

PATIENT CONTRACTS

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A Perspective on Contracts/Written Agreements Relative to
Prescribing Opioid Analgesics*

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The purpose of this paper is to address agreements/contracts between

- 1) prescribers of opioid analgesics and persons with chronic nonmalignant pain (CNP) (for proposed guidelines for the management of opioid therapy for CNP, see Portenoy, 1994), and
- 2) prescribers of opioid analgesics and actively addicted individuals with pain. (for general guidelines for the management of pain in the recovering or active addict, see Compton, 1999 and McCaffery and Vourakis, 1992).

Some agreements / contracts include all controlled substances, but the ones discussed here focus only on opioid analgesics.

Unfortunately, the differences between patients with CNP and those with pain who are also addicted tend to become confused. Here these two groups are discussed separately. Clearly, many patients receiving opioids for CNP are not addicted, and addicted patients may have a variety of types of acute and chronic pain.

Here it is not the intent to unravel the legal aspects of these agreements but rather to explore their usefulness and to raise questions about content and ethical aspects. For example, what is the justification for using agreements with some patients receiving opioids and not others? Do agreements have the potential for causing harm to the relationship between clinicians and patients?

Patients have certain rights such as those stipulated by Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (1998). These include the right to considerate and respectful care, the right to effective pain management, and the right to make decisions about their medical care. One Bill of Rights for patients with pain states, "I have the right to be treated with respect at all times. When I need medication for pain, I should not be treated like a drug abuser" (Cancer Care, Inc., no date). An important consideration in evaluating written agreements / contracts is whether or not they violate these or other patients' rights.

Terminology

The words contract and agreement both suggest an arrangement between two or more parties for the doing or not doing of something specific. An agreement ranges in meaning from a mutual understanding to a binding obligation. A contract is most often used in law and business for agreements that are legally enforceable. Thus, a contract

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usually has legal and punitive connotations that suggest a level of mistrust, whereas an agreement implies that parties have reached an amicable arrangement that is freely accepted by all parties and is open to change (Random House Webster's College Dictionary, 1992). Therefore, in this discussion the term agreement is used, and use of the term contract is discouraged.

Information Appropriate for All Patients

Most patients with chronic pain, malignant or nonmalignant, are cared for on an out patient basis. All patients should receive certain types of information about their care, including how to access care within the clinical setting. Patients need to know what they can expect from their caregivers and what is expected of them in relation to treatment. This information may be provided verbally or in writing, preferably both. Written treatment plans also should be developed and shared with all patients.

Box 1 provides an example of all information patients need when they are treated with opioid analgesics in outpatient settings, such as an office or clinic. For example, patients should know if a new written prescription is required each time a refill is needed or if prescriptions can be refilled by telephone. Patients also should receive information about their specific opioid analgesics as well as any other analgesics and related medications, including benefits and potential side effects.

If the above is provided for the patient verbally or in writing and is documented appropriately in the patient's record, it constitutes informed consent. Signatures of the patient and clinician are not necessary. However, in some states, regulations or acts such as the Intractable Pain Treatment Act require or recommend a signed informed consent. Regardless, the patient's medical record should reflect that informed consent was given.

Agreements with Patients with CNP

The controversial nature of opioid maintenance therapy for patients with CNP seems to be the underlying reason for requiring these patients to sign agreements. Clinicians should remember that it is the use of opioids for treatment of CNP that is in question, not the patients themselves.

How often written agreements are used with patients receiving opioid analgesics for CNP is unknown, but use appears to be widespread. For example, in one issue of a newsletter published by the American Society of Pain Management Nurses, two separate authors state that in their pain facilities all patients receiving opioid analgesics for CNP are required to sign agreements (Brooke, 1998; Kowal, 1998). There are also reports of similar written agreements being used with parents of children who have chronic pain such as sickle cell disease related pain.

Currently the trend appears to be that clinicians who are inexperienced in chronic opioid maintenance therapy for CNP are interested in exploring the use of signed agreements between clinician and patient. However, those clinicians who have become experienced in the treatment CNP with opioids seem to be abandoning contracts and agreements, tending to provide written information and using agreements only when a patient's behavior repeatedly results in difficulties.

