

## Opioid treatment recommendations for acute pain:

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### Acute Pain Recommendation 1:

Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief. *Reference Guidelines: 3*

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Most acute pain is better treated with non-opioid medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs (NSAID), or therapies such as exercise, or specific stretching) than opioid medications which have less desirable adverse effect profiles in acute pain patients. Care should be taken to assure that use of opioid pain treatment does not interfere with early implementation of functional restoration programs such as exercise and physical therapy. The developing brain may be more susceptible to addiction when exposed to opioid medications and nonmedical use is more common among younger people. Those risks should be considered when prescribing to an adolescent.

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### Acute Pain Recommendation 2:

When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on usual duration of pain severe enough to require opioids for that condition.

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Prescribing more medications than the amount likely to be needed leads to unused medications being available for non-medical use or abuse. Use of opioid pain medications should be stopped when pain severity no longer requires opioid medications.

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### Acute Pain Recommendation 3:

When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, not share with others, and to dispose of properly when the pain has resolved in order to prevent non-medical use of the medications.

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It is important that patients understand the need to store medications securely. Encourage patients to keep medications in a locked environment rather than in typical locations, such as the bathroom or kitchen cabinet, where they are accessible to unsuspecting children, curious teenagers, and can be a target for theft. Tell the patient that if they have leftover medication after they have recovered, they should dispose of their medication immediately to help protect them from being a target for theft as well as protect others from getting into the medications. The Federal Guidelines on Proper Disposal of Prescription Drugs are included in the Tool Section.

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### Acute Pain Recommendation 4:

Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted. Methadone is rarely if ever indicated for treatment of acute pain.

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### Acute Pain Recommendation 5:

The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

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Patients with acute pain who fail to recover in a usual timeframe or otherwise deviate from the expected clinical course for their diagnosis should be carefully evaluated. The continuation of opioid treatment in this setting may represent the initiation of opioid treatment for a chronic pain condition without being recognized as such at the time. The diagnosis and appropriateness of interventions should be reevaluated and the patient's medical history should be reviewed for comorbidities that could interact with opioid treatment and for risk factors for problems during opioid treatment, including substance abuse or history of substance abuse. It is recommended that the provider check the Utah Controlled Substances Database at this time as well.

## Opioid treatment recommendations for chronic pain:

### Before prescribing opioid treatment for chronic pain:

#### 1. Comprehensive initial evaluation/assessment of patient

##### 1.1 Recommendation:

A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain.  
*Reference Guidelines: 1, 2, 4, 6*

There are many reasons for using caution when initiating opioid therapy, therefore the recommended comprehensive initial evaluation is very important. A major goal when prescribing opioids should be to provide greater benefit than harm to patients. Potential for serious harm exists, up to and including death, due either to overdose or to dangerous behaviors that occur while under the influence of these medications. The patient may be harmed, but others may also be harmed through diversion or because of an act performed by the patient on opioids. The most frequent harms are diversion, misuse, abuse, addiction, and overdose and predicting which patients will be affected by these harms is difficult. Initiating opioid treatment often results in short term relief, but that relief might not be maintained. Long-term use of opioid medications to treat chronic pain safely requires the commitment of adequate resources to regularly monitor and evaluate outcomes and identify occurrence of adverse consequences.

The goal of the comprehensive evaluation is to determine the nature of the patient's pain, evaluate how the pain is affecting the patient's function and quality of life, identify other conditions or circumstances that could affect the choice of treatment or the approach to managing that treatment, assess and evaluate prior approaches to pain management, and serve as a basis for establishing a plan for treatment and evaluation of treatment outcomes.

The evaluation should specifically address these issues:

##### 1) Assess pain and prior treatment of pain.

- Determine the cause of the pain and whether the pain is acute or chronic.

- Assess previous treatment approaches and trials for appropriateness, adequacy, and outcome.

##### 2) Assess presence of social factors, and medical or mental health conditions that might influence treatment especially those that might interfere with appropriate and safe use of opioid therapy (Department of Veterans Affairs & Department of Defense [VA/DOD], 2003):

- Obtain history of substance use, addiction or dependence (if present, refer to Recommendations 12.2 and 12.3).
- Identify psychiatric conditions that may affect pain or treatment of pain (if present, refer to Recommendation 12.4).
- Identify use of other medications that might interact with medications used to treat the pain. Particular attention should be given to benzodiazepines and other sedative medications.
- Assess social history, including employment, social network, marital history, and any history of legal problems especially illegal use or diversion of controlled substances.
- Assess for presence of medical conditions that might complicate treatment of the pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea.
- Central sleep apnea is common among persons treated with methadone and other opioid medications, especially at higher dosages. Some clinicians recommend that all patients who are considered for long-term opioid treatment receive a sleep study prior to therapy or when higher dosages are considered.

