WI Medical Examining Board Opioid Prescribing Guidelines

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Michael McNett, M.D. is the medical director for chronic pain for a large healthcare organization in Wisconsin. He has a background in family practice, addictions, emergency medicine, clinical research, and psychology. After starting his career in primary care, he worked in emergency medicine, briefly in an integrative medical clinic, ran a multidisciplinary fibromyalgia treatment center, and has been doing non-interventional pain management for the last 16 years (including his work in fibromyalgia). Recently, he has worked with the Wisconsin Medical Society, the WI Medical Examining Board, Attorney General Brad Schimel, and Rep. Nygren on developing CME, public information, guidelines, and legislation to address the prescription opioid epidemic.

DISCLOSURE

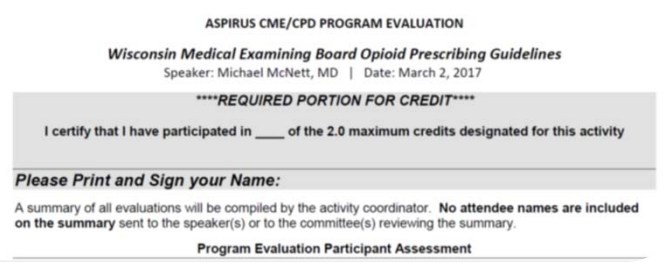
Disclosures

Speaker: None to disclose.

All other persons in control of content have no relevant financial disclosures.

WI MEB approval & Sign-in

This course has been approved by the Wisconsin Medical Examining Board as meeting the requirements for the two-hour continuing education course on responsible opioid prescribing per Med 13.03(3) of the Wisconsin Administrative Code.



ASPIRUS CME/CPD PROGRAM EVALUATION

Wisconsin Medical Examining Board Opioid Prescribing Guidelines

Speaker: Michael McNett, MD | Date: March 2, 2017

*****REQUIRED PORTION FOR CREDIT*****

I certify that I have participated in ____ of the 2.0 maximum credits designated for this activity

Please Print and Sign your Name:

A summary of all evaluations will be compiled by the activity coordinator. **No attendee names are included on the summary** sent to the speaker(s) or to the committee(s) reviewing the summary.

Program Evaluation Participant Assessment

Please complete the attestation / evaluation form. Thank you!

Learning Objectives

Brief Description

This program provides participants with a comprehensive review of the *Wisconsin Medical Examining Board's (MEB)* **Opioid Prescribing Guidelines** (released July 2016), including the rationale behind opioid guidelines in general, as well as that of each of the MEB's specific guidelines. A prescriber practicing according to these guidelines will be providing the best evidence-based treatments for patients needing pain relief. In addition, thanks to a clear understanding of the guidelines, prescribers can be confident that their opioid prescribing protocols remain in compliance with state licensure statutes.

Objectives

At the end of this educational activity, participants should be able to:

1. Describe the problems associated with drug diversion, misuse, addiction, and overdose deaths.
2. Identify the rationale behind each of the Wisconsin MEB opioid prescribing guidelines for the treatment of acute as well as chronic pain.
3. Recognize opioid abuse and intervene to wean patients from opioids both for aberrant behavior and for lack of benefit.

The Dilemma

- *Patient Rights Groups:*
- *The Joint Commission (JCAHO):*
- *Press-Ganey:*
- *Attorneys:*

Treat Pain Aggressively!

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- *State Licensing Boards:*
- *DEA/Law Enforcement:*
- *The Press:*
- *Attorneys:*

Don't Feed Addiction!

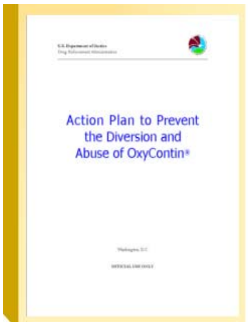
iStock photo by Getty Images

Some Historical Background

- Ancient beliefs: opioids are bad, cause addiction, should be used only for acute and cancer pain
- 1996: OxyContin® approved by FDA
  - Claimed to be "non-addictive" due to extended release
  - Advocated for use in chronic non-cancer pain
- 1996: American Pain Society promotes pain as a vital sign
  - NOTE: APS heavily funded by Purdue Pharmaceuticals
- 1998: JCAHO and CMS adopted enforcing pain as the "5th Vital Sign"
  - Not implemented until ~2000
- 2010: More deaths from prescription opioid overdoses than motor vehicle accidents

OxyContin Product Data Brochure: 1996

"Delayed absorption, as provided by OxyContin® tablets, is believed to reduce the attraction of a drug for abuse."