Unfortunately, there are very few publications addressing contents of agreements and criteria for their use. No research was found that examined the benefits or harm resulting from the use of such agreements. Burchman and Pagel (1995) have published the most extensive report to date on the use of contracts with patients with CNP. Over a 3 year period they used a written agreement in the management of CNP in 64 patients. Although these patients were characterized as having a positive response to opioid therapy, these patients were not

compared to a similar group of patients who were managed without the agreement. Therefore, it is not possible to identify harmful or beneficial effects of the agreement .

The agreement used by Burchman and Pagel (1995) is published in their article. However, a copy is not included here since the agreement is being revised (Burchman 1998), and several pain specialist pain specialist have raised questions about the content. Since this agreement is typical of other agreements informally obtained by this author (McC) from a variety of pain facilities, concerns about some of its content are discussed below.

Distrust and inflexible medication regimen.

Some of the conditions in the agreement for patients with CNP are intimidating, convey mistrust, and are notably inflexible with regard to amount and frequency of opioid analgesic the patient is allowed to take (Rose 1996). The agreement may specify no early prescription refills, no replacement of lost prescriptions or drugs, a threat of discharge from the program for failure to abide by the conditions, and a requirement of random blood or urine tests for alcohol and other drugs.

By contrast, patients with cancer pain are not required to sign such agreements when they receive opioid analgesics for chronic pain. In fact, patients with cancer pain are given considerable latitude with rescue doses prescribed as often as every hour if pain is not relieved by the ongoing analgesic regimen. Compared with CNP, cancer pain is probably more unstable, and there is certainly a greater chance that the disease process will escalate quickly and pain along with it. However, exacerbations of CNP are common and require adjustment of analgesia.

Crucial to the success of any agreement is the staff's willingness to accept the patient's report of pain and provide sufficient analgesic medication to maintain comfort. Inflexibility easily results in inadequate pain control. Understandably, when patients are asked to sign agreements that provide inadequate pain relief, they are not likely to abide by the rules. When they violate the agreement, the tendency is to blame the patient rather than realize that the pain management plan was poor.

Double standard of care.

Use of agreements with patients who have CNP may represent a double standard of care. If two patients, one who is terminally ill and another who has CNP, are receiving identical opioid analgesics for pain, why should the one who is not terminally ill be required to sign an agreement?

Suspicion of addiction

Many agreements focus on patient behaviors that the clinician associates with addiction. Some behaviors that are considered "red flags" for addiction and that patients are asked to avoid are actually potential indicators of undertreated pain. For example, multiple requests for early refills, repeated episodes of prescription loss, obtaining opioids from multiple providers, and even prescription forgery may be indications that pain is undertreated (Pankratz, Hickman, Toth 1989; Portenoy 1994; Weissman, Haddox 1989).

Failure to comply with the terms of the agreement sometimes results in discharge from the clinic. More appropriate alternatives would be to modify the agreement so that the patient could more easily comply or to continue treatment in the clinic but without opioids.

Being required to submit to random drug testing is not recommended in the care of patients with chronic cancer pain, and it clearly violates one of the four points in the previously mentioned Bill of Rights – "When I need medication for pain, I should not be treated like a drug abuser" (Cancer Care, Inc., no date). Random drug testing along with being threatened with discharge from the treatment center is also intimidating and degrading to patients.

Rather than being reassured about addiction being a rare consequence of taking opioids for pain relief, as is done in patient teaching materials for patients with cancer pain, patients with CNP are often given erroneous information. They may be told that addiction is a risk rather than a rare occurrence.

The issue of addiction appears to influence the use of contracts with patient with CNP. Yet, there is no evidence that the incidence of addictive disease is any greater in patients with CNP than in the general population.

Current estimates are that between 3 and 19% of patients with chronic pain are addicted to opioid analgesics (Fishbain, Rosomoff, Rosomoff 1992). This parallels the lifetime prevalence rates of 6.1 to 16.7% of addiction disease in the general population (Regier, Farmer, Rae et al 1990).

Exclusion of patients with past or current substance abuse.

