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# Managing Risk in Long Term Opioid Prescribing for Persistent Pain

*By Maxim S. Eckmann, M.D.*

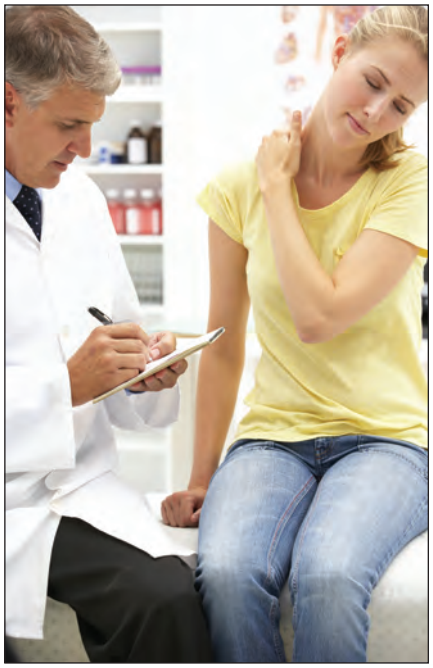
The goal of *Physician Connection* is to feature articles by leaders in the medical, legal and risk management professions, and we believe you'll enjoy the in-depth perspectives shared by our authors. We realize the practice of medicine is an art and not a science. A patient's medical history and treatment plan should be based on both the patient's condition and the physician's clinical opinion. Therefore, the views and opinions expressed are those of the authors and do not reflect the policy or position of PSIC.

## Pain: a Symptom and a Disease

Almost every practicing physician must deal with patients in pain at some point, especially considering that pain is often the most likely presenting symptom of disease or injury. Unfortunately, a small but significant portion of the population that experiences pain will go on to experience persistent, or chronic, pain long after apparent healing of damaged tissues.[1]

Persistent pain and subsequent costs have quietly become an epidemic in the industrialized world. In the U.S., direct and indirect costs likely exceed $500 billion annually, challenging diseases like diabetes, cardiovascular disease, and cancer as one of the major stresses on the "economic health" of U.S. healthcare.[2]

Pain medicine has evolved in recent medical history to try and understand pain, especially persistent pain, as a distinct disease entity rather than a symptom alone. The mechanisms of persistent pain are numerous; altered nervous system processing and response to stimulation are likely at the core of many chronic pain syndromes.[3] Diverse treatments include allopathic and homeopathic medicine pathways, exercise and physical modalities, diverse drug classes, psychological therapies, and sometimes procedures directed at diseased tissues or neural structures.



Sometimes persistent pain cannot be cured, but rather managed like a chronic disease. The few existing pain specialists are finding some syndromes or individual cases difficult to treat, even with their considerable expertise. Thus, primary care physicians, hospitalists, and surgeons— just to name a few—are also taking on the brunt of managing persistent pain in both urgent and longitudinal care settings.

Opioids, being relatively flexible, tolerable, potent, and familiar options for physicians, have long been a mainstay of treating moderate to severe acute pain. In the 1990s, pain societies advocated more aggressive treatment of severe pain and movement away from "opioidophobia."[4]

Those recommendations, which were intended especially for terminally ill or cancer patients, became broadly applied to non-terminally-ill patients as well, or patients with "non-cancer chronic pain." Based on increasing awareness of potential problems such as tolerance, abuse, and addiction with prescription pain medications, as well as unintended or intentional diversion of the medications to others, the societies had to amend their original recommendations to now recommend a new culture of risk assessment, drug monitoring, and continual re-evaluation[5] (Figure 1).

