Safer Opioid Prescribing; Review of the CDC Guidelines, Naloxone Use, and Office Strategies and Protocols (Parts 1 and 2)

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Disclosures

None

Thanks to Annika Maly, Dr. Magni Hamso (TRHS), and Elisha Figueroa and Marianne King (Governor’s Office of Drug Policy) for sharing some slides.
Goals

• Brief comments on Epidemiology
• Discuss possible risks to physicians
• New CDC Guidelines
• Methadone and Benzo Risks. Fentanyl risks and prescribing
• Some Tips on Using the Idaho PMP (Prescription Monitoring Program)
• Naloxone
• Suboxone
• Office Work Flow Tips and Ideas
“To hear about pain is to have doubt; to experience pain is to have certainty.”
Elaine Scarry, *The Body in Pain; The Making and Unmaking of the World*

“Pain upsets and destroys the nature of the person who feels it.” ~ Aristotle
The Problem

• Opioid pain reliever prescribing has quadrupled since 1999.

• Drug overdose is the most common cause of death in the United States in people less than 50.

• Non prescription use of opiates now the second most common cause of substance abuse disorder in the US.
Opiate use out of control

• USA has 5% of the world’s population but uses 80% of the world’s opiates.

• 20% of patients presenting to physicians offices with non-cancer pain get opiates. In 2012, enough for a bottle for every person in the USA.

• Heroin use up over 70% in recent five year period in large part due to increased opiate use in younger people and the fact that prescription opiates are more expensive to buy on the street than heroin.

• Also increased purity and availability.
The Burden on our Rural Communities

• Overdose/death rates have increased in rural areas greater than urban areas.¹

• Methadone treatment programs don’t exist in rural settings.

• Limited mental health resources

You are more likely to die from an overdose in a rural setting compared to an urban setting.

The DEA is starting to crack down

Many examples of physicians sentenced with drug dealing charges:

• Dec 2015: California MD sentenced to 27 years in prison.
• May 2015: 22 physicians and pharmacists arrested by DEA in Arkansas, Alabama, Louisiana, and Mississippi.
• Nov 2013: California MD sentenced to 11 years in prison.
February 5 2016: PRECEDENT SETTING CASE

- LA doctor charged with second-degree murder of 3 patients, sentenced to 30 years/life in prison.

- “Tseng wrote that she lacked sufficient training in prescribing addictive narcotics and was in denial about what was going on in her practice”.

  [Link](http://www.cnn.com/2016/02/05/health/california-overdose-doctor-murder-sentencing/)
More news!

The Comprehensive Addiction and Recovery Act (CARA) passed 94-1 in the Senate on March 11, 2016.

◦ $80 million. The most expansive federal, bipartisan legislation ever for addiction support.
◦ Strengthen prescription drug monitoring programs, launch opioid and heroin treatment and intervention programs, make Naloxone more widely available.
◦ Senate hearing
Review of Recent CDC Recommendations

12 Recommendations

Recommendations pertain to patients who have chronic pain outside of cancer patients.

Quote from palliative care experts: “Opiate use in patients without underlying serious illness for example sports injuries, headaches, or fibromyalgias, is associated with risk of substance use disorder and unintentional overdose. Pain in this patient population is best addressed in multidisciplinary pain programs with the appropriate psychosocial and behavioral health expertise and supports.”
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (recommendation category: A, evidence type: 3).
Quotes

“Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder, highlighting the value of guidance on safer prescribing practices for clinicians”

“Primary care clinicians report having concerns about opioid pain medication misuse, find managing patients with chronic pain stressful, express concern about patient addiction, and report insufficient training in prescribing opioids”

“Prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions”
“In summary, evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent. These findings supplement findings from a previous review of the effectiveness of opioids for adults with chronic noncancer pain. In this previous review, based on randomized trials predominantly ≤12 weeks in duration, opioids were found to be moderately effective for pain relief, with small benefits for functional outcomes; although estimates vary, based on uncontrolled studies, a high percentage of patients discontinued long-term opioid use because of lack of efficacy and because of adverse events”

“Few studies have been conducted to rigorously assess the long-term benefits of opioids for chronic pain (pain lasting >3 months) with outcomes examined at least 1 year later. “
Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least 6 months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves. These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients."
Other problems with opiates

• Association with increased cardiovascular events.
• Possible increased fracture risk.
• One study found that opioid dosages $\geq 20$ MME/day were associated with increased odds of road trauma among drivers
• Androgen deficiency
Avoid opiate when chronic visceral or central pain syndromes. This differs from palliative care recs.
Other options for pain

- Regular use of Tylenol
  - Dosing
  - Liver disease, ETOH
- NSAIDS including topical
  - Knee, Hip good, Back?
  - Synergy
  - Concerns
- Topical Capsaicin
- Steroid injections
- SNRI’s-Cymbalta (FDA approved for treatment of musculoskeletal pain), Effexor, Pristiq, Savella TCA’s
- Lidoderm patches or gel
- Nitroglycerin patches for chronic tendinitis (.2 mg/hr-cut in quarters)
- Address sleep, psych conditions

