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Monitoring outcomes during long-term opioid therapy for noncancer pain: Results with the Pain Assessment and Documentation Tool

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ABSTRACT

The increasingly common practice of long-term opioid therapy for chronic noncancer pain must be guided by ongoing assessment of four types of outcomes: pain relief, function, side effects, and drug-related behaviors. Our objective was to gather initial pilot data on the clinical application of a specialized chart note, the Pain Assessment and Documentation Tool (PADT), which was developed and tested with 27 physicians. This pilot test provided the means to collect cross-sectional outcome data on a large sample of opioid-treated chronic pain patients. Each of the physician volunteers (located in a variety of settings across the United States) completed the PADT for a convenience sample of personally treated chronic pain patients who had received at least three months of opioid therapy. Completion of the PADT required a clinical interview, review of the medical chart, and direct clinical observation. Data from the PADTs were collated and analyzed. The results suggested that the majority of patients with chronic pain achieve relatively positive outcomes in the eyes of their prescribing physicians in all four relevant domains with opioid therapy. Analgesia was modest but meaningful, functionality was generally stabilized or improved, and side effects were tolerable. Potentially aberrant behaviors were common but viewed as an indicator of a problem (i.e., addiction or diversion) in only approximately 10 percent of cases. Using the PADT, physician ratings can be developed in four domains. In this sample, outcomes suggested that opioid therapy provided meaningful analgesia.

Key words: opioids, noncancer pain, assessment, documentation, outcomes

INTRODUCTION

The use of opioid analgesics is a cornerstone of pain management. Although still controversial, chronic opioid therapy for noncancer pain is becoming a more widely accepted therapeutic option.[1-5] A large gap exists between the empirical literature on the safety and efficacy of long-term chronic opioid therapy and the expanding use of this approach in clinical practice.

To use opioids safely and effectively, candidates for therapy should be appropriately selected, drug administration should be optimized, and ongoing monitoring should provide detailed information in multiple domains. Based on extensive clinical experience, four domains have been proposed as most relevant: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors.[6] These domains have been summarized as the "Four As" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors).[7] The monitoring of these outcomes over time should inform therapeutic decision-makers and provide a framework for documentation of the clinical use of these controlled drugs.

Suboptimal physician monitoring and documentation during opioid therapy is a significant problem[8] and may have adverse clinical, medicolegal, and regulatory implications.[9] In an effort to improve the approach to monitoring and simultaneously provide a standardized chart note for the purposes of documentation, a brief, physician-rated Pain Assessment and Documentation Tool (PADT)

was developed and successfully field tested.[10] The PADT was developed from a series of questions and checklists that together assessed each of the Four As.

PADT items that evaluated pain relief and function were modeled on the Brief Pain Inventory,[11] a validated patient-rated instrument. Side effects were tabulated. A list of potentially aberrant drug-related behaviors was developed from descriptions in the medical literature[3] and clinical experience. The list included drug-related behaviors that are illegal (e.g., altering of prescriptions, lying to obtain a controlled substance, drug diversion), those that strongly suggest addiction (e.g., continued use despite harm), and those that raise concern about drug abuse or addiction but are not, in themselves, diagnostic (e.g., multiple requests for higher doses, repeated visits to an emergency room).

The process by which the PADT was developed and refined, using application of the tool clinically by physicians, has been described previously.[10] The pilot clinical application itself yielded outcomes data on a large and diverse patient sample. These data, described later, reflect the perceptions of treating physicians pertaining to a broad set of outcomes achieved by a selected population of opioid-treated chronic pain patients. As such, they represent a type of survey data that has not heretofore been explored as a means to define the spectrum of responses observed in clinical practice. Our objective was to gather initial pilot data on the clinical application of a specialized chart note, the PADT, which could then be used in the design of future validation and reliability trials.

