Opioid Prescribing for the Podiatric Physician

Robert G. Smith DPM, MSc, R.Ph., C.Ped

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Thank you
Learning Objectives

• Define risk factors for potential misuse, abuse, and diversion of prescribed opioid medications.

• Recognize the importance of both Federal and State Opioid prescribing regulations and be consistent with adhering to these regulations while practicing podiatry.

• Follow an evidence-based protocol for starting patients on opioid analgesic therapy, including safely initiating and titrating opioids.
Introduction

• Each year, millions of patients are treated for a variety of serious medical conditions with prescription drugs whose therapeutic benefits can alter behavior, mood, and consciousness.

• This is particularly true of the management of chronic pain, which often involves potent opioid pain relievers.

• The misuse and abuse of prescription opioid pain relievers is on the rise.

• Physicians and other health care professionals thus face the challenge of minimizing the potential for misuse of these important medications without impeding patients’ access to needed medical care.
Analgesic Global Use

The U.S. Food and Drug Administration (FDA) is strengthening an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke.

More than 98 million nonsteroidal anti-inflammatory drugs (NSAIDs) prescriptions in 2012.

NSAIDs have accounted more than 70 million prescriptions and 30 billion purchases. NSAIDs are also among the most inappropriate prescribed inappropriately to older Americans.

It is estimated that the United States consumes 80 percent of the global opioid supply and 99% of Hydrocodone.

According to the U.S. Food and Drug Administration (FDA), more than 50 million Americans were prescribed some type of narcotic pain medication in 2011, which represents a nearly 100 percent increase in narcotic pain medication prescriptions since 2008.
Analgesic Prescribing in Podiatry

The unpleasant and subjective sensation resulting from a noxious sensory stimulus defines the phenomenon of pain.

The podiatric physician is no stranger to the difficulties in achieving optimal pain therapy. Podiatric physicians must develop analgesic regimens to treat patients with acute, chronic, and postoperative pain. (2006)

The topic of pain management remains a minor component of the formal education and training of residents and physicians in the United States.

Misguided attitudes concerning acute and chronic pain management, in addition to reservations about the legal aspects of pain management, often translate into a "fear of the unknown" when it comes to narcotic prescribing. (2010)
Opioid Reference

Clinical Literature 2006

Opioid Chemical Structures
Historical Perspective

- 1803 Friedrich Sertürner isolates morphine from opium poppy.
- 1861-1865 Morphine addiction becomes known as the soldiers’ disease.
- 1874 Alder Wright creates heroin
- 1916 Oxycodone is developed in Germany
- 1942 The Opium Poppy Control Act outlaws possession of Opium poppies in the United States
- 1976 Oxycodone is approved in the United States
- 1997 NIH estimates 600,000 in US are opiate dependent
Top 200 Products in the US Market by Dispensed Prescriptions, 2014

- Hydrocodone/APAP (1)
- Oxycodone/APAP (27)
- Celebrex (111)
- Ibuprofen (17)
- Oxycodone (56)
- Suboxone (13)
- Morphine ER (145)
- Tramadol HCL (15)
- Naproxen (53)
- Oxycontin (180)
- Carisoprodol (122)
- Meloxicam (36)
- Fentanyl (175)
Long-Acting Opioid Analgesics

- Avinza (Morphine ER)
- Dolophine (Methadone)
- Embeda (Morphine/Naltrexone)
- Hysingla (Hydrocodone)
- MS Contin
- Opana (Oxymorphone)
- Targiniq (Oxycodone/Naloxone)
- Butrans (Buprenorphine transdermal)
- Duragesic
- Exalgo (Hydromorphone)
- Kadian (Morphine)
- Nucynta (Tapentadol)
- Oxycontin
- Zohydro (Hydrocodone ER)
The U.S. Opioid Epidemic

The Opioid Epidemic in the U.S.

In 2015...

