

**METHODS FOR MONITORING MEDICATION USE IN CHRONIC PAIN  
PATIENTS\***

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## **ABSTRACT**

The purpose of this present article is to review the best methods for helping to assess chronic pain patients who are potentially at-risk for misuse/abuse of pain-reduction medications. Based upon this review, a recommendation is made to conduct a comprehensive biopsychosocial assessment of such patients, with questionnaire/tools specifically developed for evaluating potential for abuse/misuse. The Pain Medication Questionnaire is used as an example of one such tool. The advantages of this comprehensive assessment approach, which has been shown to be the most heuristic perspective for the evaluation and treatment of chronic pain, is discussed. Finally, an algorithm for the ongoing evaluation of opioid treatment is presented.

*“... the need to strike a balance between risk management strategies to prevent and deter prescription opioid abuse and the need for physicians and patients to have appropriate access to opioid pharmaceuticals for the treatment of pain”<sup>3</sup>(p. 215)*

## OVERVIEW

As Katz and Barkin<sup>4</sup> have recently reviewed, although a variety of pharmacologic treatments are currently available for use with patients suffering from chronic and persistent pain, such pain is often inadequately managed. This results in such pain remaining a substantial problem for patients and society as a whole. Katz and Barkin go on to point out a number of reasons for the inadequate pharmacologic treatment: the need for multiple doses of opiates for continuous pain relief, with the resultant inconvenience/time-compliance issues that may prevent patients from achieving adequate pain relief; side effects, such as gastrointestinal, cardiovascular, and organ toxicity; and the fear of abuse or addiction. Of these aforementioned reasons, the one which is of special concern for many health care professionals is the fear of potential perceived complicity on their part in increasing abuse or addiction (see<sup>5</sup>). Indeed, in an effort to control the potential misuse/abuse of controlled substances such as opiates in our society, which is escalating at a rate commensurate with the number of prescriptions<sup>6,7</sup>, prescribing physicians are legally required to consider a number of issues prior to dispensing such prescriptions: the drug must be for justifiable medical use; patients must be assessed for possible current addiction prior to dispensing a prescription; and accurate records of prescribing practices for each patient must be kept in each patient's chart,

which are subject to a Drug Enforcement Agency (DEA) audit at any time. Medical licenses have been revoked for failure to adhere to the above. As a consequence, many physicians have developed “opiophobia” (a term coined by the pharmacologist John Morgan in 1986). This term is defined as a fear of opiate prescribing, with an inherent prejudice against these types of drugs, regardless of appropriate clinical utility.

Thus, today, we are faced with a major conundrum: despite the benefits of opioid therapy for many patients, and the growing number of such medications available for patients with chronic pain (e.g.<sup>8,9</sup>), many physicians hesitate to prescribe them because they are either “opiophobic” or do not have an adequate understanding of the risks for potential misuse or abuse. As Turk, Swanson and Gatchel<sup>2</sup> have reviewed, this has stimulated a search for strategies to identify patients who are at-risk for the potential of misuse or abuse. Turk, Swanson and Gatchel<sup>2</sup> have also noted that a subset of patients (estimated to be anywhere from 2.8% to 62.2%), depending on the study and patient group evaluated, have such potential (e.g.<sup>7, 10-12</sup>). Of course, for these patients, *greater vigilance* is required. Thus, the following guidelines should be followed: (1) have a single physician take the primary responsibility for the opioid medication; (2) do not refill prescriptions over the telephone; the patient needs to be evaluated in person when the prescription is to be refilled; (3) a clear Medication Agreement is needed to delineate what “emergency” situations will allow an early refill of a prescription. These early refills need to be minimized and carefully monitored, using only one pharmacy.

In passing, the terms “abuse” and “misuse” will be used throughout this paper. *Abuse* is a diagnostic category of the DSM-IV to refer to a maladaptive pattern of psychoactive substance usage outside sociocultural conventions, or when there are no

longer positive therapeutic indications. As noted by Polatin and Gajraj<sup>13</sup>: “By definition, all use of illicit drugs is abuse, as is use of drugs not according to a physician’s orders” (pp. 276-277). The term *misuse* reflects the latter part of the above quotation; that is to say, not using the medication in the prescribed manner.