- Tramadol
  - Mechanism
  - Efficacy-neuropathic, fibromyalgia, Other pain-any better than NSAIDS?
  - Concerns-Death, Suicide, seizures, metabolism in older adults and liver disease.
  - Addicting.
- Anticonvulsants-Neurontin, Lyrica, Tegretol
- Intrathecal opiates.
- PT, CBT, aerobic exercise, smoking cessation, TENS, spinal cord stimulation, acupuncture, OMT,
- Epidural steroids, Biofeedback
- Fascial Distortion Model
CDC Guidelines

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).
PEG Pain Screening Tool

1. What number best describes your pain on average in the past week:

   0  1  2  3  4  5  6  7  8  9  10
   No pain                           Pain as bad as you can imagine

2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?

   0  1  2  3  4  5  6  7  8  9  10
   Does not interfere               Completely interferes

3. What number best describes how, during the past week, pain has interfered with your general activity?

   0  1  2  3  4  5  6  7  8  9  10
   Does not interfere               Completely interferes

To compute the PEG score, add the three responses to the questions above, then divide by three to get a final score out of 10.

The final PEG score can mean very different things to different patients. The PEG score, like most other screening instruments, is most useful in tracking changes over time. The PEG score should decrease over time after therapy has begun.
Monitoring Efficacy

- Clinically meaningful improvement has been defined as a 30% improvement in scores for both pain and function.
- Also look at patient centered functional goals like walking the dog, returning to work, ability to do recreational activities etc.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type)

- Addiction
- Complete pain relief, function.
- Interactions (benzos, etoh, other CNS depressants)
- Side effects like constipation
- Motor vehicle issues particularly when first starting or increasing dose. One study showed impaired driving over 20 MME.
- Safeguarding from others in house. Lock up
- Naloxone (more on this later)
- You can integrate this into controlled substance contract or discussion.
- Informed consent.
4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4)

- ER/LA opioids include methadone, transdermal fentanyl, and extended-release versions of opioids such as oxycodone, oxymorphone, hydrocodone, and morphine
- Evidence review found a fair-quality study showing a higher risk for overdose among patients initiating treatment with ER/LA opioids than among those initiating treatment with immediate-release opioids
- And not more effective.

- Time-scheduled opioid use was associated with substantially higher average daily opioid dosage than as-needed opioid use in one study
“ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week.”

“Although there might be situations in which clinicians need to prescribe immediate-release and ER/LA opioids together (e.g., transitioning patients from ER/LA opioids to immediate-release opioids by temporarily using lower dosages of both), in general, avoiding the use of immediate-release opioids in combination with ER/LA opioids is preferable, given potentially increased risk and diminishing returns of such an approach for chronic pain.”

When an ER/LA opioid is prescribed, using one with predictable pharmacokinetics and pharmacodynamics is preferred to minimize unintentional overdose risk. In particular, unusual characteristics of methadone and of transdermal fentanyl make safe prescribing of these medications for pain especially challenging.

“Methadone should not be the first choice for an ER/LA opioid”

Only physicians who familiar with the dosing and problems with methadone and Fentanyl should prescribe them and monitor/educate their patients closely.
Death Rate from Overdose Caused by a Single Prescription Painkiller

Adapted from: Substance Abuse and Mental Health Administration, Center for Behavioral Statistics and Quality, Drug Abuse Warning Network Medical Examiner Component, 2009
Which of the following is a false statement about Methadone?

1. It can take greater than 7 days to build up a steady state.
2. It is effective as an analgesic when dosed bid.
3. The smallest 5mg tablet size is 4-12 times as potent as the smallest 5mg size of Oxycodone. The DME conversion changes as you change the dose, with it becoming greater as the Methadone dose goes up. This adds to the risk and challenge.
4. It can be especially deadly when combined with drugs like benzos or etoh or when used on a PRN basis.
5. It accounts for 1/3 of all unintentional deaths from opiates.
It is effective as an analgesic when dosed bid

- Not really
- More frequent dosing usually needed
Methadone for Chronic Pain

• Advantage: Euphoria side effect may be a little less than with other opiates, so abuse risk may be a little lower. (But is still present.)

• Disadvantage: Although methadone is “long-acting” by its prolonged ability to stave off opiate withdrawal (effective for heroin addiction), as an analgesic it needs to be dosed 3-4 times per day.

• So it's a short-acting analgesic, but if used prn like other short acting drugs, it can be deadly.
Methadone Continued

• Extremely variable, idiosyncratic dose response.
• Variable speed of metabolism.
• Extremely Long Half life (128 Hours)
• Only comes in 5 and 10 mg which by MME’s are very potent.
• Can take weeks to reach a steady state. May not be controlling pain optimally during that time, but can cause dangerous respiratory suppression.
• Special concern (as always but probably more here) for combination with sleep apnea, benzos etoh, other cns depressants.
• DON’T make any change to dose for at least the first 7 days, then must be titrate up very slowly. Don’t be fooled or lulled by the dose you see heroine addicts on.

