ICSI Institute for Clinical Systems Improvement

Health Care Protocol

Acute Pain Assessment and Opioid Prescribing Protocol

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Acute Pain Assessment and Opioid Prescribing Protocol

First Edition
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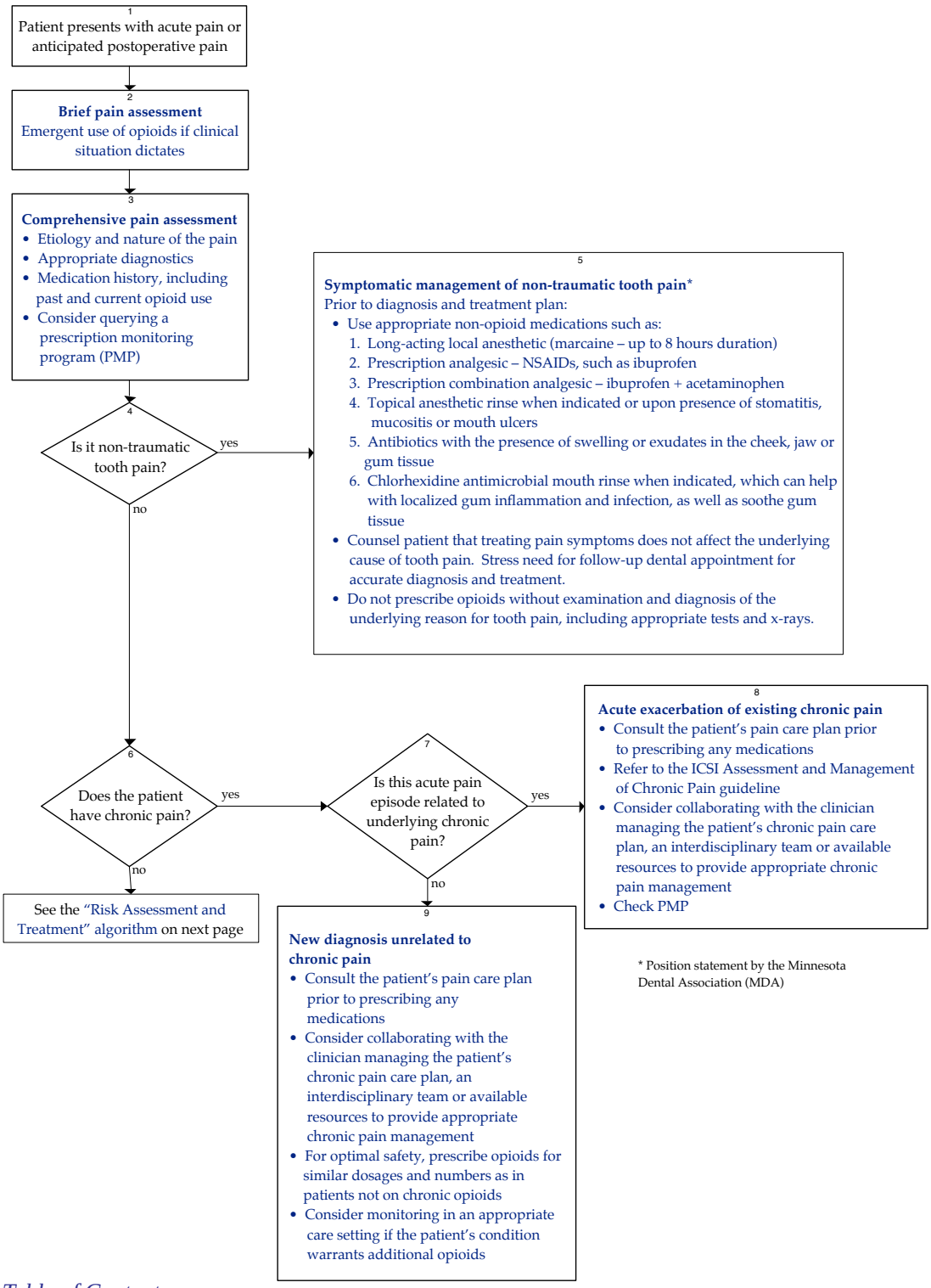
Main Algorithm

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



* Position statement by the Minnesota Dental Association (MDA)

