PAIN TREATMENT TOPICS Pain-Topics.org

Commonsense Opioid-Risk Management in Chronic Noncancer Pain

A Clinician's Perspective

Author: **James D. Toombs, MD**

Medical Editor: Stewart B. Leavitt, MA, PhD

Medical Reviewers: Paul Jones, DO; Lee A. Kral, PharmD, BCPS; Paul W. Lofholm, PharmD, FACA

Release Date: August 2007

Evolving Role of Opioids

Chronic noncancer pain (CNP) is a serious and likely undertreated public health problem. In a 2005 survey, 19% of US adults reported chronic pain and 34% reported recurrent pain [Kuehn 2007]. The annual costs of pain-related healthcare, litigation, and compensation are estimated at $100 billion in the United States alone [Sinatra 2006]. While opioids have been a mainstay in the treatment of acute pain, the role of opioids in treating chronic pain is less well defined and overshadowed by persistent concerns of misuse, abuse, and addiction. Fortunately, during the past 20 years, there have been major advances in clarifying these issues.

Publication of the World Health Organization (WHO) Analgesic Stepladder in 1986 provided a tool for guiding nonspecialists in the logical use of opioids for cancer pain [Ballantyne 2003]. In the early 1990s, clinicians began to acknowledge that opioids also had a genuine role in the treatment of CNP [Portenoy 1990]. The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) placed additional emphasis on the appropriate treatment of pain through its publication of pain management standards in 1999 [Dahl et al. 2000]. Since then, key organizations have developed consensus statements to guide providers in prescribing opioids for CNP [Atluri et al. 2003; CPSO 2000; VA/DoD 2003]. Many states also have responded by adopting "Intractable Pain Treatment Acts" that specifically allow opioids to be prescribed for CNP and reduce the fear of Board actions against practitioners who prescribe them [IPTA 2006].

The emphasis on improving treatment of CNP has produced a dramatic increase in the prescription of opioid analgesics. From 1999-2002, the sales of opioids reported through the DEA's Automation of Reports and Consolidated Orders System (ARCOS) database increased by an astounding 76% [Paulozzi 2006]. While opioids can be a powerful option in treating

URL links in this PDF document – **indicated in blue lettering** – are activated for easier navigation. To follow a link…

1. Select the Hand Tool (on the PDF Reader menu bar).

2. Position the hand over the linked area until the Hand Tool changes to a hand with a pointing finger. Then click on the link.

3. To return to this document, click the back button on the browser.

chronic pain, their use comes with some potential side effects and risks of serious medical complications including misuse, abuse, addiction, overdose, and death.

While opioids can be a powerful option, their use comes with some potential side-effects and risks of serious medical complications.

Through the same period (1999-2002), the increase in deaths from opioids roughly matched the increase in sales for each type of opioid. During this timeframe, there was a 95% increase in deaths related to opioids, and by 2002, prescription opioids replaced illicit drugs as the most common cause of fatal drug poisoning [Paulozzi 2006]. While misuse, abuse and addiction are thought to be relatively infrequent, recent work examining chronic pain patients in primary-care settings found a point prevalence for any DSM-IV-defined substance-use disorder of 9.7% [Fleming et al. 2007]. Other studies have noted higher rates in certain subpopulations of patients [Højsted and Sjøgren 2007].

There is a substantial risk to providers who prescribe opioids for CNP. While a particular state's Intractable Pain Treatment Act may help protect providers against Board action, the Act often prohibits opioid prescriptions in cases where the provider "knows or should know" that the opioids are going to be misused [IPTA 2006]. Furthermore, physicians may face criminal charges for inappropriate prescribing, especially when opioids may be involved in a patient's death [Guglielmo 2006; Satel 2004]. Complicating this issue, malpractice suits have been brought against physicians for the undertreatment of pain [Shapiro 1996].

Commonsense Approach

Commonsense steps can help to manage opioid risks to both patient and healthcare provider.

Short of not prescribing them at all, there is no way to completely eliminate the risks of opioids. There are, however, certain commonsense steps to take that can help manage the risks to both patients and providers. In 2004, there was a *Model Policy for the Use of Controlled Substances for the Treatment of Pain* developed by the Federation of State Medical Boards of the United States [Model Policy… 2004]. A stated aim was to promote "adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny."