• Also cardiac concerns for arrhythmias and QT prolongation. It is contraindicated in patients with prolonged QT’s. Consider EKG to look for prolonged QT before starting and definitely get one if giving 100 mg or more a day.
• Don’t ever use on opiate naïve patient (cutoffs for opaite naïve-60mg oral morphine/day, 30 mg oral oxycodone, 8 po Dilaudid) NOT no opiates.
• In fact, I wouldn’t use it. Palliative care literature states should only be prescribed by pain palliative or pain specialists.
Transdermal Fentanyl

• Gradually increasing serum concentration during the first part of the 72-hour dosing interval.
• Variable absorption based on factors such as external heat.
• Dosing of transdermal Fentanyl in mcg/hour, which is not typical for a drug used by outpatients, can be confusing.
• Increased body fat seen in elderly can make it stick around for long time even after removed.
• Only clinicians who are familiar with the dosing and absorption properties of transdermal Fentanyl and are prepared to educate their patients about its use should consider prescribing it, and NEVER prescribe it to an opiate naïve patient. Neither should parenteral Fentanyl.
Conversion Tables

• Dangerous to rely on these.

• People respond to different molecules of opiates differently. (hyperalgesia, euphoria, sedation, resp depression). Incomplete cross tolerance. Also consider renal and liver disease.

• Designed for 24 hour acute pain periods after surgery.

• In rotating to another opioid decrease the equianalgesic dose by 25 to 50 percent. 50% of pain is well controlled and 25% if it is not.

• In rotating to Methadone, reduce the dose by 75 to 90 percent, and remember the equivalent morphine dose changes with different doses (dangerous).
Compared to oral morphine on per mg basis...

- Codeine is 1/10th as potent
- Tramadol is 1/10th as potent
- Hydrocodone is ~ 1 - 1.5 times as potent
- Oxycodone is ~ 1.5 times as potent
- Parenteral morphine is ~ 3 times as potent
- Hydromorphone is ~ 4 times as potent
- Parenteral hydromorphone is ~ 20 times as potent
CDC Guidelines

When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians 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)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day (recommendation category: A, evidence type: 3)
“The contextual evidence review found that although there is not a single dosage threshold below which overdose risk is eliminated, holding dosages <50 MME/day would likely reduce risk among a large proportion of patients who would experience fatal overdose at higher prescribed dosages.”

“No single threshold could be identified.”

0-20 safer than 20-50

Randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy and maintenance of current dosage (40 verses 52).

“Most experts agreed that, in general, increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function”

“Most experts also agreed that opioid dosages should not be increased to ≥90 MME/day without careful justification based on diagnosis and on individualized assessment of benefits and risks”.

Extra caution in the elderly or renal or hepatic impairment

Wait at least 5 half lives before going up on dose and at least a week before going up on Methadone.

If going over 50, what are goals, need closer monitoring, precautions, Naloxone.
Lower Doses

HR for Overdose by Morphine Equivalents

Opiate Induced Hyperalgesia & Allodynia

• Well established easily, reproducible in labs.
• Studies have shown that Methadone-maintained individuals reliably show poor tolerance for experimental pain.
• Hyperalgesia and spontaneous bone and pain are cardinal symptoms of opioid withdrawal.
• Is this clinically relevant?
• Definitely suspect if more pain, more diffuse pain, or possibly delirium with increased dosing.

• Palliative care literature talks about accompanying neuroexcitation (agitation, anxiety, restlessness) and risk factors being DME of over 200, renal failure, dehydration with accumulation of toxic metabolites as possible mechanism.
• Can be good reason to not use high doses and also to justify tapering dose.
• Tolerance to the analgesic effect of opiates almost never occurs, as opposed to tolerance to sedation, nausea, itching.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4)
Acute pain

• Opiate use is associated with long term use and the more opiates used the bigger the risk.

• Physical dependence after a few days. “Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit”

• More pills, more risk of diversion

• Most cases of acute pain, excluding surgery or trauma, 3 or less days of opiates is adequate. In many other cases, no longer than 3-5 days. Up to 7-there is disagreement.
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (recommendation category: A, evidence type: 4)
Quotes and Statements

• “Continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”

• “The contextual evidence review found that patients who do not have pain relief with opioids at 1 month are unlikely to experience pain relief with opioids at 6 months.”

• Risk for overdose associated with ER/LA opioids might be particularly high during the first 2 weeks of treatment.

