# Tips for achieving good results and taking the worry out of prescribing opioids

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The following are suggestions based on our experience, and based on discussions with various regulatory agencies in Arizona. These are not intended to be practice guidelines. Similar information id found in the "Prescription Pain Medication FAQ created by the Pain Policy Study Group of the University of Wisconsin and other documents. This is a work in progress, because there is always new information coming forth and because the policy and regulatory environment in which we practice is fluid. Please feel free to e-mail comments to bdavis@ipcaz.org. We want to make this useful as possible and feedback is appreciated.

## 1. Informed consent and the pain contract

a. This can be covered in a written "opioid contract" that is saved in the patient's medical record and a copy given to the patient. There are numerous examples of pain contracts on the Internet, a search of "pain and contract" will yield quite a few results. An interesting variation of the pain contract is a contract that involves not only the treating physician and the patient, but a three-way contract between the primary care physician, the specialist, and the patient.

b. Make sure the informed consent includes the following:

   i. That physical dependence is likely to occur. Spell it out: The patient is likely to experience physical withdrawal if the medications are discontinued suddenly and that this can be avoided with slow tapering off medication, and that children born to women on chronic opioids will need to be withdrawn slowly as well. Patients need to know about this to avoid nasty surprises if, for example, they loose their medication. Conversely, patients who want to stop the medications sometimes believe that they cannot,

because when they try they experience withdrawal symptoms. They need to know that a slow withdrawal will work.

ii. Name the main side effects for the patient in this document.

iii. Forthright statement that psychological dependence is a possible adverse outcome/complication.

1. Clearly state that by signing the document, the patient gives you permission to talk to their family, other health-care providers including pharmacists, and even their work supervisor to assess for behaviors that might indicate misuse of the medication[i].

iv. Forthright statement that during initial titration, anytime the dosage is increased, and anytime the patient feels sleepy or impaired from the medication the patient is at risk for cognitive impairment and good judgment must be used in operating motor vehicles and dangerous machinery.

v. Forthright statement that opioid or combination of opioid with other sedative hypnotics may produce dangerous cognitive impairment and increase the risk of operating motor vehicles and dangerous machinery. While there is no research showing cognitive impairment from stable doses of opioid, patients should be advised to self-monitor and avoid driving if they feel impaired. Because of the consequences of DUI, consider informing your patient that it is possible to be cited for DUI if a law enforcement office feels that they are impaired while driving. This is no different from the law surrounding alcohol and driving.

vi. Include written rules regarding how you want the patient to handle refill requests, how your office will handle the inevitable calls for early refills, how you will handle lost or stolen prescriptions. The patient will not usually read them thoroughly, but they provide a basis for creating a consistent message to patients from your office staff.

vii. Clearly state that only one practitioner is to provide opioids and leave room for addition of the words "any sedative or pain medication" so that you may include this if you want to.

viii. Include the reasons that you may require the patient to taper off opioids, and the reasons that you may terminate care. In doing this, emphasize the fact that the patient is taking on specific duties and responsibilities [such as owing your instructions and instructions of your office staff, not losing prescriptions, not allowing them to be stolen, not allowing prescriptions to run out before calling your office, discussing an increase in dose with the physician prior to actually doing it, etc.] and that it is failure to consistently perform these duties and live up to the responsibilities that will lead to discontinuing the medication and perhaps discharging the patient from care.

ix. State clearly that the patient, in signing the opioid contract, agrees to comply in a timely fashion with requests for pill counts and urine and serum drug screening.
x. Have your lawyer go over your informed consent. You don't want your lawyer to write the document for you, but your lawyer may point out things that are specific to your area that you did not think of.

2. **Follow generally accepted outcomes for pain treatment with opioids:**
   a. pain relief;
   b. side effects;
   c. functioning, both physical and psychosocial (and overall quality of life); and
   d. problematic drug-related behaviors (which may suggest misuse, abuse, addiction, or even diversion).