Unlike terminally ill patients with pain, to be eligible to receive opioid analgesics from some pain facilities, patients with CNP must have no history of or current problems with substance abuse and must have never been

involved in illegal activities related to controlled substances. However, there is no evidence that history of addiction predicts which patients will exhibit problematic drug taking behavior such as frequent calls for early refills. In a study of 76 patients taking opioid analgesics for CNP, past opioid or alcohol abuse failed to identify which patients would become problematic opioid users (Chabal, Erjavec, Jacobson, et al 1997). Such data should help dispel the myth that patients with a history of substance abuse are predisposed to difficulties with opioid analgesics (Doleys 1998).

In addition, patients with past or current substance abuse do not appear to be more likely to exaggerate their pain. Research comparing pain reports and analgesic therapy in AIDs patients with and without a history of substance abuse showed no significant differences between their reports of pain and its intensity (Breitbart, Rosenfeld, Passik, et al 1997). Even among patients who acknowledged continued drug use there was no difference in report of pain intensity and pain relief compared to those who denied recent drug use or were participating in a methadone maintenance program.

Regulatory scrutiny

The physician's perception of regulatory scrutiny is a well known deterrent to prescribing opioids appropriately for pain, especially chronic pain. Although some physicians feel that the use of written agreements may protect them from inappropriate investigation, no evidence supports this belief (Burchman 1998). Ongoing evaluation and documentation are the best protection. Documentation should include comfort (pain rating), opioid related side effects, functional status, and any aberrant drug-related behaviors (Portenoy, 1994).

The clinician's concern about loss of license to practice may result in asking the patient to adhere to certain rules, such as use of only one pharmacy. This should be explained to the patient honestly, emphasizing that the rules are not because the clinician distrusts the patient but because the clinician feels the rules will protect his or her license.

Agreements with Active Addicts with Pain

Whether the actively addicted patient with pain is being cared for in an outpatient or inpatient setting for acute or chronic pain, the question of using contracts or agreements often arises. As with all patients, treatment plans should be developed, along with specific goals of treatment and potential means of accomplishing those goals. Box 2 presents an example of a written agreement for opioids given by IV PCA to a hospitalized patient who is actively addicted. As noted, this is not necessarily recommended. One reason for caution in using such as agreement, is that it could be considered a double standard of care. One solution to this is to use the same format, omitting goal #3, and to provide it as written information for all patients whose pain is being treated with IV PCA.

Another consideration is that no research has demonstrated that use of a written agreement in the treatment of acute pain in the addicted patient will result in any improvement in the patient adhering to the treatment plan. In fact, research has suggested that the addicted individual may be capable of conduct similar to the nonaddicted person being treated with opioids for pain relief. A small study by Paige and colleagues (1994) found no differences in PCA analgesic use between opioid and/or cocaine abusing patients and normal controls, indicating that addicted patients can use PCA responsibly.

Box 3 presents an example of a written agreement for an addicted patient with pain being treated with oral opioids on an outpatient basis. The objection related to double standard of care, presented above, also pertains to this agreement. Many agreements for addicted patients require them to submit to drug screens and agree to refrain from use of alcohol and other drugs. These stipulations seem to serve no purpose. Unless the active addict is interested in recovery from substance abuse, use of alcohol and other drugs most likely will continue, and drug tests will be positive.

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Box 1. Example of patient information regarding prescription of opioid analgesics in an outpatient setting. Obviously, specific information will differ from one setting to another. This type of patient information form is recommended for all patients with chronic pain, both malignant and nonmalignant, who are treated with opioids on an outpatient basis. Source: Adapted from University of Texas, MD Anderson Cancer Center, Houston Texas, 1995.

Clinic Guidelines: Pain Management*

1. Your physician is Dr. _____. Your doctor is available for pain clinic appointments during the hours of 8:00am to 1:00pm on :

Monday	Tuesday	Wednesday	Thursday	Friday
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Telephone: _____.

2. For emergencies that occur at other times, please call _____.

3. Write down the time and date of your next clinic appointment and double check this with the _____ clerical staff before leaving the clinic.

4. To cancel or reschedule your appointment, please let us know at least 3 days in advance.

5. Please use only one pharmacy for refills of your pain medication. The pharmacy you have chosen is: _____. If you wish to change pharmacies, tell your doctor. (Using the same pharmacy helps assure that the pharmacy will stock your medication for refills and that the pharmacy will know that you have a legitimate need for pain medication.)

