Identifying and managing the risk of opioid misuse

Opioids have become an accepted, if sometimes debated, part of pain management. With increased use, there has been a rise in the abuse and diversion of opioids. Providers need to acknowledge this relationship and perform due diligence when assessing whether a patient with chronic pain is a good candidate for a trial of opioid therapy, and assess the amount of oversight and monitoring needed based upon potential risk factors. While it might be advantageous to consult a board-certified pain practitioner, the reality is that there are few such practitioners available, and the job of treating pain often falls to the primary care provider. To aid in the endeavor, several suggestions for practice are made to help primary care providers feel more comfortable treating pain patients.

Chronic pain, whether cancer-related or nonmalignant, is a significant medical problem in the USA. More than 75 million Americans suffer with chronic pain, causing a drain on medical services, an increase in vocational and other forms of disability, and untold social, familial and personal consequences [1–4,101]. Recent advances in pain management, such as the wider use of opioids in the treatment of non-cancer pain and the emergence of new adjuvant analgesic drugs, have relieved the symptoms of an increasing number of patients. It should be noted, however, that some healthcare practitioners have expressed growing discomfort with opioid therapy and pharmacological treatment in general [5,6]. In addition to fears of regulatory scrutiny, this disillusionment may stem from the negative outcomes (i.e., initial trial of opioids leading to escalating doses without an exit strategy, lack of oversight associated with short monthly or tri-monthly visits, lack of increased functionality as a result of treatment but patient’s unwillingness to change therapies, and so on) associated with the frequent administration of opioid monotherapy instead of a more comprehensive treatment plan (i.e., making referrals to physical therapy and behavioral medicine, along with evaluation for injective therapies). Indeed, given the prevalence of addiction, misuse, diversion and/or efficacy issues often associated with opioid monotherapy, it is no surprise that many in the practitioner community are uncomfortable prescribing a controversial and complicated treatment option.

The potentially negative outcomes of opioid therapy have far-reaching implications. Prescription opioid abuse has increased seven-times faster than cocaine use, and almost 100-times faster than heroin use within the past decade [102]. According to the National Survey on Drug Use and Health, the number of prescription opioid initiates among persons aged 12 years or older in 2005 was 2.2 million, compared with 872,000 for cocaine initiates and 108,000 for heroin initiates [103].

In addition to abuse, the related problem of diversion should be considered. While activities defined as diversion vary by state, between researchers, and among law enforcement agencies, diversion has been characterized as the criminal behavior that moves legally obtainable drugs into illegal channels [7,8,104]. The Drug Enforcement Administration (DEA) classifies certain activities as diversion [105,106]. These activities include: unauthorized removal of opioids from manufacturing plants and distribution centers; illegal sales of prescriptions by physicians and pharmacists; ‘doctor shopping’ by individuals who visit multiple physicians to obtain prescriptions; theft, forgery, or alteration of prescriptions by patients; robberies from pharmacies; thefts of prescription pads and institutional drug supplies; cross-border smuggling by traffickers and tourists; medicine cabinet thefts by family and friends; and shipments via nonlegitimate internet sources [9]. In addition, sharing of controlled substances such as opioids, even for the treatment of legitimate pain problems, is considered diversion, because

KEYWORDS: abuse assessment diversion misuse opioids

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there is no recognized prescriber–patient relationship. While the magnitude of prescription opioid diversion is not clear owing to some limitations of sampling and reporting, the DEA estimates that prescription drug diversion is a US$25 billion a year industry [107]. Surveys and studies have found that a limited number of reported abusers obtain medication from their own prescriptions; the top two sources of opioids are dealers, friends and families [108].

With these challenges complicating the decision to treat or not treat a patient with chronic pain issues, prescribers must think about the risk profile of the patient across from them before making the decision to initiate a trial of opioid therapy. To this end, the preopioid prescribing period (POPP) becomes a critical stage in the therapeutic relationship. Some guidance to approaching this important period follows.

