDMP use varies greatly across the United States, with variability in PDMP design; the state's health information technology infrastructure; and current regulations on prescriber registration, access, and use.

- **Recommendation 1a:** Check PDMPs, in conjunction with other risk stratification tools, upon initiation of opioid therapy, with periodic reevaluation.
- **Recommendation 1b:** Provide clinician training on accessing and interpreting PDMP data.
- **Recommendation 1c:** Physicians and other health care providers should engage patients to discuss their PDMP data rather than making a judgment that may result in the patient not receiving appropriate care. PDMP data alone is not error proof and should not be used to dismiss patients from clinical practices.
- **Recommendation 1d:** The health care provider team should determine when to use PDMP data. PDMP use should not be mandated without proper clinical indications to avoid unnecessary burden in the inpatient setting.
- **Recommendation 1e:** Conduct studies to better identify where PDMP data is best used (e.g., inpatient versus outpatient settings). Adjust PDMP data use based on the findings of the recommended studies to minimize undue burdens and overutilization of resources (i.e., streamline PDMP data use).
- **Recommendation 1f:** EHR vendors should work to integrate PDMPs into their system design at minimal to no additional cost to providers (to eliminate barriers to accessing PDMP data), especially when these data points are mandated.
- **Recommendation 1g:** Enhance the interoperability of PDMPs across state lines to allow for more effective use.
- **Recommendation 1h:** Physicians and other health care providers within and outside federal health care entities should have access to each other's data to ensure safe continuity of care.
- **Recommendation 1i:** Include all opioid prescribers, including physician and nonphysician providers and dentists, in PDMPs.

2.2.1.2 Screening and Monitoring

Screening and monitoring in pain management seek to identify and reduce the risk of substance misuse, abuse, and overdose as well as improve overall patient care. Evaluations of patient physical and psychological history can be done to screen for risk factors and characterize pain to inform treatment decisions. Screening approaches to assess for concurrent substance use and mental health disorders that may place patients at higher risk for OUD and overdose include screening for drug and alcohol use and the use of urine drug testing.^{69,138} These approaches seek to enable providers to identify high-risk patients so that they can consider substance misuse and mental health interventions, ADFs, and education materials to mitigate opioid misuse.¹³⁹

Screening tools can help clinicians identify risks in individual patients that can be help in identifying which medication classes may be appropriate for the patient, including for long-term opioid therapy. Effective screening can include single questions, such as, “How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?”¹⁴⁰ Other validated screening tools include the Drug Abuse Screening Test¹⁴¹ and the Alcohol Use Disorders Identification Test.¹⁴² Clinicians must recognize the limits of screening tools in detecting prior or developing SUD or OUD. There should also be screening tools to address the long-term use of nonopioids and potential for overuse, including NSAIDs causing renal, gastric, and cardiac issues and acetaminophen overuse causing serious liver issues, especially in medications that are over the counter and combine these medications in a manner that patients may not be aware of.

Urine drug tests (UDTs) can provide information about drug use that is not reported by the patient, including not using prescribed medications as intended and unreported drug use. UDTs can also potentially inform treatment decisions by assessing an individual’s drug metabolism rate. However, according to a systematic review by the Agency for Healthcare Research and Quality (AHRQ), there is a lack of evidence demonstrating the effectiveness of UDTs for risk mitigation during opioid prescribing for pain.^{143,144} UDT results can be subject to misinterpretation and may sometimes be associated with practices that can harm patients (e.g., stigmatization, inappropriate termination from care). Clinicians do not consistently use practices intended to decrease the risk for misuse, such as UDT,¹³⁸ and opioid treatment agreements,¹⁴⁵ likely in part because of competing clinical demands, perceived inadequate time to discuss the rationale for UDT and to order confirmatory testing, and feeling unprepared to interpret and address results.¹⁴⁶

To mitigate the risks of prescription opioid misuse, medical societies, with state and federal regulatory agencies, have recommended specific risk-reduction strategies, including written treatment agreements for patients with chronic pain who are prescribed opioids. (Starrels et al., 2010).Pain agreements or treatment agreements can be useful in defining the responsibilities of the patient and the provider, and they create a structure to guide and evaluate opioid use. The agreement should be viewed as an opportunity for ongoing dialogue about the risks of opioids and what the patient and clinician can expect from each other.¹⁴⁷ The agreement should not be about simply getting a form signed or a means to “fire” a patient for breaking the terms of the agreement; rather, it is a tool for facilitating a conversation between the clinician and the patient.¹⁴⁵

Monitoring approaches should be applied transparently and consistently in a manner that emphasizes safety so that miscommunication and accidental stigmatization is minimized.¹⁴⁸ At follow-up, doctors should assess benefits in function, pain control, and QoL using tools such as the three-item “Pain average, interference with Enjoyment of life, and interference with General activity” Assessment Scale¹⁴⁹ or asking patients about progress toward functional goals that have meaning for them. Clinicians should also screen for factors that predict risk for poor outcomes and substance abuse, such as sleep disturbance, mood disorder, and stress, either by using a pain rating scale such as the Defense and Veterans Pain Rating Scale, which includes brief questions, or by routinely asking about these

factors on clinical examination.¹⁵⁰ Clinicians should ask patients about their preferences for continuing opioids, given their effects on pain and function relative to any adverse effects experienced.¹²⁶ These factors illustrate the importance of time with the patient that allows the doctor to thoroughly evaluate the patient.

Gaps and Recommendations

Gap 1: Comprehensive screening and risk assessment of patients is time-consuming but vital for proper evaluation of their chronic pain conditions. Lack of sufficient compensation for time and payment for services have contributed to barriers in best practices for opioid therapy.

- **Recommendation 1a:** Provide sufficient compensation for time and payment for services to implement the various screening measures (e.g., extensive history taking, review of medical records, PDMP query, urine toxicology screenings). These are vital aspects of risk assessment and stratification for patients on opioids and other medications.
- **Recommendation 1b:** Consider referral to pain and other specialists when high-risk patients are identified.

Gap 2: UDTs are not consistently used as part of the routine risk assessment for patients on opioids.

- **Recommendation 2a:** Use UDTs as part of the risk assessment tools prior to the initiation of opioid therapy and as a tool for reevaluating risk, using the clinical judgment of the treatment team.
- **Recommendation 2b:** Physicians and other health care providers should educate patients on the use of UDTs and their role in identifying both potential inappropriate use and appropriate use.

Gap 3: There is variability in what is included in opioid treatment and opioid agreements.

- **Recommendation 3a:** Conduct studies to evaluate the effectiveness of the different components of opioid treatment agreements. Treatment agreements should include the responsibilities of both the patient and the provider.
- **Recommendation 3b:** Use opioid treatment discussions as an educational tool between providers and patients to inform the risks and benefits of and alternatives to chronic opioid therapy.

2.2.2 Overdose Prevention Education and Naloxone

Naloxone is a medication designed to rapidly reverse opioid overdose.^{151,152} It is an opioid antagonist that binds to opioid receptors and can reverse and block the effects of other opioids. It can very quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of overdosing with illicit fentanyl, heroin, or prescription opioid pain medications.

The use of naloxone to treat those who have overdosed on opioids by family members, bystanders, and first responders can save lives,¹⁵³ and both intramuscular or nasal formulations are available. Widespread, rapid availability of bystander and take-home naloxone rescue kits, coupled with

enhanced education on naloxone's proper use, is essential, particularly in cases where higher doses of opioids are to be prescribed or there is evidence of underlying OUD.¹⁵⁴

Gaps and Recommendations

Gap 1: Bystander/take-home naloxone distribution is associated with a cost-effective reduction in mortality as well as improved connection to OUD; however, distribution is not widely available.

- **Recommendation 1a:** Provide naloxone co-prescription/dispensing and education for patients and family members when the patient is on long-term opioids.
- **Recommendation 1b:** Increase naloxone distribution programs and education for first responders.
- **Recommendation 1c:** Research the potential risks and benefits of making naloxone available over the counter.

2.3 Restorative Therapies

Restorative therapies include physical therapy (PT), occupational therapy (OT), physiotherapy, therapeutic exercise, and other movement modalities that are provided as a component of interdisciplinary, multimodal pain care. Restorative therapies play a significant role in acute and chronic pain management, and positive clinical outcomes are more likely if restorative therapy is part of a multidisciplinary treatment plan following a comprehensive assessment. Restorative therapies can be administered by different providers, including physical therapists and occupational therapists, in a variety of settings. Patient outcomes related to restorative and physical therapies tend to emphasize improvement in outcomes, but there is value in restorative therapies to help maintain functionality. Use of restorative therapies is often challenged by incomplete or inconsistent reimbursement policies.

The following paragraphs briefly describe restorative therapies, which can be considered singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions. This list is not inclusive or exhaustive but instead describes just a few examples of common restorative therapies.

The role of **therapeutic exercise** in the treatment of pain is tied to the underlying diagnosis responsible for the pain. Bed rest was scientifically recognized and prescribed as a treatment for low-back pain as recently as the 1980s,¹⁵⁵ but high-quality scientific evidence has since emerged establishing the superiority of movement therapies over rest.¹⁵⁶ The majority of pain-related PT guidelines exist for the treatment of spinal pain. In addition to improving physical functioning, a more contemporary biopsychosocial treatment approach to therapeutic exercise helps patients understand and overcome “secondary pathologies,” including fear of movement, pain catastrophizing, and anxiety, that contribute to pain and disability.”⁴⁵

Transcutaneous electric nerve stimulation (TENS) has been applied to treat pain, but studies of its efficacy are lacking in number and design, with high risks of bias commonly reported.¹⁵⁷ An evaluation of 49 systematic reviews, randomized clinical trials (RCTs), and observational studies found

insufficient evidence to assess the effectiveness of TENS for acute low-back pain.¹⁵⁸ More recent individual studies have investigated the effectiveness of TENS for postpartum pain,¹⁵⁹ phantom limb pain,¹⁶⁰ and knee osteoarthritis.¹⁶¹ Despite the overall limited evidence of efficacy, partially stemming from a lack of large RCTs, TENS is considered a safe self-care option for patients with appropriate education.¹⁶²

Massage therapy can be effective in reducing pain.¹⁶³ There are a variety of types of massage therapy, including Swedish, shiatsu, and deep tissue (myofascial release).^{164,165} In Swedish massage, the therapist uses long strokes, kneading, and deep circular movements. Shiatsu massage uses the fingers, thumbs, and palm to apply pressure. Deep tissue massage focuses on myofascial trigger points, with attention on the deeper layers of tissues.

Traction is a technique from the PT field that is used to treat spinal pain. Review of the evidence has failed to demonstrate the clinical effectiveness of traction as an effective, evidence-based best practice; however, the field in general lacks high-quality RCTs that examine effectiveness of traction as an isolated treatment modality for low-back^{158,166} or neck pain.¹⁶⁷

Cold and **heat** have been used in the treatment of symptoms of a variety of acute and chronic pain conditions. The application of cold has long been used as a component of the RICE (rest, ice, compression, elevation) paradigm for the treatment of acute pain syndromes. Because it treats only symptoms, the effects and duration of this therapy are mitigated by the initial cause of the pain. For instance, cold therapy has been shown to decrease the pain of hip arthroplasty on the second but not the first or third day after surgery and did not decrease blood loss from the surgery.¹⁶⁸ Evidence is not robust for all locations and types of pain, but there is significant evidence for the efficacy and safety of heat wraps in specific conditions, most notably for acute low-back pain. In fact, a review of nonpharmacologic therapies found that superficial heat had good evidence of efficacy for treatment of acute low-back pain.¹⁶⁹ Another review found moderate evidence for heat wraps for both symptom and functional improvements.¹⁵⁸

Therapeutic ultrasound (TU) is thought to deliver heat to deep tissues for improved injury healing.^{170,171} A 2001 review concluded that there was little evidence that TU is more effective than placebo for pain treatment in a range of musculoskeletal conditions.¹⁷² More recent reviews of specific pain syndromes available through the Cochrane Database of Systematic Reviews reveal similar findings, although there is some evidence for TU in knee osteoarthritis.^{173,174}

Bracing has generally been discouraged in pain management because of fears of deconditioning and muscle atrophy. However, there is evidence that, for at least short periods of time, bracing (especially nonrigid bracing) may improve function and does not result in muscle dysfunction.¹⁷⁵

Gaps and Recommendations

Gap 1: There is a lack of clarity on which restorative therapy modalities are indicated in the various pain syndromes.

