

## Forward

### **For: Passik S, et al.: Addiction-Related Assessment Tools and Pain Management: Instruments for Screening, Treatment Planning, and Monitoring Compliance**

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The guiding paradigm for long-term opioid therapy is rapidly evolving. Two decades ago, a cultural shift from “opioids are a last resort” to “opiophobia must be stopped” seemed well on its way. Evidence of undertreatment was accumulating, and although evidence of long-term opioid effectiveness and safety was lacking, accumulated experience seemed to make the case obvious: Opioid therapy held the promise of enhanced comfort and improved function for large numbers of patients with diverse types of chronic pain, and a medical community that could grasp straightforward pharmacotherapeutic principles and resist the unjustified drag of stigma and regulatory fear would drive a large and sustained benefit to the public health.

This paradigm of “safe and effective, and underused” was founded on many truisms, but from present vantage, was extraordinarily naïve as well. Although it was widely acknowledged that opioids are abusable drugs, there was clear neglect of the risks linked to chemical dependency, including abuse, addiction and diversion. Early on, well meaning pain specialists used data that were not relevant to chronic pain therapy, and a risk:benefit analysis that prioritized redress of undertreatment above public health concerns related to addiction, to promulgate reassuring messages that implied, essentially, that the management of abuse, addiction and diversion does not need to be front and center in the practice of pain medicine.

The paradigm has shifted again, driven by stark observations. Pain specialists have seen the steady rise in national measures of prescription drug abuse and the devastation associated with endemic areas of high abuse. The realization has taken hold that inadequately trained clinicians trying to do the right thing can cause real harm to individuals and to the community. The medical community overall has realized that regulators and law enforcement, charged with protecting the public health, will react negatively to rising abuse and may not temper this reaction with a careful analysis of the effect on pain treatment.

These observations have supported a national policy perspective encapsulated by the term “balance,” which highlights the need for policies that both protect

medical use of long-term opioid therapy and concurrently reduce the public harm associated with drug abuse and diversion. From the perspective of the clinician, the new paradigm is essentially “balance at the bedside”: Safe and effective opioid therapy requires that clinicians both optimize pharmacologic outcomes and undertake the assessment and management of risks associated with abuse, addiction and diversion.

A new paradigm brings new messages for the clinical community. “Universal precautions” may be a useful concept, suggesting as it does that every patient given a potentially abusable drug should undergo proactive risk assessment, risk stratification, and an approach to treatment that provides monitoring commensurate with risk. No one regimen can be right in every case, but every case deserves assessment and thoughtful implementation of therapy.

Risk assessment and risk management represent a new skill set for many clinicians. The strategies can be easily learned, however, and practice will improve sensitivity. Tools to assess different elements of risk are now available and may eventually prove useful in practice, as well as in future research. Indeed, the number of tools developed and validated to predict risk of nonadherence or risk of addiction, or to diagnose addiction, has grown exponentially during the past few years. A careful review of the available instruments, including their potential clinical use, is timely and immensely valuable to the clinical community.

Clinicians who read this review and understand its implications should be encouraged to incorporate systematic assessment of risk, whether or not a validated tool actually is used. The key is assessment, and informed actions based on the findings. The tools described in this review are a welcome adjunct to a process that has now become central to the paradigm guiding long-term opioid therapy.

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## **Addiction-Related Assessment Tools and Pain Management: Instruments for Screening, Treatment Planning, and Monitoring Compliance**

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## **ABSTRACT**

*Objective:* To review and critique the various assessment tools currently available to pain clinicians for assessing opioid use and abuse in patients with chronic noncancer pain to allow pain clinicians to make informed selections for their practices.

*Methods:* A literature search on PubMed was conducted in June 2006 using the search terms *opioid plus screening or assessment* with or without the additional term *risk*, and *opioid-related disorders/prevention and control* in order to identify clinical studies published in English over the previous 10 years. Additional studies were identified using the PubMed link feature and Google. When abstracts described or referred to a tool for opioid abuse screening, the corresponding publication was acquired and reviewed for relevance to the pain treatment setting.

