

Special Article

The Opioid Contract in the Management of Chronic Pain

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Abstract

Although the "opioid contract" is widely used in the administration of chronic opioid therapy, its use has not been well defined and there are few guidelines for developing or revising such tools. We reviewed opioid contracts from 39 major academic pain centers and analyzed every statement for its core meaning. These statements were grouped into general categories and then into specific statement groups. Substantial diversity in the content of the 39 contracts was found. Statements could be grouped into 12 general categories, 43 statement groups, and 125 individual statements. Each of the 39 contracts reviewed contained 22.5% ± 10.9% of the entire list of 125 statements and 32.6% ± 11.2% of the 43 statement categories. Contract length averaged less than 3 pages (range: 1 to 1 mean 2.2). We describe frequent and infrequent themes that may be well suited for inclusion in any given contract. While there are many significant issues related to the usage of a formal contract in chronic opioid therapy, there was substantial consistency among the contracts in their universal attempts to improve care through dissemination of information, facilitate a mutually agreed-upon course, or enhance compliance. This study serves as an initial step in considering the risks and benefits of an opioid contract as well as its ideal content and presentation. J Pain Symptom Manage 1999;18:27-37. © U.S. Cancer Pain Relief Committee, 1999.

Key Words

Opioids, contract, chronic opioid therapy

Introduction

Contracts are widely used in the chronic administration of potentially abusable substances or management of lethal behaviors. However, the efficacy of contractual agreements between physician and patient is not well established.

Many academic pain management centers use an "opioid contract" as part of their standard practice. While contracts are used in many areas of patient care, they are best described in managing patients with suicidal ideation¹⁻³ or character pathology.⁴ Burchman and Pagel have effectively described their experience with using an opioid contract in a pain management center.⁵ However, to our knowledge, there is, at present, no standard or validated contract, particularly as it relates to chronic opioid delivery. Although contracts are widely

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used in chronic opioid therapy, there are few guidelines for developing or revising such tools.

A contract is defined as “an explicit bilateral commitment to a well-defined course of action.”⁶ In the physician–patient contract, this definition implies several basic assumptions, as described by Quill:⁷ (1) The terms and consequences for breaching the contract are explicitly stated; (2) the doctor and patient have unique responsibilities; (3) the doctor/patient relationship is consensual, not obligatory and; (4) both physician and patient are willing and able to negotiate. Responsible parties in the contract usually have a clearly stated understanding of their individual obligations. The typical opioid contract includes clear descriptions and expectations of medication use and abuse, as well as the consequences of violating the contract, and there is a procedure for opioid discontinuation should this become necessary. Other specific topics, such as educational or administrative issues, and terms for routine, random substance testing as part of the treatment plan, also may be explicitly stated.

The contract is ideally intended to enhance the therapeutic relationship by initiating and supporting an alliance between the patient and the physician. It may enable a patient to have an active role in treatment, establish participation, and possibly curb the potential for rebellion against what may be perceived as an omnipotent staff.⁴ Unfortunately, it is not known exactly how effective such contracts are in mitigating noncompliance, particularly with drugs such as opioids for chronic pain. Data from observing patient–physician interactions regarding acceptance of a contract are not conclusive. Studies reviewing use of contracts for patients in methadone programs indicate that improved compliance is transient, with efficacy seen only early in treatment.^{8,9} Saxon et al.¹⁰ found that, when used in the setting of opioid abuse, contracts were most effective when the contract placed increased responsibility on the patient and included specific descriptions of these responsibilities. Although data on contract usage are limited, there is no direct evidence that use of contracts is significantly detrimental to treatment.

To gain wider perspective on the “opioid contract,” we reviewed opioid contracts from major academic pain centers (Table 1). We believe this represents a useful sample from

which common themes and formats can be examined. We hope this will help guide clinicians in need of developing or revising an opioid contract based on the collective practice of other centers.

Methods

Sixty sites were selected from the 1998 American Pain Society Directory of Pain Management Facilities.¹¹ These were chosen because of their university affiliation and national reputations and not by random selection. The term “contract” is used to represent all documents serving as a written agreement regarding the terms and conditions of opioid therapy. Many documents carried labels other than “contract.”

