

The SISAP: A new screening instrument for identifying potential opioid abusers in the management of chronic nonmalignant pain within general medical practice

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BACKGROUND: Many physicians are overly cautious about prescribing opioids for chronic pain because of fears of iatrogenic addiction. However, in patients with chronic pain, addiction to opioid analgesics is exceedingly rare when there is no prior history of alcohol or drug abuse.

OBJECTIVE: To validate an instrument that separates possible opioid abusers from those who are at low risk.

DESIGN/METHODS: The Screening Instrument for Substance Abuse Potential (SISAP) was designed to identify individuals with a possible substance abuse history quickly and accurately. It is based on the National Alcohol and Drug Use Survey (n=9915). Using the first half of the sample (n=4967), two previously validated alcohol use items were combined with three illicit drug use items. These five questions identified those with a history of alcohol and/or illicit drug use.

RESULTS: Using the second half of the sample (n=4948), the validation procedure showed that the five combined items correctly classified 91% of substance abusers and had a low rate of false negatives.

DISCUSSION: The SISAP is brief and resistant to misrepresentation or falsification. The SISAP is expected to improve pain management by facilitating focus on the appropriate use of opioid

analgesics and therapeutic outcomes in the majority of patients who are not at risk of opioid abuse, while carefully monitoring those who may be at greater risk.

Key Words: *Addiction, Analgesics, Chronic nonmalignant pain, Opioids, Screening Instrument for Substance Abuse Potential (SISAP), Substance abuse testing*

Le SISAP : un nouvel instrument de dépistage des personnes susceptibles d'abuser des opioïdes lors du traitement de la douleur chronique non cancéreuse dans le cadre d'une pratique de médecine générale

HISTORIQUE : De nombreux médecins démontrent une extrême prudence pour prescrire des opioïdes contre la douleur chronique, car ils redoutent le développement d'une dépendance iatrogène. Cependant, chez les patients accusant des douleurs chroniques, la dépendance aux opioïdes analgésiques est extrêmement rare en l'absence d'antécédents d'abus d'alcool ou de drogues.

OBJECTIF : Valider un instrument qui sépare les personnes susceptibles d'abuser des opioïdes de celles qui sont à faible risque.

MODÈLE/MÉTHODES : L'Instrument de dépistage de l'abus potentiel de substances (SISAP : Screening Instrument for Substance Abuse Potential) a été conçu pour identifier rapidement et précisément les personnes ayant possiblement des antécédents d'abus de substances. Cet instrument est basé sur la National Alcohol and Drug Use Survey (n=9915). En utilisant la première moitié de l'échantillon (n=4967), deux items relatifs à la consommation d'alcool, et validés antérieurement, ont été combinés avec trois

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items sur la consommation de drogues illicites. Ces cinq questions ont identifié les personnes ayant des antécédents d'abus d'alcool ou de consommation de drogues illicites.

RÉSULTATS : La procédure de validation a été conduite sur la deuxième moitié de l'échantillon (n=4948). La combinaison des 5 items classifie correctement 91 % des personnes abusant des substances et démontre un faible pourcentage de faux-négatifs.

DISCUSSION : Le SISAP est bref et résiste aux interprétations fautives ou aux falsifications. On s'attend à ce qu'il améliore le traitement de la douleur en permettant de mettre l'emphase sur l'utilisation appropriée des analgésiques opioïdes et sur leurs résultats thérapeutiques chez la plupart des patients qui ne sont pas susceptibles d'abuser des opioïdes, tout en surveillant soigneusement ceux qui présentent un risque plus élevé de dépendance.

Opioids have been used to treat pain since the beginning of recorded history (1,2). Until the early 20th century, these drugs could be readily obtained without prescription (3). Heroin, a synthetic derivative of opium, was known as the 'miracle medicine', and its medical use in treating pain and other related ailments was widely endorsed (3). However, by the 1920s, attitudes shifted and heroin was depicted as an evil that led to rampant addiction and moral corruption (3). Increasing prohibition led to a decline in the prevalence of use, but left a small number of individuals whose deviant lifestyles became associated with opioid use and moral decay (3). Fear of addicting patients to opioids continues to be a major issue for physicians (4-6). Chronic opioid therapy is well accepted as the standard of care in the treatment of cancer pain, but most physicians are reluctant to prescribe these drugs for chronic nonmalignant pain (6). This distinction is somewhat arbitrary, given that nonmalignant pain can be as severe, debilitating and protracted as that experienced by cancer patients (6). Undermedication of nonmalignant pain is widespread and causes needless suffering, despite the fact that adequate analgesia is possible in most cases (4-7).