- 12.5 million people misused prescription opioids
- 2.1 million people misused prescription opioids for the first time
- 33,091 people died from overdosing on opioids
- 2 million people had prescription opioid use disorder
- 15,281 deaths attributed to overdosing on commonly prescribed opioids
- 828,000 people used heroin
- 9,580 deaths attributed to overdosing on synthetic opioids
- 135,000 people used heroin for the first time
- 12,989 deaths attributed to overdosing on heroin
- $78.5 billion in economic costs (2013 data)

Opioid Prescribing Overview

- Doctors wrote 72.4 opioid prescriptions per 100 persons in 2006. This rate increased 4.1% annually from 2006 to 2008 and 1.1% annually from 2008 to 2012. It then decreased 4.9% annually from 2012 through 2016, reaching a rate of 66.5 per 100 persons in 2016. That year, 19.1 per 100 persons received one or more opioid prescriptions, with the average patient receiving 3.5 prescriptions.

- Between 2006 and 2016, the annual prescribing rate per 100 persons for high-dosage opioid prescriptions (>90 morphine milligram equivalents (MME)/day) decreased from 11.5 to 6.1, an overall 46.8% reduction and an average annual percentage change of 6.6%. The rate leveled off between 2006 and 2009, then decreased 9.3% annually from 2009 to 2016.

Unlike the product-specific approach to the drug approval process usually taken by the FDA, the committee recommends a systems approach for analyzing the benefits and risks of opioid medications to more comprehensively assess the public health consequences of opioids.

This approach should incorporate public health considerations, including benefits and risks to individual patients, their family members, and the broader community, as well as effects on the overall legal and illicit markets. Public health considerations should also be incorporated into clinical development and into opioid scheduling decisions.

Transparency is critical to maintain public trust and to find the balance between preserving access to opioids when needed and mitigating opioid-related harms. Therefore, the committee recommends that FDA increase the transparency of its regulation of opioid medications.

The FDA should also strengthen the post-approval oversight of opioids and conduct a full review of currently marketed or approved opioids.
Influencing prescribing practices

• Many treatments are available to manage pain. Some nonopioid therapies are likely to be as effective as opioids, or even more so, and potentially carry lower risk when used appropriately.
• Any meaningful effort to improve pain management will require a basic culture shift in the nation’s approach to mandating pain-related education for all health professionals who provide care to people with pain. Prescribing guidelines may be most effective when accompanied by education, and so an evidence-based national approach to pain education, including pharmacologic and nonpharmacologic treatments and materials on opioid prescribing, is needed.
• Insurance-based policies have substantial potential to reduce the use of specific prescription drugs. Coverage for and access to comprehensive pain management that includes both pharmacologic and nonpharmacologic options should be expanded.
• Prescription drug monitoring programs (PDMPs) can help address the opioid epidemic by enabling prescribers and other stakeholders to track prescribing and dispensing information, but PDMP data currently are not being used to their full potential.
Restricting the lawful supply of opioids

- Although more research is needed, limited evidence suggests that state and local interventions aimed at reducing the supply of prescription opioids in the community may help curtail access. Importantly, however, none of these studies investigates the impact of reduced access on the well-being of individuals suffering from pain whose access to opioids was curtailed.

- Drug take-back programs allow people with unused medications to bring them in for proper disposal. These programs can increase awareness of the need for the safe disposal or return of many unused drugs. Access to these programs should be expanded, with states convening public-private partnerships to implement take-back programs year-round rather than the standard occasional take-back event.
Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use, states that a sustained, coordinated effort is necessary to stem the still-escalating prevalence of opioid-related harms, including a culture change in prescribing for chronic noncancer pain, aggressive regulation of opioids by the FDA, and multi-pronged policies by state and local governments. However, the committee also counsels against arbitrary restrictions on access to opioids by suffering patients whose health care providers have prescribed these drugs responsibly.
Opioid Prescribing Strategies