3. **Develop and be clear on (with the patient and in documentation) patient specific treatment goals**
   Have the patient help you establish clear-cut, individualized, and achievable functional goals for therapy, and document these. Function will be your "blood pressure" to gauge whether or not there be is effective, functional change or lack thereof is what you will use to decide whether or not to continue opioid. Measurement of function is tremendously useful because it is independent of concerns related to the question: “is there a biological disturbance causing/explaining all the patient’s pain?”. There is no "one-size-fits-all" tool for patient assessment. Perhaps the most useful single tool is the Brief pain Inventory, however. Individualized goals in the main domains of function listed below are the simplest and the best, and I include some examples of simple scales to assess change for better or for worse.
   a. Sleep
   b. Mood (“ Rate your mood as good, poor, bad”) (Beck Depression Inventory Fast Screen 2® is a good tool for patients with pain)
   c. Work life (“ how many days of work are you missing per month?”)
   d. Social life (“ What activities this or pain prevents you from doing that you would like treatment to enable you to do again?”)
   e. Recreational life (“ What activities this or pain prevents you from doing that you would like treatment to enable you to do again?”)
   f. Sex life
   g. Specific activities in common to all of us (standing tolerance and sitting tolerance in minutes: the amount of time a person can stay seated before having to stand up and move about)

4. **Patient education**
   Do a good job of educating the patient regarding what to expect, ie: only partial relief of pain with opioids. Discuss the patient’s responsibilities and the conditions under which you would stop prescribing medication: lay the

foundation for your exit strategy. This all can all be taken care of with written documents, reviewed with the patient by nursing staff. Discuss specific treatment goals with the patient, and arrive at (and document) individualized realistic treatment goals that will be easy to assess (like: "I want to be able to sit through a meal, go shopping for food, go bowling etc), and which will serve as the main indicator of success or failure of therapy. Discuss side effects and what to do about them, the difference between physical and psychological dependence, the fact that opioids are nontoxic, and the fact that they may experience withdrawal if they stopped the medication suddenly but that this can be avoided with slow decrease.

a. Provide the patient with written instructions for preventing constipation, because this is such a common side effect and so frequently the reason that patients discontinue the medication.
b. Consider including general information on side effects and risks in your patient opioid agreement (make it serve also as an "informed consent to treat").
c. Consider leaving space in the opioid contract for documenting specific treatment goals, for easy reference for the patient in the future.

5. **Sustained release versus short acting medication**:
   a. Use sustained release preparations unless the patient has only occasional, intermittent pain such as occasional migraine headache, or has pain at only certain times of the day and does not need a constant level of medication.
   b. For patients with constant daily pain, a general rule of thumb is that roughly ¾ of the total daily opioid dose should be in the form of long acting/sustained release medication

6. **Dosage titration**:
   a. Increase the dosage between one and three times in the first 1-2 months, until the patient is clear that there has been some improvement in comfort and function. An opioid naïve patient who has no improvement during this initial period of titration will probably not respond to further dose escalation.
   b. Further increases in dosage should be done no more often than monthly intervals, to allow the initial 1-2 weeks of transient improvement that frequently occurs every time the dosage is increased to pass. Once this "honeymoon" period has passed, assess improvement in comfort and function. If there is sustained improvement in comfort and function after an increase in dose, the maximum effective dose has not yet been reached.
   c. Stop increasing the dose when:
      i. An increase in dose provides no sustained improvement in function. This defines the "maximum effective dose". Patients will sometimes complain that their pain is not adequately controlled at the maximum effective dose, but the fact remains that further increases will not improve their situation.
      ii. Side effects outweigh the benefit.

iii. Your patient has met enough of their functional goals that further dose escalation is not needed.

**7. Breakthrough pain.**

Provide a method for dealing with "breakthrough pain". In general, daily use of breakthrough medication is not appropriate unless it is being used to extend the duration of action of a sustained release opioid, or to treat a cyclic phenomenon that recurs for good reason – such as pain at the end of the work day or upon rising in the morning. Frequently we run into insurance company restrictions on dosing that limit patients to b.i.d. dosing of a sustained release opioid medication that may only last eight hours, and a dose of 'breakthrough" medication is required in between doses of sustained release medication.

Daily and frequent usage of "breakthrough medication" is a sign that the patient is either on too low a dose of sustained release medication or, if maximum effective dose has already been achieved, the patient is using the breakthrough medication in a fruitless effort to improve analgesia. Sometimes a patient will insist that they need the breakthrough medication every 4 hrs, and there are a number of explanations, some innocent some not. The most common innocent situation is that the patient likes the breakthrough medication because he can "feel" it working, whereas the sustained release give no physiologic cues that it is working.