• Experts noted that risks for opioid overdose are greatest during the first 3–7 days after opioid initiation or increase in dosage, particularly when Methadone or transdermal Fentanyl are prescribed; that follow-up within 3 days is appropriate when initiating or increasing the dosage of methadone; and that follow-up within 1 week might be appropriate when initiating or increasing the dosage of other ER/LA opioids.
So what should follow-up be

• Follow-up in 1-4 weeks.
• Shorter end if 50 or more MME.
• Follow-up *within week* if on ER/LA
• Within 3 days if starting or increasing dose of Methadone
• I would do the same with transdermal Fentanyl
What do you assess

- Pain average, interference with enjoyment of life, and interference with general activity (PEG) Assessment Scale
- Side effects: ie constipation, drowsiness.
- Warning signs for OD, sedation, slurred speech.
- Warnings for opiate abuse disorder: cravings, wanting to increase use, difficulty controlling use, disruption of job, family.
Long term follow-up

• At least 3 months
• More frequent indications
  ◦ 50 MME or more.
  ◦ Psych issues.
  ◦ On CNS depressants also.
  ◦ History of OD
  ◦ Greater risk of opioid abuse disorder
Opiates not the way to go. Risks outweigh benefits or problems.

Taper:
- 10-50% of original dosage q week. But may have to go slower ie. 10%/month eg. particularly if they have been on them for years.
- You want to minimize S and S of withdrawal. 10%/week may be good place to start.
- Signs of withdrawal: early signs are drug craving, agitation, anxiety, insomnia, diaphoresis, mydriasis, tremor, tachycardia, insomnia, tearing, piloerection, yawning. Later signs are abdominal cramping, diarrhea, nausea, vomiting.
- CINA
  - They talk about rapid over 2-3 weeks if severe event like OD, but I would consider stopping all together and using Clonidine and other meds.
  - Clinicians should discuss with patients undergoing tapering the increased risk for overdose on abrupt return to a previously prescribed higher dose.
  - Tapering may have to paused and/or slowed when you get to lower doses.
- Psychosocial support and treatment
- Naloxone if off but opiate use disorder
8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4)
Risk factors and situations

Sleep disorder breathing including sleep apnea, chf, obesity. Avoid opiates whenever possible if moderate to severe. Adjust dose in others.

◦ Tolerance to respiratory effects of opiates not what we thought.

◦ Sleep apnea very common.

◦ Decrease dose of opiates 50% when patient has a respiratory condition (eg. URI, PNA, influenza).

◦ Sleep studies of patients on morphine equivalent doses of 150 mg or more or on Methadone of 50 mg a day or more.
More Risk factors

• Pregnancy: Not covered in depth here. Codiene taken by breast feeding mothers associated with neonatal toxicity and death.

• Hepatic, renal insufficiency. Don’t use codiene in either and don’t use morphine is renal failure, and dosing/frequency of all opiates should be reduced for both renal and hepatic failure.

• Neurological diseases.

• Elderly (cognitive problems may also play a role). Avoid morphine and codiene in the frail elderly.

• Psych issues (especially anxiety), depression.

• Prior nonfatal overdose

• Substance abuse.

• Don’t overestimate risk assessment tools. Current evidence does not show great evidence for identifying who is at risk, but I would still use them.
Other risk factors

- Personal and family history
- Males, smokers
- DUI's
- Unemployed
- Isolated
- Tools ORT, SOAPP, DIRE
- History of preadolescent sexual or other abuse
- PTSD
- 1/5 people at risk for addiction
The question “How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?” (with an answer of one or more considered positive) was found in a primary care setting to be 100% sensitive and 73.5% specific for the detection of a drug use disorder compared with a standardized diagnostic interview.

- AUDIT, DAST

- Educate patients regarding the risk of combining opiates with etoh, benzos or other cns depressants.

- Opiate Risk Tool (see next slide): http://www.partnersagainstpain.com/printouts/Opioid_Risk_Tool.pdf

- Also consider the Screener and Opioid Assessment for patients (SOAPP) with pain: https://nhms.org/sites/default/files/Pdfs/SOAPP-14.pdf

- And/or the DIRE questionnaire: http://integratedcare-nw.org/DIRE_score.pdf
# Opioid Risk Tool

<table>
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<tr>
<th></th>
<th>Mark each box that applies</th>
<th>Item Score If Female</th>
<th>Item Score If Male</th>
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<tbody>
<tr>
<td><strong>1. Family History of Substance Abuse</strong></td>
<td>Alcohol: [ ]</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Illegal Drugs: [ ]</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Prescription Drugs: [ ]</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>2. Personal History of Substance Abuse</strong></td>
<td>Alcohol: [ ]</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Illegal Drugs: [ ]</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Prescription Drugs: [ ]</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>3. Age (Mark box if 16 – 45)</strong></td>
<td>[ ]</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>4. History of Preadolescent Sexual Abuse</strong></td>
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<tr>
<td><strong>5. Psychological Disease</strong></td>
<td>Attention Deficit Disorder, Obsessive Compulsive Disorder, Bipolar, Schizophrenia: [ ]</td>
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<tr>
<td></td>
<td>Depression: [ ]</td>
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</tr>
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</table>