In brief, the *Model Policy* requires:

- **Evaluation of the Patient** – A medical history and physical examination must be obtained, assessed, and documented in the medical record.
- **Treatment Plan** – A written plan should state treatment objectives that will be used to determine therapeutic success.
- **Informed Consent and Agreement for Treatment** – The physician should discuss with the patient the risks and benefits of using controlled substances.
- **Periodic Review** – The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health.
- **Consultation** – The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.
- **Medical Records** – The physician should keep accurate and complete records.
- **Compliance with Controlled Substances Laws and Regulations** – To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations.

While the *Model Policy* was not intended to be a clinical practice guideline, at its core ***is*** a framework for commonsense opioid prescribing and risk management. The items listed above

reflect necessary steps, including the due diligence required to protect both the patient and the provider, and their universal application can help manage risks when prescribing opioids. In the following sections, these 7 requisites are addressed with a particular focus on opioid risk management.

Evaluation of the Patient

A thorough evaluation involves taking a complete medical history. For patients with chronic pain, this is frequently the lengthiest part of the visit. Unfortunately, with regard to medication doses and previous therapies, patients' memories are sometimes inaccurate and often incomplete. In addition to the history provided by the patient, it is advisable to review medical records from current providers, previous providers, and pharmacies. This provides independent source verification of the patient's treatment history and is done prior to contemplating *any* therapy, including opioid prescriptions. Objectives of this step include:

- Confirm current therapies;
- Verify present opioid use;
- Identify failed medication therapies;
- Validate previous medication reactions; and
- Expose undisclosed substance misuse, abuse, or addiction.

There is a clear need to verify current opioid use as this translates directly to opioid tolerance and equianalgesic dose conversion. Patients may overstate their current opioid doses in an effort to increase their new dose to a desired level. Other patients may report current opioid use, but upon records review it may become apparent that the medication was discontinued. The historical dose, which was discontinued, may now be a lethal one. Records may reveal other comorbid conditions (eg, sleep apnea) that are absolute or relative contraindications to opioid therapy or unreported drugs that may interact with opioids (eg, benzodiazepines) and pose overdose risks.

While patients often bring in piecemeal medical records or old pill bottles, information should be obtained directly from the sources. It may take some time to collect these records; however, there are steps to reduce this wait to only days and sometimes even hours. A HIPAA-compliant request for medical records can be prepared during the office visit and then faxed to each of the previous providers and pharmacies. At times, additional providers are discovered during the initial records review, and these providers can be faxed requests as well.

In brief, patients currently using opioid pain medications should be able to name their present provider and pharmacy. Those who are unable or unwilling to provide this information should not be prescribed opioids. Physicians should be concerned about being duped by "professional patients." Knowing that old records will be requested and reviewed tends to filter out some patients who are simply "doctor shopping."

If there is concern about continuity of care (ie, running out of opioid medication) the records request can be completed in advance of the first visit. Patients can be made aware of this requirement when scheduling an appointment or through a "New Patient Letter," which includes a section similar to the following:

Practice Pointer:
Request and review medical records prior to prescribing opioids.

Author's Comment: Regarding substance misuse, abuse, and addiction – while there are a number of questionnaires available to help predict a patient's risk of abuse or addiction, we do not use them routinely. Some patients will lie and honest patients may be unfairly penalized. When taking a patient's medical history, we routinely ask about substance abuse. If a patient does admit to past problems with opioids, this becomes an opportunity to reflect on the past utility of opioids and how they might be used in the current care plan.

Certainly, we want to know about a patient's history of substance abuse. Unfortunately, this information is often unavailable from the patient or the medical record. Regardless, it is not our clinic's practice to deny access to opioid pain medications because of a history of substance abuse. When a history of substance abuse is admitted or discovered, the treatment plan will likely be more tightly constructed and involve a team approach.

"For patients with chronic pain we will need to review your medical and pharmacy records before prescribing any pain medications. We cannot accept your personal copies; they must come directly from your previous providers. To ensure we have an opportunity to review these prior to your appointment, you may stop by the clinic in advance and complete a Request for Medical Records form. Otherwise, we will not be able to obtain your records until after your first visit."

Treatment Plan

A treatment plan involving opioids does not have to be complex to be complete. It should state simply and clearly how one can recognize if the treatment is successful. That is, the treatment plan often begins with the question: "How will we know if the therapy is working?" While an overall reduction in pain is a primary goal of most therapy, pain scores may not change appreciably during the course of treatment.

Practice Pointer:
Prescribe opioids as a trial with criteria for both treatment success and failure.