The most common method for dealing with breakthrough pain is to provide a small supply of immediate release oxycodone, hydrocodone, morphine, transmucosal fentanyl (although this is approved only for cancer pain), or hydromorphone of an adequate dose relative to the patient's daily consumption of sustained release opioid.

8. **Follow-up and documentation**.
   a. See the patient at monthly intervals at first unless circumstance clearly indicate that this is not needed (Ex: a debilitated cancer patient who lives 150 miles away and who has been taking 2 hydrocodone a day for 6 months with solid documentation from the prior physician that there have been no problems), and then at intervals dictated by the stability of their medical problems, side effects, behavior, and risk of misuse and diversion. Since the maximum period that the DEA will permit schedule 2 opioids to be prescribed at one visit is 90 days, it is wise to see the patient at least every 3 months to document medical indication for continued therapy and to assess whether or not the patient is managing medications responsibly.
   b. **Documentation** (this is what the medical boards emphasize as the main problem in more than 90% of cases where the physician was censured)
      i. At the start of therapy
         1. When you start the medication document the reason for starting opioid (the DEA Sept 6, 2006 Policy statement published in the Federal register requires that "each

prescription is issued for a legitimate medical purpose", so as trite as it seems to say this, be sure that the purpose of the prescription is well documented), document functional improvement goals (ex: 'this prescription was given in an effort to improve sleep", "to improve standing tolerance", "to improve the patient's ability to perform ADLs in a reasonable time", 'to reduce missed time at work and improve work productivity", etc), and document that you have discussed alternatives with the patient and that the patient had a say in choosing the opioid alternative… or that you feel there are no alternatives if that is the case.

2. Document that you discussed with the patient conditions for which opioid may be discontinued, that you told them their responsibilities (this can be done by placing this information in the opioid agreement and having the patient initial this section of the document).
3. Document that you discussed possible adverse effects – the "informed consent" (this can be done by placing this information in the opioid agreement and having the patient initial this section of the document).
4. Document that you discussed issues related to securing the medications so others cannot get them (this can be done by placing this information in the opioid agreement and having the patient initial this section of the document).
5. Document that you did an assessment of misuse and diversion risk, and what your assessment is. High, moderate and low risk is one way to do this (high risk more or less mandates pain specialty consultation for back-up, at the least. Managing high risk patients is for practitioners with an interest in this and who can demonstrate that they maintain regular pain medicine CME efforts).

ii. At each visit document progress toward the general (pain relief, function, side effects, problematic behaviors) specific treatment goals that you and the patient identified at the start of opioid treatment. In general, document comfort, change in function, side effects, absence of presence of aberrant behaviors, and general mental status. If the dose is increased it should be clear to anyone reading your notes why, and the patient specific end point for future dose increase should be clear (see #6 above).

iii. When aberrant behaviors occur, it should be clear in your notes what action you will take in response. This is the biggest single reason that physicians have been censured: a clear and persistent pattern over time of patient aberrant behavior related to pain medications and either nothing in the physician's notes describing it or no evidence that the treatment plan was altered in response.

**9. Handling problems**

a. Require a written explanation from the patient whenever a prescription is lost or stolen, and keep this in the chart.

b. Do not hesitate to order a same day urine drug screen to document that your patient is actually taking the prescribe medication. Be aware that routine "tox screens" frequently do not pick up oxycodone, hydromorphone, and Fentanyl. Specific written request that these substances be included in the screen is a wise idea when your patient is taking one of these drugs. Find out if the laboratory has sufficient procedures for taking the specimen and documenting chain of custody to make you comfortable that the specimen will not be tampered with, and if they do not, have your staff take the specimen and clearly document chain of custody.

c. Know the "egregious" behaviors that suggest abuse or diversion
- Deterioration in functioning at work, in the family, or socially
- Illegal activities, such as selling medications, forging prescriptions, stealing drugs from other patients, buying prescription drugs from nonmedical sources
- Injection or snorting of medication
- Multiple episodes of "lost" or "stolen" prescriptions
- Resistance to changes in therapy, regardless of adverse effects
- Refusal to comply with random urine drug screens or referral to specialist
- Concurrent abuse of alcohol or illicit drugs
- Use of multiple physicians and pharmacies