##### 3) Assess the effects of pain on the person's life and function.

- Assess the severity of pain, functional status of the patient, and the patient's quality of life using a method/instrument that can be used later to evaluate treatment effectiveness.

##### Tools to accompany Recommendation 1:

- Sheehan Disability Tool
- Pain Management Evaluation Tool

## 2. Consider alternative treatment options

### 2.1 Recommendation:

Alternatives to opioid treatment should be tried (or an adequate trial of such treatments by a previous provider documented) before initiating opioid treatment.

*Reference Guidelines: 1, 2, 3, 4, 5*

Opioid medications are not the appropriate first line of treatment for most patients with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. This approach is consistent with the World Health Organization's Pain Relief Ladder (WHO).

### 2.2 Recommendation:

Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions.

Tools to accompany Recommendation 2:

- Non-opioid Pain Management Tool

## 3. Screening for risk of addiction or abuse

### 3.1 Recommendation:

Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication long-term for chronic pain. *Reference Guidelines: 3*

A number of screening tools have been developed for assessing a patient's risk of misuse of medications. Several of these are included in the Tool Section. The screening tool results are intended to assist the clinician in determining whether opioid therapy is appropriate and in determining the level of monitoring appropriate for the patient's level of risk.

### 3.2 Recommendation:

Consider performing drug screening before initiating long term opioid treatment for chronic pain.

Research and experience have shown that drug testing can identify problems, such as use of undisclosed medications, non-use of reported medications (i.e., diversion), undisclosed use of alcohol, or use of illicit substances, that are not identified without that testing. Several experts involved in the development of these guidelines recommended that drug screening be done on all patients before initiating opioid treatment for chronic pain. However, drug testing can damage a provider-patient relationship, the results of testing can be difficult to interpret, and that recommendation attracted a substantial number of negative comments during the public comment period. It is recommended that drug testing be strongly considered and conducted especially when other factors suggest caution.

The drug screening should be either a urine drug screen or another laboratory test that can screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use. It is recommended that this testing be considered for all patients. When screening is limited to situations when there is suspicion of substance misuse, some misuse may be missed. In one study, testing results at first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most of these discrepancies involved finding substances not reported by the patient; a small minority reported taking medications that were not found on testing (Berndt, Maier, & Schutz, 1993).

The clinician may consider testing for illegal substances (See list of Urine Drug Testing Devices in the Tool Section) in addition to screening for opioids.

A positive drug screen indicates the need for caution, but does not preclude opioid use for treatment of pain. Consideration should be given to referral to substance abuse counseling and/or to a pain management specialist. If opioid medication is subsequently prescribed, the patient should be more carefully monitored and conditions

under which opioids are being prescribed should be well documented in the treatment plan (See Recommendations 5, 6, 8, 12).

Immunoassays can be done in the office. These can determine if opioids are present but do not identify specific ones, which can subsequently be determined by confirmatory laboratory testing. However, in many cases, going over the results of the initial in-office test carefully with the patient can eliminate the need for confirmation testing. It is extremely important to keep in mind that immunoassays have both false positive and false negative results. Over-the-counter medication, for example, can cause a positive result (Washington State Agency Medical Directors' Group [WSAMDG], 2007). The prescriber may want to consider confirmatory testing or consultation with a certified Medical Review Officer if drug test results are unclear (WSAMDG, 2007).

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### 3.3 Recommendation:

The prescriber should check Utah's Controlled Substance Database before prescribing opioids for chronic pain.

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Most patients who request treatment for pain are legitimately seeking relief of the pain. However, a subset of patients who present seeking treatment for pain are seeking drugs for recreational use, to support an established addiction, or for profit. Information about past patterns of controlled substance prescriptions filled by the patient, such as obtaining medications from multiple providers or obtaining concurrent prescriptions, can alert the provider to the potential for problems.

The State of Utah's Division of Occupational and Professional Licensing (DOPL) maintains the Controlled Substance Database Program, which is a searchable record of all prescriptions that are filled in the state for controlled substances. The Utah Controlled Substance Database Program was legislatively created and put into effect in 1995. It is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. Access to the data is provided to authorized individuals and used

to identify potential cases of drug over-utilization, misuse, and potential abuse of controlled substances throughout the state. This database is accessible to all controlled substance prescribers online at [www.csdb.utah.gov](http://www.csdb.utah.gov). A "Getting Started" presentation is available to help orient users to the site and to appropriate uses of the database.