The preopioid period
The POPP is the period during which the physician determines whether opioids should be prescribed. The POPP provides an opportunity for the clinician to review the patient’s case and again confirm that the benefits of chronic opioid therapy (COT) (i.e., increased analgesia, along with increased functioning) outweigh the risks (i.e., intolerable side effects, presence of potentially aberrant drug-taking behaviors) for this particular patient. Also, it is the time in which providers may gather as much information as is appropriate surrounding the patient’s baseline ‘preopioid’ pain and its impact on their baseline ‘preopioid’ functional status, physical abilities, endurance, range of motion, emotional status, social/recreational activities, neurocognitive status and overall quality of life. Furthermore, the POPP is when providers have a further chance to engage in ‘preopioid’ patient counseling and patient education, as well as having patients read and sign informed consent for COT, opioid agreements and other potential agreements/tools/tests (e.g., urine drug testing). However, consideration must be given to balancing real-world concerns, such as time management with patients and the limitations placed upon prescribers by insurance, and a general lack of understanding towards reimbursing this much-needed period. The POPP also provides the clinician an opportunity to re-assess how realistic the patient’s expectations of COT are, and possibly have the patient/clinician design and sign a goal-directed therapy agreement (GDTA) prior to initiating COT. Finally, the POPP allows clinicians a chance to decide if this is the appropriate point in time to initiate COT, or if it may be better to postpone COT, perhaps to try another non-opioid therapy or referral to a pain specialist. Potential tools (e.g., the Readiness for Chronic Opioid Therapy form; see Figure 1 and description below) may be helpful to certain clinicians with regards to making decisions on the timing of when to initiate chronic opioid therapy.

Readiness for Chronic Opioid Therapy
After evaluating for substance abuse issues (e.g., Opioid Risk Tool [ORT], Screener and Opioid Assessment for Patients with Pain [SOAPP]-R), some clinicians (e.g., primary care providers) may find it useful to utilize a newly developed tool, referred to as the Readiness for Chronic Opioid Therapy (RCOT). The RCOT is a clinically-derived tool, with no current psychometric evaluation or track record, which attempts to help less experienced clinicians who are thinking of employing COT gain some perspective on when to initiate COT. The RCOT is a brief seven-item clinician-generated tool in which the provider/prescriber scores each item and then summates the scores to get a total RCOT score. A total RCOT score of 10 or above is considered possibly ready for COT. An RCOT score of 10–14 is considered possibly ready for COT. If a patient has a total RCOT score of below ten it is considered uncertain if they are ready for COT, and it may be reasonable to wait before initiating COT, or perhaps send the patient to a pain specialist for an opinion on their suitability for COT at this point in time.

Risk assessment tools in screening for opioid abuse potential
Potential opioid use must be accompanied by risk stratification and management (i.e., proper screening to assign the likelihood of abuse or misuse of opioid medication and subsequent design of how to structure treatment to minimize this risk, often seen as more frequent urine drug screens and a small amount of opioid supply given at any one time). This process begins with an assessment of addiction risk, which can be very brief or might entail a comprehensive psychiatric evaluation. Given time constraints, time-sensitive measures are clearly needed to help in this endeavor. The acknowledgment of this need has led to a substantial increase in addiction-related screening tools [10]. Many screening tools contain items on personal and family history of addiction, as well as other
Identifying & managing the risk of opioid misuse

Some of the tools are particular to pain management, whereas others simply assess risk factors for addiction in general. While there is merit to having some form of risk assessment, it must be noted that it is unclear exactly which assessment tools ultimately provide the best results. Whatever tool the clinician chooses, it is advised that he or she present the screening process to the patient with the assurance that there are no answers that will negatively influence effective pain management. Some examples are discussed below.

