



HEALTH CARE GUIDELINE:

**Pain: Assessment, Non-Opioid Treatment
Approaches and Opioid Management**

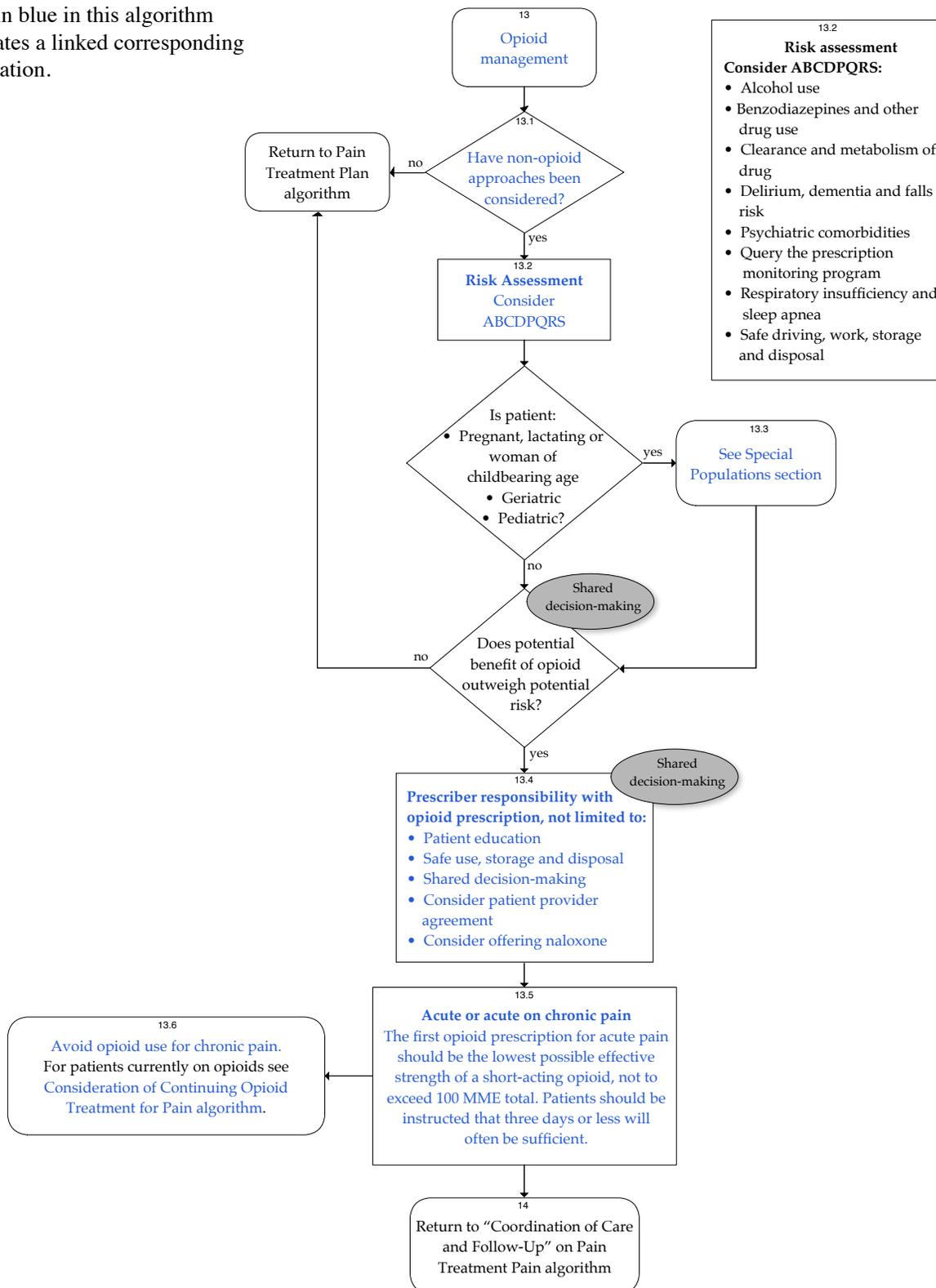
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This document is an excerpt from the **ICSI Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management Guideline**. The information in this excerpt covers acute through chronic opioid management, and a few special populations or situations to guide overall management of patients who are candidates for opioid treatment.

The complete document can be found at <https://www.icsi.org/guideline/pain/>

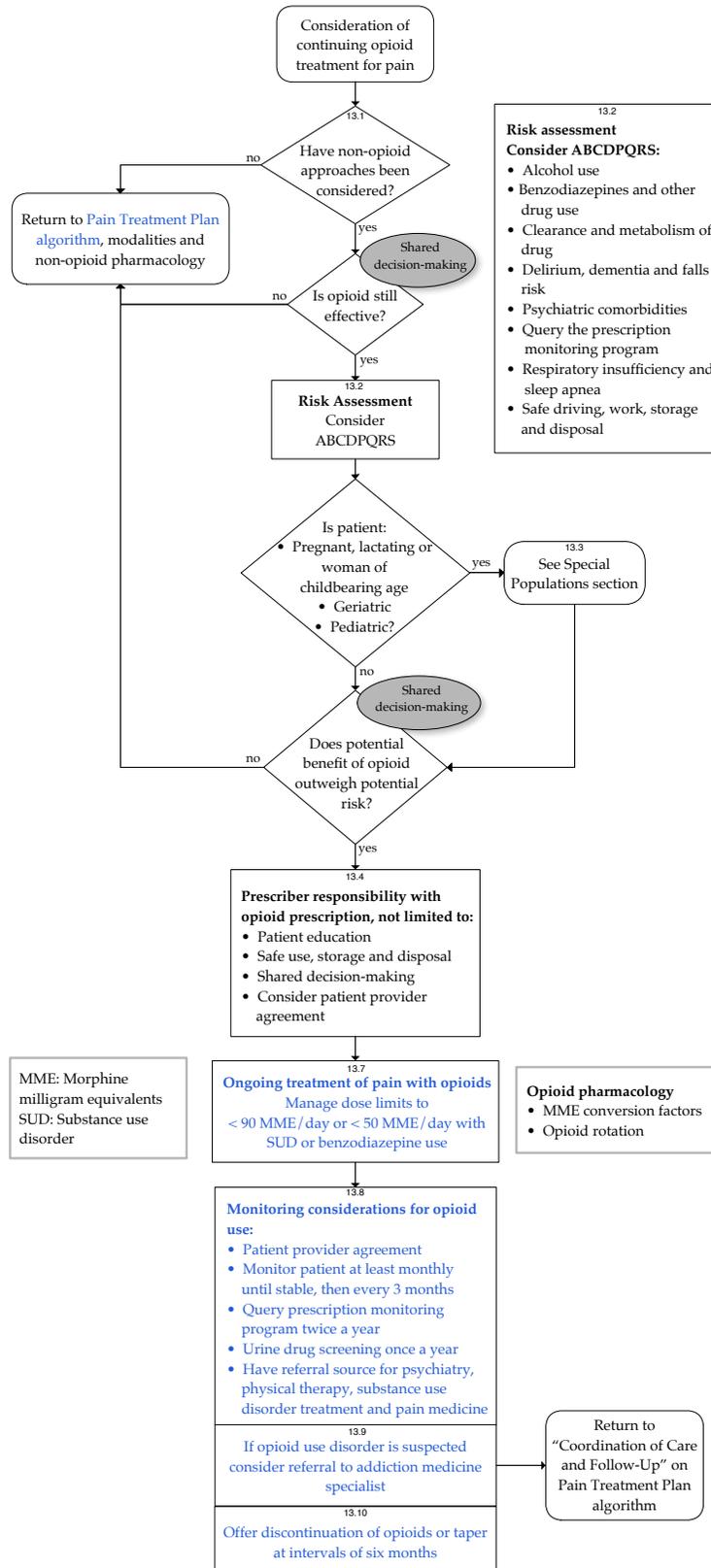
Acute Opioid Treatment Algorithm

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Consideration for Continuing Opioid Treatment Algorithm

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13. Opioid Management

Opioid Overview

In 2014, 245 million prescriptions of opioids were dispensed in the United States. Three to four percent of Americans are taking chronic opioids (Volkow, 2016b), and hydrocodone combined with acetaminophen was the most common prescription written in 2010 (DeNoon, 2011). Musculoskeletal complaints occupy three of the five top causes of years lived with disability in America (Murray, 2013).

Opioids encompass a large group of chemicals, that activate the muopioid receptor, reducing pain among other actions. While the potency (or dosing) varies, the efficacy of all opioid agonists is comparable. No opioid is inherently safer, or more efficacious, or more addictive than another. The dose, the route it is administered, the individual differences of the patient and the medication formulation are some variables that account for different individual responses to opioids. Opioids are regulated by the Drug Enforcement Agency (DEA) as schedule II medications. One exception is tramadol, a schedule IV medication, which is sometimes overlooked as an opioid because of its mixed receptor action (*Drug Enforcement Administration, 2014a; Drug Enforcement Administration, 2014b*). Emergency visits due to tramadol-related harms are rising (*Substance Abuse and Mental Health Services Administration, The, 2015*). Another exception is heroin, chemically called diacetylmorphine, which is a schedule I in the United States but used medicinally in other countries. Heroin is not fundamentally different from the opioids clinicians routinely prescribe, a fact that accounts for the rising use of heroin among pharmaceutical opioid users (Compton, 2016; Dart, 2015; Cicero, 2014; Thomas, 2014; Kuehn, 2013). The heroin epidemic and pharmaceutical opioid epidemic are intertwined.

Starting in the 1990s, because of an increased focus on improving patient pain scores, changing federal and state regulations, and a growing array of pharmaceutical opioids being marketed, opioid prescriptions increased dramatically (Zgierska, 2012; Dhalla, 2011; Von Korff, 2011). Clinicians began prescribing new opioid formulations for a growing list of indications to a wider spectrum of patients, for durations and in dosages not previously used (Chen, 2016; Kuehn, 2014). These changes happened without high-quality medical evidence to support them (Chou, 2015; Dowell, 2013; Okie, 2010; Chou, 2009a). A new standard of practice evolved, embracing the widespread use of opioids for pain (Von Korff, 2011).

