New Mexico Clinical Guidelines on Prescribing Opioids for Treatment of Pain

New Mexico Department of Health
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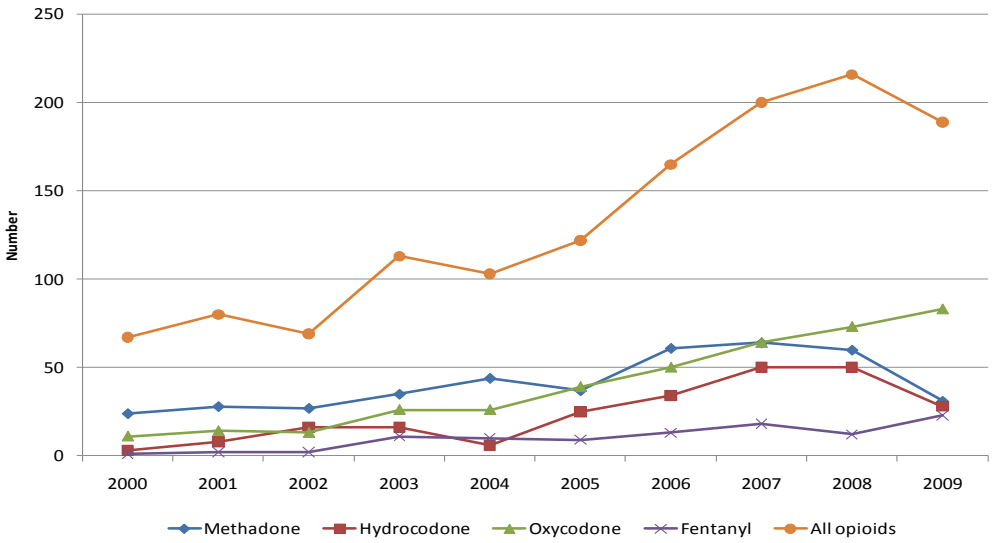
Background and Introduction

Unintentional fatalities due to prescription medications are an increasing problem in the U.S. and New Mexico (CDC, 2005; Mueller et al., 2006; Shah et al., 2008). The New Mexico death rate from prescription medication poisoning, or overdose, was fairly stable until 2003, but increased in subsequent years (New Mexico Office of the Medical Investigator). Since 2003, opioid medications that are typically used for pain management accounted for 80-90% of prescription medication overdose deaths in New Mexico, and nearly half of all unintentional overdose fatalities. The number of inpatient hospitalizations caused by heroin and synthetic opioids also increased nearly 140% during this same time period (New Mexico Health Policy Commission).

Nationally, opioid analgesics were listed as the cause of drug overdose death in 28.1% of all cases in 1999. By 2002, this had increased to 36.5% of overdose deaths, more than either cocaine or heroin (Substance Abuse and Mental Health Services Administration [SAMHSA], 2007). In New Mexico during 2000-2009, overdose death (of an unintentional or undetermined intent) attributed to prescription opioids increased by 180%, from 67 to 189 deaths. Although the overdose death rate from opioid medications decreased from 2008 to 2009 among New Mexicans, deaths from oxycodone continued to increase, causing as many overdose deaths in 2009 as methadone, hydrocodone and fentanyl combined.

Figure 1. Number of Overdose Deaths by Year and Drug: Unintentional and Undetermined Cause, New Mexico, 2000-2009



Of the roughly 5 million prescriptions for controlled substances Schedule II-IV dispensed in New Mexico during a recent two-year period, 57% were base opioids. Prescribing of opioid medications has substantially increased over the

past two decades, including greater use for acute and chronic pain. The rapid increase in sales (milligram/person) has led to greater availability and accessibility of opioid medications, accompanied by an increase in adverse outcomes related to these medications.

Prescription opioids are also diverted and increasingly abused. In 2009, 4.9% of Americans aged 12 or older reported using prescription pain medications non-medically in the past year. There was a statistically significant increase in the number of people aged 12 and older who received treatment in the past year for opioid addiction from 466,000 people in 2005 to 739,000 in 2009 (59% increase). Prescription pain medications (17%) were second only to marijuana (59%) as the first drug among those who initiated illicit drug use (SAMHSA, 2010a). During 2006-2008, it was estimated that 5.9% of New Mexicans aged 12 or older used pain medications non-medically in the past year (SAMHSA, 2010b).