- **Recommendation 1a:** Conduct further research to provide evidence-informed data on which restorative therapy modalities are indicated as part of a multidisciplinary approach to specific pain syndromes.
- **Recommendation 1b:** For those modalities where there are clear indications for benefits in the treatment of chronic pain syndromes (e.g., OT; PT; aqua therapy; TENS; movement-based modalities, including tai chi, Pilates, and yoga), there should be minimal barriers to accessing these modalities as part of a recommended multidisciplinary approach to the specific pain condition.
- **Recommendation 1c:** Make harm-free, self-administered therapies such as TENS freely available (e.g. over the counter) to support pain management treatment plans.

2.4 Interventional Procedures

Interventional pain management is part of the pain specialty that applies image-guided and minimally invasive procedures toward the diagnosis and treatment of pain conditions.¹⁷⁶ Many interventional procedures for pain have been around for decades, and they vary in their invasiveness. Image-guided interventional procedures (using ultrasound, fluoroscopy, and computed tomography) can greatly benefit comprehensive assessment and treatment plans by identifying the sources and generators of pain.¹⁷⁷ Diagnostic and therapeutic interventional techniques can be valuable options prior to the initiation of extensive surgical or opioid treatment or in concert with other treatment modalities. Additional research, with further evidence establishing clinical benefits of specific interventional procedures for specific pain conditions, would be beneficial and can further identify various procedures for specific clinical conditions,¹⁷⁸ particularly for certain populations, such as children.¹⁷⁹ Many interventional pain procedures are available on an outpatient basis, which is vital to ensuring access to care. Some minor interventional procedures may be performed in the primary care setting, while other more advanced procedures require specialty training. The definition of a successful outcome varies depending on whether the intervention is used to treat short-term acute flares or is part of a long-term management plan that will depend on the individual patient and his or her unique medical status. Finally, in certain types of pain conditions where there is a specific physical cause of the pain, direct surgical intervention can be therapeutic and beneficial to patients.

The following paragraphs briefly describe interventional procedures that can be considered singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions. This list is not inclusive or exhaustive but instead describes just a few examples of common interventional procedures.

Epidural steroid injections (ESIs) deliver anti-inflammatory medication directly into the epidural space — the region outside the sac of fluid surrounding the spinal cord. Lumbar epidural injections treat back pain and radicular pain resulting from chemical irritation of nervous tissues by eliminating the inflammatory compounds mediating nervous tissue irritation in the epidural space.¹⁸⁰ ESIs are one of the most common procedures in pain management and, in well-selected patients, can provide significant pain relief as part of a pain management plan.¹⁸¹ Although risks are associated with ESIs, they offer significant advantages to the patient, notably in that they may potentially reduce health care costs, health care utilization, and the need for future surgical intervention.¹⁸² Transforaminal epidural steroid injections and selective nerve root injections are specialized approaches to the epidural space that target specific nerve root pathology.

Facet joint nerve block and denervation injection are common fluoroscopy-guided procedures for facet-related spinal pain of the low back and neck area in which local anesthesia with or without steroids is injected onto the medial branch nerves that supply these joints (medial branch blocks or less commonly directly into the facet joint). These injections are primarily diagnostic but can also be therapeutic, providing long-term relief. If there is only temporary relief, these nerves can be ablated by using radio-frequency (RF) ablation^{183,184} or cryoneuroablation.¹⁸⁵ Both of these procedures are used to treat a common cause of lower back pain as well as cervical neck pain caused by facet joint sprain (cervical whiplash) or degenerative changes and have proven effective in the treatment and diagnosis of cervical neck pain, axial back pain, and chronic spinal pain originating from facet joints.^{183,186-188} Compared with some intraspinal interventional treatments, procedures related to the facet joints can be simpler and lower risk.¹⁸⁶

Cryoneuroablation is a specialized interventional pain management technique that uses a cryoprobe to freeze sensory nerves at the source of pain to provide long-term pain relief.^{189,190} Cryoneuroablation can be indicated for numerous persistent and intractable painful conditions; including temporomandibular joint (TMJ) pain, paroxysmal trigeminal neuralgia, chest wall pain,¹⁹¹ phantom limb pain, neuroma, peripheral neuropathy,¹⁹¹ knee osteoarthritis,¹⁹² and neuropathic pain caused by herpes zoster.^{189,193}

RF Ablation. Conventional RF lesioning and pulse RF (PRF) are both means to ablate certain nerves that have been identified as contributing to chronic pain syndromes, and they continue to have great value as a treatment modality in the management of a variety of pain syndromes. Furthermore, studies have shown conventional RF provides benefits in appropriate patients.^{190,194} PRF uses short, high-voltage bursts of energy produced by needles inserted next to nerves to “stun” nerves, thereby blocking transmission of pain signals.^{195,196} Although more research is required to better understand both the exact mechanism of action of PRF and its efficacy in treating various chronic pain syndromes, PRF has already demonstrated its potential as a promising interventional modality in the treatment of cervical radicular pain,¹⁹⁷ though there is no current procedural terminology (CPT) code for the technique, and insurance usually does not cover it.

Peripheral nerve injections, commonly referred to as peripheral nerve blocks (PNBs), are injections of local anesthesia frequently mixed with anti-inflammatory steroid medication or clonidine for both diagnostic and therapeutic pain relief purposes.¹⁹⁸ Administered either through a single injection or in a continuous infusion by catheter, PNBs are often employed in the perioperative and postoperative period for acute pain care.^{199,200} PNBs are advantageous in that they allow for quicker discharge times in ambulatory settings, less postoperative nausea and vomiting because of less opioid medication use, and improved patient satisfaction. There has been a growth in this area as part of improved perioperative pathways and the use and advancements in ultrasound-guided nerve blocks that allow for more effective anesthetic blocks.^{201,202} Ultrasound has also improved the ability to diagnose and treat peripheral neuropathies, nerve entrapments,^{203,204} and PNBs can also have a role in potentially diminishing or preventing the development of chronic pain syndromes^{205,206} such as CRPS,²⁰⁷ headaches,²⁰⁸ pelvic pain,²⁰⁹ and sciatica.²¹⁰

Similar to PNBs, **sympathetic nerve blocks** (SNBs) — injections of local anesthesia at the sympathetic nerve chain — can be used to diagnose or treat pain that involves the sympathetic nervous system.²¹¹ SNBs have been used to treat neuropathic pain, CRPS, and reflex sympathetic dystrophy as well as manage chronic abdominal, pelvic pain, and perineal pain.²¹²⁻²¹⁴

Neuromodulation techniques use device-based electrical or magnetic stimulation to activate central or peripheral nervous system tissue associated with pain pathways to produce analgesia or reduce sensitivity to pain. This is an area of growth and innovation for chronic pain treatment, including neuropathic pain, and for both the central and peripheral nervous system.^{215,216} Spinal cord stimulation using a variety of waveforms and frequencies and dorsal root ganglion stimulation, collectively, have five level-1 studies demonstrating their efficacy in low-back and lower extremity pain.²¹⁷⁻²²¹ Peripheral nerve stimulation has gained popularity and effectiveness with the recognition of peripheral nerve entrapments, increased use of ultrasound, and improvement in technology. More recently, noninvasive neuromodulation therapies have been studied in headache disorders. There are now multiple level-1 studies and multiple level-2 studies demonstrating that noninvasive vagus nerve stimulation can be effective in ameliorating pain in various types of cluster headaches and migraines.²²²⁻²²⁴ These therapies provide an electric field to the brain, cranial nerves, or peripheral nerves without actually requiring a surgical procedure or implant.

Intrathecal Pain Pumps. Because there are opioid receptors on the spinal cord and at specific areas of the brain, small doses of opioids in the spinal fluid can provide significant analgesia at much lower doses than oral opioids. Implanted intrathecal pumps with catheters in the spinal fluid can supply medication continuously, and they have been used for cancer as well as noncancer pain.²²⁵ The largest trial ever performed in cancer patients demonstrated improved pain control and fewer side effects and had a trend toward improved life expectancy with implantable pumps.²²⁶ However, there are significant side effects, including delayed respiratory depression, granuloma formation, and opioid-induced hypogonadism.²²⁷

Vertebral augmentation stabilizes the spine through the application of cement to vertebral compression fractures that are painful and refractory to medical treatment²²⁸; this approach can include vertebroplasty (injecting cement into a fractured vertebra) or balloon kyphoplasty (using an inflatable balloon to create injection space). Evidence suggests that balloon-assisted kyphoplasty is one of the most effective vertebral augmentation procedures.^{229,230} Vertebral augmentation has also been combined with RF ablation to manage pain caused by vertebral damage secondary to fractures from various conditions or as a result of spinal metastases.²³¹

Trigger points are palpable, tense bands of skeletal muscle fibers that, upon compression, are capable of producing both local and referred pain.²³² Using either dry needling or injections of local anesthesia, trigger points can be disrupted, resulting in relaxation and lengthening of the muscle fiber, thereby providing pain relief.^{232,233} Trigger point injections can be used therapeutically to treat pain associated with headaches, myofascial pain syndrome, and low-back pain.²³⁴⁻²³⁶ Other types of direct injections include intramuscular, intrabursal, and intra-articular injections for muscle pain, bursitis, and joint pain, respectively.

Joint Injections. In addition to the facet joints, corticosteroid injections into other joints (e.g., shoulder, elbow, wrist, knee, ankle) are common interventional procedures, particularly in the treatment of inflammatory arthritis and basal joint arthritis.^{237,238} When local anesthesia is combined with corticosteroids, the joint injection can also be used therapeutically to treat joint pain resulting from injury or disease or diagnostically to identify the source of joint pain.²³⁹

Interspinous Process Spacer Devices. Research has shown that interspinous process spacer devices can provide relief for patients with lumbar spinal stenosis with neuroclaudication.^{240,241}

Regenerative/adult autologous stem cell therapy may show promise in the treatment of multiple painful conditions.²⁴²⁻²⁴⁴ Further research is needed and encouraged to investigate the potential of these therapies.

Gaps and Recommendations

Gap 1: Interventional pain procedures can provide diagnostic information when evaluating patients in pain and provide therapeutic pain relief. A comprehensive assessment by a skilled pain specialist needs to be available to assess which particular procedure is indicated for a patient's pain syndrome. Unfortunately, pain physician specialists are typically not involved in the multidisciplinary approaches of treating a pain patient early enough in his or her treatment, which can lead to suboptimal patient outcomes.

- **Recommendation 1a:** Adopt well-researched interventional pain guidelines to guide the appropriate use of interventional pain procedures as a component of a multidisciplinary approach to the pain patient. Guidelines are particularly important for guiding the collaboration of primary care and pain medicine.

- **Recommendation 1b:** Conduct additional clinical research that establishes how interventions work in conjunction with other approaches in the process of caring for chronic pain patients, especially early in the process, when combined appropriately with goal-directed rehabilitation therapy and appropriate medications.
- **Recommendation 1c:** Establish criteria-based guidelines for properly credentialing physicians who are appropriately trained using interventional techniques to help diagnose, treat, and manage patients with chronic pain.

Gap 2: There are inconsistencies and frequent delays in insurance coverage for interventional pain techniques that are clinically appropriate for a particular condition and context.

- **Recommendation 2a:** Provide consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate. These procedures can be paired with medication and other therapies to improve function and QoL.
- **Recommendation 2b:** Restore reimbursement to nonhospital sites of service to improve access and lower the cost of interventional procedures.

Gap 3: There is a trend of inadequately trained physicians and nonphysicians performing interventional procedures. This trend can potentially lead to serious complications and inappropriate utilization. For example, outside the Accreditation Council for Graduate Medical Education (ACGME)-accredited residency and fellowship programs, there is currently little to no oversight over training requirements for interventional procedures.

- **Recommendation 3a:** Establish credentialing criteria for minimum requirements for training physicians in interventional pain management.
- **Recommendation 3b:** Only clinicians who are credentialed in interventional pain procedures should perform interventional procedures.
- **Recommendation 3c:** Clearly identify physicians who specialize in pain management by their training. This identification should be determined by ACGME-accredited pain medicine programs and by well-recognized credentials, such as the American Board of Pain Medicine (ABPM) and the American Board of Interventional Pain Physicians.

2.4.1 Perioperative Management of Chronic Pain Patients

Perioperative pain management in chronic pain patients presents unique challenges,^{[245,246](#)} particularly for patients with opioid tolerance or those vulnerable to opioid-associated risks. Patients on long-term opioid therapy can be more complicated to manage in the perioperative period compared with patients who are opioid naive. Considerations for managing these patients include use of multimodal approaches as well as preoperative consultation and planning. In addition, behavioral interventions show promise for use in pre- and perioperative periods for the management of postsurgical pain.^{[247-250](#)} Other experts have suggested use of PSHs for this patient population.^{[251](#)} Chronic pain patients whose pain is managed by a clinician should have their pain management specialist consulted and involved in the planning of their pain control during and after the perioperative process.

Gaps and Recommendations

Gap 1: Chronic pain patients undergoing a surgical procedure often have complex issues that go unaddressed that may lead to incomplete and poor care.