Mere exposure to opioids does not lead to addiction (8). Kandel and colleagues (9) showed that most opioid abuse follows drug use that begins with tobacco, alcohol and cannabis in early adolescence. In addition, psychological, social and genetic factors play important roles in the etiology of addiction (7,8). Several studies have shown that 3% to 19% of chronic pain patients treated with opioids may become addicted (10), but almost all of those have a previous substance abuse history (11-16). In other words, it is highly unlikely for a person with no previous history of drug or alcohol abuse to become addicted to opioids.

Fear of addiction may be based on superficial similarities between the drug-seeking behaviours of a street addict and those of a chronic pain patient (6,8,17). While a drug abuser actively seeks opioids for their mood-altering properties, the pain patient may actively seek opioids because the pain has not been adequately relieved (6). Addicts typically report experiencing euphoric effects from opioids, whereas in the clinical population, dysphoria is often observed. It is possible that these different reactions to opioids reflect physiological differences or the willingness of addicts to use drugs to cope with difficulties (6,18,19).

There have been many attempts to define addiction. There are at least three aspects of the disorder that recurrently appear in these definitions: loss of control over drug use, compulsive drug use and continued use despite harm (6). However, addiction is often confused with physical dependence and tolerance. Tolerance is a physiological phenomenon in which increasingly larger doses of a drug must be administered to obtain the effects observed with the original dose (2). While chronic pain patients may show some signs

of tolerance, the dose of opioid needed to produce analgesia stabilizes after an initial adjustment phase (5,14,20-22). Furthermore, when higher doses are required, it is usually because of worsening pain, rather than developing tolerance (14). Physical dependence is an altered physiological state produced by repeated administration of a drug, where removal of the drug leads to withdrawal symptoms (2). Symptoms of opioid withdrawal are minimal and short-lived if the opioid analgesic dose is gradually reduced before discontinuation (11,14). Patients who chronically receive opioids will develop physical dependence, which in itself is not harmful (2).

Because the risk of developing iatrogenic addiction to opioids is very small for the average patient (7,14,15,20,22-24), it is important to distinguish those who are prone to becoming addicted to opioids from those who are not. This would allow clinicians to pay closer and ongoing attention to patients with an elevated risk of addiction, and be less concerned with addiction in the majority of patients who are not at risk. The College of Physicians and Surgeons in Alberta (16) and others have developed guidelines for treating chronic nonmalignant pain. The guidelines outline how to use opioids responsibly in pain treatment. Recommendations include the use of a screening instrument (history taking) to determine drug use status of patients because it is rare for patients to become addicted to prescription opioids if they do not have a drug abuse history. This paper is concerned with the development of the Screening Instrument for Substance Abuse Potential (SISAP), a five-item screening questionnaire designed to identify individuals who are at risk of abusing opioids, namely those who use alcohol at problem levels and/or use illicit drugs.

MATERIALS AND METHODS

The SISAP was developed and validated using data from the National Alcohol and Drug use Survey (NADS) of 1989, conducted by Statistics Canada and Health and Welfare Canada (25). The NADS data set is considered to be a representative study of the use of prescription medication, over-the-counter medication, illicit drugs and alcohol in Canada. Two random digit dialling methods were used to select the subjects for the NADS interviews. The 'elimination of nonworking banks design' (26) was used in Newfoundland, Nova Scotia, Ontario and Alberta. The 'Waksberg' method (27) was used for the other provinces. This was done so that Canadian households in general were equally likely to be selected. Both the Waksberg method and the elimination of nonworking banks design generate lists of random telephone numbers. Both methods guarantee random digit dialling.

The data collection was conducted from centralized telephone interviewing locations in the eight regional offices of Statistics Canada. The NADS involved telephone interviews with approximately 11,634 Canadians aged 15 years and older from all 10 provinces.