At the time, providers were encouraged to titrate opioid doses to a patient's report of pain and not to functional status. Clinicians were reassured that addiction was a rare adverse event when opioids were prescribed for pain (Porter, 1980). Risk assessment tools were developed to screen for patients at high risk of addiction and overdose (Passik, 2008; Webster, 2005). Some prescribers incorrectly concluded that those who do not screen positive were risk-free. Experts advised that very high doses of opioids do not pose a risk to patients, as long as the patient had tolerance. However, increasing evidence disproves these recommendations (Dhalla, 2011; Von Korff, 2011).

It is now clear that many people are hurt and even killed by opioids (Dhalla, 2011; Centers for Disease Control and Prevention, 2011). Families and communities have suffered from what the CDC calls the "opioid epidemic" (Centers for Disease Control and Prevention, 2015). Medical experts, payers, regulatory agencies and members of the public are calling for a change in current opioid prescribing practices: fewer prescriptions, fewer pills, lower dosages, tamper-proof formulations, and increased screening and referrals for opioid addiction. Some of the above reactions to the opioid epidemic have evidence supporting them, but many do not.

Even though the medical/dental community clearly acknowledges that our past prescribing practices created a problem, current opioid prescribing practices are still largely informed by poor-quality medical evidence (Chou, 2015; Nuckols, 2014; Von Korff, 2011). In this vacuum of evidence, the standard of care has begun shifting away from liberal opioid prescribing toward increased demands on patients and prescribers (Buppert, 2015). Some clinicians and patients are concerned about these changes, particularly that pain may be undertreated or that patients will be harmed by abrupt discontinuation of opioids.

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Every day patients seek medical care in droves, hoping for relief from painful conditions. Some patients already on opioids continue to experience pain even as they face adverse effects of the opioids. Sometimes the risks are so great that the opioids need to be stopped immediately despite the patients' pain. Clinicians feel that their training and the health care systems employing them do not support the right decisions. Providing meaningful recommendations for opioid prescribers in this charged and changing climate is challenging. In the following section, the work group has highlighted the available evidence to date and relied on expert opinion (of this group and other work groups) in areas lacking evidence to summarize recommended courses of action and the range of acceptable clinical practice. Special attention will be paid to providing other modalities to minimize the harms of opioids.

Overall, it is clear that the best way to reduce the harms of opioids is to prescribe them only when needed and only in the minimum quantity needed (*Coffin, 2014; Lembke, 2012*).

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13.1. Have Non-Opioid Approaches Been Considered?

Rarely should the first choice for management of pain be opioids. The first opioid prescription should be given only after other options are tried or carefully considered. Furthermore, even after an initial prescription for opioids, prescribers should consider non-opioid treatment alternatives before prescribing refills. Such alternatives, detailed elsewhere in the guideline, include psychotherapy strategies, complementary alternative medicine, physical modalities and rehabilitation, non-opioid pharmacology and interventional treatment.

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13.2. Risk Assessment

Before initiating opioids for pain, providers should seek a specific diagnostic cause of the pain, and document objective findings on physical exam or other objective tests.

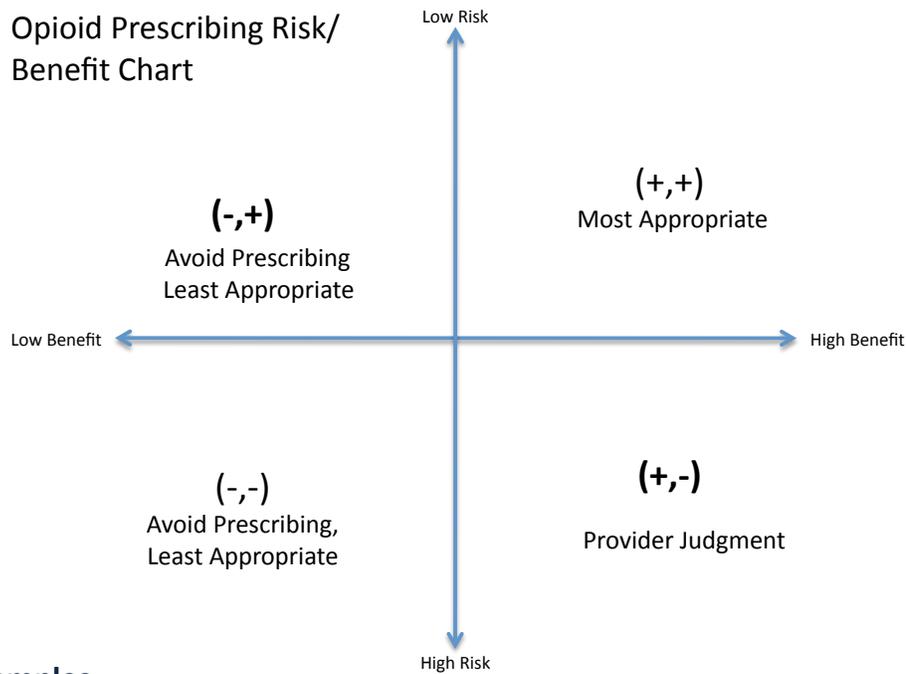
Risk Assessment Tools

Recommendation
<p>Opioid risk assessment tools and knowledge of opioid-related risks should be used in combination with the overall clinical picture to guide care, including the decision to prescribe as well as how closely to monitor.</p>
<p>Benefit: Assessment of opioid-related risks may help physicians weigh risks against benefits when deciding if to prescribe opioids. In addition, knowledge of the risk factors for the various adverse outcomes of opioids helps physicians determine the intensity of monitoring and follow-up for patients. Reviewing the risks also serves as a patient education tool.</p> <p>Harm: The use of risk assessment tools does not have an adequate sensitivity or specificity to predict opioid-related harms or to rule them out. Universal precautions should be used for all patients receiving opioids. Using risk assessment tools has not been shown to improve clinical outcomes. Risk assessment tools should not be used to exclude patients with mental health or addictive disorders from proper treatment of pain.</p> <p>Benefit-Harms Assessment: Used correctly, knowledge of the risks of opioid related harm, including risk assessment tools, can help providers more carefully monitor those at high risk. In cases where the risk/benefit of opioids is uncertain, risk assessment can tip the provider against use of opioids. These tools can also be used incorrectly; for instance, they cannot be used to assure a patient that he or she has no risk, and they should not be used to exclude mentally ill patients from routine treatment of pain.</p>
<p>Relevant Resources: <i>Volkow, 2016b (Report); Wasan, 2015 (Observational Study); Argoff, 2014 (Systematic Review); Jones, 2014 (Observational Study); Atluri, 2012 (Review); Jones, 2012 (Observational Study); Moore, 2009 (Observational Study)</i></p>

Many risk assessment tools have been developed but unfortunately none of them has the sensitivity or specificity required to reassure a patient that he or she is risk-free from the harms of opioids (*Jones, 2014; Jones, 2012; Moore, 2009*). There is limited evidence that the use of risk assessment tools in practice decreases adverse effects (*Argoff, 2014; Chou, 2009a*). Risk assessment tools have been used to exclude patients from receiving opioid analgesia, but this is not their proper use. The risks must be balanced against the benefits. Patients at high risk must be carefully considered, and conditions with low or no benefit should avoid opioid use. (See the following Opioid Prescribing Protocol Risk/Benefit Chart.)

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Algorithm Annotations



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

A patient determined to be high risk requires closer monitoring if opioids are prescribed. An algorithmic approach, including risk assessment and monitoring, has shown promise (*Atluri, 2012*). Two important lessons emerge from the risk assessment tool literature. First, no patient can reliably be determined risk-free. Second, mental health disorders, particularly childhood sexual trauma, and addictive disorders, particularly opioid use disorder, confer increased risk of adverse events in those receiving opioids. Depression and anxiety symptoms correlate to higher opioid doses and less pain relief (*Wasan, 2015*).

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Algorithm Annotations

The ABCDPQRS mnemonic is one useful tool that addresses potential contraindications/risks to opioid use. Please see Appendix A for more detailed information.

- A – Alcohol Use
- B – Benzodiazepines and Other Drug Use
- C – Clearance and Metabolism of Drug
- D – Delirium, Dementia and Falls Risk
- P – Psychiatric Comorbidities
- Q – Query the Prescription Monitoring Program
- R – Respiratory Insufficiency and Sleep Apnea
- S – Safe Driving, Work, Storage and Disposal

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13.3. Special Populations

Pregnant, Lactating or Women of Childbearing Age

Work Group Recommendation
<p>Prior to prescribing opioids, women of childbearing age should be counseled on the risks of opioids in pregnancy and on contraception, and offered pregnancy testing.</p>
<p>Benefit: There may be teratogenic effects to opioids. Neonatal abstinence syndrome is costly and burdensome on the family and medical system. Opioid withdrawal in pregnancy may compromise obstetrical outcomes. Many opioid prescribers are uncomfortable continuing opioids in pregnancy.</p> <p>Harm: There is no harm in counseling the patient. Counseling takes additional time during the patient encounter.</p> <p>Benefit-Harms Assessment: The use of opioids in women of childbearing age, and in pregnancy, is widespread. Most pregnancies are unaffected by exposure to low dose or intermittent opioids. Some pregnancies are affected, including a low rate of teratogenicity, rising neonatal abstinence syndrome rates, and challenging the comfort of the opioid prescriber and the obstetrician. A discussion on the risks and benefits of opioids use seems prudent for this population.</p>
<p>Relevant Resources: <i>Desai, 2015 (Observational Study); Han, 2015 (Observational Study); Desai, 2014 (Observational Study); Maeda, 2014 (Observational Study); Whiteman, 2014 (Observational Study); Yazdy, 2013 (Observational Study); Broussard, 2011 (Observational Study)</i></p>

Unlike almost all other addictive drugs, men and women are equally affected by opioids (*Han, 2015; Centers for Disease Control and Prevention, 2011; Voelker, 2013*). Opioids can be used for pain during pregnancy; 22% of all pregnant women receive opioids during their pregnancy (*Volkow, 2016a; Desai, 2014; Maeda, 2014*). While earlier studies did not show a link to birth defects (*Viteri, 2015*), recent studies suggest there may be an association with certain birth defects. A large retrospective cohort study in Ireland found an association between methadone and major congenital anomalies (*Cleary, 2011*). Broussard et al. evaluated data from the National Birth Defects Prevention Study (a population-based case-control study from 1997-2005) and found that opioid use was significantly associated with conoventricular septal defects, atrioventricular septal defects, hypoplastic left heart syndrome, spina bifida and gastroschisis (*Broussard, 2011*). Analysis of data from the Slone Epidemiology Center Birth Defects Study spanning 1998-2010 suggests that opioid use in the periconceptual period appears to be associated with increased risk of neural tube defects (*Yazdy, 2013*). While these studies had limitations and further research is needed, clinicians and patients should be aware of the evolving evidence and the potential association between opioid use and certain birth defects.