**10. Special cases and issues**

a. Multiple prescriptions for schedule 2 medications

i. As of December 19th, 2007, the DEA has issued a final rule that it is permissible to issue up to three prescriptions for a schedule 2 medication, such as oxycodone, fentanyl, morphine, and methadone; one for the current month, and up to 2 more for the following consecutive months. These are NOT refills; these are separate prescribing documents that we are now legally permitted to issue to patients (the language of the final rule implies that we believe a patient receiving multiple prescriptions to be at relatively low risk for misuse or diversion) It is a violation of the Controlled substance act to issue "refills" for schedule 2 drugs so don't ever use the term refills for schedule 2 medications.

ii. The consecutive prescriptions must, according to the DEA final rule, have clear language that provides to the pharmacists "written instructions on each prescription (other than the first prescription intended for filling immediately) indicating the earliest date on which a pharmacy may fill each prescription". No pharmacy may fill a prescription before the date you specify {according to 21 CFR 1306.14(e)}.

iii. Do not "post date" any prescription, ever. The date the prescription was written needs to be on every prescription {according to 21 CFR 1306.05(a)}
iv. If you are issuing multiple prescriptions for up to 3 months of medication, be aware that the DEA Sept 6, 2006 Policy statement published in the Federal register says "The individual practitioner concludes that providing the patient with multiple prescriptions…does not create an undue risk of diversion or abuse". Multiple prescriptions should be for patients that you have assessed and documented as "low risk" for misuse or diversion".

b. Prescribing a 90 day supply for mail order
   i. There is no Federal rule that limits the number of days worth of medication that a physician may prescribes. There is no rule in the State of Arizona as of 2007 that prohibits this, either, but there is in some states. It is legal to prescribe 90 days of schedule 2 medication.
   ii. However, the language of documents published by the DEA clearly states that the diversion risk of a 90 day supply is greater than that of a 30 day supply, and this can be construed as a "suggestion" that only the most reliable patients be entrusted with 90 day supplies of scheduled medications. You would be wise to be confident of and to document said reliability/trustworthiness if you are prescribing 90 day mail order supplies.

c. Methadone
   Methadone has been singled out for special treatment due to a rise in deaths associated with methadone. This is described in a 2003 Department of health and Human Services Substance abuse and Mental health Services Administration report entitled "Methadone-Associated Mortality: Report of a National Assessment" abuse and its 2007 update (http://dpt.samhsa.gov/pdf/Methadone_Draft_Report_10%2018%2007_Brief%20w%20attch.pdf). Several risk factors for methadone-related mortality have been identified: (1) the concomitant use of benzodiazepines, other opioids, and/or alcohol; (2) an elevated risk of some patients for Torsades de Pointes; (3) inadequate or erroneous induction dosing and monitoring by physicians, primarily when prescribing methadone for pain; and (4) drug poisoning that occurs as a result of diversion of the drug and its nonmedical use.
   i. Physician CME for methadone prescribing is offered through the American Academy of Pain Medicine and others.
   ii. FDA labeling was updated in 2003 and anyone prescribing should be familiar with this information

d. Patients with substance abuse problems.
   If a patient receiving opioid therapy engages in an episode of drug abuse, is the physician required by law to discontinue therapy or to report the patient to law enforcement authorities?

Federal drug laws do not require physicians to report to law enforcement authorities patients who have engaged in drug abuse. The controlling federal legal standard is that the physician must issue prescriptions for controlled substances only for legitimate medical purposes and in the usual course of professional practice. However, some state policies state that a physician should not prescribe, administer, or dispense opioid analgesics to a person the physician knows or should know is using controlled substances for nontherapeutic purposes (not AZ). State laws and regulations should be consulted on whether a report of patient drug abuse is necessary or use of opioids must cease under such circumstances.

In states with no specific legal requirements on this subject, if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. Additional monitoring and oversight of patients who have experienced such an episode is recommended. Incontrovertible evidence of criminal activity, such as diversion, is grounds for termination of the doctor-patient relationship.
Is it legal and acceptable medical practice to prescribe long-term opioid therapy for pain to a patient with a history of drug abuse or addiction, including heroin addiction?
It is within the scope of current federal law to prescribe opioids for pain to patients with a history of substance abuse or addiction. However, some state policies may be more restrictive than federal law – not AZ (see http://www.medsch.wisc.edu/painpolicy/2003_balance/).