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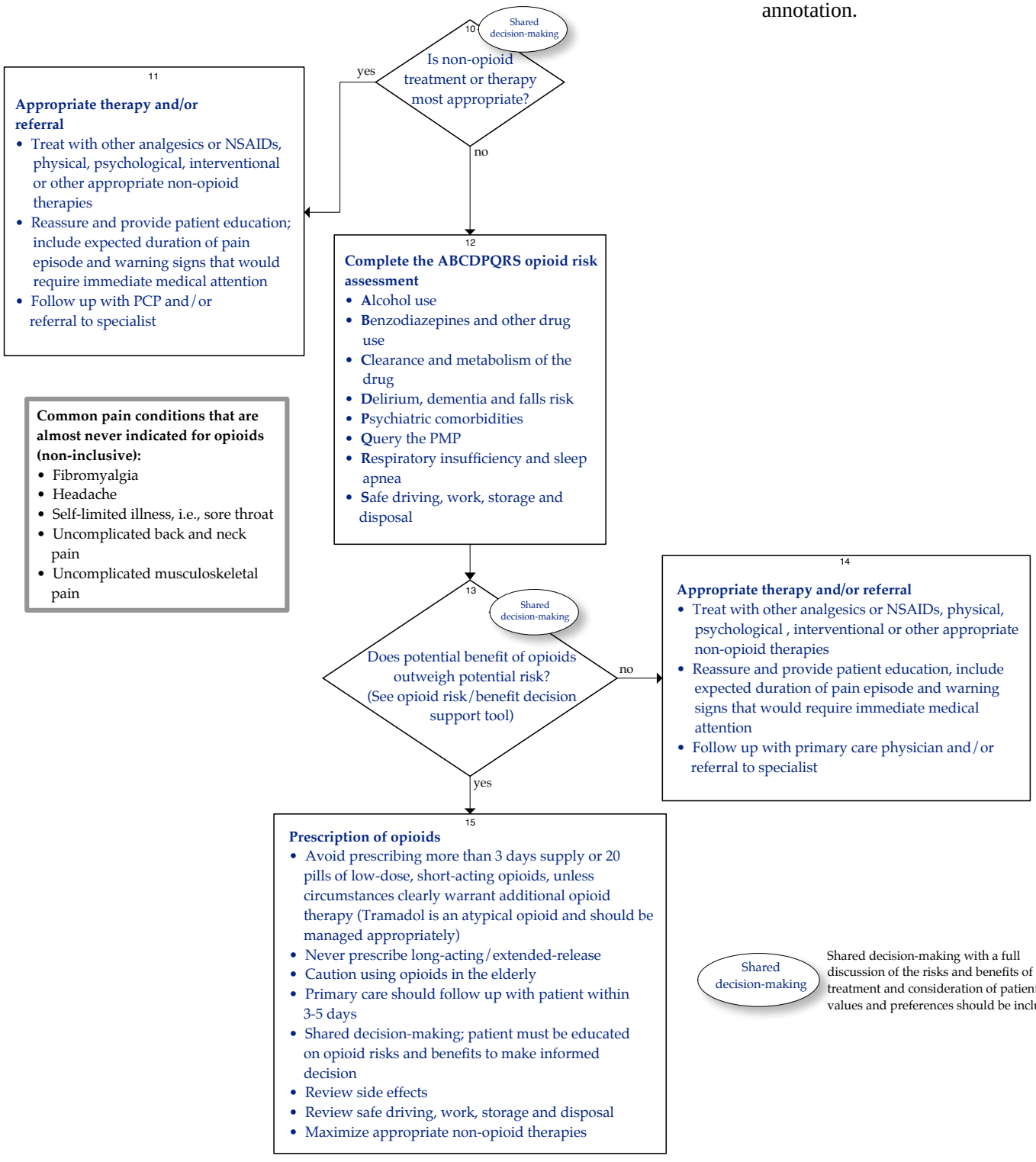
Risk Assessment and Treatment Algorithm

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



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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 related to opioids: prescribing, acute pain management, misuse, abuse, tolerance, addiction, overdosing, cost, diversion, pain specialists and risk assessments; they 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.

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Foreword

Introduction

Pain is an unavoidable part of the human experience. However, there is no way to objectively measure an individual's pain. It is a subjective experience, informed by each individual's particular physical, psychological, historical, social and cultural experiences and circumstances.