According to the Highlights report of the NADS, approximately 2% of households in Canada do not have telephones and were therefore excluded from the study. The NADS excluded individuals living in institutions, such as prisons and hospitals. The data were weighted to take into account households without telephones, households where there was no response, multiple telephones in single households, number of individuals living in the household, census projection counts of the provinces, and age and sex of the population. After weighting, the sample size was reduced to 9915 subjects. Seventy-nine per cent of those contacted responded to the interviews. Reasons for the nonresponse rate (21%) included refusal to participate in the survey from either the household or the respondent, illness, injury, absence during the survey, language problems and failure to make contact. The response rate of the NADS (79%) compares favourably with that of other nationwide health surveys (28-30). The impact of the minor selection bias inherent to the NADS methodology is addressed in the Discussion.

The SISAP development took place in two steps. The first step was to develop an operational definition of substance abuse and then identify items in the NADS that best represented that definition. The second step consisted of finding items in the NADS that could be used in clinical settings (ie, physicians' offices) to predict substance abuse accurately. For this study, the NADS data set was randomly split into two subsets; this made it possible to develop the instrument and test its performance on the first subsample (n=4967) and to verify its stability on the second subsample (n=4948) (31).

Development of substance abuse criteria

The first step in the creation of the SISAP was to develop a set of criteria for an operational definition of substance abuse. Alcohol abuse (including early stage problem drinking) and illicit drug use constitute the main types of substance abuse, and both are associated with prescription opioid abuse (7,14,15,20,22-25). Abuse of licit drugs was not included in this definition because most licit drug abuse occurs in a context of alcohol and illicit drug abuse (32,33). Thus the identification of licit drug abuse was inherent to the identification of illicit drug abuse. In the development of this instrument, as in other studies (34-37), alcohol abusers were defined as men who consumed five or more drinks per day or 17 or more drinks per week, and women who consumed four or more drinks per day or 12 or more drinks per week. Illicit drug users were defined as those who had used at least one of the following within the previous 12 months: cannabis, cocaine/crack, lysergic acid diethylamide (LSD), amphetamine and its congeners (speed) or heroin.

Development of predictors (screening instrument questions)

The second step was to identify items from the NADS that could accurately screen substance abusers within a clinical setting. Items selected for inclusion in the screening instrument had to be significantly related to the criterion by univariate analysis; be conceptually related to the criterion; be conceptually different from each other; show good specificity, sensitivity and/or a high rate of correct classification; and appear resistant to falsification by patients. In this context, sensitivity refers to the capacity to classify correctly as abusers those individuals who are in fact substance abusers (ie, correct positives/[correct positives + false negatives]). Specificity refers to the capacity to classify correctly as nonsub-

stance abusers those individuals who are in fact not substance abusers (ie, correct rejections/[correct rejections + false positives]) (38). Correct classification represents hits plus correct rejections. The ideal instrument in this context should correctly identify an acceptable percentage of nonsubstance abusers (specificity) and yield a good correct classification rate. However, it is most important to identify correctly as many actual substance abusers as possible (high sensitivity). The final instrument sacrifices specificity and correct classification rate somewhat to maximize sensitivity.

Alcohol predictors: In the NADS, early stage problem drinking was identified by two commonly used questions: If you drink, how many drinks do you have on a typical day?; and How many drinks do you have in a typical week? These two questions were used as predictors in the screening instrument and have been shown to be effective in correctly classifying problem drinkers (34-37). Approximately 1% to 20% of patients in treatment for alcoholism under-report their previous level of alcohol consumption (39-41). The NADS is an anonymous survey, and the reported levels of alcohol consumption can be expected to be reasonably accurate. However, in the clinical setting of a physician's office (where the screening instrument is to be used), problem drinking patients may be somewhat motivated to under-report their drinking levels. Therefore, an under-reporting factor of 20% was assigned to this question as part of the screening instrument. This was done by randomly selecting 20% of those who had been classified as problem drinkers in the NADS and misclassifying them as nonproblem drinkers. This renders a more conservative estimate of the performance of the instrument and decreases the probability of false negatives.

Illicit drug use predictors: The next step was to develop predictors of illicit drug use. Except in the case of cannabis, directly asking patients about their drug use (eg, heroin or speed) may lead to a high rate of false reporting. For example, self-reports of marijuana use are considerably more valid than self-reports of cocaine use (42). Therefore questions within the NADS that were both unobtrusive and highly correlated with the drug use criteria developed above were identified.