Given these concerning trends related to prescription medications, U.S. states have taken action to formulate and implement interventions. The New Mexico Department of Health and the University of New Mexico convened an Overdose Task Force to identify state-level strategies to address the problem in 2010. Following, in 2011, the New Mexico State Legislature passed House Memorial 77 requesting that the New Mexico Department of Health lead a Prescription Drug Abuse and Overdose Task Force to address the rising rate of abuse, addiction and unintentional overdose death due to prescription drugs. Task Force representatives included those from the University of New Mexico Health Sciences Center; University of New Mexico Poison Information Center; Office of the Medical Investigator; the various health care provider licensing boards; Drug Enforcement Administration; Behavioral Health Planning Council and experts in pain management. Task Force recommendations included the adoption of New Mexico Clinical Guidelines for Prescribing Opioids for Treatment of Pain developed by other states through extensive examination and expert consensus.

The Task Force elected to review and adopt Guidelines developed by the Utah Department of Health Prescription Pain Medication Program, and formally endorsed in that state in 2009. The Utah development process was rigorous and thorough, including the following: guideline evidence review, rating of evidence and recommendations, and convening of two multidisciplinary panels to review evidence for development of recommendations and tools. The process undertaken by Utah is described in Appendix B.

A key goal of these Guidelines is to seek a balance between appropriate treatment of pain and safety in the use of opioids for that purpose. The Model Policy for the Use of Controlled Substances for the Treatment of Pain[1] (Federation of State Medical Boards, 2004) acknowledged that “undertreatment

[1] The Model Policy for the Use of Controlled Substances for the Treatment of Pain was developed by the Federation of State Medical Boards.

of pain is…a serious public health problem," but also sought to establish the importance of balance in treating pain as stated in the following sentence:

> *"…the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments."*

At the time these Guidelines were produced, **adequate evidence was not available to determine the benefits of long-term treatment with opioids for persons with chronic pain due to musculoskeletal and other non-cancer causes on patient function and quality of life** (Von Korff & Deyo, 2004). Despite that lack of evidence, the use of these medications for treatment of these conditions has increased substantially in recent years. In the absence of adequate evidence to determine the true benefits and best practices in use of these medications, these Guidelines were developed to assist physicians who choose to use opioids to treat patients with pain to manage that treatment as safely as possible.

The principal focus of these Guidelines is on the use of opioids in the long-term treatment of chronic pain, especially chronic, non-cancer pain[2]. These guidelines were not developed to guide treatment of patients with malignant cancer or for patients in hospice or palliative care settings and should not limit treatment for patients for whom pain relief is the primary goal and improved function is not expected.

The diversion of opioid medications for non-medical use also has contributed to the increased numbers of deaths. Therefore, these Guidelines also include several recommendations on the use of opioids to treat acute pain to help address that public health problem. For purposes of these Guidelines, acute pain is considered to be an episode of pain lasting six weeks or less and chronic pain to be pain lasting more than three months. Episodes of pain lasting from one to three months are sometimes referred to as subacute pain and were not explicitly addressed by these Guidelines, however many of the recommendations are applicable to subacute pain.

The New Mexico Department of Health recognizes that clinicians have many demands on their time and hope that these Guidelines are perceived as practical and concise. However, long-term use of opioid medications to treat chronic pain carries substantial risks and the benefits of this treatment approach have not been adequately established by appropriate studies. The time commitment required to safely manage patients on these medications should be considered

[2] These Guidelines uses the term chronic non-cancer pain to refer to chronic pain that is not associated with active cancer or occurs at the end of life (Chou et al., 2009). Some of the tools and references included in these Guidelines use the term, "chronic non-malignant pain" to describe a similar or identical set of conditions.

when they are prescribed. The New Mexico Department of Health agrees with Von Korff and Deyo (2004) that,

> ***"Long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up and close supervision are ensured."***

Medicine is practiced one patient at a time and each patient is unique with individual needs and vulnerabilities. The Guidelines have attempted to guide clinicians but not to inappropriately constrain practice. The art of medicine is recognized. However, these Guidelines were based on evidence or consensus recommendations by experts. They are intended to improve outcomes of patient care and in particular to prevent deaths due to opioid use. Departures from these recommendations will be appropriate for some patients, but should be justified and documented.

Summary of Recommendations

Opioid Treatment for Acute Pain

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.
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 the usual duration of pain severe enough to require opioids for that condition.
3) When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, to not share with others, and to dispose of medications properly when the pain has resolved in order to prevent non-medical use of the medications.
4) Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely, if ever, indicated for treatment of acute pain.
5) The use of opioids should be re-evaluated carefully, including assessing the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

Opioid Treatment for Chronic Pain

1) A comprehensive evaluation (including the pathophysiologic causation, risk for abuse, and other co-morbid conditions) should be performed before initiating opioid treatment for chronic pain.
2) Alternatives to opioid treatment should be tried (or an adequate trial of such treatment by a previous provider documented) before initiating opioid treatment.
3) The provider should screen for risk of abuse or addiction before initiating opioid treatment.
4) 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.[3]
5) 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.
6) Opioid treatment for chronic pain should be initiated as a treatment trial, usually using short-acting opioid medications.