The pain-relieving properties of opium have been recognized for millennia. So has its potential for abuse and addiction. The mass production of opium and the identification of the morphine alkaloid in the early 19th century soon led to rapid growth in the commercial distribution of opioid preparations, legal and otherwise. In the November 2013 New England Journal of Medicine, it has been aptly stated, "By the 1940s, opioids were so tightly restricted that they could be used legally only when they were prescribed by physicians according to strict regulatory controls." The legal use of opioids was thus placed entirely in the hands of physicians, who were, and still are, liable to lose their medical licenses and risk criminal prosecution if they prescribe these drugs inappropriately. The immediate effect of such strict regulatory control was that physicians became reluctant to prescribe opioids, and as a result pain was woefully undertreated *(Ballantyne, 2003 [Low Quality Evidence])*.

Over the last 30 years, the use of opioids to manage acute pain, cancer pain and suffering caused by terminal conditions has regained its place in accepted medical practice. Pain management theory and groups such as The Joint Commission promoted pain as the "fifth vital sign" with the intent of swinging the pendulum back to appropriately treating patients' pain. However, these efforts coincided with "new evidence" touted as supporting the safe and effective management of chronic pain with opioids, as well. In fact, some of the most vocal and persuasive proponents of this approach now admit a gross misapplication and promulgation of the evidence – namely, a small case series report suggesting that the use of opioids in this situation was safe and carried an addiction risk of < 1% *(Ballantyne, 2003 [Low Quality Evidence])*.

In this milieu, though, expert panels and specialty groups developed guidelines and position statements encouraging providers to take an aggressive opioid-prescribing stance for ALL pain. As a result, the last 20 years has seen a tenfold increase in opioid prescriptions in the U.S. *(U.S. Department of Health and Human Services, 2011 [Reference])*. It has caused the pendulum to again swing too far to the extreme, leading to a dangerous underestimation and relative complacency regarding the risks of opioids, including abuse, misuse, addiction, diversion and unintentional overdose, even in the management of acute pain.

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, from 15% in 2001 to 41% in 2011. 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.

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- Urine toxicology screening is increasing. The U.S. screening industry estimate in 2000 was $800 million and in 2013, $2 billion.

(Meier, 2013 [Reference])

While some costs can be quantified, the more difficult measurement is the human toll as addiction increases, families struggle and are fractured, diversion of prescription drugs to the street and to our youth increases, 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])*.

Every day, 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 outstate areas, *(Minnesota Department of Human Services, 2012 [Guideline]; Substance Abuse and Mental Health Services Administration, 2010 [Low Quality Evidence])* 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 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.

It is within this context that the work group seeks to highlight several specific values that helped guide the development of this protocol with the aim of supporting both the patient and the clinician. They include:

- Patient safety – as with any other drug, opioids have known side effects with potentially significant adverse effects, particularly in patients with specific comorbid conditions. The potential for misuse, addiction and diversion should also be considered. Safe prescribing, therefore, comprises careful assessment of patient risk and history of opioid use from available data sources, including patient self-report, review of the medical record and a prescription monitoring program.
- Supportive pain management – patients expect their clinician to collaborate with them to determine the best course of treatment to manage their acute pain.
- Community safety and population health – easy access to opioids in the home and elsewhere may contribute to inappropriate use, addiction and subsequent crime related to drug abuse.
- Prevention of inappropriate or overutilization of opioids – the protocol offers clinical guidance for clinicians and patients for appropriate use of opioids and appropriate non-opioid therapies.

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- Patient information and shared decision-making – the patient must be informed and included in shared decision-making about the risk and benefits of opioid use. This partnership will support the change in culture over time, and patient expectations of clinicians and opioid prescriptions.

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 be successful only with community agreement, commitment to a structured protocol and development of effective communication strategies across organizations coordinating care across the health care continuum.

The overall purpose of this protocol is an attempt to redirect the swinging pendulum of opioid prescribing back toward a more rational approach that appropriately balances the clinician's desire and obligation to alleviate unnecessary pain and suffering that reflects best practice in light of the lack of high-quality evidence. The guidance provided in this protocol reflects the opinions of a broad spectrum of experts promoting consistent risk assessment and standards of care. Thus, while the primary focus is to more effectively and safely manage patients seeking care for acute pain, it encourages the clinician to consider carefully the unintended consequences (abuse, misuse, overdose, addiction and diversion) and prescribe only enough opioids to manage the acute pain episode when the potential benefit outweighs potential harm, as determined by the clinician in partnership with the patient.

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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.

The assessment of pain and management of patients with active cancer and/or receiving palliative or hospice care, including non-cancer diagnoses, are not addressed within the context of this protocol and are out of the scope and target population.