METHODS

Procedure

Twenty-seven physicians attending a training program for a pain-oriented speakers' bureau were recruited to participate in the pilot study. The physicians practiced in all regions of the continental United States and spent at least part of their clinical practice time caring for patients with chronic noncancer pain. They were chosen for their collective expertise in pain management and their ready access to patients with chronic pain issues being maintained on opioid therapy. Although this is a potential source of bias, it was felt that having physicians with interest and expertise in pain administer the PADT was important for gathering initial data on the tool.

The physicians were given the checklists that together constituted the first draft of the PADT and were asked to identify patients from their practices who had been receiving opioid therapy for a period of at least three months. They were then instructed to obtain the information necessary to complete the PADT from a clinical interview, review of the medical chart, and direct clinical observation.

A total of 388 patients with a diverse assortment of pain syndromes and a wide variety of opioid and adjuvant medications were interviewed for the study. As stated previously, all patients with chronic noncancer pain were eligible to be selected as long as they had been on opioids for a period of three months or longer. This selection criterion was chosen in the hopes of obtaining a patient sample that was not new to the various physicians so they could render judgments based on some established relationship. In addition, it was hoped that this time period would also maximize the chance that any "dose-finding" for opioids would be well underway or stable in those who were selected. After the checklists were completed by the physician, the forms underwent removal of identifying information and were sent to the lead investigator for analysis.

Study instrument

The PADT was developed by the investigators with input from a group of experts in pain and addiction medicine.[10] The tool has four sections: physician demographics, patient demographics, assessment of the Four As, and the physician's diagnostic impression of the patient. The physician demographics section includes information such as age, mode of practice, practice location, and the number of prescriptions written for opioids in the last month. The patient demographics section includes gender, ethnicity, employment status, pain diagnosis, and medical history.

The section on the Four As requires the physician to rate the effectiveness of the analgesic regimen, the presence of side effects and their severity, the current impact of the pain on function, and the presence of any aberrant drug-taking behaviors. The last section, physician impression, asks the physician to note whether aberrant drug-related behaviors, if present, most likely owed to addiction, unrelieved pain, criminal intent (diversion), or nonaddiction-related psychiatric disturbance (e.g., depression, anxiety, personality disorder).

Analysis plan

The goal of the study was to characterize the impressions of physicians who were treating patients on chronic opioid regimens according to the PADT. To this end, the data analysis plan was to collate and describe the participating physicians and the patients they interviewed. A series of descriptive analyses was conducted, including frequency and mean calculations. Overall, the objective was to simply tally and report the findings from the clinical application of the PADT. However, we were also interested in some exploratory areas that might lead to future research questions. Exploratory analyses were conducted on how each of the Four As related to each

other and to demographic information through a series of Pearson correlations and t-tests. To accomplish this, global scores for each of the Four As were created by summing the items from each section of the instrument. As a final analysis, a series of one-way analysis of variance (ANOVA) tests was conducted to determine whether or not the opioid regimen chosen for the patient had an effect on any of the Four As.

RESULTS

Physician data

A total of 27 physicians volunteered to participate in the trial. Physicians interviewed an average of 14.4 patients, for a total sample of 388 patients (described later). The majority of physicians were in the 41- to 50-year-old range (n = 15, 55.6 percent), followed by those in the 51- to 60-year-old range (n = 6, 22.2 percent), and then the 30- to 40-year-old range (n = 5, 18.5 percent). Specific ages were not requested to avoid potential identification of the physicians, given the small physician participant pool. Most were male (n = 21, 77.8 percent), and all were board certified (n = 27, 100 percent) in their specialty areas. The most common mode of practice was family practice (n = 10, 45.5 percent), followed by anesthesia (n = 7, 31.8 percent), and neurology (n = 2, 9.1 percent).

