

# Acute Pain Assessment and Opioid Prescribing Protocol

## Introduction Memo

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The prescribing of opioids for acute pain is a complex and controversial issue in health care. It affects providers, patients, policy makers and the general public. There is currently a gap between good clinical practice and current knowledge, thus creating a strain on our society's resources.

In June 2013, The Institute for Clinical Systems Improvement (ICSI) convened a work group to create a protocol addressing acute pain and opioid prescribing in adults (18 years and older). This effort grew out of ICSI's work on low back pain and discussions with the Minnesota Medical Association (MMA) and the Minnesota Council of Health Plans, all of which sought specific strategies for improving organizational and physician management of opioid prescribing. The group included several disciplines, including; addiction medicine, anesthesiology, dentistry, emergency medicine, family medicine, internal medicine, neurology, orthopedics, pain medicine, pharmacy, psychiatry, psychology and research science.

When assessing patients, providers are often faced with complex decisions and considerable uncertainty and must rely on the scientific literature, when available, but also on their knowledge, experience, and clinical judgment.

The work group found that although there was evidence for appropriate assessment and avoidance of excess opioid prescribing, there was a lack of evidence about how this should be done, and what steps should be taken by health systems, communities, and providers. The work group was in agreement that practice variation in prescribing opioids is a large roadblock and that a usable, practical document, including a work-flow algorithm, would assist in minimizing the overuse of opioids upstream and standardize the process.

Initial thoughts on how this could be implemented included:

- Communicate a clear and consistent opioid usage message for clinicians, that clarifies the benefits and risks for patients.
- Create educational materials for patients and consumers to understand the benefits and risks of opioid use.
- Use health care medical records, and the Minnesota Prescription Monitoring Program (PMP), to identify overprescribing.
- Document opioid prescriptions along with any additional risk factors or comorbidities in the patients medical records.

### **Outcome**

The group has decided that this protocol while, being a stand-alone document, can also best be used with other ICSI guidelines, including Assessment and Management of Chronic Pain, Diagnosis and Treatment of Headache and Adult Acute and Subacute Low Back Pain. This protocol will be reviewed for inclusion with the above-mentioned guidelines at their next revision.

### **2013 Work Group Members**

# ICSI Institute for Clinical Systems Improvement

## Health Care Protocol

### Acute Pain Assessment and Opioid Prescribing Protocol

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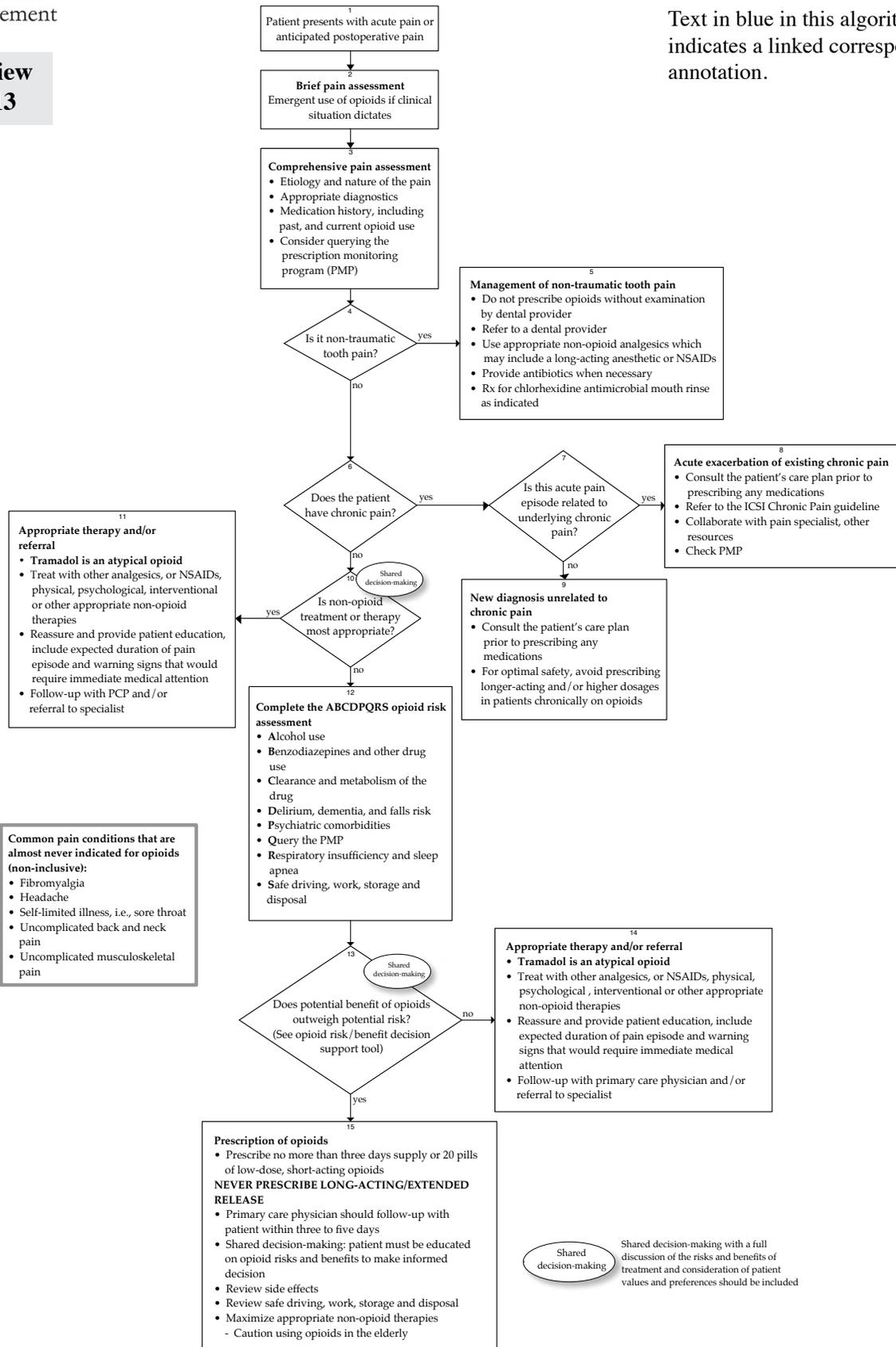
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# Acute Pain Assessment and Opioid Prescribing Protocol

Text in blue in this algorithm indicates a linked corresponding annotation.

**Critical Review**  
**August 2013**



## Table of Contents

<p><b>Work Group Leader</b>                  David Thorson, MD  <i>Sports Medicine, Entira Family Clinics</i></p> <p><b>Work Group Members</b></p> <p><b>Allina Medical Clinic</b>                  Justin Hora, PharmD  <i>Pharmacy</i></p> <p><b>Emergency Physicians, PA</b>                  Chris Johnson, MD  <i>Emergency Medicine</i>                  Susan Van Pelt, MD  <i>Emergency Medicine</i></p> <p><b>Essentia Health</b>                  Faris Keeling, MD  <i>Psychiatry</i></p> <p><b>Fairview Health Services</b>                  Anne Kokayeff, MD  <i>Pain Medicine</i></p> <p><b>HealthPartners Medical Group and Regions Hospital</b>                  Bret Haake, MD  <i>Neurology</i>                  Mary Pat Noonan, PhD, ABPP  <i>Clinical Psychology</i></p> <p><b>Hennepin County Medical Center</b>                  Charles Reznikoff, MD  <i>Internist, Addiction</i></p> <p><b>Hutchinson Health</b>                  Brian Bonte, DO  <i>Family Medicine</i></p> <p><b>MAPS Medical Pain Clinic</b>                  Marsha Thiel, RN, MA  <i>Pain Medicine</i>                  Anne Trujillo, RN, CNP  <i>Pain Medicine</i></p> <p><b>Mayo Clinic</b>                  Michael Hooten, MD  <i>Anesthesiology</i></p> <p><b>Minneapolis VA Health Care System</b>                  Erin Krebs, MD, MPH  <i>Internal Medicine</i></p> <p><b>Minnesota Dental Association</b>                  John Wainio, DDS  <i>General Dentistry</i></p> <p><b>Physicians Neck and Back Clinic</b>                  Brian Nelson, MD  <i>Orthopedics</i></p> <p><b>Twin City Orthopedics</b>                  Paul Biewen, MD  <i>Physical Medicine and Rehabilitation</i></p> <p><b>ICSI</b>                  Howard Epstein, MD  <i>Chief Health Systems Officer</i>                  Carmen Hansen, RN, BSN  <i>Project Manager</i>                  Cassie Myers  <i>Clinical Systems Improvement Facilitator</i></p>	<p><b>Algorithms and Annotations</b> ..... 1-21</p> <p style="padding-left: 20px;">Algorithm .....1</p> <p style="padding-left: 20px;">Evidence Grading .....3</p> <p>Foreword</p> <p style="padding-left: 20px;">Introduction ..... 4-5</p> <p style="padding-left: 20px;">Scope and Target Population.....5</p> <p style="padding-left: 20px;">Aims ..... 5-6</p> <p style="padding-left: 20px;">Implementation Recommendation Highlights .....6</p> <p style="padding-left: 20px;">Related ICSI Scientific Documents .....6</p> <p style="padding-left: 20px;">Definitions.....6</p> <p style="padding-left: 20px;">Annotations ..... 7-21</p> <p><b>Quality Improvement Support</b> ..... 22-27</p> <p style="padding-left: 20px;">Aims and Measures ..... 23-25</p> <p style="padding-left: 20px;">Implementation Recommendations .....26</p> <p style="padding-left: 20px;">Implementation Tools and Resources.....26</p> <p style="padding-left: 20px;">Implementation Tools and Resources Table .....27</p> <p><b>Supporting Evidence</b>..... 28-35</p> <p style="padding-left: 20px;">References ..... 28-32</p> <p style="padding-left: 20px;">Appendices ..... 33-35</p> <p style="padding-left: 40px;">Appendix A – Sample Opioid Prescription Informed Consent.....33</p> <p style="padding-left: 40px;">Appendix B – Scripting Support for Saying No to a Patient and an Opioid Prescription..... 34-35</p> <p><b>Disclosure of Potential Conflicts of Interest</b> ..... 36-39</p> <p><b>Acknowledgements</b>..... 40-41</p> <p><b>Document History and Development</b> ..... 42-43</p> <p style="padding-left: 20px;">Document History .....42</p> <p style="padding-left: 20px;">ICSI Document Development and Revision Process .....43</p>
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## **Evidence Grading**

### **Literature Search**

A consistent and defined process is used for literature search and review for the development and revision of ICSI protocols. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are opioids: prescribing, acute pain management, misuse, abuse, tolerance, addiction, overdosing, cost, diversion, pain specialists and risk assessments and include literature from May 2010 through May 2013.