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Aims

1. Decrease the rate of opioid prescriptions for adults 18 years and older with diagnoses that do not warrant opioids (diagnoses may include fibromyalgia, headache, sore throat, uncomplicated neck and back pain, uncomplicated musculoskeletal pain). *(Annotations #10, 13 and freestanding box: Common pain conditions that are almost never indicated for opioid [non-inclusive])*
2. Increase the number of opioids prescriptions for adults 18 years and older that have documented review of prescription monitoring program in EHR. *(Annotations #3, 5, 8, 12)*
3. Decrease the rate of adult patients 18 years and older with opioid prescriptions for non-traumatic tooth pain. *(Annotation #5)*
4. Increase the rate of adult patients 18 years and older who receive information on risks and benefits of opioid prescription. *(Annotations #11, 12, 14, 15)*

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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 a checklist from the ABCDPQRS Opioid Risk Assessment in the electronic health record.
- Create educational materials for patients and consumers to clarify the benefits and risks of opioid use.
- Use health care medical records and a prescription monitoring program (PMP) to identify a patient's opioid history.
- Document opioid prescriptions, along with any additional risk factors or comorbidities, in the patient electronic health record.

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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

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Definition

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

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Algorithm Annotations

Main 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.

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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 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 of pain improvement over time, but responding to the pain score by merely prescribing opioids is problematic. Pain perception is multifactorial, and the clinician should obtain additional contextual information from the patient regarding his or her experience and limitations with the pain, as well as psychosocial issues potentially impacting the pain experience.

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 opioid treatment may not be safe and 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 the identification of 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 problematic for clinicians to accurately assess a patient's past opioid prescription history, querying a prescription monitoring program (PMP) is recommended. Use of the PMP offers a clinician an opportunity to identify concerns about prescription opioids if the patient is a poor historian or is not forthcoming.

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5. Symptomatic Management of Non-Traumatic Tooth Pain

Many patients experiencing tooth pain, may use the emergency department as a source for pain relief if dental insurance is not available or if it is an issue to obtain access to care, such as weekend coverage or after-hours emergency. Due to these potential situations, the Minnesota Dental Association (MDA) developed a position statement in regards to opioid use in non-traumatic tooth pain from which this annotation was derived:

- Prior to diagnosis and treatment plan for underlying source of pain, use appropriate non-opioid medications for pain management, such as:
    1. Long-acting local anesthetic (i.e., Marcaine for up to eight hours)
    2. Prescription analgesics – NSAIDs such as ibuprofen, which can be very effective for tooth pain
    3. Prescription combination analgesics – ibuprofen in combination with acetaminophen *(Moore, 2013 [Meta-analysis]; Weil 2012, [High Quality Evidence]; Menhinick, 2004 [Low Quality Evidence])*
    4. Topical anesthetic rinse when indicated or upon presence of stomatitis, mucositis or mouth ulcers
    5. Antibiotics with the presence of swelling or exudates in the cheek, jaw or gum tissue
    6. Chlorhexidine antimicrobial mouth rinse when indicated, to help with localized gum inflammation and infection, as well as soothe gum tissue
- Do not prescribe opioids without an examination and diagnosis of the underlying reason for the tooth pain by a dental provider as soon as possible. Opioids can mask pain and allow the patient to ignore a potential underlying serious dental problem, such as an abscess.
- Diagnosis should include appropriate tests and x-rays.
- Refer to a dental provider and assist with access to follow-up when possible.

Collaboration is needed between the medical and dental community to help patients access a dental provider who can then diagnose and create an appropriate treatment plan, which would not typically necessitate the use of opioid medications. When deemed absolutely necessary, the dental provider could prescribe an opioid medication, but only after an examination and diagnosis of the dental complaint.

Patients often seek dental care in medical facilities because they are more accessible and may not be able to refuse treatment. 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.

The work group also recognizes the MDA for the development of this position statement and acknowledges that there are situations that represent challenges to care, including dental insurance coverage and dental provider availability. Health care delivery systems and dental organizations need to collaborate and develop standards of care and processes that support the clinician and the patient when managing tooth pain.

Referral and Treatment Strategies for the Medical Community

- Recognize local and systemic diseases that present as tooth pain requiring treatment by a medical clinician (such as Herpes zoster, trigeminal neuralgia, osteonecrosis, etc.).
- Evaluate medical history and any concerns that may affect having a dental treatment referral.
- Actively use a prescription monitoring program and convey any concerns to the dental provider.
- Determine the patient's intent to seek dental care. Follow-up should be as soon as possible, as dental infection or abscess can progress rapidly.