Most physicians were located in an urban setting (n = 18, 69.2 percent), followed by those in suburban (n = 7, 26.9 percent) and rural settings (n = 1, 3.9 percent). Most practice settings were in an office (n = 10, 50 percent) or university hospital (n = 5, 25 percent). The physicians reported an average of 14 years in practice (SD = 10.6). Most stated that more than one-half of their patients had chronic pain (mean = 62.7 percent, SD = 36.6); overall, they treated an average of 912.6 patients per year with chronic pain (SD = 1,211.9).

The physicians reported that they managed more than one-half of their chronic pain patients with an opioid regimen (50.6 percent, SD = 31.3), and that they treated an average of 576.9 patients per year with opioids (SD = 927.2). Table 1 lists the estimated number of prescriptions for opioids that were written by the physicians during the month prior to completion of the PADT. Oxycodone-containing products (mean = 39.2, SD = 71.9), hydrocodone-containing products (mean = 31.9, SD = 37.2), and methadone (mean = 16.4, SD = 27.6) were the most frequently prescribed opioid analgesics.

Patient data

A total of 388 chronic pain patients were interviewed and rated by the physicians. The sample was comprised of 233 women (63.7 percent) and 133 men (36.3 percent), and had a mean age of 50.1 years (SD = 13.6, range = 21 to 87 years, median = 47.0). Most were white (n = 322, 84.1 percent), followed by African American (n = 29, 7.6 percent) and Hispanic (n = 23, 6.0 percent). Most had some college experience (n = 115, 30.5 percent), followed by those who were high school (n = 93, 24.7 percent) or college (n = 63, 16.7 percent) graduates. Many were disabled (n = 160, 41.2 percent), while others were working full-time (n = 80, 20.6 percent), or retired (n = 60, 15.5 percent). Before their pain diagnosis, most of the patients were working full-time (n = 250, 67.4 percent) or part-time (n = 32, 8.6 percent). They were most likely to be married (n = 218, 56.2 percent), followed by divorced (n = 76, 19.6 percent), single (n = 47, 12.1 percent), and widowed (n = 32, 8.3 percent). Most lived with a spouse (n = 208, 53.9 percent) and the next largest group lived alone (n = 95, 24.6 percent).

Nearly one-half of the sample (n = 178, 45.9 percent) reported only one source of chronic pain; the remainder endorsed two or more causes of pain. Somatic pain was documented for 291 patients (75 percent), followed by mixed/other sources (n = 160, 41.2 percent), neuropathic pain (n = 125, 32.2 percent), and visceral pain (n = 37, 9.5 percent). Only 17.8 percent of the sample (n = 69) stated that the pain was related to a past job, and an additional 4.4 percent (n = 17) stated that the pain was related to their current job.

Outcomes: The Four As

Analgesia. On a scale of 0 to 10 (0 = no pain, 10 = worst pain imaginable), patients rated their average pain for the prior week as 5.4 (SD = 2.2) and their worst pain during that time as 7.9 (SD = 2.1). When asked what percentage of pain had been relieved since starting treatment, the average response was 57.8 percent (SD = 24.4). More than three-fourths of the patients (n = 301, 77.6 percent) stated that they had a meaningful degree of pain relief, and 85.1 percent of the physician responses (n = 330) also indicated that they believed the degree of pain relief from the analgesic regimen was clinically meaningful.

Activities of daily living. Physicians rated aspects of functioning as "better," "same," or "worse" compared to a baseline defined as before the current opioid therapy (Table 2). Overall, physicians rated their patients' physical (n = 307, 79.1 percent), psychological (n = 250, 64.4 percent), and social functioning (n = 214, 55.2 percent) as improved since starting their current regimen.