[3] "Function" as used here is defined broadly to include physical, emotional, cognitive, psychological and social function.

7) Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period).
8) Once a stable dose has been established (stable chronic dose period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects are monitored. Patients should be monitored for aberrant behavior (tools include drug screening and prescription drug monitoring program report surveillance).
9) 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. A second opinion or consult may be useful in making that decision.
10) 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.
11) 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.
12) 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.
13) Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use, and who are prepared to conduct the necessary careful monitoring.
14) Clinicians should be aware of the potential toxicity of acetaminophen in opioid-acetaminophen combination products, warn patients not to exceed the maximum daily dose of acetaminophen and monitor acetaminophen doses in the patient’s known medication regimen.

Recommendations

Previously published evidence-based or consensus-based guidelines have been used as the foundation for many of the recommendations. Each guideline has been assigned a number. After each recommendation, the numbers of the guidelines with similar or supporting recommendations are listed.

Reference Guidelines:

1. Department of Veterans Affairs, Department of Defense. (2003). *VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain.*
2. College of Physicians and Surgeons of Ontario. (2000). *Evidence-based recommendations for medical management of chronic non-malignant pain*
3. American College of Occupational and Environmental Medicine's Occupation Medicine Practice Guidelines. (2008).
4. *Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines*
5. Washington State Agency Medical Directors' Group. (2007). *Interagency guideline on opioid dosing for chronic non-cancer pain: An educational pilot to improve care and safety with opioid treatment*
6. Federation of State Medical Boards of the United States, Inc. (2004) *Model policy for the use of controlled substances for the treatment of pain*

Opioid treatment recommendations for acute pain:

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

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.

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.*

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

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.*

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.

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.*

Acute Pain Recommendation 5: *The use of opioids should be re-evaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.*

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 re-evaluated and the patient's

medical history should be reviewed for co-morbidities 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 New Mexico Prescription Monitoring Program database at this time, and consider drug screening 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. 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 (i.e., tolerance). 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 patients 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 11.2 and 11.3).
- Identify psychiatric conditions that may affect pain or treatment of pain (if present, refer to Recommendation 11.4).
- 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., acupuncturist, chiropractor, doctor of oriental medicine, exercise

physiologist, massage therapist, pharmacist, physical therapist, psychiatrist, psychologist), 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 Organizations 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, and periodicallyduring long term opioid treatment.

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. 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 should 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). It is critical to understand the metabolism of opioids when interpreting confirmatory laboratory results for appropriate positives and appropriate negatives (gas chromatography/mass spectrometry). (For opioid information see http://www.paineducation.vcu.edu/documents/UDTbyOpioidPrescribed.pdf) and for comprehensive drug testing information see http://www.workplace.samhsa.gov/DrugTesting/Level_1_Pages/Drug%20Testing%20Resources.html.)

3.3 Recommendation: The prescriber should check New Mexico's Prescription Monitoring Program database before prescribing opioids for chronic pain.

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 New Mexico's Board of Pharmacy maintains the Prescription Monitoring Program database, which is a searchable record of all prescriptions for controlled substances that are filled by patients in the state. The Prescription Monitoring Program was created through legislation and put into effect in 2005. It is used to track and collect data on the dispensing of Schedule II-IV 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 who register online at https://www.pmp.state.nm.us/pmpwebcenter. Instructions and User's Manual are 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

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.

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.

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

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 or the employer. Permission to discuss the patient's condition with these persons should have previously been obtained and documented (See Recommendation 5.5).

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

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.

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)
- Active diversion of controlled substances (providing medication to someone for whom it was not prescribed)

Relative contraindications for opioid prescribing:

- Co-administration of drug capable of inducing life-limiting drug-drug or drug-disease interaction (extreme caution and ongoing monitoring is necessary for patients already stabilized on, and tolerating, specific drug-drug interactions without clearly appropriate alternatives. Consider specialty referral)
- Presence of medical conditions that might complicate treatment of pain, including cardiac or respiratory disease and sleep apnea or risk factors for sleep apnea (consider specialty referral before starting opioids)

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 of respiratory depression while on opioids:

- 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; or
- 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.

5.3 Recommendation: Providers should recognize the different educational and support requirements of patients prescribed opioids based on substance use disorder history and recovery experience.

The following recommendations focus on the appropriate use of prescribed opiates by the patient for pain management; this pain may be either acute or chronic. Four different categories of patients are recognized that have different education and support requirements from the provider based on these characteristics:

1. Patients who have little or no personal experience with opiate pain medications (personal experience can refer to themselves or a member of their family) or patients with personal experience but no history of a substance use disorder.
2. Patients who are in recovery from opiate addiction
3. Patients who are in recovery from alcohol or other non-opiate drug addictions
4. Patients who are in active alcohol / drug addiction.