The contracts were analyzed and compared for similarities and differences. Each statement of every contract was analyzed for its core meaning and then grouped into a general category of statements and then into specific statement groups. Unique statements were assimilated into 12 general categories, 43 statement groups, and 125 individual statements. The 12 general categories included: education about treatment, goals of treatment, terms of treatment, issues around possible termination of treatment, exclusions for receiving opioids, possible outside involvement of other clinicians or agencies, patient responsibilities, clinician responsibilities, prohibited behaviors, discouraged behaviors, legal issues, emergency procedures, and specifics about the nature of the contract (Table 2). We also examined who was required to sign the contract, what the contract was labeled (contract vs. agreement, etc.), and page length. Data are reported as percentages or as mean and standard deviation (SD).

Results

Sixty centers were contacted, 55 responded (92%), and 39 provided contracts for review (65%). Of the 16 centers that responded but did not provide contracts, 3 (5%) refused to contribute their contract for unknown reasons, 1 (2%) stated that their contract was not available, and 12 (20%) did not have or use a contract in their program. Collectively, the 39 reviewed contracts resulted in 125 unique statements and 43 statement groups. The 43 statement groups are listed in Table 3, includ-

Table 1
Academic Centers That Submitted Contracts for Analysis

1. Allegheny University Hospitals
2. Baystate Medical Center
3. Beth Israel Deaconess Medical Center, Pain Management Center
4. Brigham and Women's Hospital, Pain Management Center
5. City of Hope National Medical Center
6. The Cleveland Clinic Foundation
7. Columbia Presbyterian Medical Center, Pain Management Center
8. Dartmouth Hitchcock Medical Center, Pain Management Center
9. Georgetown University Medical Center, Pain Management Center
10. Henry Ford Hospital, Pain Management Center
11. Hospital of the University of Pennsylvania, Anesthesia Pain Management Center
12. Johns Hopkins Anesthesiology and Critical Care Medicine, Division of Pain Medicine
13. Massachusetts General Hospital, Pain Center
14. Medical University of South Carolina, University Medical Associates
15. Mayo Clinic Jacksonville, Pain Clinic
16. New England Medical Center, Pain Management Program
17. Oregon Health Sciences University, Pain Management Center
18. Pacific Pain Treatment Center
19. The Rush Pain Center
20. Stanford Health Services, Pain Management Center
21. Stony Brook University Hospital, Comprehensive Pain and Rehabilitation Center
22. Thomas Jefferson University Hospital, Pain Center
23. University of California Davis Medical Center
24. University of California San Diego, Pain Management Medical Group
25. University of California San Francisco Mount Zion Medical Center, Pain Management Center
26. The University of Texas–Houston Health Science Center, University Center for Pain Medicine and Rehabilitation at Herman
27. University of Colorado Health Sciences Center, Pain Management Center
28. University Hospitals Cleveland, Anesthesia Pain Service
29. University of Kentucky Chandler Medical Center, The Pain Management Center
30. University of Maryland at Baltimore, Pain Center
31. University of Massachusetts Medical Center, Pain Control Center
32. University of New Mexico, Pain Management Center
33. University of Pittsburgh Medical Center, Pain Evaluation and Treatment Institute
34. University of Wisconsin Hospital and Clinics (for patients with substance abuse history)
35. University of Wisconsin Hospital and Clinics (for patients without substance abuse history)
36. University of Utah, Pain Management Center
37. Vanderbilt University Medical Center, Pain Center
38. Wake Forest University Medical Center, Pain Control Center
39. Yale University School of Medicine, Center for Pain Management

ing the percentage of contracts using each statement group. Of the 39 contracts reviewed, each contained approximately $22.5\% \pm 10.9\%$ of the entire list of 125 statements and $32.6 \pm 11.2\%$ percent of the 43 statement categories.

