Brief Report

A New Tool to Assess and Document Pain Outcomes in Chronic Pain Patients Receiving Opioid Therapy

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ABSTRACT

Background: Opioid analgesics are the cornerstone of management for malignant pain. Their use in managing chronic, nonmalignant pain, albeit controversial, has increased in recent years. The decisions about whether to initiate opioid therapy or continue it over time should be guided by a comprehensive patient assessment. During long-term treatment, this assessment should focus on a broad range of outcomes, each of which should be documented in the medical record.

Objective: The goal of this study was to develop an instrument, the Pain Assessment and Documentation Tool (PADT), to focus on key outcomes and provide a consistent way to document progress in pain management therapy over time.

Methods: Items that assess 4 domains (pain relief, patient functioning, adverse events, and drug-related behaviors) were generated with input from a MEDLINE literature search and experts in pain and addiction management. The original tool was field tested by clinicians who applied it to the assessment of patients receiving long-term opioid therapy for the management of chronic, nonmalignant pain. Data analysis and debriefing telephone interviews with a formalized set of questions were then used to rephrase, delete, and refine items to create the final tool.

Results: A 6-member expert panel contributed to the initial development of the PADT. Twenty-seven clinicians completed the preliminary version of PADT for 388 patients. The original 59-item tool was modified to create a 41-item tool. The revised PADT was formatted for use as a chart note designed to assist clinicians in assessing and documenting 4 main outcome domains during long-term opioid use.

Conclusions: In this study, the PADT appeared to be a useful tool for clinicians to guide the evaluation of several important outcomes during opioid therapy and provide a simple means of documenting patient care. (*Clin Ther*. 2004;26:552–561) Copyright © 2004 Excerpta Medica, Inc.

Key words: opioid therapy, pain assessment, pain relief, patient functioning.

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INTRODUCTION

The use of long-term opioid therapy to treat chronic, nonmalignant pain is growing, spurred by evidence from clinical trials and an evolving consensus among pain specialists.[1–5] The appropriate use of these drugs requires skill in opioid prescribing, knowledge of addiction medicine principles, and a commitment to perform and document a comprehensive assessment repeatedly over time. Inadequate assessment can lead to undertreatment,[6,7] compromise the effectiveness of therapy when implemented,[8] and prevent an appropriate response when problematic drug-related behaviors occur. In turn, the failure to perceive and address problematic behaviors can have both regulatory and medicolegal consequences for the clinician.

Physicians who adequately assess patients before and during opioid therapy may still encounter problems as a result of poor documentation. In a chart review of 300 patients with chronic pain,[9] 61% had no documentation of a treatment plan. A review of the initial consultation notes of 513 patients with acute musculoskeletal pain[10] revealed that only 43% of historical findings and 28% of physical examination findings were documented. In a review of 520 randomly selected visits at an outpatient oncology practice,[11] quantitative assessment of pain scores was virtually absent (<1%), and qualitative assessment of pain occurred in only 60% of cases. Finally, a review of the medical records of 111 randomly selected patients who underwent urine toxicology screens in a cancer center[12] found that 37.8% of the physicians failed to list a reason for the test and 89% of the charts did not include the results of the test.

According to model guidelines for opioid therapy developed by the Federation of State Medical Boards of the United States,[13] the medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. To assess the appropriateness, course, and outcome of therapy, information should be available concerning the patient evaluation, treatment plan, informed consent and agreement for treatment, monitoring approach, consultation requests, medical record keeping, and compliance with the controlled-substances laws and regulations.[13] Recent standards promulgated by the Joint Commission on the Accreditation of Healthcare Organizations[6] also recommend that physicians record the results of their pain assessment in a way that facilitates regular reassessment and follow-up.

Clearly, strategies are needed to translate these recommendations for patient assessment during long-term opioid therapy to front-line practice. This effort would certainly benefit from the availability of a consistent method of documentation of analgesia, adverse events, activities of daily living, and aberrant drug-related behaviors. To that purpose, we describe the development of the Pain Assessment and Documentation Tool (PADT), a simple charting device that is intended to focus on key outcomes and provide a consistent way to document progress in pain management therapy over time.