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In a cross-sectional analysis of pregnancy-related discharges from 1998-2009 in the United States, Whiteman et al. found opioid use was associated with increased odds of threatened preterm labor, early onset delivery, poor fetal growth and stillbirth (*Whiteman, 2014*). In their retrospective cohort study, Cleary et al. found that methadone was associated with increased risk of very preterm birth, being small for gestational age, and admission to the neonatal intensive care (NICU) (*Cleary, 2011*). Heavy exposure to opioids during pregnancy may result in neonatal abstinence syndrome (NAS), which is neonatal opioid withdrawal (*Desai, 2015*). NAS may require weeks of care in the NICU, during which the neonate is weaned using an opioid (typically morphine or methadone). Children who have NAS meet their normal childhood milestones but long-term complications of NAS are unknown. NAS rates are rising steadily in America (*Tolia, 2015*). Four percent of NICU beds are occupied by NAS cases (*Tolia, 2015*).

How to best manage opioids for pain in pregnancy is not known – when or if to wean, whether long or short acting is better, how to minimize the risk of NAS. A pregnant patient on continuous opioids may be referred to high-risk obstetrics. In addition, pregnant women on opioids should be screened for opioid use disorder, and if present should be promptly referred to methadone maintenance clinics or a trained buprenorphine provider (*Park, 2012*). Prior to prescribing opioids, women who are not pregnant but of child-bearing age should be counseled on the risks of opioids in pregnancy, counseled on contraception and offered pregnancy testing. Women who are not pregnant but of childbearing age and already on chronic opioids should regularly be counseled on birth control. Pregnant women not on opioids should be urged to minimize their exposure to opioids.

This work group recognizes that pain control for pregnant women is a difficult issue as there is a paucity of treatment options. The discussion of opioids is part of a larger conversation on the risk and benefits of all the available options. A full, detailed discussion of pain treatment in pregnancy is beyond the scope of this guideline.

The American Academy of Pediatrics classifies morphine as compatible with breastfeeding. Long-term effects on neurobehavior and development are unknown. Morphine is passed on to infants in breast milk in concentrations ranging from 0.8 to 12% of the maternal dose. Occasional doses of hydrocodone probably represent a minimal risk to a nursing infant, but higher and more frequent maternal doses may cause toxicity (*Briggs, 2014*). In summary, low doses of as needed (prn) opioids used while breastfeeding are a minimal risk, but infants should be observed for changes in breathing and sedation. Breastfeeding is best avoided in infants when the mother is using higher doses or chronic administration of opioids.

In 2007, the FDA issued a warning on codeine for nursing mothers. Please see the FDA Information for Healthcare Professional sheet for more information: <https://www.fda.gov/media/104268/download>.

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Geriatrics

Work Group Recommendation
<p>Geriatric patients should be assessed for risk of falls, cognitive decline, respiratory malfunction, and renal malfunction before receiving opioids.</p> <p>If impairment or risk is detected in a geriatric patient, consider reducing the initial opioid dose by at least 50%.</p>
<p>Benefit: Doing a unique assessment for geriatric patients is important because of this group's unique vulnerabilities. Lowering the dose of opioids may lower the risk of opioid-related harm, such as falls and respiratory suppression, in this population.</p> <p>Harm: Geriatric patients are a diverse group of patients, some more fragile and others more robust. They should not be treated as having equal risk of opioids as a group. The most fragile geriatric patients may also have contraindications to the common alternatives to opioids. This may lead to undertreatment of pain.</p> <p>Benefit-Harms Assessment: Like many of the high-risk populations, using special precautions and lower doses in the geriatric population lowers the risk of opioid-related harms while also risking undertreating pain.</p>
<p>Relevant Resources: <i>Makris, 2014 (Review); Rubin, 2014 (Report); Rolita, 2013 (Observational Study); Saunders, 2010 (Observational Study); Solomon, 2010 (Observational Study); Spector, 2007 (Observational Study); Vestergaard, 2006 (Observational Study)</i></p>

Geriatric populations are more likely to have vulnerabilities to the adverse effects of opioids: impaired drug clearance, polypharmacy, past response to opioids, increased likelihood of falls and fractures, chronic medical conditions, liver and renal malfunction, respiratory insufficiency and cognitive impairment. Harm to older populations receiving opioids is increasingly recognized (*Han, 2015; Kronick, 2014; Rubin, 2014; Rolita, 2013; Saunders, 2010; Solomon, 2010; Spector, 2007; Vestergaard, 2006*). Careful consideration of the unique risks and benefits in this population is warranted (*Makris, 2014*). Our work group emphasizes the need for risk assessment and an individualized approach to the elderly patient based on their functional status and comorbidities.

Pediatrics

To safely prescribe opioids to pediatric patients requires consultation with a pharmacist or clinician trained in age- and weight-appropriate dosing. Codeine has a black box warning against use in pediatric patients due to its incidence of accidental overdose.

Adolescents prescribed opioids require special care. A study by Miech et al. of 6,220 individuals found that adolescents exposed to opioids for traditional indications prior to high school graduation had a 33% increase in future opioid misuse (*Miech, 2015*). In addition, adolescents may have undiagnosed mental health issues, as well as early substance use disorder, conferring additional risk. DeVries et al. found that despite guideline recommendations against opioid use for adolescents with headaches, 46% of adolescents studied received opioids for this indication (*DeVries, 2014*). Further, there was a correlation between opioid use for headache and subsequent emergency room visit (*DeVries, 2014*).

Opioids should be avoided if possible in this population. If opioids are to be prescribed, it is ideal for there to be close parental/caregiver supervision of opioid use whenever possible.

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13.4. Prescriber Responsibility with Opioid Prescription

Patient Education and Shared Decision-Making

Work Group Recommendation
The first opioid prescription should include patient education, shared decision-making and assessment for related risks.
<p>Benefit: Appropriate informed consent and shared decision-making should occur early in the course of prescribing opioids. Much opioid-related harm, including overdose, can happen early in the course of pain treatment. Aberrant behaviors and comorbidities should be identified as early as possible. Patient expectations should be set early in the course of opioid treatment.</p> <p>Harm: Patients may feel that they are being treated with suspicion. Very low-risk patients will be asked to spend time and energy to receive opioids. Clinician time and clinical resources will be dedicated early in the course of opioid prescribing.</p> <p>Benefit-Harms Assessment: Early patient education, re-education, screening for comorbidities and detecting aberrant behaviors represent a burden to patients and clinicians that is outweighed by the benefit of promptly addressing opioid-related harms and providing the patient with up-to-date and thorough education about the risks of opioids. This approach emphasizes universal precautions.</p>
<p>Relevant Resources: <i>Hooten, 2015a (Observational Study)</i></p>

Shared decision-making should happen at the time of the first opioid prescription and frequently thereafter. Patients are typically not given adequate information about the risks and benefits of opioids, many of which start with the first use. The decision to initiate or continue opioids should involve careful description of the risks and benefits of opioids. Repetition is necessary, as patients in pain may be less able to remember this critical information. All patients, even those deemed low risk, should be given information about the harms of opioids. Patients should have these harms explained free of stigma and judgment, assuming that any patients could experience them. The information should be clearly stated in understandable language. If available, a pharmacist may also provide education.

Clinicians and patients should understand that 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*).
- Opioids profoundly influence the synaptic plasticity that underlies learning and memory, leading to the potential development of addiction (*Christie, 2008*).
- Opioids can cause inhibition of LH- and gonadotropin-releasing hormone secretion, resulting in lower steroid hormone levels.
- Opioids can cause inhibition of estradiol and testosterone secretion, resulting in hypogonadism, menstrual irregularities, sexual dysfunction, infertility and osteoporosis.
- Opioids can cause inhibition of insulin secretion, leading to hyperglycemia and worsening diabetes.

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Safe Use, Storage and Disposal

Work Group Recommendation
<p>Patients newly on opioids, or having recently had their opioid dose increased, should be advised not to operate heavy machinery, including driving a car, or participate in other work or home activity that may be affected by the sedating effect of opioids.</p> <p>An individualized approach that weighs the risks and benefits of driving and other activities should be taken with patients chronically on stable opioids who have tolerance and do not show evidence of sedation.</p>
<p>Benefit: The sedating effect of opioids impairs one's ability to drive a motor vehicle and carry out other tasks similarly sensitive to wakefulness and reaction time. As a safety measure, it is important to clearly warn patients about the risk to themselves and others performing potentially dangerous tasks while on opioids. With the development of opioid tolerance and the absence of sedation, studies have shown that patients can safely drive a motor vehicle.</p> <p>Harm: Driving, work and household prohibitions can be burdensome and may prevent timely return to normal life activities.</p> <p>Benefit-Harms Assessment: The risk to public safety of patients newly on opioids operating motor vehicles and carrying out similar tasks clearly outweighs the inconvenience to the individual on opioids. Determining when the patient has enough tolerance to safely drive is a subjective judgment call, and prescribers should err on the side of caution and document carefully.</p>
<p>Relevant Resources: <i>National Highway Traffic Safety Administration (Fact Sheet) (2016); Schisler, 2012 (Expert Opinion)</i></p>

Work Group Recommendation
<p>Clinicians should discuss storage and opioid disposal options with patients at the first opioid prescription and in follow-up visits as needed.</p>
<p>Benefit: Proper storage and disposal can reduce opioids involved in diversion and overdose.</p> <p>Harm: There are no easy options for disposal of opioids.</p> <p>Benefit-Harms Assessment: Considering the great harm of excess opioids to the community, every opioid prescription should be accompanied with storage and disposal information. Disposal information is everchanging and complicated. While communicating the information is not highly burdensome, staying abreast of the latest information may be.</p>
<p>Relevant Resources: <i>Centers for Disease Control and Prevention, 2016 (Guideline); Centers for Disease Control and Prevention, 2010 (Summary Article)</i></p>

According to the National Highway Traffic Administration panel, classification of risk of driving with morphine "depends on tolerance, dose, time of exposure, acute or chronic use, presence or absence of underlying pain, physiological status of the individual and the presence of other drugs" (*National Highway Traffic Safety Administration, 2016*). Non-tolerant opioid users will likely experience greater impairment. Education about driving safety on opioids can reduce drugged driving (*McCarthy, 2015*). Local law may vary on what meets the definition of "driving under the influence" of a controlled substance, and prescribers should understand and follow local laws.