- On July 13, 2017, the Board on Health Sciences Policy of the Health and Medicine Division of the National Academies of Sciences Engineering and Medicine issued a report titled “Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use.”
- The US Food and Drug Administration (FDA) commissioned this comprehensive report to provide an update on current evidence on research, care, and education in the pain field, and to identify actionable measures for the FDA to more adequately address the ongoing opioid epidemic.
- The report highlights the fact that “A sustained, coordinated effort is necessary to stem the still-escalating prevalence of opioid-related harms, including a culture change in prescribing for chronic noncancer pain, aggressive regulation of opioids by the FDA, and multi-pronged policies by state and local governments.”
<table>
<thead>
<tr>
<th>State</th>
<th>Policy Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alaska</td>
<td>7 days</td>
</tr>
<tr>
<td>Arizona</td>
<td>5 days</td>
</tr>
<tr>
<td></td>
<td>14 days Sx</td>
</tr>
<tr>
<td>Conn</td>
<td>7 days</td>
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<tr>
<td>Florida</td>
<td>3 days</td>
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<td>7 days Med Nec</td>
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<tr>
<td>Hawaii</td>
<td>7 days</td>
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<tr>
<td>Indiana</td>
<td>7 days</td>
</tr>
<tr>
<td>Kentucky</td>
<td>3 days</td>
</tr>
<tr>
<td>Louisiana</td>
<td>7 days</td>
</tr>
<tr>
<td>Maine</td>
<td>7 days &amp; 30 days</td>
</tr>
<tr>
<td>Maryland</td>
<td>Lowest amount</td>
</tr>
<tr>
<td>Minnesota</td>
<td>4 days</td>
</tr>
<tr>
<td>Nebraska</td>
<td>7 days</td>
</tr>
<tr>
<td>Nevada</td>
<td>14 days (90 MME/day)</td>
</tr>
<tr>
<td>NJ</td>
<td>5 days</td>
</tr>
<tr>
<td>NY</td>
<td>7 days</td>
</tr>
<tr>
<td>NC</td>
<td>5 days</td>
</tr>
<tr>
<td></td>
<td>7 days (P Sx)</td>
</tr>
<tr>
<td>Penn</td>
<td>7 days (ER AC)</td>
</tr>
<tr>
<td>RI</td>
<td>30 MME/day</td>
</tr>
<tr>
<td>Utah</td>
<td>7 days</td>
</tr>
<tr>
<td>WV</td>
<td>7 days</td>
</tr>
</tbody>
</table>
Reducing Demand

• The committee’s recommended changes to provider education and payer policy should be accompanied by a change in patient expectations with respect to the treatment and management of chronic pain. Attention is not being paid to educating the general public on the risks and benefits of opioid therapy, or the comparative effectiveness of opioids with nonopioid or nonpharmacologic therapies.

• Medication-assisted treatment for Opioid Use Disorder is the standard of care, but it is underused. Evidence-based treatment for Opioid Use Disorder should be expanded by states, and barriers to coverage for these medications should be removed.
Prescriber’s Role to Improve Opioid Prescription Writing

• Protect Prescriptions
• Protect access to prescription pads.
• Keep prescription pads in a locked office or drawer.
• Keep track of prescriptions that are used (prescription numbers).
Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are state-based monitoring programs for controlled substances that are prescribed by licensed practitioners and dispensed by pharmacies.

Although prescription drug monitoring programs have existed for many years, the White House Office of National Drug Control Policy recommended the use of prescription drug monitoring programs to reduce abuse in 2011.

Congress passed the National All Schedules Prescription Electronic Reporting Act (NASPER) requiring the Secretary of Health and Human Services (HHS) to award grants to states to establish or improve PDMPs. Unfortunately, the amount of funding to support this program has been limited, and the plan to fully integrate the PDMPs across the country has yet to be realized.