Length of contracts averaged less than 3 pages (range: 1 to 10, mean 2.2). There was substantial diversity among the content of the 39 contracts. For instance, one required patients receiving chronic opioid therapy to abstain from driving an automobile while another stated that a private detective might be used to monitor abuse. Several cited pregnancy as a contraindication (18%). Most documents were titled “contract” or “contract/agreement” (62%), and a large minority had the label “consent” (31%). A few documents were labeled either “agreement/consent” (3%) or “guideline” (5%). Pa-

tients were required to sign the contract in 95% of cases whereas staff signature was required in 62% of cases.

The 12 general classes of statements distributed into 3 distinct groups (Table 2): those found in greater than 90% of contracts (*Most Common*), those found in 70–85% of contracts (*Moderately Common*), and those found in less than 40% of contracts (*Least Common*). The *Most Common* general categories (found in >90% of reviewed) dealt with terms of treatment including prohibited behaviors and the potential termination process (Table 2). Prevalent commentary related to opioid abuse, potential problems with handling, modulating or replacing opioids, or rules for interacting with the clinic and caregivers. Other significant points were less frequently cited, such as the

Table 2
General Statement Categories

Category	# of Contracts including category	Percent including category
Most common categories (>90% of contracts)		
1. Terms of treatment	38	97%
2. Prohibited behavior	37	95%
3. Points of termination	36	92%
Moderately common categories (70–85% of contracts)		
4. Patient responsibilities	33	85%
5. Education	31	79%
6. Additional treatment	29	74%
Least common categories (<70% of contracts)		
7. Emergency issues	15	38%
8. Goals	15	38%
9. Limitations on prescriptions	15	38%
10. Legal considerations	13	33%
11. Discouraged behavior	12	31%
12. Staff responsibilities	7	18%

need for a single dispensing pharmacy, and strict compliance with prescribed dosing and breakthrough dosing. Additional common themes included patient responsibilities (such as reporting adverse reactions); education about the intent, nature, and risks of the treatment; and involvement of outside treaters or agencies, such as the primary care physician. Frequently, there was language requiring the patient to agree to numerous tenets of treatment such as informing the opioid prescriber of relevant information, willingness to submit to random drug screens, adherence to medication changes or tapering schedules, and others.

Educational content was also common. These themes most frequently related to risks and benefits of treatment, including the purpose of opioid therapy, appropriate treatment end points (such as function), and addiction.

Within the 3 general categories, the most common statement groups related to improper use of controlled substances (95%). The concerns expressed in this category mostly focused on issues related to addiction and diversion of controlled substances, as well as safety. In fact, the single most frequently cited statement of the 125 unique statements indicated that controlled substances could not be sought outside of the designated prescriber (92% of all contracts).

The next most common statement groups dealt with mandatory termination and ensuring that patients did not seek opioids outside of the pain center (92% each). Most of the ter-

mination criteria were based on noncompliance, inappropriate behavior, and global violations of the contract. Another common concern addressed expectations about changes in therapy. Most contracts (85%) included terms related to how and when medication changes could be made. Terms regarding limitations on scheduled appointments and prescriptions were found in 62% and 56% of the contracts respectively.

Other important issues were not as frequent, such as requiring that medication be obtained from a single opioid dispensing pharmacy (44%), and defining limitations on dosing (i.e., that patients demonstrate strict compliance with prescribed dosing (31%). More than half the contracts commented on informing or involving additional health care providers (59%). Only a minority of reviewed contracts indicated that the patient's primary care physician be informed of the chronic opioid therapy. Also, few contracts suggested the patient might be referred back to their primary care physician for continued opioid prescriptions once stabilized (13%). Very few contracts required the patient to have a primary care physician during opioid treatment or offered guidelines for obtaining a primary care physician (5%).