With the above issues in mind, an important goal for those advocating the use of opioid medication is the development of a reliable method to evaluate the patient-risk associated with potential abuse/misuse. This is especially important for patients with chronic pain, where urine toxicology screening results indicate that such abuse/misuse is a significant problem for chronic pain patients treated with opioids (with a range from 27.2% to 42%<sup>2</sup>). Indeed, as noted by Ballantyne and Mao<sup>14</sup>, the optimally effective use of opioids must include an evaluation of the potential for abuse in all patients being considered for opioid therapy.

At the outset, it should also be kept in mind that the use of opioid therapy for chronic pain should be only one part of a more comprehensive biopsychosocial evaluation of the chronic pain patient. As previously elucidated by Gatchel<sup>15</sup> and Turk and Monarch<sup>16</sup>, the biopsychosocial model has become the most heuristic approach to truly understanding and treating chronic pain. This model views a physical syndrome, such as chronic pain, as the result of an intricate and dynamic interaction among biological, psychological and social factors that can often exacerbate the pain condition. Thus, individuals tend to express variability in their pain experiences due to the range of interaction of these factors that modulate the interpretation of symptoms. The biopsychosocial model, therefore, uses physical, psychological, social, cognitive, affective, and behavioral measures—along with their interactions—to best assess the

individual's unique pain condition. Factors such as a patient's positive/negative coping skills, current level of stress, social support, negative cognitions (such as catastrophizing), etc. must be taken into account in order to get a "complete picture" of the patient's strengths and weaknesses. A treatment program can then be tailored to each patient so as to further maximize his/her strengths, and to help eliminate the weaknesses. Obviously, assessment data are also greatly needed by the health-care professional in order to more effectively evaluate the potential benefits-risks of prescribing long-term opioid treatment.

### **MONITORING THE POTENTIAL FOR MEDICATION ABUSE/MISUSE**

The purpose of the present article is to review the best methods for helping to assess potential at-risk patients for misuse/abuse of pain-reduction medications. This will be a synthesis of some recent reviews on the topic by Bernstein, Stowell et al <sup>5</sup>, Schatman <sup>17</sup>, and Turk, Swanson and Gatchel <sup>2</sup>. Of course, the "gold standard" for detecting drug use (be it substance abuse, misuse or simply recreational use) is urine toxicology screens, which many suggest should be routinely used for all patients who receive chronic opioids <sup>18</sup>. However, as noted by Turk et al <sup>2</sup>, even these results need to be interpreted with some caution because of the following:

- Lack of an initially positive urine screen cannot be mindlessly used as a predictor of all future drug abuse/misuse behavior in all patients.
- Katz et al <sup>19</sup> have shown that even patients with an initially negative screen may subsequently display behaviors indicative of substance abuse/misuse.
- Katz et al <sup>19</sup> have also shown that an initial positive urine toxicology screen may not predict future abuse/misuse problems.

One important “starting point” for avoiding the potential of medication abuse is to address the issue at the very beginning of any intervention. A *Medication Agreement* can help achieve this by clearly stating that it is the responsibility of the patient not to misuse any drugs, and having the patient sign an agreement to that effect. In passing, it should also be noted that the term *agreement* should be used rather than *contract*, because the latter implies a legal document (which it is not <sup>15</sup>). Moreover, if the patient has many medications prescribed over the years by many different physicians (e.g., benzodiazepine for anxiety/stress, a muscle relaxant, a medication for sleep, as well as multiple narcotic medications for pain), then a detoxification program (either in-patient or out-patient) may need to be prescribed so that the patient-physician team can start a new opioid intervention strategy with a “clean slate.” Unfortunately, there are no standard empirical guidelines to make this decision, and it has been generally left to the clinician’s preference/experience with such issues.

## **MEASURES FOR MONITORING POTENTIAL MEDICATION ABUSE/MISUSE**

Of course, we are still left with the issue of what other measure(s) can be used to “flag” those patients who are potentially “at risk” for future medication abuse/misuse so that physicians will be able to take “special precautions” in treating them. In response to this, a number of instruments have been developed. Table 1 provides a listing of those that fall into this category. It has been adapted from Turk, Swanson and Gatchel <sup>2</sup>

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**INSERT TABLE 1 ABOUT HERE**  
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Of the above instruments, the *Pain Medication Questionnaire* (PMQ) has been receiving a great deal of interest as a result of the initial studies by Adams, Gatchel et al.,<sup>20</sup> and Holmes, Gatchel et al.<sup>21</sup>. As a result, for the purpose of brevity, the present article will focus on this questionnaire. The PMQ was designed to assess the risk for medication misuse in chronic pain patients. Adams, Gatchel et al.<sup>20</sup> initially found a positive relationship between higher PMQ scores and concurrent measures of substance abuse, psychopathology, and physical/life-functioning. Holmes, Gatchel et al.<sup>21</sup> subsequently replicated these results, and also found that high PMQ score patients were:

- 2.6 times more likely to have a known substance-abuse problem, relative to low PMQ score patients.
- 3.2 times more likely to request early refills of prescription medications.
- 2.3 times more likely to drop out of treatment.
- Had diminished biopsychosocial functioning.
- 6-months following treatment discharge, patients who completed the program showed a significant decrease in PMQ scores over time.

There are also a number of other important benefits of using the PMQ. For example, it has been shown to be psychometrically-sound. The two core psychometric properties of any test are *reliability* and *validity*. Reliability refers to the reproducibility of a test from one administration to the next. One would expect that if a test is administered at two points in time, with no major intervening circumstances possibly affecting the test, then the test-retest reliability should be high. The PMQ has been shown to have good reliability (e.g., test-retest reliability coefficient of 0.86; internal consistency, Chronbach's alpha=0.73). Validity refers to the appropriateness and



usefulness of a particular test or measurement in making an inference about an individual's behavior (in this case, the potential for medication misuse by a patient). The PMQ has also been shown to have good validity (e.g., concurrent validity with indices of substance use/abuse,  $p < .01$ ; known opioid abuse,  $p < .05$ ).

The PMQ is also a brief 26-item self-report instrument which can be easily filled out by patients (it also only requires a third-grade reading level). Finally, the other advantages of using the PMQ include the following:

- Good to use to demonstrate due diligence in monitoring prescription use for any potential DEA audit.
- Increased quality assurance of treatment program, as well as “tailoring” program to specific needs of patients.
- Can produce better overall outcomes of program – good “PR” to use with insurance carriers.
- High sensitivity = .90

## **SUMMARY AND CONCLUSIONS**

Opioids and other pain-reducing medications (such as benzodiazepines, anti-depressants, neuroleptics) have a very important role in chronic pain management. However, because of the cultural-legal atmosphere in the U.S. against narcotics, health care professionals get “mixed messages” from federal agencies about over-utilizing or under-utilizing such medications. Also, many physicians are not blameless in this area, because they have often been quite cavalier in the past in their prescription behaviors. With this universal precaution in mind, health-care providers are required to document the steps they have taken to minimize the risk of potential abuse/misuse of opioid

medications they prescribe. The use of an at-risk screening instrument, such as the PMQ, should be used with the other data gleaned from the rest of the biopsychosocial assessment material in order to maximize obtaining the best estimate of risk potential. An algorithm for the ongoing evaluation of opioid treatment is presented in Figure 1.

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Finally, another important aspect in the treatment of chronic pain is that simple monotherapy (such as opioid therapy alone) is not as effective as a more comprehensive, interdisciplinary pain management program<sup>22</sup>. Such interdisciplinary programs require the integrated treatment of all the biopsychosocial aspects of the chronic pain syndrome<sup>15</sup>. This includes pharmacotherapy, behavioral medicine treatment, physical therapy and occupational therapy, all coordinated by a physician-nurse team. Also, an appropriate “exit strategy” needs to be in place to discontinue the use of opioids whenever a patient is not attaining appropriate goals of the comprehensive treatment program, or if problematic behaviors develop and persist over time.

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**Table 1. Methods Developed to Identify Potential Medication Misuse**

Interviews and Observations<sup>23</sup>

- Aberrant Behaviors Identified by Clinicians (e.g. <sup>24, 25</sup>). Such behaviors include: forging prescriptions; stealing or borrowing drugs; frequently losing prescriptions; and resisting changes to medication, despite adverse side effects.
- Checklist of Risk Behaviors (e.g. <sup>11</sup>). This Checklist consists of the following items: patient's strong focus on opioids during treatment; a pattern of early refills or escalating medication use in the absence of positive clinical change; multiple telephone calls or visits related to requests for opioid prescriptions; a pattern of prescription "problems" (e.g., lost or stolen medication); and access to supplemental sources of opioids.
- Prescription Drug Use Questionnaire (PDUQ <sup>26</sup>). The PDUQ follows a structured interview format, with patients being questioned about a number of factors: their pain condition; opioid use pattern; family history of pain and substance abuse; social and family factors; history of substance abuse; and psychiatric history. One limitation of the PDUQ is that it must be administered by a trained clinician.