An index of declining function was created by adding all the domains of function that were scored by the physician as declining since the opioid regimen was begun. The domains included physical functioning, mood, family relationships, social relationships, sleep pattern, occupational functioning, and overall functioning. Therefore, a range of 0 to 7 was possible for domains that had worsened. Overall, only 16.3 percent (n = 63) of the sample

Table 1. Frequency of opioids prescribed in the past month				
Item	**n**	**Mean (SD)**	**Median**	**Range**
Morphine products	27	14.50 (18.00)	8	0 – 80
Oxycodone-containing products	27	39.23 (71.85)	15	0 – 350
Fentanyl patch	27	15.54 (25.62)	5	0 – 125
Methadone	27	16.42 (27.55)	6.5	0 – 100
Hydromorphone	27	5.50 (6.49)	3.5	0 – 20
Tylenol #3	27	3.92 (3.43)	3	0 – 10
Tylenol #4	27	1.27 (2.44)	0	0 – 10
Hydrocodone-containing products	27	31.85 (37.23)	15	0 – 125
Tramadol	27	12.92 (16.02)	5	0 – 50
Levorphanol	27	0.15 (0.46)	0	0 – 2
Dihydrocodeine	27	0.08 (0.27)	0	0 – 1
Butorphanol	27	0.35 (0.69)	0	0 – 2
Pentazocine	27	0.31 (0.68)	0	0 – 2
Others	27	0 (0)	0	0

SD, standard deviation.

was rated as worsening in one or more domains of function. This was broken down as follows: one (n = 31, 8 percent), two (n = 9, 2.3 percent), and three (n = 15, 3.9 percent).

Adverse effects. The most common side effects and ratings of their severity by the patients are listed in Figure 1. A total of 132 (34 percent) patients required treatment for constipation, 23 (5.9 percent) for nausea, 14 (3.6 percent) for sedation, and seven (1.8 percent) for mental clouding. Forty-nine patients (12.6 percent) stated that side effects forced them to cut down their medications, and five (1.3 percent) stated that they had to stop taking the medications entirely. Ninety percent (n = 349) considered the side effects of the medications tolerable.

Only 32.8 percent (n = 127) of the sample rated one or more of the possible adverse side effects as moderate or severe in nature. Most reported only one (n = 97, 25 percent) or two side effects (n = 25, 6.4 percent) as being moderate or severe.

Potentially aberrant drug-related behaviors. When asked whether there was concern about a patient's responsibility in the use of the current analgesic regimen, physicians reported 71 times (18.3 percent) that they were concerned, 299 times (77.1 percent) that they were not concerned, and 13 times (3.4 percent) that they were uncertain. When asked whether the patients' families raised concerns over their use of medications, the physicians responded "yes" 53 times (13.7 percent) and "no" 330 times (85.1 percent).

In a series of related questions, physicians rated the degree to which they suspected problematic behaviors on the part of their patients. Table 3 lists the behaviors as well as the physicians' impressions. Overall, the physicians believed that their patients answered clinical questions in a completely truthful (n = 308, 79.4 percent) or somewhat truthful (n = 74, 19.1 percent) manner. In only two cases (1.0 percent) was it felt that their patients were "not at all truthful." In 46 cases (11.9 percent), physicians concluded that their patients had exhibited worrisome aberrant drug-taking behaviors, and in 40 cases (10.3 percent) they felt that the aberrant behavior was related to unrelieved pain.

Nearly one-half of the sample (n = 173, 44.6 percent) was rated as having engaged in at least one of the 29 listed aberrant drug-related behaviors. The range of aberrant behaviors was from 0 to 17, with a mean of 1.48 behaviors per patient (SD = 2.65). Most often, patients engaged in one (n = 62, 16 percent) or two (n = 36, 9.3 percent) aberrant drug-related behaviors. When examining the percentage of patients engaging in multiple behaviors, 19.3 percent of the sample engaged in three or more potentially aberrant behaviors, with 10.8 percent of the