Tools to accompany Recommendation 3:

- SOAPP-R
- Opioid Risk Tool
- Prescription Drug Use Questionnaire
- List of Recommended Urine Drug Screens

## Establishing Treatment Goals and a Written Treatment Plan:

### 4. Establish treatment goals

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#### 4.1 Recommendation:

When opioids are to be used for treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function.

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The treatment plan should be tailored to the patient's circumstances and the characteristics and pathophysiology of the pain. The pathophysiology helps to predict whether opioid medication is likely to help reduce pain or to improve function and therefore should be considered when establishing treatment goals. Non-opioid treatment modalities should be included in the treatment plan whenever possible, to maximize the likelihood of achieving treatment goals.

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#### 4.2 Recommendation:

Goals for treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain.  
*Reference Guidelines: 1, 3, 5*

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For most chronic pain conditions, complete elimination of pain is an unreasonable goal (College of Physicians and

Surgeons of Ontario, 2000). Goals for treatment of chronic pain should include improvement in the tolerability of the pain and in function (College of Physicians and Surgeons of Ontario, 2000). The clinician should counsel the patient on reasonable expectations for treatment outcomes so that together they can agree on achievable treatment goals addressing pain, function, and quality of life.

The pathophysiologic basis of the pain can help establish a prognosis for future improvement (or worsening) in function and pain and should influence the goals of treatment. Goals for functional improvement and measures to track progress against those goals should be established and documented to serve as a basis of evaluating treatment outcome (VA/DOD, 2003; Hegmann, Feinberg, Genovese, Korevaar, & Mueller, 2008). These include:

- Objective physical findings obtained by the examining clinician (e.g., improved strength, range of motion, aerobic capacity);
- Functional status at work (e.g., increase in physical output, endurance, or ability to perform job functions); and
- Functional status at home (e.g., increased ability to perform instrumental activities of daily living, and frequency and intensity of conditioning).

Targets for improved quality of life should also be identified and documented to serve as a basis for evaluating treatment outcomes. These may include:

- Patient rating of quality of life on a measurement scale
- Psychosocial status (e.g., increased social engagement or decreased emotional distress)
- Familial status (e.g., improved relationships with or decreased burden on family members)
- Physical status (e.g., increased ability to exercise, perform chores, or participate in hobbies).

Pain intensity should be assessed at each visit using a standard instrument such as the Numerical Rating Scale. See the Pain Management Evaluation Tool, Patient Pain and Medication Tracking Chart, Sheehan Disability Scale, and Brief Pain Inventory Form in the Tool Section or page 17 of VA/DOD guidelines.

Clinicians should consider cultural differences in assessing function, quality of life, and pain intensity (See <http://prc.coh.org/culture.asp> for examples). These measures of improvement could be reported by the patient, family members, and/or the employer. Permission to discuss the patient's condition with these persons should have previously been obtained and documented (See Recommendation 5.5).

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#### 4.3 Recommendation:

Treatment goals should be developed jointly by patient and clinician. *Reference Guidelines: 2*

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Engage patients in their own healthcare. Clinicians have observed that when patients assume a significant portion of the responsibility for their rehabilitation they are more likely to improve and that when they participate in goal setting they are more likely to achieve the goals. As with any other chronic illness (such as diabetes or heart disease), the clinician should focus not just on pain control, but also on treating the patient's underlying diseases and encouraging them to engage in ownership of their own health.

Tools to accompany Recommendation 4:

- Pain Management Evaluation Tool
- Patient Pain and Medication Tracking Chart
- Sheehan Disability Scale
- Brief Pain Inventory Form
- Sample Treatment Plan for Prescription Opioids
- Cultural considerations in assessing function, quality of life, and pain intensity:  
<http://prc.coh.org/culture.asp>

## 5. Informed consent and formulation of a treatment plan

### 5.1 Recommendation:

The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement.

*Reference Guidelines: 4*

The patient should be counseled about appropriate use of the medication, possible adverse effects, and the risks of developing tolerance, physical or psychological dependence, and withdrawal symptoms (Trescot et al., 2008; WSAMDG, 2007). Adverse effects can include nausea, constipation, decreased libido, sexual dysfunction, hypogonadism with secondary osteoporosis (Hegmann et al., 2008), opioid-induced hyperalgesia (Hegmann et al., 2008; WSAMDG, 2007), allodynia (WSAMDG, 2007), abnormal pain sensitivity (WSAMDG, 2007), and depression (Daniell, 2007).