Spring, 2001
The DEA launches the "OxyContin® Action Plan" to counteract skyrocketing abuse, addiction, and death; the only action plan the DEA has ever enacted for a prescription medication.

The Consequences of Liberal Opioid Prescribing

- Approximately 7% of people in the US have a substance use disorder
- Opioids now kill twice as many people per year as AIDS at its peak
- In the past 10 years, opioids have caused 3 x as many US deaths at the Vietnam War
- Prescription overdose deaths (OD) exceed 39,000/year in US, greater than motor vehicle accident fatalities
- Prescription opioids have now caught up to marijuana as most abused drugs
- Drug OD death rate 4X greater in 2008 than 1999
- 75% of fatal ODs in 2008 involved prescription drugs
- Middle-aged whites were at highest risk of prescription opioid OD death
- 85% of misused narcotics are physician prescriptions
- 27% of addicts were first exposed to narcotics by prescription from MD

Since the two worst adverse drug reactions from opioids are overdose and addiction, prescribers must have a high index of suspicion

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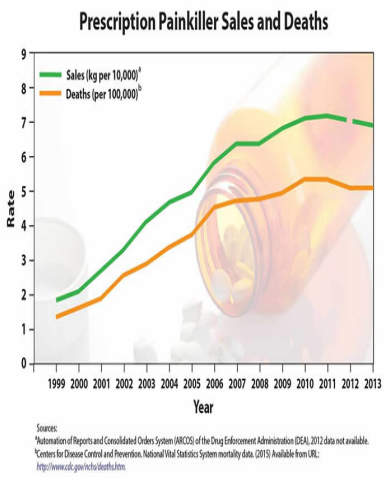
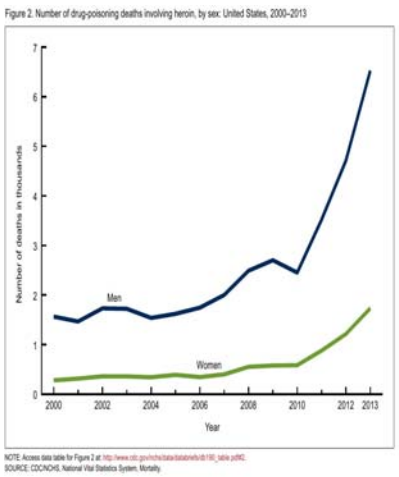
An Epidemic of Prescription Opioid Overdoses



http://www.cdc.gov/drugoverdose/data/index.html. Accessed February 26, 2016

Heroin Overdose Deaths (by gender)



This reflects a maturing of the addictive process.

And What Has Been Gained?

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"From 1999 to 2013, the amount of prescription painkillers prescribed and sold in the U.S. nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report."

http://www.cdc.gov/drugoverdose/data/index.html
Accessed February 26, 2016

The Cause of the Problem

The prescription opioid addiction epidemic is a multifactorial disease based in part on numerous provider misconceptions:

"Opioids are the best drugs for pain"

"There's an infinite dose-response curve"

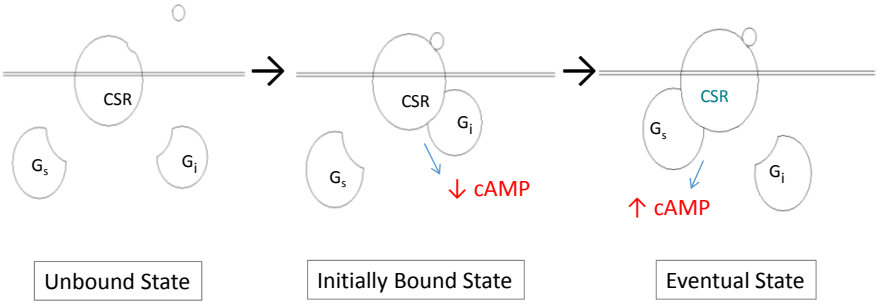
"*My* patients aren't abusing"

"Addiction is a moral failing"

"It's impossible to ID a potential abuser"

Why Opioids Don't Work for Chronic Pain: Mu Receptor Physiology

This is the basis for opioid tolerance and hyperalgesia.
Initially, opioids help pain; later, they tend to worsen it.