*Results:* Forty-three publications were selected for review from the abstracts identified, and 19 were rejected because they did not describe a specific tool or provide adequate information regarding the screening tool used. The remaining 24 publications described relevant screening tools for opioid abuse risk and were reviewed.

*Conclusions:* A variety of self-administered and physician-administered tools differing in their psychometrics and intended uses have been developed, but not all have been validated for use in chronic pain patients seen in a clinical practice setting. Some tools assess abuse potential in patients being considered for opioid therapy, whereas other tools screen for the presence of substance abuse. By recognizing the psychometrics of each tool, clinicians can select the ones most appropriate for their patient population and screening needs.

**Key Words:** Analgesics, Opioid, Pain Measurement, Substance Abuse Detection

## INTRODUCTION

In the early days of the movement that has broadened the use of, and indications for, opioid therapy, it was common to trivialize the potential for substance abuse when these medications were being used for pain. This trivialization sometimes took the form of rhetoric suggesting that the risk in the population of potential patients to be exposed is low or nonexistent.<sup>(1)</sup> Further, there were “miscalculations” made about how much control over addiction or abuse the use of certain delivery systems might bestow. This overestimation of the protective effects of long-acting delivery systems took the form of rhetoric suggesting that these systems could lower or eliminate risk.<sup>(1)</sup> It has become clear that if a broader “swath” of the population of those with chronic pain is to be exposed to opioids, the risk of addiction, abuse, and aberrant behaviors is at least as high as it is in the general population. Risk is higher still if the pain is related to disease states wherein substance abuse is a common comorbidity.<sup>(2)</sup> In fact, the risk of opioid exposure is related to the interaction between the rewarding properties of these drugs (which also vary according to their differing ability to deliver the drug rapidly) and the personal vulnerabilities in individual patients, and the degree to which this interaction can be contained within certain treatment settings.

There is now an evolving consensus that safe opioid prescribing hinges on risk stratification and the accommodation of that risk into a treatment plan. Pain clinicians need to become proficient in performing and documenting a risk assessment. The use of a screening or another assessment tool fulfills the growing requirement for due diligence in the area of screening for the individual patient’s vulnerabilities and risk and incorporating the results of the assessment in treatment planning (drug selection and the degree of safeguards to be built into the setting). Additionally, the use of validated tools not only helps guide the assessment, but when incorporated into the medical record, also upgrades the clinician’s documentation of this assessment.

However, until recently, there was a lack of empirical studies on addiction-related aspects of chronic pain management in general, and even fewer devoted to creating validated tools for assessing addiction-related risk and outcomes in pain patients being considered for, or being managed on, opioid therapy. Over the last few years, however, there has been a significant increase in the number and types of addiction-related tools that are now available to pain clinicians. The existing tools vary in length, focus, and psychometric sophistication. They also vary with regard to the subgroup of pain patients in which they were validated—for example, a pain clinic subgroup versus a primary-care-based pain subgroup versus populations being screened for addiction in the absence of pain. Although no standard of care exists for how addiction-related assessments should be performed (i.e., structured vs unstructured; measurement tool vs clinical interview), it is clear that the standard of care is fast becoming one in which some form of risk stratification of patients being considered for opioid therapy must be

carried out and documented, especially in light of the growing problem of prescription drug abuse.

Many pain clinicians are struggling to find addiction-related assessment tools that they can incorporate into their practice settings and medical record keeping. As these tools continue to be developed, clinicians may find it difficult to choose for their pain patients the best tool that fits into the treatment setting. The challenge relates to the now large number of measures and the many differences among them. Dimensions in which screening tools differ include their mode or ease of administration, their psychometrics, the population best suited for each tool, and the aspects of addiction each tool is meant to monitor or predict. In this supplement, we intend to clarify these aspects for each of a number of assessment tools (Table 1). After reading this article, pain clinicians will be able to make better-informed decisions on the best-suited assessments to use, which in turn should enable treatment more tailored to each patient's pain/risk level. Because this risk is higher in noncancer pain populations, and because cancer pain patients represent a unique population, the focus of this review is noncancer pain.