For example, one study of age-dependent dose escalation saw no change in Visual Analog Scale (VAS) pain scores for younger patients treated with opioids over a two-year period [Buntin-Mushock et al. 2005]. However, successful treatment for chronic pain also may be reflected by verbally reported pain relief as well as improvements in mood, ability to cope with pain, and sleep [Couzzi et al. 2005]. Other criteria for success may include functional goals, such as participating in physical therapy sessions or returning to work or school. The treatment plan should also list any further investigations (eg, MRI), nonopioid medications, and referrals to other specialty treatment providers.

If opioids are to be prescribed, the treatment plan should also include the criteria of failure and how the practitioner will know if/when opioids should be tapered, changed, or discontinued. It must be clear early in the discussion process that opioids are being prescribed as a ***trial*** and that the initial opioid prescription does not constitute a lifelong contract to continue the therapy indefinitely. If it is unambiguous from the beginning that opioids are being prescribed as a trial, eliminating them and moving on to other therapies will be an easier step. It should also be clear that the goal of treatment with opioids is pain reduction, not pain elimination. In a review of opioid efficacy involving more than 1000 patients with a variety of pain conditions, the mean decrease in pain intensity was 30% [Kalso et al. 2004]. While this is a significant reduction, it is less than the complete relief expected by many patients.

There is justified concern regarding the prescription of opioid pain medications for patients with a history of substance abuse or who are suspected of opioid misuse. For these patients, a rigidly structured trial involving frequent office visits, regular urine drug tests (UDTs), and day-by-day or week-to-week dispensing may be necessary. This trial should be time-limited, and the appearance of aberrant behavior should prompt referral to an integrated pain and addiction treatment program [Kahan et al. 2006].

A more rigidly structured trial of opioids is necessary for patients with a history of substance abuse or who are suspected of opioid misuse.

There are three phases to an opioid trial: Initiation, Titration, and Maintenance…

1. **Initiation** — During initiation, patients not currently using opioids are started at suitable naïve-level doses. Opioid-tolerant patients are continued on appropriate equianalgesic doses, adjusted for incomplete cross-tolerance if the current opioid is to be changed to another product.

2. **Titration** — In this process, the dose of the medication is progressively increased in meaningful steps. For outpatients, dosing might be increased week by week after each assessment. Even a modest 25%-per-week step-up affords nearly a 600% cumulative dose increase over 8 weeks. Proper titration in an opioid trial can address concerns of *pseudoaddiction*. That is, some patients with undertreated chronic pain may exhibit "drug-seeking behaviors," even though their motivation is pain relief and not the rewarding effects of the drugs. Their behavior may falsely resemble addiction, and this "pseudoaddiction" may be difficult to distinguish from true addiction. However, with proper titration during an opioid trial aberrant behaviors disappear once adequate pain relief is achieved.
3. **Maintenance** — Once an effective dose has been reached, patients enter a maintenance phase. There is some concern that opioid tolerance will build over time; however, for CNP, regular dose escalation has been shown to be uncommon during long-term treatment [Adriaensen et al. 2003].

Recognizing Failure

Some forms of opioid treatment failure may be more subtle than worsening function or intolerable side effects.

Most providers would recognize a failed opioid trial if a patient's function worsened or if the patient developed an intolerable side effect. Other forms of failure may be more subtle.

Opioids typically have a dose-response curve, with larger doses providing greater relief than smaller doses. Clearly, if a patient does not gain at least partial relief at low doses and titration fails to produce further relief, elimination of the opioid or rotation to another opioid is appropriate.

Another pattern of failure is rapid and intractable opioid tolerance manifested by the constant need for dose escalation [Coluzzi et al. 2005]. A patient may report good relief at low to moderate opioid doses but this is short-lived. Each incremental dose increase restores the relief but, again, only for a short period. This stair-step pattern is doomed and elimination of the opioid or rotation to another opioid is appropriate.

Failure of an opioid trial may also become evident as a pattern of persistent noncompliance; that is, the patient's inability to use the medication safely and comply with the treatment plan. Some typical examples include: failing to follow a prescribed dosing schedule, reporting loss of prescriptions, neglecting other recommended therapies, or missing follow-up visits [Manchikanti et al. 2006].

Maximum Doses

For pure opioids there are no upper limits to titration. The literature describes patients who have been prescribed morphine in doses as high as 2000 mg per day for CNP [Zenz et al. 1992]. Practically, however, the useful range of opioids for CNP appears to be much lower. There is concern that daily doses of morphine (or a morphine equivalent) greater than 180 mg have not been validated adequately by clinical trials [Ballantyne et al. 2003]. Typical opioid doses from controlled trials are shown in the ***Table*** below.