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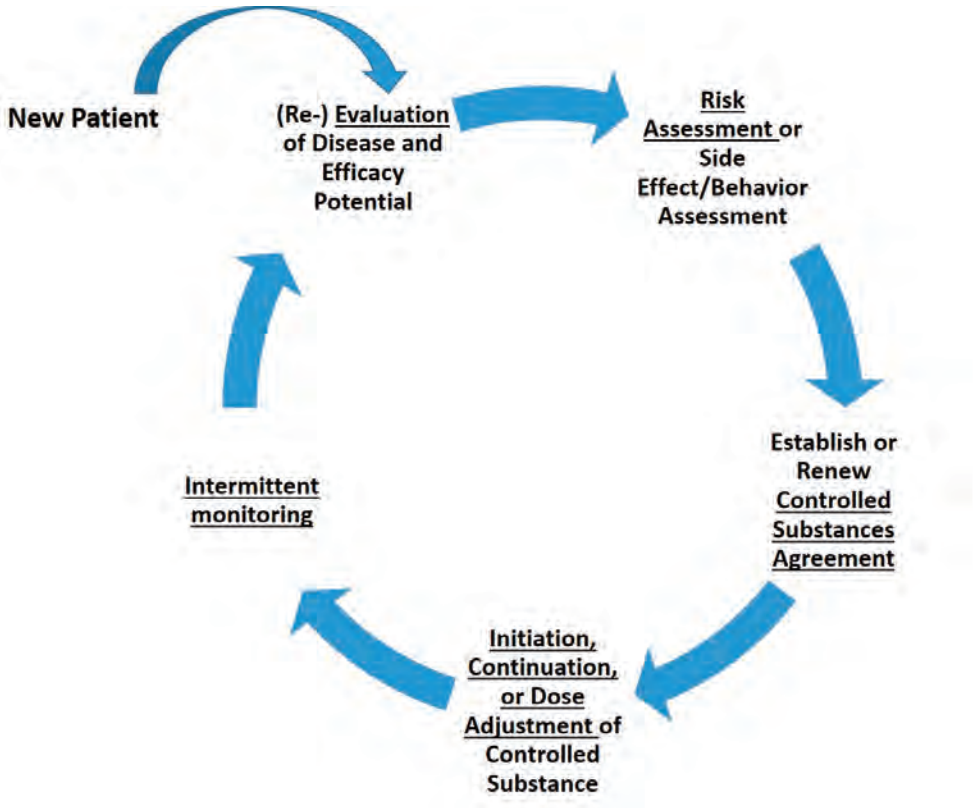
## Physicians are likely to have prescribed opioids, so there is a need for their effective management.

**Figure 1**

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### Reducing Opioid Burden Upfront

Opioids do have side effects (respiratory depression, constipation) and long-term health consequences (tolerance, increased pain, abuse/addiction, sex hormone suppression, stress hormone suppression, sleep cycle disruption).[6] Physicians and non-physician licensed providers are likely to have to prescribe opioids at some point, so their unique properties and issues create a need for organized and logical management to minimize patient harm, reduce liability, and adhere to regional regulations/practice standards while also providing analgesia to patients in need.

### Establishing a Diagnosis

Although pain is a disease process of itself, it is still widely recognized as being secondary to a primary disease by both health insurance payors and clinicians. The importance of establishing a likely diagnosis or differential is partly in understanding the expected course of recovery and directed treatment, if applicable, other than the management of pain symptoms. Physicians should be aware of the syndromes they commonly treat and any recommendations by their professional societies on the relevant evidenced based treatment.[7]

### Bringing all Tools to Bear (…Before Opioids)

When drugs are needed for more distressing or debilitating pain, consider the wide array of classes and the pain receptors where they act (Figure 2).
For example, membrane stabilizing medications like carbamazepine are more specific for neuropathic pain conditions like trigeminal neuralgia. While opioids could also work, they would probably be less efficient. Yet, severe pain from a long bone fracture would probably need a base therapy of opioids in conjunction with other techniques.

If well-tolerated, using "adjunctive" medications in conjunction with opioids can improve the durability of the therapy and operation in therapeutic windows of both (or more) pain medications. Also, the patient may be a candidate for referral to a specialist/surgeon for definitive treatment or interventional pain procedures such as joint and spine injection.

## Figure 2

| Pain Receptors | Common Medication Examples |
|---|---|
| *μ (mu)* | Opioids |
| *Cyclooxygenase* | NSAIDS, Acetaminophen |
| *Phospholipase $A_2$* | Steroids |
| $\alpha_2\delta$ (alpha 2-delta calcium channel) | Gabapentin, Pregabalin |
| *5HT* | Tricyclic AD's (amitriptyline)<br>SSRI's (sertraline)<br>SNRI's (venlafaxine, duloxetine) |
| *Norepinephrine* | Tricyclic AD's, SNRI's |
| *Na+ (sodium)* | Local anesthetics, Antiepileptic Medications (carbamazepine, topiramate) |
| *$\alpha_2$ (alpha 2)* | Clonidine / Dexmedetomidine |
| *$GABA_A$* | Benzodiazepines / Barbituates |
| *$GABA_B$* | Baclofen |
| *NMDA* | Ketamine / Memantine / Magnesium / Dextromethorphan / Methadone |
| *Ach (acetylcholine)* | Orphenadrine |

## Evaluation and Monitoring

There are many reasons why opioids will be necessary for pain management. Some pain conditions are so severe in intensity that opioids are needed even in the presence of comprehensive multimodal therapy. As opioids are widely needed and prevalent in clinical practice, physicians are exposed to potential liability or reprimand if prescribing practice falls well outside the intent of the Drug Enforcement Agency (DEA) and state agencies to limit the diversion of prescription medications, which are the leading source of drug abuse and drug overdose fatalities in the U.S.[8]

Fortunately, the bar for demonstrating responsible prescribing is very achievable with proper knowledge and processes. Current interest from state and federal drug enforcement agencies is especially focused on systematic intentional diversion of prescription medication from clinics dubbed "pill-mills."