### **GRADE Methodology**

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international protocol developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

### **This document is in transition to the GRADE methodology**

Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available Systematic Reviews in literature searches.
- All new literature considered by the work group for this revision has been assessed using GRADE methodology.

# Foreword

## Introduction

Pain is an unavoidable part of the human experience. Everyone will experience pain sometime and most likely, multiple times in his or her lifetime. Each experience is unique to that person, and unique to that specific interaction with pain. While the patient is feeling the pain, there is no way to objectively quantify pain: the reality, severity, and intensity of pain. Clinicians are challenged to help patients effectively manage pain while identifying its source.

In the last 20 years, pain management theory promoted pain as the "fifth vital sign," and recommended aggressive treatment of pain, including the prescription of opioids. In support of this direction, medical and specialty bodies have developed guidelines supportive of the use of opioids. Within that pain management milieu, there has been a 10-fold increase in opioid prescriptions in the last 20 years (*U.S. Department of Health and Human Services, 2011 [Reference]*). The CDC estimates that enough prescription painkillers were prescribed in 2010 to medicate every American adult around-the-clock for a month (*Centers for Disease Control and Prevention, 2011 [Reference]*).

The statistics are staggering:

- Americans, which comprise 5% of the world's population, consume 80% of the opioid world's supply.
- The cost of prescribing opioids is significant. Sales of opioids are up 110% from \$3.97 billion in 2001 to \$8.34 billion in 2012.
- At Hazelden, a drug treatment facility in Minnesota, the portion of patients treated for painkiller or heroin addiction nearly tripled, to 41% in 2011 from 15% in 2001. Average cost for four to six weeks of inpatient treatment at private facility can range from \$20,000 to \$32,000.
- U.S. emergency room costs are affected. Cases related to opioids increased 299,498 in 2004 to 885,348 in 2011.
- Urine toxicology screening is increasing. The size of U.S. screening industry estimate in 2000 was \$800 million and in 2013, \$2 billion.

While some costs can be quantified, the more difficult thing to measure is the human toll as addiction rises, families struggle and are fractured, diversion of prescription drugs to the street and to our youth, and death rates from poisoning and overdose continue to rise. Although most people take prescription medications responsibly, an estimated 52 million people (20% of those, ages 12 and older) have used prescription drugs for nonmedical reasons at least once in their lifetime (*U.S. Department of Health and Human Services, 2011 [Reference]*; *Substance Abuse and Mental Health Services Administration, 2007 [Low Quality Evidence]*).

Everyday, 2,500 youth (ages 12-17) abuse a prescription pain reliever for the very first time. "In Minnesota, unintentional poisoning/drug deaths will soon exceed motor vehicle traffic deaths" (*Minnesota Department of Human Services, 2012 [Guideline]*). When access to prescription opioids dwindles, desperate users will turn to illicit drugs to obtain the same effect. State trends show a rise in heroin and opioid addiction from treatment admissions data in both metro and out state areas, (*Minnesota Department of Human Services, 2012 [Guideline]*) and many from diverted prescription opioids.

In a 2009 survey, it was reported that the majority of the opioids were prescribed by multiple specialties, including family practice, internal medicine, dentistry, emergency medicine, and orthopedic surgeons, rather than pain physicians. Primary care physicians prescribed 42% of immediate release opioids and 44% of long-acting opioids, whereas specialties identified as pain management, including anesthesiology and physical

## Foreword

medicine and rehabilitation, contributed to 6% of immediate release opioids and 23% of long-acting opioids (Volkow, 2011 [Low Quality Evidence]).

All of these factors contribute to the current state of opioid use, misuse and abuse in the country. Many states have mandated opioid prescription management and monitoring reform for chronic pain and/or mobilized interagency departments to address the issues and create systemic and statewide change (*Utah Department of Health, 2008 [Guideline]; Washington State Agency Medical Directors, 2010 [Guideline]*). The state of Minnesota has also created a comprehensive substance abuse strategy (<https://edocs.dhs.state.mn.us/lfserver/public/DHS-6543-ENG>) and organizations throughout the state are focusing efforts on improving processes that support appropriate prescribing, monitoring, treatment alternatives, care planning, patient contracts and care management.

The opioid epidemic has focused attention on the management of the chronic pain patient who continues to seek relief. Yet, the chronic pain patient on opioids potentially began as an acute pain patient. The opioid tidal wave must also be stemmed upstream with an individualized patient approach, appropriate prescribing for the right conditions, limits on dose and quantity of pills and maximum prescription duration, careful assessment and diagnosis of the etiology of pain, alternative therapies to manage pain, as well as, patient education of the risks and benefits of opioids and shared decision-making about treatment options. This can only be successful with community agreement, commitment to a structured protocol and development of effective communication strategies across organizations coordinating care across the health care continuum.

## Scope and Target Population

This protocol will include recommendations for acute pain assessment, risk assessments, therapies and treatment options, and conservative opioid prescribing for:

- the adult, non-cancer, acute and subacute pain outpatient;
- the adult, non-cancer chronic pain patient experiencing unrelated acute pain; and
- the adult, non-cancer patient with acute exacerbation of chronic pain.

The target population is the adult (18 years and older) non-cancer, acute or subacute pain outpatient.

## Aims

1. Increase the rate of non-cancer patients 18 years and older who present with acute or subacute pain in outpatient care settings who have comprehensive pain assessment that includes all of the following: general history and physical, etiology and nature of the pain, appropriate diagnostics, and evaluation and treatment for acute conditions. (*Annotation #3*)
2. Increase the rate of adult patients 18 years and older with appropriate medication management of non-traumatic tooth pain. (*Annotation #5*)
3. Increase the rate of adult patients 18 years and older with chronic pain who are appropriately managed for acute exacerbation. (*Annotation #8*)
4. Increase the rate of adult patients 18 years and older who are already on opioids who are appropriately managed for acute pain. (*Annotation #9*)
5. Increase the rate of adult patients 18 years and older who are prescribed therapies other than opioids for treatment of acute or chronic pain. (*Annotation #11*)

## Foreword

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6. Decrease the rate of adult patients 18 years and older at risk for opioid contraindications or adverse effects. (*Annotation #12*)
7. Increase the rate of adult patients 18 years and older who are prescribed opioids who have a timely follow-up with clinician. (*Annotation #15*)

## Implementation Recommendation Highlights

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

- Communicate a clear and consistent opioid usage message for clinicians that clarifies the benefits and risks for patients.
- Create educational materials for patients and consumers to clarify the benefits and risks of opioid use.
- Use health care medical records, and the Minnesota Prescription Monitoring Program (PMP) to identify overprescribing.
- Document opioid prescriptions along with any additional risk factors or comorbidities in the patient medical records.

## Related ICSI Scientific Documents

### Guidelines

- Adult Acute and Subacute Low Back Pain
- Assessment and Management of Chronic Pain
- Diagnosis and Treatment of Headache
- Preoperative Evaluation

### Protocols

- Perioperative Protocol

## Definition

**Clinician** – All health care professionals whose practice is based on interaction with and/or treatment of a patient.

## Algorithm Annotations

### 2. Brief Pain Assessment

In the emergency setting, the work group recommends judicious use of opioids to alleviate pain when it overwhelms the patient's ability to contribute to the assessment process.

### 3. Comprehensive Pain Assessment

All patients have the right to an adequate assessment that includes general history and physical, etiology and nature of the pain, appropriate diagnostics, evaluation and treatment for acute conditions. This assessment is important in identifying the onset and progression of the pain and may help focus diagnosis and treatment of the source of the pain. Document pain location, intensity, and quality of the patient's pain, and potentially the patient's pain score.

However, since the initiation of standards for pain evaluation, including a pain scale and evidence of responsive treatment by JCAHO in 1999, there has been minimal assessment evaluating the effect of this heightened measurement and activity around aggressive pain management. While the use of the visual analog pain scale is widespread, concern has risen regarding its accuracy and the appropriate response to scores (*Krebs, 2007 [Low Quality Evidence]*).

Past literature identifies that while pain screening, using a numeric pain scale, or developing pain management standards within an organization, increases the rate of pain assessments used it doesn't seem to affect treatment prescriptions or levels of pain (*Fraenkel, 2011 [Low Quality Evidence]*; *Mularski, 2006 [Low Quality Evidence]*; *Narasimhaswamy, 2006 [Low Quality Evidence]*).

A numeric pain scale to assess patient perception of pain, can be valuable as a measure for pain improvement over time, but responding only to the pain score by prescribing opioids, is problematic. Pain perception is multifactorial and the clinician should obtain additional contextual information from the patient regarding their experience and limitations with the pain, as well as psychosocial issues potentially contributing to pain.

An editorial from the American Academy of Pain Medicine suggests that analgesia is often equated with administering more opioid, rather than careful individualized assessment, planning, and multimodal treatment approaches (*Burgess, 2006 [Low Quality Evidence]*). Responding to a pain score with aggressive treatment may not be safe; therefore, not in the patient's best interest (*Vila, 2005 [Low Quality Evidence]*).