**TOTAL**

**Total Score Risk Category**
- Low Risk: 0 – 3
- Moderate Risk: 4 – 7
- High Risk: ≥8
Naloxone HCl = Generic
Narcan, Evzio = Brand Name
Naloxone

Temporarily reverses an opioid overdose by slipping the drug off the brain’s opioid receptors and allow breathing to be restored

Effects last 30-60 minutes, after that it wears off and overdose can come back

Only works for opioids

NOT: Alcohol, benzos or stimulants (cocaine, meth)
History of Naloxone Use

• Used in emergency settings and anesthesiology for more than 40 years

• 1996-2014, CDC reports administration by laypersons has resulted in over 26,000 overdose reversals\(^{12}\)

• 42 states have amended laws to increase access and reduce liability fears\(^{3}\)
History of Naloxone Use

![Graph showing the increase in the number of survey respondents reporting the beginning or continuing provision of naloxone kits to laypersons by year, 1996-2014.]

*Results of a survey conducted in July 2014 by the Harm Reduction Coalition, in which 136 organizations reported 644 local sites where laypersons were trained to recognize an opioid drug overdose and provided naloxone kits.

†As of June 2014.
Survey of 329 Drug users
64.6% had witnessed an overdose\(^7\)
34.6% had unintentionally overdosed\(^7\)

World Health Organization
- Increasing the availability of naloxone could prevent more than 20,000 deaths in US each year\(^8\)

Project Lazarus in North Carolina
- Naloxone access and training
- 69% decrease in overdose deaths in a two year period\(^10\)

Centers for Disease Control
- From 1996-2010, 53,000 persons received training and naloxone\(^13\)
- Reports of over 10,000 overdose reversals\(^13\)
Idaho’s Law – H108

Any **prescriber** or **pharmacist** may prescribe to:

- A person at risk of experiencing an opiate-related overdose
- A person in a **position to assist**
- A person who, in the course of **official duties**, may encounter
- A person with a **valid reason** to be in possession
Idaho’s Law – H108

• Any person may administer, but shall contact EMS

• Any person who prescribes or administers shall NOT be held liable in a civil or administrative action or subject to criminal prosecution

• DHW and ODP will create and maintain an online education program
High Risk Situations

• Recent rehab
• Recent prison
• Recent dose increase
• Recent overdose
• High dose (>100 morphine-equivalents/day)
• Concomitant use of depressants, including benzodiazepines and alcohol
• Obesity with OSA/OHS, liver disease, renal disease
• Acute illness reducing tolerance
• But good idea to provide it for anyone on opiates.
Pharmacies

More and more pharmacies are stocking and providing without a prescription from physician.
Prescribing Naloxone

• Teaching takes about 5 minutes – plus 7 minutes for watching video (which an MA can facilitate)

• Great opportunity when
  ◦ Renewing pain agreement
  ◦ New prescription
  ◦ Dosage change
  ◦ Establishing care
Some more valuable things to know about Naloxone

• Pharmacist can write rx for patient. Insurance will pay if written in patients name and patient gives consent, but other person can get.

• Pharmacist may charge consultation fee if no Doctor’s rx. This is being done less and less (maybe not at all??).

• Naloxone (0.4mg/1mL or 4mg/10mL vial)
  • Rx with 1mL syringe, alcohol swabs, and 1-inch 25g needle
  • Sig: **Call 911.** Inject 1mL IM for opioid overdose. If no response in 2-3 minutes. Repeat with 2nd dose.
  • Ask pharmacist to teach
  • At Costco $27 for 1 ml (.4mg), $189-237 for 10 ml vial although not available at Costco. You can a pre-filled syringe which has two doses at Costco for $55.28.
  • Here at FMRI they can get two .4 vials syringes, and needles for $27 under our sliding scale.
Some more valuable things to know about Naloxone Cont.

• Narcan Nasal Spray 4mg
  • Sig: **call 911.** 1 spray in nostril for opioid overdose. If no response in 2-3 minutes. Administer 2nd spray in other nostril.
  • Generic option. $100 for kit of 2 doses. They have to screw two pieces together. Can’t be done in advance. Brand name is $150 and does not need to be put together.

• Evzio autoinjector (epi-pen). **Call 911 and use.** Cash price 2= $4,500. Of course much cheaper if covered by insurance or other plan.

• Person should always have access to at least two doses/injections.

• Multiple doses may be needed especially for Fentanyl and especially nonpharmaceutical Fentanyl.
MAD Nasal™ Intranasal Mucosal Atomization Device*

The MAD Nasal™ Intranasal Mucosal Atomization Device from Teleflex is the safe and painless way to deliver medications with rapid absorption across mucosal membranes to your patients' blood stream without an intravenous line.