Table 2. Results of patient interviews and physician impressions on activities of daily living (N = 388)				
	Better	**Same**	**Worse**	**Missing**
Patient interview				
Physical functioning	303 (78.09)	67 (17.27)	14 (3.61)	4 (1.03)
Mood	368 (69.07)	96 (24.74)	22 (5.67)	2 (0.52)
Family relationships	219 (56.44)	151 (38.92)	16 (4.12)	2 (0.52)
Social relationships	194 (50.0)	171 (44.07)	20 (5.15)	3 (0.77)
Sleep pattern	226 (58.25)	129 (33.25)	30 (7.73)	3 (0.77)
Occupational functioning	155 (39.95)	176 (45.36)	19 (4.90)	38 (9.79)
Overall functioning	289 (74.48)	81 (20.88)	12 (3.09)	6 (1.55)
Physician impression				
Physical functioning	307 (79.12)	64 (16.49)	13 (3.35)	4 (1.03)
Psychological functioning	250 (64.43)	112 (28.87)	22 (5.67)	4 (1.03)
Social functioning	214 (55.15)	137 (35.31)	29 (7.47)	8 (2.06)
Numbers in parentheses are percentages.				

sample having engaged in five or more of these behaviors.

Table 4 indicates the aberrant drug-related behaviors recorded by the physicians and the average number of occasions on which a behavior occurred. Because this was a cross-sectional survey, physicians noted the number of times an aberrant behavior occurred over the course of treating the given patient. Requests for frequent early renewals (n = 69) and insisting on a particular medication (n = 63) were the most common potentially aberrant behaviors. Five patients (1.3 percent) had been arrested or detained by the police, four (1.0 percent) had associates who were arrested or detained by the police, and six (1.5 percent) were victims of abuse or violence.

Exploratory analyses of the Four As

It was of interest to determine whether the Four As were correlated and how they were associated with psychological, alcohol, or drug problems or demographic variables. For purposes of determining analgesia level, the question pertaining to the percentage of pain relieved was selected for the analysis. For the remaining domains, summary scores (i.e., total score of each item in that domain) were used as global representations of outcome. Only the activities of daily living domain was significantly related to the other three. Decreased functioning as measured by activities of daily living was associated with a smaller degree of reported pain relief ($r = –0.20$, $p < 0.01$), as well as more problems with side effects from medications ($r = 0.17$, $p < 0.01$) and a greater number of aberrant drug-related behaviors being endorsed ($r = 0.10$, $p < 0.05$).

Several other relationships were significant and noteworthy. Concerning the demographic variables, gender was associated with reported pain relief ($t1, 361 = 2.09$, $p < 0.05$), with women (mean = 55.8 percent, SD = 25.5) experiencing a lesser percent of pain relief from treatment than men (mean = 61.4 percent, SD = 22.3). Younger age was also found to be significantly related to an increase in the number of aberrant drug-related behaviors recorded ($r = –0.21$, $p < 0.01$).

With regard to psychiatric issues, a past psychiatric history of any kind was associated with engaging in more aberrant drug-related behaviors ($r = –0.14$, $p < 0.01$). A final set of interesting correlations concerned the smoking status of the patients. A history of having smoked cigarettes was associated with poorer functioning in their activities of daily living ($r = –0.14$, $p < 0.01$). Current smoking activity was associated with a greater number of aberrant drug-related behaviors ($r = –0.17$, $p < 0.01$).

Exploratory statistics based on medication

Another key area of interest concerned the effect of

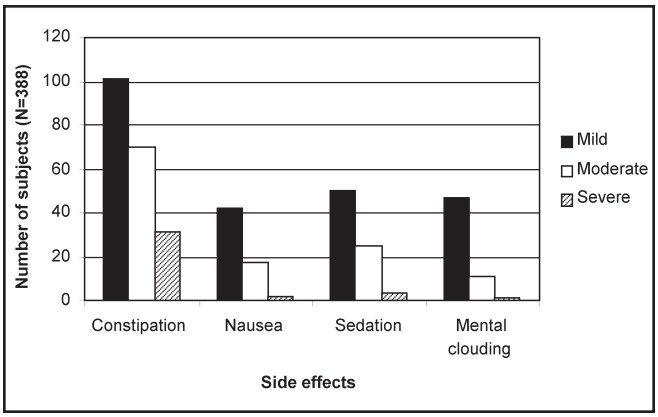

Figure 1. Side effect severity of opioid therapy (N = 388).