The *Moderately Common* general categories included statements found in 70–85% of the contracts. These statement groups related to patient responsibilities, education about the intent, nature, and risks associated with treatment, as well as involvement of outside treaters

Table 3
**Specific Statement Groups in Order of Frequency:
 Subgroups of the General Statement Categories**

Rank	Statement category	# of Contracts	Percent
1.	Avoid improper use of controlled substances (includes overdosing, seeking medication elsewhere, selling medication, stopping medication abruptly).	37	95%
2.	Terms for disciplinary termination (abusing medication, missed appointments, violating contract, inappropriate behavior).	36	92%
3.	Limitations for replacing medication or changing prescriptions.	33	85%
4.	Inform physician of relevant information (i.e., side effects, medications, changes in condition).	29	74%
5.	Submit to random drug screens.	27	69%
6.	Terms regarding appointments (missed appointment, follow-up, appearing without appointment).	24	62%
7.	Include additional health care providers involved in care (primary care physician [PCP], PT, Psychologist, etc.).	23	59%
8.	Limits on drug refills (phone allowances, only in person, call in advance, normal office hours).	22	56%
9.	Side effects education (including withdrawal).	22	56%
10.	Terms of nondisciplinary termination (no improvement, pregnancy, tolerance, toxicity, etc.).	20	51%
11.	Education on addiction risks and behaviors.	19	49%
12.	Education on opioids and chronic pain.	19	49%
13.	Health care providers informed of prescription (may include PCP, pharmacist, etc.).	18	46%
14.	Pharmacy issues included (one pharmacy, in-state pharmacy).	17	44%
15.	Goals (outlines goals).	15	38%
16.	Additional risks discussed (other drugs, masking conditions, misusing, pregnancy).	15	38%
17.	Necessity of contract discussed (reasons why necessary including federal guidelines and abuse).	14	36%
18.	Legal considerations discussed.	13	33%
19.	Single prescriber for all opioid prescriptions.	13	33%
20.	Dosing limitation (how much, interval rx made, rescue dosing, prn, dose escalation).	12	31%
21.	Disclaimer for emergency situations (i.e., makes exceptions).	12	31%
22.	Operation of motor vehicle, heavy machinery, or firearms discouraged.	12	31%
23.	Substance abuse exclusion (current or history, including selling drugs).	12	31%
24.	Terms regarding specific medication (type prescribed: long-acting, generic brands, etc.).	11	28%
25.	Outlines time course/Trial period.	9	23%
26.	Agrees to medications changes and tapers.	8	21%
27.	Contract issues (includes who receives contract, where contract is kept, and how opioids are maintained/violations).	7	18%
28.	Pregnancy is exclusionary.	7	18%
29.	Alcohol use discouraged.	6	15%
30.	Alcohol use prohibited.	6	15%
31.	Agrees to take responsibility for medications (e.g., safeguard medication).	5	13%
32.	Family involved in care.	4	10%
33.	Leftover medication brought to clinic.	4	10%
34.	Physician will offer detoxification if necessary.	4	10%
35.	Agrees to maintain good health.	2	5%
36.	Benefits of long term opioids discussed.	2	5%
37.	Patient will inform ER physician of contract.	2	5%
38.	Prohibits operation of motor vehicle, heavy machinery, or firearms.	2	5%
39.	States opioid therapy is dual responsibility of doctor and patient.	2	5%
40.	Employer may be informed of prescription.	1	3%
41.	Patient will not receive opioids in emergency room.	1	3%
42.	Physician must also agree to a contract.	1	3%
43.	Physician provides treatment information	1	3%

or agencies including the primary care physician. There were few comments regarding legal considerations, or specifics around how the contract is maintained. Specific details of the *Moderately Common* and *Least Common* statement groups are presented in Table 2.

Discussion

This analysis focused on the use of opioid contracts from 39 academic pain management centers. The results suggest there are multiple contract issues related to chronic opioid therapy, as reflected in substantial variability

among these 39 sample contracts. However, the purpose of the opioid contract appears to be fairly consistent. All contracts appeared to be attempting to improve care through dissemination of information, facilitate a mutually agreed upon course, or enhance compliance.