The introduction of addiction-related assessment tools into a pain management setting requires skill and sensitivity on the part of the clinician. On the one hand, many patients who are truly at low risk for abuse are, ironically, tremendously fearful of becoming addicted to opioids.<sup>(3)</sup> Detailed questioning about addiction via the utilization of these tools could heighten anxiety in such patients. In such instances, clinicians can use the screening process as a way of reassuring patients that they indeed do not have a history suggestive of risk. On the other hand, many patients will be fearful that admissions of substance use or abuse might lead to their exclusion from pain treatment with opioids. Given that almost all these tools are susceptible to deception, the subject's incentive to lie may be quite high. The clinician will need to introduce the screening process to patients as a way of helping to plan for safe opioid treatment, assuring them that no set of answers will automatically lead to the avoidance of appropriate pain management. Patients with a history of addiction can be reassured that safeguards will be applied to their treatment that may help them to avoid becoming out of control in their opioid use.

Pseudoaddiction (the problem of potentially difficult behavior set in motion by poorly treated pain) is not easily dealt with in the adoption of these tools in pain management settings; this is particularly true of those instruments developed mainly for use in treatment for drug addiction.<sup>(4)</sup> Certain behaviors and even illicit drug use are not unusual in the face of uncontrolled pain in some patient populations. Screening and assessment tools are better at recording behaviors than assessing the driving forces behind them. None of the existing tools has a "pseudoaddiction correction." As will often be observed in this article, a validation trial for a given measure in a pain population is needed. In the absence of a correction or an assessment of the patient's intent when he or she

is engaging in certain problematic behaviors, the best that clinicians can hope for is an estimate of how a given measure performs with pain patients.

## **METHODS**

Several methods were used to identify publications describing clinical tools used to screen patients for risk of opioid abuse. A literature search of the PubMed National Center for Biotechnology Information (NCBI) database was conducted on June 16, 2006, and was limited to human studies published in English. Three independent searches were performed for clinical trials published in the last 10 years using the search terms (a) “opioid AND (screening OR assessment),” (b) “opioid AND (screening OR assessment) AND risk,” and (c) “opioid-related disorders/prevention and control.” In addition, the PubMed “Related Articles” search link for 3 primary studies was used to supplement the articles identified in the primary searches. Search results were printed as abstracts and reviewed for relevance to the identified topic. In order to identify publications not indexed in PubMed, online searches were also performed using the Google search engine for the same terms as those utilized in the PubMed searches. Additionally, anecdotal information received from expert colleagues in the field of pain management was used to identify late-breaking publications regarding opioid abuse risk assessment tools. Regardless of the method used to identify publications, upon review, if an abstract described a tool or made reference to a tool for opioid abuse screening, the corresponding publication was acquired and reviewed in full for relevance. Limitations of this strategy include the following: No prospectively defined criteria that assessed the strength of the study designs were used, paper selection was based on a subjective assessment of perceived relevance based on the authors’ experience, and search terms may have been too narrow to capture all relevant publications.

## **RESULTS**

The 3 quantitative PubMed database searches identified 722, 83, and 15 publications for the “opioid AND (screening OR assessment),” “opioid AND (screening OR assessment) AND risk,” and “opioid-related disorders/prevention and control” searches, respectively. The majority of the hits identified by this method were excluded after abstract review, because they described no specific tool or provided inadequate information regarding the screening tool used. The number of publications identified through all search methods and subsequently reviewed during this process is shown in Table 2. After all abstracts identified through both qualitative and quantitative methods were reviewed, 43 publications were selected for review of the full-length manuscript. Nineteen of these 43 were later rejected because they either did not describe a specific tool or did not provide adequate information regarding the screening tool used. In all, 24 publications described relevant screening tools for opioid abuse risk in patients, and these are reviewed in detail here. Table 3 lists the citations included in this

review with a description of each. Table 4 provides descriptions and commentaries on each tool based on these studies.