**Opioid risk tool**

The ORT is a five-item tool with different numeric weights for historical and psychiatric variables. Positive responses are checked based upon the gender of the patients, and the scores for all the possible items are added together to calculate the probability of opioid-related aberrant behavior. The ORT was evaluated in 185 new patients at a pain clinic. Approximately 95% of patients with low-risk scores did not display aberrant behavior, while 90% of patients with high-risk scores did show aberrant behavior. These results demonstrate that the tool has both face and predictive validity, and can detect aberrant drug-related behaviors in a truthful sample of patients. It is considered the easiest and quickest way to assess a patient’s risk, and is appropriate for many busy primary care physicians. However, if a patient is not forthcoming and truthful about his or her personal and family history of substance abuse, sexual abuse and psychological disease, it can be ineffective. Thus, working the questions into a normal history and physical intake interview can help to alleviate the tendency for abusers to become defensive about the thread of the questioning, but is still no guarantee that honest answers will be provided in all cases.

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Figure 1. Readiness for Chronic Opioid Therapy form.
COT: Chronic opioid therapy.
Identifying & managing the risk of opioid misuse

The original SOAPP is a self-report questionnaire that can predict aberrant medication-related behaviors among chronic pain patients considered for COT. Originally a 24-item tool, it was reduced to a 14-item version after Butler et al. tested each item’s reliability [13,14]. Each item is measured on a five-point scale. A higher score indicates a greater risk of addiction. The revised version is perhaps the best tool psychologically and the most opaque to patients, thereby reducing the likelihood that they will provide socially desirable answers instead of honest ones. The low cut-off score (i.e., risk of addiction is recognized even if a patient underreports aberrant behavior) makes it less vulnerable to the possibility of deception, thus making it more useful with high-risk populations who might be less than completely forthcoming about their medication use. A 2008 study developed and validated an empirically-derived version of the original SOAPP (SOAPP-R) that addresses some limitations of the original [15]. This 24-item version is an improvement over the original because of improved psychometrics and risk potential screening capabilities.

Screening Instrument for Substance Abuse potential

The Screening Instrument for Substance Abuse Potential (SISAP) is a physician-administered, five-item measure that was never fully incorporated into major clinical practice. It contains a list of questions and associated behaviors or identifiers that suggest a need for caution, including alcohol consumption, marijuana use, cigarette smoking and younger age. Data from the National Alcohol and Drug Survey in Canada [16] showed that the tool was effective in identifying substance abusers; it correctly identified 91% of substance abusers and 77% of those who were nonabusers (n = 4948). Although these results from a large sample indicate the tool’s potential, validation is needed in the form of prospective trials.

Diagnosis, Intractability, Risk, Efficacy score

The Diagnosis, Intractability, Risk, Efficacy (DIRE) Score was designed for the physician to predict which chronic nonmalignant pain patients will experience effective analgesia and be compliant with long-term opioid maintenance treatment. Diagnosis, intractability, efficacy and four subcategories of risk (psychological, chemical health, reliability and social support) are rated from 1 to 3, with higher scores indicating a greater possibility of successful opioid therapy. Belgrade et al. tested the validity of the tool with an analysis of the DIRE score in 61 patients who had been treated with opioids for a median duration of 37.5 months at an outpatient pain management center [17]. The results indicated high sensitivity and specificity for predicting both
Identifying & managing the risk of opioid misuse

Categorizing patients who may be candidates for COT

The practice of pain medicine should be ‘patient-centered’ and guided by evidence-based medicine, risk assessment tools and consensus guidelines tempered by clinical experience, sound clinical judgment and common sense. Although it may be ideal for every patient with pain to be assessed and managed by an interdisciplinary ‘dream team’ of experts (each expert bringing their own vantage point and set of skills ‘to the table’), this is clearly unrealistic. Thus, it has been proposed that the complexity of issues should play a major role in efforts to determine what might be the optimal team/team members for management of a particular individual patient [18]. In general, the more complex and difficult a patient is, the more members should be involved in the interdisciplinary management team.