Patients should be informed not to expect complete relief from pain. The excitement and euphoria of initial pain relief that may occur with a potent opioid can lead the patient to expect long term complete pain relief. Without careful guidance this may lead the patient to seek excessive dosing of opioids and to disappointment.

Sedation and cognitive impairment may occur when patients are taking opioid medication. Therefore, discuss with patients the need for caution in operating motor vehicles or equipment or performing other tasks where impairment would put them or others at risk.<sup>5</sup>

Ensure the patient does not have any absolute contraindications and review risks and benefits related to any relative contraindications with the patient.

Absolute contraindications for opioid prescribing:

- Allergy to an opioid agent (may be addressed by using an alternative agent)
- Co-administration of drug capable of inducing life-limiting drug-drug interaction
- Active diversion of controlled substances (providing medication to someone for whom it was not prescribed)

More detail about absolute contraindications is contained in the Tool Section.

Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

Signs of respiratory depression:

- Snoring heavily and cannot be awakened
- Periods of ataxic (irregular) or other sleep disordered breathing
- Having trouble breathing
- Exhibiting extreme drowsiness and slow breathing
- Having slow, shallow breathing with little chest movement
- Having an increased or decreased heartbeat
- Feeling faint, very dizzy, confused or has heart palpitations

### 5.2 Recommendation:

The patient and, when applicable, the family or caregiver should both be involved in the educational process.

*Reference Guidelines: 1*

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver (VA/DOD, 2003). Educating the family about the signs of opioid overdose may help detect problems before they lead to a serious complication.

It is crucial to act within the constraints of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates the conditions under which information about the patient can be disclosed to others, such as family members, and under what conditions discussions about the patient with others are allowed.

<sup>5</sup> Health care professionals are responsible to “counsel their patients about how their condition affects safe driving. For example, if medication is prescribed for a patient which may cause changes in alertness or coordination, the health care professional shall advise the patient about how the medication can affect safe driving, and when it would be safe to operate a vehicle.” R708-7-6(1)(b) Utah Administrative Code A health care professional or other person who becomes aware of a physical, mental, or emotional impairment that appears to present an imminent threat to driving safety and reports this information to the division in good faith has immunity from any damages claimed as a result of making the report. (§53-3-303(14)(c) Utah Code Annotated) Federal law prohibits driving a commercial motor vehicle while under the influence of a narcotic (CFR §391.15).

**5.3 Recommendation:**

The treatment plan, which defines the responsibilities of both patient and clinician, should be documented.

*Reference Guidelines: 1, 2, 3, 4, 5*

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. They could also include instructions to keep a pain diary, a diary or log of daily activities and accomplishments, and/or instructions on how and when to give feedback to the prescriber (VA/DOD, 2003).

The prescribing clinician may consider requiring that the treatment plan, be documented in the form of a treatment “contract” or “agreement” that is signed by the patient. Patients should be encouraged to store opioid medication in a lock box to keep the medication out of the hands of others who should not have access to them.

**5.4 Recommendation:**

The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum medication level screening upon request, and reasons for possible discontinuation of drug therapy. *Reference Guidelines: 1, 2, 4, 5, 6*

The treatment plan (sometimes referred to as treatment “contracts” or “agreements”) should contain the items that were developed jointly by patient and clinician, such as follow-up appointments, the pharmacy and clinician to be used, as well as any non-negotiable demands or limitations the clinician wishes to make, such as the prohibition of sharing or trading the medication or getting refills early. Specific grounds for immediate termination of the agreement and cessation of prescribing may also be specified, such as forgery or selling of prescriptions or medications (VA/DOD, 2003; Trescot et al., 2008) or obtaining them from multiple providers as documented by Utah’s Controlled Substance Database Program.

Optional inclusions in the agreement:

- Pill counts may be required as a means to gauge proper medication use (VA/DOD, 2003; Trescot et al., 2008).

- Prohibition on use with alcohol or certain other medications (VA/DOD, 2003)
- Documentation of counseling regarding driving or operating heavy machinery (VA/DOD, 2003 Hegmann et al., 2008)
- Specific frequencies of urine testing

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only (VA/DOD, 2003; Trescot et al., 2008; Federation of State Medical Boards, 2004).

It is not necessary to include specific consequences for specific non-compliant behaviors, but it should be documented in the treatment agreement that continuing failure by the patient to adhere to the treatment plan will result in escalating consequences, up to and including termination of the clinician-patient relationship and of opioid prescribing by that clinician.