Cannabis use: Many cannabis users appear to view this substance as more socially acceptable than other illicit drugs and are thus more willing to admit to its use than to using other illicit drugs (42-44). Twenty-three per cent of those surveyed reported having ever used cannabis. Seven per cent reported using cannabis within the past year. However, ever use of cannabis was not as effective in identifying other current substance abuse as cannabis use within the last 12 months. Therefore this question was used: Have you used marijuana or hashish in the last year?

While in treatment, illicit drug users are fairly accurate in reporting their drug use when self-reports are compared with biochemical tests (43,45). However, outside of treatment settings the false reporting rate is much higher. When self-reports are compared with urine tests, up to 50% of substance abusers have been found to report falsely in workplace settings (46). Similarly, in physicians' offices, where systematic testing is not possible, a significant number of illicit drug users may falsify their reporting when questioned about cannabis use. Therefore, we assumed a false reporting rate of 50% in response to the cannabis question. This was included in the analysis by randomly selecting 50% of those who had identified

<p>1. If you drink, how many drinks do you have on a typical day? If less than 5 for men/less than 4 for women, then ask question 2. If 5 or more for men/4 or more for women, then you may stop here <i>Use caution when prescribing opioids.</i></p> <p>2. How many drinks do you have in a typical week? If less than 17 for men/less than 13 for women, then ask question 3. If 17 or more for men/13 or more for women, then you may stop here <i>Use caution when prescribing opioids.</i></p> <p>3. Have you used marijuana or hashish in the last year? If no, then ask question 4. If yes, then you may stop here. <i>Use caution when prescribing opioids.</i></p> <p>4. Have you ever smoked cigarettes? If no, then you may stop here <i>Probably a low opioid abuse risk.</i> If yes, then ask question 5.</p> <p>5. What is your age? If under 40 years of age, then you may stop here <i>Use caution when prescribing opioids.</i> If 40 years of age or older, then you may stop here <i>Probably a low opioid abuse risk.</i></p>

Figure 1) Screening Instrument for Substance Abuse Potential

TABLE 1
Performance of items included in the screening instrument

Question	ACTUAL SUBSTANCE ABUSE				Specificity	Sensitivity	Correct classification
	Substance abuser		Nonsubstance abuser				
	PREDICTED SUBSTANCE ABUSE						
	Yes (Hit) (%)	No (Miss) (%)	Yes (False positive) (%)	No (Correct rejection) (%)			
Q1 # drinks/day	12.9	6.3	0	80.8	1.00	0.67	93.7%
Q1a # drinks/day (20% correction)	10.3	8.9	0	80.8	1.00	0.54	91.1%
Q2 # drinks/week	5.5	13.7	0	80.8	1.00	0.29	86.3%
Q2a # drinks/week (20% correction)	4.4	14.8	0	80.8	1.00	0.23	85.2%
Alcohol total (Q1a and 2a)	13.0	6.2	0	80.8	1.00	0.68	93.8%
Q3 use of cannabis	6.9	12.3	0	80.8	1.00	0.36	87.7%
Q3a use of cannabis (50% correction)	3.6	15.6	0	80.8	1.00	0.19	84.4%
Q4 ever smoked	14.5	4.7	43.5	37.3	0.46	0.76	51.8%
Q5 age	14.7	4.5	39.1	41.7	0.52	0.77	56.4%
Illicit drug total (Q3a, 4 and 5)	11.5	7.7	18.6	62.2	0.77	0.60	73.7%
Screening total (Q 1a, 2a, 3a, 4 and 5)	17.4	1.8	18.6	62.2	0.77	0.91	79.6%

Each item was tested for its capacity to classify correctly cases according to the substance abuse criteria derived from the National Alcohol and Drug use Survey (NADS). Questions 1 and 2 assume a 20% false reporting rate. Question 3 assumes a 50% false reporting rate. Item performance was tested on a randomly selected subset comprising half of the NADS subjects (n=4967). Each question was significant at P<0.001. Significance levels relate to the phi statistic, a measure of categorical association

themselves as cannabis users in the NADS and misclassifying them as noncannabis users.

Cigarette smoking and age: Two more items related to illicit drug use were used to help identify substance abusers who denied cannabis use. The two questions, judged unlikely to produce false

reporting, were: Have you ever smoked cigarettes?; and What is your age? In the NADS, the rate of illicit drug use among those over 40 years was so small as to be unmeasurable (25). The majority of illicit drug use occurs in those younger than age 40. The NADS showed that more than 70% of those younger than 40 years of age

had neither an alcohol nor a drug problem, but this figure rises to approximately 90% in those older than 40 years of age. Finally, the majority of problem drinkers and illicit drug users smoke cigarettes (47,48).