Currently, 48 states and one territory either have PDMPs or have passed legislation to implement them.
Prescriber’s Role to Improve Opioid Prescription Writing

- Adhere to Strict Policies Regarding Prescribing
- Safeguard license and DEA numbers and only utilize them as required by state law.
- Enforce a strict refill policy and guidelines on lost prescriptions.
- Obtain unused prescription bottles if the patient switches from one controlled substance to a different one.
- Use state Prescription Drug Monitoring Programs (PDMPs), where available, to monitor patient prescribing before refilling or adding new medications.
- Limit the number of refills — ED physicians should probably never prescribe refills. (No Opioid ER visits)
- Specify on prescriptions for controlled substances that photo ID needs to be presented prior to dispensing of medication.
Decide Which Opioid to Use

Decide which opioid to switch to:

– Renal Function
– Potential for drug interactions
– Patient Specific Factors
  • Patient ability to swallow or apply a transdermal system
  • Nature of pain
  • Patient’s previous history of response
  • Safety concerns
    – Formulary,
    - Financial limitations
    – Availability of dosage
CDC Recommendations

The CDC recommends when opioids are started, providers should prescribe the lowest effective dosage. Providers should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to 50 morphine milligram equivalents (MME) or more per day, and should avoid increasing dosage to $\geq 90$ MME per day or carefully justify a decision to titrate dosage to $>90$ MME per day.
Considering Whether to Use Opioids for Chronic Pain Management

• **Recommendation 1.** Prioritize nonpharmacologic and nonopioid pharmacologic pain management strategies, unless the expected benefits of opioids for both pain and function are anticipated to outweigh risks to the patient.

• **Recommendation 2.** Establish treatment goals with patients that include realistic pain and function objectives. Ensure that patients understand that opioid therapy will only continue if there is clinically meaningful improvement in pain and function that outweighs the risks.

• **Recommendation 3.** Ensure that patients understand the risks and realistic benefits of opioid therapy and the responsibilities of both patient and clinician for managing therapy.
Prescribing Opioids for Chronic Pain Management

- **Recommendation 4.** Prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids when starting opioid therapy.

- **Recommendation 5.** Use caution when prescribing any dosage of opioids. Prescribe the lowest effective dosage when starting opioid therapy and when planning to increase dosage to ≥50 morphine milligram equivalents (MME)/day, assess the patient’s benefits versus the harms of being on the new dose. Avoid increasing dosage to ≥90 MME/day or appropriately justify a decision to do so.

- **Recommendation 6.** When opioids are used to treat a patient in acute pain, prescribe the lowest effective dose of immediate-release opioids in no greater quantity than needed for the expected duration of pain. In most cases this will be three days or less, and rarely over seven days.
Regularly Assessing the Harms and Benefits of Opioids in Chronic Pain Management

**Recommendation 7.** Conduct a harm/benefit analysis with the patient within one to four weeks of starting opioid therapy or of dose escalation, and at least every three months thereafter. When benefits do not outweigh harms, optimize other therapies and taper to lower dosages or discontinue opioids.
Mitigating Overdose Risk

- **Recommendation 8.** Regularly evaluate the patient’s overdose risk and incorporate strategies to mitigate risk in the patient’s pain management plan, for example, by offering Naloxone.

- **Recommendation 9.** Regularly review prescription drug monitoring program (PDMP) data when starting opioids and periodically during treatment to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose.

- **Recommendation 10.** Regularly use urine drug testing to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

- **Recommendation 11.** Avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
Treating Opioid Use Disorder

Recommendation 12. Offer or arrange treatment for patients with opioid use disorder.
Morphine milligram equivalent (MME)
**Opioid Conversion Guide**

These conversions are a guide only. Patients may vary in their response to different opioids. After changing opioid, close assessment should follow and the dose altered as necessary.