#### Appropriate Diagnostics

While the use of diagnostics for evaluation and treatment may be useful, it is important to remember that finding pathology on diagnostic tests does not necessarily prove that the identified pathology is causing the patient's pain. Therefore, it is important to complete appropriate diagnostics and use evidence-based guidelines when possible.

#### Medication History, Including Past and Current Opioid Use

Because it is difficult to truly assess a patient's past opioid prescription history, consider querying the Minnesota Prescription Monitoring Program (PMP). Current use of the PMP is growing and can offer a clinician an opportunity to identify concerns about prescription opioids if patient is a poor historian or is not forthcoming.

## 5. Management of Non-Traumatic Tooth Pain

- Do not prescribe opioids without an examination and diagnosis by a dental provider. Opioids can mask pain and allow the patient to ignore a potential underlying serious dental problem, such as an abscess.
- Refer to a dental provider and assist with access and follow-up when possible.
- Use appropriate non-opioid analgesics, which may include:
  - Long lasting local anesthetic (up to eight hours).
  - Use non-opioid pain medication such as NSAIDS, which can be very effective for dental pain.
  - Providing antibiotics when necessary; upon the presence of swelling or exudates in the cheek, jaw or gum tissue.
  - Providing prescription for chlorhexidine antimicrobial mouth rinse when indicated, which can help with localized gum inflammation and infection and soothe pain in gum tissue.
  - Provide topical anesthetic rinse when indicated, or upon presence of stomatitis, mucositis or mouth ulcers.

Patients often seek dental care in medical facilities because they are more accessible and may not be able to refuse treatment. Collaboration is needed between the medical and dental community to help patients access a dental provider that can provide dental care that allows for diagnosis, appropriate treatment, and typically would not necessitate the use of opioid medications. When deemed absolutely necessary, the dental provider should prescribe opioid medication, but only *after* an examination and diagnosis of the dental complaint.

The Minnesota Dental Association recognizes that a clinician should always use clinical judgment to provide the most appropriate and comprehensive care for the individual patient.

### Referral and Treatment Strategies for the Medical Community

- Recognize local and systemic diseases that need treatment by a medical clinician.
- Evaluate medical history and any concerns that may affect having a dental treatment referral.
- Actively use the Minnesota Prescription Monitoring Program and convey any concerns to dental provider.
- Determine patient's intent to seek dental care and assist with access when possible. Follow-up should be as soon as possible, as dental infection or abscess can progress rapidly.
- Maintain an updated list of dental providers in the area, as provided by the Minnesota Dental Association and affiliates.

## 8. Acute Exacerbation of Existing Chronic Pain

- Consult the patient's care plan, prior to prescribing any medications
- Refer to the ICSI Assessment and Management of Chronic Pain guideline
- Collaborate with pain specialist, other resources
- Check Prescription Monitoring Program (PMP) for history of opioid prescriptions

It is important to identify the source of pain rather than just treating for acute pain, since treatment for the chronic pain patient can be significantly different. If at all possible, review the patient's pain plan or consult with a pain specialist about other options that would promote relief without complicating the current medication and/or therapy prescribed for the patient.

## Algorithm Annotations

Because of potential risks and adverse effects, clinicians are encouraged to avoid prescribing increased dosage or additional opioids. Assess the patient's mental health status and social situation to determine if additional resources, i.e., social services, behavioral health, pain management or addiction medicine consult may be appropriate.

Include supportive family and/or caregivers, as identified by the patient, in shared decision-making.

### Opioid Withdrawal Presenting as Acute Pain

Consider opioid withdrawal when evaluating opioid-tolerant patients who present with acute pain complaints or gastrointestinal symptoms. Opioid withdrawal can occur when patients stop their medications, have an opioid use disorder (e.g., heroin addiction), or have lost or overused their medications. Patients are often reluctant to share this information with their clinician. Opioid withdrawal presents with anxiety 12 hours after the last dose, and becomes physically detectable 24 hours after the last use of short-acting opioids. Withdrawal from long-acting opioids becomes physically detectable at 48 hours after last use. In a given patient, the manifestation of opioid withdrawal is individual. Opioid addicts should not be given opioids for treatment of withdrawal, but rather referred to a treatment or detox center, per direction from the U.S. DEA Diversion Program. Patients on opioids chronically for pain often have an opioid contract, and these contracts usually have a plan in case the patient runs out of their medications early. Unless the patient is otherwise medically unstable, withdrawal is not life threatening, but may be very distressing. Reassurance and comfort measures are appropriate treatments (*Wesson, 2003 [Low Quality Evidence]; Isbell, 1947 [Low Quality Evidence]*).

## 9. New Diagnosis Unrelated to Chronic Pain

- Consult the patient's care plan or prescribing clinician, prior to prescribing any medications.
- For optimal safety, avoid prescribing long-acting and/or higher dosages in patients chronically on opioids.

Often, patients receiving chronic opioids have a pain management care plan, and this plan should be consulted prior to prescribing opioids for acute pain. The safest course in an unmonitored outpatient setting is to treat acute pain in the opioid-using patient with the same dose and number of pills as in the opioid naïve patient. This strategy improves safety at the risk of suboptimal pain management.

Dosing opioids for acute pain in a patient already on opioids is problematic. The patient may require a higher dose to achieve the same analgesic effect. The higher dose puts the patient at greater risk for an adverse event. Predicting the safe additional opioid dose in such a patient is complex, and dependent on variables that are unique to the patient and difficult to predict. Many such patients will achieve adequate analgesia from normal dosing of opioids. Patients chronically on opioids do not require a longer than normal course of treatment for acute pain.

Due to the paucity of evidence and the ongoing discussion and debate on this subject, the work group felt that the safest course in an unmonitored outpatient setting is to treat acute pain in the opioid-using patient with no greater dose or number of pills as the opioid-naïve patient. This strategy improves safety at the risk of suboptimal pain treatment.

## 10. Is Non-Opioid Treatment or Therapy Most Appropriate?

Opioids are not as effective in pain management as once believed. While pain management with opioids has been prevalent and promoted historically, recent studies have demonstrated that opioids are being used inappropriately, thus leading to dependence, long-term use and improper disposal.

In one study, preoperative factors for patients with chronic pain, including opioid experience, depressive symptoms and increased self-perceived risk of addiction, were associated more with length of opioid use than the experience of pain (*Carroll, 2012 (Low Quality Evidence)*).

## Algorithm Annotations

Another study showed that opioid dosage for treatment of acute low back pain, continued to escalate with pure formulations but was unrelated to clinical severity or surgery (*Cifuentes, 2010 [Low Quality Evidence]*). In a retrospective cohort study, an opioid prescription received within seven days from surgery was 44% more likely to result in long-term opioid use within one year (*Alam, 2012 [Low Quality Evidence]*).

Many patients fill their opioid prescriptions and do not use them for their intended purpose. A 2013 study showed that 35% of the 72 patients studied did not use the pain medicine prescribed. Forty-nine of fifty-seven patients (86%) who filled an opioid prescription had leftover pills and 26 of the 49 patients (53%) planned to keep them, potentially increasing the possibility of diversion (*Harris, 2013 [Low Quality Evidence]*).

### **Opioids actually change the chemistry of the brain and it's response to pain.**

- Homeostatic adaptations within the CNS to opioid exposure may contribute to the development of tolerance (*Christie, 2008 [Low Quality Evidence]*).
- Opioids profoundly influence the synaptic plasticity that underlies learning and memory, leading to the potential development of addiction (*Christie, 2008 [Low Quality Evidence]*).
- Opioids may lead to an enhanced pleasurable effect (*Kosten, 2002 [Low Quality Evidence]*).
- Opioids may cause increased neuropathic pain (*Trescot, 2008 [Low Quality Evidence]*).
- Opioids suppress the release of noradrenaline causing drowsiness, reduced respirations and lower blood pressure (*Kosten, 2002 [Low Quality Evidence]*).
- Opioids lead to the release of excitatory neuropeptides that cause peripheral nociceptive stimulation (*Lee, 2011 [Low Quality Evidence]*).
- Opioid-induced hyperalgesia (OIH), defined as a state of nociceptive sensitization caused by exposure to opioids, may develop resulting in increased sensitization to painful stimuli (*Lee, 2011 [Low Quality Evidence]*).

This may clinically manifest as apparent opioid tolerance, worsening pain despite accelerating opioid doses and abnormal pain symptoms such as allodynia (*Chou, 2009 [Guideline]; Angst, 2006 [ ]*).

### **Additional opioid adverse effects**

- Gastrointestinal effects (*Kurz, 2003 [Guideline]*)
  - Constipation
  - Anorexia
  - Bloating
  - Nausea/vomiting
  - Abdominal cramping
- Respiratory effects (*Koo, 2011 [Low Quality Evidence]*)
  - Decrease central drive to respiratory pump muscles and upper airway dilator muscles
  - Suppress gag reflex
  - Reduce frequency of respirations
  - Alter normal breathing rhythm
  - Inhibit brain stem arousal centers

**Algorithm Annotations**

- Blunt response to hypoxia and hypercapnia
- Effects on sleep (*Dimsdale, 2007 [Low Quality Evidence]*)
  - Increase percentage of time spent in light sleep
  - Decrease percentage of time spent in deep sleep
- Bladder effects (*Benyamin, 2008 [Low Quality Evidence]*)
  - Decrease detrusor muscle tone and force of contraction
  - Decrease sensation of fullness and urge to void
  - Inhibit voiding reflex
- Immunologic effects (*Benyamin, 2008 [Low Quality Evidence]*)
  - Inhibit cellular immune responses, natural killer cell activity, cytokine expression and phagocytic activity
- Endocrine effects (*Vuong, 2010 [Guideline]*)
  - Inhibit ACTH and cortisol secretion causing a decreased glucocorticoid response
  - Inhibit LH and gonadotropin releasing hormone secretion resulting in lower steroid hormone levels
  - Inhibit estradiol and testosterone secretion resulting in hypogonadism, menstrual irregularities, sexual dysfunction, infertility and osteoporosis
  - Inhibit insulin secretion leading to hyperglycemia and worsening diabetes

**Patient education and shared decision-making**

Recently published research demonstrates the effectiveness of pre-surgical patient education regarding the physiology of pain and the side effects of opioids. Of those patients who received the preop education, 90% declined taking home a hydrocodone prescription, pain scores and duration of pain were significantly lower than those patients who did not receive the pain physiology education. Further research in this area is needed (*Sugai, 2013 [Low Quality Evidence]*).