All patients should be instructed to store their opioids – ideally locked – in a location unreachable by family members and house guests. Patients should be instructed to dispose of the opioids promptly at the end of the pain episode. In one study of urologic procedures, 67% of patients received excess opioids, and 92% received no disposal instruction (*Bates, 2011*). Opioid disposal is a problem needing more solutions. The

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Food and Drug Agency and the Drug Enforcement Agency allow for schedule II substances (e.g., opioids) to be flushed down the toilet (*Drug Enforcement Administration, 2014a*). The Environmental Protection Agency does not endorse this method of disposal. Almost all Minnesota counties have a pill take-back site, usually at a law enforcement building (*U.S. Food and Drug Administration, 2015*). Pharmaceutical disposal bags with activated charcoal are available for safe at-home disposal. Fentanyl patches require special handling. As soon as they are removed, they should be folded sticky side inward and promptly flushed. Every year children die from inadvertent exposure to fentanyl patches (*U.S. Food and Drug Administration, 2015*). Unused opioids should be disposed of promptly at the end of the pain episode for which they were prescribed. Opioids should not be stored in case of a future pain episode, unless specifically directed by the prescriber.

Opioid Formulation

Work Group Recommendation
<p>Long-acting opioids should be reserved for patients with established opioid tolerance and in whom the prescriber is confident of medication adherence.</p> <p>Long-acting tamper-proof formulation for opioids is preferred.</p>
<p>Benefit: Tamper proof formulations of opioids have been linked to decrease diversion, abuse and death, when used for chronic pain. See the FDA site for more information: www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm</p> <p>When used for acute pain, or in patients without opioid tolerance, long-acting opioids are associated with inadvertent opioid overdose death. Methadone pharmacology is complicated, and its routine use is associated with overdose death.</p> <p>Harm: Tamper-proof formulations may not be covered or may have greater copay. For some situations, such as sleep, the duration of short acting opioids is insufficient to treat pain.</p> <p>Benefit-Harms Assessment: While there may be some select circumstances where use of long-acting opioids seems appealing in acute pain, they have failed to show benefit and are associated with overdose death. Using methadone in acute or chronic pain is associated with harm, owing to its unique pharmacology. If long-acting opioids are indicated, using a tamper-proof formulation may improve outcomes.</p>
<p>Relevant Resources: <i>Hwang, 2015 (Observational Study); Argoff, 2014 (Systematic Review); Cassidy, 2014 (Observational Study); Havens, 2014 (Observational Study); Sessler, 2014 (Observational Study); Butler, 2013 (Observational Study); Coplan, 2013 (Observational Study); Severtson, 2013 (Observational Study); Manchikanti, 2012a (Guideline); Severtson, 2012 (Observational Study); Dhalla, 2009 (Observational Study)</i></p>

Many studies have credited tamper-proof opioid formulations of opioids with a decrease in opioid misuse, diversion, death, opioid street value, and in some cases a corresponding increase in heroin use (*Dart, 2015; Hwang, 2015; Argoff, 2014; Cassidy, 2014; Havens, 2014; Sessler, 2014; Butler, 2013; Coplan, 2013; Severtson, 2013; Severtson, 2012; Cicero, 2012*). The rise in heroin use after initiation of tamper-proof formulations is interpreted to mean that addictions are exposed rather than created by this change in formulation. These formulations are currently on patent and are expensive. That said, when available, tamper-proof formulations are likely to decrease the harms of opioids.

Initially it was hoped that long-acting formulations of opioids would provide better pain control and decrease the adverse effects of immediate-release opioids, or even be less addictive. This has not been borne out in the medical literature (*Manchikanti, 2012a*). Early initiation of long-acting opioids can harm the patient by causing overdose (*Dhalla, 2009*). Long-acting opioids should be used only in patients with established opioid tolerance and in whom the prescriber is confident of their medication adherence.

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Patient-Provider Agreement (PPA)

Work Group Recommendation
<p>Initiate a patient-provider agreement (PPA) at the time an opioid is prescribed for:</p> <ul style="list-style-type: none"> • High-risk patients • Daily use of opioids > 30 days • Patient transfers to a new clinic already on opioids • Episodic use up to 90 days over the course of a year • If none of the above, initiate a PPA after 90 days of opioids is prescribed.
<p>Benefit: PPAs provide the patient with a clear set of expectations in writing.</p> <p>Harm: It has not been demonstrated that PPAs improve clinical outcomes. PPAs may be used as a pretext for dismissing undesirable patients.</p> <p>Benefit-Harms Assessment: PPAs have not been proven an effective medical intervention; however, they provide a clear set of expectations for patients and clinicians. Executed and used correctly, a PPA can help prevent patient provider disagreement and allow the clinic to insist on consistent and universal practices for opioid-receiving patients. When done incorrectly, a PPA may cause patients to be dismissed from care without appropriate referrals or follow-up.</p>
<p>Relevant Resources: <i>Centers for Disease Control and Prevention, 2016 (Guideline); Hooten, 2015a (Observational Study); Noble, 2010 (Systematic Review/Meta-analysis); Starrels, 2010 (Systematic Review); Arnold, 2006 (Review)</i></p>

A patient-provider agreement (PPA) should be used for a large proportion of patients receiving opioid prescriptions (*Arnold, 2006*). PPAs are formal written agreements between patient and clinician, stating the responsibilities of each party. PPAs have not been shown to prevent aberrant drug-related behaviors (*Starrels, 2010*). PPAs clarify the situations that will result in discontinuation of opioids, among other consequences. PPAs often inadequately describe the clinicians' responsibility to the patient. Most protocols suggest initiating a PPA after 90 days of continuous opioid use (*Reuben, 2015; Noble, 2010*), but sooner is preferable. Studies show that after a single opioid prescription, the patient's risk of opioid misuse is increased (*DeVries, 2014; Alam, 2012*).

The work group suggests initiating a PPA any time an opioid is prescribed for high-risk patients, for patients with daily use of opioids > 30 days, for patients already on opioids transferred to a new clinic, and for patients with episodic use up to 90 days over the course of a year. If none of these applies, initiate a PPA after 90 days of opioids have been prescribed. Many health care systems ask the patients to sign an informed consent at the time they sign the PPA (*Cheatle, 2012*). While the PPA and an informed consent cover much the same information, the informed consent has more medico-legal implications. Some health care systems review and renew their treatment plan, PPA and informed consent yearly.

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Consider Offering Naloxone

Work Group Recommendation
Clinicians should consider offering the patient and close contacts (family/friends/caretaker) a naloxone kit.
<p>Benefit: Community access to naloxone may save lives that would otherwise be lost to opioid overdose death. Many states explicitly support and legally protect this use of naloxone in law.</p> <p>Harm: Naloxone is not a treatment of the underlying causes of opioid overdose. Some forms of overdose are not reversed by a single dose of naloxone. Inducing opioid withdrawal may cause discomfort or other adverse effects. Training is required. Emergency services should be called when naloxone is used. Widespread use of naloxone may compromise its supply for those who need it the most.</p> <p>Benefit-Harms Assessment: Home use of naloxone can save the life of a person who would otherwise die from an opioid overdose, but it does not correct the underlying cause of the overdose, and it requires training to use appropriately.</p>
<p>Relevant Resources: <i>Coffin, 2016 (Observational Study); Coffin, 2013 (Cost-Effectiveness Analysis); Centers for Disease Control and Prevention, 2012a, (Report), Albert, 2011 (Observational Study); Yokell, 2011 (Report); Strang, 2008 (Observational Study)</i></p>

The CDC credited a recent plateauing of the opioid death curve to the widespread distribution of naloxone rescue kits (*Centers for Disease Control and Prevention, 2012a; Albert, 2011; Yokell, 2011*). Currently, one state has mandated that naloxone kits be co-prescribed with opioids, and many states have legislation explicitly protecting naloxone use for opioid overdose reversal (*Boyer, 2012*). Naloxone can be administered intra-nasally, intramuscularly or subcutaneously by a layperson (*Medical Letter, The, 2016*). Naloxone distribution will likely save health care dollars (*Coffin, 2013*).

Patients who are prescribed naloxone should be directed to a free online or community training (*Strang, 2008*). Because the reversal effect of naloxone does not outlast the sedating effect of many opioids, it is necessary to activate emergency services whenever a naloxone kit is used. The work group recommends that prescribers should consider offering a naloxone kit and training to all patients prescribed opioids and their close contacts (family/friends/caretaker). High-risk patients who should definitely be offered naloxone include those with an addiction, respiratory insufficiency, sedative/hypnotic use, dose greater than 100 MME/day, on chronic opioids with an acute injury, and history of opioid overdose. Recent laws allow pharmacists in some states to use standing orders to dispense to all who ask.