There exist multiple domains with various levels of complexity in each. These domains are discussed below.

- **Medical complexities**
  Medical complexities largely refer to the existence and severities of various co-morbidities.

- **Pharmacologic complexities**
  Pharmacologic complexities may include:
  - The number and type of other pharmacologic agents which the patient is taking;
  - Patient’s age;
  - Patient’s ideal body weight/body mass index;
  - Renal function;
  - Liver function;
  - Certain medical conditions (e.g., uncontrolled narrow-angle glaucoma, obstructive sleep apnea).

  A pharmacist may be an especially useful team member in patients with these complexities.

- **Psychological complexities**
  Psychological complexities may include:
  - Alterations in mood;
  - Emotional factors;
  - Alterations in cognitive function;
  - Psychiatric disorders;
  - Personality disorders;
  - Secondary gain issues.

- **Patient complexities**
  Patient complexities may include personal factors that significantly impact the patient’s life:
  - Social factors;
  - Economic issues;
  - Family/relationship issues;
  - Spiritual issues;
  - Educational level.

  Overall, these factors may influence adherence/compliance with the medical regimen, including whether the patient can afford the medication(s) prescribed, the level of patient understanding and the level of patient motivation. Patients may differ dramatically in their goals and expectations, perceptions of quality of life, and issues that matter most to them (e.g., if a patient’s number one priority is satisfaction with sexual activities, then the patient’s interdisciplinary team might also include a sex therapist, a psychologist, a urologist and/or gynecologist, and an endocrinologist).

- **Chemical-dependency complexities**
  Chemical-dependency complexity issues may require highly trained team members. The simple, straightforward patient who has been classified as being at low risk for substance misuse might be able to be managed by a primary care physician. However, the complex and difficult patient with multiple chemical dependencies may best be followed by an interdisciplinary pain team with a social worker, psychologist (and other behavioral medicine specialists) and an addiction medicine specialist (Figure 2). Chemical-dependency complexities may vary from the patient with a positive family history of substance abuse who is a ‘heavy’ alcohol user, to the patient with active polysubstance abuse issues who has an alcohol addiction and has lost their driver’s license and job because of alcohol-related issues.
Goal-directed therapy agreements

Given the above discussion, if an opioid trial seems warranted for an individual patient, some thought should be given to the next step. Perhaps one of the most important principles in initiating and maintaining chronic opioid therapy for persistent noncancer pain is to ‘know where you are and where you are going’. GDTAs may be helpful in initiating chronic opioid therapy for persistent noncancer pain [19]. We utilize the term ‘agreement’ here to specify that this is a working relationship as opposed to a ‘contract’, which is most often used in law and business for agreements that are legally enforceable.

Goal-directed therapy agreements should be tailored to each individual patient, should be clear and concise, should set goals that can reasonably be attained by the patient over a finite period, and optimally should be agreed upon by both patients and clinician. Examples may include increasing daily ambulation by a defined amount, increasing social/recreational activities by a defined amount, and so on. By utilizing GDTAs before instituting opioid therapy, clinicians can establish specific concrete individualized defined criteria to be met in order for opioid therapy to continue. In this manner, patients may be expected to reach certain realistic, reasonably attainable functional goals which are to be documented by a physical and/or behavioral therapist.

Revisiting opioid agreements

If a patient is a candidate to start an opioid trial, the GDTA should not be static, it should be considered a dynamic agreement that may need to be altered, re-emphasized and/or ‘re-engineered’ over time. Providers should not just file GDTAs in the chart and forget about them or they run the risk of becoming ‘dead documents’. In a ‘living’ opioid agreement, the patient is consistently reminded of the elements of the GDTA, the patient re-affirms an understanding of the GDTA elements, and may even resign or initial and date the GDTA to show that they re-reviewed the GDTA. Furthermore, there may be elements that need to be added or altered depending on the individual specific situation.