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- Maintain an updated list of dental providers in the area, and assist the patient, if needed, to access a dental provider

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8. Acute Exacerbation of Existing Chronic Pain

- Consult the patient's pain care plan prior to prescribing any medications.
- Refer to the ICSI Assessment and Management of Chronic Pain guideline.
- Consider collaborating with the clinician managing the patient's chronic pain care plan, an interdisciplinary team or available resources to provide appropriate chronic pain management.
- 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, confer with the clinician managing the patient's chronic pain, 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. Include supportive family and/or caregivers, as identified by the patient, in shared decision-making.

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, e.g., social services, behavioral health, pain management or addiction medicine consult may be appropriate.

Opioid use disorder (i.e., heroin or pharmaceutical opioid addiction) makes management of pain with opioids highly problematic. Additional 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. 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 (i.e., doses used for opioid-naive patients). 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]).*

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: http://www.justice.gov/dea/ops/diversion.shtml. Unless the patient is otherwise medically unstable, withdrawal is not life threatening, although it may be very distressing. Reassurance and comfort measures are appropriate treatments *(Wesson, 2003 [Low Quality Evidence]; Isbell, 1947 [Low Quality Evidence]).*

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9. New Diagnosis Unrelated to Chronic Pain

- Consult the patient's care plan or prescribing clinician prior to prescribing any additional medications.
- Consider collaborating with the clinician managing the patient's chronic pain care plan, an interdisciplinary team or available resources to provide appropriate pain management.
- Consider monitoring in an appropriate care setting if the patient's condition warrants additional opioids.
- 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 work group agreed that due to a lack of evidence, 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.

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.

If the clinician is concerned about the patient's risk factors and feels that the patient would benefit from carefully managed opioids, active monitoring is an appropriate care setting to ensure safety would be warranted.

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Risk Assessment and Treatment Algorithm Annotations

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

Opioids are not as effective in non-cancer pain management as once believed *(Chou, 2009 [Guideline])*. While pain management with opioids has been prevalent and promoted historically, recent studies have demonstrated that opioids are being used inappropriately, thus leading to misuse, abuse, dependence, overdose and diversion.

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])*.

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 of surgery was 44% more likely to result in long-term opioid use within one year *(Alam, 2012 [Low Quality Evidence])*.

A 2013 study showed that 35% of the 72 patients studied did not use the prescribed pain medicine. 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, increasing the possibility of diversion *(Harris, 2013 [Low Quality Evidence])*.

Opioids actually change the chemistry of the brain and its response to pain.

- Homeostatic adaptations within the central nervous system (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])*.

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- 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 or abnormal pain symptoms such as allodynia *(Chou, 2009 [Guideline]; Angst, 2006 [Low Quality Evidence])*.

Additional opioid adverse effects

- Gastrointestinal effects *(Kurz, 2003 [Guideline])*
  - Constipation
  - Anorexia
  - Bloating
  - Nausea/vomiting
  - Abdominal cramping
- Respiratory effects *(Koo, 2011 [Low Quality Evidence])*
  - Decreased central drive
  - Suppressed gag reflex
  - Reduced frequency of respirations
  - Altered normal breathing rhythm
  - Inhibition of brain stem arousal centers
  - Blunted response to hypoxia and hypercapnia
- Effects on sleep *(Dimsdale, 2007 [Low Quality Evidence])*
  - Increased percentage of time spent in light sleep
  - Decreased percentage of time spent in deep sleep
- Bladder effects *(Benyamin, 2008 [Low Quality Evidence])*
  - Decreased detrusor muscle tone and force of contraction
  - Decreased sensation of fullness and urge to void
  - Inhibition of voiding reflex
- Immunologic effects *(Benyamin, 2008 [Low Quality Evidence])*
  - Diminished cellular immune responses, natural killer cell activity, cytokine expression and phagocytic activity
- Endocrine effects *(Vuong, 2010 [Guideline])*
  - Inhibition of ACTH and cortisol secretion, causing a decreased glucocorticoid response

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- Inhibition of LH- and gonadotropin-releasing hormone secretion, resulting in lower steroid hormone levels
- Inhibition of estradiol and testosterone secretion, resulting in hypogonadism, menstrual irregularities, sexual dysfunction, infertility and osteoporosis
- Inhibition of insulin secretion, leading to hyperglycemia and worsening diabetes
- The patient should be provided with all the information regarding options, risks and benefits of treatment. Family and/or caregivers may also be included as patient indicates.