It is critical to spend time with the patient and review the benefits and risks to any treatment or therapy. Additional information about shared decision-making, and the ICSI shared decision-making model, can be found on the ICSI Web site, "Shared Decision-Making Model."

**11. Appropriate Referral and/or Therapy**

- **Tramadol is an atypical opioid.**

It is not a controlled substance in the U.S., but has some properties similar to opioids, but others that differ. While it is efficacious for fibromyalgia, it has some potential for abuse. Clinicians should prescribe appropriately and follow-up with the patient to verify effectiveness and correct usage.

- **Treat with other analgesics, or NSAIDs, physical, psychological, interventional or other appropriate non-opioid therapies.**

Prescribing non-opioid analgesics for pain and/or therapies that would support pain relief, improved function or healing should be the first consideration. Some types of pain would be better managed with alternative medications such as gabapentin for neuropathy or calcitonin for bone pain associated with

## Algorithm Annotations

osteoporosis. However, NSAIDs and other anti-inflammatories are not without their limitations and side effects. For some conditions they may prevent healing, and should be prescribed judiciously (*Stovitz, 2003 [Low Quality Evidence]*). Provide risks and benefits for all options for the patient to guide discussion and support shared decision-making.

Identification of appropriate treatment must also include evaluation of ADLs, work situation and psychosocial needs. If available, include supportive family members and/or caregivers, as identified by the patient, in the discussion. Include the type of treatment/therapy in the patient's plan of care and provide this information to the clinician who will be providing follow-up care.

For additional information on evidence-based treatment modalities for pain, see the ICSI Assessment and Management of Chronic Pain guideline.

- **Reassure and provide patient education, and include expected duration of pain episode, and warning signs that would require immediate medical attention.**

With many acute pain situations, the clinician can help the patient anticipate the endpoint for pain. For instance, viral infections have an endpoint, or a broken bone has a point where the pain should be subsiding. It is important to identify that with the patient so that the patient knows what to expect. This can also be the beginning point for reassessment should pain continue.

Patients should be encouraged to follow-up with their primary care physician or be referred to behavioral health or pain specialist as needed.

## 12. Complete the ABCDPQRS Opioid Risk Assessment

The mnemonic ABCDPQRS provides a simple way to remember contraindications to opioids.

### Alcohol Use

Alcohol impairs respiration when combined with opioids, affecting judgment and memory, all of which puts the patient at increased risk for accidental overdose and trauma. There is no known safe dose of alcohol in a patient on opioids, particularly when the patient is newly-prescribed opioids or a higher dose than normal. The safest recommendation for patients on new, or higher than baseline, doses of opioids is to abstain from alcohol altogether.

In a patient using opioids for pain, an alcohol use disorder confers particular risk: when combining alcohol and opioids in an unsafe manner or using opioids inappropriately even the absence of alcohol use. Two useful and simple screenings tools are seen below. For patients who have a positive screen, a deeper evaluation for an alcohol use disorder is indicated. For those with at-risk alcohol use, but not an alcohol use disorder, consider a brief intervention. For those with an alcohol use disorder, treatment in primary care or referral to addiction treatment is indicated (*Bohnert, 2011 [Low Quality Evidence]*; *Feldman, 2011 [High Quality Evidence]*).

### Screening tools

One simple screening tool uses two questions to assess for alcohol and drug use disorders in the primary care and emergency settings:

"How many times in the past year have you had 5 or more drinks (if male) 4 or more drinks (if female) in a day?" A response of  $\geq 1$  is considered positive.

"How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?"

## Algorithm Annotations

A response of  $\geq 1$  to either question is considered positive. A positive screen does not diagnose substance use disorder, but suggests a problem, and warrants caution in prescribing opioids. The link below is a simple pocket guide for this issue.

[http://pubs.niaaa.nih.gov/publications/Practitioner/pocketguide/pocket\\_guide5.htm](http://pubs.niaaa.nih.gov/publications/Practitioner/pocketguide/pocket_guide5.htm)

A three question screening tool for hazardous alcohol use is the AUDIT-C. This tool is also well validated and can be seen at the link below:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2517893/>

### SBIRT Model for Substance Use

For those patients who have a positive screen for misuse of drugs or alcohol, Screening, Brief Intervention, Referral to Treatment (SBIRT) is a comprehensive and integrated approach to the delivery of early intervention and treatment services. SBIRT reduces alcohol consumption and alcohol related harm when done in the outpatient or emergency department settings. Additional information can be obtained at ICSI SBIRT Model and Implementation and <http://www.samhsa.gov/prevention/sbirt/>.

### Benzodiazepines and Other Drug Use

Like alcohol, benzodiazepine (BZD) use, concurrent with opioid use, increases the risk of over-sedation, overdose and trauma. Patients using BZDs and opioids should be counseled not to combine these medications. The BZD prescriber should be made aware of opioid prescriptions if possible. Patients on opioids and BZDs and with other risks of opioid-related adverse events (respiratory compromise, risk of falls, or substance use disorder) are at an even greater risk of these harms (*Centers for Disease Control and Prevention, 2013 [Guideline]*).

Opioid use disorder (i.e., heroin or pharmaceutical opioid addiction) makes management of pain with opioids highly problematic. Opioid prescriptions should be avoided in patients actively addicted to opioids, if at all possible. These patients should be referred to appropriate addiction treatment, including a methadone maintenance clinic or a buprenorphine clinician. Methadone maintenance clinic patients will not have their methadone dose titrated for analgesia. Patients enrolled and in good standing at a methadone maintenance clinic for opioid use disorder, (including heroin) can be treated for acute pain with normal opioid dosing. It is recommended to obtain a release of information to coordinate care with the patient's methadone maintenance clinic. Buprenorphine containing products such as Suboxone, typically indicate that the patient has an opioid use disorder and is in treatment. Naltrexone, an opioid receptor antagonist, is indicated for the treatment of both alcohol and opioid use disorders. Recent buprenorphine or naltrexone use will block the analgesic effects of opioids, and could precipitate opioid withdrawal. Thus when treating a patient on buprenorphine or naltrexone who has a strong indication for opioids, it is wise to consult the patient's addiction specialist to manage the interactions of the patient's medications. The addiction clinician will require a release of information for this communication (*Code of Federal Regulations, 2013 [Guideline]*; *Alford, 2006 [Guideline]*).

Marijuana (MJ) is the most common illicit substance used in America, and the only drug currently increasing in prevalence. Greater than 50% of Americans have used MJ; greater than 35% of high school seniors use MJ every year, per the Monitoring the Future Study, supported by the National Institute on Drug Abuse, a part of the National Institutes of Health. Cannabinoids have well established analgesic and anxiolytic effects (*Hosking, 2008 [Low Quality Evidence]*). Many patients now describe these "medicinal" effects as their motivation for use of MJ. However, long-term effects of MJ on pain are unknown; and when used long term, MJ is correlated with harmful neuropsychiatric effects (*Meier, 2012 [Low Quality Evidence]*). Despite common belief, MJ addiction does occur. Infrequent MJ users are seven times more likely to use pharmaceuticals illicitly than MJ non-users; daily MJ users are fourteen times more likely to use illicit pharmaceutical than MJ abstainers. There are no major pharmacologic interactions between MJ and opioids. MJ

## Algorithm Annotations

use is so pervasive that it is not practical to test every patient in acute pain for MJ. But those patients known to consume MJ regularly warrant more careful monitoring when prescribing opioids for pain (*Pesce, 2010 [Low Quality Evidence]; Reisfield, 2009 [Low Quality Evidence]; Ellickson, 2005 [Low Quality Evidence]*).

Further information can be accessed at the link below.

<http://www.samhsa.gov/data/nsduh/2k11results/nsduhresults2011.htm>

Cocaine use has been associated with increased risk of diversion of opioids. Any substance use disorder (including tobacco use) is associated with increased risk of aberrant behaviors. Any patient with a substance use disorder should be educated carefully about the risks of combining drugs, and overusing opioids, and should receive fewer pills, smaller doses, and follow-up within three to five days. A substance use disorder is not an absolute contraindication to opioids for pain. Also, lack of an observable substance use disorder does not suggest absence of risk of opioid adverse events. The dosing guidelines of this protocol (seen elsewhere) will generally be safe for all patients, with or without a substance use disorder (*Gudin, 2012 [Low Quality Evidence]; Jones, 2012 [Meta-analysis]; Liebschutz, 2010 [Low Quality Evidence]; Becker, 2009 [Low Quality Evidence]; Ives, 2006 [Low Quality Evidence]*).

Addiction (chemical dependence) has recently been redefined in the DSM-V as a "substance use disorder". A substance use disorder must cause clinically significant impairment and can manifest as mild (2-3 symptoms), moderate (4-5 symptoms) or severe (> 6 symptoms). Symptoms include:

1. The drug is taken in larger amounts and over longer periods of time than intended.
2. There is a persistent desire or unsuccessful attempts to cut down or control use.
3. A great deal of time is spent in activities to obtain, use or recover from the effects.
4. Craving or a strong desire for the substance.
5. Recurrent use resulting in failure to fulfill major roles at work, home or school.
6. Continued use despite having persistent or recurrent social or interpersonal problems.
7. Important social, occupational or recreational activities are given up or reduced.
8. Recurrent use in situations that are physically dangerous.
9. Use is continued despite knowledge of having persistent or recurrent physical or psychological problems likely to have been caused or exacerbated by the substance.
10. Tolerance: a need for increased amounts to achieve the desired effects.
11. Withdrawal: A syndrome developing after cessation characteristic to the specific substance.