Reviewing the goals of COT

Once a decision has been made to start an opioid trial, providers should utilize every visit (especially early on) to carefully re-evaluate the patient in efforts to assess whether the patient has been improving in any domains. The patient who is receiving COT needs continued close surveillance to ensure that the benefits of COT still outweigh the risks and to re-review the goals of chronic opioid therapy with the patients. When goals are not being met, this can spark a discussion with the patient and may lead to the beginnings of an exit strategy to begin tapering the opioid dose completely, or to discuss potential rotation to other opioid analogues. As clinicians review the patient’s goals of COT in their own mind, one may appreciate the benefits of a well-documented comprehensive evaluation of how the patient was doing in the POPP, as well as the benefits of having a detailed GDTA documented in the medical record from the POPP. Furthermore, issues of any improvements in pain or function (any changes in physical examinations), future expectations/goals, opioid-induced adverse effects, aberrant drug-taking behavior, other therapies/co-morbidities, and reason(s) that clinicians are continuing COT should be documented.

There are several domains of interest in patient assessment during COT. These include pain relief (i.e., are the medications or treatments leading to pain reduction?), functional outcomes (i.e., is the patient more engaged in life as a result of treatment?), side effects (i.e., how have the medications adversely affected the patient?) and drug-related behaviors (i.e., is the patient acting in unusual or disturbing ways?). Passik and Weinreb have described a useful mnemonic for following the relevant domains of outcome in pain management [20]. The so-called four A’s (analgesia, activities of daily living, adverse events and aberrant drug-taking behaviors) are the clinical domains that reflect progress toward the larger goal of a full and rewarding life [21,22].

Analgesia

Although listed as the first ‘A,’ analgesia should not necessarily be considered the most important outcome of pain management. An alternate measure is how much relief it takes for patients to feel that their lives are meaningfully changed, enabling them to work toward the attainment of their own goals.

Activities of daily living

The second ‘A’ refers to quality-of-life issues and functionality. It is necessary for patients to understand that they must comply with all of their treatment recommendations in order to be able to return to work, leisure and social activities in the minimum amount of time.
Identifying & managing the risk of opioid misuse

**Executive summary**

- Prescription opioid use has seen greater acceptance and use for chronic pain management.
- Primary care providers need to help with pain management efforts owing to a relative shortage of board-certified pain practitioners.
- Abuse and diversion issues are growing, and must be acknowledged by prescribers considering writing for controlled substances in general and opioids in particular.
- Several risk assessment tools have shown up in the literature, with the Opioid Risk Tool (ORT) and Screener and Opioid Assessment for Patients with Pain (SOAPP) being two of the more popular and potentially useful tools for prescribers to consider.
- Prescribers should make use of goal-directed therapy agreements (GDTA) to help center the treatment goals with patients and then revisit the document over time in order to make sure those goals stay on track and current.
- Once a prescriber initiates a trial of opioid therapy, they should monitor and assess the four A’s (analgesia, activities of daily living, adverse events and aberrant drug-taking behaviors).
- Finally, prescribers should utilize the universal precautions approach with chronic pain patients.

**Adverse events**

Patients must also be made aware of the adverse side effects inherent in the use of opioids and other medications to treat pain. Side effects must be aggressively managed so that sedation and other side effects do not overshadow the potential benefits of drug therapy. The most common side effects of opioid analgesics are constipation, sedation, nausea and vomiting, dry mouth, respiratory depression, confusion, urinary retention and itching.

**Aberrant drug-taking behaviors**

Patients must be educated about the parameters of acceptable drug taking. Even an overall good outcome in every other domain might not constitute satisfactory treatment if the patient is exhibiting worrisome drug-related behaviors. Dispensing pain medicine in a highly structured fashion may become necessary for some patients who are in violation, or constantly on the fringes, of appropriate drug taking.