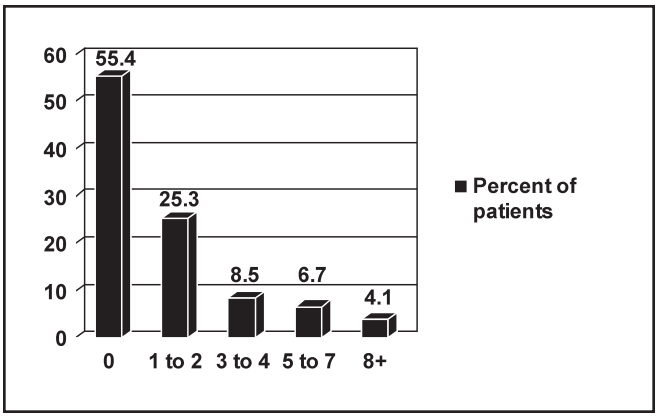

Figure 2. Total number of aberrant behaviors endorsed by each patient (N = 388).

medication choice on the Four As. Using the summary scores and analgesia items mentioned in the previous section, a series of one-way ANOVAs was conducted to compare long- and short-acting opioids. Long-acting opioids were associated with more adverse side effects than short-acting opioids ($F1, 381 = 11.86$, $p < 0.01$). There were no significant differences between these categories of opioids concerning percent pain relief, number of impairments in activities of daily living, or number of aberrant drug behaviors exhibited.

DISCUSSION

The use of opioids for noncancer pain must be accompanied by a careful and ongoing assessment of outcomes supported by documentation. In this work, we examined outcomes using a tool designed to guide this assessment and generate a comprehensive note to improve record-keeping. We attempted to put this tool into the hands of busy clinicians and examine perceptions of outcome. It is important to note that these results do not represent an epidemiological survey of outcome in chronic opioid therapy—it was neither designed (i.e., sampling) nor powered to be interpreted in this fashion.

Thus, it is important to recognize the limitations of this design to better appreciate what can be learned from such a naturalistic cross-sectional observation of pain therapy with opioids. The physicians who took part in this study were not selected at random, and all had some expertise and familiarity with chronic pain management. Indeed, chronic pain patients made up more than one-half of their respective medical practices. In addition, the patient sample was one of convenience, needing to be on an opioid regimen for a period of at least three months. In addition, the physicians interviewed the patients directly and completed all of the assessment, which could lend to a bias for under-reporting on the part of patients, especially concerning the aberrant drug-taking behaviors. Indeed, we should expect that the patients were not totally forthcoming to their physicians, although a number of aberrant behaviors were reported. Thus, the data reported in this paper are subject to multiple selection biases and may not be representative of outcome in chronic opioid therapy; in this respect, it is not terribly different from many short, often industry-sponsored, community-based studies of opioid therapy in the extant literature. However, this type of design does involve a naturalistic look at pain practice as opposed to a more contrived clinical trial and also offers some insight into how doctors perceive outcomes in their long-term opioid-treated patients.

The PADT does appear to describe outcome in a comprehensive fashion and might prove to be a useful addition to record-keeping in chronic opioid therapy. It may also aid in improving the adherence to guidelines for opioid use and the safe use of opioids for noncancer pain. However, replication studies focusing on more stringent reliability and validity data for the tool are needed. We conclude that this study is an important first step toward creating a clinically applied tool for documentation.