METHODS

Initial Development of the PADT

The literature was reviewed with the use of MEDLINE to identify existing assessment tools. Then, a cohort of coauthors asked a panel of experts in pain and addiction management (see Acknowledgments) to generate a list of items that are essential for assessment and documentation of patient response during long-term opioid therapy (**Figure 1**). To provide a framework, we suggested that the panel consider items under 4 main domains: pain relief, patient functioning, adverse events, and drug-related behaviors. These domains have been labeled the *4 A's* (analgesia, activities of daily living, adverse events, and aberrant drug-related behaviors) for teaching purposes.[14]

Items solicited through telephone and e-mail contacts with the expert panel were combined with others generated by the authors. A single list was created, which was reviewed again and further refined by the expert panel and rendered into the first iteration of the PADT.

Field Testing of the PADT

A field trial was conducted to evaluate the potential utility of the PADT in clinical practice and to begin the process of item reduction and refinement before formal validation. The original 59-item PADT was field tested by clinicians who were treating patients receiving long-term opioid therapy for chronic, nonmalignant pain. The clinicians, like the

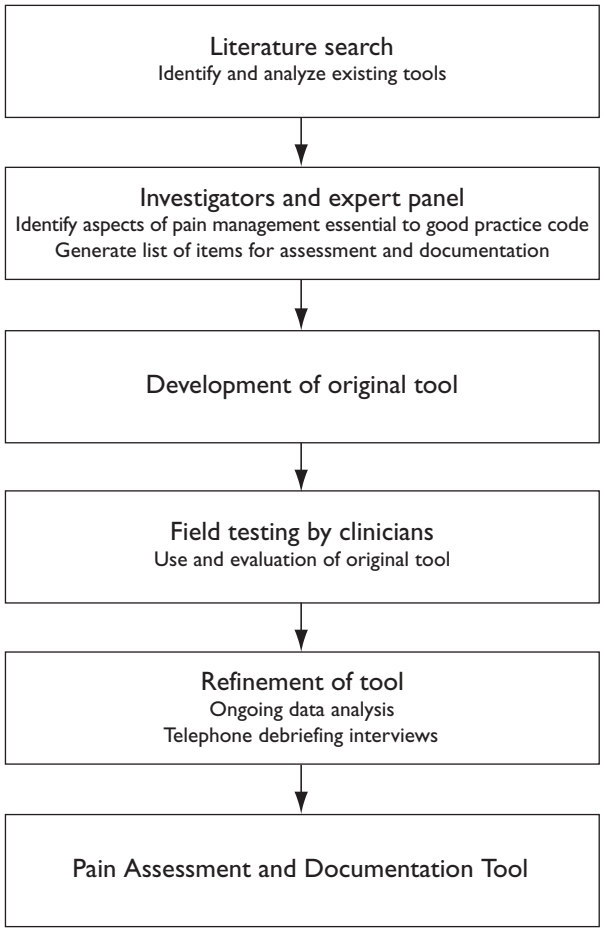

Figure 1. Steps in the development of the Pain Assessment and Documentation Tool.

expert panel, were asked to participate by the coauthors. These clinicians represented a convenience sample drawn from the primary care practices and the pain specialist practices affiliated with the investigators' institutions. Each of the participating clinicians selected a clinic day and completed the tool on all patients who met the criterion of opioid therapy for ≥3 months at the time of the assessment. The experts who participated in initial development of the 59-item tool also participated in the field testing. The protocol was reviewed by 2 institutional review boards (IRBs): the Western IRB (Seattle, Washington) and the Beth Israel Hospital IRB (New York, New York). In both cases, the protocol was deemed IRB exempt.

Patients

As described earlier, the patients who were surveyed using the tool were selected by the participating clinicians.

Revision Process

After completion of the PADT, a sample of clinicians (most of whom participated in the field trial) were contacted and asked to consent to a debriefing interview. Standard questions were asked about the PADT's length, comprehensiveness, and ease of use. Questions were asked about response codes, irrelevant items, and items or issues that respondents considered important but were missing from the tool. Respondents also were asked to share their perspectives on the documentation and regulatory needs of clinicians treating patients with chronic, nonmalignant pain. All debriefings were conducted by telephone, using the same standard questions, by interviewers trained in the use of these standard questions.