Taken together, we found the contracts serve to document information in as many as 3 main areas. These are documentation of a) the description of treatment parameters and established procedures should problems arise, b) agreement that the plan is bilaterally embraced, and c) informed consent. All of the 125 unique statements mentioned in the contracts tended to fall under one of these 3 broad categories. The term "contract" was used in this study to represent all of the documents reviewed. However, while most documents were labeled "contract" or "contract-agreement," many did not have the word "contract" associated with it. Some were labeled either "agreement" or "consent." Perhaps using terms other than "contract" attempts to avoid legal connotations or the implication of a polarized bilateral treaty. These findings as well as use of the term "agreement" instead of "contract" are consistent with the report of Burchman and Pagel.⁵ Novel to this report was the use of a Medical Alert card identifying the patient who signed the "agreement" as a participant in their program.⁵

This review is not able to answer several important questions, including whether or not contracts are efficacious, how they are best used, whether or not they are binding, and whether they may place clinicians at greater risk of liability and subject patients reduced autonomy. According to Quill's 4 essential features of a contract,⁷ the majority of contracts reviewed here consistently meet only the standard of explicitly stating the terms and consequences of breaching the contract. Perhaps it is implied that patient and physician have unique responsibilities, although only a few contracts are clear about this. The great majority of reviewed contracts had minimal content regarding specific responsibilities of the treating clinicians. It is not clear whether these contracts, in and of themselves, reflect adequate consent for treatment. We were not privy to the process by which individual contracts are presented, and cannot assess the ability of each party to negotiate the contract. However, very few of the reviewed contracts suggest patients

have any role in determining their terms. Many are sufficiently vague as to potentially allow for substantial negotiation during or after signing of the contract and starting treatment.

Clinicians wishing to develop or revise an opioid contract may find core themes that are of value. Contracts largely dealt with explicit expectations and issues that have the potential to become points of contention later in treatment. Of the 10 most common statement groups (Table 3), 6 were found in greater than 90% of the reviewed contracts (*Most Common Group*) and the remaining 4 were found in 70%–85% of reviewed contracts (*Moderately Common Group*). This collective homology suggests there may be a core group of statements that are relevant to most opioid contracts. However, the lower frequency of other statements does not imply less importance. These themes may have been overlooked, underappreciated, or of great significance to less than the majority of opioid therapy programs.

Page length was variable, ranging from 1 to 10 pages. This may reflect differing goals between producing a document that briefly offers terms of an agreement and providing exhaustive education and documentation. Most contracts did not attempt to be overly inclusive, averaging less than 3 pages (mean = 2.2), perhaps reflecting the impossible task of capturing every issue for every patient. Some contracts were written in two parts, an educational section followed by the rules. Obviously, longer contracts are more labor-intensive for patients and clinicians.

The contracts we reviewed have variable tones to their presentation. Some are more cooperative and less paternalistic. These typically elaborate on why the contract is necessary, and offer broad, less detailed, nonconfrontational guidelines. Others are more "paternalistic," with authoritative language and more detailed guidelines. These tend to outline specific ramifications for breaking the contract, are generally longer, and usually contain less educational information.

Each of these contract types has possible advantages. Those with more cooperative tones may enable patients to feel they are taking a more active role in their health care, which, according to Stanford et al.,² may increase compliance. On the other hand, less explicit terms of the contract might decrease compliance, as

the patient is not given clear guidelines. Paternalistic contracts tended to have very clear and precise guidelines which encourage clear understanding of expectations.¹⁰ However, these may tend to stigmatize opioid use, and may give the impression that the patient is doing something “bad” by taking opioids, thereby supporting the interpretation of the contract as punishment or the treatment as intrinsically problematic.⁴ Several contracts included provocative statements such as “the pain clinic reserves the right to subcontract a private investigator for the purpose of surveillance of those patients suspected of substance abuse.” While these may imply the seriousness of the contract, it remains unclear whether such strong statements foster secure parameters of care or produce fear of consequences that potentially can stigmatize treatment and advance feelings of being punished.

Patient–physician contracts may pose some potential complications. In particular, contracts have the potential to perpetuate stigma of patients with histories of substance abuse.¹² A serious potential problem with contracts is inaccurate reassurance that the patient is compliant, perhaps allowing the physician to relax vigilance. Additionally, if the contract is not carefully constructed, effectively presented, collaborated on by all health care providers and the patient, and followed through with consistent and rational responses, it may be perceived by the patient as punishment or manipulation.⁴ Presumably, the patient usually has little to no input as to the content of the contract.