- Atomizes in any position
- The soft, conical plug on the tip forms a seal with the nostril, preventing expulsion of fluid
- The spray atomizes drugs into a fine mist of particles 30-100 microns in size

*For use with drugs approved for intranasal delivery.

View in Catalog

View Video

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Prescribing Naloxone

Recognize the signs of an opioid overdose:
- Not breathing, or slow or shallow breaths
- Lips or fingernails turning blue or gray
- Won’t wake up even if you shake them or say their name
- Snoring, gurgling, or choking sounds

1. Call 911 and give naloxone
   If no reaction in 3 minutes, give a second naloxone dose.

2. Perform rescue breathing
   Follow 911 dispatcher instructions.

3. Stay with patient
   Wait at least 3 hours or until help arrives.

---

How to administer naloxone

**Nasal Spray**
1. Remove cap.
2. Screw on white cone.
3. Remove cap.
4. Gently screw naloxone into applicator.
5. Spray half of the naloxone (1 mL) into one nostril, and half (1 mL) into the other.
6. If no reaction in 3 minutes, give a second dose.

**Injectable**
1. Remove cap and unscrew needle.
2. Draw 1 mL into syringe. (1 mL = 1cc)
3. Choose upper arm, thigh, or butt. Insert the needle at a 90-degree angle, and push the plunger. Inject the entire 1 mL.
4. If no reaction in 2–3 minutes, give a second dose.

**Auto-Injector**
1. Follow this product’s voice and visual prompts to inject naloxone into the patient’s side, thigh, or upper arm, as needed.

View videos with detailed instructions at [odp.idaho.gov/facts/opiates.html](http://odp.idaho.gov/facts/opiates.html)
Our (Office of Drug Policy) Ask

Talk about and prescribe Naloxone to your patients

- Opioid use disorder
  - Prescription pain medications or heroin
  - Past or current use
  - Patients at highest risk: right out of rehab or prison/jail
- Chronic opioid pain medications
  - At any dose, but especially patients on >100 morphine equivalents per day
  - With any dose increase or medication change
- Consider co-prescribing even for short courses of opioids
9. Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).
Quotes

• “Most fatal overdoses were associated with patients receiving opioids from multiple prescribers and/or with patients receiving high total daily opioid dosages.”

• “Experts agreed that clinicians should not dismiss patients from their practice on the basis of PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions, nonopioid pain treatment [see Recommendation 1], naloxone [see Recommendation 8], and effective treatment for substance use disorder” [see Recommendation 12]).
Things to know about the PMP

There is a federal law which exists which protects the privacy of patients who go to opiate treatment/recovery centers, such that any Methadone, Suboxone, or Buprenorphine which patients get from these clinics are dispensed and not prescribed and therefore DO NOT show up on the PMP. The three local clinics where this is occurring are: Raise the Bottom in Boise, and the two Centers for Behavioral Health clinics-one in Boise and one in Meridian. Also, controlled substances filled at some VA’s do not show up. They do for the Boise VA.
More things to know about the PMP

• You have to be registered to get a controlled substance license in Idaho, but this is not dependent on use. In states where it is, over 50% do, (i.e. Kentucky) doctor shopping down 52%.

• We are not very good about using it here-9800 registered and only 90 uses per week; and the more controlled substances Rx’s a provider writes here, the less likely he/she is to use it.

• You can have a delegate check it for you. A delegate can be a nurse or medical office worker (even front desk person)

• A provider may have four delegates, and there is no limit to how many providers a staff or nurse can be a delegate for. You have to go on site and approve your delegate.

• You should run a report on what rx’s you have written and look for unfamiliar or suspicious names. Most of the time it is office staff.
You can search other states for an individual patient.

<table>
<thead>
<tr>
<th>PMP Interconnect Search</th>
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<tr>
<td>To search in other states as well as your home state for patient information, select the states you wish to include in your search.</td>
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Please read the acknowledgement.
Or you can have default states which will be searched every time, but this may slow things down some.
Default InterConnect PMPs

- Alaska
- Arizona
- Arkansas
- Colorado
- Illinois
- Indiana
- Kansas
- Maine
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Montana
- Nevada
- New Mexico
- North Carolina
- North Dakota
- Ohio
- Oklahoma
Default Interconnect PMPs continued

- Oregon
- Rhode Island
- South Carolina
- Texas
- Utah

Update Defaults
PMP Continued

- Notice Oregon and Washington are not on there, but you can order records from Washington.
- Wyoming and Montana coming by end of year.
- PMP is being integrated into EMR at clinics and pharmacies (not in Idaho yet). Interface already established with Epic, Cerner, and Allscripts. Clinic only has to pay $50 a year. May get to a point where RX’s are automatically returned to the prescribing provider.
CDC Guidelines

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).
Urine tox screens

• Do “real time” urine tox screens. Try to make them somewhat random and unpredictable to patient.