A Sample Treatment Plan for Prescribing Opioids is included in the Tool Section.

**5.5 Recommendation:**

Discuss involvement of family members in the patient’s care and request that the patient give written permission to talk with family members about the patient’s care.

This is best done before starting to treat the patient because it can be more difficult to obtain consent after an issue occurs. Prior to initiating treatment with opioids, the physician may want to consider a family conference to help assess the patient’s integrity (Trescot et al., 2008). Consultation with others, however, must be done within the constraints of HIPAA, as noted above (See Recommendation 5.2). Guidance about communications with family and others under HIPAA can be found at: [http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/provider\\_ffg.pdf](http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/provider_ffg.pdf)

Tools to accompany Recommendation 5:

- Absolute Contraindications to Opioid Prescribing
- Sample Treatment Plan for Prescribing Opioids

## Initiating, Monitoring, and Discontinuing Opioid Treatment:

### 6. Initiate opioid therapy as a treatment trial

#### 6.1 Recommendation:

Opioid medication should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life.

The clinician should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid medication treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. Criteria for cessation should be considered before treatment begins. Refer to Recommendation 9 for more information on discontinuation of treatment.

#### 6.2 Recommendation:

In most instances, the trial should begin with short-acting opioid medication.

Short-acting opioid medications are in general safer and easier to titrate to an effective dose. If the treatment trial proves successful in achieving the goals established in the treatment plan, the prescriber may consider switching the patient to a long-acting or sustained-release formulation (See the Dosing Guidelines in the Tool Section). The patient's individual situation should influence whether the patient is switched from short-acting medication. Treatment with long-acting opioid medication before a trial using a short-acting medication has been performed is an option that should be prescribed only by those with considerable expertise in chronic pain management.

#### 6.3 Recommendation:

Parenteral<sup>6</sup> (intravenous, intramuscular, subcutaneous) administration of opioids for chronic pain is, in general, discouraged. *Reference Guidelines: 2*

Daily IM or SC injections should be avoided except under a highly supervised environment such as during an admission to the hospital or hospice.

Tools to accompany Recommendation 6:

- Dosing Guidelines
- COMM

### 7. Titration phase

#### 7.1 Recommendation:

Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). *Reference Guidelines: 1*

Follow-up face-to-face visits should occur at least every 2-4 weeks during the titration phase. More frequent follow-up visits may be advisable and caution should be used when prescribing opioid medication if the patient has a known addiction problem, suspected drug-behavior problems, or co-existing psychiatric or medical problems. Frequency of visits should also be based on risk stratification (e.g., as determined by a screening tool) and the clinician's judgment (taking into account the volume of the drug being prescribed and how likely it is to be abused) (College of Physicians and Surgeons of Ontario, 2000).

#### 7.2 Recommendation:

When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered. *Reference Guidelines: 1, 2*

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than

<sup>6</sup> These guidelines did not consider intrathecal administration and this recommendation was not intended to discourage trained and qualified physicians from using intrathecal opioid medications.

necessary by going too slowly with the risk of causing harm, including fatal overdose, by going too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient (VA/DOD, 2003). Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration. Particular caution should be used in titrating dosing of methadone.

Evidence and other guidelines are not in agreement regarding the risks and benefits of high daily doses of opioid measured in morphine equivalents. It is likely that the risk-benefit ratio is less favorable at higher doses. Clinical vigilance is needed at all dosage levels of opioids but is even more important at higher doses. Clinicians who are not experienced in prescribing high doses of opioids should consider either referring the patient or obtaining a consultation from a qualified provider for patients receiving high dosages. No clear threshold for high dose has been established based on evidence. The Washington State guideline (WSAMDG, 2007) suggested a threshold of 120 mg of morphine equivalent per day, but has been criticized for that decision. It seems reasonable to increase clinical vigilance at daily doses that exceed 120-200 mg of morphine equivalent per day.

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to Use Only as Directed, that is, not to change doses or frequency of administration without specific instructions from the clinician.

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### 7.3 Recommendation:

During the titration phase, until the patient is clinically stable and is judged to be compliant with therapy, it is recommended that the clinician check the Controlled Substances Database at least quarterly.

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For more information about the Controlled Substances Database, refer to Recommendation 3.3.