Although not guaranteed, the best way to determine which group a patient may belong is to ask – using a short series of screening questions. These questions should be asked by the provider and not by an assistant, and followed with education about the prescribed opiate medication. A suggested way to ask these questions is:
“I need to ask you some questions that I ask all patients that I prescribe this medication to in order to better help and support you.

1. Have you ever had difficulty in controlling the amount you use or had an addiction to any of the following:
    a. Prescription pain medication
    b. Any other medications

   c. Alcohol
   d. Other drugs?
2. Do you have any family members or anyone living with you that has had difficulty controlling their use or an addiction to any of those substances?"

The family history question is important because patients with a family history of addiction are at higher risk for abuse/misuse of prescribed opiates. Additionally, if there are other people in the household or family members with an addiction history, there is an increased risk of diversion.

All patients prescribed opiates should be counseled with an educational pamphlet prior to receiving the prescription or having surgery (see Tools for sample pamphlet). Examples of information to include are the powerful addictive potential of opiates, that there is currently an epidemic of misuse of prescription drugs, especially in youth, and the negative consequences of taking too much such as respiratory depression and death. Suggestions for the patient could include securely storing the medication and disposing of the drug down the toilet after it is no longer needed (FDA recommendation for prescribed opiates).

1. Patients who have little or no personal experience with pain medications or who have experience without a substance use disorder history:
Whether for chronic or acute pain management, it is imperative to educate the patient (and their family) as to the potential risks involved with pain medications as well as the signs and symptoms of abuse / addiction.

2. Patients who are in recovery from opiate addiction:
These patients may or may not self-identify; the latter due to stigma or a fear of under-treatment for pain. It is important for prescribers to realize that research has demonstrated a tendency by some providers to under-treat known recovering patients. One way to manage this is to prescribe smaller amounts and schedule shorter follow-up intervals, but reassure the patient they will be prescribed more if necessary. People who are in recovery frequently already have a personal support system for their ongoing recovery in place; they should be encouraged to use that system. For example, it is best that the recovering addict not dispense their own pain medications but rather have a family member or trusted support person retain and dispense those medications, and to share and be honest with members of their support group about their use. For chronic opiate use, referral to a pain specialist is strongly recommended.

3. Patients who are in recovery from either alcoholism or other drug addictions:
These patients are at increased risk for cross-addiction to opiates, but may not realize this possibility. For example, many recovering alcoholics have relapsed on opiates after surgery by not taking precautions because of a misbelief that they were not at risk since alcohol was their drug of choice. Again these may patients may or may not self-identify, and it is important to ask. These patients should also be encouraged to engage their personal support systems.

4. Patients who are in active alcohol / drug addiction:

Elective procedures requiring postoperative opiate pain medication should be deferred whenever possible until the addiction has been adequately addressed. If use of the
pain medication cannot be avoided, the patient's existing support system should be educated along with the patient as to the risks of using this medication. These patients should be informed honestly about the provider's concerns of using opioid pain medication. If medication is prescribed, the patient should be informed in advance that there will be a limit on the pain medication prescribed, and about the use of the prescription monitoring program. The healthcare provider should also consider consultation with an addiction specialist to help with management, and referral for treatment and support, including Alcoholics Anonymous and Narcotics Anonymous.

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 New Mexico's Prescription Monitoring 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); and
- 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 of the United States, Inc. [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/coveredentities/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 used only by those with considerable expertise in chronic pain management.

6.3 Recommendation: Parenteral[4] (intravenous, intramuscular, subcutaneous) administration of opioids for chronic pain is, in general, discouraged.
Reference Guidelines: 2

[4] These guidelines did not consider intrathecal administration and this recommendation was not intended to discourage trained and qualified physicians from using intrathecal opioid medications.

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 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 (MED). 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 updated Washington State guideline (WSAMDG, 2010) suggests avoiding prescribing more than an average MED of 120mg without either the patient demonstrating improvement in function or first obtaining consultation from a pain management expert. A recent cohort study (Dunn et al, 2010) supported this recommendation and showed that risk substantially increased at doses at or above 100mg MED, so attention to the dose of 120mg MED should be considered a benchmark.

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.

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 Prescription Monitoring Program database at least quarterly.

For more information about the Prescription Monitoring Program, refer to Recommendation 3.3.

Tools to accompany Recommendation 7:

- Dosing Guidelines

8. Chronic stable dose – Periodic monitoring and dose adjustments:

8.1 Recommendation: Once a stable dose has been established (chronic stable dose 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

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.

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

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.

8.3 Recommendation: During chronic stable dose phase, the Prescription Monitoring Program database should be checked at least annually.