	Typical Dose Range (mg/day)	
Opioid	**Nociceptive Pain**	**Neuropathic Pain**
Morphine	20-120	70-300
Oxycodone	20-40	20-80

Adapted from Kahan et al. 2006

There is absolutely no suggestion in the literature that there should be a fixed maximum dose for any particular opioid. When prescribing opioids, a provider should recognize when to re-evaluate chronic opioid therapy, and reaching a predetermined, self-imposed limit is an occasion to do so. The College of Physicians and Surgeons of Ontario reviewed opioid dosing practices and indicated that it was unusual for patients to require more than 300 mg/day of oral morphine for CNP [CPSO 2000].

Author's Comment: In our practice, doses higher than 300 mg/day of oral morphine for CNP are unusual but not unheard of. There is a significant interindividual variability in the response to opioids. Regardless of the milligram strength, if a patient is receiving pain reduction with improved function, and not suffering any intolerable side effects or exhibiting any opioid-abuse behavior, then that is considered the proper dose for the patient.

Informed Consent and Agreement for Treatment

With any medical therapy, a treatment plan and informed consent are necessary before initiation. With respect to opioid therapy, the Federation of State Medical Boards recommends the use of a written agreement when a patient is at high risk for medication abuse.

Unfortunately, there is very little evidence regarding the efficacy of these treatment agreements [Manchikanti et al. 2006]. It is not clear that outcomes or compliance are improved through the use of a written agreement for treatment; yet, some studies report positive outcomes for nearly all patients who sign a written treatment agreement [AMDG 2007]. In another study of opioid "contracts," the most common reason for physician cancellation was positive urine drug testing (50%), followed by prescription drug abuse (26%) [Hariharan et al. 2007].

Some experts believe that patient consent in the form of a written treatment agreement should be universally applied and obtained from all patients before initiation of opioid therapy [VA/DoD 2003]. A written *Agreement for Treatment with Opioids* affords an explicit opportunity to discuss opioid risks, benefits, and common side effects. This is essential information, prompting the patient to weigh the benefits against the risks and costs and to make an informed decision concerning opioids.

The opioid agreement also provides both an entrance and exit strategy for the patient and provider as well as defining criteria for both events [Jacobson and Mann 2004]. It may specify boundaries of the opioid trial and when opioids may be discontinued. In addition, it can be used to outline requirements for follow-up visits, additional therapies, drug testing, and the process for medication refills, so there is a clear delineation of patient and practitioner responsibilities.

A sample opioid agreement is shown in the **Appendix** on page 12.

Practice Pointer:
Use an "Agreement for Treatment with Opioids" to obtain informed consent.

Author's Comment: In our clinic, opioid agreements are used for all patients beginning chronic opioid therapy, and the standard form is part of our electronic medical record system. The agreement is completed electronically and printed to review with the patient. Once there is informed consent and understanding of patient and provider responsibilities, it is signed electronically by the patient and physician using a signature pad. The paper copy is kept by the patient.

Periodic Review

Practice Pointer:
Monitor progress with regular visits and adherence with periodic urine drug testing.

Managing opioid therapy requires regular clinic visits to monitor progress toward the predetermined treatment goals. Failure to do so may result in the prescription of large doses of opioids in the absence of improvement in pain levels or function. At each visit, the patient's status should be reassessed with regard to the 4 A's [Coluzzi et al. 2005]:

- **Analgesia** – Is the patient receiving tolerable pain relief? VAS pain scores may not change appreciably during treatment, but patients may still report their pain is "much better."
- **Activities of daily living** – Has the patient improved functionally? What goals has the patient achieved from the treatment plan?
- **Adverse effects** – Have any side effects (eg, constipation, somnolence) developed? Can the side effect be treated, or should the opioid be decreased, changed, or discontinued?
- **Aberrant drug-taking behaviors** – Is the patient using the medication as prescribed? While aberrant drug-related behavior may well indicate substance misuse or abuse, it might also signify poorly treated pain (pseudoaddiction) or worsening mental health [Fishbain et al. 1992; Olsen and Alford 2006].

The frequency of visits is both phase and patient-dependent. During the titration phase, visits may be necessary every 1 to 4 weeks. During maintenance, visit intervals may be extended, with a comprehensive follow-up visit completed, optimally, every 3 months [Ballantyne et al. 2003]. Some experts recommend that dosing adjustments only be made during clinic visits [VA/DoD 2003]; whereas, others will prescribe adjustments during the titration phase after a brief telephone assessment. Once a patient has entered the maintenance phase, a loss of analgesia should prompt re-evaluation before contemplating dose escalation.