Tools to accompany Recommendation 7:

- Dosing Guidelines

## 8. Maintenance – Periodic monitoring and dose adjustments:

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### 8.1 Recommendation:

Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. *Reference Guidelines: 2, 4*

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Assess each of the following four areas of concern at each visit: Analgesia, activity, adverse effects, and aberrant behavior. These assessments can be remembered as the “four A’s” (Passik & Weinreb, 2000):

- Analgesia: inquire about level of pain (current, recent, trends, etc.)
- Activity: assess both the patient’s function and overall quality of life
- Adverse events: determine whether the patient is having medication side effects
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior

A sample checklist for signs of aberrant behavior is included in the Tool Section.

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### 8.2 Recommendation:

Providers should consider performing drug screening on randomly selected visits and any time aberrant behavior is suspected.

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As discussed in recommendation 3, drug testing has been shown to identify problems that might otherwise go undetected. It may not be appropriate or necessary for all patients, but should be strongly considered by providers and may provide an opportunity to discuss the risks and problems that can occur with opioid treatment. Base the frequency of random drug screening on the assessed degree of risk of aberrant behavior for the individual patient. Pill counts may also be useful in some circumstances.

**8.2 Recommendation:**

During maintenance phase, Controlled Substances Database should be checked at least annually.

After the titration phase is complete and the maintenance phase is underway, the frequency of checks of the Controlled Substances Database can be based on clinical judgment, but should be done no less than annually. The Controlled Substances Database should be checked more often for high risk patients and patients exhibiting aberrant behavior. For more information about the Controlled Substances Database, refer to Recommendation 3.3.

Consider evaluating for possible drug abuse-related behavior at each visit. A sample checklist is included in the Tool Section.

Provide reinforcement for previous counseling and additional education for patients at follow-up visits (Trescot et al., 2008).

Review the pathophysiologic hypothesis (to see if the diagnosis is still valid) at each visit (Trescot et al., 2008).

**8.3 Recommendation:**

Continuation or modification of therapy should depend on the clinician's evaluation of progress towards stated treatment goals. *Reference Guidelines: 4*

These include reduction in a patient's pain scores and improved physical, psychological and social function. If treatment goals, including patient compliance with agreed-upon activity levels, are not being achieved despite medication adjustments, the clinician should reevaluate the appropriateness of continued treatment with the current medications (WSAMDG, 2007; Federation of State Medical Boards, 2004).

A frequent need for dose adjustments after a reasonable time interval of titration is an indication to reevaluate the underlying condition and consider the possibility the patient has developed opioid hyperalgesia, substantial tolerance, or psychological/physical dependence.

**8.4 Recommendation:**

Adjustments to previously stable maintenance therapy may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant.

*Reference Guidelines: 1*

Options for adjustment include reducing medication or rotating opioid medication. If it is documented that the patient is compliant with agreed-upon recommendations such as exercise, working, etc., addition of supplemental short-acting medications for control of break-through pain exacerbation (e.g., as related to an increase in activity, end-of-dose pain, weather-related pain exacerbation, or specific medical conditions) can be considered as well. If patients do not achieve effective pain relief with one opioid, rotation to another frequently produces greater success (Quang-Cantagrel, Wallace, & Magnuson; 2000).

Only if the patient's situation has changed permanently and consideration has been given to increased risk of adverse events, is it reasonable to consider an ongoing increase in maintenance dosing (VA/DOD, 2003).

If rotating among different opioid medications, refer to a standard dosing equivalence table taking into account the current drug's half-life. (See the Dosing Guidelines in the Tool Section)

In general, if the patient's underlying medical condition is chronic and unchanging and if opioid-associated problems (hyperalgesia, substantial tolerance, important adverse effects) have not developed, it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level (VA/DOD, 2003).

**8.5 Recommendation:**

Dosing changes should generally be made during a clinic visit. *Reference Guidelines: 1*

If the patient's underlying pain-producing chronic medical condition improves, it is expected that the clinician will begin tapering the patient off the opioid medication (See Recommendation 10 for guidelines on discontinuation.)

Tapering opioid medication with or without the goal of discontinuation may be performed as described below (Recommendation 10) or as described in Strategies for Tapering and Weaning in the Tool Section.

Tools to accompany Recommendation 8:

- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse
- Pain Management Evaluation Tool
- Dosing Guidelines
- Strategies for Tapering and Weaning

## 9. Evaluate the treatment trial

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### 9.1 Recommendation:

Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient.

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### 9.2 Recommendation:

A second opinion or consult may be useful in making the decision to continue or discontinue the opioid treatment trial.