- **Recommendation 1a:** The perioperative team should be consulted to form a treatment plan that addresses the various aspects that would be necessary for best outcomes in this pain population.

2.5 Behavioral Health Approaches

In recent decades, pain management experts have recognized the important relationship between pain and psychological health.^{34,252,253} Psychological factors can play an important role in an individual's experience and response to pain^{254,255} and can affect treatment adherence, pain chronicity, and disability status.^{252,256} Undiagnosed and untreated psychological concerns in individuals with pain are associated with increased health care utilization and readmissions, decreased treatment adherence, and increased disability.²⁵⁷⁻²⁵⁹ Chronic pain patients are at increased risk for psychological distress, maladaptive coping, and physical inactivity related to fear of reinjury.³⁴ Individuals with chronic pain are more likely to have disabilities than patients with other chronic health conditions, such as stroke, kidney failure, cancer, diabetes, and heart disease.²⁶⁰ High-impact chronic pain is especially disruptive to multiple aspects of patients' life, including their relationships, work, physical activity, sleep, self-care, and self-esteem. Psychological interventions can play a central role in reducing disability in these patients. Furthermore, preliminary evidence indicates that psychological interventions administered prior to surgery have been shown to reduce postsurgical pain and opioid use.^{248,261}

Behavioral health approaches as part of pain management are to be considered as a key component of the biopsychosocial model and multidisciplinary pain management. These approaches aim to improve the overall pain experience and restore function by addressing the cognitive, emotional, behavioral, and social factors that contribute to pain-related stress and impairment.^{252,256,262} They target a variety of domains, including physical functioning, pain medication use, mood, cognitive patterns, and QoL.²⁵²

The following paragraphs briefly describe behavioral health approaches, which can be considered singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and their medical conditions. This list is not inclusive or exhaustive, but instead describes just a few examples of common behavioral health approaches.

Behavioral therapy (BT) for pain treatment focuses largely on applying the principles of operant conditioning to identify and reduce maladaptive pain behaviors (e.g., fear avoidance) and increase adaptive or "well" behaviors. This improvement is achieved by minimizing reinforcement of maladaptive behaviors, providing reinforcement of well behaviors, and reducing avoidance behaviors through gradual exposure to the fear-provoking stimuli (e.g., exercise). The overall goal of BT in the treatment of pain is to increase function despite pain.^{263,264} BT has demonstrated effectiveness for reducing pain behaviors and distress and improving overall function, and it is more cost-effective than

active physical treatment.^{[265,266](#)}

Cognitive behavioral therapy (CBT) aims to reduce maladaptive behavior and improve overall functioning. However, in addition to focusing on altering behavioral responses to pain, CBT focuses on shifting cognitions and improving pain coping skills.^{[267](#)} CBT includes psychoeducation about the relationship between psychological factors (e.g., thoughts, feelings) and pain; cognitive restructuring of maladaptive thought patterns; and training in a variety of pain coping strategies, including activity pacing and pleasant activity scheduling.^{[252](#)} The use of CBT for pain management is effective for a variety of pain problems^{[268](#)} and can help improve self-efficacy, pain catastrophizing, and overall functioning.^{[269,270](#)} The AHRQ found that CBT can lead to long-term improvements in patients with low-back pain and fibromyalgia.^{[271](#)}

Acceptance and commitment therapy (ACT) is a form of CBT that emphasizes observing and accepting thoughts and feelings, living in the present moment, and behaving in a manner that serves an individual's chosen values. Unlike traditional CBT approaches, ACT focuses on creating psychological flexibility through acceptance of psychological and physical experiences rather than by challenging them.^{[272,273](#)} Several studies have shown that greater pain acceptance, facilitated through the delivery of ACT, is associated with lower pain intensity, less pain-related avoidance and anxiety, improved mood, and less physical and psychosocial disability.^{[274,275](#)}

Mindfulness-based stress reduction (MBSR) is a mind-body treatment developed by Jon Kabat-Zinn typically delivered in a group format that focuses on improving patients' awareness and acceptance of their physical and psychological experiences through intensive training in mindfulness meditation.^{[276](#)} Mindfulness meditation teaches patients to self-regulate their pain and pain-related comorbidities by developing nonjudgmental awareness and acceptance of present moment sensations, emotions, and thoughts.^{[277,278](#)} Research suggests that MBSR is an effective intervention for helping individuals cope with a variety of pain conditions, including rheumatoid arthritis, low-back pain, and MS.^{[279,280](#)} MBSR has a positive impact on pain intensity sleep quality, fatigue, and overall physical functioning and well-being.^{[276,281-283](#)}

Emotional awareness and expression therapy (EAET) is an emotion-focused therapy for patients with a history of trauma or psychosocial adversity who suffer from centralized pain conditions.^{[284](#)} In this approach, patients are taught to understand that their pain is exacerbated or maintained by unresolved emotional experiences that influence neural pathways involved in pain. Patients are taught to become aware of these unresolved experiences, which include suppressed or avoided trauma, adversity, and conflict, and to adaptively express their emotions related to these experiences. Patients learn that control over pain can be achieved through emotional awareness and expression. Enhancing the patient's capacity to approach and experience rather than inhibit or avoid important emotions and interpersonal interactions leads to increased engagement in life activities. Research indicates that EAET has a positive impact on pain intensity, pain interference, and depressive symptoms.^{[285](#)}

Self-regulatory or psychophysiological approaches include treatments such as biofeedback, relaxation training, and hypnotherapy. These approaches use the mind-body connection to help patients with pain develop control over their physiologic and psychological responses to pain.²⁵² **Biofeedback** entails monitoring and providing real-time feedback about physiologic functions associated with the pain experience (e.g., heart rate, muscle tension, skin conductance). The overall goal of biofeedback is to improve awareness and voluntary control over bodily reactions associated with pain exacerbations.²⁸⁶ The use of biofeedback training has been shown effective for chronic headache and migraine in adults and children.²⁸⁷ **Relaxation training** and hypnotherapy involve altering attentional processes and heightening the experience of physical and psychological relaxation. Relaxation training is often used in conjunction with biofeedback to increase physiological awareness and enhance relaxation skills.²⁵² Both of these approaches have empirical support in pain management.^{288,289} Empirical evidence also provides support for the use of **hypnotherapy** for pain management for cancer pain, low-back pain, arthritis, pain from SCD, TMJ pain, fibromyalgia, and other pain conditions.²⁸⁸ Similar to relaxation training, hypnotherapy induces an altered state of consciousness guided by a hypnotherapist that focuses the individual's attention to alter his or her experience of pain.

Behavioral health interventions can be effective in improving clinical outcomes for pain,^{256,284,290} but treatment should be tailored to address patient preferences and needs. This tailoring requires careful assessment of patients' pain perceptions, cognitive and emotional responses, coping skills, and social and environmental status.²⁹¹ It also requires accurate diagnosis of comorbid psychosocial concerns.

2.5.1 Access to Psychological Interventions

Despite widespread understanding of the importance of psychological interventions in the management of pain, many patients with pain receive inadequate care.^{292,293} Many factors contribute to the problem of inadequate care for pain, including clinical barriers (e.g., treatment accessibility, knowledge gaps, provider attitudes), health care system-related barriers (e.g., cost and reimbursement issues), and patient-related barriers (e.g., stigma, attitudinal variables). When access to providers and costs are limiting factors, evidence-based low-cost and scalable approaches delivered through telehealth and Internet technologies may provide a low-burden and effective alternative to traditional treatment approaches.^{247,294} Research suggests that brief telehealth and digitally delivered treatments allow for broad patient access and yield outcomes similar to traditional in-person psychological interventions for chronic pain.²⁹⁵

To further enhance patient acceptance and engagement in psychological treatment, patients and providers need to be educated about how psychological treatments work. Health professionals should have sufficient understanding of the biopsychosocial model of pain and how to appropriately assess and refer patients for behavioral health treatment.^{262,296} This can be accomplished by improving training and education in pain management^{21,297,298} and initiating public campaigns to reduce stigma and enhance public awareness of the biopsychosocial nature of pain.²⁹⁹ As noted in other sections of this

report, the lack of health care insurance coverage for psychological services has also been cited as a significant barrier to adequate pain management. Both a need for trained pain psychologists and appropriate incentives are required to fill the work gap. Although several organizations have identified policy recommendations to close gaps in access to pain management services,^{300,301} coverage barriers persist. These barriers continue to hinder patients' access to skilled behavioral health providers, integrated and multidisciplinary care, and (for OUD and SUD) co-morbid treatment, as required.³⁰²⁻³⁰⁵

Gaps and Recommendations

Gap 1: Access to evidence-based psychological and behavioral health approaches for treating chronic pain and mental health comorbidities (e.g., post-traumatic stress disorder [PTSD], depression, anxiety, mood disorders, SUD) is limited by geography, reimbursement, and education in primary care and specialty care settings.

- **Recommendation 1a:** Increase access to evidence-based psychological interventions through alternative treatment delivery (e.g., telehealth, Internet self-management, group, telephone counseling) and hub-and-spoke models.
- **Recommendation 1b:** Educate physicians and other health care providers on the benefits of psychological and behavioral health treatment modalities in the multidisciplinary approach to acute and chronic pain management.
- **Recommendation 1c:** Improve reimbursement policies for integrated, multidisciplinary, multimodal treatment approaches that include psychological and behavioral health interventions through traditional and nontraditional delivery methods.

2.5.2 Chronic Pain Patients With Mental Health and Substance Use Comorbidities

The occurrence of pain and behavioral health comorbidities, including depression, PTSD, and SUD, is well documented.³⁰⁶⁻³¹⁰ It is established that psychosocial distress can contribute to pain intensity, pain-related disability, and poor response to chronic pain treatment. Untreated psychiatric conditions and current or historical SUD also increase the risk of both unintentional and intentional medication mismanagement, OUD, and overdose.³¹¹ Given the intersection between psychiatric/psychological symptoms and chronic pain, it is important that the behavioral health needs of patients with pain are appropriately and carefully evaluated and treated with the concurrent physical pain problem.

Although the literature exploring the effectiveness of interventions for patients with painful conditions and comorbid psychiatric concerns is limited, research suggests that regular monitoring and early referral and intervention can improve pain and psychiatric outcomes and prevent negative opioid-related outcomes.^{248,252,303,312} Many CBPs recommend thoroughly screening and regularly monitoring the psychological health concerns and substance misuse risk of all patients with pain, using multidisciplinary approaches and referring patients to behavioral health and substance use specialists as clinically indicated.^{34,313} Technological advances in the delivery of clinical tools (e.g., mobile applications) may improve assessment, monitoring, and treatment delivery,³¹⁴ although further research

is needed.

Gaps and Recommendations

Gap 1: CBPs for chronic pain do not adequately address how to treat individuals with comorbid psychological health concerns.

- **Recommendation 1a:** Screen for psychological health and SUDs in patients with acute or chronic pain, and consider early referral to psychologists or psychiatrists who have expertise in pain.
- **Recommendation 1b:** Use an integrated multidisciplinary approach that may include existing evidence-based psychological and behavioral interventions (e.g., CBT, coping skills, stress reduction, mindfulness-oriented recovery) to address complex chronic pain.
- **Recommendation 1c:** Refer patients to both pain and addiction specialists when OUD is suspected.
- **Recommendation 1d:** When opioids are indicated for someone with a history of OUD (e.g., postoperative injury, cancer), clinicians should use the lowest effective dose in conjunction with nonopioid treatment modalities, with enhanced monitoring and collaboration with addiction specialists. Conduct regular reevaluation and assessment, with a treatment plan and established goals, to achieve optimal patient outcomes.

Gap 2: Many CBPs for chronic pain do not adequately address barriers to acceptance of psychological treatments.

- **Recommendation 2a:** Enhance and inform patient, clinician, and public understanding of the importance of a biopsychosocial model approach for certain chronic pain conditions.

Gap 3: Research gaps exist on the effectiveness of existing psychological interventions for the treatment of psychological health and substance use in the subpopulation of patients with chronic pain and psychological health comorbidities.

- **Recommendation 3a:** Conduct research on the applications and indications of existing evidence-based psychological health interventions for chronic pain patients with psychological health and/or substance use comorbidities.
- **Recommendation 3b:** Conduct research on the efficacy of novel and promising psychological and behavioral health treatments (e.g., biofeedback, hypnosis, relaxation therapies, meditation, tai chi).

Gap 4: There has not been sufficient validation of mobile and electronic health applications (apps) used for clinical treatment of pain patients with comorbid psychological conditions.

- **Recommendation 4a:** Conduct peer-reviewed validation research to guide the use of mobile and electronic health (e-health) applications within the context of the biopsychosocial treatment modalities for chronic pain.
- **Recommendation 4b:** Add a category for electronic and mobile treatments to the Substance Abuse and Mental Health Services Administration evidence-based practices resource center and

a designation for pain for target audiences when evidence of benefit exists.