• Can do them when patients come is to pick up Rx. Or you can ask them to come in within 24-48 hours and include a pill count.
“Clinicians should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.”
CDC Guidelines

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible (recommendation category: A, evidence type: 3)

A large proportion of overdose deaths from opiates are in patients who are also taking benzos.

Taking benzos with opiates nearly quadruples your risk of death.
Quotes

“Experts agreed that although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible.”

“Because of greater risks of benzodiazepine withdrawal relative to opioid withdrawal, and because tapering opioids can be associated with anxiety, when patients receiving both benzodiazepines and opioids require tapering to reduce risk for fatal respiratory depression, it might be safer and more practical to taper opioids first”

“A commonly used tapering schedule that has been used safely and with moderate success is a reduction of the benzodiazepine dose by 25% every 1–2 weeks (213,214). CBT increases tapering success rates and might be particularly helpful for patients struggling with a benzodiazepine taper”
Need to carefully look at risks verses benefits of other CNS depressants (etoh, muscle relaxants, hypnotics, Phenergan, Visteril, etc.) and try to avoid with opiates.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 2).
Opioid Use Disorder. Need at least two of the following

1. Opioids are often taken in larger amounts or over a longer period than was intended.

2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.

3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.

4. Craving, or a strong desire or urge to use opioids.

5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.

6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.

7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.

8. Recurrent opioid use in situations in which it is physically hazardous.

9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.

10. Tolerance, as defined by either of the following: a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect. b. A markedly diminished effect with continued use of the same amount of an opioid. Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

11. Withdrawal, as manifested by either of the following:
   - a. The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal).
   - b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.
Medication Options

• Methadone: we can’t use methadone for opiate addiction maintenance outside of an approved addiction treatment clinic

• Naltrexone: Need highly motivated patient as hard to get them to take PO Naltrexone. There is IM Naltrexone but very expensive.

• Buprenorphine or Suboxone
Buprenorphine (Subutex)

• Partial Mu opioid receptor agonist. At low doses it is an agonist and at higher doses it is an agonist or antagonist depending on the circumstances.

• Because it is a partial agonist, it has the following advantages:
  o Lower abuse potential
  o Lower level of physical dependence
  o Safer than other opiates if ingested in overdose amounts.
  o Implantable Buprenorphine now available.
Suboxone (Buprenorphine/Naloxone)

• Naloxone is 100 times more potent when injected versus taken sublingually. So if injected receptors get blocked, but SL, not enough Naloxone effect to really interfere with Buprenorphine.

• Also, Buprenorphine is given SL because it has poor bioavailability if given PO.
Other issues with it being a partial agonist

• It can knock other full agonist opiates off of opiate receptors and cause an abstinence syndrome because of its lower efficacy at these receptors. And because of its tight binding and slow dissociation from the receptors, this cannot be readily reversed or overcome.

• Also because of this slow dissociation, it can be given on a less than daily basis (as infrequently as 2-3 times a week)
The Study: This double-blind randomized controlled trial enrolled patients 16 years or older who presented to the emergency department with acute extremity fracture. Patients were eligible for participation if they rated their pain as higher than 3 on a scale of 0 to 10, with 0 being no pain and 10 being the worst possible pain. A total of 89 patients were randomized, with 44 patients in the buprenorphine group and 45 patients in the control group. Patients in the buprenorphine group received 0.4 mg of sublingual buprenorphine and 5 mL of intravenous sterile water, whereas those in the control group received 5 mg of intravenous morphine plus a sublingual placebo. Pain was assessed using the same numeric rating scale used at baseline, and again at 30 and 60 minutes after the medications were administered. Adverse effects were recorded.

Results: Pain scores were similar between groups at 30 and 60 minutes after the medications were administered (median pain scores of 5 at 30 minutes and 2 at 60 minutes in both groups). Adverse effects were minimal in both groups and included nausea, dizziness, and hypotension.

Conclusion: In adults with acute bone fracture presenting to the emergency department, sublingual buprenorphine is as effective and safe as intravenous morphine, with quicker and easier administration.

KARI KUBALANZA, MSIV

SOURCE:
Who can prescribe Buprenorphine

• Has to be a physician. At this point nurse practitioners or PA’s are not eligible
• Has to meet one of 7 criteria, but the one most applicable to us is that you take an 8 hour online course.
• You can have up to 30 patients on Buprenorphine (100 if you jump through a lot of hoops)
Tips

• Be stingy with opiates-even for acute pain. In general keep less than 50 MME and don’t go over 90.

• In general don’t give opiates for chronic pain on the first visit (I have made exceptions if I have good records and have talked to the prior provider). Check picture ID. Do point of care urine tox screens before prescribing.

• Look closely at risk factors. Do good H and P, do labs (eg. do you have renal or hepatic failure). Urine tox, Cbc, cmp, Pregnancy test. ?RPR, HIV, hepatitis serologies.