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## 10. Discontinuing opioid treatment

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### 10.1 Recommendation:

An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated. *Reference Guidelines: 5*

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### 10.2 Recommendation:

Discontinuation of opioid therapy is recommended if any of the following occurs:

- Dangerous or illegal behaviors are identified
- Patient claims or exhibits a lack of effectiveness
- Pain problem resolves
- Patient expresses a desire to discontinue therapy
- Opioid therapy appears to be causing harm to the patient, particularly if harm exceeds benefit

*Reference Guidelines: 1*

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The decision to discontinue opioid treatment should ideally be made jointly with the patient and, if appropriate, the family/caregiver (Federation of State Medical Boards, 2004). This decision should include careful consideration of the outcomes of ongoing monitoring.

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### 10.3 Recommendation:

When possible, offer to assist patients in safely discontinuing medications even if they have withdrawn from treatment or been discharged for agreement violations.

*Reference Guidelines: 1*

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The goal is to taper all patients off opioid medication safely. “Strategies for Tapering and Weaning” in the Tool Section contains advice on tapering opioid medications (WSAMDG, 2007). If the patient is discharged, the clinician is obliged to offer continued monitoring for 30 days post-discharge.

Tools to accompany Recommendation 10:

- Strategies for Tapering and Weaning

## Other Issues:

### 11. Documentation and Medical Records

#### 11.1 Recommendation:

Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed. *Reference Guidelines: 1, 2, 4, 5, 6*

#### 11.2 Recommendation:

A written treatment plan should document objectives that will be used to evaluate treatment success. *Reference Guidelines: 1, 2, 4, 5, 6*

The objectives should address pain relief, improved physical and psychosocial function, including work and exercise compliance, and should indicate if additional diagnostic tests, consultations, or treatments are planned (Trescot et al., 2008). Use of validated instruments to measure pain and function is preferred. Details on establishing treatment goals and formulation of a treatment plan are covered elsewhere in these guidelines (Recommendations 4 and 5.)

#### 11.3 Recommendation:

The prescription for opioid therapy should be written on tamper-resistant prescription paper in a manner to help reduce the likelihood of prescription fraud or misuse. *Reference Guidelines: 2*

The written prescription for opioid therapy should contain the name of the drug, the strength, the number of dosage units, (written numerically and in text), how the drug is to be taken, the full name, address, and age of the patient, the name, address, and DEA registration number of the practitioner, and the signature of the physician or other authorized practitioner. It shall be dated and signed on the day when issued. After a stable maintenance therapy dosage has been established and therapy goals have been achieved, schedule II opioid medications may be prescribed for three months by providing the patient

with prescriptions for each of the three months. Each prescription for a one month supply of medication should include the date the prescription is written and the date when that prescription is to be filled.

To reduce the chance of tampering with the prescription, write legibly, and keep a copy (College of Physicians and Surgeons of Ontario, 2000). (See the Tamper Resistant Requirements in the Tool Section.)

#### 11.4 Recommendation:

Assessment of treatment effectiveness should be documented in the medical record. *Reference Guidelines: 2, 4, 5*

Document the patient's progress toward treatment goals, including functional status, at every visit, rather than merely reporting the patient's subjective report of decreased pain. Ideally, this progress would be evaluated using validated tools (Trescot et al., 2008).

Both the underlying medical condition responsible for the pain, if known, and other medical conditions that may affect the efficacy of treatment or risks of adverse events should be evaluated and documented at every visit.

#### 11.5 Recommendation:

Adherence to the treatment plan, including any evidence of aberrant behavior, should be documented in the medical record. *Reference Guidelines: 1*

Specific components of the treatment plan for which adherence should be assessed include:

- Use of opioid analgesics
- Follow-up referrals, tests, and other therapies

Clinicians are encouraged to make use of resources provided by the state of Utah that are designed to assist them in managing patients with aberrant behavior (See Checklist for Adverse Effects, Function, and Opioid Dependence and Signs of Substance Misuse in Tool Section). Referral to law enforcement/legal agencies may be appropriate if actions by patients are occurring that could be criminal in nature (VA/DOD, 2003). Clinicians

should consider consulting with legal counsel before contacting law enforcement (VA/DOD, 2003). Serious non-adherence issues (illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid therapy. See Recommendation 10.

Tools to accompany Recommendation 11:

- Tamper Resistant Requirements
- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse

## 12. Consultation and management of complex patients

### 12.1 Recommendation:

Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment. *Reference Guidelines: 4, 5*

Prescribers may wish to consider referring patients if any of the following conditions or situations is present or if other concerns arise during treatment:

- The patient has a complex pain condition and the clinician wishes verification of diagnosis;
- The patient has significant co-morbidities (including psychiatric illness);
- The patient is high-risk for aberrant behavior or addiction; or
- The clinician suspects development of significant tolerance, particularly at higher doses.