### Equianalgesic doses of oral opioids

<table>
<thead>
<tr>
<th>Oral opioid</th>
<th>Conversion factor (opiod dose x or ÷ by factor = morphine dose)</th>
<th>Practical equianalgesic dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>morphine</td>
<td></td>
<td>10 mg</td>
</tr>
<tr>
<td>hydromorphone</td>
<td>÷ 5</td>
<td>2 mg</td>
</tr>
<tr>
<td>oxycodone</td>
<td>÷ 1.5</td>
<td>5-7.5 mg*</td>
</tr>
<tr>
<td>codeine</td>
<td>+ 8</td>
<td>75-90 mg*</td>
</tr>
<tr>
<td>tapentadol</td>
<td>+ 3</td>
<td>50 mg*</td>
</tr>
<tr>
<td>tramadol</td>
<td>+ 5</td>
<td>50 mg</td>
</tr>
</tbody>
</table>

* dose guided by strength of medication available.

**Methadone** conversions are complicated and prescribing should be restricted to medical specialists with experience of methadone prescribing for pain management.

### Subcutaneous route conversions

<table>
<thead>
<tr>
<th>Opioid</th>
<th>Oral dose</th>
<th>Equianalgesic subcutaneous dose</th>
<th>Conversion factor (oral dose ÷ by factor = subcut dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>morphine</td>
<td>30 mg</td>
<td>10 mg</td>
<td>+ 3</td>
</tr>
<tr>
<td>hydromorphone</td>
<td>6 mg</td>
<td>2 mg</td>
<td>+ 3</td>
</tr>
</tbody>
</table>
Opioids - Titrate, Rotate, Convert

- Opioid management frequently requires dose or drug changes to balance efficacy, tolerability, compliance and risk
- Short vs Long-Acting opioids
- Abuse Deterrent Formulations (cost / benefit)
- Breakthrough pain
- QHS dosing (sleep apnea)
- Limited formulary options for CMS, Tricare
- Poor evidence-based management data
Opioid Conversion Example

- Patient is taking Oxycontin 60mg TID want to convert to Morphine extended release.
  - Oxycodone 20mg = Morphine 30 mg po
  - Oxycodone 60mg = Morphine 90 mg
  - Morphine 30 mg TID

- Morphine 20mg IV: — ___ mg PO morphine

- Oxycodone 60mg PO: —-- ___ mg PO Hydrocodone

- Hydrocodone 30mg PO: ___ mg IV morphine
**Opioid Conversion Example**

- Patient is taking Oxycontin 60mg TID want to convert to Morphine extended release.
  - Oxycodone 20mg = Morphine 30 mg po
  - Oxycodone 60mg = Morphine 90 mg
  - Morphine 30 mg TID

- Morphine 20mg IV: _60 mg PO morphine
- Oxycodone 60mg PO: _90 mg PO Hydrocodone
- Hydrocodone 30mg PO: _10 mg IV morphine
STOP BANG

• Screening for Obstructive Sleep Apnea The “S T O P  B A N G” assessment tool assists providers with identifying patients who may be at a high risk of respiratory depression due to the use or abuse of opioids. The acronym “STOP BANG” relates to symptoms the patient may experience prior to sleep apnea diagnosis and treatment. Use of alcohol or opioids can significantly increase the incidence of obstructive sleep apnea, worsen existing cases and may cause death by completely disrupting normal breathing. An assessment of sleep disturbances is a key metric for evaluating patient risk as well as for monitoring opioid therapy.

• If the patient answered yes to two or more questions on the STOP portion, he or she is at risk of obstructive sleep apnea.