Self-Report Questionnaires

- The Screening Tool for Addiction Risk (STAR <sup>27</sup>). The STAR consists of questions about the following: employment status; history of, and current presence of, emotional problems, drug/alcohol/cigarette use and treatment;

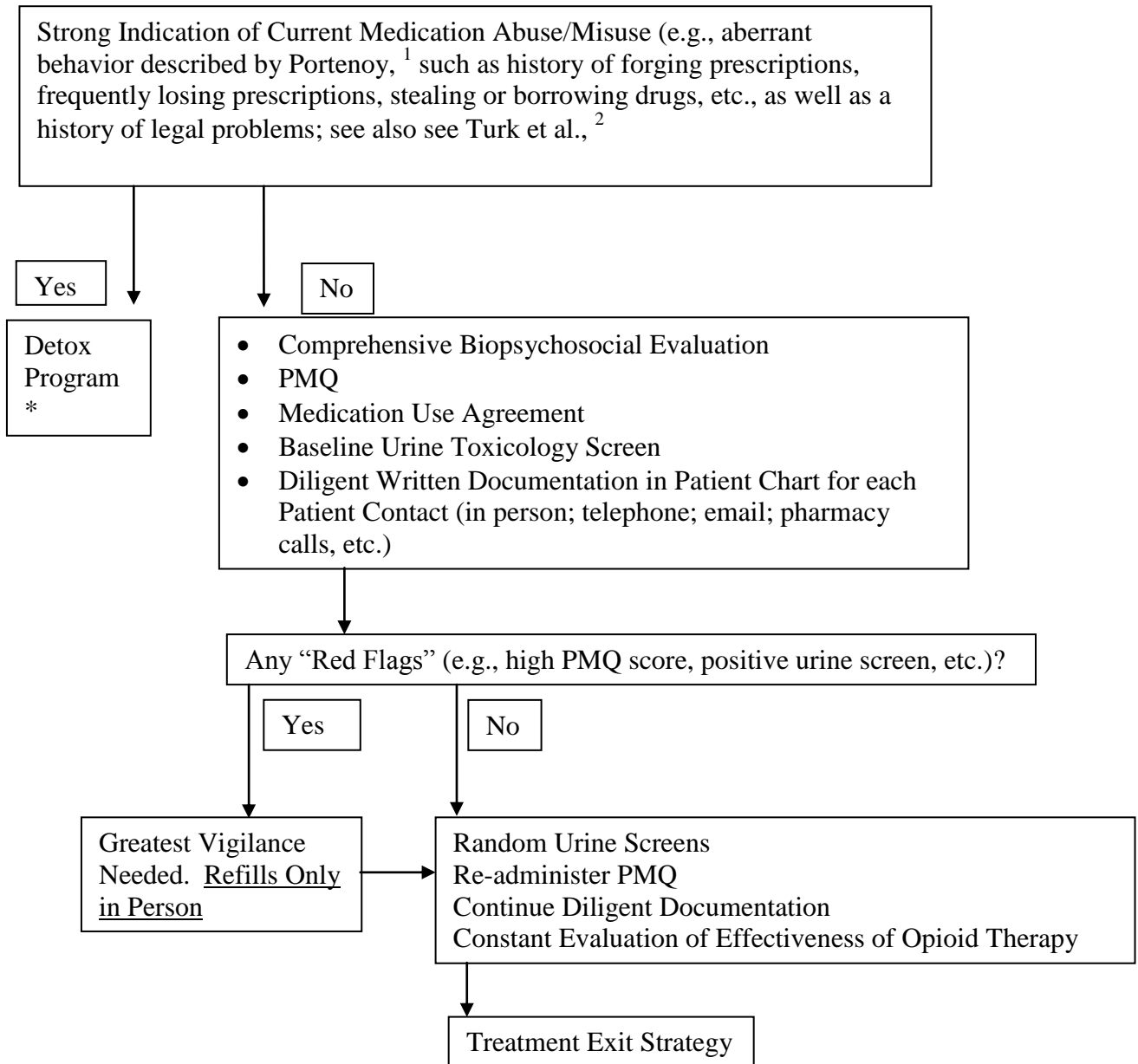
family history of illicit drugs, pain treatment; and history of childhood physical or verbal abuse.