### Initiating Opioid Therapy

For the common scenario of the new patient who presents already on opioid therapy previously started by another practice, confirmation of prior medical records and inquiry into last dose/remaining medications is important. Risk assessment tools, like the SOAPP-R, COMM, DIREScore, and others, are public domain and available to assist in assessing patients for risk of aberrant medication use/abuse.

Having a prior history of drug abuse would be an example factor that increases risk of similar future behavior. If high risk is identified, this may influence whether the provider feels he/she has the expertise to manage such a patient at all, and with how much monitoring. The patient should be duly informed of opioid side effects, adverse effects, and long term risks such as dependence, hormone suppression, sleep disruption, and increased pain.[6]
A controlled substance agreement (a.k.a. "narcotics contract") should be explained to the patient, signed/witnessed, and saved for future reference by both provider and patient. Many examples of controlled substance agreements include information about risks of therapy, but also will advise the patient to adhere to important tenets like:

***A narcotics contract should be explained to the patient, signed/witnessed and saved for future reference.***

- Using medications only as prescribed and for the symptoms indicated by the provider.
- Avoiding illicit drugs.
- Refraining from giving medications to others (diversion).
- Using a single pharmacy.
- Refraining from obtaining controlled substances from other physicians without informing the current provider.
- Agreeing to undergo periodic drug testing.[9]

If these conditions are violated, the practitioner has a robust basis from which to discontinue the therapy, which has been explained in writing to the patient previously. While such agreements and subsequent monitoring may not be warranted for short terms of pain medications for brief painful conditions, they may be needed for long term therapy with expected multiple/indefinite refills of pain medication.

### Monitoring

Drug testing is an emerging and important tool for monitoring compliance to therapy (the patient is taking the medication prescribed) and for the presence of any illicit substances or controlled substances prescribed

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## Figure 3

| "Pill Mill" | Abusers/Traffickers |
|---|---|
| Cash business transactions<br>• Not accepting insurance<br>• Taking payment for prescriptions or encouraging onsite pharmacy purchace | Diversion stems from black market demand<br>• Hotbed in south Florida, southeast, Texas and Louisiana, others |
| No longitudinal care or meaningful evaluation<br>• No physical examinations performed or documented<br>• Asking patients "what meds do you want?"<br>• No concern for patients clearly appearing intoxicated or addicted | Faking injuries / stolen MRIs / forged medical records / forged prescriptions |
| Liberal prescribing habits:<br>• High Pill Counts<br>• Multiple Controlled Substance Classes per Patient (e.g. alprazolam, hydrocodone, carisoprodol "trinity") | Very specific about wanting particularly potent name-brand medications, quantities, and refusing other definitive treatment or reasonable evaluation. |
| Practice also has ownership of a nearby or onsite Pharmacy<br>• Pharmacy carries abnormally high stock in these medications | Sponsoring other "patients" to pay for the visits and medications. Sometimes these "patients" are homeless and are "rounded up" for hire. |
| Unusually high patient volume<br>• Lines coming out the door | Provide transport of multiple patients to the same clinic location in the same day. |
| Doctors linked to high numbers of patient overdoses | Doctor and Pharmacy "shopping" to get more frequent prescriptions<br>• Not using established pharmacy franchises. |
| Clinic office frequently relocates to non-medical appearing buildings/facilities. | Inaccurate / false contact information and residence addresses provided.<br>• Lacking / forged identification card.<br>• Refuse or attempt to circumvent drug screening tests. |

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unknowingly by others. Rationale for intermittent testing are that testing alone may reduce the incidence of future illicit use,[10] concurrent use of illicit substances increases the risk of patient death from overdose due to interactions, and that diversion of medication (implied by the absence of the prescribed medicine in the urine) can be very difficult to detect otherwise. It is possible that a patient may need testing every 3 months to a year or more depending on a risk assessment.[10] Getting a baseline drug screen on initiation of therapy can detect unforeseen findings and establish a reference point for future testing.