After the titration phase is complete and the chronic stable dose phase is underway, the frequency of checks of the *Prescription Monitoring Program* database can be based on clinical judgment, but should be done no less than every six months. The database should be checked more often for high risk patients and patients exhibiting aberrant behavior. For more information about the *Prescription Monitoring Program*, 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).

8.4 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 re-evaluate 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 re-evaluate the underlying condition and consider the possibility the patient has developed opioid hyperalgesia, substantial tolerance, or psychological/physical dependence.

8.5 Recommendation: Adjustments to previously stable chronic 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 stable chronic 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).

8.6 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

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.

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

10. Discontinuing opioid treatment

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

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, or*
- *Opioid therapy appears to be causing harm to the patient, particularly if harm exceeds benefit.*

Reference Guidelines: 1

The decision to discontinue opioid treatment should ideally be made jointly

with the patient and, if appropriate, the family/caregiver [6]. This decision should include careful consideration of the outcomes of ongoing monitoring.

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

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

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 include the patient's full name, address, prescriber name, address and DEA registration number. The prescription must also include drug name, strength, dosage, quantity prescribed, directions for use and number of refills (if any) authorized. It shall be dated and signed when issued. It must be written in ink, indelible pencil or typewritten, and manually signed by the prescriber on the date issued.

After a stable chronic therapy dosage has been established and therapy goals have been achieved, Schedule II opioid medications may be prescribed for up to 90-days or by providing the patient with prescriptions for each of the 3 months. The DEA regulations (revised in 2006) concerning a prescriber issuing multiple prescriptions for a patient to receive a total of up to a 90-day supply of Schedule II controlled substances are as follows: (1) the prescriber provides written directions for use on each prescription (other than the first prescription if the prescriber intends for that prescription to be filled immediately) indicating the earliest date that a pharmacy can fill the prescription; and (2) based on sound medical judgment and in accordance with established medical standards, the prescriber should determine whether to issue multiple prescriptions and how often to see the patient when doing so. A prescriber may designate an individual (nurse or secretary) to prepare prescriptions for the prescriber's signature (DEA Practitioner's Manual, August 2006).

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 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 New Mexico 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. Awareness of opioid maintenance therapy (addiction treatment) restrictions is necessary to avoid illegal prescribing.

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 stable chronic dose phase.

12.4 Recommendation: Patients with a co-existing psychiatric disorder should receiving ongoing mental health support and treatment while receiving opioid medication for pain control.

Management of patients with a co-existing 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 co-existing 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.

Since the late 1990's, methadone gained popularity among clinicians in the U.S. as an effective and relatively inexpensive analgesic. Overall, the number of prescriptions dispensed for methadone increased by nearly 700% between 1998 and 2006. However, the rapid increase in prescribing methadone for the purpose of pain treatment, as opposed to opioid replacement therapy, was a primary contributor to an almost 7-fold increase in the number of methadone-involved overdose deaths from 1999 (790 people) to 2006 (5,420 people) (SAMHSA, 2010c).

It is not conclusive that New Mexico experienced the same trend found for the U.S., where the increase in methadone prescribing was due to treatment of pain and not addiction therapy. A study of methadone-caused death in New Mexico during 1998-2002 showed that half were caused in combination with illicit drugs, 24% were caused in combination with other prescription drugs, and 22% were caused by methadone alone (Shah et al., 2005). The rate of methadone-related death increased until 2006 and has recently stabilized. Methadone accounted for 24-41% of unintentional prescription drug overdose deaths during 1999-2008 (New Mexico Office of the Medical Investigator). This proportion fell to just 13% in 2009. Methadone overdose death had the second highest prescription adjusted mortality rate with an average of 359 deaths for every 100,000 prescriptions during January 2006-March 2008, following less prescribed oxymorphone.

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 100mg 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 200mg MED 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

14. Acetaminophen

14.1 Recommendation: Opioid-acetaminophen combination products pose additional risks from acetaminophen toxicity, both from unintentional overdosing of the opioid-acetaminophen product to obtain pain relief, combination of the product with other prescribed or over-the-counter acetaminophen products, or abuse of the product for its opioid effects. Clinicians should be aware of the potential toxicity of acetaminophen, warn patients not to exceed the maximum daily dose of acetaminophen (currently 3 grams/24 hours) and to monitor acetaminophen doses in the patient's known medication regimen.