As a risk-management measure, periodic review also entails routine urine drug testing. The *Agreement for Treatment* should include consent to regular and random drug testing. This is done to help ensure a patient is taking the prescribed medications as directed and refraining from using illicit substances. Since there are no consistent indicators of opioid misuse, as a safety measure, all chronic pain patients should be required to submit a urine sample prior to receiving their first opioid prescription.

While it appears straightforward, the interpretation of urine drug test (UDT) results should be made cautiously and in complete view of the patient's medical history. False positives and false negatives can and do occur. Certain synthetic (eg, methadone) and semi-synthetic opioids (eg, oxycodone) may not reliably appear on immunoassays. Additional and more specific testing with individual blood serum tests or GC/MS is often necessary. Ideally, providers should become familiar with their particular laboratory, understanding which assays they use and what limitations those have [Olsen and Alford 2006].

For additional helpful information on patient monitoring, see:

Gourlay DL, Heit HA, Caplan YH. Urine Drug Testing in Clinical Practice: Dispelling the Myths & Designing Strategies. California Academy of Family Physicians. 2006. Available at: http://www.pain-topics.org/opioid_rx/risk.php#UDT.

Gourlay DL, Heit HA. Universal Precautions in Pain Medicine: The Treatment of Chronic Pain With or Without the Disease of Addiction. Medscape Neurol Neurosurg, 7(1), 2005. At: http://www.pain-topics.org/opioid_rx/risk.php#UniverPrecautions.

Consultation

Practice Pointer: ***Involve consulting practitioners to help clarify or confirm.***

Pain is rarely simple. In addition to physical features there may also be psychological, social, and behavioral factors. During the course of therapy, providers must be able to recognize the limits of their training and experience and should be willing to refer the patient for additional evaluations.

Consultation can be a call for assistance or a request for confirmation. A second opinion from a subject-matter expert may be in order when the working diagnosis remains in question after a complete evaluation. Consultation is also appropriate when progress toward treatment goals is inexplicably stalled. As noted above, reaching certain triggering doses of opioids may prompt consideration of referral. At times, frustrated patients might ask for referrals, and in most cases, their requests should be granted.

Psychiatric and personality disorders may manifest during therapy, and affected patients should be referred to appropriate mental health professionals. Suicidal ideation requires immediate referral. Behaviors suggesting substance misuse or addiction should be addressed by an addiction specialist experienced in treating pain.

Author's Comment: Unfortunately, there is a national shortage of pain specialists, with only an estimated 6 of them per 100,000 persons with chronic pain in the United States [Breuer et al. 2007]. For many areas of the United States, there may not be local referral options. In such cases, patients may be required to travel to larger metropolitan areas or tertiary care centers to receive a pain or other specialist consultation.

Medical Records

Practice Pointer: ***Document the decision-process to trial, continue, or discontinue opioid therapy.***

The Federation of State Medical Boards *Model Policy* recommends that patients' medical records include a number of items:

- The medical history and physical examination;
- Diagnostic, therapeutic, and laboratory results;
- Evaluation and consultations;
- Treatments recommended;
- Treatment objectives;
- Medications (including date, type, dosage, and quantity prescribed);
- Discussion of risks and benefits;
- Informed consent;
- Instructions and agreements, and;
- Periodic reviews.

Not every patient visit requires addressing each of the above elements. Beyond these, the medical record should document the thought process of the provider regarding the decision to trial, continue, or discontinue opioid therapy. There should be a clear identification of the risks and the steps taken to mitigate those risks, such as a structured opioid trial for a patient with a history of substance abuse. Additional documentation would include: the interpretation of drug testing, equianalgesic dose conversions, compliance regarding refill requests, lost medications, and missed appointments.

Compliance with Controlled Substances Laws and Regulations

Opioid medications are regulated at both federal and state levels to ensure that efforts to control drug abuse are balanced against the need for maintaining drug availability for legitimate medical purposes [Joranson 1990]. Clearly, to prescribe controlled substances, the provider must be appropriately licensed. Complying with controlled substances directives involves reading the laws, guidelines, and regulations. Fortunately, in the United States, nearly half of the states have adopted the Federation of State Medical Boards *Model Policy*.

Practice Pointer:
Learn and follow federal and state directives regarding controlled substances.

While a State Medical Board is the best source of information, this website may provide links directly to a state's pain policies: http://www.medsch.wisc.edu/painpolicy/matrix.htm.