## **DISCUSSION**

### **Measures of Tool Effectiveness**

The effectiveness of opioid assessment tools is characterized by their sensitivity, specificity, positive predictive value, and negative predictive value. The sensitivity of a tool reflects the proportion of persons with a condition (e.g., a substance abuse disorder) who test positive, whereas the specificity represents the proportion without the condition who test negative. The positive predictive value of a tool reflects the proportion of persons who test positive who have the condition, whereas the negative predictive value represents the proportion with negative test results who do not have the condition. A *c* statistic is sometimes used to assess the predictive ability of a tool by taking both sensitivity and specificity into consideration ( $c = 0.5$  indicates no discrimination, whereas  $c \geq 0.8$  shows excellent discrimination). Correlation coefficients show the strength of a relationship between two variables, with a coefficient of 1.0 reflecting a perfect correlation. The Pearson *r* coefficient is often used to show the reliability between initial testing and retesting; Cronbach's alpha coefficient is used to estimate the internal consistency or reliability of a test; and kappa coefficients are used to show agreement between categorical variables.

### **Risk-Assessment Instruments for Pain Populations**

#### The Screener and Opioid Assessment for Patients with Pain (SOAPP)

The SOAPP is a 14-item, self-report measure that is designed to assess the appropriateness of long-term opioid therapy for chronic pain patients.<sup>(5)</sup> Each item is measured on a 5-point scale (0 = never, to 4 = very often), with a cutoff score of 8. The SOAPP—created by an expert panel of 26 members—was reduced from an initial 24 items to 14 items after Butler et al. <sup>(6)</sup> tested each item's reliability and validity. Akbik et al. <sup>(5)</sup> found that 355 of 396 noncancer chronic pain patients (90%) answered all 14 items. (A high rate of completion is important, as partially completed tools have limited usability.) Patients with scores of 8 or higher were younger (mean age, 40.7 vs. 45.5 years,  $P < .05$ ), more likely to have had a urine screen (46.4% vs. 31.1%,  $P < .01$ ), and more likely to have had abnormal urine screen results (33.7% vs. 27.5%,  $P < .05$ ) than those with scores below 8. The SOAPP is given a low cutoff of 8, because individuals who believe that their responses may determine their opioid treatment may underreport their behavior, and because some patients fear that their answers may be misconstrued. Whereas the SOAPP is an accurate tool for assessing abuse potential in patients being considered for opioid therapy, it remains problematic in a few areas, most notably in that the data are correlational and not causal. Another problem is that very few demographic and medical data were recorded in the validation of SOAPP, raising the possibility of there being differences in the cutoff scores among different subpopulations.

*Comment:* The SOAPP has undergone a number of iterations. It is presently briefer and perhaps less susceptible to deception than some of the more “face-valid” tools. The assessment is also more accurate at predicting problematic behavior in people prescribed opioids for pain than expert clinician predictions (T. Jones, personal communication 2007). In high-risk pain populations, these advantages may make its use desirable despite its greater length and scoring requirements as compared with other similar measures, most notably the Opiate Risk Tool (ORT), below. The SOAPP probably has the best psychometrics of any of the measures designed to predict aberrant drug-taking behavior prior to the initiation of opioid therapy.

#### Diagnosis, Intractability, Risk, and Efficacy Score (DIRE)

The DIRE is a clinician-rated scale designed to predict the analgesic efficacy of, and patient compliance to, long-term opioid treatment in the primary care setting. The scale is intended for use in patients who have chronic noncancer pain and who are currently being treated with opioids or are being considered for opioid treatment. The DIRE includes 4 categories: diagnosis, intractability, risk, and efficacy. The risk category is further divided into 4 subcategories: psychological, chemical health, reliability, and social support. Each factor is rated from 1 to 3, with higher scores indicating a more persuasive case for opioid therapy in terms of treatment efficacy and compliance. Patients with scores of 14 and above are considered good candidates for long-term opioid treatment, whereas those with lower scores are not considered good candidates.