• Also at first visit, pmp, functional assessment (PEG), psych assessment PHQ9, GAD 7 for anxiety, PTSD screen, Opiate Risk tool. Refer to behavioral health if results abnormal.

• Consider a criminal background check: https://www.idcourts.us/repository/start.do

• Work up their pain syndrome. Refer to PT/OT specialist as needed. Don’t ever put in chart chronic pain as diagnosis. Be specific.
Tips Continued

• Don’t start with long acting opiates and be very selective regarding who you put on these, and wait at least a week after starting short acting opiates. Don’t rely too much on conversion tables, and adjust new opiate downward.

• Use controlled substance contract and integrate education into it, like not taking opiates together with benzos or other CNS depressants. Safe storage. This can also function as informed consent about the risks of opiates.

• Frequent visits and monitoring, FUNCTION IS KEY. Opiates only given on trial basis. Need to see improvement. Consider using PEG.

• Use nurse case managers to help you manage these patients.

• Establish a registry. Calculate MME on every patient.

• Do random pill counts. Patient must respond within 24 hours and come in within 48.
Tips Continued

• Develop tier system based on ORT, early refill requests etc.

• Higher risk patients get lesser amount of pills (eg. week at a time), more frequent pill counts, tox screens, maybe giving meds to trusted family member.

• Resign controlled substance contracts every year. Do teach backs.

• Obtain permission to contact other providers, family/friends when appropriate, inform you will be checking the PMP.

• Check PMP initially and then at least q 3 months if not with every refill. (nurse case managers). Several states mandating a PMP check with every Rx.

• Do urine tox screens at least once a year and more frequent as needed. (nurse case managers).

• Consider using the COMM
Tips Continued

• Don’t use Methadone and know what you are doing with Fentanyl, and be careful especially in the elderly. Don’t use either in the opiate naïve patient.

• Make teaching about Naloxone part of your work flow and have patients (and hopefully friends and family) watch video before they leave your office, and prescribe it. Give URL for ODP web site.

• Integrate psychosocial treatments (e.g., contingency management, community reinforcement, psychotherapeutic counseling, and family therapy).

• Consider becoming a Suboxone provider, or expand and encourage access/use of substance use treatment (Methadone/Suboxone/Subutex).
What is medication-assisted treatment (MAT)?

MAT is a combination of counseling and behavioral therapy and medication that is effective in treating opioid dependency.
A beautiful example of MAT

Chronic Pain and Substance Use Assessment Map

- Chronic Pain Identified at Intake:
  - ROI’s
  - Chronic Pain Agreement
  - BH Screen:
    - ORT
    - PHQ-9
    - GAD-7
  - PTSD Screen

- Occupational Therapy Assessment

- If + BH Screen

PCP Appt #1

- H&P, Record Review, OPDMP query

4 weeks

PCP Appt #2

Controlled substance review committee
Reviews Data and recommends:

- No Opioids + Care Plan Recommendations
  -- OR --

- Empiric Trial Opioids + Level of Care + Care Plan Recommendations:
  - Hot Sauce (Level 3)
  - RENEW Provider Groups (Level 2)
  - Primary Care Only (Level 1)
  - Other recs such as BH, medication regimen, monitoring guidelines, etc.

Step 3: Segment the Population and “Hardwire” the Changes

- **High addiction risk:**
  - Brief relapse
  - Early Recovery
  - Minimal support

- **Low addiction risk BUT:**
  - Low self-management
  - Low social supports
  - Low function/activity

**Level Three**
- Hot Sauce
- Weekly
- Opioids or Suboxone

**Level Two**
- RENEW
- Monthly Group Visits with OT/PCP
- Behav Health Assessment and Tx

**Level One**
- Primary Care Only
- q 2-3 mo visits

**Graduation Criteria:**
- Level 3: completion of Hot Sauce
- Level 2:
  - Progress toward goals
  - Engaged in Behavioral health
  - Reduction in opioid dosage

**Risk Management**
- Drug screen – q 3 months
- Pill count – q 6 months
- Adverse drug reaction review – q 3 months
- Prescription Drug Monitoring Database (OPMDP): annually
Do a QI project in your clinic

Performance measures

• Documented screening for depression
• Documented pain assessment
• Opioid agreement form
• Policy around urine drug testing
• Documented Board of Pharmacy reviews
• Documented goals and follow up plan
Get your buprenorphine waiver

• Multiple online courses
  • http://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training

• Google buprenorphine waiver online course
  • 8 hours
  • $200ish
Create a quick text/smart phrase for opioid prescribing

Quick text from Annika Maly R3:
- Pain assessment:
- Current dose:
- Date treatment started:
- BOP:
- UDS:
- Controlled substance agreement, signed:
- Harm/benefit discussion:
- Counseling/non-pharm:
- Goals:
- Scripts given today: (include do not fill dates and date rx will be out)
- Follow up plan:
Contact Information

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