Additionally, see the ***Opioid Rx Regulatory & Legal Issues*** section at Pain-Topics.org: http://www.pain-topics.org/opioid_rx/regulatory.php, which includes the following documents and others…

- DEA, Office of Diversion Control. Practitioner's Manual – An Informational Outline of the Controlled Substances Act. August 2006. Available at: http://www.pain-topics.org/opioid_rx/regulatory.php#DEA_manual.
- Pain & Policy Studies Group; Univ. of Wisconsin. Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (4th Edition). July 2007. Available at: http://www.pain-topics.org/opioid_rx/regulatory.php#Eval_Guide.

Summary

Opioids have a legitimate role in treating CNP. While there are risks to their use, these medications should be available to patients who gain benefit from them and are able to use them safely. The risks can be managed by using a well-planned opioid treatment program for all patients. The Federation of State Medical Boards *Model Policy*, adopted by nearly half of the states, provides a suitable program framework, and its universal application can help to minimize risks when prescribing opioids. In particular, providers should:

Opioids have a legitimate role in treating noncancer pain and should be available to patients who can benefit from them and use them safely.

1. Request and review patient medical records prior to prescribing.
2. Prescribe opioids as a trial, with criteria for both treatment success and failure specified.
3. Use an *Agreement for Treatment with Opioids* to obtain informed consent.
4. Monitor progress with regular visits and adherence with periodic urine drug testing.
5. Involve consulting physicians as necessary to help clarify or confirm.
6. Document the decision process to trial, continue, or discontinue opioid therapy.
7. Learn and follow federal and state laws regarding controlled substances.

Application of the *Model Policy* should help standardize the *process* of opioid management but not dictate the individual therapy. Pain management is not a "one-size-fits-all" proposition. Treatment decisions regarding the use of opioids should only be made after a comprehensive evaluation of patients and in view of their complete medical history. Due consideration should be given to factors such as past or potential substance misuse. Opioid selection, doses, and treatment monitoring will need to be tailored to the patient.

Providers must also recognize the evolving risks to their patients. Regular visits are a necessary component of pain management, and chronic pain patients often require more frequent visits than non-pain patients. Changes in health status as well increases in medication use should prompt re-evaluation of the diagnosis and treatment plan.

References:

All URL links listed below were valid at the time of posting; however, the Internet is constantly changing, and some linked documents may be moved or inactivated with time.

Adriaensen H, et al. Opioid tolerance and dependence: an inevitable consequence of chronic treatment? Acta Anaesth Belg. 2003;54:37-47.

AMDG (Agency Medical Directors Group, State of Washington). Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain. 2007. Available at: http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf. Accessed 8/10/07.

Atluri S et al. Guidelines for the use of controlled substances in the management of chronic pain. Pain Physician. 2003;6:233-257.

Ballantyne JC, et al. Opioid therapy for chronic pain. NEJM. 2003;349:1943-53.

Ballantyne JC. Chronic pain following the treatment for cancer: the role of opioids. The Oncologist. 2003;8:567-575.

Breuer B, Pappagallo M, Tai JY, Portenoy RK. US board-certified pain physician practices: uniformity and census data of their locations. J Pain. 2007;8(3):244-250.

Buntin-Mushock C, et al. Age-dependent opioid escalation in chronic pain patients. Anesthesia and Analgesia. 2005;100:1740-1745.

Coluzzi F, et al. Opioid therapy for chronic noncancer pain: practice guidelines for initiation and maintenance of therapy. Minerva Anestesiol. 2005;71:425-433.

CPSO (College of Physicians and Surgeons of Ontario). Evidence-based recommendation for medical management of chronic non-cancer pain: reference guide for clinicians. November 2000. Available at: http://www.cpso.on.ca/Publications/pain.PDF. Accessed 8/9/07.

Dahl J, Pasero C, Patterson C. Institutionalizing effective pain management practices: the implications of the new JCAHO pain assessment and management standards. Program and Abstracts of the 19th Annual Scientific Meeting of the American Pain Society; November 2-5, 2000; Atlanta, Georgia. Symposium Abstract 302.

Fishbain D, et al. Drug abuse, dependence and addition in chronic pain patient. Clin J Pain. 1992;8:77-85.

Fleming MF, Balousek SL, Klessig CL, et al. Substance use disorders in a primary care sample receiving daily opioid therapy. Journal of Pain. 2007;8(7):573-582.

Guglielmo WJ. Doctors: the new target in the war on drugs? Medical Economics. 2006;83:50-4, 56-7.

Hariharan J, et al. Long-term opioid contract use for chronic pain management in a primary care practice. A five year experience. J Gent Intern Med. 2007;22:485-490.