• To find out if the patient is at moderate to severe risk of obstructive sleep apnea, he or she should complete the BANG questions below.
## STOP BANG Questions

|   |  
|---|---|
| 1. **Snoring**  | Do you snore loudly (louder than talking or loud enough to be heard through closed doors)? | Yes/No |
| 2. **Tired**    | Do you often feel tired, fatigued, or sleepy during daytime? | Yes/No |
| 3. **Observed apnea** | Has anyone observed you stop breathing during your sleep? | Yes/No |
| 4. **Blood pressure** | Do you have or are you treated for high blood pressure? | Yes/No |
| 5. **BMI more than 35 kg/m²?** |  | Yes/No |
| 6. **Age**      | Age over 50 yr old? | Yes/No |
| 7. **Neck circumference** | Neck circumference greater than 40 cm? | Yes/No |
| 8. **Gender**   | Gender male? | Yes/No |

**High risk of OSA:** answering yes to three or more items  
**Low risk of OSA:** answering yes to fewer than three items
**Opioid Management / Monitoring**

- The 4 A’s
- Analgesia
  - Numerical or Subjective
  - Activity level to include:
    - Work duties, exercise, domestic chores, leisure
- Adverse reactions / effects
  - Side effects, affect / personality, family dynamics
- Aberrant behaviors
- Misuse/Abuse/Diversion
Aberrant Use Definitions

• Misuse - using a medication in a manner other than as specifically directed by a healthcare professional
• Self titration due to poor pain control or anxiety
• Abuse – deliberate nonmedical use: crushing, snorting, injecting
• Diversion (buying/selling/stealing)
• All contribute to opioid-related deaths
Aberrant Use Definitions

- Tolerance - adaptive state after drug exposure, increased dose required for clinical effect *** Alone, does not indicate addiction***

- Dependency – physiological adaptation wherein discontinuation or reversal of drug causes withdrawal syndrome
  - *****Occurs in all patients on sufficient doses over time ---Alone is not indicative of addiction*****

- Addiction – primary, chronic, neurobiological disease with genetic, environmental, and psychosocial elements
  - One or more of the following:
  - Impaired control over use, compulsive use, continued use despite harm, and craving– Defines addiction
Opioid Prescribing and Tapering

For patients requiring daily opioid therapy for longer than a few days to a few weeks, consider switching from short-acting opioids to long-acting oral therapy.
First, convert any opioid in use to its equivalent amount of morphine in mg/day. Then, divide into BID (or, occasionally TID) Morphine ER doses.

Fentanyl patches are another option, but are expensive and difficult to titrate.

Buprenorphine (Suboxone®) is an option if opioid abuse, misuse or extreme opioid tolerance is a risk. (Be observant of State Regulations)

Typical taper. Taper every week by 10% of original dose until 20% remains. Then taper the remaining 20% by 5% of original dose each week until off or at goal.

Rapid taper. Reduce by 25% every 3–7 days, depending upon short vs. longer drug half life.
Controlled Substance Agreement

- Informed consent + treatment “contract”
- Risks/benefits/alternatives to chronic opioid therapy
- Outlines prescriber expectations of patient
- Single pharmacy / single prescriber
- Patient accountability to safeguard medication
- No refills for lost/stolen/destroyed medication
- Keep out of reach of children, elderly, pets
- No selling or sharing of medication with others
- Take ONLY as prescribed, no self-titration
- No early refills or nights, weekends, holidays
- Consent to toxicology testing and pill-counts Refills are contingent upon keeping scheduled appointments
- Refill requests and appointment rescheduling: 3 days notice- 24 hour wait time for Rx refills
- Privacy waved in the event of law enforcement involvement
- Therapy may be discontinued at any time for misuse, lack of efficacy, risk > benefit, noncompliance with terms.
References

- Smith RG Opioid Prescribing Podiatry Management June/July 2018
Conclusions

► Counteract “opioid misuse, abuse, and diversion”
  – Open and nonjudgmental discussion with providers and patients
  – Follow up on opioid use by our patients by proper prescribing and following guidelines and regulations
  – Explain importance of potential drug interactions

► Avoid prescribing opioids and products that may contribute to adverse effects and addiction

► Patients on complicated analgesic medical regimens should avoid herbs, supplements, energy drinks and illicit drugs unless carefully screened/supervised, but prioritize analgesic drugs that have a narrow therapeutic index