Clinical Studies Confirm Lack of Benefit

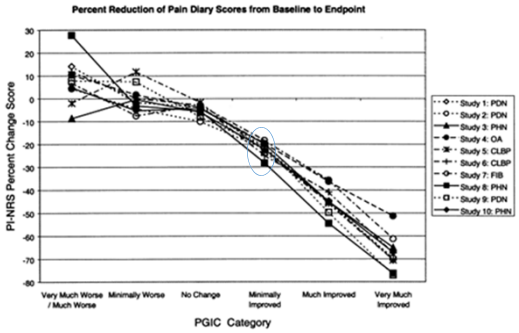
Multiple meta-analyses on opioids in chronic pain have been done:

Months	Evidence of Benefit
0-2	Good
2-6	Weak ~ 15%, less than patients consider effective
> 6	None No decent studies > 6 months Longer studies < 6 months tend to have less benefit

What Level of Reduction is Meaningful?

Farrar JT, Young JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain*. November 2001;94(2):149-158.

20-30% ↓ necessary (20-30/100 points) before patient finds treatment worthwhile



http://www.asipp.org/reference/32Farrar.pdf

Do Higher Doses Work for More Severe Chronic Pain?

Numerous large-scale studies show this is not true.

Patients on high doses have:

- More pain, disability, psychological distress
- Worse quality of life
- Lower probability of recovering from chronic pain

(NOTE: These studies have selection bias, but they all show that opioids are not effective at what they are being prescribed to do)

More than linear ↑ in annualized mortality:

at 100 MMEs, risk ratio 8.8 x normal
at 200 MMEs, risk ratio 24 X normal

And these are **tripled** if also on a benzodiazepine!

NOTE: Rofecoxib (Vioxx®) risk ratio was 1.9 x normal, and it was taken off the market!

So Why Do Patients Say They Work?

AmeriTox data: 12 months, 400,000 urine drug tests

61% showed aberrant behavior:

- 38% - Prescribed drug not present
- 31% - Non-prescribed controlled substances
- 13% - Illicit drugs
- 17% - Levels more than 2 standard deviations from expected

And these tests were done when patients *knew* they could be tested!

Direct effect on reward center: positive reinforcement
Euphoria may counteract misery of pain
Linus' blanket
Reverse placebo effect
Some patients may genuinely benefit

Reward is its Own Reward

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Opioids → Ventral tegmentum → Nucleus accumbens → Take another opioid

Opioids directly stimulate the dopaminergic reward centers
With chronic use, changes in these structures can be identified on MRI
This occurs whether they are taken for abuse or for pain
This causes the brain to confuse the primal drive to take more with pain relief

The Guidelines§

Approved July, 2016 by the Wisconsin Medical Examining Board

§ http://dsps.wi.gov/Documents/Board%20Services/Other%20Resources/MEB/20161116_MEB_Guidelines_v4.pdf

#1. Choosing Whether to Start an Opioid

Opioids are the *LAST* resort, not the first.

They should only be used for pain deemed legitimate.

Guideline #1

Pain is a subjective experience and at present, physicians lack options to objectively quantify pain severity other than by patient reported measures including pain intensity. While accepting the patient's report of pain, the clinician must simultaneously decide if the magnitude of the pain complaint is commensurate with causative factors and if these have been adequately evaluated and addressed with non-opioid therapy.

"But doc, *my* acne ***hurts***!"