Højsted J, Sjøgren P. Addiction to opioids in chronic pain patients: a literature review. European Journal of Pain. 2007;11:490-518.

IPTA (Intractable Pain Treatment Act). Missouri Revised Statutes. 2006. Section 334.105-107. Available at: http://www.moga.state.mo.us/STATUTES/C334.HTM. Accessed 8/9/07.

Jacobson P, Mann J. The valid informed consent-treatment contract in chronic non-cancer pain: it role in reducing barrier to effective pain management. Comp Ther. 2004;30:101-104.

Joranson D. Federal and state regulation of opioids. Journal of Pain & Symptom Management. 1990;5:S12-S23.

Kahan M, et al. Misuse of and dependence on opioids. Canadian Family Physician. 2006;52:1081-1087.

Kalso D, et al. Opioids in chronic non-cancer pain: systematic review of efficacy and safety. Pain. 2004;112:372-380.

Kuehn B. Opioid prescriptions soar. JAMA. 2007;297:249-251.

Manchikanti L, et al. Does adherence monitoring reduce controlled substance abuse in chronic pain patients? Pain Physician. 2006;9:57-60.

Model Policy for the Use of Controlled Substances for the Treatment of Pain. Federation of State Medical Boards of the United States, Inc. May 2004. Available at: http://www.pain-topics.org/opioid_rx/regulatory.php#Model_Policy. Accessed 8/10/07.

Olsen Y, Alford D. Chronic pain management in patients with substance use disorders. Advanced Studies in Medicine. 2006;6:111-123.

Paulozzi L. Increasing deaths from opioid analgesics in the United States. Pharmacoepidemiology and Drug Safety. 2006;15:618-627.

Portenoy RK. Chronic opioid therapy in nonmalignant pain. J Pain Symptom Management. 1990;5(1 Suppl):S46-62.

Satel S. Doctors behind bars. Treating pain is now risky business. New York Times, October 19, 2004.

Shapiro RS. Health care providers' liability exposure to inappropriate pain management. Journal of Law, Medicine & Ethics 1996;24:360-364.

Sinatra R. Opioid analgesics in primary care: challenges and new advances in the management of noncancer pain. Journal of the America Board of Family Medicine. 2006;19:165-77.

VA/DoD Clinical Practice Guideline for the management of opioid therapy for chronic pain. Department of Veterans Affairs/Department of Defense. March 2003. Available at: http://www.pain-topics.org/opioid_rx/safety.php#VA_DoD. Accessed 8/10/07.

Zenz M, et al. Long term opioid therapy in patients with chronic non-cancer pain. J Pain Symptom Management. 1992;7:69-77.

About the Author:

James D. Toombs, MD, is a Staff Physician in the Division of Primary Care/Pain Medicine at the Harry S. Truman Memorial Veterans' Hospital in Columbia, Missouri. He is a Diplomate of the American Board of Family Practice and holds a Subspecialty Certification in Pain Medicine from the American Board of Physical Medicine and Rehabilitation. Dr. Toombs has published several papers focusing on pain management. He is a Senior Flight Surgeon in the Missouri Army National Guard and served two tours of active duty as a Field Surgeon in Iraq during Operation Iraqi Freedom.

Medical Editor:

Stewart B. Leavitt, MA, PhD, is the Publisher/Editor-in-Chief of *Pain Treatment Topics* and was the founding editor of *Addiction Treatment Forum* in 1992. He has served as a consultant to the US Center for Substance Abuse Treatment and as an officer in the US Public Health Service, stationed at the National Institutes of Health. He has more than 25 years experience as a medical researcher/writer.

Medical Reviewers:

Paul Jones, DO, is a Staff Physician at the Harry S. Truman Memorial Veterans' Hospital and an adjunct Assistant Professor of Physical Medicine and Rehabilitation at the University of Missouri-Columbia School of Medicine in Columbia, Missouri. He is Board Certified in physical medicine and rehabilitation (ACGME and AOBPM&R); family practice (AOBFP); and by the American Board of Electrodiagnostic Medicine.

Credentials of other reviewers **Lee A. Kral, PharmD, BCPS** and **Paul W. Lofholm, PharmD, FACA,** are available at: http://www.pain-topics.org/contacts_aboutus/index.php#MedAdvisors.

Disclosures:

Pain Treatment Topics is supported by an unrestricted educational grant from COVIDIEN/Mallinckrodt, St. Louis, MO, a manufacturer of generic opioid analgesics. However, the sponsor did not participate in the conception, research, development, or revision of this paper. The author, editor, and reviewers have no conflicts of interest to declare relating to the subject of this paper or its contents.