Belgrade and colleagues (7) performed a retrospective analysis of the DIRE score in 61 patients who had been treated with opioids for chronic noncancer pain at an outpatient pain management center. Most patients had chronic musculoskeletal back and neck pain (41%), abdominal pain (15%), or neuropathic pain (13%) and were treated with opioids for a median duration of 37.5 months. In this cohort, the DIRE score exhibited high internal consistency, with a Cronbach's alpha coefficient of 0.80. All factors besides diagnosis were significantly related to treatment compliance ( $P < .001$ ), and all except intractability were significantly associated with efficacy ( $P < .05$ ). This was to be expected because, by definition, efficacy is hard to achieve in an intractable condition. Although the diagnosis subscore was not correlated with outcome, it is included in order to avoid treating with opioids patients who do not have a diagnosis or condition that is associated with moderate or severe pain. At a cutoff point of 13, the sensitivity and specificity of the DIRE score for predicting compliance in the study cohort were 94% and 87%, respectively, and for predicting efficacy, 81% and 76%, respectively. Interclass correlation for interrater reliability and intrarater reliability was 0.94 and 0.95, respectively.

*Comment:* The DIRE score performed well in identifying suitable candidates with chronic noncancer pain for long-term opioid therapy, but the retrospective nature of the study raises several limitations, most notably that investigators scored patients according to case history. Moreover, the study population was relatively

small and included a variety of chronic pain etiologies. Prospective analyses in more homogeneous chronic pain populations are still needed for confirming the utility of the DIRE score. However, for pain clinicians who prefer an observer-based, clinician-rated assessment strategy, the DIRE has tremendous potential. Using the DIRE is actually a process of systematizing the clinical judgments that pain clinicians typically make and quantifying them. This process is comfortable for, and familiar to, most pain clinicians and avoids the use of paper-and-pencil measures, where these may be less a part of particular clinics' routines.

### Opioid Risk Tool (ORT)

The ORT is a 5-item yes-or-no self-report that is designed to predict the probability of a patient's displaying aberrant behavior when prescribed opioids for chronic pain. It consists of items on family history of substance abuse, personal history of substance abuse, age, history of preadolescent sexual abuse, and psychological disease. The items on substance abuse contain three subsections covering alcohol, illegal drugs, and prescription drugs, and the item on psychological disease has two subsections that distinguish depression from other disorders. Each positive response is given a score based on patient gender, and then the scores are summed to derive the probability of opioid-related aberrant behavior. Scores of 0 to 3 are associated with low risk, 4 to 7 with moderate risk, and 8 and over with high risk. Webster and Webster (8) evaluated the ORT in 185 consecutive new patients at a pain clinic. Seventeen of 18 patients (94.4%) in the low-risk category did not display aberrant behavior. In contrast, 40 of 44 patients (90.9%) in the high-risk category and 35 of 123 patients (28.5%) in the moderate-risk category did display aberrant behaviors. The most common aberrant behaviors were solicitation of opioids from other providers, unauthorized escalation of opioid dose, abnormal urine or blood screening, and use of more opioids than those prescribed. The ORT displayed excellent discriminatory ability in both men and women, with observed *c* statistic values of 0.82 and 0.85, respectively.

*Comment:* Because of its brevity and ease of scoring, the ORT has tremendous clinician appeal and is clearly the easiest way to perform a risk assessment with a tool validated in pain patients and specifically designed to predict problematic behavior in people prescribed opioids for pain. Its lone drawback is its susceptibility to deception. Clinicians will have to decide if guarding against deception is important enough to use a longer and more cumbersome tool or if the documentation of risk assessment (not to mention clear evidence of deception, should it occur) satisfies their requirements.

### Atluri Screening Tool

Atluri and Sudarshan (9) developed a clinician-rated screening tool to detect the risk of inappropriate prescription opioid use in patients with chronic pain. Using a case-control design, the investigators retrospectively identified 107 patients who were dismissed from the pain clinic for inappropriate prescription opioid use, and compared them with 103 randomly chosen chronic pain patients who did not

have evidence of inappropriate prescription opioid use. On multivariate analysis, 6 clinical criteria were significantly associated with opioid abuse; these included focus on opioids, opioid overuse, other substance abuse, low functional status, unclear pain etiology, and exaggeration of pain. The investigators identified a checklist of questions for each of these 6 criteria. The screening tool is based on the number of positive criteria, ranging from 0 to 6. Most patients (77%) in the inappropriate use group scored above the cutoff of 3, whereas most (84%) in the control group scored below this cutoff level. Notably, patients with scores greater than 3 had an odds ratio of 16.6 (95% CI: 8.3-33;  $P \leq .001$ ) for opioid abuse, compared with the odds ratio for those with scores below this cutoff.