The following is from:
http://www.fda.gov/advisorycommittees/calendar/ucm143083.htm

Acetaminophen is one of the most commonly used drugs in the United States, yet it is also an important cause of serious liver injury…Unlike other commonly used drugs to reduce pain and fever (e.g., nonsteroidal antinflammatory drugs (NSAIDs), such as aspirin, ibuprofen, and naproxen), at recommended doses acetaminophen does not cause adverse effects, such as stomach discomfort and bleeding, and acetaminophen is considered safe when used according to the directions on its OTC or Rx labeling. However, taking more than the recommended amount can cause liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death. Many cases of overdose are caused by patients inadvertently taking more than the recommended dose (i.e., 3 grams a day) of a particular product, or by taking more than one product containing acetaminophen (e.g., an OTC product and an Rx drug containing acetaminophen).

The mechanism of liver injury is not related to acetaminophen itself, but to the production of a toxic metabolite. The toxic metabolite binds with liver proteins, which cause cellular injury. The ability of the liver to remove this metabolite before it binds to liver protein influences the extent of liver injury. In a study that combined data from 22 specialty medical centers in the United States, acetaminophen-related liver injury was the leading cause of acute liver failure for the years 1998 through 2003. Patients in this study were found to have taken too much acetaminophen from OTC, Rx products, or both. Almost half of these cases involved overdose in which the patient had not intended to take too much acetaminophen (unintentional overdoses), although many cases of liver injury with acetaminophen result from self-harm, i.e., intentional self-poisoning.

…[I]t appears that there are distinct factors associated with acetaminophen and acetaminophen products that contribute to this public health problem…

- Taking just a small amount of acetaminophen over the recommended total daily dose (4 grams per day) may lead to liver injury. Currently recommended doses and tablet strengths of acetaminophen leave little room for error and the onset of liver injury can be hard to recognize…The symptoms of liver injury may not be readily identified by an individual because they may be non-specific and mimic flu symptoms. The antidote for acetaminophen poisoning, N-acetylcysteine, is less effective when liver injury has progressed too far.

- Some individuals may be especially sensitive to liver injury from acetaminophen…Available information suggests that some individuals, such as those who use alcohol or have liver disease, may have a greater sensitivity to the effects of the toxic metabolite because they produce more or are unable to clear it from the body as easily…
- There is a wide array of OTC and Rx acetaminophen products used in a range of doses for various indications…Acetaminophen is in many widely used OTC single ingredient products, such as those to treat headaches, and multiple ingredient (combination) products, such as those to treat symptoms of the common cold, like aches and fever. Acetaminophen is also a component of a number of Rx drug products in combination with narcotic pain medicines. So, consumers…not realize that acetaminophen is an ingredient common to each.
- It can be difficult to identify acetaminophen as an ingredient. Rx products that contain acetaminophen (usually with codeine or oxycodone) are often labeled as containing ‘‘APAP’’ on pharmacy dispensed containers…
- The association between acetaminophen and liver injury is not common knowledge. Consumers are not sufficiently aware that acetaminophen can cause serious liver injury, and their perceptions may be influenced by the marketing of the products.

15. Medical Cannabis

15.1 Recommendation: The State of New Mexico Medical Cannabis Program authorizes the use of medical marijuana for indicated conditions including chronic severe pain. Before prescribing opioids, practitioners should ask if the patient is using medical marijuana. The practitioner should consider risks and benefits of the use of opioids and/or medical marijuana in these patients.

16. Buprenorphine

16.1 Recommendation: Referral to a physician who is certified and experienced in medication-assisted treatment with buprenorphine should be considered for those patients determined to have opiate addiction.

There are 3 medications that are used in the medication-assisted treatment (MAT) of opioid addiction- methadone, buprenorphine/naloxone, and naltrexone. Of these 3, methadone is not authorized for office-based

prescription to treat opioid addiction. Buprenorphine/naloxone is the most commonly prescribed office-based medication for MAT.

Buprenorphine/naloxone is a prescription medicine used to treat adults who are addicted to opioid drugs (either prescription or illegal) as part of a complete treatment program that also includes counseling and behavioral therapy. Buprenorphine/naloxone is a sublingual tablet that contains buprenorphine HCl, a mu-receptor partial agonist and kappa-opioid receptor antagonist, and naloxone HCl dehydrate, an opioid receptor antagonist, at a ratio of 4:1. When taken under the tongue, the naloxone is not absorbed and so is not active. When injected, the naloxone is active and causes withdrawal. This combination lowers the potential for abuse. Buprenorphine is used for pregnant patients and in some instances for other patients with no history of intravenous drug use.

After an induction when the patient is switched from the previously used opiate to buprenorphine, the patient is typically maintained on a dose of 12-16 mg daily of the buprenorphine. After a period of several months, the patient can be tapered off of the buprenorphine/naloxone or maintained on the MAT for a more extended period of time.

Only physicians with a special DEA DATA waiver number can prescribe buprenorphine/naloxone or buprenorphine for MAT. An 8-hour training course and a special DEA license are required.