- **Recommendation 4c:** Establish a validation process for apps used for biopsychosocial treatments to better inform physician, provider, and patient users of these apps that are evidence-based and effective for the management of various chronic pain syndromes.

2.6 Complementary and Integrative Health

CBPs generally recommend a collaborative, multimodal, multidisciplinary, patient-centered approach to treatment for various acute and chronic pain conditions to achieve optimal patient outcomes. Clinicians are encouraged to consider and prioritize, when clinically indicated, nonpharmacologic approaches to the management of pain.^{48,315-320} Complementary and integrative health approaches for the treatment or management of pain conditions consist of a wide variety of interventions, including mind-body behavioral interventions, acupuncture and massage, osteopathic and chiropractic manipulation, meditative movement therapies (e.g., yoga, tai chi), and natural products, among others.³²¹ The National Institutes of Health (NIH) National Center for Complementary and Integrative Health defines “complementary approaches” as those nonmainstream practices that are used together with traditional medicine, and defines “alternative approaches” as those used in place of conventional medicine, noting that most patients who use nonmainstream approaches do so with conventional treatments.³²² There are many definitions of “integrative” health care, but all involve bringing conventional approaches, as well as complementary and integrative health approaches together in a coordinated way.

The current opioid crisis has spurred intense interest in identifying effective nonpharmacologic approaches to managing pain. The use of complementary and integrative health approaches for pain has grown within care settings across the United States over the past decades. As with other treatment modalities, complementary and integrative health approaches can be used as stand-alone interventions or as part of a multidisciplinary approach, as clinically indicated and based on patient status. Examples of complementary and integrative health approaches to pain include acupuncture, hands-on manipulative techniques (e.g., osteopathic or chiropractic manipulation, massage therapy), mindfulness, yoga, tai chi, biofeedback, art and music therapy, spirituality, and the use of natural or nutritional supplements. These therapies can be provided or overseen by licensed professionals and trained instructors. The use of complementary and integrative health approaches should be communicated to the pain management team.

Overall, most complementary and integrative health approaches can provide improved relief, when clinically indicated, when used alone or in combination with conventional therapies, such as medications, behavioral therapies, and interventional treatments, although more research and evidence-informed studies are necessary.³²¹

Improved reimbursement policies for complementary and integrative health approaches as well as improved education for medical professionals and a greater workforce of pain management specialists can address key barriers to acceptance and implementation of complementary and integrative health approaches for pain.³²¹ Additional research, greater patient and clinician education — including clinical guidance and indications for use — and expanded coverage of complementary and integrative health approaches are essential for a comprehensive solution to reduce the reliance on opioids.

The following paragraphs briefly describe complementary and integrative health approaches, which can be considered singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions. This list is not inclusive or exhaustive; rather, it provides just a few examples of common complementary and integrative health approaches.

Acupuncture is a recognized form of therapy that has its origins in ancient Chinese medicine. It involves manipulating a system of meridians where “life energy” flows by inserting needles into identified acupuncture points. An estimated 3 million American adults receive acupuncture each year.³²³ Acupuncture is generally considered safe when performed by a licensed, experienced, well-trained practitioner using sterile needles, although there are risks as with any intervention. The therapeutic value of acupuncture in the treatment of various pain conditions, including osteoarthritis; migraine headaches; and low-back, neck, and knee pain has growing evidence in the form of systematic reviews and meta-analyses.³²⁴⁻³³⁰ Existing CPGs concerning the use of acupuncture for pain are inconsistent and often differ regarding the evidence-based science and accepted mechanisms by which acupuncture has persisting effects on chronic pain.^{48,315-320,327,331-334} As with all medicine, a risk-benefit analysis, consideration of clinical indications, and patient acceptance need to be considered.

Massage and manipulative therapies, including osteopathic and chiropractic treatments, are commonly used for pain management. Such interventions may be clinically effective for short-term relief^{335,336} and is best accomplished in conjunction with consultation with the primary care and pain management team. Studies on massage have considered various types, including Swedish, Thai, and myofascial release. These studies do not provide adequate details of the type of massage provided. Systematic reviews note that the few studies looking at the effect of massage on pain use rigorous methods and large sample sizes.^{337,338} Other reviews recognize positive clinical effects on various pain conditions, including postoperative pain; headaches; and neck, back, and joint pain.³³⁹⁻³⁴²

MBSR, also discussed above in the Behavioral Health Approaches section, is a program that incorporates mindfulness skills training to enhance one’s ability to manage and reduce pain. Mindfulness enables an attentional stance of removed observation and is characterized by concentrating on the present moment with openness, curiosity, and acceptance. This approach allows for a change in one’s point of view on the pain experience. Studies support statistically significant beneficial effects for low-back pain.^{343,344} A meta-analysis demonstrated that mindfulness meditation significantly reduces the intensity and frequency of primary headache pain.³⁴⁵

Yoga, a practice rooted in ancient Hindu practice and a way of life that incorporates mind, body, and a spiritual approach, has shown improved outcomes for a variety of medical and nonmedical conditions. Yoga has become popular in Western cultures as a form of mind and body exercise that incorporates meditation and chants. Yoga's use of stretching, breathing, and meditation has also been therapeutic in the treatment of various chronic pain conditions, especially low-back pain.^{346–350} Although there have been limited reports of pain symptoms becoming more severe with yoga, overall, the risk-benefit analysis suggests that yoga is generally safe, beneficial, and cost-effective, especially when administered in the group setting.³⁵¹

Tai chi originated as an ancient Chinese martial art used to balance the forces of yin and yang. Modern tai chi has become popular for core physical strengthening through its use of slow movements and meditation. It has demonstrated long-term benefit in patients with chronic pain caused by osteoarthritis and other musculoskeletal pain conditions.^{352,353} Like yoga, tai chi appears to be safe; demonstrates positive results, especially over the long term; and can also be cost-effective in the group setting. Both yoga and tai chi can be delivered remotely via telemedicine/telehealth.

Gaps and Recommendations

Gap 1: There is a large variety of complementary and integrative health approaches that remain unknown to the broader medical community and that are often overlooked in the management of pain.

- **Recommendation 1a:** Consider complementary and integrative health approaches, including acupuncture, mindfulness meditation, movement therapy, art therapy, massage therapy, manipulative therapy, spirituality, yoga, and tai chi, in the treatment of acute and chronic pain, when indicated.
- **Recommendation 1b:** Develop CPGs for the application of complementary and integrative health approaches for specific indications.

Gap 2: There is a gap in the understanding of complementary and integrative health approaches in terms of mechanisms of action, clinical studies examining the feasibility of integrating complementary and integrative health approaches into current care models, the efficacy of individual complementary and integrative health approaches in special populations, and clinical evaluation of complementary and integrative health approaches in the perioperative surgical period as part of a multimodal approach to acute and chronic pain settings.

- **Recommendation 2a:** Conduct further research on complementary and integrative health approaches to determine therapeutic value, risk and benefits, mechanisms of action, and economic contribution to the treatment of various pain settings, including the acute perioperative surgical pain period and various other chronic pain conditions and syndromes.
- **Recommendation 2b:** Consider the inclusion of various complementary and integrative health approaches as part of an integrated approach to the treatment of chronic pain, as clinically indicated, while evidence is further developed.
- **Recommendation 2c:** Conduct further research on supplements such as alpha lipoic acid, L-carnitine transferase, and vitamin C and their effect on acute and chronic pain management.

2.7 Special Populations

Pain and pain management are complex in part because various populations have unique issues that affect acute and chronic pain. Special populations in pain management identified by the Task Force include children, older adults, women, pregnant women, individuals with SCD, individuals with other chronic relapsing pain conditions, racial and ethnic minority populations, and active-duty service members and veterans.

2.7.1 Unique Issues Related to Pediatric Pain Management

Chronic pain has been estimated to affect 5% to 38% of children and adolescents.^{354–356} These pain conditions can be congenital diseases (i.e., SCD), where pain begins in the infant or toddler age period; chronic noncongenital diseases (i.e., juvenile idiopathic arthritis, fibromyalgia, inflammatory bowel disease); or primary chronic pain conditions (i.e., headaches, chronic abdominal pain, chronic musculoskeletal pain, CRPS). The origination of pain conditions in the pediatric age group is important because the developing pediatric nervous system can be especially vulnerable to pain sensitization and development of neuroplasticity.³⁵⁷ Data support the finding that early neonatal and childhood pain experiences can alter pain sensitivity in later life.³⁵⁸ Poor pain management in children can put them at risk for persistent pain and increased impairment as they transition into adulthood and may even be linked to the development of new chronic pain conditions.^{359,360} The application of the biopsychosocial model to pediatric pain care is vital. Psychological conditions resulting from chronic disease and pain syndromes can contribute to long-term pain. These psychological conditions can include difficulty coping, pain catastrophizing, anxiety, and depression. Incorporation of parents and family into pain care is especially important in the pediatric population because childhood pain can be affected by family and parental factors, including family functioning and parental pain catastrophizing, anxiety, and depression. Appropriate pain management in childhood is imperative because their early pain experiences can shape their response to pain as adults. Overall, there is a great need for more trained pediatric pain specialists to address the often complex aspects of pediatric pain. There is a greater challenge in attracting top physicians to further specialize in pediatric pain fellowships, and this aspect of medical education would address an ongoing gap in this area. It is of utmost importance to introduce comprehensive pain care early in the pediatric age group to optimize their QoL now and in the future.³⁶¹

Gaps and Recommendations

Gap 1: The significant shortage of pediatric pain specialists and comprehensive pain service centers presents a barrier to addressing the needs of pediatric acute and chronic pain patients and their medical issues. This limited access is further compromised by lack of reimbursement and coverage for services related to comprehensive pain management, including non-pharmacologic evidence-based pain therapies.

- **Recommendation 1a:** Increase access to pediatric pain services with pain expertise, which can likely be achieved through an increase in the workforce and novel care delivery models.

- **Recommendation 1b:** Deliver and appropriately reimburse and cover pediatric pain care in the context of comprehensive, multidisciplinary treatment.

Gap 2: Pediatric patients with chronic pain conditions eventually transition to adult care, during which they may experience gaps in care, increased health care utilization, poor patient outcomes, and other health care vulnerabilities and morbidities.

- **Recommendation 2a:** Develop models of care for appropriate transition for pediatric patients with acute or chronic pain conditions to ensure seamless care delivery as well as decreased morbidity and mortality.

Gap 3: Most physician pain specialists are not credentialed in pediatric pain and, therefore, are not permitted by their institutions to take care of children with chronic pain.

- **Recommendation 3a:** Encourage and assist pain physicians in obtaining the necessary training for credentialing in pediatric pain. This is a significant step toward improving pediatric patient access.

Gap 4: Many current CBPs do not address pediatric opioid prescribing best practices. Further, there is a lack of RCTs and real-world evidence on nonopioid pharmacologic therapies in pediatric patients for chronic pain.

- **Recommendation 4a:** Develop pediatric pain management guidelines that address appropriate indications for opioids and responsible opioid prescribing.
- **Recommendation 4b:** Conduct pediatric pain research to inform national guidelines using multimodal approaches to optimize pain management for children and adolescents.

2.7.2 Older Adults

Chronic pain is one of the most common, costly, and incapacitating conditions in older adults.³⁶² Chronic pain in older adults usually results from a physical or psychological pathology, especially those conditions such as cancer and arthritis that may increase in frequency with age.³⁶³ Managing pain in older adults can be complex because of age-related physiologic changes, associated medical comorbidities, polypharmacy, increases in pain thresholds, decreases in pain tolerance, and alterations in pharmacokinetics and pharmacodynamics that increase the risk of side effects from pharmacologic treatment.^{317,363} Effective pain management for older adults requires an understanding of the special considerations associated with the physiology of aging, validated assessment tools, common pain presentations in the older adult population,³⁶⁴ and the use of evidence-informed CPGs for common conditions such as low-back pain.³⁶⁵

Gaps and Recommendations

Gap 1: There is a lack of opioid prescribing guidelines for the aging population given this population's increased risk of falls, cognitive decline, respiratory depression, and renal impairment.

- **Recommendation 1a:** Develop pain management guidelines for older adults that address their unique risk factors.
- **Recommendation 1b:** Use a multidisciplinary approach with a nonpharmacologic emphasis given the increased risk of medication side effects in this population.
- **Recommendation 1c:** Establish appropriate pain management education for physicians and other health care providers who treat older adults.