Note: 10 and 11 do not count as criteria if they are due to a prescribed medication taken appropriately

### Clearance and Metabolism of the Drug

Many common opioids require renal clearance of active metabolites. Morphine and meperidine are toxic in renal insufficiency (GFR < 60). For patients with severely decreased renal function (GFR < 30), hydrocodone and oxycodone will have delayed elimination. Before prescribing opioids, consider whether the patient may be at risk of renal insufficiency and check the medical record for a recent serum creatinine.

Hepatic impairment, if severe, can affect the metabolism of many opioids. A dosage adjustment or change of dosing interval may be necessary for morphine, hydrocodone and oxycodone. For patients with impaired liver function, avoid acetaminophen. The safe dose of acetaminophen in liver impairment is not known, but two grams a day is a reasonable maximum. Half of the liver transplants in America are caused by acetaminophen-related liver failure; and half of those are caused by combination opioid/acetaminophen

## Algorithm Annotations

product overuse. Before prescribing a combination product evaluate the patient for possible liver impairment. If acetaminophen is not needed, do not prescribe the combination product (*Johnson, 2007 [Low Quality Evidence]*).

### Delirium, Dementia and Falls Risk

Patients on acute dosing of opioids are at an increased risk of falling and other forms of accidental trauma. This is particularly so for geriatric patients on opioids. For those patients with past falls, or at an increased risk of fracture, opioids should be used cautiously. Some guidelines suggest prescribers use half the normal initial dose when treating the elderly. Other CNS depressants such as anticholinergic medications, alpha adrenergic blockers, and benzodiazepines will compound the risk of falls and fractures in patients on opioids.

Opioids can precipitate a delirium in some patients. Patients at risk for opioid induced delirium include the elderly, patients with cognitive impairments, polypharmacy, advanced liver or kidney disease, or patients with prior episodes of delirium precipitated by opioids. Consider these factors when dosing opioids, and educate the patient and his/her family of the risks (*Manchikanti, 2012 [Guideline]*).

### Psychiatric Comorbidities

World Health Organization data obtained in primary care centers worldwide show that 22% of all primary care patients suffer from persistent debilitating pain and that these patients are four times more likely to have comorbid anxiety or depressive disorder than pain-free primary care patients (*Lépine, 2004 [Low Quality Evidence]*).

Opioids should be regarded as having powerful anxiolytic properties as well as analgesic properties. Opioids have no indication for mental health disorders, yet this anxiolytic effect is readily recognizable by the distressed patient. Psychic distress may exacerbate nociceptive (physical) pain, or be confused for physical pain. The most common reason for illicit opioid use in high school is for relief of anxiety. Many mental health disorders are correlated with increased opioid misuse, opioid related accidents, and accidental opioid overdose death. Post-traumatic stress disorder and childhood sexual trauma increase the risk of opioid-related adverse events tenfold. Depression and anxiety disorders (including generalized anxiety disorder, social anxiety disorder, and obsessive compulsive disorder) are known to increase the risk of opioid misuse and harm as well. Childhood attention deficit hyperactivity disorder is a risk for later pharmaceutical misuse. Opioid withdrawal can exacerbate psychotic symptoms (*Seal, 2012 [Low Quality Evidence]*; *Liebschutz, 2010 [Low Quality Evidence]*; *Fleming, 2008 [Low Quality Evidence]*; *Wasan, 2007 [Low Quality Evidence]*).

A mental health condition does not preclude opioid use for pain. But doctors prescribing opioids for pain should carefully consider if the pain reported is a surrogate for psychic distress. Patients with mental health disorders should be educated that they will experience psychic relief from the opioids – and that this relief is not the intended effect of the pain medication. Patients with untreated or under treated mental health disorders should be offered safe and appropriate psychiatric care. Before prescribing opioids to mentally ill patients, an assessment of suicide risk is wise. The Safe-T tool is recommended by the American Psychiatric Association practice guidelines at [http://www.integration.samhsa.gov/images/res/SAFE\\_T.pdf](http://www.integration.samhsa.gov/images/res/SAFE_T.pdf).

### Mental Health Screening Tools

The PHQ-2 is a two question screening tool well validated to screen for depression. A score greater than three has 82% sensitivity and 90% specificity for major depressive disorder.

"Over the past two weeks how often have you been bothered by any of the following?" (on a 0 through 3 scale)

- Little interest or pleasure in doing things
- Feeling down, depressed or hopeless

(*Gilbody, 2006 [Low Quality Evidence]*)

## **Algorithm Annotations**

The GAD-2 also has high sensitivity and specificity for anxiety disorders. The GAD-2 has a similar introduction and scoring but the questions are:

- Feeling nervous, anxious or on edge
- Not being able to stop or control worrying

(Kroenke, 2007 [1])

### **Query the Prescription Monitoring Program**

Query the Minnesota Prescription Monitoring Program (PMP) when prescribing opioids for an acute pain condition. In greater than 50% of acute pain visits the patient has already received an opioid for that pain within one month from a different clinician. The PMP lists all controlled substances filled in this state in the last 12 months. Prescriptions from methadone maintenance clinics, Indian Health Services, long term care facilities, and the Veterans Administration pharmacy are currently not included. Non-prescribers (administrative help, nurses, interns) can query the PMP as a physician proxy in order to expedite the process (Volkow, 2011 [Low Quality Evidence]; Gugelmann, 2011 [Low Quality Evidence]; Paulozzi, 2011 [Low Quality Evidence]; Wang, 2009 [Low Quality Evidence]).

See the link below to register and/or access the database.

<http://pmp.pharmacy.state.mn.us/>

For information about monitoring programs within your state or country, contact your pharmacy board.

### **Respiratory Insufficiency and Sleep Apnea**

Patients with hypoxia, hypercapnea, or conditions or medications that affect their drive to breathe will be at an increased risk of respiratory insufficiency and respiratory arrest on opioids. Common conditions to consider include sleep apnea, chronic obstructive pulmonary disease, congestive heart failure, and concurrent use of benzodiazepines, alcohol or barbiturates. Sleep apnea is a commonly missed diagnosis, and the symptoms of this disease are often not readily apparent to the patient or physician. Opioids likely exacerbate both obstructive and central sleep apnea.

### **Safe Driving, Work, Storage, Disposal**

Minnesota law states that driving under the influence of a controlled substance or having any amount or the metabolites of a schedule two controlled substance constitutes a DWI. Aside from the legal implications, it is unsafe to drive on new or newly-increased doses of opioids, let alone attempting to drive while in acute pain. For this reason, any patient receiving opioids for pain should be instructed not to drive within 24 hours of taking opioids, or when having a severe episode of pain. Similarly, work, parenting and other duties requiring concentration and coordination will be impaired by opioids and by acute severe pain itself. Patients in acute pain, especially if receiving opioids, should be instructed to avoid sole parenting duties and work responsibilities until 24 hours from their last dose and when the pain becomes manageable.

To access a hard copy, see the link below.

<http://www.house.leg.state.mn.us/hrd/pubs/dwiover.pdf>

Ten percent of high school seniors report using opioids illicitly every year, and 24% have used pharmaceuticals illicitly in their life per the Monitoring the Future Study, supported by the National Institute of Drug Abuse, a part of the National Institutes of Health. Of remainder opioids stored in the household medicine cabinet, 50% of the time, opioids have been taken from this supply unbeknownst to the intended user. One fourth of illicit opioid users identify their source as taking opioids from a relative or a friend without asking,

## **Algorithm Annotations**

per the 24th Annual Partnership Attitude Tracking Study, 2013. For additional information, see <http://www.drugabuse.gov/sites/default/files/rrprescription.pdf>. Numerous deaths have occurred when a toddler has accidentally consumed opioids that were improperly stored. Opioids should be kept in a spot where only the intended user can obtain them, ideally in a lock box, a locked drawer, or a safe to which only the patient has a key. Provide the patient with education and information to take home. See the Implementation Tools and Resource Table for additional patient information.

Once the patient has completed his/her opioids for pain, they should be disposed of safely and promptly. Saving the remainder for future possible pains, or sharing the medications with friends and family is illegal and unsafe. The FDA now suggests that Schedule II medications be flushed down toilets due to safety concerns. Other pharmaceuticals can be combined with unpalatable substances (e.g., used coffee grounds) in a bag and thrown away. Nearly every county in Minnesota has an anonymous drop box where patients can dispose of unwanted pharmaceuticals. See below for further details on disposal. <http://rxdrugdropbox.org/>

Patients in acute pain may have difficulty understanding or remembering important safety information and should be provided with written safety instructions, and if possible inform their family of the safety issues surrounding opioids use.

Organizations may consider an informed consent approach to encourage patient responsibility in the use and storage of opioids. (See Appendix A, "Sample Opioid Prescription Informed Consent.")

### **Additional consideration – urine toxicology screen**

To verify the patient report of current substance use, a urine toxicology screen may be considered. If the patient has a history of substance use, a record of urine toxicology results will aid addiction clinicians in the process of assessing the patient and referring to addiction treatment. Urine toxicology screening during a pain crisis is often part of the care plan for patients on a chronic pain contract. Standard urine toxicology is done by immunoassay, and is fraught with false positives and false negatives. When interpreting this test consult with a toxicologist or a knowledgeable clinician (*Manchikanti, 2010 [Low Quality Evidence]*; *Pergolizzi, 2010 [Low Quality Evidence]*; *Reisfield, 2007 [Low Quality Evidence]*).