In describing outcomes in these patients, the PADT helps to explicate the Four As of pain outcomes. The patients described in this study overall were assessed as having moderate to severe pain while on opioid therapy. Their degree of pain relief is best described as modest, but meaningful, in that it was overwhelmingly felt to make "a real difference" in patients' lives. The actual degree of relief noted was a diminution of approximately 58 percent from baseline pain. This is an important and telling observation, one that says much about the need to set appropriate expectations for opioid therapy. With most patients attaining this level of pain relief, a figure which compares favorably with those previously reported in the literature,[12,13] it is clear that the average patient will have significant residual pain with which to cope. Patients should be informed of this when first going into treatment, thus helping them to see they will likely require lifestyle changes, fitness enhancement, coping strategy acquisition, etc. to realize a satisfying outcome. Patients who have the capacity to improve in their function with

Table 3. Physician-reported impressions of behaviors			
Behavior	**Yes**	**No**	**Do not know**
Opioid prescription abuse/addiction	23 (5.93)	342 (88.14)	18 (4.64)
Prescription opioid dependence	92 (23.71)	261 (67.27)	19 (4.90)
Prescription drug abuse/addiction	11 (2.84)	358 (92.27)	9 (2.32)
Prescription drug dependence	6 (1.55)	349 (89.95)	10 (2.58)
Alcohol abuse/addiction	5 (1.29)	364 (93.81)	11 (2.84)
Alcohol dependence	9 (2.32)	349 (89.95)	12 (3.09)
Other illicit drug abuse/addiction	7 (1.80)	356 (91.75)	17 (4.38)
Any illicit drug dependence	0	351 (90.46)	15 (3.87)
Drug-taking behavior related to criminal intent	2 (0.52)	367 (94.59)	10 (2.58)
Drug-taking behavior resulting from family dysfunction	16 (4.12)	346 (89.18)	17 (4.38)
Has a psychiatric disorder that may be causing or contributing to aberrant drug-related behavior	21 (5.41)	344 (88.66)	16 (4.12)
Numbers in parentheses are percentages.			

this degree of relief are probably fairly uncomplicated and could be considered for opioid therapy in routine medical management settings. Patients who do not functionally improve with this degree of relief are likely to have other clinical problems, such as comorbid psychiatric issues (i.e., depression, anxiety, secondary gain issues, a deep-seated need to stay in the sick role), and would require specialized attention for a satisfying outcome to be realized.

Additionally, nearly four of five patients were seen as improved in overall functioning with this rather gross approach to assessment and documentation. This is an important consideration in the wake of the negative attention focused on opioid therapy owing to OxyContin abuse.[14-15] There is a suggestion of the validity of these ratings given that most of the improvement comes in the areas of physical functioning and mood where opioids have their most direct impact.

Opioid side effects were common in this study, but overwhelmingly seen as tolerable and manageable by patients and physicians. Constipation was the most common side effect and was severe in one-third of patients, which is similar to results found elsewhere.[16,17] Side effects can detract from ability to function and must be aggressively managed.

The results from this study in the area of aberrant drug-related behavior, should they be replicated in an adequately designed and powered epidemiological survey, are powerful. For many years, pain experts have argued that addiction is rare in people receiving adequate and appropriate opioids as part of the medical management of pain.[18,19] While this may be true, large-scale studies are, in fact, lacking.

Addiction may not be the central issue facing pain clinicians. In the phenomenology of the pain clinician, the management of noncompliance behavior arising from multiple causes is the central issue. These results suggest that noncompliance is fairly common and challenges the clinician to note, understand, and react to it in nearly 50 percent of patients. Noncompliance has a complex "differential diagnosis," including addiction, uncontrolled pain (pseudoaddiction), self-medication of psychiatric and physical symptoms other than pain and situational stressors, family dysfunction, and diversion.[6,20-22] The clinician must know how to assess and come to decisions about the meaning of this behavior and importantly, document about it. Physicians noted noncompliance in 45 percent of patients but considered it worrisome only one in 10 times, and so must have a repertoire for responding to psychiatric and other causes of noncompliance.