To help prescribers to think of the four A’s in a systematic way, Passik and colleagues developed the Pain Assessment and Documentation Tool (PADT) [21,22]. It essentially creates a one-page, two-sided chart note that uses the four A’s to generate a brief clinical interaction with questions among the four domains that can be asked by the prescriber. It has been shown to be both brief and useful for bolstering documentation efforts.

**Overview of universal precautions**

As the prevalence of addiction in the general population is a relatively stable phenomenon worthy of our attention, it seems prudent to utilize the ten steps of ‘universal precautions’ in patients receiving COT [23,24]. These are:

- Reasonable attempts to make a diagnosis with an appropriate differential;
- Comprehensive patient assessment including risk of addictive disorders;
- Informed consent;
- Treatment agreement;
- Pre- and post-intervention assessment of pain level and function;
- Appropriate trial of opioid therapy ± ‘adjunctive’ medications;
- Reassessment of pain score and level of function;
- Regular assessment of the four A’s of pain medicine;
- Periodic review of pain diagnosis and comorbid conditions, including addictive disorders;
- Documentation.

Application of the universal precautions is intended to help the clinician identify and interpret aberrant behavior and, where they exist, diagnose underlying substance misuse disorders [23,24].

**Conclusion**

The use of opioids in a primary care practice is fraught with difficulties, yet they are not insurmountable or irreconcilable. By maintaining a set of approaches to these patients, the risk can intuitively be reduced. However, is should be noted that levels of abuse, best practices to limit abuse and the prescriber’s unintended role in abuse and diversion are not clearly defined. While prescribers should do everything in their power to limit diversion and abuse by their patients, we must also be cognizant of other potential abuse and diversion sources, such as the internet, counterfeiting, pharmacy theft and the gray market.

**Future perspective**

The next several years will be a time of change and transition with regards to the field of pain management. For one thing, the field will likely see the approval and marketing of a multitude of new products offering features that can be
interpreted to be ‘abuse deterrent’ or somewhat less likely to have their route of normal administration altered (i.e., crushing or otherwise destroying a pill for purposes of snorting, chewing or injecting) in order to get a bolus dose of the medication. Some systems will present antagonist agents that will nullify the effects of the main drug or at least offer no utility in the amount of abusable drug when the structure is altered. In addition, the pain field might become more restricted overall, and relatively few prescribers will have the necessary qualifications to write for controlled substances. The US FDA is at present considering how to employ a Risk Evaluation Mitigation Strategy for classes of medications such as opioids. Setting this up effectively will be a daunting task, and will likely require several iterations and periods of refinement in order to make it a functional system.

Financial & competing interests disclosure
The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, such ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Bibliography

** Provides a comprehensive review of the risk assessment tools to be developed in recent years, along with commentary on the pros and cons of each measure.
12 Recent review discussing the utility of opioid therapy for noncancer pain patients.
** Original article on the Opioid Risk Tool (ORT), which has become one of the most widely used risk assessment tools.
** Original article discussing the concept of the four A’s of pain management to be addressed when considering opioid therapy.
Identifying & managing the risk of opioid misuse


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Sets forth the argument that universal precautions can and should be applied to pain management.
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Websites


102 National Center on Addiction and Substance Abuse. Under the counter: the diversion and abuse of controlled prescription drugs in the US (2005)

www.casacolumbia.org/supportcasa/sub-category.asp?CatalogVar=0&cID=12

103 SAMHSA. Office of Applied Studies of the Substance Abuse and Mental Health Services Administration. Results from the 2005 National Survey on Drug Use and Health: national findings. Department of Health and Human Services. Publication No. SMA 06–4194

www.oas.samhsa.gov/NSDUH/2k5NSDUH/2k5results.htm.

104 Virginia Board of Pharmacy, Department of Health Professions. Drug laws for practitioners (2005).


www.deadiversion.usdoj.gov/pubs/brochures