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11. Appropriate Therapy and/or Referral

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

  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 of 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 in the discussion supportive family members and/or caregivers as identified by the patient. Document treatment recommendations 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, including 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, and a broken bone has a point where the pain should be subsiding. It is important to share the information so the patient knows what to expect.

  If the pain does not appropriately improve in the expected time frame, patients should follow up with their primary care physician for reassessment and referral to a behavioral health or pain specialist as needed.

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12. Complete the ABCDPQRS Opioid Risk Assessment

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

Alcohol Use

Alcohol affects judgment and memory, and impairs respiration when combined with opioids, all of which place the patient at increased risk of accidental overdose and trauma. There is no known safe dose of alcohol for a patient on opioids, particularly when the patient is opioid naive or on a higher dose than previously taken. The safest recommendation for patients on new or higher-than-baseline, doses of opioids is to abstain from alcohol completely.

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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 in the absence of alcohol use. Two useful and simple screenings tools are included 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 five or more drinks (if male), four or more drinks (if female) in a day?" A response of ≥ 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?"

A response of ≥ 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

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) used concurrently with opioids increases the risk of oversedation, 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 factors for opioid-related adverse events (respiratory compromise, risk of falls, or substance use disorder) are at a particularly increased risk of harm *(Centers for Disease Control and Prevention, 2013 [Guideline])*.

Marijuana use is so pervasive that it is not practical to test every patient in acute pain for marijuana. But those patients known to consume it 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])*.

Cocaine use has been associated with increased risk of diversion of opioids, and any patient with a substance use disorder should be educated carefully about the risks of combining drugs and overusing opioids. Clinicians may chose to prescribe fewer pills, use smaller doses and follow up within three to five days *(Gudin,*

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2012 [Low Quality Evidence]; Jones, 2012 [Meta-analysis]; Liebschutz, 2010 [Low Quality Evidence]; Becker, 2009 [Low Quality Evidence]; Ives, 2006 [Low Quality Evidence]).

Further information on substance use issues can be accessed at the link below:

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

Also see Appendix C, "DSM-V Substance Use Disorder Criteria."

Clearance and Metabolism of the Drug

Many 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, consider lowering the dose of acetaminophen or, preferably, avoiding the use of acetaminophen/opioid combination medication altogether. Half of the liver transplants in America are caused by acetaminophen-related liver failure; and half of those are caused by combination opioid/acetaminophen 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 from falls and other accidental trauma. This is particularly so for geriatric patients. Opioids should be used cautiously for patients with past falls or at an increased risk of fracture. Some guidelines suggest prescribing 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 delirium in some patients. Those with significant risk factors for opioid-induced delirium include the elderly; patients with cognitive impairments, polypharmacy, advanced liver or kidney disease; and 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.

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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 undertreated 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 and can be found at http://www.integration.samhsa.gov/images/res/SAFE_T.pdf.

Mental Health Screening Tools

The PHQ-2 is a well-validated, two-question screening tool 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])

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 about:

- feeling nervous, anxious or on edge; and
- not being able to stop or control worrying.

(Kroenke, 2007 [Low Quality Evidence])

Query the Prescription Monitoring Program

Query a 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 the state in the last 12 months and increasingly includes data from other states, as well. (Prescriptions from methadone maintenance clinics, Indian Health Services, long-term care facilities, and the Veterans Administration pharmacy are currently not included in Minnesota.) Non-prescribers (administrative help, nurses, interns) can query the PMP as a physician proxy in Minnesota 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 ability to breathe will be at an increased risk of respiratory insufficiency and respiratory arrest from opioids. Common risk factors 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 and Disposal

Minnesota law states that driving under the influence of a controlled substance or having any amount or the metabolites of a Schedule II 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. Involve and inform the patient's family and/or caregiver to provide additional support in the areas above.

To access a hard copy of the statute, 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 or Health. Of remaining opioids stored in the household medicine cabinet, 50% of the time opioids have been taken from this supply without the knowledge of the intended user. One-fourth of illicit opioid users identify their source as taking opioids from a relative or a friend without asking, 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 lockbox, a locked drawer or a safe to which only the patient or designated caregiver 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 no longer requires opioids for pain, remaining pills 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 link 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, their family should be informed of the safety issues surrounding opioid 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 Patient Agreement.")