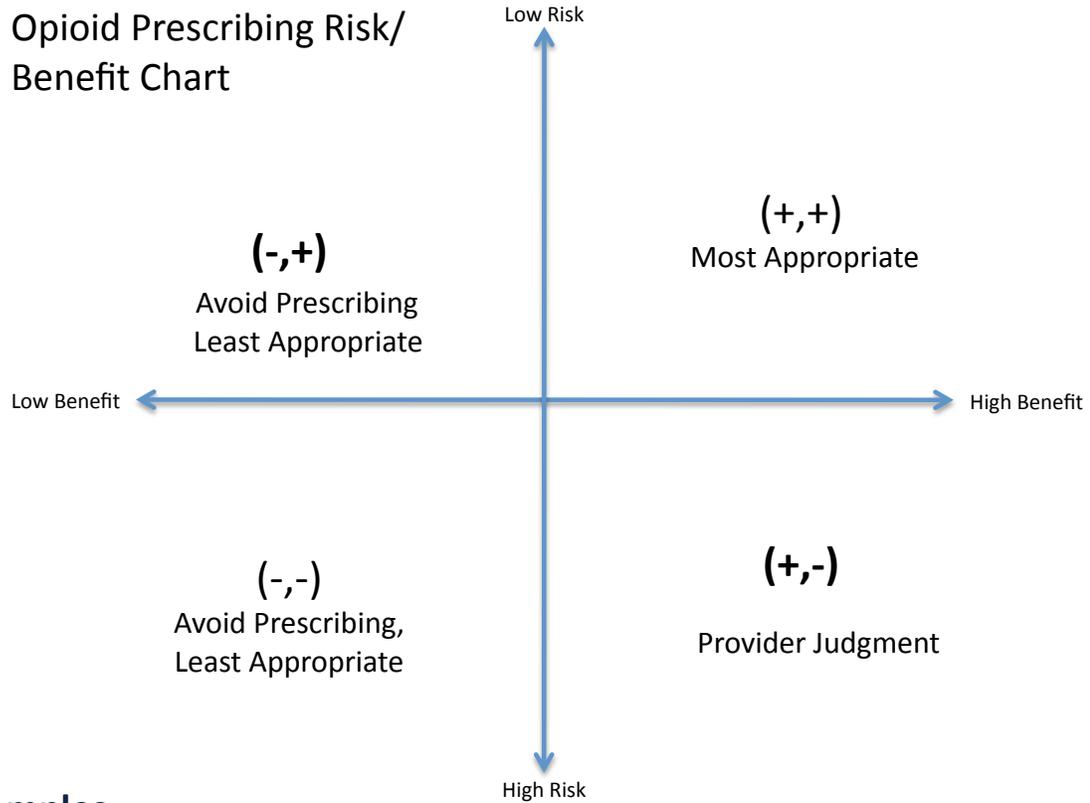
## **13. Does Potential Benefit Outweigh Potential Risk?**

**Clinicians should assure the benefit clearly outweighs the risk, when prescribing opioids.**

The work group discussed the need not only to assess the patient's perception of pain, but also consider the severity of the injury/condition. In tandem, patient risk for adverse effects and potential harm from opioids should also be considered. The graph below is a way to assess the appropriateness of opioid prescription by understanding the continuum of risk and benefit.

Algorithm Annotations

Risk Benefit Graph



Examples

Condition	Risk Factors	Appropriateness
Pancreatitis	None	(+,+) High Benefit, Low Risk= <b>Most Appropriate</b>
Pancreatitis	Alcoholic	(+,-) High Benefit, High Risk= <b>Provider Judgment</b>
Fractured Ankle	None	(+,+) High Benefit, Low Risk= <b>Most Appropriate</b>
Fractured Ankle	Sleep Apnea	(+,-) High Benefit, High Risk= <b>Provider Judgment</b>
Strep Throat	None	(-,+) Low Benefit, Low Risk= <b>Least Appropriate</b>
Strep Throat	Severe Depression	(-,-) Low Benefit, High Risk= <b>Least Appropriate</b>
Headache	None	(-,+) Low Benefit, Low Risk= <b>Least Appropriate</b>
Headache	Drug use disorder	(-,-) Low Benefit, High Risk= <b>Least Appropriate</b>

**Algorithm Annotations**

An additional tool for assessing risk for harms of opioid therapy, recommends a comprehensive clinical evaluation of potential risk factors with a table identifying adverse outcomes for each one.

**Assessing Risk for Harms of Opioid Therapy**

Inadequate evidence is available to support the predictive value of any screening measure for opioid risk; therefore, we do not recommend any particular screening tool. Instead, we recommend that physicians undertake a comprehensive clinical evaluation of potential risk factors prior to initiating opioid therapy. The table below outlines factors that have been associated in published studies with risk of opioid misuse or adverse opioid outcomes.

**Risk Factors for Adverse Outcomes of Opioid Therapy and Opioid Misuse\***

	Overdose	Trauma	Opioid use Disorder	Opioid Misuse
Opioid dose > 50 morphine-equivalent mg/day	x	x		
Sedative-hypnotic use	x	x	x	
Alcohol or drug use disorder (past or current)	x	x	x	x
Depression or other mental health disorder	x	x	x	x
Past legal problems or jail time			x	x
Smoking			x	x
Higher reported pain severity or pain impairment			x	x
Younger age			x	x
Family history of substance use disorder			x	

\* Overdose includes fatal and non-fatal events; trauma includes fractures and driving-related injuries; opioid use disorder includes opioid abuse and opioid dependence; opioid misuse includes a variety of aberrant behaviors including concurrent illicit substance use, sharing or borrowing opioids, and using opioids for purposes other than prescribed.

(Gomes, 2013 [Low Quality Evidence]; Seal, 2012 [Low Quality Evidence]; Bohnert, 2011 [Low Quality Evidence]; Boscarino, 2010 [Low Quality Evidence]; Dunn, 2010 [Low Quality Evidence]; Edlund, 2010 [Low Quality Evidence]; Liebschutz, 2010 [Low Quality Evidence]; Park, 2010 [Low Quality Evidence]; Saunders, 2010 [Low Quality Evidence]; Chou, 2009 [Guideline]; Morasco, 2008 [Low Quality Evidence]; Turk, 2008 [Low Quality Evidence]; Edlund, 2007 [Low Quality Evidence])

Many clinicians fear or have experience with irate patients who are seeking relief and/or seeking drugs. It is important to have self-awareness about the issues involved and personally identify colleagues to gain insight and advice when dealing with these patients.

Developing personal scripting and also having discussions with colleagues about how to approach these patients is supportive to developing confidence in managing potentially tense dialogue with the patient.

**Saying "no"**

- Do not negotiate with intoxicated patients, or patients in withdrawal.
- Before saying "no" or evincing resistance, gather information using a neutral tone
- Be self aware of your own discomfort. If feeling emotionally pressured (patient anger, or pleas for sympathy), separate your feelings from the medical facts you are observing and standard of care you practice. Do not respond to emotion with emotion. And do not prescribe emotionally.

## Algorithm Annotations

- Before you say "no," ask the patient about their function, life stress, pill use behaviors, and other substance use. Then use their own reports, if appropriate, to reframe opioids from "pain killer" to function restorer; remind the patient that pain is amplified by life stress.
- Suggest to the patient that the pain may resolve on its own without risking increased tolerance and other adverse events of opioids. Recommend waiting one week or more before a dose change.
- Make sure the patient is well-informed about what they are asking. Clinicians may erroneously assume patients know more than they do or feel manipulated by them. Yet, often patients approach this naively and need education. Explain to them your thinking, assuming they are being sincere.
- If you are uncertain about the medical/pharmacologic issues, step out and confer with a colleague or a team. Admit you need advice before you proceed, and you would like to review the case with an expert. Consider referral to a specialist.
- Focus on what therapy you are providing, and how it will help the patient's pain.
- Remind the patient of the hospital or clinic policy, if they are requesting an exception; legal issues if relevant; health issues, side effects and contraindications, including safety (falls, driving, etc).
- Maintain a sympathetic approach. Listen unrushed. Work towards building a relationship. Express that you are not "denying them" to be punitive, but you think the medication request is actually ill-advised. Offer close follow-up and reevaluations.

Clinicians and organizations are encouraged to develop scripting, for patients who have a history of substance use and/or for whom opioid therapy is not appropriate. (See Appendix B, "Scripting Support for Saying No to a Patient and an Opioid Prescription.")

## 14. Appropriate Therapy and/or Referral

- **Tramadol is an atypical opioid.**

It is not a controlled substance in the U.S. but has some properties similar to opioids, but others that differ. While it is efficacious for fibromyalgia, it has some potential for abuse. Clinicians should prescribe appropriately and follow-up with the patient to verify effectiveness and correct usage.

- **Treat with other analgesics, or NSAIDs, physical, psychological, interventional or other appropriate non-opioid therapies.**

Prescribing non-opioid analgesics for pain and/or therapies that would support pain relief, improved function or healing should be the first consideration. Some types of pain would be better managed with alternative medications such as gabapentin for neuropathy or calcitonin for bone pain associated with osteoporosis. However, NSAIDs and other anti-inflammatories are not without their limitations and side effects. For some conditions they may prevent healing, and should be prescribed judiciously (*Stovitz, 2003 [Low Quality Evidence]*). Provide risks and benefits for all options for the patient to guide discussion and support shared decision-making. Additional information on the "Shared Decision-Making Model," can be found on the ICSI Web site.

Identification of appropriate treatment must also include evaluation of ADLs, work situation and psychosocial needs. If available, include supportive family members and/or caregivers, as identified by the patient, in the discussion. Include decision and type of treatment/therapy in the patient's plan of care and provide this information to the clinician who will be providing follow-up care.

For additional information on evidence-based treatment modalities for pain, see the ICSI Assessment and Management of Chronic Pain guideline.

**Algorithm Annotations**

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- **Reassure and provide patient education, and include expected duration of pain episode, and warning signs that would require immediate medical attention.**

With many acute pain situations, the clinician can help the patient anticipate the endpoint for pain. For instance, viral infections have an endpoint, or a broken bone has a point where the pain should be subsiding. It is important to identify that with the patient so that the patient knows what to expect. This can also be the beginning point for reassessment should pain continue.