Statistical Methods

The purposes of this study were to evaluate the item performance of the PADT, examine alternative scoring methods, and provide recommendations for revising the measure to yield a brief inventory for use by physicians treating chronic pain patients in their daily practice. Data from the PADT and qualitative information from the debriefings were used to rephrase, delete, and refine items. Missing data were considered minimal to small if <2% of the data were missing. Missing data ranging from 2% to 8% were considered moderate, and anything >8% was considered substantial or large. Recommendations for deleting or revising an item were based on content, clarity, and the empirical properties of the item. Analyses that were used to revise the PADT included appraisal of missing data and examination of the distributional characteristics of items (mean, median, and floor or ceiling effects). Traditional psychometric properties of reliability and validity were not assessed at this point in instrument development.

RESULTS

Six experts in pain and addiction management participated in the expert panel. Twenty-seven clinicians completed the preliminary version of the PADT for 388 opioid-treated patients. **Table I** shows the clinicians' demographic information; **Table II** shows the

Table I. Demographics of 27 health care providers who participated in field testing the Pain Assessment and Documentation Tool.

Characteristic	No. (%) of Clinicians
Age group, y (n = 27)	
30–40	5 (18.5)
41–50	15 (55.6)
51–60	6 (22.2)
61	1 (3.7)
Sex (n = 27)	
Men	21 (77.8)
Women	6 (22.2)
Mode of practice (n = 22)	
General practitioner/family practice	10 (45.5)
Physiatrist	0 (0.0)
Psychiatrist	1 (4.5)
Psychologist	1 (4.5)
Pharmacist	0 (0.0)
Nurse	0 (0.0)
Neurologist	2 (9.1)
Anesthesiologist	7 (31.8)
Surgeon	0 (0.0)
Dentist	1 (4.5)
Specialty area (n = 13)	
Addiction medicine	1 (7.7)
Rheumatology	2 (15.4)
Pain management	4 (30.8)
AIDS	1 (7.7)
Hematology/oncology	1 (7.7)
Orofacial pain	1 (7.7)
Hospitalist	1 (7.7)
Geriatrics/pain medicine	1 (7.7)
Physical medicine/rehabilitation	1 (7.7)
Board certified (n = 27)	
Yes	27 (100.0)
No	0 (0.0)
Primary practice location (n = 26)	
Urban	18 (69.2)
Suburban	7 (26.9)
Rural	1 (3.8)
Primary practice setting (n = 20)	
University hospital	5 (25.0)
Hospital-based	2 (10.0)
Office	10 (50.0)
Other	3 (15.0)

demographics of participating patients. Nineteen clinicians (17 physicians, 1 nurse, and 1 psychologist) participated in the debriefing. Twelve of the 19 clinicians had participated in the field trial before the debriefing. The debriefing interview for these clinicians used the same standard questions to evaluate both the original and revised PADT. Seven clinicians who participated in the development of the PADT, but not in the field trial, reviewed only the revised PADT. Telephone debriefings were conducted by 2 interviewers (L.K. and Gabrielle Ciesla, MS).

On the basis of the analysis, 18 items were deleted from the original tool. The debriefing suggested the need for an overall assessment question and a 5-item section for *specific analgesic plan*, which were added to the revised tool (**Figure 2**).

Analgesia

The *analgesia* section was unchanged except for simplification of item 3. Questions 1 and 2 (pain level on average and at its worst) of the original PADT were similar to the well-validated visual analog scales used in pain research and were retained with no changes. The third item in the analgesia domain originally was as follows: *Compare your average pain during the past week with the average pain you had before you were treated with your current pain relievers. What percent of your pain has been relieved?* The small amount of missing data indicates that patients were willing to answer the question; however, there was concern during the debriefing that some patients might have found the cognitive task of considering pain during the past week, recalling pain during prior treatment, and comparing these 2 appraisals to be relatively complex, and the responses might have been unreliable. This item was revised such that patients were asked to estimate the percentage of their pain relieved during the past 2 weeks. Questions 4 and 5 in the revised PADT were also used in the original PADT.