Sequence of screening instrument questions: After identifying the five predictors listed above, the questions were formatted for use in a clinical setting. The SISAP is organized such that a patient undergoing examination can pass or fail at any stage of the screening. Figure 1 outlines the correct sequence of questions in the instrument. Specifically, the first two questions asked are about alcohol use to determine whether a patient is drinking at problem levels. If the patient is drinking at problem levels, the interviewer may stop and opt to use caution in prescribing opioids. If the patient does not report alcohol use at problem levels, testing should proceed to the next question.

The next step is to identify those who use illicit drugs. Question 3 collects information about the patient’s cannabis use within the past year. If the patient responds yes, the interviewer may stop and should use caution when prescribing opioids. For those who deny cannabis use, the patient should be asked whether he or she smokes cigarettes. If the answer is no, that patient is declared to have a low probability of opioid abuse. If the patient does smoke cigarettes, then the physician proceeds to the last question, which asks the patient’s age. If the patient is under 40 and smokes, the physician should use caution when prescribing opioids.

Once the questions were selected and organized into a suitable sequence (see Figure 1) on the basis of their performance on the first NADS subset (n=4967), they were validated on the second subset (n=4948). Validation was done by measuring how well the instrument performed as a whole in identifying problem drinkers and illicit drug users, as defined by the substance abuse criteria outlined in the ‘Development of substance abuse criteria’ section above.

RESULTS

Results from the development of the SISAP

Individual question performance: Predictors selected according to the criteria outlined in ‘Development of predictors’ were individually tested for their capacity to classify correctly individuals identified as substance abusers. This first level of testing was done on the first half of the NADS. The performance of each question is illustrated in Table 1 and is described in detail below.

The two questions used to identify alcohol abusers were: If you drink, how many drinks do you have on a typical day?; and How many drinks do you have in a typical week? As noted in the ‘Materials and Methods’, a 20% false reporting rate was added to approximate the false reporting that may occur in clinical settings. Therefore, these two questions identified 80% of all alcohol abusers within the group of substance abusers defined by the criteria for substance abuse. Together, these questions correctly classified 68% of all substance abusers.

The question, Have you used marijuana or hashish in the last year?, correctly classified 36% of substance abusers, without a correction rate. Because a 50% false reporting rate was superimposed to remain conservative in the evaluation of the overall performance of the instrument, the question correctly identified 19% of substance abusers. The questions, Have you ever smoked cigarettes?

TABLE 2
Validation of the opioid abuse screening instrument conducted by testing the questions from the screening instrument on the second half of the NADS sample (n=4948)

		Actual substance abuse (licit or illicit)		Total
		Substance abuser	Nonsubstance abuser	
Predicted substance abuse	Substance abuser	16.0% correct positive	18.2% false positive	34.2%
	Nonsubstance abuser	1.6% false negative	64.2% correct negative	65.8%
Total		17.6%	82.4%	100%

NADS National Alcohol and Drug use Survey

and What is your age?, correctly classified 76% and 77% of substance abusers, respectively.

Performance of the total screening instrument: The five questions combined correctly identified 91% of substance abusers (17.4%/ 19.2%) and 77% (62.2%/80.8%) of nonsubstance abusers as defined by the study criteria. Overall, the instrument correctly classified 79.6% of all cases (substance abusers and nonsubstance abusers).

Validation of the screening instrument

The next step was to verify the stability of the screening instrument. While the first half of the total subject pool was used to develop and test the performance of the instrument, the second half was used to test its stability (31).

All five questions, used according to the sequence outlined in Figure 1, were used to identify substance abusers in the second half of the NADS sample (Table 2). The screening instrument performed virtually identically on the second half of the NADS data set as it had on the first half. The phi test of association was used for these data because the presence of cell frequencies of zero precludes use of the ² statistic and because phi is a measure of categorical association and is similar to correlation, which fits the goals of this study (49). The phi associated with the cell frequencies was significant: $r_{\phi}=0.699, P<0.001$. The correct classification rate for the SISAP was 80.2% (correct positive and correct negative), meaning that 91% of actual substance abusers were correctly identified by the screening instrument (16.0%/17.6%) and 78% of the nonsubstance abusers were correctly classified (64.2%/82.4%). Thus, the sensitivity and specificity of the SISAP were 0.91 and 0.78, respectively.