2.7.3 Unique Issues Related to Pain Management in Women

Central to the unique issues women face in pain management are the differences between men and women with respect to pain sensitivity, response to pain medication, and predisposition to clinical pain conditions.³⁶⁶ Data and recent literature suggest that women experience more pain than men, have higher sensitivities to painful stimuli compared with men, and report experiencing greater intensities in pain.^{367,368} In addition to the response to pain medication, there exist gender differences in the patterns of nonmedical use and abuse of prescription opioids.^{369,370} Research has identified that women are more likely than men to misuse prescription opioids.³⁷¹ Furthermore, from 1999 to 2010, the percentage increase in opioid-related overdose deaths was greater in women than in men.³⁷² Finally, women face unique pain management challenges in the pregnancy and postpartum periods. To mitigate the heightened risk associated with pain management in these periods, it is important to emphasize the importance of obstetricians and gynecologists (OB-GYNs) on the multidisciplinary pain management team.

Gaps and Recommendations

Gap 1: Women face unique challenges regarding their physical and mental health, interactions with the health care system, and roles in society. Women use the health care system as patients, caregivers, and family representatives and can be particularly affected by costs, access issues, and gender insensitivity from health care providers and staff. Several diseases associated with pain — in particular, chronic high-impact pain — have a higher prevalence in women or are sex specific, including endometriosis, musculoskeletal and orofacial pain, fibromyalgia, migraines, and abdominal and pelvic pain.

- **Recommendation 1a:** Increase research to elucidate further understanding of the mechanisms driving sex differences in pain responses and research of mechanism-based therapies that address those differences.
- **Recommendation 1b:** Raise awareness in the public and health care arenas to the unique challenges that women face during pregnancy and in the postpartum period, including various pain syndromes and psychosocial comorbidities.

Gap 2: Women may experience increased pain sensitivity. Of note, OB-GYNs may be one of the first health care providers a woman with pain encounters, yet they are not often included as part of a multidisciplinary care team.

- **Recommendation 2a:** Include OB-GYNs as part of multidisciplinary care teams because they are likely to play an important role in the treatment of pain for women.

2.7.4 Pregnancy

Managing pain in pregnant women is uniquely challenging because clinical decision making must account for two patients: the mother and the fetus.¹⁴⁷ Further complicating pain management in the peripartum period is the lack of CPGs for non-pharmacologic treatments that can decrease the potential adverse newborn outcomes associated with opioid therapy in pregnancy, such as neonatal abstinence syndrome (NAS). Greater research in chronic pain management in pregnancy is needed.^{179,373,374}

Gaps and Recommendations

Gap 1: There is a need for evidence-based CPGs for the use of analgesics during pregnancy and the postpartum period.

- **Recommendation 1a:** Develop pain management guidelines for pregnant and postpartum women in collaboration with the national specialty societies (the American College of Obstetricians and Gynecologists, neonatologists, obstetricians, perinatal pediatricians, and other specialists).
- **Recommendation 1b:** Counsel women of childbearing age on the risks of opioids and other medications in pregnancy, including risks to the fetus and newborns.

2.7.5 Chronic Relapsing Pain Conditions

Chronic pain in pediatric and adult populations with periods of remission and frequent relapses defines “chronic relapsing pain conditions.” Examples of such conditions include various degenerative, inflammatory, immune-mediated, rheumatologic, and neurologic conditions such as MS, various cancer syndromes, trigeminal neuralgia, lupus, Parkinson’s disease, postherpetic neuralgia, CRPS, porphyria, systemic lupus erythematosus, lumbar radicular pain, migraines, and cluster headaches. Acute pain flares on top of the chronic pain condition can be a common occurrence that may affect daily routines and overall functionality, resulting in additional morbidity and the need for comprehensive pain care.

Gaps and Recommendations

Gap 1: There is often a lack of partnership between the disease specialist (i.e., the hematologist, oncologist, rheumatologist, or neurologist) and providers of comprehensive multidisciplinary pain programs.

- **Recommendation 1a:** Provide referrals to a comprehensive pain program early in the course of the chronic disease (e.g., MS, cancer, porphyria, systemic lupus erythematosus, migraine, Parkinson’s disease, neuropathic pain syndromes) to determine the optimal approach to

managing acute or chronic pain exacerbations, including potential nonopioid, alternative therapies and nonpharmacologic therapies. Establish a partnership between the disease specialist (i.e., the hematologist, oncologist, neurologist, or rheumatologist) and the pain team to optimize care.

2.7.6 Sickle Cell Disease

SCD is a group of inherited disorders characterized by complex acute and chronic symptoms, including pain.³⁷⁵ An estimated 90,000 people in the United States have SCD, which disproportionately affects minority populations, particularly African-Americans.³⁷⁶ Acute pain episodes, or “pain crises,” associated with SCD are abrupt in onset, unpredictable, and drive patients to seek care in the ED and inpatient unit, with estimated health care costs of almost \$2 billion per year.^{377,378} Chronic, severe, daily pain also occurs in approximately 30% to 40% of adolescents and adults suffering from SCD, significantly impairing their functioning and increasing in incidence and severity with age.^{379–381} Pain in SCD is unique in that it occurs throughout the patient’s lifespan, from infancy to adulthood, and develops directly from the disease.³⁸² The biology of SCD pain is complex, varied, and likely arises from multiple mechanisms depending on whether an individual is suffering from acute or chronic pain.³⁸³ Pulmonary,³⁸⁴ orthopedic,³⁸⁵ psychosocial,³⁸⁶ and other comorbidities of SCD can also give rise to painful complications in adults and children.

Gaps and Recommendations

Gap 1: There is a lack of evidence-based management guidelines for the treatment of acute and chronic pain in children and adults with SCD.

- **Recommendation 1a:** Develop comprehensive, evidence-based guidelines for the treatment of acute and chronic SCD pain in children and adults.
- **Recommendation 1b:** Conduct research targeted at nonopioid pharmacologic therapies and nonpharmacologic approaches for SCD pain management.

Gap 2: Unpredictable, episodic exacerbations of acute pain pose a challenge for SCD pain management, and the majority of patients have failed nonopioid pain drugs prior to presentation for acute care. Constraints on opioid treatment duration can be restrictive for individualization of pain management. Further, limited access to oral opioids at home for the treatment of unplanned acute pain events can result in increased use of health care services that could have been avoided.

- **Recommendation 2a:** Protect access to the appropriate and safe use of opioids for patients with SCD, with consideration for exemption from prescribing guidelines and state prescribing laws that do not specifically address patients with SCD because of the complex nature and mechanism of acute and chronic sickle cell pain.
- **Recommendation 2b:** Consider the lowest effective dose of opioids to treat acute pain crises, and prescribe within the context of close follow-up and comprehensive outpatient pain care.

- **Recommendation 2c:** Develop an individualized approach to pain management that includes consideration of opioid and nonopioid therapies, such as behavioral health strategies and multimodal approaches.
- **Recommendation 2d:** Provide patient education on the risks and benefits of opioids.

Gap 3: The SCD patient population faces significant health care disparities that affect access to and delivery of comprehensive pain care and mental health services. Further, stigma, negative provider attitudes, and perceived racial bias may possibly be associated with SCD pain, which may compromise care, thus leading to increased suffering from pain and pain care delivery.

- **Recommendation 3a:** Develop comprehensive care delivery models for SCD pain management, including collaborative partnerships between pain medicine and hematology.
- **Recommendation 3b:** Develop outpatient infusion clinics/day hospitals for SCD pain management to decrease reliance on the ED for pain treatment.
- **Recommendation 3c:** Increase access to and reimbursement for mental health services for patients with SCD.
- **Recommendation 3d:** Provide education focused on stigma, negative provider attitudes, and perceived racial bias at all levels of health care to optimize delivery of pain treatment to patients with SCD.

2.7.7 Health Disparities in Racial and Ethnic Populations, Including African-Americans, Latinos, American Indians, and Alaska Natives

Considerable evidence exists documenting health disparities in racial and ethnic minority populations, particularly substantial disparities in the prevalence, treatment, progression, and outcomes of pain-related conditions.³⁸⁷ These disparities in care are attributed to factors related to social disadvantage as well as factors within health systems.³⁸⁸ Health disparities contributing to sub-optimal pain management in these special populations may be related to many factors, including barriers to accessing health care, lack of insurance, discrimination, lack of a PCP, lack of child care, a lower likelihood to be screened or receive pain management treatment, and environmental barriers that impede effective self-management. Effective strategies and plans to address these issues specifically in these disparate communities are necessary to address these gaps to improve patient outcomes.

Gaps and Recommendations

Gap 1: Socioeconomic and cultural barriers may impede patient access to effective multidisciplinary care. There is evidence of racial and ethnic disparities in pain treatment and treatment outcomes in the United States, yet few interventions have been designed to address these disparities. Lower quality pain care may be related to many factors, including barriers to accessing health care, lack of insurance, discrimination, lack of a PCP, lack of child care, lower likelihood to be screened or receive treatment, and environmental barriers that impede self-management.

- **Recommendation 1a:** Develop intervention programs informed by the biopsychosocial model to reduce racial and ethnic disparities in pain.

Gap 2: Research shows that ethnic minorities may have greater pain sensitivity and are at increased risk for chronic pain, yet they are underserved.

- **Recommendation 2a:** Develop biopsychosocial interventions for pain that are scalable and culturally enhanced.

2.7.8 Military Personnel and Veterans

The experience of pain is prevalent in military and veteran populations.³⁸⁹ Pain management can be more complex in military populations, who sustain severe battlefield injuries (e.g., blasts) in addition to complications from accompanying conditions such as PTSD and traumatic brain injury (TBI), both of which are more prevalent in veterans than in the civilian population.^{43,390,391} Delayed pain treatment following injury may lead to the increased likelihood of acute to chronic pain change in service members and veterans.⁴³

Gaps and Recommendations

Gap 1: Active-duty service members and veterans have unique physical and mental health challenges related to their military service that contribute to the development of or exacerbate acute and chronic pain conditions. Medical and mental health comorbidities such as TBI, PTSD, limb loss, and musculoskeletal injuries often interfere with successful treatment outcomes. Assessment and treatment of pain conditions in active-duty service members and veterans require military-specific expertise and a coordinated, collaborative approach between medical and mental health providers.

- **Recommendation 1a:** Physicians and other health care providers taking care of active-duty service members, regardless of practice setting, should consider in their pain care plan prior military history and service-connected health factors that may contribute to acute or chronic pain, as relevant to the clinical presentation.
- **Recommendation 1b:** Physicians and other health care providers should work collaboratively to deliver comprehensive pain care that is consistent with the biopsychosocial model of pain.
- **Recommendation 1c:** Conduct research to better understand the biopsychosocial factors that contribute to acute and chronic pain in active-duty service members and veterans, with a focus on TBI, PTSD, and other mental health and substance use disorders.
- **Recommendation 1d:** Conduct studies to better understand the contributing factors predisposing these patients to movement along the spectrum from acute pain to persistent pain.

Gap 2: The transition of active-duty service members to veteran status can be complicated. A multitude of factors may affect a successful transition, including incomplete integration of EHRs and imposed changes or delays in access to primary care, pain specialty, and mental health physicians and other health care providers.

- **Recommendation 2a:** The integration of DoD and VHA health care systems is important for effective and timely pain care. This integration should include coordination of the transition from active duty to veteran status and care coordination across the health care spectrum that

includes a smooth transition to primary care, mental health and pain specialty physicians, and other health care providers.

Gap 3: Active-duty military service members and veterans increasingly receive care in the community (including care provided through external payment systems and DoD/VHA purchased care). A fragmented health care system results in lack of coordinated care provided in the community, within the Military Health System, and in the VHA as well as differing care standards (such as the implementation of opioid risk-mitigation strategies). Within VHA, access to primary care and specialty care — and multidisciplinary pain specialty care in particular — is difficult for some veterans because of geographical factors, limited availability of providers, and the need for specialized pain care treatment.

- **Recommendation 3a:** To improve care coordination across health care systems, streamlined access to medical records and collaboration across systems are needed to provide more timely and effective pain care.

3. Cross-Cutting Clinical and Policy Best Practices

3.1 Stigma

Stigma associated with the condition of chronic pain, especially when opioid therapy is used as a treatment modality, is a major concern and has far-reaching effects on patients and all those involved in their care.³⁹² These different facets of stigma — at the patient, provider, and social levels — collectively serve as a significant barrier to effective treatment of chronic pain.³⁹³ There is a growing body of empirical research into stigmatization and the resulting barriers to care. Studies suggest that patients are receiving or who have previously received long-term opioid therapy for nonmalignant pain face both subtle and overt stigma from their family, friends, coworkers, the health care system, and society at large for their opioid treatment modality.^{392–395} Compassionate, empathetic care in which there is a provider-patient partnership is best for countering the stigma, isolation, and psychosocial challenges of living with pain.