Activities of Daily Living

The original *activities of daily living* section was divided into subsections for recording the patient's responses and the clinician's observations. This section covered the patient's perception of changes in physical functioning, mood, family relationships, social relationships, sleep pattern, occupational functioning, and overall functioning. Occupational

Table II. Demographics of 388 patients on whom the Pain Assessment and Documentation Tool was field tested.*

Characteristic	No. (%) of Patients
Sex (n = 366)	
Men	133 (36.3)
Women	233 (63.7)
Ethnic background (n = 383)	
White	322 (84.1)
Black	29 (7.6)
Hispanic	23 (6.0)
Asian	2 (0.5)
Other	7 (1.8)
Highest educational level achieved (n = 377)	
Grades 1–8	13 (3.4)
Some high school	41 (10.9)
High school degree or equivalent	93 (24.7)
Some college	115 (30.5)
College degree	63 (16.7)
Some postcollege work	24 (6.4)
Advanced degree	28 (7.4)
Current employment status (n = 388)	
Full-time	80 (20.6)
Part-time	31 (8.0)
Homemaker	25 (6.4)
Disabled	160 (41.2)
Unemployed	26 (6.7)
Retired	60 (15.5)
Student	6 (1.6)
Employment status before pain diagnosis (n = 371)	
Full-time	250 (67.4)
Part-time	32 (8.6)
Homemaker	25 (6.7)
Disabled	25 (6.7)
Unemployed	8 (2.2)
Retired	24 (6.5)
Student	7 (1.9)

*Data missing for some patients for various demographic characteristics.

functioning had the most missing data (9.8%), most likely because many patients were unemployed and there was no category for *not applicable*. Results of an exploratory factor analysis demonstrated that the items loaded on 1 factor (range of loadings, 0.67–0.80). The Cronbach α was 0.86, indicating good internal consistency. Based on these results, occupational functioning was removed from this section. Additional questions asking the clinician to rate the patient's functioning were also excluded because the focus of the PADT is the patient's perception.

Adverse Events

The *adverse events* section was expanded to include more of the adverse events commonly seen in patients receiving opioids. The *treatment needed* column was deleted after it was determined that the information would be covered elsewhere in the patient's chart. The *aberrant drug-related behavior* section was the most extensively revised. The title was changed to *potential aberrant drug-related behavior*, which was more meaningful to some clinicians, and items that were infrequently or never recorded were deleted.

The original adverse events section asked the severity (mild, moderate, or severe) of constipation, nausea, sedation, mental clouding, and any other adverse event, as well as whether treatment was needed. Large amounts of data were missing, ranging from 48% for constipation to 85% for mental clouding. Data could have been missing because the event was absent or the question was skipped.

Because the responses for adverse events allowed ambiguity, the final questions about them were revised such that the clinician could rate individual event severity from none (event not present) to severe, and then rate the overall severity of the adverse event(s). More than 20% of the patients reported itching as an adverse event of opioid use. Expert clinician review of this section suggested the addition of several adverse events: nausea, vomiting, itching, sweating, fatigue, and drowsiness. Sedation was removed from the instrument.

Aberrant Drug-Related Behaviors

The original section on aberrant drug-related behaviors contained 4 subsections: adverse consequences as a result of use, possible loss of control or diversion of medication, preoccupation with opioid or other drug use, and other occurrences of potential concern. The original questionnaire asked about the frequency with which certain behaviors occurred, as well as who noted the behavior (eg, family member, physician, pharmacist). Many items had low levels of endorsement and were removed from this section.