DISCUSSION

The SISAP is useful in identifying patients who are expected to be at risk of abusing opioids. It is conceptually related to previously published screening instruments for substance abuse (50,51), simple to use, typically requires only a few minutes to administer and is designed to minimize misrepresentation and falsification. The instrument exhibits good sensitivity – 91% of substance abusers are correctly identified – and good specificity – 78% of nonsubstance abusers are correctly identified.

The performance of the SISAP is comparable with that of well known instruments such as the Michigan Alcohol Screening Test

(MAST) (sensitivity 0.96, specificity 0.51) (50) and the Drug Abuse Screening Test (DAST) (sensitivity 0.99, specificity 0.76) (51). Both the MAST and the DAST contain more items and take much longer to administer than this instrument. The SISAP is also quite conservative. While the MAST and DAST assess the severity of an already diagnosed substance abuse problem, this instrument detects individuals who may be at risk of developing a substance abuse problem, based on a level of current substance abuse that can be very low. Finally, the SISAP was developed specifically for general and family practitioners to use to identify those who may be at risk of abusing opioids within the context of their clinical practice.

The development and validation of the SISAP was carried out on the NADS. This data set is considered a representative study of the use of prescription medication, over-the-counter medication, illicit drugs and alcohol in Canada. However, the NADS data may underrepresent the number of substance abusers in Canada due to a systematic selection bias. For example, according to the NADS highlights report, approximately 2% of households in Canada do not have telephones and were therefore not included within the sample of respondents. Households without telephones are generally inhabited by young, single men who are less educated than the general population (52,53). This bias underestimates the prevalence of substance abusers in the NADS population since other studies have shown that young, single males of lower education are more likely to abuse drugs and alcohol than other groups (54).

Anonymous surveys such as the NADS are likely to provide the most accurate type of self-report information available regarding licit and illicit drug use because anonymity reduces the likelihood of under-reporting (55). Of those who qualified for inclusion in the NADS, a number declined to participate. This may also underestimate the prevalence of substance abusers within this sample; individuals who are reluctant to disclose their alcohol and/or drug consumption are probably more likely to decline to participate in such a study. One may speculate that such individuals are more likely to be substance abusers than those who willingly disclose their alcohol and/or drug consumption. Finally, the NADS excluded individuals living in institutions, such as prisons and hospitals. This is also likely to underestimate the prevalence of substance abusers in Canada because inmates and hospitalized patients are more likely to be substance abusers than the general population (54,56,57).

In summary, the NADS has selection biases that underestimate the prevalence of substance abusers in Canada. This can be a concern because the SISAP was developed on the basis of its capacity to identify substance abusers classified as such by the NADS. However this bias appears to be small, given that the populations excluded from the NADS represent a small proportion of Canadians. Individuals who declined to respond could be a concern, but the NADS had a very high response rate. Therefore, this is unlikely to have had a significant impact. In general, the pattern of substance abuse among the nonresponders could be expected to be the same or more severe than that of the responders. Thus, it is likely that the screening instrument would have detected substance abuse among nonresponders as well as it had detected it among responders.

Substance abusers were defined as problem drinkers or illicit drug users, and questions were selected for inclusion in the instrument only if they correctly assigned individuals to one of these two groups. The validity of the alcohol use questions has been estab-

lished (34-37). The sensitivity of the alcohol questions is not as strong as was shown in previous studies (34-37), for two reasons. First, all previous studies were conducted on patients in treatment for problem drinking. Because the reporting rates in physicians' offices may be less accurate than those for patients in treatment for alcohol abuse, the maximum false reporting rate found in the literature of 20% was applied (39-41). This necessarily decreased the sensitivity of the alcohol questions. The second reason for the decreased sensitivity of the alcohol questions is that the two alcohol questions identify only one type of abuser, while the goal of the SISAP was to identify both problem drinkers and illicit substance abusers. Alcohol abusers and illicit drug abusers are not mutually exclusive populations, and it is desirable to assess the performance of each question on both of these types of abusers. However, the sensitivity of the alcohol questions appears somewhat reduced because illicit drug users in the population are not well detected by the alcohol questions. Similarly, the sensitivity of the illicit drug use questions is underestimated because the problem drinkers in the population are not well detected by the illicit drug use questions.