Feelings of guilt, shame, judgement, and embarrassment resulting from such stigma can increase the risk for behavioral health issues, such as anxiety and depression, which can further lead to symptom chronicity.³⁹⁵ Reducing barriers to care that exist as a consequence of stigmatization is crucial for patient engagement and treatment effectiveness.³⁹³

Furthermore, the sub-population of patients with painful conditions and comorbid SUD face additional barriers to treatment because of stigmatization of both chronic pain and addiction.³⁹⁶ Chronic pain is common among individuals with SUD, including opioid misuse,³⁹⁷ yet stigma remains a significant barrier to implementation of programs and treatments for OUD, such as medication-assisted treatment^{398,399} and naloxone.⁴⁰⁰ Patients with comorbid problematic opioid use and chronic noncancerous pain report significant perceived stigma associated with methadone and buprenorphine treatment.³⁹⁴ Stigma not only makes individuals less likely to seek treatment but also makes

marshaling investment more challenging for prevention and treatment programs associated with substance abuse. Clinicians who treat acute and chronic pain, particularly with opioids and other controlled substances, experience stigma from colleagues and society in general that — in addition to fear of scrutiny from state medical boards and the DEA — dissuades many, particularly in primary care, from using opioids at all in the treatment of pain. PCPs are overburdened with time constraints, EHR demands, and other administrative tasks, which has led to unprecedented levels of burnout among physicians. Stigma, combined with the enhanced time required to effectively evaluate and treat pain, leads to over-referral and patient abandonment.⁴⁰¹ Only 12.2% of individuals who require treatment for an SUD seek that treatment. Stigma is a significant barrier, with 20.5% not seeking treatment because of fear of a “negative effect on job,” and 17.2% thought it “might cause neighbors or community to have a negative opinion” of them.⁴⁰¹

Gaps and Recommendations

Gap 1: Chronic pain patients may face barriers in access to pain care due to being stigmatized as people seeking medications to misuse. Contributing to this stigmatization are the lack of objective biomarkers for pain, the invisible nature of the disease, and societal attitudes that equate acknowledging pain with weakness.

- **Recommendation 1a:** Increase patient, physician, other health care provider, and societal education on the underlying disease processes of acute and chronic pain to reduce stigma.
- **Recommendation 1b:** Increase patient, physician, other health care provider, and societal education on the disease of addiction.
- **Recommendation 1c:** Counter societal attitudes that equate pain with weakness through an awareness campaign that urges early treatment for pain that persists beyond the expected duration for that condition or injury.
- **Recommendation 1d:** Encourage research aimed at discovering biomarkers for neurobiological mechanisms of chronic pain.

Gap 2: The national crisis of illicit drug use, with overdose deaths, is confused with appropriate therapy for patients who are being treated for pain. This confusion has created a stigma that contributes to raise barriers to proper access to care.

- **Recommendation 2a:** Identify strategies to reduce stigma in opioid use so that it is never a barrier to patients receiving appropriate treatment, with all cautions and considerations for the management of their chronic pain conditions.

3.2 Education

Public, patient, and provider education is critical to the delivery of effective, patient-centered pain management and is necessary for optimizing patient outcomes, promoting appropriate use of pain medication, and reducing the risk associated with prescription opioids. This common theme is underscored across many federal reports, including the Institute of Medicine’s (IOM) *Relieving Pain in America* report, the *National Pain Strategy*, and other pain management and opioid-related consensus

documents.^{1,42,107,402} These reports consistently describe the extent to which pain and SUD education is insufficiently covered in medical education and training programs, which has a downstream impact on the extent to which patients are educated about pain and SUD.

To begin to address the growing need for educational initiatives, multiple entities, including government agencies, nonprofit organizations, pharmaceuticals manufacturers, academic institutions, and health systems, have developed and disseminated pain- and opioid-related patient education programs, toolkits, pamphlets, and other interventions. Similarly, state-level continuing education requirements have been established for several provider types (e.g., physicians, dentists, nurse practitioners [NPs], physician assistants [PAs], pharmacists) that mandate education about appropriate opioid prescribing and dispensing. Addressing multiple education gaps simultaneously will likely be necessary to optimize patient outcomes tied to public, patient, and provider education. Other programs that could be considered are the development and effectiveness testing of a reimbursable pain self-management training program that incorporates a pain educator, or evaluation of the role of a certified pain educator, in optimizing pain care and improving patient education.

3.2.1 Public Education

The evidence base for public education about pain is limited. Whereas some evaluation of mass media campaigns for low-back pain have been conducted in other countries, analyses in the United States are lacking.^{403–405} The gaps and recommendations specific to public pain education, as outlined below, that will inform best practices in public pain education are consistent with those described elsewhere, including the National Pain Strategy.⁴² There is a significant need for improved public education on and understanding of the distinction between acute and chronic pain — notably, that chronic pain, regardless of its etiology, can become a chronic disease itself, with measurable changes in the nervous system, spinal cord, and brain.¹ An estimated 50 million to 100 million people have chronic pain, making it the most prevalent, costly, and disabling health condition in the United States.^{1,2} Yet, despite its pervasiveness, it remains largely unknown to the broader public.

Gaps and Recommendations

Gap 1: National public education about pain is needed.

- **Recommendation 1a:** Develop a national evidence-based pain awareness campaign that emphasizes the public’s understanding of acute and chronic pain syndromes.
- **Recommendation 1b:** Establish a mechanism to finance a large-scale, systematic, coordinated public campaign to address pain awareness.

3.2.2 Patient Education

Patient education is another key component of any best practice model for outcomes. Patients benefit from a greater understanding of their underlying disease process and pain triggers and knowing how to seek appropriate professional care. It is important for patients to know that pain as a symptom is typically a warning of injury or disease that can affect the body and mind. Finding the underlying cause

of the pain and appropriately addressing it is considered the best management strategy for improving patient outcomes. It is also important for patients to understand that pain can be a disease in its own right, particularly when pain becomes chronic and loses its protective function. In this context, pain is often detrimental to the patient's health, functionality, and QoL. A category of diseases is characterized by chronic debilitating pain (e.g., trigeminal neuralgia, CRPS, postherpetic neuralgia). In such conditions, there is rarely a cure, but appropriate assessment; accurate diagnosis; and patient-centered, multidisciplinary treatment can optimize pain relief, improve function, and enhance QoL. In addition, education and training in patient self-management support are essential for care of patients with chronic pain.⁴⁰⁶ Self-management skills training may include relaxation, pacing, cognitive restructuring, maintenance planning, and relapse prevention.^{36,37,41,407} Innovative delivery systems, including telehealth (e.g., Extension for Community Healthcare Outcomes [Project ECHO]) and other Web-based applications, can offer technology-based education and self-management support to further engage and empower patient in their care plan.^{408–410}

Gaps and Recommendations

Gap 1: Current patient education is lacking for both acute and chronic pain.

- **Recommendation 1a:** Prioritize time and patient access to educational tools that include clinician visits, patient handouts, Web resources, and support groups to optimize patient outcomes.
- **Recommendation 1b:** Explore and test innovative methods of delivering patient education and support for acute and chronic pain patients using technology, particularly in rural areas that have little access to multimodal treatment. Examples of means to provide patient access in such situations include telemedicine, the Project ECHO hub-and-spoke model, online support groups, networks of in-person support groups with training and guidance of leaders, and applications easily accessible on mobile phones.

Gap 2: Patient expectations regarding the management of their pain in the perioperative arena are frequently not aligned with current surgical practices or procedures that require pain management.

- **Recommendation 2a:** Emphasize discussions about pain control after surgery during the preoperative visit. This discussion should be conducted by both the surgical team and the preoperative team.
- **Recommendation 2b:** For major surgeries, use models such as the PSH or ERAS protocols to emphasize the importance of patient education and management.
- **Recommendation 2c:** CMS and other payors should recognize that the time spent educating and managing patients' expectations provides a significant value that reduces the length of hospital stays and improves patients' postoperative pain management, allowing for faster recovery through earlier PT and mobility that decreases the risk for postoperative complications (e.g., blood clots). CMS and other payors should compensate according to physician-patient time spent.

Gap 3: Current educational materials and interventions for patients with chronic pain lack consistency,

standardization, and comprehensive information.

- **Recommendation 3a:** Establish an online resource of evidence-informed educational materials for common pain conditions and appropriate treatment modalities.
- **Recommendation 3b:** Convene a chronic pain expert panel that includes experienced patients, patient advocates, and clinicians to develop a set of core competencies and other essential information specific to patient pain education. Provide grants for the creation of patient education programs and materials based on these core competencies, and disseminate them widely to patients and their families and caregivers through clinics, hospitals, pain centers, and patient groups.

3.2.3 Provider Education

Experts have noted the benefits that could be realized from the development of a more comprehensive pain curriculum for training and continuing education of providers.¹⁰ Encouraging licensing and education practices that do more to emphasize safe and effective pain management in addition to assessment has the potential to improve pain management and mitigate factors that contribute to the current opioid crisis.^{21,411} Health care professionals who prescribe opioids are in a key position to balance the benefits of analgesics against the risk of adverse clinical outcomes. It is estimated that “apart from federal prescribers who are required to be trained, fewer than 20% of the over one million prescribers licensed to prescribe controlled substances to patients have some form of training on how to prescribe opioids safely and effectively.”⁴¹² Providers can access educational resources, receive accreditation, or renew existing licenses through public- or private-sector enterprises.¹³¹ National stakeholders have recommended that accrediting organizations develop, review, promulgate, and regularly update core competencies for pain care education, licensure, and certification at the prelicensure (i.e., undergraduate professional) and postlicensure (i.e., graduate) levels.^{42,304}

Clinician education is most effective when varying media and instructional techniques are used. Educational interventions for pain should be guided by core competencies and target both the training and practice levels.²¹ Provider education research specific to patient outcomes is limited, but systematic reviews on continuing medical education (CME) indicate interventions that include multimedia, multiple instructional techniques, and multiple exposures are associated with improved provider knowledge outcomes compared with alternatives (e.g., print materials, one-time interventions).^{413–415} Likewise, regardless of whether educational interventions are targeted at clinicians in training or in practice, aligning educational interventions with core competencies (i.e., outcomes) for pain care education for all health professions, all physicians,⁴¹¹ and all medical specialties¹⁰ is a best practice.⁴² In addition, while Frank et al.⁴¹⁶ demonstrated the effectiveness of a longitudinal distance learning approach that uses telemedicine to change clinical pain practice in primary care, a recent systematic review by Rochfort et al.⁴⁰⁶ found a scarcity of studies on the effectiveness of educational interventions implemented by a PCP designed to promote optimal patient outcomes. Results do indicate that education and skills training of PCPs may positively affect patient

performance of self-management pain-reduction activities, improve patient lifestyle behaviors, and increase perceived QoL. This underscores the importance of further training for health care professionals in patient self-management support as part of patient-centered care and as a mechanism for improving pain outcomes.

Gaps and Recommendations

Gap 1: There are gaps in pain management understanding and education throughout the medical school curriculum, graduate medical education, residency training, and all levels of other health care providers' training and education.

- **Recommendation 1a:** Incorporate further development of a biopsychosocial education model for physicians and other health care providers at all levels of training.
- **Recommendation 1b:** Develop effective educational resources for PCPs to improve the current understanding and knowledge of pain treatment modalities, initially available treatments, and early referral to pain specialists.
- **Recommendation 1c:** Explore intensive continuing pain education for PCPs, including telehealth, telementoring, and the Project ECHO model, as a means of providing pain education for PCPs by pain specialists. Consider the State Targeted Response Technical Assistance model for pain training as it currently exists for addiction training.

Gap 2: Pain is generally treated as a symptom of other illness, disease, or injury, not commonly recognized as a separate category of disease. The lack of education on pain syndromes and pain mechanisms limits the ability to recognize chronic pain as a category of disease.

- **Recommendation 2a:** Recognize chronic pain as a category of disease when the pain persists for more than the expected recovery time (3-6 months) despite appropriate treatment of the original inciting injury or disease.
- **Recommendation 2b:** Conduct further education on pain syndromes and mechanisms through physician and other health care provider training, such as CME, the Project ECHO model, telementoring, and other continuing education programs.