Behaviors varied tremendously in their frequency. The very aberrant and illegal behaviors were rare and occurred in less than 2 percent of patients overall. The less obvious behaviors were common, seen in the cases of nearly one in five patients in some instances. Most behaviors were seen in approximately 6 percent of

Table 4. Noted aberrant drug-taking behaviors and mean number of occasions observed by physician or through reports from family/outside sources (N = 388)		
Behavior	**n**	**Mean number of occasions noted per patient (SD)**
Requests frequent early renewals	69	2.88 (2.35)
Asks for medication by name	63	2.68 (1.79)
Increases dose without authorization	51	2.59 (2.38)
Requests higher dose in a worrisome manner	33	3.29 (2.45)
Reports lost/stolen prescriptions	32	1.36 (0.54)
Oversedation	31	4.92 (13.12)
Negative mood change	30	3.05 (2.23)
Attempts to obtain medication from other doctors	30	1.98 (1.33)
Successfully obtains medications from other doctors	27	1.80 (1.13)
Misses appointments except for medication renewal	22	2.23 (1.57)
Does not comply with other recommended treatments	21	3.26 (2.65)
Reports no effect of other medications	18	2.78 (1.77)
Uses medication for purpose other than described	17	2.21 (1.10)
Declining physical function	16	2.38 (1.82)
Declining social function	13	2.15 (1.63)
Declining psychological function	13	2.04 (1.51)
Intoxicated seeming	13	2.62 (1.82)
Contact with street culture	13	1.31 (0.63)
Abusing alcohol or street drugs	11	1.27 (0.47)
Staff splitting	10	2.70 (1.64)
Involved in motor vehicle or other accident	7	1.14 (0.38)
Increasingly unkempt or impaired	6	2.33 (1.21)
Hoarding of medications	6	2.00 (1.67)
Worrisome drug effects	5	2.30 (1.72)
Changes route of administration	4	3.50 (2.89)
Engaging in the sale of sex to obtain drugs	0	0
SD, standard deviation.		

patients, an interesting observation in that the rate of substance abuse/addiction in the United States is thought to be approximately 6 to 10 percent of the population,[23-25] and recent reports in chronic pain populations have ranged from 3 to 18 percent.[26] Thus, if this observation is replicated in larger epidemiologic surveys, it suggests that the subgroup of patients expected to be problematic on opioids could have been predicted from the baseline population norms.

Inter-relationships between the Four As and other patient variables

It is interesting that there was not a greater degree of intercorrelation among the Four As. Although they tap vastly different areas, overall we expected that the chronic pain experience would lend an overarching thread to combine these four important areas. Indeed, only the second "A," activities of daily living, was significantly correlated to the other aspects of the chart note. This may suggest a rather important role for paying attention to the functionality of patients being treated for chronic pain. Poor functioning in this sample was related to lesser amounts of pain relief, more adverse side effects, and a greater number of aberrant drug-related behaviors being engaged in by patients. It might be that assessing functionality is a rather innocuous means of getting a global impression of the patient and whether or not he or she is going to ultimately respond to opioid therapy. This notion has been at least initially supported by a recent study of 158 patients treated in an inpatient chronic pain setting.[27]

Regarding aberrant drug-related behaviors, it is important to highlight the predictors that were significant in this study. Those who were younger, had a psychiatric history of any kind, and were current smokers were all more likely to engage in a greater number of aberrant drug-related behaviors. Further assessment of psychiatric history, addiction history, and smoking status and the ability of these factors to predict aberrant behavior is warranted.

CONCLUSION

We attempted to implement a new documentation aid, the PADT, in a naturalistic study of outcomes in opioid therapy. Although subject to the types of selection biases that are common in the field of community-based trials in pain management, the study does suggest that the measure records a comprehensive view of outcomes. The study also suggests that, in general, patients on ongoing opioid therapy were seen as having favorable outcomes by their treating physicians. Future trials are needed to explore the factor structure, reliability, and validity of the tool.

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