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13.5. Acute or Acute on Chronic Pain

Work Group Recommendation
<ul style="list-style-type: none"> • The first opioid prescription for acute pain should be the lowest possible effective strength of a short-acting opioid, not to exceed 100 MME total. Patients should be instructed that three days or less will often be sufficient. • For patients presenting in acute pain, already on chronic opioids, opioid tolerant or on methadone, consider prescribing an additional 100 MME maximum for this acute episode, with a plan to return to their baseline dose as soon as possible.
<p>Benefit: This limited dosing would reduce surplus opioid prescriptions as well as reduce potential of opioid abuse, overdose and diversion. It encourages frequent follow-up for pain requiring opioids and facilitates early recognition of aberrant opioid use.</p> <p>Harm: This limited dosing has potential to undertreat pain. It may cause inconvenience to patients by making them return to clinic for ongoing opioids and places some burden on providers arranging for early follow-up. In addition, some pain generators typically require more than three days of opioids. The opposite may also be true if providers automatically prescribe the full 100 MME when the patient could find relief with much less.</p> <p>Benefit-Harms Assessment: The medical community has typically overprescribed opioids for acute pain to ensure that no patient is ever undertreated, but at the risk of providing surplus opioids to the patient and the community, and specifically harming those with vulnerability to opioids. Lowering the total quantity of opioids prescribed will prevent much of this harm, but in exchange some patients with ongoing pain will receive insufficient opioids, forcing them to return for evaluation from their primary clinician. While this may be a short-term burden to the patient and system, it will, over time, lessen the burden to patients and clinicians by decreasing the harms of opioids. Those already taking opioids chronically have higher tolerance and thus may receive less analgesia from opioids. These patients are also at a higher risk, may have more comorbidity, may already be on opioid doses known to have adverse effects, and are likely to have an opioid patient-provider agreement. Thus, while treating the opioid-tolerant patient with equivalent doses will provide less analgesia, it will also mitigate harms.</p>
<p>Relevant Resources: <i>Shah, 2017 (Observational Cohort Prospective Study); Bohnert, 2016 (Observational Study); Centers for Disease Control and Prevention, 2016 (Guideline); Liang, 2015 (Observational Study); Miller, 2015 (Cohort Study)</i></p>

The first opioid prescription for acute pain should be the lowest possible effective dose of a short acting opioid, not to exceed 100 MME total. Patients should be instructed that three days or less will often be sufficient. For instance 20 hydrocodone 5 mg tablets, or 13 oxycodone 5 mg tablets, would equal 100 MME total, the maximum recommended dose for acute pain. Long-acting opioids should not be prescribed as the initial therapy for acute pain (*Miller, 2015; Dhalla, 2009*). For patients presenting in acute pain, already on chronic opioids, opioid tolerant or on methadone, consider prescribing an additional 100 MME maximum for this acute episode, with a plan to return to their baseline dose as soon as possible. The benefit to an opioid-tolerant patient is less, but the risks are higher (*Franklin, 2012; Gomes, 2011; Dunn, 2010*). The chances of chronic opioid use begin to increase after the third day supplied and rise rapidly thereafter (*Shah, 2017*). At the end of this initial prescription, if the patient believes there would be benefit from continued opioids, a follow-up visit should be scheduled since the likelihood of chronic use also increases with the second prescription (*Shah, 2017*).

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13.6. Avoid Opioid Use for Chronic Pain

Work Group Recommendation
Avoid using opioids to treat patients with chronic pain.
<p>Benefit: This will lower the total opioid use in the United States and the corresponding harms from opioids. Opioids have no proven efficacy for chronic pain but do have known harms. Preventing chronic exposure to opioids is easier and preferable to detoxing a patient chronically on opioids.</p> <p>Harm: A subset of patients with chronic pain may benefit from chronic opioids. Patients already on chronic opioids cannot be easily detoxed from opioids, and this recommendation should not be taken as advice to detox existing chronic pain patients on long-term opioids.</p> <p>Benefit-Harms Assessment: Pain that has no easily identifiable pain generator, and no cure, is a daunting problem in medicine and causes great suffering. These patients try many modalities of care and too often end up on chronic opioid therapy. There are no proven benefits of opioids for most patients with chronic pain, but there are proven harms. Until further knowledge emerges, it is prudent to avoid initiating opioids in these patients.</p>
<p>Relevant Resources: <i>Chou, 2015 (Systematic Review); Chaparro, 2014 (Systematic Review/Meta-analysis); Manchikanti, 2006 (Observational Study)</i></p>

Since chronic pain is a complex problem, it requires a multidisciplinary approach. There is no evidence that opioids for chronic pain relieve pain or improve function (*Chou, 2015; Chaparro, 2014; Gaskell, 2014; Loder, 2013; Manchikanti, 2006*). In the absence of evidence, we urge all providers to avoid treating chronic pain with opioids. Those already taking opioids for chronic pain require careful monitoring and prevention of dose escalation or other adverse events. It is reasonable to suggest a voluntary and slow taper for patients on chronic opioids.

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13.7. Ongoing Treatment of Pain with Opioids

If the use of continued opioids is unavoidable, we urge providers to consider the following issues.

Manage Dose Limits

Work Group Recommendation
<ul style="list-style-type: none"> Every effort should be made to keep chronic opioid using patients under 90 morphine milligram equivalents (MME)/day. Prescribers should consider seeking pain medicine consultation if greater than 90 MME is reached.
<p>Benefit: Opioid doses greater than 90 MME/day are associated with overdose death; as the dose increases, so do the risk and the strength of the associations.</p> <p>Harm: Some patients will have undertreated pain. Patients already on higher dose of opioids may struggle to lower their dose to a safe range. It is impossible to predict who will or will not overdose. Some patients who would not have been harmed by opioids will have their dose limited.</p> <p>Benefit-Harms Assessment: Given a fairly clear dose response association between MME and death, patients should be kept under 90 MME/day, even at the cost of potentially undertreating pain in some.</p>
<p>Relevant Resources: <i>Han, 2015 (Observational Study); CDC, 2016 (Guideline); Turner, 2015 (Observational Study); Franklin, 2012 (Observational Study); Gomes, 2011 (Observational Study); Dunn, 2010 (Observational Study)</i></p>

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Work Group Recommendation
<ul style="list-style-type: none"> • Opioids should be avoided for patients with substance use disorder or concomitant benzodiazepines use. • If a patient with substance use disorder is prescribed opioids, the opioid dose should be less than 50 MME/day. • If patient requires both opioids and benzodiazepines, opioids should be less than 50 MME/day, taking into careful consideration the benzodiazepine dose. There should be good communication among providers regarding dosing.
<p>Benefit: Patients with substance use disorder or benzodiazepine use are at higher risk of overdose if given opioids. Therefore, it is prudent to avoid opioids in these populations. If opioids are prescribed, the work group recommends a dose less than 50 MME/day to minimize adverse events.</p> <p>Harm: Some patients will have undertreated pain.</p> <p>Benefit-Harms Assessment: The risk of prescribing opioids to these populations outweighs the beneficial pain relief opioids may provide. Alternative pain management strategies should be employed.</p>
<p>Relevant Resources: <i>Han, 2015 (Observational Study); Turner, 2015 (Observational Study)</i></p>

Studies have examined the relationship of the total daily dose of oral opioids, expressed as daily morphine milligram equivalents (MME), and opioid overdose death. In almost all cases a dose-response relationship is found, reaching statistical significance at 100 MME/day, with an increased risk of death thereafter (*Han, 2015; Gomes, 2011; Dunn, 2010*). The risk of death at 100 MME/day appears to be at least twofold, with some studies finding a higher risk than that. In a study of Washington state, where the maximum dose of opioids was limited, overdose deaths decreased (*Franklin, 2012*). The goal is to reduce the risk. The Centers for Disease Control and Prevention guideline for prescribing opioids for chronic pain recommends assessing balance of benefits and risks when considering increasing dosage to ≥ 50 MME/day and to avoid increasing dosage to ≥ 90 MME/day (*CDC, 2016*). This work group agrees that every effort should be made to keep chronic opioid use below 90 MME/day using the lowest dose possible to effectively treat pain.

Opioids incur greater risk of overdose in certain populations, including patients with substance use disorder or benzodiazepine use (*Centers for Disease Control and Prevention, 2016; Han 2015; Turner, 2015*). Therefore, opioids should be avoided in patients with substance use disorder or benzodiazepine use. Alternative pain management strategies should be employed for these patients. However, the work group recognizes there may be situations where opioids are given to these populations. It is the consensus of this expert work group that if opioids cannot be avoided for patients with substance use disorder or benzodiazepine use, the opioid dose should be less than 50 MME/day. This threshold is intended to provide guidance in the absence of direct evidence. The clinician must also carefully consider the benzodiazepine dose. Communication among providers is critical for patient safety.

For additional information about MME, please see Appendix C, "Opioid Pharmacology."

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Opioid Rotation and Conversion

Work Group Recommendation
<p>Opioid conversion tables should be used only as guidance when changing opioids.</p> <p>Doses of the new opioid should be reduced by 50% of the previous daily MME dose and titrated to achieve analgesia.</p>
<p>Benefit: This avoids overestimating opioid needs with a new opioid due to incomplete cross-tolerance and reduces the risk of adverse events and harm with the new opioid.</p> <p>Harm: Patients may not experience adequate pain relief if taking opioids chronically and may experience mild withdrawal until the new opioid can be titrated to effective dose. This dose reduction may lead to more frequent dose changes and clinic visits until adequate pain control is achieved.</p> <p>Benefit-Harms Assessment: Opioid conversion tables were developed from opioid-naïve patients and do not account for incomplete cross-tolerance in opioid-tolerant patients. Despite the chance of mild withdrawal, it is safer to underestimate the dose titrating as necessary than overestimate the dose causing harm.</p>
<p>Relevant Resources: <i>Pasternak, 2014 (Report); Vissers, 2010 (Review); Fine, 2009 (Consensus); Pasternak, 2005 (Summary Article)</i></p>

Opioid rotation refers to a switch from one opioid to another in order to minimize adverse effects or improve therapeutic response (*Pasternak, 2014*). The exact mechanism by which opioid rotation improves response is not known, but the theoretical basis relates to individual variation between opioids and their relative potencies (*Knotkova, 2009*). Equianalgesic tables can be used to estimate the optimal dose of a new opioid, but they provide only an estimate (*Vissers, 2010*). Most patients will require a lower dose than what is calculated, due to the development of cross-tolerance.

The long-term exposure to any medication, which results in the development of tolerance to the effects of other structurally similar medication, is the phenomenon known as cross-tolerance (*Dumas, 2008*). The cross-tolerance that develops from long-term exposure to opioids is incomplete and may be due to multiple mechanisms (*Dumas, 2008*), including genetic differences between individuals that result in reduced receptor densities (*DuPen, 2007*), altered binding affinities and desensitization of the mu opioid receptors (*Ross, 2005*).

Due to the incomplete cross-tolerance of opioids and the variability of the equianalgesic tables, the range of dose reductions used by studies for opioid rotation is broad. A dose reduction of 33-75% (*Pasternak, 2014; Vissers, 2010; Pasternak, 2005*) has been identified in the literature. Regardless of the conversion used, it is recommended to initiate the new opioid at the lowest dose and gradually titrate the dose, if necessary, to provide adequate analgesic response (*Vissers, 2010*). The work group recommends that doses of the new opioid should be reduced by 50% of the previous daily MME dose and titrated to achieve analgesia.