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#2. Starting Opioids for Acute Pain

- Consider non-opioid treatment first.
- If you must use an opioid, use the lowest dose and fewest pills possible (and avoid oxycodone).
- Most acute injuries require < 3 days' prescription.
- Few require more than 5 days.
- Vastly more pills are currently prescribed than taken, seriously contributing to drug abuse
- Consider meds you can refill (i.e., APAP/codeine)

Guideline #2

In treating acute pain, if opioids are at all indicated, the lowest dose and fewest number of opioid pills needed should be prescribed. In most cases, less than 3 days' worth are necessary, and rarely more than 5 days' worth. Left-over pills in medicine cabinets are often the source for illicit opioid abuse in teens and young adults. When prescribing opioids, physicians should consider writing two separate prescriptions for smaller amounts of opioids with specific refill dates, rather than a single large prescription. Most patients do not fill the second prescription, thus limiting opioid excess in a patient's home and potential misuse.

#3. Do Non-narcotics Really Work?
Cochrane Review Results

NNT* to get 50% postop pain relief from one dose:

Medication	NNT*
Oxycodone 15 mg	4.6
Naproxen	2.7
Percocet 5/325	2.7
Ibuprofen 200/APAP 500	1.6

*Number needed to treat

So 1 Advil® + 1 Tylenol® ES is 3 times as likely to give 50% pain relief as OxyIR 15 mg!

http://www.nsc.org/RxDrugOverdoseDocuments/evidence-summary-NSAIDs-are-stronger-pain-medications-than-opioids-with-IFP.pdf

Guideline #3. How bad is overprescribing?

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Every year in the US, over 9 ***billion*** hydrocodone pills are prescribed.

Studies show that only 33-66% of these are taken.

So every year 3-6 ***billion*** more hydrocodone pills are added to people's medicine cabinets.

These are the #1 source for teen opioid abuse!

Guideline #3a. 1st Priority: Treat the cause

Patients truly in pain *want* to get better; they will accept reasonable treatments.

Opioids should be avoided in patients who won't accept reasonable treatments.

"I don't need an ortho, doc, I just need more oxy!"

iStock photo by Getty Images

Guideline #3b. The condition should justify opioids

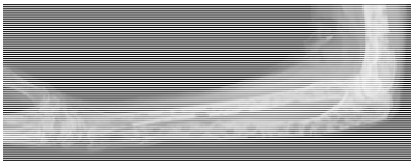
If the pain condition isn't reasonable, or if it wouldn't reasonably cause pain bad enough to require opioids, opioids should be avoided.

Examples:

1. Non-anatomic radicular pain
2. Residual pain at multiple different sites where they've had surgery
3. Severe pain from seborrhea

Guideline #3c. Refer patient if needed

If treating the underlying problem is beyond a practitioner's expertise, the patient should be referred.



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https://commons.wikimedia.org/wiki/File:Plasmozytom_multiple_Osteolysen_Unterarm.png

Guideline #3

A practitioner's first priority in treating a patient in pain is to identify the cause of the pain and, if possible, to treat it. While keeping the patient comfortable during this treatment is important, it is critical to address to the extent possible the underlying condition as the primary objective of care.

a) Patients unwilling to obtain definitive treatment for the condition causing their pain should be considered questionable candidates for opioids. If opioids are prescribed to such patients, documentation of clear clinical rationale should exist.

b) Opioids should not be prescribed unless there is a medical condition present which would reasonably be expected to cause pain severe enough to require an opioid. For conditions where this is questionable, use of other treatments instead of opioids should be strongly considered.

c) Consultation should be considered if diagnosis of and/or treatment for the condition causing the pain is outside of the scope of the prescribing practitioner.

#4. Opioids are not "go-to" drugs for pain

A) Acute Pain

- Evidence for effectiveness is weak
- Consider non-narcotic treatments first

  Remember the Cochrane findings
- Go to opioids only if needed
- If pain severe, may give opioids with non-opioids right away, but emphasize non-opioids

#4. Opioids are not "go-to" drugs for pain

A) Acute Pain – Alternatives

- Acetaminophen
- NSAIDs
- Topical – anesthetics, NSAIDs, capsaicin
- Stabilization/bracing
- Hematoma blocks
- Pre-emptive analgesia for surgery
- Regional blocks
- Diversion (encouraging them not to focus on the pain)
- PT/OT/self-care
- Manipulation (chiropractic, osteopathic, nurse)