Additional consideration – urine toxicology screen

To verify the patient report of current substance use or abstinence, 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. When interpreting this test, consider consultation with a toxicologist or other knowledgeable clinician *(Manchikanti, 2010 [Low Quality Evidence]; Pergolizzi, 2010 [Low Quality Evidence]; Reisfield, 2007 [Low Quality Evidence]).*

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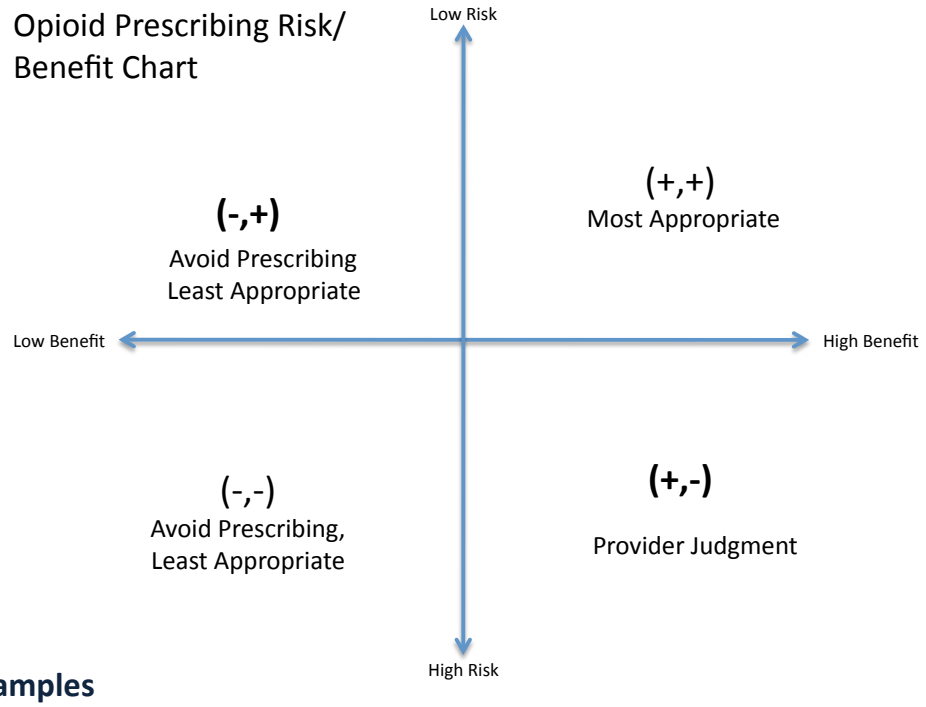
13. Does Potential Benefit of Opioids Outweigh Potential Risk?

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

The work group recommends that the severity and nature of the injury or illness, and the patient's perception of pain, be weighed carefully against the relative risk of adverse effects and potential harm from the use of opioids. The following graph is a way to assess the appropriateness of an opioid prescription by understanding the continuum of risk and benefit.

Risk Benefit Graph



Examples

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

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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 systematic 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.

If opioids are required and the patient is at a very high risk of opioid complications, hospitalization or other close monitoring may be required.

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])

Saying "no"

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, advice and support when dealing with these patients.

Developing personal scripting and also having discussions with colleagues about how best to approach and care for these patients may be supportive and help develop confidence in managing a potentially tense discussion.

- 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.
- Before you say "no," ask the patient about his or her function, life stress, pill use behaviors and other substance use. Then use the patient's 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 he or she is 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. Before you proceed, admit you need advice 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 he or she is requesting an exception; legal issues if relevant; and health issues, side effects and contraindications, including safety (falls, driving, etc).
- Maintain a sympathetic approach. Listen unrushed. Work toward building a relationship. Express that you are not "denying them" to be punitive but that 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.")

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, and 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 to review the benefits and risks to any treatment or therapy, and explore the patient's values and preferences. 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."

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14. Appropriate Therapy and/or Referral

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

  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 of 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 in the discussion supportive family members and/or caregivers as identified by the patient. Document treatment recommendations 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.

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- **Reassure and provide patient education, including 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, and a broken bone has a point where the pain should be subsiding. It is important to share the information so the patient knows what to expect.

  If the pain does not appropriately improve in the expected time frame, patients should follow up with their primary care physician for reassessment and a referral to a behavioral health or pain specialist as needed.

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15. Prescription of Opioids

- **Avoid prescribing more than three days supply or 20 pills of low-dose, short-acting opioids, unless circumstances clearly warrant additional opioid therapy. (Tramadol is an atypical opioid and should be managed appropriately.)**

  A recent study demonstrated that many patients who fill their opioid prescriptions may not use them as prescribed, and may have leftover pills or save them for a later pain episode, potentially increasing the possibility of diversion *(Harris, 2013 [Low Quality Evidence])*.