Advances in mobile technology have brought many opportunities to access reference material in a variety of formats (*Haffey, 2013*). Although the number of available apps continues to increase, there is little data regarding the reliability and effectiveness of these tools (*Wallace, 2014*). The majority of the applications available for download have no evidence of health care professional (HCP) involvement (*Wallace, 2014; Haffey, 2013*). Of the 23 applications identified in one study, 11 (48%) provided a direct reference for their opioid conversions and 10 (43%) had a dose reduction tool to account for cross-tolerance (*Haffey, 2013*).

A statistically significant difference in conversion outputs for hydromorphone was found between mobile applications with and without medical involvement, but the differences for codeine, oxycodone, fentanyl and morphine were not significant (*Haffey, 2013*). The FDA has recently released guidance for mobile

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medication applications with plans to enforce medical devices applications but does not explicitly list opioid conversion calculators. For additional information, refer to <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>.

This guideline does not endorse the use of one specific application over another, but does recommend using applications with health care provider involvement and transparency about the source of the information used.

Opioid Hyperalgesia

A consequence of high-dose opioids besides overdose is hyperalgesia. Some patients become sensitized to pain as their dose of opioids increases. The prevalence of this condition is not known (*Meldrum, 2003*). Escalating pain despite escalating opioid doses, in the absence of corresponding tissue damage, suggests this condition. If the patient has opioid-induced hyperalgesia, lowering the dose will produce relief. If opioids are unavoidable and the patient has opioid-induced hyperalgesia, consultation with a pain specialist is warranted.

Methadone

Work Group Recommendation
Initiating an opioid-tolerant patient on methadone for chronic pain should be reserved for experienced clinicians who are familiar with its use because its long half-life is associated with overdose and death.
<p>Benefit: Trained clinicians are more familiar with the pharmacokinetic/pharmacodynamics properties of methadone and are better equipped to dose appropriately and provide the necessary monitoring to avoid adverse events.</p> <p>Harm: Clinicians trained in methadone prescribing may not be available to all patients who may benefit from methadone.</p> <p>Benefit-Harms Assessment: Methadone has a long and variable half-life that is not consistent between patients. It is highly lipophilic, and the respiratory depressant effect lasts longer than the analgesic effect. Methadone requires close follow-up and should only be initiated by clinicians experienced with its use.</p>
<p>Relevant Resources: <i>Wong, 2013 (Summary Article); Chou, 2009b (Guideline)</i></p>

Of all the opioids, methadone has one of the longest and most variable half-lives, thereby increasing the risk for accumulation of toxic levels (*Paulozzi, 2012*). In addition, there are many important drug-drug interactions. Consequently, choosing the dose for acute pain management using methadone requires slow, careful titration of the dose. Patients need careful education. Methadone has been associated with a disproportionate number of overdose deaths relative to how often it is prescribed (*Centers for Disease Control and Prevention, 2016*). Many opioid guidelines, including ours, advise prescribers against using methadone for pain unless they have specific training.

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Fentanyl

Recommendation
<ul style="list-style-type: none"> • Initiating transdermal fentanyl should be done only for patients with chronic opioid use greater than 60 MME daily, adequate subcutaneous adipose tissue and the cognitive ability to apply, remove and dispose of the patches safely. • Patches should be removed after 72 hours, folded upon themselves sticky side inward and promptly flushed down the toilet. • Sublingual fentanyl should be reserved for only those in need of palliative care for extreme pain and unable to take any alternatives.
<p>Benefit: Fentanyl patches are long-acting, renal-safe synthetic opioids, and as such they occupy a fairly unique niche in the opioid pharmacopeia. There are not many replacement medications.</p> <p>Harm: Fentanyl products are associated with accidental overdose deaths, including when an improperly disposed patch sticks to a toddler or household pet. Transdermal fentanyl is unsafe in cachectic patients lacking adipose tissue, given fentanyl's lipophilicity. SL fentanyl is exceedingly potent and apt to cause overdose if overused.</p> <p>Benefit-Harms Assessment: Fentanyl is a highly potent, lipophilic synthetic opioid that can be used to good effect treating pain if opioids are indicated. However, due to its high potency, fentanyl has caused accidental overdoses, and the transdermal patches need special handling and disposal instructions. Only patients with established opioid tolerance should receive fentanyl. Fentanyl SL formulations can be very helpful but are best reserved for those in pain in the dying process.</p>
<p>Relevant Resources: <i>U.S. Food and Drug Administration, 2013; U.S. Food and Drug Administration, 2012</i></p>

Every year transdermal patches are responsible for accidental opioid poisoning deaths of children and house pets inadvertently exposed to discarded patches (*U.S. Food and Drug Administration, 2013; U.S. Food and Drug Administration, 2012*). Therefore, careful disposal information is critical. Inappropriate handling or tampering with fentanyl patches is extremely dangerous and may cause death.

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13.8. Monitoring Considerations for Opioid Use

All recent opioid-related guidelines agree that patients receiving opioid analgesics require monitoring (*Gaither, 2016*), though the nature of the monitoring is not supported by high-quality evidence.

Risk Assessment Tools

Risk assessment tools may be used in the monitoring of a patient taking opioids. Please see the "[Risk Assessment](#)" section in 13.2 for more detail.

Patient-Provider Agreements (PPA)

A patient-provider agreement (PPA) should be initiated at the time an opioid is prescribed for:

- High-risk patients
- Daily use of opioids > 30 days
- Patient already on opioids transfers to a new clinic
- Episodic use up to 90 days over the course of a year

However, if none of the above applies, initiate a PPA after 90 days of opioids is prescribed.

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Please see the "Patient-Provider Agreement" section in 13.4, "Prescriber Responsibility with Opioid Prescriber," for more detail.

Prescription Monitoring Program (PMP)

Work Group Recommendation
<p>The prescription monitoring program (PMP) should be queried in the following situations:</p> <ul style="list-style-type: none"> • If opioids are prescribed in dental, emergency department and urgent care settings, and when doses are changed. • In every instance where there are concerns of substance use disorder, overdose, diversion, indeterminate pain disorder or polypharmacy. • For those patients with an established stable dose of opioids for a chronically painful condition and a history of compliance with the prescriber, PMP checks should be at least twice per year. <p>Consider querying the PMP when initiating opioid therapy</p>
<p>Benefit: Detect clinician shopping, polypharmacy, opioid exposure and tolerance, and estimate the likely home supply of opioids. The PMP may reveal other prescribers whom to contact before prescribing opioids. A PMP query can help verify the patient's story. A PMP query affects clinician decision-making and may lower overall opioids prescribed and overdoses.</p> <p>Harm: PMP queries take time and training. Each state has a different program, with different laws governing their use, and incomplete cross-talk between states. Not every source of opioids is captured in a state PMP.</p> <p>Benefit-Harms Assessment: To query the PMP is yet another time and energy burden on medical providers, but it provides invaluable knowledge about the patient's exposure to opioids and other controlled substances, as well as other prescribers. Clinicians should know the loopholes and omissions inherent to their state's PMP.</p>
<p>Relevant Resources: <i>Han, 2015 (Observational Study); Rutkow, 2015 (Observational Study); Johnson, 2014 (Report); Albert, 2011 (Observational Study)</i></p>

Most guidelines recommend querying the PMP before prescribing an opioid, in all settings, even before giving a one-time opioid prescription to seemingly low-risk patients. Greater than 50% of the time an opioid is prescribed, the patient has already received an opioid from a different prescriber within the last month (*Gugelmann, 2011*). Opioid misuse and opioid use disorders do not obey the typical demographics of other drug use disorders (*Han, 2015*). In a study looking at opioid prescribing behavior before and after a PMP query, a high proportion of prescribing decisions is changed in light of the information the PMP query provided, both decreasing and increasing the total opioid prescribed (*Gugelmann, 2011*). After mandating PMP queries prior to all opioid prescriptions, deaths from opioid overdoses and total opioids prescribed decreased in New York, Oregon and Florida (*Vowles, 2015; Rutkow, 2015; Johnson, 2014; Oregon Health Authority, 2013; Albert, 2011; Porter, 1980*). It is helpful to document the results of the PMP in the medical record, both to demonstrate the physician's diligence in decision-making, and to capture outside information in the medical chart for future review.

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Urine Drug Screening

<p>Work Group Recommendation</p> <ul style="list-style-type: none"> • Routine random urine drug screens (UDS) for all patients on chronic opioid therapy for pain should be done at least once per year. • UDS should be done if there is concern of aberrant behavior based on a prescriber's assessments and clinical judgment.
<p>Benefit: UDS can identify other substances being used that were not disclosed by the patient. UDS can identify when the patient is not taking the prescribed substance.</p> <p>Harm: UDS are costly. UDS have many false positives and negatives and may be difficult to interpret. Patients may not be prepared to provide a UDS. Use of UDS has not been shown to improve outcomes. UDS does not, in itself, make a diagnosis of substance use disorder or diversion.</p> <p>Benefit-Harms Assessment: Despite many complicating factors and lack of evidence that it improves outcomes, it is still standard of care, and universally recommended, that opioid prescribers check UDS on all patients routinely, and in any patient when there is concern of diversion or unsanctioned substance use. The ideal frequency and type of urine drug screen is not known.</p>
<p>Relevant Resources: <i>Centers for Disease Control and Prevention, 2016 (Guideline); Starrels, 2012 (Observational Study), Reisfield, 2009 (Review); Michna, 2007 (Observational Study); Heit, 2004 (Review)</i></p>

Used properly, the UDS helps to identify patients at risk of adverse events and refer them to the appropriate level of care. Referral to mental health or substance use disorder treatment, however, does improve mortality (Gaither, 2016). Most guidelines recommend that a UDS be done before every new controlled substance prescription and routinely for existing prescriptions (Michna, 2007). There is scant evidence demonstrating that this leads to improved outcomes (Gaither, 2016; Starrels, 2010). In addition, a UDS can be costly and difficult to interpret (Reisfield, 2009; Michna, 2007; Heit, 2004). Even if interpreted accurately, a UDS does not diagnose a substance use disorder or confirm opioid diversion. Some clinicians use inappropriate UDS results as grounds for tapering opioids or dismissing the patient from care, but no evidence suggests this benefits the patient. The optimal frequency of UDS is not known, but random testing at least once per year, and as dictated by clinical suspicion, may be appropriate.

Pill Count Callbacks

Patients with higher risk may be asked to randomly come to the clinic or a pharmacy with less than 24 hours notice to count remaining opioid pills.