A

PROGRESS NOTE
Pain Assessment and Documentation Tool (PADT™)

Patient Stamp Here

Patient Name: _____ Record #: _____

Assessment Date: _____

Current Analgesic Regimen

Drug name	Strength (eg, mg)	Frequency	Maximum Total Daily Dose

The PADT is a clinician-directed interview; that is, the clinician asks the questions, and the clinician records the responses. The Analgesia, Activities of Daily Living, and Adverse Events sections may be completed by the physician, nurse practitioner, physician assistant, or nurse. The Potential Aberrant Drug-Related Behavior and Assessment sections must be completed by the physician. **Ask the patient the questions below, except as noted.**

Analgesia

If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. What was your pain level on average during the past week? (Please circle the appropriate number)

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Pain as bad as it can be**

2. What was your pain level at its worst during the past week?

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Pain as bad as it can be**

3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100%.) _____

4. Is the amount of pain relief you are now obtaining from your current pain reliever(s) enough to make a real difference in your life?
❑ Yes ❑ No

5. Query to clinician: Is the patient's pain relief clinically significant?
❑ Yes ❑ No ❑ Unsure

Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)

	Better	Same	Worse
1. Physical functioning	❑	❑	❑
2. Family relationships	❑	❑	❑
3. Social relationships	❑	❑	❑
4. Mood	❑	❑	❑
5. Sleep patterns	❑	❑	❑
6. Overall functioning	❑	❑	❑

* If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.

(Continued on reverse side)

Figure 2. The revised Pain Assessment and Documentation Tool shown as a 2-sided chart note. (A) Front.

B

PROGRESS NOTE
Pain Assessment and Documentation Tool (PADT™)

Adverse Events

1. Is patient experiencing any side effects from current pain reliever(s)? ❑ Yes ❑ No

Ask patient about potential side effects:

	None	Mild	Moderate	Severe
a. Nausea	❑	❑	❑	❑
b. Vomiting	❑	❑	❑	❑
c. Constipation	❑	❑	❑	❑
d. Itching	❑	❑	❑	❑
e. Mental cloudiness	❑	❑	❑	❑
f. Sweating	❑	❑	❑	❑
g. Fatigue	❑	❑	❑	❑
h. Drowsiness	❑	❑	❑	❑
i. Other _____	❑	❑	❑	❑
j. Other _____	❑	❑	❑	❑

2. Patient's overall severity of side effects?
❑ None ❑ Mild ❑ Moderate ❑ Severe

Potential Aberrant Drug-Related Behavior

This section must be completed by the physician.

*Please **check** any of the following items that you discovered during your interactions with the patient.* Please note that some of these are directly observable (eg, appears intoxicated), while others may require more active listening and/or probing. Use the "Assessment" section below to note additional details.

- ❑ Purposeful over-sedation
- ❑ Negative mood change
- ❑ Appears intoxicated
- ❑ Increasingly unkempt or impaired
- ❑ Involvement in car or other accident
- ❑ Requests frequent early renewals
- ❑ Increased dose without authorization
- ❑ Reports lost or stolen prescriptions
- ❑ Attempts to obtain prescriptions from other doctors
- ❑ Changes route of administration
- ❑ Uses pain medication in response to situational stressor
- ❑ Insists on certain medications by name
- ❑ Contact with street drug culture
- ❑ Abusing alcohol or illicit drugs
- ❑ Hoarding (ie, stockpiling) of medication
- ❑ Arrested by police
- ❑ Victim of abuse

Other: _____

Assessment: (This section must be completed by the physician.)

Is your overall impression that this patient is benefiting (eg, benefits, such as pain relief, outweigh side effects) from opioid therapy? ❑ Yes ❑ No ❑ Unsure

Comments: _____

Specific Analgesic Plan:

- ❑ Continue present regimen — Comments: _____
- ❑ Adjust dose of present analgesic
- ❑ Switch analgesics
- ❑ Add/Adjust concomitant therapy
- ❑ Discontinue/taper off opioid therapy

Date: _____ Physician's signature: _____

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Figure 2. (continued) The revised Pain Assessment and Documentation Tool shown as a 2-sided chart note. (B) Back.