Diagnostic interpretation of behavior at the time of initiation of the contract is of unproven value. Some believe that a patient who reacts to the prospect of signing a contract with apprehension may tend toward noncompliance, whereas a patient who is agreeable to the contract, and plays an active role in formulating its terms, may be more likely to comply.² Such conclusions risk overinterpretation.

It is unclear whether or not opioid contracts have legal ramifications. Because the patient–physician contract is a bilateral agreement, there may be consequences should the contract be broken by the clinician. In a recent case in Massachusetts, a tort was brought against a physician for being lenient and refilling an opioid prescription despite knowing

that doing so would result in breaching the terms of the opioid contract due to known patient noncompliance. The patient subsequently had an opioid-related overdose and the physician was found liable.

Some of the statements related to prohibited behaviors did not appear to have clear justification. Two such issues of great significance include driving while using opioids and opioid use while pregnant. Thus, we have addressed each of these in greater detail below.

Driving while taking opioids is vaguely and inconsistently dealt with in the contracts we reviewed. Only 14 of the 39 contracts (36%) include statements warning patients about the potential dangers of driving a motor vehicle while taking opioids. Two of these contracts (5%) prohibit driving altogether. Unfortunately, review of the literature does not offer definitive conclusions about driving safety while using prescribed chronic dosages of opioids. Because driving is often associated with freedom and autonomy, prohibiting driving can be an important consideration in opioid therapy, particularly given that the goal of chronic opioid therapy is usually to increase function and quality of life. If chronic opioid use is a real safety hazard, patients must be prohibited from driving. However, if there is not increased risk, forbidding patients from driving imposes unnecessary limitation on freedom. Some physicians believe opioids alter the mental state so profoundly that their use contraindicates driving.¹³ However, such beliefs are not based on clear empirical evidence, as most studies have not supported this.^{14–18}

In studies of driving safety and opioid use, it is essential to distinguish between illicit and prescription opioid use. The effects of illicit drug use may inaccurately reflect that of licit drug use on driving because the effects of prescribed chronic opioids in pain patients may differ significantly from those in drug abusers.^{19–21} The effects of opioids and driving have been investigated both by analyzing accident records and by performing laboratory tests that ask subjects to perform tasks that mimic driving skills or driving situations.^{22–25} Some studies found that drivers taking prescribed opioids were involved in fewer automobile accidents than those taking either benzodiazepines^{14,15} or tricyclic antidepressants.¹⁴ Laboratory studies are even less clear than those from accident

records. While some studies suggest opioid use may impair driving skills,²⁶⁻²⁸ others found that opioids, when taken in the laboratory setting, have little negative impact on psychomotor and cognitive skills,¹⁶⁻¹⁸ and one study suggests that adequate pain control with opioids may enhance cognitive function.²⁹ Several laboratory studies found that while initially opioids negatively impacted cognitive and psychomotor skills, the effects wore off within a few hours.^{18,30-32} For patients taking chronic opioids, adverse cognitive and psychomotor effects may subside over short periods of time. O'Neill³³ found patients on stable doses of opioids had no evidence of cognitive impairment, unlike those who recently had a dosage increase. These investigators suggest that patients should abstain from driving for approximately 7 days following opioid implementation or dose increase. This study is consistent with the findings of Bruera et al.,³⁴ who report that most patients experience some sedation at initiation of opioids which subsides after 1 to 2 weeks.

We know of no law prohibiting driving while on prescribed opioids. In Massachusetts, it is the formal policy of the Medical Division of the Registry of Motor Vehicles to discourage patients who are taking prescription opioids from driving. It is unclear whether state or federal agencies that may take issue with patients who drive while using opioids have fully considered the potentially significant difference between acute and chronic opioid use. Considering the current knowledge of both the laboratory studies and accident reports, cautious practice for patients taking chronic opioids might suggest precluding driving for one to several weeks after opioid initiation or dose escalation. It also seems reasonable to suggest to patients that, as with any potentially sedating drug such as alcohol, it is their personal responsibility to monitor themselves and make judgments on a moment-by-moment basis about their capacity to safely operate a motor vehicle.