The medical literature has shown no well-established benefit of callbacks. Patients often express frustration that their life has been interrupted. Callbacks should be done only for patients demonstrating repeated difficulty taking their medicine as prescribed and for patients in whom there is suspicion of diversion. Some patient-provider agreements have a callback provision, so it is wise to warn patients in advance that a random pill count is possible, and confirm their contact information and travel plans.

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Visit Frequency

Work Group Recommendation
<p>When initiating an opioid prescription, patients should be monitored within a month to evaluate harms and benefits, and assess treatment goals.</p> <p>Patients on stable opioid doses should be seen every three months.</p>
<p>Benefit: Developing a strong relationship is important for both opioid prescribing and pain treatment. There is an increasing number of recommendations and regulations that apply to opioid prescribing. These can be time consuming and overwhelming to the patient if attempted on a single visit. Therefore, repeated education is necessary.</p> <p>Harm: There is not certain evidence that frequency of visits improves outcomes. Increasing frequency of visits may be burdensome to patients. Some patients have maintained stability on opioids with less frequent visits and may expect to continue the current expectations.</p> <p>Benefit-Harms Assessment: While there is a lack of definitive evidence, and this will consume health care resources and potentially burden patients, increasing the frequency of visits for those receiving opioids, in particular those early in treatment for their pain, allows for many critical tasks to take place between provider and patient including education, screening and relationship building.</p>
<p>Relevant Resources: <i>Centers for Disease Control and Prevention, 2016 (Guideline)</i></p>

Drug Enforcement Agency (DEA) recommendations are that every month's prescription for a schedule II controlled substance (e.g., most opioids) be accompanied by a doctor's visit and a medical document including physical exam, diagnosis and rationale for prescribing. For patients at a low risk of harm, the DEA allows for three months of opioids to be given at one time, using three separate written prescriptions (DEA Rules for Prescribers). In practice, patients on opioids are seen far less frequently than this, and often the documentation needs are not met. While research has not yet assessed whether more frequent visits improve outcomes, opioid prescribers should be prepared to see their patients frequently to ensure that treatment goals are met. In the highest risk patients, weekly visits may be necessary. The work group recommends that when initiating an opioid prescription, patients should be monitored within a month to evaluate harms and benefits, and assess treatment goals. The frequency of visits for a patient on chronic opioids is every three months, and this should be reserved for the most stable and long-term patients, never new patients.

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Referrals for High-Risk Patients

Work Group Recommendation
Opioid prescribers should have a referral source for psychiatric treatment, substance use disorder treatment, physical therapy and pain medicine available if needed.
<p>Benefit: It is important to provide patients with a multidisciplinary approach to the treatment of pain when necessary. Multidisciplinary care may improve pain outcomes and mitigate the harms caused by mental health and addiction, specifically lowering the risk of inadvertent overdose and death.</p> <p>Harm: Access to addiction and psychiatric resource in the community may be sparse.</p> <p>Benefit-Harms Assessment: Patients with mental health and/or addictive disorders receiving opioids are at high risk for harm, including death. To safely treat such patients, prescribers perform better and have better outcomes if they have access to referrals for assessment and treatment of these disorders.</p>
<p>Relevant Resources: <i>Gaither, 2016 (Observational Study); Reuben, 2015 (Report)</i></p>

Patients in pain benefit from a team approach. Recent evidence suggests that access to physical rehabilitation services, psychiatric care and substance use disorder treatment confers mortality benefit for patients on chronic opioids (*Gaither, 2016; Reuben, 2015; Coffin, 2014*). Communication among the many clinicians caring for a patient in pain is essential. Communication among clinicians may require a release of information (*Substance Abuse and Mental Health Services Administration, The, 2016*). Typically the patient should be expected to receive opioids from only one clinician and allow open communications among all clinicians.

Overdose

Opioid overdose is the most serious adverse effect of opioids. Pharmaceutical opioid overdose deaths rose dramatically in the late 1990s and early 2000s, accounting for more than 18,800 deaths in 2014 (*Centers for Disease Control and Prevention, 2016; Bock, 2015; Jones, 2013b; Centers for Disease Control and Prevention, 2011*). This was the highest toll yet recorded. One does not need to have an opioid use disorder (OUD) to have an opioid overdose, though OUD is the most important risk factor. Other risks for opioid overdose include total opioid doses greater than 100 MME/day (*Liang, 2015; Gwira, 2014; Paulozzi, 2012; Bohner, 2011*), recent initiation of a long-acting opioid formulation (*Dhalla, 2009*), advancing age, any substance use disorder (excluding tobacco), a mental health disorder, past opioid overdose (*Jones, 2013b*) and concomitant benzodiazepine use (*Dasgupta, 2016; Han, 2015; Turner, 2015; Jones, 2015; Dhalla, 2009*). Important medical comorbidities that make a patient vulnerable to opioid overdose include renal insufficiency, respiratory insufficiency, sleep apnea and cognitive impairment.

In a patient surviving an opioid overdose, it is crucial to diagnose OUD if present, and to refer for appropriate treatment (*Gaither, 2016; Volkow, 2016b*). Absent an OUD diagnosis, the clinical intervention should be tailored to the cause of the overdose. In a study of non-fatal opioid overdoses, 91% of patients are maintained on opioids after surviving the overdose. Continuing opioids after surviving an opioid overdose confers risk of repeated overdose and death (*Larochelle, 2016*). Short of discontinuing the opioid, other actions clinicians may take after opioid overdoses include renal dosing, discontinuing a benzodiazepine and home health services to assist in adherence. Efforts should be made to minimize polypharmacy. A urine drug screen and an evaluation of alcohol use can uncover high-risk behaviors. Whatever the provider does, careful monitoring is required in patients who survive an opioid overdose. Providers should carefully document patients' understanding of the event and their reaction to it.

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13.9. If Opioid Use Disorder is Suspected, Consider Referral to Addiction Medicine Specialist

Opioid Use Disorder Assessment

Work Group Recommendation
<p>Opioid prescribers should recognize the symptoms of opioid use disorder.</p> <p>Opioid prescribers should understand the treatment options for opioid use disorder and have a referral source available.</p>
<p>Benefit: Patients with opioid use disorder (OUD) receiving opioids for pain are at high risk of aberrant behavior and overdose death. Making the diagnosis of OUD and offering the proper referral for treatment may be a lifesaving intervention. Buprenorphine and methadone, given by a certified and trained specialist in their use, confers mortality benefit for patients with OUD. Intramuscular naltrexone decreases illicit use of opioids.</p> <p>Harm: Physicians are largely untrained at recognizing, counseling and treating patients with OUD. Referral options for medication-assisted therapy are sparse in many communities.</p> <p>Benefit-Harms Assessment: Of all the patients receiving opioids for pain, those with OUD are at the greatest risk of harm. Yet knowledge of diagnosis and treatment of OUD is insufficient among opioid prescribers. It is critical that providers take the time to become versed with this important risk factor of harm from opioids.</p>
<p>Relevant Resources: <i>Cousins, 2016 (Observational Study); Gaither, 2016 (Observational Study); Fullerton, 2014 (Review); Thomas, 2014 (Review); Carrieri, 2006 (Report)</i></p>

A systematic review of 38 studies by Vowles et al. (2015) found that the rates of opioid misuse averaged between 21 and 29% among adult patients with chronic non-cancer pain. Misuse was defined as opioid use contrary to the directed or prescribed pattern of use, regardless of the presence or absence of harm or adverse effects (Vowles, 2015). In 2013, the nationwide 12-month prevalence of nonmedical use of prescription opioids and opioid use disorder (OUD) was 4.9 and 0.9%, respectively (Han, 2015). Adolescents with healthy attitudes about drugs who are exposed to sanctioned opioid pharmaceuticals for pain have a 33% increase in future opioid misuse after high school (Miech, 2015). Opioid-naïve adults who received opioids after a cataract removal had a 62% increased chance of still taking opioids a year later (Alam, 2012). Opioid misuse, and later OUD, should not be viewed as "aberrant behavior" happening in difficult patients. It should be viewed as a potential adverse effect of opioids in all patients (Volkow, 2016b; Kirschner, 2014; Dowell, 2013).

Risk factors for developing opioid misuse include another addiction (including tobacco), mental health disorders, history of childhood sexual trauma, past incarceration, family history of addiction, young age and higher reported pain severity (Sehgal, 2012; Liebschutz, 2010; Chou, 2009d; Lanier, 2009). Twin studies show that the heritability of OUD is 55%, and in some groups even higher (Sun, 2012). Knowledge of risk factors is critical, but no patient is free of risk of developing OUD.

Opioid use disorder, or addiction, is one of the most consequential and feared adverse effects of opioid use (Volkow, 2016b; Kirschner, 2014). The best clinical tool for diagnosing OUD is the recently updated DSM-5 criteria (American Psychiatric Association, 2013). The ASSIST-2 is a validated tool used to screen for substance use disorders. Patients with OUD can be challenging. Some physicians find it hard to address these patients' needs in the current medical system (Lembke, 2012; Zgierska, 2012).

Pain and OUD are not mutually exclusive (Neumann, 2013; Alford, 2006). A patient can suffer from chronic pain and secondarily develop an OUD; patients with OUD commonly develop painful conditions. The prevalence of OUD has been estimated at 10% or higher, by various authors, among patients taking opioids

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chronically for pain (Vowles, 2015; Juurlink, 2012; Boscarino, 2011). Some patients on chronic opioids for pain who develop OUD report improved pain control in a medication-assisted treatment setting using methadone or buprenorphine (Neumann, 2013).

Opioid Use Disorder Treatment

OUD is a treatable chronic disease (Volkow, 2016b; Volkow, 2014). Patients taking opioids chronically, who have access to substance use disorder services have a lower rate of overdose death (Gaither, 2016). Treatment of OUD is the same regardless of the primary opioid used. No opioid should be considered inherently less addictive.

All opioid prescribers should understand the diagnostic criteria of OUD and have a referral for appropriate treatment available (Coffin, 2014). FDA approved treatments of OUD include sublingual buprenorphine, oral methadone and intramuscular naltrexone (Volkow, 2014). Methadone and buprenorphine have a well-established record of improving mortality, decreasing incarceration, decreasing IV needle use and improving pregnancy outcomes (Cousins, 2016; Fullerton, 2014; Thomas, 2014; Volkow, 2014; Schwartz, 2013; Carrieri, 2006). Intramuscular naltrexone for OUD maintained sobriety in greater than 50% of patients for the first year (Krupitsky, 2013). Intramuscular naltrexone can be prescribed by doctors and advanced practice providers. Only physicians can prescribe buprenorphine after completing an eight-hour training course (Volkow, 2014). Methadone maintenance therapy for OUD should be provided only by a licensed addiction clinic (Volkow, 2014). If a methadone or buprenorphine patient is admitted to the hospital, his or her maintenance drug can be continued by the inpatient provider if deemed medically suitable (Alford, 2006).