Revision of Original PADT

Table III presents the responses to selected debriefing questions. Among the 12 clinicians who evaluated both versions of the tool, 9 (75.0%) agreed with the changes made to the instrument. Most of the 19 clinicians who were debriefed agreed that it was helpful to have a standardized tool to place in patient charts, that the PADT would be a useful tool to place in patient charts, that the revised PADT could be useful to them in their practice, and that the PADT could be used to document behaviors or concerns for legal purposes (52.6% to 68.4% agreement).

DISCUSSION

The present PADT (Figure 2) is a brief, 2-sided chart note that can be readily included in the patient's medical record. It was designed to be intuitive, pragmatic, and adaptable to clinical situations. In the field trial, it took clinicians 10 to 20 minutes to complete the tool. The revised PADT is substantially shorter and should require a few minutes to complete.

By addressing the need for documentation, the PADT can assist clinicians in meeting their obligations for ongoing assessment and documentation. Although the PADT is not intended to replace a progress note, it should complement existing documentation with a focused evaluation of outcomes that are clinically relevant and address the need for evidence of appropriate monitoring.

The decision to assess the 4 domains, subsumed under the shorthand designation of the *4 A's*, was based on clinical experience, the positive comments received by the investigators during educational programs on opioid pharmacotherapy for nonmalignant pain, and an evolving national movement that recognizes the need to approach opioid therapy with a balanced response. Such a response would recognize both the legitimate need to provide optimal therapy to appropriate patients and the need to acknowledge the potential for abuse, diversion, and addiction.[14] Studies have repeatedly emphasized the value of assessing pain relief,[15–17] adverse events,[18] and aspects of functioning.[9,19] Documentation of drug-related behaviors is a relatively new concept that is being explored for the first time in the PADT.

Potential aberrant drug-related behavior has a complex differential diagnosis, including addiction, inadequate analgesia (pseudoaddiction), self-medication of psychiatric and physical symptoms other than pain (eg, encephalopathy, borderline personality disorder, depression, anxiety), situational stressors, family dysfunction, and diversion.[20] The challenge for the clinician is to recognize these behaviors, take actions to limit them, and determine the most appropriate management based on the diagnosis. The PADT assesses 17 aberrant behaviors. Some of the items in the checklist are directly observable (eg, appears intoxicated), whereas others require some probing. The availability of this checklist may improve the ability of clinicians to detect problematic behaviors and implement appropriate actions because the relevant questions can be asked consistently over time.

Studies to validate the PADT are under way, and current limitations must be acknowledged. The PADT is a descriptive tool intended to assist clinicians to better organize and document their chart notes. Although measures of internal consistency (based on a single administration of the instrument) were completed, measures of stability were not done; measures of the latter are intended to provide evidence of how a tool performs on different occasions. Interobserver

Table III. *Yes* responses from 19 clinicians to selected debriefing questions regarding the Pain Assessment and Documentation Tool (PADT).

Question	n/N (%)
Do you agree with changes made to the original PADT?	9/12 (75.0)
Would it be helpful to have a standardized tool?	13/19 (68.4)
Do you think that the PADT would be a useful tool to place in patient charts?	12/19 (63.2)
Do you think that the revised PADT could be useful to you?	10/19 (52.6)
Do you think that the PADT would be helpful for documenting behaviors or concerns for legal purposes?	12/19 (63.2)

reliability (the degree of agreement between different observers) and intraobserver reliability (the degree of agreement between observations made by the same observer) were not tested. Furthermore, observations of the same patient at 2 different times were not done. Further studies are needed to confirm the reliability and validity of the individual items and sections of the PADT. Predictive validity through longitudinal use of the tool must be confirmed, and studies are needed to clarify the interval of assessment that optimally balances the need to minimize clinician burden with the need to validly assess and document outcomes that may change continually over time.

Finally, the PADT does not capture many characteristics of pain or domains that may be affected by pain or its treatment, and it is not meant to substitute for a comprehensive clinical assessment.

CONCLUSIONS

In this study, the PADT appeared to be a useful tool for clinicians to guide the evaluation of several important outcomes during opioid therapy and provide a simple means of documenting patient care. It could prove helpful in clinical management and offers a mechanism for documenting the types of practice standards that the regulatory and law enforcement communities seek to ensure.

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