GLOSSARY	
Term	**Definition**
Aberrant drug-related behavior	A behavior associated with drug abuse, addiction, and diversion.
Abuse	Maladaptive pattern of drug use that results in harm or places the individual at risk of harm, including 'misuse' or 'nonmedical use'. Often with the intent of seeking a psychotropic/euphoric effect.
Acute pain	An episode of pain lasting 6 weeks or less
Addiction	A primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
Breakthrough pain	An acute worsening of pain in a person with chronic pain.
Chronic pain	An episode of pain lasting more than three months
Chronic non-cancer pain	Chronic pain that is not associated with active cancer or occurs at the end of life
Diversion	The intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution.
Hyperalgesia	Increased or heightened sensation to pain or pain stimulation.
IADL	Instrumental activities of daily living are activities related to independent living and include preparing meals, managing money, shopping for groceries or personal items, performing light or heavy housework, and using a telephone
Misuse	Use of a drug in ways other than prescribed by a health professional. Misuse usually does not include use for euphoric or psychotropic effects—that would be classified as "abuse"
Physical dependence	A state of adaptation manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
Pseudo addiction	The development of abuse-like behaviors due to unrelieved pain, and that should be eliminated by measures that relieve the pain.
Trial Period	A period of time during which the effectiveness of using opioids is tested to see if goals of functionality and decreased pain are met. A trial should occur prior to treating someone with long-acting opioids and should include goals. If trial goals are not met, the trial should be discontinued and an alternative approach taken to treating the pain.
Tolerance	A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more opioid effects over time.

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Appendix A

10/10	• *Extremely* explicit evidence-based guidelines • The “gold standard” • Evidence has been analyzed thoroughly through an explicit rating system • Recommendations are based on the evidence with the highest rating of quality • Expert consensus creates the recommendations, • Recommendations verified through a peer review
9/10	• *Very* explicit evidence-based guidelines • Evidence has been analyzed thoroughly through an explicit rating system • Recommendations are based on the evidence with the highest rating of quality • Expert consensus creates the recommendations
8/10	• Explicit evidence-based guidelines • Evidence has been analyzed thoroughly through an explicit rating system • Expert consensus
7/10	• Evidence-based guidelines • No record of the evidence from which the guidelines have been created is present • No rating system of the evidence is present either
6/10	• Evidence-based guidelines • *Limited details* to how they were created • No record of the evidence from which the guidelines have been created is present • No rating system of the evidence is present either
5/10	• Expert consensus statement only • *Very* detailed explanation of how the consensus was formed • Reviewed thoroughly by pain experts
4/10	• Expert consensus statement only • Detailed explanation of how the consensus was formed
3/10	• Expert consensus statement only • Little explanation of how the consensus was reached
2/10	• Expert consensus statement only • No explanation of how the consensus was reached
1/10	• No explanation of how guidelines were created

Appendix B.

Methods

Purpose and Target audience

The guidelines provide recommendations for the use of opioids for management of pain that are intended to balance the benefits of use against the risks to the individual and society and to be useful to practitioners. The target audience for these Guidelines includes all clinicians who prescribe opioids in their practice.[5]

Guideline Evidence Review

The steering committee of the Utah Department of Health's Prescription Pain Medication Program developed the key questions, scope, and inclusion criteria used to guide the evidence review process. The process began with a literature review to identify existing guidelines on pain, chronic pain, opioids, pain management, and related topics. Guidelines were identified through electronic databases, reference lists from evaluated guidelines, and recommendations from experts. Electronic databases that were searched include: PubMed, Medline, CINAHL, and the National Guideline Clearinghouse. Investigators identified and evaluated 40 individual guidelines.

Grading of the Evidence and Recommendations

As guidelines were identified they were reviewed for key information. They were evaluated based on the following categories:

- Title
- Year Published: Guidelines were included only if they were published after the year 1999. Articles published before 2000 were merely noted in the grid by their title and date with no additional information.
- Sponsorship and funding
- Medical Perspective
- Target Audience
- The Process: This describes how the guidelines were created. Most guidelines fell into two categories: "evidence-based" and/or "consensus".
- The Rating Scale: This was based on the quality of research that went into the development of the guidelines. Explicit evidence-based guidelines received higher ratings and less explicit, consensus-based guidelines received lower ratings.

[5] In Utah as of January 2009 (R156-37), clinicians who can be licensed to prescribe controlled substances as part of practice (human) includes physicians and surgeons, osteopathic physicians and surgeons, podiatrists, dentists, physician assistants, advanced practice registered nurses, certified nurse midwifes, certified nurse anesthetists, and optometrists.

The complete evaluation matrix of the 40 guidelines is available from the Utah Department of Health, Bureau of Epidemiology upon request.