The main goal of a consultation is for the prescribing clinician to receive recommendations for ongoing treatment.

### 12.2 Recommendation:

Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be considered for referral to an addiction specialist for evaluation of recurrence risk and for assistance with treatment.

*Reference Guidelines: 1, 4, 5*

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Utah where there is a shortage of readily available addiction specialists. The Directory of Resources in the Tool Section includes information on available resources for these patients.

### 12.3 Recommendation:

Pain patients who are addicted to medications/drugs should be referred to a pain management, mental health or substance use disorder specialist if available, for recommendations on the treatment plan and possibly for assistance in management.

The clinician may consider prescribing opioid medication for pain even if the patient has a self-reported or documented previous problem with opioids, as long as monitoring is performed during titration and maintenance phase.

### 12.4 Recommendation:

Patients with coexisting psychiatric disorder should receive ongoing mental health support and treatment while receiving opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation (Trescot et al., 2008; Federation of State Medical Boards, 2004). Unless the clinician treating the patient is qualified to provide the appropriate care and evaluation of the coexisting psychiatric disorder, consultation should be obtained to assist in formulating the treatment plan and establishing a plan for coordinated care of both the chronic pain and psychiatric conditions.

Tools to accompany Recommendation 12:

- Strategies for Tapering and Weaning
- Directory of Resources

### 13. Methadone

#### 13.1 Recommendation:

Methadone should only be prescribed by clinicians familiar with its risks and use, and who are prepared to conduct the necessary careful monitoring.

Methadone-related death rates have been increasing in Utah and the U.S. In 2006, methadone was implicated in 30% of non-illicit drug-related deaths in Utah. Methadone was the most common drug identified by the Utah Medical Examiner as causing or contributing to accidental deaths, accounting for a disproportionate number of deaths compared to its frequency of use. Methadone was the single drug most often associated with overdose death and had the highest prescription adjusted mortality rate (PAMR) with an average of 150 deaths for every 100,000 prescriptions during 1998-2004. From 1997-2004, population-adjusted methadone prescriptions increased 727%. The increase in the methadone prescription rate was for treatment of pain and not addiction therapy.

The half-life of methadone is long and unpredictable, increasing the risk of inadvertent overdose. The peak respiratory depressant effect of methadone occurs later and lasts longer after treatment initiation or dosage change than does the peak analgesic effect.

Conversion tables that have been established to assist with converting a patient from another opioid medication to methadone are considered by many experts to be unreliable.

Methadone metabolism is complicated and varies among individuals. Methadone interacts with several other medications that can alter its metabolism changing the effects of a given dose on pain and on respiratory depression. Potential for interactions should be considered before starting methadone in a patient taking other medications and before starting any medication in a patient taking methadone.

Methadone can prolong the rate-corrected QT interval (QTc) and increase the risk of Torsades de Pointe, and sudden cardiac death. Caution should be used in prescribing methadone to any patient at risk for prolonged QTc interval, including those with structural cardiac disease, cardiac arrhythmias or cardiac conduction abnormalities and in patients taking another medication

associated with QTc interval prolongation (Arizona Center for Education and Research on Therapeutics 2008). A useful on-line reference of such medications is available at: <http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm>

Clinicians should consider obtaining an electrocardiogram (ECG) to evaluate the QTc interval in patients treated with methadone, especially at higher doses. A recently published consensus guideline (Krantz 2009) recommended that an ECG be performed before prescribing methadone, within the first 30 days, and annually. Additional ECG examinations were recommended if the methadone dose exceeds 100 mg per day or if a patient on methadone has unexplained syncope or seizure. Guidance was provided for actions to be taken at two levels of QTc prolongation (450-500 ms and greater than 500 ms).

Methadone and other opioids have been associated with worsening obstructive sleep apnea and new onset of central sleep apnea. Clinicians should question patients about symptoms and signs of sleep apnea and consider obtaining a sleep study in patients treated with opioids if they develop any signs of sleep-disordered breathing or respiratory depression. This is particularly important for patients receiving higher doses of opioid medications. In one recent study, 92% of patients on opioid doses at or above 200 mg morphine equivalents had developed ataxic or irregular breathing (Walker, 2007).

Some clinicians recommend that all patients for whom higher doses of opioid medications are considered should be tested with a sleep study.

Tools to accompany Recommendation 13:

- Dosing Guidelines
- The Role of Methadone in the Management of Chronic Non-Malignant Pain