- The Screening Instrument for Substance Abuse Potential (SISAP<sup>23</sup>). The SISAP was designed to work best as an adjunct, when the patient is well known to the clinician, as well as in a clinical practice where the clinical judgment of the clinician plays an important role. It was developed and validated using data acquired from a population-based telephone National Alcohol and Drug Use Survey conducted by the Statistics Canada and Health and Welfare Canada in 1989.
- Screener and Opioid Assessment for Patients with Pain (SOAPP<sup>28</sup>). The SOAPP includes questions about substance abuse, medication use problems, smoking behavior, psychosocial problems and legal problems. Questions were based on items that were provided by an expert panel asked to identify and rate risk factors of potential problems of opioid use by chronic pain patients.
- Opioid Risk Tool (ORT<sup>29</sup>). The ORT includes questions in the following areas: family history and personal history of substance abuse; psychiatric diagnoses; history of sexual abuse; and age. The questions are weighted, and then summed together to yield a level of risk.
- Current Opioid Misuse Measure (COMM<sup>30</sup>). The major goal of the COMM, in contrast to the other measures discussed, is to monitor the misuse of medications in patients who have been prescribed opioids over an extended period of time. An expert panel of pain and addiction specialists, as well as



primary care providers, identified a specific list of aberrant and drug-related behaviors of chronic pain patients who were already prescribed and taking opioids.

- Pain Medication Questionnaire (PMQ<sup>20</sup>). The PMQ has been described at length in this article.



\* It should be noted that, as indicated earlier in this article, there are no standard empirical guidelines to make the decision for the need of a detoxification program, and it has been generally left to the clinician’s preference/experience with such issues. Many factors need to be considered and, when in doubt, getting a consult from a pain management-addiction specialist should be considered.

**Figure 1. Proposed algorithm for the ongoing evaluation of opioid treatment.**

## CME QUIZ QUESTIONS

- 1) When prescribing opiate prescriptions, physicians are legally required to do all of the following EXCEPT:
  - a The drug must be shown to be for justifiable medical use.
  - b Patients must be assessed for possible current addiction prior to dispensing a prescription.
  - c Accurate records of prescribing practices for each patient must be kept in each patient's chart.
  - d Be amenable to DEA audits
  - e Must consider all potential side effects of any medication.\*
  
- 2) Who coined the term "opiophobia"?
  - a Sigmund Freud
  - b Ronald Melzack
  - c John Morgan\*
  - d H. K. Beecher
  - e John Loesser
  
- 3) What is considered the "gold standard" for detecting possible substance abuse?
  - a A physician's medical evaluation.
  - b Psychological tests such as the MPI.
  - c A patient's past history of substance abuse.
  - d A urine toxicology screen\*
  - e A functional capacity evaluation

- 4) Which of the following is NOT a self-report measure specifically developed for identifying potential medication abuse/misuse?
- a The Pain Medication Questionnaire
  - b The Screening Tool for Addiction Risk
  - c The SOAPP
  - d The DSM-IV\*
  - e Opioid Risk Tool
- 5) What does “psychometrically-sound” mean when describing a self-report questionnaire?
- a The questionnaire has been used a great deal.
  - b The questionnaire was developed for a specific group of patients.
  - c Patients do not hesitate answering the questions on it.
  - d The questionnaire is easy to read
  - e The questionnaire has good reliability and validity.\*
- 6) What is the major reason why health care professionals receive “mixed messages” from federal agencies about over-utilizing or under-utilizing opioid medications for pain?
- a Because of the uncertainty of the drugs’ effectiveness.
  - b Because of the cultural-legal atmosphere in the U.S. against narcotics.\*
  - c Because all physicians have a tendency to over-prescribe such medications.
  - d Because of the high costs of such medications.
  - e Because these drugs can be purchased “over the counter.”

- 7) The most effective assessment approach for evaluating potential medication misuse in patients is:
- a A comprehensive assessment of all patients.
  - b A comprehensive assessment of all patients, along with the use of a specific “at-risk” questionnaire.\*
  - c There is no effective way.
  - d The use of insurance companies to keep track of medication refill patterns.
  - e A clinical interview with the patient.
- 8) The most effective treatment approach for patients who potentially require the use of opiate medication is:
- a The use of opiate medication is only needed.
  - b The use of opiates with other medications.
  - c An in-patient treatment program.
  - d A comprehensive interdisciplinary pain management program.\*
  - e There is currently no effective treatment.