In total, 40 guidelines for pain management were reviewed and evaluated. As each guideline was reviewed, it received a rating from 1-10 (for a breakdown of the rating scale, see Appendix A). Guidelines that received scores of seven (7) or lower were excluded. Four (4) sets of guidelines received scores of eight (8) or above. Three (3) public health professionals reviewed the ratings given to ensure that the scores given were consistent with the rating scale.

Panel composition

The Utah Department of Health convened two multidisciplinary panels (see page 4 for complete list of panel members). The Guideline Recommendation Panel convened on four (4) occasions between May and July 2008. Their purpose was to review the evidence and formulate recommendations based on the evidence in the selected guidelines. Each member signed a Conflict of Interest disclosure. Conflicts were reported as described below (See Disclosure of Conflicts on page 12). The Guideline Implementation and Tool Panel convened twice (2) between July and August 2008 to review the recommendations to ensure that they were implementable as well as to identify tools needed in order to put the recommendations into use. The first panel consisted of twelve (12) experts and the second consisted of nine (9) experts from throughout the state of Utah.

Recommendation Development Process

The Guideline Recommendation Panel met in person on four occasions between May and July 2008. The purpose of the first meeting was to provide panel members with copies of the selected, high-scoring guidelines and to present the purpose and plan for developing the guidelines. Prior to the second meeting, panel members were asked to review the four guidelines for commonalities. The recommendations that were supported by multiple guidelines created the basis of the first draft of the recommendations used by the Guideline Recommendation Panel. Consideration was given to adopting one of the existing evidence-based guidelines outright, but the panel felt that no single guideline represented sufficiently what was desired of the Utah guidelines. The panel voted to include two (2) additional sets of guidelines that had not met the inclusion criteria for consideration while drafting the recommendations. In total, content for the Utah guidelines was drawn from six (6) guidelines. The key topics to be developed into specific recommendations were posted on a website where the Guideline Recommendation Panel members posted comments and edited the text. The panelists' postings were the basis on which content was selected from the chosen guidelines. This content was then used to create a draft of actual recommendation statements and supporting paragraphs. At the third meeting, a straw poll was taken on the recommendation draft. Through discussion and rewording, consensus on content was achieved for all of the recommendations discussed over the course of the two meetings. Outside the meetings, non-content editing of the recommendations and supporting statements was

performed, based on the panel's discussions, to create the final draft of the recommendations and supporting paragraphs.

Tool Development Process

The Guideline Implementation and Tools Panel met in person on two occasions between July and August 2008. Prior to the first meeting, a book was compiled that included all tools that were identified in the forty (40) guidelines. Sample tools were solicited from panel members as well. In total, the workbook contained forty-seven (47) tools. At the first meeting, the panel reviewed the draft recommendations and discussed whether any specific recommendations were impossible or burdensome to implement. Panel members were each given a book containing all the tools. In between the first and second meeting, panel members reviewed and graded each tool according to usefulness and whether or not it should be included in the guidelines. Votes and rating were tallied prior to the second meeting. Tools that received an average rating of below two (2) were eliminated. At the second meeting, the remaining tools were discussed and it was determined which of the remaining tools should be included, modified, or eliminated.

Following the final panel meetings, Utah Department of Health staff formally drafted the complete guidelines document.

Drafts of the complete guidelines were then distributed to all panel members and several Utah Department of Health internal staff for feedback and revisions. External peer reviewers were solicited for additional comments. The final draft recommendations were posted for public comment during November-December 2008 and revisions were made based on consideration of those comments (copies of comments are available from the Bureau of Epidemiology, Utah Department of Health). Prior to publication, the guideline was submitted to the Utah Department of Health Executive Director for approval.

Tools

Tools to Use in Evaluating & Monitoring……

Pain Management Evaluation Tool
Patient Pain and Medication Tracking Chart
Sheehan Disability Scale
Brief Pain Inventory Form
COMM
Sample Treatment Plan for Prescribing Opioids
SF-12

Tools to Screen for Risk of Complications……..

SOAPP-R
Opioid Risk Tool
Urine Drug Testing Devices
Signs of Substance Misuse
Checklist for Adverse Effects, Function, and Opioid Dependence

Informational Tools……

Federal Guidelines on Proper Disposal of Prescriptions
Non-Opioid Pain Management Tool
Absolute Contraindications to Opioid Prescribing
Strategies for Tapering & Weaning
Information for Patients—Opioid Analgesics for Non-Cancer Pain
The Role of Methadone in the Management of Chronic Non-Malignant Pain
Dosing Guidelines
Cautious, Evidence-Based Opioid Prescribing
Safe Use of Prescription Opiate Pain Medication

For more tools and information visit:
http://prc.coh.org/culture.asp
http://www.PainEdu.org

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