Buprenorphine and naltrexone displace opioid agonists from the opioid receptors, blocking the action of opioid analgesics. Providers treating patients in pain who are taking these opioid blockers should consult with a physician or pharmacist knowledgeable about these medications. Patients on methadone maintenance therapy (MMT) can be given conventional opioid analgesics for pain, in the same quantity and strength. MMT patients will have diminished effect of the opioids and also have a higher risk of overdose and misuse of the opioids (Alford, 2006). Therefore careful consideration of the risks and benefits for these patients is important. The most important step when treating a patient with an OUD on medication-assisted therapy is to communicate with his or her addiction provider. This will require a specific release of information (Substance Abuse and Mental Health Services Administration, The, 2016).

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13.10. Offer Discontinuation of Opioids or Taper at Intervals of Six Months

The following are indications for discontinuation/taper of opioids:

- Patients who have had an opioid overdose require rapid dose reduction or opioid discontinuation, or another appropriate adjustment of medical care. Laroche (2016) found that of 91% of opioid overdoses requiring hospitalization, the opioid dose is not adequately tapered.
- Patients at very high risk of opioid-related harm need rapid dose reduction or opioid discontinuation in a safe place.
- Patients not at risk of withdrawal (e.g., on low doses) can be discontinued without a taper.
- Patients with repeated infractions of the patient-provider agreement or with known diversion can be discontinued without a taper.
- Every patient on opioids should be offered individualized opioid tapering and additional treatment options at six-month intervals.

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Patients of any risk level who are not at risk of withdrawal can discontinue opioids without adverse effects. Patients at high risk for harm who are in pain may have an increase in pain as their opioids are decreased. Discontinuing opioids usually does not resolve the underlying pain generator; nor does it address the cause of any aberrant opioid-related behaviors. Providers who discontinue opioids incautiously may cause a health care crisis in the patient and create burden in other parts of the medical system.

Providers need to carefully assess when the harm to the patient of continuing opioids outweighs the harm of discontinuing the opioids. Patients are not always willing participants in the discontinuation of their opioids, but in select circumstances there are established benefits.

Immediate Discontinuation of Opioids

In some cases, an ongoing prescription of opioids should be discontinued immediately without a taper. Such cases include life-threatening side effects from the opioid, known diversion or a serious breach of the patient-provider agreement. Immediate discontinuation is also appropriate if the patient's exposure to opioids was minimal to begin with. If the patient has already passed through withdrawal – five or more days from his or her last opioid – the patient does not require a taper.

A past opioid overdose is the most compelling reason to immediately discontinue or drastically lower opioids. One study found that after non-fatal opioid overdoses, 93% of patients remain on opioids, conferring risk of repeat overdose and death (*Larochelle, 2016*). With or without an overdose, OUD should warrant prompt referral to a medication-assisted addiction program and discontinuation of opioids. Patients with OUD who are tapered off opioids are at risk of self-harm unless referred to treatment (*Compton, 2016; Nagar, 2015*). Inpatient detoxification programs are available for those who do not want to attend an addiction program but also do not want to experience withdrawal.

Tapering Opioids

Work Group Recommendation
<p>Once the patient and clinician agree to taper opioids, it should be individualized to the patient's circumstances, and a referral source should be available.</p> <p>While tapering opioids, patients should be offered additional treatment options and frequent follow-up.</p> <p>Opioid tapering should be discussed and offered at intervals of six months for all patients on chronic opioids.</p>
<p>Benefit: Each patient has unique reactions to opioids and exposure to them, making uniform tapering protocols impractical. Patient involvement in their own taper may improve outcomes. Intensified care during an opioid taper may improve patient-doctor communication and identify complications early.</p> <p>Harm: No good trial demonstrates how to best taper patients receiving opioids.</p> <p>Benefit-Harms Assessment: Guidelines and protocols are encouraging less use of opioids and emphasizing the harms of opioids but no one can say with certainty how to best taper a patient already on opioids. A reasonable recommendation is that providers work closely with patients, monitoring for risks, and individualize an opioid taper.</p>
<p>Relevant Resources: <i>Accurso, 2016 (Observational Study); Centers for Disease Control and Prevention, 2016 (Guideline); Berna, 2015 (Review)</i></p>

Clinicians should routinely ask patients on chronic opioids if they would like to try to discontinue their opioids, even if there are no adverse events. It is the consensus of the work group that opioid tapering

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should be discussed and offered at intervals of six months for all patients on chronic opioids. This discussion should be part of the review of pain, function, quality of life, medications, adverse effects and the risk/benefit analysis for opioid use.

It is impossible to know the correct number of days, or increments of change, to make an outpatient opioid taper successful. Therefore, providers tapering opioids should maintain open communication and close follow-up throughout the process. Factors that complicate outpatient tapers include long duration of opioid therapy, high-dose opioids, past failed tapers, psychiatric comorbidity, substance use disorders and cognitive impairment.

Traditionally opioids are tapered in increments of 10% of the original dose. The fastest taper is 10 days, each day lowering by an equal amount (*Berna, 2015*). Tapers are often 30, 45 or 60 days, decreasing opioids by 10% at regular intervals throughout (*Centers for Disease Control and Prevention, 2016*). Exact increments of 10% are often not possible and are not necessary. Patients may tolerate increments as great as 30% early in the taper and prefer increments less than 10% late in the taper (Washington state guideline). What matters most is open communication and steady progress toward the goal of cessation of opioids (*Accurso, 2016*).

Pregnant women who are at risk of opioids withdrawal should not be tapered off opioids without expert guidance. Opioid withdrawal in pregnancy can cause preterm labor and miscarriage.

A prolonged taper may be preferred for patients on long-term, high-dose opioids without an urgent reason for a taper. Decreasing the opioid dose once a week, or even once every other week, allows the patient to adjust fully to the new, lower dose before the dose changes again. Prolonged tapers allow the patient to take the same number of pills every day for a week or more, simplifying the regimen and helping adherence. If the patient is feeling unwell, a brief pause in the taper is acceptable. Patients may take six months or longer, slowly and steadily lowering the opioid dose, before they discontinue the opioid entirely.

Troubleshooting a Failed Taper

During a taper, patients may experience sweats, chills, gastrointestinal symptoms, poor sleep, restlessness and a variety of types of pain (*Wesson, 2003*). It is appropriate to reassure the patient that this is an expected part of withdrawal and offer symptomatic support. As the taper progresses, the pain treated with opioids may reemerge. Addressing that pain through other modalities is critical. Patients are less likely to adhere to the taper if they are not provided with other tools to address their pain.

Sometimes a taper fails because it involves too many small doses of opioids. Simplifying the taper by switching to a comparable opioid dose, but consolidating to fewer long-acting pills, may improve outcomes. For example, a patient may fail to taper from 24 five mg oxycodone tablets taken daily but succeed at tapering from two long-acting oxycodone taken daily. This should be done only by an experienced clinician as long-acting opioids are generally not preferable to short-acting opioids and medication adherence is essential. In addition, consulting with a pharmacist may help you design the optimal taper.

As opioids are tapered, anxiety will increase. The more rapid the taper, the more pronounced the effect. If the patient has an underlying mental health disorder he or she is less likely to tolerate the taper, particularly a rapid taper (*Wasan, 2015*). Pain psychology consults and psychiatry may be necessary if a taper is failing. Giving the patient some control over the speed of the taper may also help.

Patients with underlying substance use disorders may struggle with tapering opioids. They are also at risk of harming themselves after a taper by seeking opioids through other, sometimes illicit, channels (*Dart, 2015; Nagar, 2015*). Patients with OUD should be referred to a medication-assisted treatment program, which can either maintain or taper the patient on an alternative and safer medication (buprenorphine or methadone) (*Berna, 2015*). Patients with other substance use disorders need close follow-up and careful monitoring of their substance use as they taper. An alcoholic may compensate for decreased opioid by increasing alcohol intake.

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Patients unable to consistently follow instructions may need an intervention to assist adherence. Patients with cognitive impairments may not be able to execute a taper. Benzodiazepines cause amnesia and disinhibition, both of which may interfere with a taper. Sometimes the very aberrant behavior that prompts the taper (erratic pill taking) is the thing that makes the taper fail. Home health services with automated medicine cabinets help some patients. Some pharmacies are willing to accept multiple short-term prescriptions for the opioid taper, breaking the taper up into a week at a time or less frequently.

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14. Coordination of Care and Follow-Up

The collaborative care model is an approach to health care delivery that includes providing care management and system support (Katon, 1999). It utilizes a team approach including the patient as a team member and specialty consultation support.

Elements of a collaborative care model include:

- Dedicated staff to coordinate, support and educate patients
- Methods for reliable and systematic patient follow-up
- Consistent use of evidence-based treatment practices

The care team may include members outside of the health care system or clinic. The creation of information-sharing protocols among the entities is crucial; the patient's consent for this sharing must be obtained. Primary care clinicians can play an important role in the seamless coordination of care, with the help of nurse care managers and community health workers.

Ongoing shared decision-making

The care team must have the tools and resources needed to engage in close communication with the patient while the care plan is being instituted. Alterations to the plan are common and need to be reflected in the written care plan. Again, mutual agreement between the patient and the care team regarding changes in the plan is vital.

Contracts and patient self-management

Physicians use "medication contracts" to monitor the patient's adherence to the care plan. These contracts are instituted most often when opioids are prescribed but could be used in other instances where the care team deems them necessary. The use of a pain management contract allows for the documentation of understanding between the care team and the patient. This document should be seen as a means to facilitate care and can, if used appropriately, improve communication among the clinicians and patient. Many of the elements within a pain agreement hold the patient accountable for his or her own self-management of the pain medication.

Follow-up and communication plan

A follow-up plan as well the patient's preferred means of communication should be outlined in the care plan. Coordination of appointments is the obligation of the care team. With the many new ways patients communicate with their care team (e.g., text messaging, patient portals) or receive care (e.g., telehealth visits), the ease of communication has been improved when these tools are implemented.