*Comment:* These preliminary results are promising, but it is important to recognize that the study was retrospective in design, included only patients being treated with opioids for chronic pain, and excluded those with cancer pain or acute pain.

#### Screening Instrument for Substance Abuse Potential (SISAP)

SISAP is a physician-administered screening tool designed to identify chronic noncancer pain patients who may be at risk of abusing opioids if prescribed. The instrument is easy to use and takes only a few minutes to administer. SISAP was developed and validated using data from the National Alcohol and Drug Survey (NADS), conducted in Canada in 1989.<sup>(10)</sup> The 5 questions elicit information about the number of drinks in a typical day and typical week, use of marijuana in the past year, history of cigarette smoking, and age. In the development cohort of 4,948 NADS respondents, SISAP correctly identified 91% of substance abusers and 77% of those who did not have alcohol or drug abuse problems. SISAP was validated in the other half of the subject pool from NADS and showed comparable performance by correctly classifying 91% of the actual substance abusers and 78% of the nonabusers. Overall, SISAP exhibited an accuracy of 80%, with sensitivity of 91% and specificity of 78%. Thus, SISAP can stratify chronic pain patients seen in a primary care setting, thereby allowing increased opioid availability to those who are not at risk of opioid abuse and providing improved monitoring or referral to those who are at risk.

*Comment:* The SISAP was developed on perhaps the largest database of pain patients of any of the screening tools included in this review. It is unclear why, in the several years since its development, the tool has not received further validation in prospective trials. Perhaps the requirement that clinicians ask a set of pointed questions about alcohol and drug use has delayed the tool's adoption by pain clinicians. Its brief format, though, would lend itself to use in pain clinics, and a prospective trial of the tool's ability to predict aberrant drug-taking behaviors is needed.

#### Screening Tool for Addiction Risk (STAR)

STAR, a screening tool for addiction risk, consists of 14 yes-or-no questions relating to cigarette, alcohol, and drug use; family or household members with

drug or alcohol abuse; visits to pain clinics and emergency rooms; and feelings of depression, anxiety, and altered mood. Friedman and coworkers (11) evaluated STAR in a sample of 48 chronic pain patients, including 14 with a history of substance abuse. Individual screening questions related to tobacco abuse, prior treatment in a drug or alcohol rehabilitation facility, or treatment at another pain clinic were more likely to be positive in patients with current substance abuse ( $P < .05$ ). On logistic regression, a history of treatment in a drug or alcohol rehabilitation facility was a significant predictor of addiction (positive predictive value 93%; negative predictive value 5.9%).

*Comment:* The STAR is brief, has been used in chronic pain patients, and has potential as an aid to screening and treatment planning. Larger prospective studies that examine the tool's ability to predict aberrant drug-taking behaviors are needed.

#### Chemical Coping Inventory (CCI)

The CCI is a tool in development meant to capture personality traits and attitudes that could lead to problematic drug use, failure to progress toward functional goals, and an overreliance on medication as a sole way of coping with chronic pain.(12) Inventory items are designed to assess somatization, sensation-seeking, alexithymia, and overcentrality of drug-taking. Kirsh and colleagues (12) contend that there is a vast middle ground of chronic pain patients who have some of the aforementioned personality traits and who are at risk for problematic drug use unrelated to substance use disorder (SUD). Initial instrument development work has been promising, and a large validation trial is under way.

*Comment:* The CCI will add a great deal to pain treatment planning (i.e., to bring in psychosocial treatments early and to utilize drug regimens that are unlikely to become problematic for psychological reasons) should its psychometrics prove to be acceptable.