What strategies can be used to treat pain successfully in patients who are actively abusing drugs?
Federal law and regulations do not prohibit the use of opioids to treat pain if a patient is abusing controlled substances. However, state policies vary with respect to this therapy. Some states' policies discourage, if not prohibit, physicians from prescribing opioid analgesics to patients whom they know or should know are using controlled substances for nontherapeutic purposes – not AZ.

Using opioids to treat pain in such patients is very challenging and is best carried out by those with additional training and expertise.

Continued drug abuse despite repeated interventions may, in some cases, indicate the need to discontinue prescribing of potentially abusable drugs, and in other cases, provide
the impetus for termination of the physician-patient relationship. The clinician should be prepared to respond in these ways, and should understand both the options for nondrug therapies and the approach to termination without abandonment.

**11. Monitoring for misuse, abuse and diversion**

In general, pain patients fall into three groups.

a. The first includes patients whose pain is not complicated by current addiction or a history of substance abuse. This group includes the majority of patients.
b. The second group comprises those patients who have histories of substance abuse or addiction but are in established recoveries. Some of these patients are receiving substitution therapy (methadone or buprenorphine), and some are in drug-free recovery. It is prudent to consult with a specialist in addiction medicine when considering long-term opioid therapy for patients who fall into this group. Therapy for patients in this group typically includes more controls than does therapy for those with no such history.
c. The third group, which includes those who are actively abusing substances, poses the greatest challenge. These patients require care of an advanced nature, which may not available in the primary care setting. Referral of such patients to an addiction medicine specialist is appropriate (see state lists of addiction medicine specialists at www.asam.org).

These are some of the more common reasons that prescribing opioids can become very uncomfortable, and hopefully this information will help you to avoid them:

- **No exit strategy in place from the start**
- **Expectations for success not defined clearly and managed**
- **Dose escalated too quickly**
- **Opioids used to treat anxiety or depression**
- **Inadequate patient education**
- **Inadequate documentation**

**For more information on the use of opioids in the management of pain, see:**

http://www.aapainmanage.org/education/Education.php
• American Academy of Pain Medicine

http://www.painmed.org/cme
• American Academy of Physician Assistants

http://www.mecgeducation.com/jaapa/pain_management/default.asp
• American Board of Pain Medicine

http://www.abpm.org/index.htm
• American Headache Society

http://www.ahsnet.org
• American Medical Association

http://www.ama-assn.org/ama/pub/category/10171.html
• American Pain Society

http://www.stoppain.org/
• California Academy of Family Physicians

http://www.familydocs.org/
• National Pain Education Council

**CME online for Primary**
http://www.vlh.com
NIH funded: Improving outcomes in chronic pain management

**Arizona Law governing opioid prescription: Title 36 Public Health and Safety Chapter 27 Uniform controlled substances act**
http://www.pharmacy.state.az.us/controlledsubstances.html

**Federation of State Medical Boards Model Guidelines**
http://www.fsmb.org/pdf/2004_grpol_controlled_substances.pdf

**Arizona medical Board Guidelines**
http://www.azmd.gov/pain_management/Guidelines.pdf

**Methadone Mortality Sponsored by the Center for Substance Abuse Treatment Substance Abuse and Mental Health Services Administration**
http://dpt.samhsa.gov/pdf/Methadone_Draft_Report_10%2018%2007_Brief%20w%20attch.pdf).

[i] It would be wise to discuss this with your lawyer, because different states handle patient confidentiality issues differently and it may be that by talking to family members, people at the patients work, etc. you would open yourself to civil litigation - even if you cross no regulatory line. The key legal issue is the healthcare provider's "duty to protect the public". If a patient is suspected to be misusing medication they may pose a risk to others that work and on the roads. This is not new, it applies to anticonvulsants and other medications. However, when prescribing medications that have street value a new aspect presents itself: diversion. If there is any suspicion that the patient may be diverting medication, we have a duty to protect in that it is our duty to try to keep medications off the streets. How far you want to go in this regard must be a personal choice. You should be aware of the issues, both legal and ethical. The University of Wisconsin's opioid policy research program, run by Dr. David Joranson, your state and county medical Association, and various pain societies yearly seminars (such as the international Association for the study of pain meeting at Stanford in2002, and concurrent programs run at the yearly American Pain Society meetings) are good places to look for more quality information.