Patients should be encouraged to follow-up with their primary care physician or be referred to behavioral health or pain specialist as needed.

The Aims and Measures section is intended to provide protocol users with a menu of measures for multiple purposes that may include the following:

- population health improvement measures,
- quality improvement measures for delivery systems,
- measures from regulatory organizations such as Joint Commission,
- measures that are currently required for public reporting,
- measures that are part of Center for Medicare Services Physician Quality Reporting initiative, and
- other measures from local and national organizations aimed at measuring population health and improvement of care delivery.

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the protocol.

The subdivisions of this section are:

- Aims and Measures
- Implementation Recommendations
- Implementation Tools and Resources
- Implementation Tools and Resources Table

## **Aims and Measures**

1. Increase the rate of non-cancer patients 18 years and older who present with acute or subacute pain in outpatient care settings who have comprehensive pain assessment that includes all of the following: general history and physical, etiology and nature of the pain, appropriate diagnostics, and evaluation and treatment for acute conditions. (*Annotation #3*)

Measures for accomplishing this aim:

- a. Percentage of adult patients 18 years and older who present with acute or subacute pain in outpatient care settings who have pain assessment that includes numeric pain scale (example Visual Analogue Scale), general history taking regarding pain experience and limitations, physical exam, evaluation for acute conditions and appropriate diagnostics.
  - b. Percentage of clinicians who query the Minnesota Prescription Monitoring Program (PMP) before prescribing any opioids.
2. Increase the rate of adult patients 18 years and older with appropriate medication management of non-traumatic tooth pain. (*Annotation #5*)

Measures for accomplishing this aim:

- a. Percentage of patients who have referral to dental clinician for non-traumatic tooth pain.
- b. Percentage of patients who have non-opioid analgesic medical treatment for non-traumatic tooth pain, which may include any of the following:
  - Long lasting local anesthetic (up to eight hours).
  - Use of other non-opioid pain medication such as NSAIDS, which can be very effective for dental pain.
  - Providing antibiotics when necessary; upon the presence of swelling or exudates in the cheek, jaw or gum tissue.
  - Providing prescription for chlorhexidine antimicrobial mouth rinse when indicated, which can help with localized infection and soothe pain in gum tissue.
  - Providing topical anesthetic rinse when indicated, or upon presence of stomatitis, mucositis or mouth ulcers.

**Aims and Measures**

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3. Increase the rate of adult patients 18 years and older with chronic pain who are appropriately managed for acute exacerbation. (*Annotation #8*)

Measure for accomplishing this aim:

- a. Percentage of patients who have the following done before prescribing any medication for acute exacerbation:
  - Consult the patients care plan, prior to prescribing any medications
  - Follow chronic pain guideline protocols for management of acute exacerbation
  - Consult with pain specialist or other resources
  - Check PMP for history of opioid prescriptions
  - Mental health status and social situation

4. Increase the rate of adult patients 18 years and older who are already on opioids who are appropriately managed for acute pain. (*Annotation #9*)

Measures for accomplishing this aim:

- a. Percentage of patients who have care plan consulted prior to prescribing any opioids for acute pain.
- b. Percentage of patients with new opioid prescription dosage for acute pain no higher than the existing chronic opioid prescription dosage.

5. Increase the rate of adult patients 18 years and older who are prescribed therapies other than opioids for treatment of acute or chronic pain. (*Annotation #11*)

Measures for accomplishing this aim:

- a. Percentage of patients prescribed other analgesics or NSAIDs for acute or chronic pain.
- b. Percentage of patients who have referral for other interventions or therapies for acute or chronic pain to include physical, psychological, interventional or other appropriate non-opioid therapies.
- c. Percentage of patients with education on expected duration of pain episode, and warning signs that would require immediate medical attention.

6. Decrease the rate of adult patients 18 years and older at risk for opioid contraindications or adverse effects. (*Annotation #12*)

Measures for accomplishing this aim:

- a. Percentage of patients who have ABCDPQRS Opioid Risk Assessment.
- b. Percentage of patients screened for alcohol and drug misuse or abuse.
- c. Percentage of patients screened for co-morbid psychiatric disorders such as anxiety, depression or bipolar disorder.
- d. Percentage of patients screened for respiratory insufficiency and sleep apnea.

**Aims and Measures**

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7. Increase the rate of adult patients 18 years and older who are prescribed opioids who have a timely follow-up with the clinician. (*Annotation #15*)

Measure for accomplishing this aim:

- a. Percentage of patients who have a follow-up with the clinician within three to five days of prescription.

## **Implementation Recommendations**

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization.

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol:

- Communicate a clear and consistent opioid usage message for clinicians that clarifies the benefits and risks for patients.
- Create educational materials for patients and consumers to clarify the benefits and risks of opioid use.
- Use health care medical records, and the Minnesota Prescription Monitoring Program (PMP) to identify overprescribing.
- Document opioid prescriptions along with any additional risk factors or comorbidities in the patient medical records.

## **Implementation Tools and Resources**

### **Criteria for Selecting Resources**

The following tools and resources specific to the topic of the protocol were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content are included where possible.
- The content is clear about potential biases and when appropriate conflicts of interests and/or disclaimers are noted where appropriate.

## Implementation Tools and Resources Table

Author/Organization	Title/Description	Web Sites/Order Information
Minnesota State Substance Abuse Strategy	This Minnesota Substance Abuse Strategy was designed to develop a collaborative and comprehensive multi-agency approach. It is based on the knowledge that addiction is a treatable disease, that a continuum of care is needed to effectively address the needs of individuals, families and communities affected by substance abuse and addiction; and that the nature of addiction specialty services will change as they become more integrated into the broader health care system.	<a href="https://edocs.dhs.state.mn.us/lf-server/Public/DHS-6543-ENG">https://edocs.dhs.state.mn.us/lf-server/Public/DHS-6543-ENG</a>
National Institute on Alcohol Abuse and Alcoholism	A Pocket Guide for Alcohol Screening and Brief Intervention	<a href="http://pubs.niaaa.nih.gov/publications/Practitioner/pocketguide/pocket_guide5.htm">http://pubs.niaaa.nih.gov/publications/Practitioner/pocketguide/pocket_guide5.htm</a>
Originally conceived by Douglas Jacobs, MD, and developed as a collaboration between Screening for Mental Health, Inc. and the Suicide Prevention Resource Center. This material is based upon work supported by the Substance Abuse and Mental Health Services Administration.	Suicide Assessment Five-step Evaluation and Triage	<a href="http://www.integration.samhsa.gov/images/res/SAFE_T.pdf">http://www.integration.samhsa.gov/images/res/SAFE_T.pdf</a>
Substance Abuse and Mental Health Services Administration	Screening, Brief Intervention, Referral to Treatment (SBIRT)	<a href="http://samhsa.gov/prevention/sbirt/">http://samhsa.gov/prevention/sbirt/</a>
U.S. Department of Health and Human Services/ National Institutes of Health	Patient education material on prescription drugs: abuse and addiction.	<a href="http://www.drugabuse.gov/sites/default/files/rrprescription.pdf">http://www.drugabuse.gov/sites/default/files/rrprescription.pdf</a>

The subdivisions of this section are:

- References
- Appendices

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# Appendix A – Sample Opioid Prescription Informed Consent

Please consider this information carefully before agreeing to take your \_\_\_\_\_ prescription.

**Side effects of this pain medicine:**

- Dizziness
- Light-headedness
- Feeling faint
- Sleepiness
- Nausea or vomiting
- Constipation

**You must not drink alcohol with this medicine.**

If you take this medication and drink alcohol, it can slow down your breathing, or stop it altogether.

**When you take this medicine, you should not drive.**

If you are driving and are stopped while on this medicine, you may be charged with a DUI.

**You should not run machinery or other heavy equipment.**

You may have difficulty thinking clearly, or you may not be able to respond quickly when taking this medicine, which could place you, or others around you, in danger.

**This medication can be addictive.**

Usually, patients do not become addicted to this medication if used as prescribed and if taken for a short period of time. However, people respond to medications in different ways and it is important to know that there are risks.

**Store this medicine in a locked cabinet, drawer or lock box.**

Because of its potential for addiction and misuse, this medication should be kept away from anyone for whom it is not prescribed. Do not share this medication with anyone. Find a place that you can lock to keep it away from children, teens and young adults.

**Dispose of this medication properly if you no longer have the need and have leftover tablets.**

Extra tablets can be flushed, mixed in with composted materials in the trash, or turned in to specific locations. See link for more information: <http://rxdrugdropbox.org/>

**Potential serious long-term effects**

**If you chose to continue with this drug or get additional prescriptions from other clinicians you run the risk of addiction, increased pain, inability to perform sexually, serious health problems, and death.**

**Agreement**

The risks of using this medicine have been sufficiently explained and I understand what precautions I should take while taking it. I understand that I should do everything I can to prevent others from taking this medicine.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Name (print): \_\_\_\_\_

## Appendix B – Scripting Support for Saying No to a Patient and an Opioid Prescription

### **Sit down.**

Putting yourself on the same level with the patient creates a different experience for them. Instead of an authority figure, you are now a little closer to them, to their experience, to a genuine and caring friend sitting by their bedside.

### **Get the story from the patient.**

If you haven't listened to their story about their pain, you need to do so with empathy. Jot notes. Ask questions. Summarize to make sure that you've heard which can also be used to move a patient through their story if it is extensive.

*"After examining you and thinking through everything we've talked about, I don't feel that I could safely recommend a narcotic for your pain. I'd like to talk about the alternatives that could help and would like to review them with you."*

If the patient is hostile and demands pain meds – draw on the emotional words that the patient uses to demonstrate that you're listening. "The pain is killing me," "I can't stand the pain," "I'm on edge all the time."