6. Request for medication refills will be taken between 8:00 AM and 1:00 PM on Monday, Wednesday, and Thursday. Calling during these hours assures the most prompt response to your request.

- Please call in your refill at least 3 days prior to your last dose of medication. Do not wait until the day your medications run out.
- Some prescriptions cannot be refilled by phone or mail. Your prescription for _____ requires a new written prescription which may be picked up at this clinic.

7. Please keep your medications in a secure place, and do not sell, trade, or give away your medication. If your medication is damaged, stolen, or lost, please discuss the problem with your doctor at once.
8. At each clinic visit you and your doctor decide on the medication, dose and schedule to be followed to relieve your pain. If you need to change this plan, contact your physician at once.
9. Do not stop taking your pain medication. Contact your doctor first.
10. Please do not seek pain medication from any other doctor. Let us know if at any time another doctor prescribes pain medication for you.

*From McCaffery M, Pasero C: Pain: clinical manual. St. Louis, Mosby, 1999.
May be duplicated for use in clinical practice.

Box 2. Example of possible written agreement for use of opioid via IV PCA to treat acute pain in the addicted patient. Although popular, use of such agreements is not necessarily recommended. See text for discussion. Adapted from suggested made by Peggy Compton and Chris Pasero.

Patient-controlled Analgesia (PCA) for Acute Pain

Goals of treatment:

1. To achieve my pain rating and activity goals: _____
Example: 2/10 to turn, cough, and deep breathe.
2. To relieve my pain without causing sedation.
3. To keep me from experiencing withdrawal symptoms.
4. Other: _____

Patient and staff responsibilities:

1. I will use the pain rating scale to report pain to the staff.
2. The staff will accept and respect my reports of pain as the best indicator of how much pain I have.
3. The staff will be responsible for providing as much analgesia as necessary to relieve my pain, unless it would endanger my health.
4. I will not tamper in any way with the PCA pump.
5. I will not take any unordered medication.
6. I will not allow visitors to bring illicit drugs or alcohol into the hospital setting.

7. The staff will gradually taper the infusion before it is stopped. They will consider my pain ratings and my progress toward recovery to determine when and by how much to reduce doses and to provide other means of pain relief, if necessary.

We mutually agree to the above.

Signature of patient

Date: _____

Signature of clinician

Date: _____

Box 3. Example of possible written agreement for use of oral opioids for outpatient treatment of pain in the addicted patient. Although popular, use of such agreements is not necessarily recommended. See text for discussion. Adapted from suggestions made by Peggy Compton and Chris Pasero.

Outpatient Opioid Analgesia

Goals of treatment:

1. To achieve my pain rating and activity goals: _____
2. Example: 3/10 to return to work.
3. To relieve my pain without causing sedation.
4. To keep me from experiencing withdrawal symptoms.
5. Other: _____

Patient and staff responsibilities:

1. I will use the pain rating scale to report pain to the staff.
2. The staff will accept and respect my reports of pain as the best indicator of how much pain I have.
3. The staff will be responsible for providing as much analgesia as necessary to relieve my pain, unless it would endanger my health.
4. I will receive my analgesics from a single provider only, Dr. _____. I will not seek medication from a dentist or the emergency room without this doctor's knowledge.
5. I will not sell, trade, or give my pain medication to others.
6. I will not engage in illegal activities to obtain pain medication.
7. I will be responsible for keeping my medication out of the reach of children, pets, and others and for not misplacing or losing it.
8. I understand that taking my medication when using alcohol or other drugs could be extremely dangerous to my health.

9. I understand that my doctor has supplied me with _____ "rescue doses" per day of medication to take if my pain increases. I will inform my doctor as soon as possible if I need to take more rescue doses than this, and I will come in for re-evaluation as instructed.

10. If I have difficulty with the above responsibilities or if other problems occur, I understand that I may need to attend clinic more frequently to pick up prescriptions that cover a shorter period of time.

We mutually agree to the above.

Signature of patient
Date: _____

Signature of clinician
Date: _____