  Tramadol is not considered a controlled substance in the U.S., and 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.

- **Never prescribe long-acting/extended-release opioid preparations for acute episodes of pain.**
- **Caution using opioids in the elderly.**
- **Primary care should follow up with patient within three to five days.**

  The prescribing clinician should schedule and/or communicate to the patient and his or her primary care clinic the need to follow up within three to five days to assess pain management and appropriate use of pain medication. Depending on the patient condition, this follow-up may be done telephonically by a care manager or other primary care team member, as well as face to face.

- **Shared decision-making; patient must be educated on opioid risks and benefits to make an informed decision.**

  Patients may opt for an alternative pain medication or treatment after being made aware of the potential side effects, driving and work limitations, and disposal and diversion considerations. Patients also benefit from reassurance and discussion about the anticipated duration of pain.

- **Review side effects.**

  Discuss all potential side effects with the patient, including discussion of potential constipation side effects and ways to manage.

- **Review safe driving, work, storage and disposal.**

  See Annotation #12, "Complete the ABCDPQRS Opioid Risk Assessment."

- **Maximize appropriate non-opioid therapies.**

  Consider other treatments and therapies that may provide support pain management. Inform the patient of expected results and outcomes from these options.

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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. Decrease the rate of opioid prescriptions for adults 18 years and older with diagnoses that do not warrant opioids (diagnoses may include fibromyalgia, headache, sore throat, uncomplicated neck and back pain, uncomplicated musculoskeletal pain). *(Annotations #10, 13 and freestanding box: Common pain conditions that are almost never indicated for opioid [non-inclusive]).*

   Measure for accomplishing this aim:

   a. Percentage of patients with diagnosis of fibromyalgia, headache, sore throat, uncomplicated neck and back pain, or uncomplicated musculoskeletal pain prescribed opioids.

2. Increase the number of opioids prescriptions for adults 18 years and older that have documented review of prescription monitoring program in EHR. *(Annotations #3, 5, 8, 12)*

   Measure for accomplishing this aim:

   a. Percentage of opioid prescriptions that have documented review of PMP in EHR prior to dispensing.

3. Decrease the rate of adult patients 18 years and older with opioid prescriptions for non-traumatic tooth pain. *(Annotation #5)*

   Measure for accomplishing this aim:

   a. Percentage of patients with non-traumatic tooth pain receiving opioids prescription.

4. Increase the rate of adult patients 18 years and older who receive information on risks and benefits of opioid prescription. *(Annotations #11, 12, 14, 15)*

   Measures for accomplishing this aim:

   a. Percentage of patients who have documentation in their EHR that risks and benefits have been reviewed.

   b. Percentage of surveyed patients receiving an opioid prescription who identify they have received information of risks and benefits.

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Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specifc 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 conficts of interests and/or disclaimers are noted where appropriate.

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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.	https://edocs.dhs.state.mn.us/lfserver/Public/DHS-6543-ENG
National Institute on Alcohol Abuse and Alcoholism	A Pocket Guide for Alcohol Screening and Brief Intervention	http://pubs.niaaa.nih.gov/publications/Practitioner/pocketguide/pocket_guide5.htm
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	http://www.integration.samhsa.gov/images/res/SAFE_T.pdf
Substance Abuse and Mental Health Services Administration	Screening, Brief Intervention, Referral to Treatment (SBIRT)	http://samhsa.gov/prevention/sbirt/
U.S. Department of Health and Human Services/ National Institutes of Health	Patient education material on prescription drugs: abuse and addiction.	http://www.drugabuse.gov/sites/default/files/rrprescription.pdf

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The subdivisions of this section are:

- References
- Appendices

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Links are provided for those new references added to this edition (author name is highlighted in blue).

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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 him or her. Instead of an authority figure, you are now a little closer to him or her, to his or her experience, and to being a genuine and caring friend sitting at the bedside.

Get the story from the patient.
If you haven't listened to the pain story, you need to do so with empathy. Jot notes. Ask questions. Summarize to make sure that you've heard; this can also be used to move a patient through his or her 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 the 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 destress 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.

Use the teaching opportunity.
Teach about compounding factors and opioids. Use drawings or brochures. Don't ever assume that the patient knows and take the time again to explain, for example, how his or her apnea in combination with opioids would slow 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 tell 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.

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Appendix C – DSM-V Substance Use Disorder Criteria

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.

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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.

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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.

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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.

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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.

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