Disclaimer:

PAIN TREATMENT TOPICS

Published by…
Pain Treatment Topics
202 Shermer Road
Glenview, IL 60025
http://www.Pain-Topics.org

Supported by an unrestricted educational grant from COVIDIEN/Mallinckrodt, St. Louis, MO, USA.

To comment on this document send e-mail to: Info@Pain-Topics.org

Appendix – Sample "Agreement for Treatment with Opioids"

_____ _____

Patient Name Identification Number

Your healthcare team has decided to manage your chronic pain with opioid medications. The goal of this treatment is to improve your quality of life, your functional ability (including social and work activities), and your pain level. This form of treatment has risks and potential side effects, including the following:

1. Sedation.
2. Constipation.
3. Nausea and vomiting.
4. Confusion or change in thinking ability.
5. Difficulty with balance, which may make it unsafe to operate heavy equipment or motor vehicles.
6. Sleepiness and drowsiness.
7. Decreased respiration or breathing.
8. Physical dependence, which means if you abruptly stop taking this medication you may experience withdrawal. Symptoms of withdrawal include: restlessness, sweating, diarrhea, abdominal cramping, "goose flesh," and anxiety.
9. Psychological dependence or addiction.
10. Tolerance, which means that you may need more medication to get the same effect.
11. Risks regarding pregnancy: Children born to mothers on opioids will likely be physically dependent on the drug at birth.

Your healthcare provider is willing to prescribe treatment with opioids if other reasonable non-opioid treatments have been ineffective and you agree to the following conditions:

1. I do not have current problems with substance abuse or dependence (addiction).
2. I am not currently involved in the sale, diversion, illegal possession, or transport of controlled substances, which include the following: opioids ("narcotics"), sleeping pills, anxiety ("nerve") pills, and/or painkillers.
3. I will obtain opioid prescriptions only from _____ and use only the _____ pharmacy.
4. I will take pain medications exactly as prescribed and under no circumstances allow any other individual to take these medications.
5. I will actively participate in additional pain therapies as requested by my healthcare provider, such as physical therapy or psychological counseling.
6. I will allow other relevant healthcare providers to communicate with my physician, nurses, and/or pharmacists regarding my use of opioids.
7. I may be asked to bring opioid medications with me to office/clinic visits for pill counts.
8. If I am a female of childbearing years, I certify that I am not pregnant and will use appropriate measures to prevent pregnancy during the course of this treatment.

9. I will keep all scheduled appointments. If I need to cancel, I will do so at least 24 hours in advance of my scheduled appointment.
10. I understand that NO ALLOWANCE will be made for lost prescriptions of drugs.
11. I will request opioid refills by telephone at least 7 days before my prescription runs out, unless I have made other arrangements in advance.
12. I will not request refills outside of the normal business hours of my prescribing provider.
13. I will consent to having all opioid prescriptions filled in person, if requested to do so by my prescribing provider.
14. If I feel I that need to increase my pain medication, or change the times I take the medication, I will contact my prescribing provider prior to doing so. Prescriptions will not be refilled early, without provider approval.
15. I will consent to unannounced blood or urine screening tests in order to properly assess the effects of opioids and patient compliance. Opioids may not be prescribed if I refuse testing.
16. I will follow the advice of healthcare providers in regard to stopping controlled substances if it is felt that this is necessary.
17. I understand that this treatment option will be discontinued if any of the following occur:
    a. If my healthcare providers believe that the opioids have not been effective in helping to manage my pain.
    b. If I give away, sell, or misuse the medication.
    c. If I am using illegal substances or abusing alcohol.
    d. If medication-related side effects become intolerable.
    e. If I obtain opioids from any unapproved source.
    f. If other, more effective, treatments become available.
    g. If I am unable to manage my pain medication according to this agreement.
18. If my healthcare providers choose to discontinue my opioid treatment, they will manage the dose to avoid withdrawal symptoms. If providers believe I have a drug dependence problem, they may refer me elsewhere for management of that condition.

My primary opioid prescriber is:_____.

In the absence of my primary opioid prescriber, I will contact only the following physician/clinic/team for opioid medication refills: _____.

_____ _____

Physician Signature Date

I have read this document, understand it, and have had all questions answered satisfactorily. I consent to the use of opioids to help control my pain and understand that this treatment will be conducted in accordance with the conditions stated above.

_____ _____

Patient Signature Date