Pregnancy and chronic opioid therapy was mentioned in 14 (36%) of the 39 contracts reviewed. Of these, half (7 of 14) explicitly stated that pregnancy was an exclusionary criterion for receiving opioids. Because nearly one-fifth of the reviewed contracts deny expectant mothers opioid medication, we further reviewed the literature on the effects of opioids

on the fetus and found it to be less than complete. Most studies have looked only at the effects of illicit drug abuse.³⁵⁻⁴⁵ However, some have looked at the effects of opioids on pregnancy in methadone maintenance programs⁴⁶⁻⁴⁸ or compared the effects on the fetus between illicit opioids and prescribed methadone use in a maintenance program.^{49,50} We found only one case report on the effect of opioids on the fetus which were prescribed for pain.⁵¹

The literature is conflicted about long-term consequences from prenatal opioid exposure. Illicit opioid use, compared to prescribed drug use and methadone, appears to pose the greatest potential danger to the fetus. Short-term effects on the fetus include withdrawal,^{35,36,52} low birth weight,^{36,37,41} reduced head circumference,^{41,44} and death.^{35,47} However, most studies of illicit opioids indicate that children born to opioid-addicted mothers catch up to their peers, both physically and cognitively, within the early years of life,^{41,52} and do not have higher mortality rates.⁴⁴ Children born to mothers on methadone maintenance had less frequent signs of withdrawal,⁵⁰ longer gestation periods,⁴¹ larger head circumference, and better respiratory status⁴¹ than those born to drug-abusing mothers. One study found that other than withdrawal symptoms, there was no difference between children born to mothers supervised on methadone programs than to those born to non-drug-using mothers.⁴⁹ We found only one case report discussing the effects of chronic opioid therapy on the fetus. The birth was normal without complications to the mother or fetus, and adequate pain control was achieved.⁵¹

Several confounding factors may play an important role in assessing the effects of opioids on the fetus. Generally, the only studies that found opioids to have a detrimental effect on the fetus were those where the mother was a drug abuser. Drug abuse often correlates with impoverished environment and poor prenatal care, perhaps relating more to adverse effects than opioid exposure.^{38,39} Additionally, drug abusers may also abuse other substances, thus confounding the issue of which particular agent produces the adverse effects on the fetus.⁴⁰

Because the effects of chronic pain on pregnancy are not known (e.g., stress response), and there is insufficient evidence of detrimen-

tal effects from prescribed chronic opioid therapy, it would seem that strict contraindication of chronic opioid therapy in pregnancy is not warranted. Such determinations are likely to be made on an individual basis. The opioid contract may assist the prescriber by indicating concerns about pregnancy and opioids and forming an agreement for immediate notification should pregnancy occur or be anticipated.

Conclusions

Although its use is widespread, efficacy of the opioid contract has not been proven. The contract may be an appealing tool for clarifying terms, addressing potential pitfalls, acquiring informed consent, and helping to establish a therapeutic relationship. Its efficacy in improving compliance, enhancing the treatment process, or protecting the rights of patients or clinicians is far from certain. While the contract seems to be of intuitive utility as an educational document that clearly articulates rationale and expectations of treatment, the large amount of information required for producing an exhaustive document dictates choosing only the most important and/or relevant points. We have described many frequent and infrequent themes that may be well suited to inclusion in any given individual contract. Whether it is best to have more or less authoritarian or restrictive tone, or greater or lesser detail, will require further investigation. It seems clear, however, that the opioid contract may not be entirely benign for either patient or clinician. Thus, if we are to continue to use this tool, we must carefully consider our purpose and methods.

This analysis should be viewed as an initial step in considering the content and presentation of an opioid contract. Developers of individual contracts may wish to consider both the most frequent themes used in the collective sample presented here, as well as the less frequent inclusions which may have particular relevance or significance for certain practices. We must be careful in applying restrictions on patients without clear evidence to support such restraints. Legal considerations may bear on the limits of contractual agreements between patient and physician. Exactly how binding the contract is on any aspect of clinical care remains unclear. However, clinicians should take care to follow their own guidelines or expose

themselves to potential liability. Future advances in this area will require validation of the contract as efficacious, and clarification of which parts are most useful, how to best use the contract once invoked, and particular strategies for managing contractual enforcement and difficult outcomes.

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