3.3 Access to Pain Care

It is estimated that approximately 80% of the world's population has limited access to adequate treatment for moderate to severe pain.^{292,417} Specifically, in the United States, the estimated number of patients with chronic daily pain is 50 million, with 19.6 million having chronic, high-impact pain.² Several factors act as barriers to adequate care, including poorly functioning drug supply systems,⁴¹⁸ inadequate insurance coverage for pain management services,²⁹³ shortages in medical and behavioral pain management specialists,¹ provider underestimation of patients' reports of pain,⁴¹⁹ lack of research on innovative and effective pain management approaches,²² and — more recently — widespread fear among providers of regulatory scrutiny. The recent advent of retail pharmacies limiting the duration of prescriptions, making changes to dosage, amounts, or placing restrictive barriers to obtaining properly

prescribed pain medications has had the unintended consequence of limiting access to pain care. Without access to sufficient pain care, many patients face unnecessary medical complications, prolonged suffering, and increased risk for psychiatric conditions.⁴²⁰ Medical complications from inadequately treated acute pain may include prolonged recovery time, unanticipated readmissions, and transition to chronic and persistent pain.⁴²¹ Unremitting and inadequately treated pain is also associated with increased anxiety, depression, disability, unemployment, and lost income.³⁰⁸

In addition to experiencing medical and psychiatric consequences, individuals who receive inadequate pain treatment may potentially transition to illicit opioid use or other substance misuses. Although the pathway to illicit substance use in pain is not well understood, a small but growing number of individuals who misuse prescription opioids without the supervision or oversight of a medical provider transition to using illicit substances, such as heroin, within a year of use.⁴²² The nonmedical and illicit use of opioids may increase an individual's risk for substance use problems, accidental or intentional overdose, or death.⁴²³ Heroin, fentanyl, and other illicit synthetic opioids continue to drive increasing numbers of overdose deaths.⁴ Understanding the indicators associated with inappropriate opioid use may improve the ability of health care providers to tailor treatments and surveillance without placing arbitrary limitations on all patients who are prescribed opioids. This understanding could also potentially improve access to effective care.

3.3.1 Medication Shortage

Shortages of pharmacologic and biological products, including opioid and nonopioid analgesics, can have severe and immediate consequences on patient care. Appropriate treatment can be delayed or denied because of unavailability and, in other cases, result in the use of second-line, less effective alternatives, which may further affect patient care.^{424,425} Several underlying factors have contributed to national shortages, including manufacturing problems that affect the drug supply chain and quality control, as well as regulatory changes in response to the opioid overdose public health crisis.^{418,425} Tracking data from the FDA show that drug shortages peaked in 2011, with more than 250 new drug shortages, and although the number has steadily declined, 2017 saw an influx of 39 new shortages and a failure to adequately address existing shortages.⁴²⁵

Health care systems and providers, including anesthesiologists, intensivists, and other specialty clinicians, including dentists, PAs, and NPs, along with critical clinical pharmacists are responding to the drug shortages by identifying therapeutic alternatives and prioritizing supplies. Patient safety events — namely, medication errors — are more likely to occur during times of shortages because of the increased prescribing of less familiar pharmacologic agents.^{418,426} Use of compounded products or alternative preparations is a common underlying cause of errors.⁴²⁷ An investigation by the Institute for Safe Medication Practices into shortage-related patient safety events cited that use of an alternative drug or alternative dosage form/strength of a substitute drug accounted for up to 27% of reported harmful outcomes.^{426,428} Advance notice of shortages, communication and education, consultation with clinical pharmacists, and standardized management algorithms help mitigate the effects of drug

shortages. For instance, a retrospective chart review of patients admitted to the pediatric intensive care unit during a 2011-2012 peak shortage of injectable benzodiazepines (e.g., midazolam, lorazepam, diazepam) and fentanyl reported no significant increase in rates of prescribing error and adverse patient outcomes because of well-established guidelines for prioritized and alternative analgesic and sedative management protocols.^{[429](#)}

Current widespread shortages of several key parenteral opioids used for fast and reliable analgesic effects, including morphine, hydromorphone, and fentanyl, are affecting hospitals and cancer centers nationwide, leading to compromised acute pain management in the critical care and postoperative settings. Morphine, hydromorphone, and fentanyl are the most commonly used opioid injectables because of their fast and reliable analgesic effects and because they offer a viable option for patients unable to tolerate oral administration.^{[418,424](#)} In addition to these three opioids, other analgesics facing shortages include the NSAIDs ketoprofen and ketorolac tromethamine, methocarbamol, methadone, promethazine, and remifentanyl. In July 2018, the FDA established the Agency Drug Shortages Task Force. That task force is charged with identifying the root causes of medication shortages and proposing holistic long-term solutions to address and prevent shortages, which will be summarized in a report to Congress, informed by input from the pharmaceutical and health care industries, patient representatives, the FDA's federal partners, and Congress.^{[430](#)}

Gaps and Recommendations

Gap 1: Recurrent shortages in opioid and nonopioid medications have created barriers to the proper continuity of treatment in acute and chronic pain patients. This creates the unintended consequence of poor patient care.

- **Recommendation 1a:** The FDA should monitor, report, and prioritize the availability of key opioid and nonopioid medications, including injectables such as local anesthetic agents.
- **Recommendation 1b:** The FDA should make available alternative sources for these medications when critical shortages occur (e.g., stop-gap measures such as obtaining these medications from other countries, compound pharmacies).
- **Recommendation 1c:** Support the Agency Drug Shortages Task Force in its endeavors to find solutions to the critical challenges of drug shortages.

3.3.2 Insurance Coverage for Complex Management Situations

Patients with complex and persistent pain often experience barriers to care related to nonexistent or insufficient insurance coverage and reimbursement for evidence-based medical, behavioral, and complementary pain management services. Although the HHS National Pain Strategy calls for greater access and coverage for pain management services, there is a lack of uniformity in insurance coverage and lack of coverage alignment with current practice guidelines for pain management.^{[293,431](#)} This is particularly true for the coverage of nonpharmacologic^{[293](#)} and behavioral health interventions.^{[293,432](#)}

The process for determining insurance coverage for pain management services is lengthy and complex,

often requiring product testing, assessment against evidence-based protocols, determination of medical necessity, and review by physician networks and stakeholders. Moreover, there is substantial variability in the availability and structure of guidance regarding the data needed to qualify for coverage provided to developers working on innovative nonpharmacologic treatments.²⁹³ For example, CMS requires testing of products in the Medicare-aged population for national coverage determinations. Guidance to medication and product developers working on alternatives to opioids and opioid-sparing technologies; procedures concerning data needed to qualify for CMS coverage determinations; and innovation payments under CMS programs, especially for Medicare-eligible Americans in pain, is limited to basic statutory language. In contrast, the FDA provides extensive guidance on data needed to qualify for labeling for products like “abuse deterrent” medicines.

The inconsistencies in insurance policies, the variability in guidance regarding coverage determinations, and the variability in utilization management tools that coverage providers use can cause delays in service delivery, provision of inadequate treatment, and added financial and psychosocial burden for patients with pain.³⁰³ Requiring patients and health care professionals to navigate burdensome and variable coverage policies may contribute to the slow development, adoption, and implementation of timely and effective pain treatments as well as potentially force providers to treat patients in a less than optimal fashion. Consistently forcing providers to try a series of non-first-line treatments prior to authorizing treatment plans can be problematic, hindering appropriate patient care, creating tremendous inefficiency, and resulting a loss of time and resources. This situation is problematic when patients change insurance coverage, requiring a new set of preauthorization rules to be followed and potentially leading to delay in critical, ongoing treatment.⁴³¹

Gaps and Recommendations

Gap 1: Time and resources are not sufficient for complex and safe opioid management.

- **Recommendation 1a:** Reimburse complex opioid and nonopioid management consistent with the time and resources required for patient education, safe evaluation, risk assessment, reevaluation, and integration of alternative, nonopioid modalities.
- **Recommendation 1b:** CMS and private payors should investigate and implement innovative payment models that recognize and reimburse holistic, integrated, multimodal pain management, including complementary and integrative health approaches.

Gap 2: Payor guidelines are outdated and not in sync with the current medical and clinical guidelines.

- **Recommendation 2a:** CMS and other payors should align their reimbursement guidelines for acute and chronic multidisciplinary pain management with current CPGs.

Gap 3: Payors often do not reimburse for nonopioid pharmacologic therapies that are more expensive than opioids.

- **Recommendation 3a:** CMS and other payors should align their reimbursement guidelines for nonopioid pharmacological therapies with current CPGs.

Gap 4: Coordinated, individualized, multidisciplinary care for chronic pain management is a best practice and has been shown to result in better and more cost-effective outcomes, yet this model of care is nearly impossible to achieve with current payment models.

- **Recommendation 4a:** Payors should reimburse pain management using a chronic disease management model. CMS and private payors should reimburse integrative, multidisciplinary pain care by using a chronic disease management model in the manner they currently reimburse cardiac rehabilitation and diabetes chronic care management programs. In addition, reimburse care team leaders for time spent coordinating patient care.

3.3.3 Workforce

A 2011 IOM report highlighted the current shortage of pain management specialists, citing that for every physician who is board certified in pain care, there are more than 28,500 Americans living with chronic pain.¹ As of August 2018, there were 2,300 ABPM-certified pain specialists⁴³³ and 6,595 physicians certified in pain management by the American Board of Medical Specialties⁴³⁴; many of these physicians have both certifications. Pain management specialists possess expertise and are specially trained in the evaluation, diagnosis, and treatment of all types of pain.⁴³⁵ Because of an inadequate number of specialized pain physicians, PCPs are tasked with managing the majority of patients with painful conditions, often without adequate time and resources.⁴³⁶ This further emphasizes the need for an increase in the pain specialist workforce to support PCPs while also ensuring that specialists and PCPs have adequate time, incentives, and resources to manage patients with painful conditions. Likewise, access to behavioral pain management is limited because financial incentives are lacking for psychologists and other providers to specialize in pain. Many insurance programs do not reimburse for behavioral pain treatments, or they reimburse at a much lower rate than for pharmacologic or interventional treatments. Because of the lack of incentives, not enough providers are trained in behavioral pain management.^{294,297} Taken together, the severe shortage of pain medicine specialists and under-resourced and insufficiently trained PCPs treating pain along with behavioral therapists, pharmacists, and other members of the pain management team has hindered the development of efficient, cost-effective health care delivery models to treat the vast population of Americans living with chronic pain.^{1,10,437}

Gaps and Recommendations

Gap 1: There is a lack of multidisciplinary physicians and other health care providers who specialize in pain. These physicians and other health care providers include pain specialists, addiction psychiatrists, psychologists, pharmacists, and others who are trained to be part of the pain management team.

- **Recommendation 1a:** Enhance physician and other health care provider pain management specialty workforce training in treating chronic pain with psychological comorbidities. This training should include improved curriculum training in residency, fellowship, and CME courses as well as other continuing education modules that help improve patients' understanding of and engagement in psychological treatment.

- **Recommendation 1b:** Expand graduate medical residency positions to train in pain specialties, including adult pain specialists, pediatric pain specialists, behavioral health providers, pain psychologists, and addiction psychiatrists.
- **Recommendation 1c:** Expand the availability of nonphysician specialists, including physical therapists, psychologists, and behavioral health specialists.

3.3.4 Research

Research is fundamental to advancing both the understanding and treatment of acute and chronic pain. A request by NIH in a 2011 IOM report called for new knowledge development in all areas of pain research, with particular emphasis placed on molecular and cellular mechanisms of pain, the genetics of pain, biobehavioral pain, models of pain, diagnosis and assessment of pain, pain management, the epidemiology of pain, health disparities, and translational pain research.¹ Supporting research initiatives throughout these fields across the basic science, translational, and clinical research arenas will aid in addressing current research gaps, better understanding the mechanisms of pain and SUD, translating promising advancements into effective therapies, and identifying best practices to implement in the treatment and management of acute and chronic pain.

Gaps and Recommendations

Gap 1: Incentives for innovations in the treatment of chronic and acute pain are necessary for the advancement of treatment.

- **Recommendation 1a:** Increase federal (and state) funding through the NIH, DoD, and other agencies to support and accelerate basic science, translational, and clinical research of pain. Allocate funding to develop innovative therapies and build research capabilities for better clinical outcomes tracking and evidence gathering.

Gap 2: Genetic and experiential factors in the progression of pain are not clearly understood.

- **Recommendation 2a:** Improve understanding of the specific interplay of genetic and experiential contributions to pain, including identification of biomarkers, factors that play a role in persistent pain and eventually chronic pain, the role of comorbid conditions, and predictive risk factors.

Gap 3: There is a lack of understanding of contributing factors that predispose certain patients to SUD and addiction.

- **Recommendation 3a:** Further evaluate the lifelong risk factors for the development of SUD rather than the isolated evaluation of prescription opioid use (e.g., adolescent substance use, early life trauma).
- **Recommendation 3b:** Conduct research to identify biomarkers, genetic predisposition, and other patient factors to assist in improved and accurate identification of those patients at risk for SUD and addiction disease.

Gap 4: There is a lack of research on and funding of potentially innovative modes of delivery and treatment.