*"The pain is making you feeling desperate and edgy and I hear that, but I can't safely and in good conscience, prescribe medication that could harm you or kill you."*

### **Use their story to list the things that warrant this decision.**

*"You've told me a lot about your pain. You've told me about what you've tried and what doesn't work. You've told me about the stress in your life and the pressures you feel. You've told me about your attempts to de-stress with drinks after work and your use of marijuana. Stress is adding to your pain. All of those things tell me that adding a narcotic would be asking for trouble. It would be dangerous to you and maybe those around you, and a big part of my job is to make sure that the treatment we agree upon will keep you safe."*

And as necessary, talk about the organizational policy or legal ramifications that prevent you from prescribing.

### **Teaching opportunity.**

Teach about compounding factors and opioids. Use drawings or brochures. Don't ever assume that they know and take the time again to explain, for example, how their apnea in combination with opioids would slow their breathing down even more, to the point of stopping, or that opioids changes the brain and its response to pain.

Have strong ideas for an alternative plan.

*"We've talked about some of the things that may help you control your pain. Out of all those, what would you like to try?"*

Or

*"The complex needs you have really tells me that we need additional support for your pain. Would you be willing to talk to one of our pain specialists..."*

Or

*"There are strong connections with feeling down and discouraged and pain, so would you be willing to schedule an appointment with our behavioral health therapist..."*

If at any time you feel threatened or need to diffuse the situation, you can excuse yourself to consult a colleague or get additional help.

1. Frankel RM, Stein T. Getting the most out of the clinical encounter: the Four Habits Model. *Perm J* 1999;3:79-88. (Low Quality Evidence)
2. White MK, Keller VF. Difficult clinician-patient relationships. *Journal of Clinical Outcomes Management* 1998;5:32-36.
3. <http://xnet.kp.org/permanentejournal/fall02/sayno.html>

## **Acute Pain Assessment and Opioid Prescribing Protocol**

ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI protocols and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, *Clinical Practice Protocols We Can Trust* (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at <http://bit.ly/ICSICOI>.

### **Funding Source**

The Institute for Clinical Systems Improvement provided the funding for this protocol revision. ICSI is a not-for-profit, quality improvement organization based in Bloomington, Minnesota. ICSI's work is funded by the annual dues of the member medical groups and five sponsoring health plans in Minnesota and Wisconsin. Individuals on the work group are not paid by ICSI but are supported by their medical group for this work.

ICSI facilitates and coordinates the protocol development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

## **Disclosure of Potential Conflicts of Interest**

### **Paul Biewen, MD (Work Group Member)**

Physician, Physical Medicine and Rehabilitation, Twin Cities Orthopedics

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: Payment for independent medical examination testimony from Woodlake Medical Examworks, Integrity, and Expert Physician Evaluations

### **Brian Bonte, DO (Work Group Member)**

Physician, Family Medicine, Hutchinson Health

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: ICSI Adult and Subacute Low Back Pain

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

### **Bret Haake, MD (Work Group Member)**

Assistant Medical Director of Neuroscience, Neurology, HealthPartners Medical Group and Regions Hospital

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: ICSI Adult and Subacute Low Back Pain. ICSI Management of Chronic Pain

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

### **Michael Hooten, MD (Work Group Member)**

Physician, Anesthesia, Mayo Clinic

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: ICSI Management of Chronic Pain

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

### **Justin Hora, PharmD (Work Group Member)**

Pharmacist, Allina Health

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: Payment for Pain Competition Moderator from the Minnesota Pharmacists Association

### **Chris Johnson, MD (Work Group Member)**

Physician, Emergency Medicine, Emergency Physicians, PA

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

### **Faris Keeling, MD (Work Group Member)**

Integrated Behavioral Health Medical Director, Psychiatry, Essentia Health

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

**Disclosure of Potential Conflicts of Interest**

---

**Anne Kokayeff, MD (Work Group Member)**

Physician, Pain Medicine, Fairview Health Services  
National, Regional, Local Committee Affiliations: None  
Guideline Related Activities: None  
Research Grants: None  
Financial/Non-Financial Conflicts of Interest: None

**Erin Krebs, MD, MPH (Work Group Member)**

Women's Health Medical Director, Internal Medicine, Minneapolis VA Health Care System  
National, Regional, Local Committee Affiliations: None  
Guideline Related Activities: None  
Research Grants: None  
Financial/Non-Financial Conflicts of Interest: Programmatic support for research on chronic pain and opioid therapy from the National Institute of Health and the Veterans Affairs Health Care System, also programmatic support of travel for presentations focused on chronic pain and opioid therapy from the American College of Physicians, Group Health Foundation and Eastern Tennessee State University

**Brian Nelson, MD (Work Group Member)**

Physician, Orthopedics, Physicians Neck & Back Clinics  
National, Regional, Local Committee Affiliations: None  
Guideline Related Activities: None  
Research Grants: None  
Financial/Non-Financial Conflicts of Interest: None

**Mary Pat Noonan, PhD, ABPP (Work Group Member)**

Clinical Psychologist, Clinical Psychology, HealthPartners Medical Group and Regions Hospital  
National, Regional, Local Committee Affiliations: None  
Guideline Related Activities: ICSI Management of Chronic Pain  
Research Grants: None  
Financial/Non-Financial Conflicts of Interest: None

**Chalres Reznikoff, MD (Work Group Member)**

Assistant Professor of Medicine, Internal Medicine and Addiction, Hennepin County Medical Center  
National, Regional, Local Committee Affiliations: Board member of the Steve Rummeler Hope Foundation and the American College of Physicians Scientific Committee  
Guideline Related Activities: None  
Research Grants: None  
Financial/Non-Financial Conflicts of Interest: Programmatic support for travel and accommodation expenses as an addiction speaker for events through Winona Health and Dodge County School District

**Marsha Thiel, RN, MA (Work Group Member)**

Chief Executive Officer, Pain Medicine, MAPS Medical Pain Clinic  
National, Regional, Local Committee Affiliations: None  
Guideline Related Activities: None  
Research Grants: None  
Financial/Non-Financial Conflicts of Interest: None

**David Thorson, MD (Work Group Leader)**

Medical Director, Sports Medicine and Family Medicine, Entira Family Clinics  
National, Regional, Local Committee Affiliations: Board chair for the Minnesota Medical Association (MMA), and on the board of directors for Midwest Medical Insurance Company.  
Guideline Related Activities: ICSI Adult and Subacute Low Back Pain  
Research Grants: None  
Financial/Non-Financial Conflicts of Interest: None

**Disclosure of Potential Conflicts of Interest**

---

**Anne Trujillo, RN, CNP (Work Group Member)**

Director Clinical Operations, Pain Medicine, MAPS Medical Pain Clinic

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

**Susan Van Pelt, MD (Work Group Member)**

Director of Quality Improvement, Emergency Medicine, Emergency Physicians, PA

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

All ICSI documents are available for review during the revision process by member medical groups and sponsors. In addition, all members commit to reviewing specific documents each year. This comprehensive review provides information to the work group for such issues as content update, improving clarity of recommendations, implementation suggestions and more. The specific reviewer comments and the work group responses are available to ICSI members at <http://Opioids>.

The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

In addition, this document was available for public review on the ICSI Web site during this revision cycle.

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**Original Work Group Members**

Paul Biewen  
*Physical Medicine and  
Rehabilitation*  
**Twin Cities Orthopedics**

Brian Bonte, DO  
*Family Medicine*  
**Hutchinson Health**

Howard Epstein, MD  
*Chief Health Systems Officer*  
**ICSI**

Bret Haake, MD  
*Neurology*  
**HealthPartners Medical Group  
and Regions Hospital**

Carmen Hansen, RN, BSN  
*Project Manager*  
**ICSI**

Michael Hooten, MD  
*Anesthesiology*  
**Mayo Clinic**

Justin Hora, PharmD  
*Pharmacy*  
**Allina Medical Clinic**

Chris Johnson, MD  
*Emergency Medicine*  
**Emergency Physicians, PA**

Faris Keeling, MD  
*Psychiatry*  
**Essentia Health**

Anne Kokayeff, MD  
*Pain Medicine*  
**Fairview Health Services**

Erin Krebs, MD, MPH  
*Internal Medicine*  
**Minneapolis VA Health Care  
System**

Cassie Myers  
*Clinical Systems Improvement  
Facilitator*  
**ICSI**

Brian Nelson, MD  
*Orthopedics*  
**Physicians Neck and Back Clinic**

Mary Pat Noonan, PhD, ABPP  
*Clinical Psychology*  
**HealthPartners Medical Group  
and Regions Hospital**

Charles Reznikoff, MD  
*Internist, Addiction*  
**Hennepin County Medical Center**

Marsha Thiel, RN, MA  
*Pain Medicine*  
**MAPS Medical Pain Clinic**

David Thorson, MD  
*Sports Medicine, Work Group  
Leader*  
**Entira Family Clinics**

Anne Trujillo, RN, CNP  
*Pain Medicine*  
**MAPS Medical Pain Clinic**

Susan Van Pelt, MD  
*Emergency Medicine*  
**Emergency Physicians, PA**

John Wainio, DDS  
*General Dentistry*  
**Minnesota Dental Association**

**Contact ICSI at:**

8009 34th Avenue South, Suite 1200; Bloomington, MN 55425; (952) 814-7060; (952) 858-9675 (fax)  
Online at <http://www.ICSI.org>

## **ICSI Document Development and Revision Process**

### **Overview**

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

### **Audience and Intended Use**

The information contained in this ICSI Health Care Protocol is intended primarily for health professionals and other expert audiences.

This ICSI Health Care Protocol should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Protocol and applying it in their individual case.

This ICSI Health Care Protocol is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

### **Document Development and Revision Process**

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other protocols, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the protocol. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each protocol as part of the revision process. They provide comment on the scientific content, recommendations, implementation strategies and barriers to implementation. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the protocol is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

### **Implementation Recommendations and Measures**

These are provided to assist medical groups and others to implement the recommendations in the protocols. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

### **Document Revision Cycle**

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals every month for the protocols for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group midcycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a protocol.