Question four, Have you ever smoked cigarettes?, was designed to identify substance abusers on the basis of their cigarette smoking behaviour. More substance abusers were identified when both previous smoking and current smoking behaviour were used as predictors. This suggests that many individuals who formerly smoked cigarettes continue to abuse drugs or alcohol. Previous research indicates that most illicit drug users are smokers (58), which confirms that individuals who have never smoked are at a low risk for substance abuse. The NADS also shows that heavy drug users are more likely to smoke and to smoke more than the general population (25). Of course, many smokers are not illicit drug users. Question 5, inquiring about the individual's age, is useful to clarify which smokers might be at risk of substance abuse. If the patient smokes and is younger than 40 years, he or she is at increased risk of abusing substances. The rates of illicit drug use among those older than 40 years of age is extremely low (25). Therefore, those older than 40 who report that they have never smoked are considered to be at low risk for abusing opioids.

In combination, the alcohol questions (1 and 2) have reasonable specificity and sensitivity (1.00 and 0.68, respectively) (Table 1). The illicit drug screening questions (3, 4 and 5) also show reasonable specificity and sensitivity (0.77 and 0.60, respectively) (Table 1). The number of misses is relatively high; this is because some problem drinkers do not have an illicit drug use problem and vice versa. The alcohol questions combined with the drug questions correctly identify 91% of all substance abusers (Table 2).

False negatives are a problem within a clinical setting. However, substance abusers were labelled as such according to very stringent criteria. For example, an individual who took one puff of a marijuana cigarette in the previous 12 months would have been classified as a substance abuser. This may be missed by the screening instrument if an individual forgets to mention it. Technically, this would be a false negative. However, the level of risk of addiction to prescription opioids for individuals with such low levels of consumption is unclear. Severe substance abusers are unlikely to be missed by this instrument. By definition, such individuals are usually either alcoholics, drug addicts or both. Alcoholics are likely to consume large amounts of alcohol and to report levels of consump-

tion that exceed the cutoffs used here, even if they minimize their drinking. Drug addicts are more likely to be younger than age 40 and to smoke. In the NADS, the likelihood of smoking increases with the variety of illicit drugs used by an individual ($r=0.16$, $P<0.001$).

Eighteen per cent of the population were incorrectly classified as substance abusers by the SISAP (Table 2). While this figure may appear to be a large rate of false positives, it has the advantage of decreasing the possibility of falsely classifying substance abusers as nonsubstance abusers. Being classified as a potential substance abuser or high risk patient does not absolutely contraindicate opioid therapy. In some cases, it may be acceptable to prescribe opioids to those who have an elevated risk of abusing them. This may be justified if the pain is significant, other medications are unsatisfactory, the patient is known to the physician and prescription use is carefully monitored. Treatment contracts are particularly useful for patients classified as high risk by the SISAP (5). Referral of high risk patients for substance abuse treatment is also recommended (37).

The SISAP is to be used within clinical practice, where the clinical judgement of the physician plays an important role. Despite the high correct classification rate of the SISAP, it cannot replace clinical judgement or intuition. It is likely to work best when the patient is well known to the physician. The SISAP should not be the sole component in the process of deciding to prescribe opioids because

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- Moulin DE, Iezzi A, Amireh R, Sharpe WKJ, Boyd D, Merskey H. substance-abusing patients may inaccurately report alcohol or drug use. Although it is designed to correct for this problem, falsification beyond the screening capabilities of the SISAP may still occur, particularly among patients who are less familiar to the physician. Physicians should be wary of patients treated with opioids who show evidence of worsening function, unauthorized dose increases, violation of treatment contracts, anomalous drug seeking behaviour, or intoxication or withdrawal symptoms during interviews because these are all signs of addiction (16).
- The screening instrument described has been subjected to a first level of validation. Further validation is needed to confirm its usefulness. For example, future research should investigate the capacity of the SISAP to distinguish between substance abusers and nonabusers in a clinical setting. Research should also focus on physicians' perceived usefulness of the SISAP in their clinical practices.

CONCLUSIONS

The SISAP exhibits good specificity and sensitivity, a high correct classification rate and a low rate of misses, but clinical judgment and intuition should be used to supplement its efficacy. This instrument promises to improve the management of pain by increasing opioid availability to those who are not at risk of opioid abuse and to improve the care, monitoring or referral of those who are at risk.

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