- **Recommendation 4a:** Increase the levels of research into novel strategies that target the underlying mechanisms of chronic pain, including pharmacologic and biologic research and development, medical devices, new and innovative technological advancements, medication delivery systems, neuromodulation, regenerative medicine, and complementary and integrative health approaches, as well as movement-based modalities.

4. Review of the CDC Guideline

In 2016, in response to growing concerns about overprescribing opioids for pain management and opioid-related overdose, the CDC published a widely read guideline on opioid therapy for chronic pain.¹⁰⁷ Recommendations focus on the use of opioids in treating chronic pain in patients 18 years or older. The *CDC Guideline for Prescribing Opioids for Chronic Pain* is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

The CDC guideline provides useful general guidance for prescribing opioids. Various organizations, such as the American College of Physicians, supported the guideline when it was initially released, but important limitations have been highlighted by various clinicians, patients, professional organizations and other stakeholders in the two years since publication. A commentary by Busse et al.⁴³⁸ identified several limitations to the CDC guideline related to expert selection, evidence inclusion criteria, method of evidence quality grading, support of recommendations with low-quality evidence, and instances of vague recommendations. In addition, the CDC used the criterion of a lack of clinical trials with a duration of one year or longer as lack of evidence for the clinical effectiveness of opioids, whereas Tayeb et al.⁹⁴ found that that was true for all common medication and behavioral therapy studies. Long-term studies of therapies for chronic, moderate, or severe pain are difficult to conduct because of patient drop-out for ineffective treatment.¹⁴⁴ One long-term study from the VA assessed patients on opioids versus nonopioid medications over a 12-month study evaluation period.⁹³ According to this study, both groups showed similar changes in pain severity and pain-related function over 12 months. Results in this study do not support initiation of opioid therapy alone for moderate to severe chronic back pain or hip or knee osteoarthritis pain.⁹³ Noting that the CDC guideline focused primarily on patients initiating opioid treatment, Gordon and Connolly⁴³⁹ discussed application of the guidelines to patients who are already receiving opioid maintenance therapy for chronic pain. Given that chronic pain has many different underlying conditions, with great patient variability in metabolism, risk for abuse and medical conditions, further studies are needed to assess the value of long-term opioids when other measures have failed to relieve a patient's pain, coupled with risk assessment and periodic reevaluation.

The Task Force recognizes the utility of the 2016 CDC guideline for many aspects of pain management and its vital role in much-needed consideration of mitigating adverse outcomes of opioid exposure. Interpretation of the guideline, in addition to some gaps in the guideline, have led to unintended

consequences, some of which are the result of misapplication or misinterpretation of the CDC guideline. Public comments from the Task Force noted this concern in regard to treatment access issues and provider disincentives as well as directly noting the CDC guideline. In November 2018, the American Medical Association issued a statement advocating against *the misapplication of the CDC Guideline for Prescribing Opioids for Chronic Pain*.⁴⁴⁰ Educating stakeholders about the intent and optimal application of this guideline and reemphasis of core beneficial aspects to these guidelines are essential.

The 2016 CDC guideline, which provided a comprehensive synthesis of scientific evidence on opioid prescribing, was intended as a tool for PCPs to help inform their decisions about managing pain with opioids and to encourage dialogue and discussion of risks between providers and patients (shared decision making). However, at least 28 states have enacted legislation related to opioid prescription limits, and many states and organizations have implemented the guideline without recognizing that the intended audience was PCPs; have used legislation for what should be medical decision making by healthcare professionals; and have applied them to all physicians, dentists, NPs, and PAs, including pain specialists.^{441–444} Some stakeholders have interpreted the guideline as intended to broadly reduce the amount of opioids prescribed for treating pain; some experts have noted that the guideline emphasizes the risk of opioids while minimizing the benefit of this medication class when properly managed.⁴⁴⁵ The CDC guideline was not intended to be model legislation for state legislators to enact.

An unintended consequence of the guideline is the forced tapering or patient abandonment that many patients with chronic pain on stable long-term doses of opioids have experienced. The Task Force received public comments indicating that many patients have experienced access issues related to provider fears and concerns with how the guideline would be interpreted and have caused some to consider obtaining opioids from illicit sources or suicide. PCPs should be encouraged to refer to or seek input from pain specialists and (potentially) addiction specialists in complex or high-risk patient scenarios. The CDC guideline, along with concern about undue burdens of investigation and prosecution by drug enforcement, has been cited in part by doctors and other key health care providers when deciding to limit or not to provide pain treatment.¹³ Experts have also noted that the CDC guideline does not sufficiently emphasize that optimal pain management begins with identification of the cause of the pain and the biopsychosocial mechanisms that contribute to its severity and associated disability.

The CDC guideline recommends that opioids prescribed for acute pain be limited to three or fewer days and that more than a seven-day supply is rarely necessary.¹⁰⁷ Various health insurance plans, retail pharmacies, and local and state governments are implementing the CDC guideline as policy, limiting the number of days a patient can receive prescription opioids. A more even-handed approach would balance addressing opioid overuse with the need to protect the patient-provider relationship by preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.⁴⁴⁶ Policies should help ensure safe prescribing practices, minimize workflow disruption, and ensure that beneficiaries have access to their medications in a timely manner, without additional,

cumbersome documentation requirements.⁴⁴⁶ In essence, clinicians should be able to use their clinical judgement to determine opioid duration for their patients.

Recommendations noted in this section are organized into two groups:

- **Update:** Requires updated scientific evidence since the release of the CDC guideline in March 2016
- **Emphasize or Expand:** Refers to content already in the CDC guideline or areas to expand on

Update

1: There is an absence of high-quality data on the duration of opioid effectiveness for chronic pain, which has been interpreted as a lack of benefit.

- **Recommendation 1a:** Support studies to determine the long-term efficacy of opioids in the treatment of chronic pain syndromes (primary and secondary) in different populations as determined by clinical context, clinical conditions, and comorbidities.
- **Recommendation 1b:** Conduct clinical trials on specific disease entities, with a focus on patient variability and response to tissue injury and on the effectiveness of opioid analgesics. Design trials to be applicable in real-world settings (e.g., patients receiving trialed opioid medications while maintaining the usual multimodal therapy).

2: There is an absence of criteria for identifying the sub-population of patients for whom opioids may make up a significant part of pain management.

- **Recommendation 2:** Conduct clinical studies or complete systematic reviews to identify which sub-populations of patients with different chronic pain conditions may be appropriate for long-term opioid treatment in conjunction with the various nonopioid modalities.

Emphasize or Expand

3: There is wide variation in factors that affect the optimal dose of opioids.

- **Recommendation 3a:** Consider patient variables that may affect opioid dose in patients prior to initiation of opioid therapy, including respiratory compromise, individual patient metabolic variables, or differences between opioid medications that could affect plasma opioid concentrations.
- **Recommendation 3b:** Perform comprehensive initial assessments for patient management, with an understanding of the need for periodic comprehensive reevaluation to adjust the medication dose.
- **Recommendation 3c:** Careful consideration should be given to patients on an opioid pain regimen who have additional risk factors for OUD.

4: Specific guidelines addressing opioid tapering and escalation need further elucidation.

- **Recommendation 4a:** Undertake opioid tapering or escalation with a thorough assessment of the risk-benefit ratio. This should be done in collaboration with the patient whenever possible.

- **Recommendation 4b:** Develop guidelines for tapering and dose escalation for the sub-populations of patients who have chronic pain conditions that includes consideration of their comorbidities.
- **Recommendation 4c:** Consider maintaining therapy for patients who are stable on long-term opioid therapy and for whom the benefits outweigh the risks.

5: There are multiple potential causes of worsening pain that are often not recognized or considered. Non-tolerance-related factors include iatrogenic causes such as surgery, flares of the underlying disease or injury, and increased ergonomic demands or emotional distress (e.g., anxiety disorders, catastrophizing, depression).

- **Recommendation 5a:** When a stable dose has been established for at least two months, avoid increases in the dose until the patient is reevaluated for the underlying causes of elevated pain or possible OUD risk.
- **Recommendation 5b:** Considerations to avoid dose escalation should include opioid rotation, non-opioid medications, interventional strategies, cognitive behavioral strategies, complementary and integrative health approaches, and PT.

6: Although the risk of overdose by benzodiazepine co-prescription with opioids is well established, this combination may still have clinical value in patients who have chronic pain and comorbid anxiety, which commonly accompanies pain, and in patients who have chronic pain and spasticity.

- **Recommendation 6a:** If clinically indicated, co-prescription should be managed and coordinated by physicians, providers, and clinician specialists who have knowledge, training, and experience in co-prescribing benzodiazepines with opioids. For those patients who have anxiety disorders or SUD who have been prescribed benzodiazepines, collaboration with experts in mental health and the use of psychological modalities should be considered.
 - **Recommendation 6b:** Develop CPGs that focus on tapering for co-prescription of benzodiazepines and opioids.
- 7:** The risk-benefit balance for opioid management may vary for individual patients. Similarly, the balance of benefit and risk for doses above 90 MME/day may be favorable to some patients, while for other patients, doses below 90 MME/day may be a greater risk because of individual patient factors. The variability in the effectiveness and safety of low doses of opioids and the variability in the effectiveness and safety of high doses of opioids are not clearly defined. The clinician should maintain caution with higher doses in general.
- **Recommendation 7a:** Use the lowest effective opioid dose that balances benefits, risks, and adverse reactions. Physicians and other health care providers should individualize doses based on a carefully monitored medication trial by the patient, with frequent monitoring of analgesic effectiveness with each dose adjustment and with regular risk reassessment.
 - **Recommendation 7b:** Additional factors influence risk and benefit that should be considered; therefore, guidance regarding dose should not be applied as strict limits. Providers can use established and measurable goals such as functionality, ADL, and QoL measures.

8: The duration of pain following an acute, severely painful event such as trauma, surgery, or burn is widely variable.

- **Recommendation 8a:** Appropriate duration of therapy is best considered within guidelines, and then ultimately determined by the treating clinician. The CDC recommendation for duration of treatment should be emphasized as guidance only for a general approach, with individualized patient care as the primary goal and the clinician then considering all modalities for best outcomes.
- **Recommendation 8b:** Develop acute pain management guidelines for common surgical procedures and trauma management, as noted in Acute Pain Recommendation 2a.
- **Recommendation 8c:** To address this variability and provide an easy solution to the challenges of medication duration, consideration should be given to a partial refill system.

Acronyms

ABPM - American Board of Pain Medicine

ACGME - Accreditation Council for Graduate Medical Education

ACT - Acceptance and Commitment Therapy

ADF - Abuse-deterrent formulations

ADL - Activities of Daily Living

AHRQ - Agency for Healthcare Research and Quality

BT - Behavioral Therapy

CARA - Comprehensive Addiction and Recovery Act

CBP - Clinical Best Practice

CBT - Cognitive Behavioral Therapy

CDC - Centers for Disease Control and Prevention

CME - Continuing Medical Education

CMS - Centers for Medicare & Medicaid Services

COX - Cyclooxygenase

CPG - Clinical Practice Guideline

CPT - Current Procedural Terminology

CRPS - Complex Regional Pain Syndrome

DoD - U.S. Department of Defense

EAET - Emotional Awareness and Expression Therapy

ECHO - Extension for Community Healthcare Outcomes

ED - Emergency Department

EHR - Electronic Health Record

ERAS - Enhanced Recovery After Surgery

ESI - Epidural Steroid Injections

FDA - U.S. Food and Drug Administration

HHS - U.S. Department of Health & Human Services

HIS - Indian Health Service

IOM - Institute of Medicine

MBSR - Mindfulness-based Stress Reduction

MME - Morphine Milligram Equivalents

MS - Multiple Sclerosis

NIH - National Institutes of Health

NP - Nurse Practitioners

NSAID - Nonsteroidal Anti-inflammatory Drug

OB-GYN - Obstetricians and Gynecologists

OT - Occupational Therapy

OUD - Opioid Use Disorder

PA - Physician Assistant

PCP - Primary Care Physician

PDMP - Prescription Drug Monitoring Program

PNB - Peripheral Nerve Block

PRF - Pulse Radio-Frequency Lesioning

PSH - Perioperative Surgical Home

PT - Physical Therapy

PTSD - Post-traumatic Stress Disorder

QoL - Quality of Life

RCT - Randomized Clinical Trial

RF - Radio Frequency

SCD - Sickle-cell Disease
SNB - Sympathetic Nerve Block
SNRI - Serotonin and Norepinephrine Reuptake Inhibitor
SUD - Substance Use Disorder
TBI - Traumatic Brain Injury
TCA - Tricyclic Antidepressant
TENS - Transcutaneous Electrical Nerve Stimulation
TMJ - Temporomandibular Joint
TU - Therapeutic Ultrasound
UDT - Urine Drug Test
VA - U.S. Department of Veterans Affairs
VHA - Veterans Health Administration

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