Records of these prescriptions should be maintained and safeguards made to protect them from fraud and theft. Positive official identification of the patient or clinic approved patient representative is a sound practice when dispensing physical paper prescriptions. The clinic should establish standard practices to handle patient refill requests with timeliness and scrutiny.

Many states now have electronic monitoring databases for controlled substance prescriptions. Such tools can be used to confirm that a patient has an expected history of filling controlled prescriptions from known providers—potentially detecting "doctor shopping" that has been otherwise undisclosed. Caution should be used with these databases considering the sensitive nature of information, and incomplete/delayed information present in the system.

## Re-evaluating the Patient

Patients on long-term opioid therapy should be periodically re-examined prior to continuation. Their painful disease condition should be evaluated for progression or resolution. Treatment efficacy should be assessed; in particular that opioids are assisting the patient to lead a more functional life in the presence of persistent pain. The patient should be evaluated for mood/sleep disruption that may occur from opioids or from independent psychiatric disease that could complicate opioid management. Side effects like constipation, sex hormone suppression, and cognitive impairment should be assessed. Evidence of aberrant behaviors like losing prescriptions, frequently calling for refills too early, seeking other doctors or emergency room care for pain medication in the absence of evident disease changes, should be reviewed.

If the adverse effects outweigh the benefit potential of opioids, then weaning or co-management with other specialists may be warranted. If dose increases are

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on cognition is debated, increasing pain medications acutely can cause transient cognitive impairment[11] until accommodations and this may warrant counseling if the patient has duties that raise a safety concern. Some literature now suggests certain daily doses are associated with more risk of overdose.[10]

## Summary

The vast majority of contemporary medical practices have almost nothing in common with pill-mills. However, it is useful to be informed about common pill-mill practices. It is known that a commonality of factors link such illegal clinics and the patients that frequent those clinics for non-therapeutic purposes[12] (Figure 3). A responsible medical practice would therefore on the contrary have:

- Robust documentation of medical evaluations.
- Written established clinic policies pertaining to prescribing and handling of controlled substances.
- Strict documentation of clinic stock/accounting/administration of controlled substances.
- Evidence of a stable practice location and history, mechanisms for accepting insurance reimbursement or traceable financial transactions.
- Prescribing habits that show restraint and fall within specialty and community norms.
- Lack of obvious financial conflict of interest between the physician and subsequent medication dispensing.

It is unlikely that a medical practice following these responsible patterns would be targeted by drug regulatory agencies; however, the practice should always be prepared for an audit, be cooperative and forthcoming, and have well-kept records. Since a potential source of drug abuse, diversion, and prescription fraud can unfortunately be from clinic and pharmacy staff, it is incumbent on the practice to continually re-assess the accounting for chain-of-custody/administration of on-site controlled substances (like midazolam or fentanyl used for procedural sedation) and adherence to the clinic/hospital policies for proper handling. Often, state legislatures will publish minimal standards for handling controlled substances in the state administrative code.[13]

***The safety and efficacy of long-term opioid therapy for pain continues to be debated.***

The safety and efficacy of long-term opioid therapy for pain is debated, however opioids remain an important tool for managing pain. As practitioners, groups, and health systems are highly likely to deal with these and other controlled substances on a regular basis, review and adherence to current standards on controlled substance prescription is warranted. Although these substances do pose unique risks, particularly overdose, death, abuse/addiction, and diversion, these risks can be managed and mitigated through thorough documentation, risk stratification, controlled substances agreement, periodic drug screening, and continual patient re-evaluation.

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# Risks can be mitigated through documentation and a variety of strategies.

## Figure Legend

**Figure 1:** Validated risk assessment survey tools like the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), Current Opioid Misuse Measure (COMM), Diagnosis Intractability Risk Efficacy Score (DIREScore) can assist the clinician in differentiating patients with higher risk of aberrant drug use. Controlled Substance Agreements (a.k.a. "Narcotics Contracts") specify a set of boundaries/rules under which the patient is permitted to be a candidate for opioid therapy. Level of risk can suggest how frequently a patient should be monitored for adherence to therapy and absence of illicit substance use, for example, through urine drug testing every few months to years. There should be intermittent evaluation of efficacy, side effects, aberrant behaviors, and the disease progression or resolution if any.

**Figure 2:** A multitude of receptors that modulate pain have available drug options. Multimodal therapy may be warranted for difficult or severe pain conditions, and can reduce reliance on opioid agents.

**Figure 3:** Behavior patterns commonly seen among patients who abuse or divert medications, and the "pill mills" that knowingly engage in sale of medications for no real therapeutic utility. Based on published work of interviews with actual patients.

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