Guideline #4a

Opioids should not necessarily be the first choice in treating acute or chronic pain.

a. Acute pain: Evidence for opioids is weak. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments should be attempted prior to initiating opioid therapy. Although opioids could be simultaneously prescribed if it is apparent from the patient's condition that he/she will need opioids in addition to these. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

#4. Opioids are not "go-to" drugs for pain

B) Acute pain lasting longer than expected

- Evaluate cause – check for complication
- Treat complication if present
- If not:

  Wean opioids (10-25%/week)

  Consider other acute pain non-narcotic treatments

  Consider starting treatments for chronic pain
  - TCA/SNRIs, anticonvulsants, CBT, etc.

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Guideline #4b

Opioids should not necessarily be the first choice in treating acute or chronic pain.

b. Acute pain lasting beyond the expected duration: A complication of the acute pain issue (surgical complication, nonunion of fracture, etc.) should be ruled out. If complications are ruled out, a transition to non-opioid therapy (tricyclic antidepressant, serotonin/ norepinephrine re-uptake inhibitor, anticonvulsant, etc.) should be attempted.

#4. Opioids are not "go-to" drugs for pain

C) Chronic Pain

- Definitions: a. pain lasting well past expected
  b. pain > 3 months
- Evidence for effectiveness is poor
  - Benefit so low patients can't perceive it
  - Dramatic increases in mortality
  - The typical term for treatment like this: contraindicated
- Avoid starting patients on chronic treatment (wean)
- If already on and behaving, can continue it
  - But need close monitoring

Remember:

Pain is *not* a narcotic deficiency disease!

#4. Non-Opioid Treatment of Chronic Pain p.1

Acetaminophen
TCA/SNRIs
Anticonvulsants
NSAIDs (inflammatory conditions only)
Topicals (anesthetics, SNRIs, capsaicin)
Electrical (TENS, etc.)
PT/OT/self-care
Manipulation (chiropractic, osteopathic, nursing)
Massage or trigger point therapy
Acupuncture/acupressure/suction

#4. Non-Opioid Treatment of Chronic Pain p.2

Alpha2 agonists (clonidine, tizanidine)

Psychological (CBT, family treatment, grief counseling, redirecting, biofeedback, etc.)

Holistic/energy (therapeutic touch, herbs, Tai Chi, aromatherapy, reflexology, Reiki, shamanic, etc.)

Interventional (epidurals, nerve blocks, MBB/RFA, spinal stim, ...)

Ketamine or lidocaine infusions

Prialt (intrathecal)

Guideline #4c

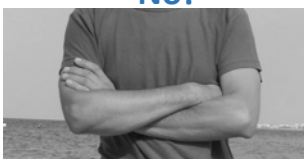
Opioids should not necessarily be the first choice in treating acute or chronic pain.

c. Chronic pain: Evidence for opioids is poor. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments (such as yoga, exercise, cognitive behavioral therapy and complementary or alternative medical therapies) should be utilized. Multiple meta-analyses demonstrate that the benefits of opioids are slight, while annualized mortality rates dramatically increased. There are few if any treatments in medicine with this poor a risk/benefit ratio, and there should be adequate clinical indication to indicate why chronic opioid therapy was chosen in a given patient. Note: There is no high-quality evidence to support opioid therapy longer than 6 months in duration. Despite this fact, it is considered acceptable although not preferable to continue patients on treatment who have been on chronic opioid therapy prior to this Guideline's release and who have shown no evidence of aberrant behavior.

#4. Opioids are not "go-to" drugs for pain.

D) Non-compliant patients

No!



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Patients genuinely in pain want to get better

They will try reasonable treatments

Drug-seekers only want opioids

Avoid prescribing opioids to patients claiming not to tolerate or benefit from multiple non-narcotics

Note: the statistical probability that a patient can't tolerate 5 different non-narcotic meds is < 1:5000!

Guideline #4d

Opioids should not necessarily be the first choice in treating acute or chronic pain.

d. Patients unwilling to accept non-pharmacological and/or nonnarcotic treatments (or those providing questionably credible justifications for not using them) should not be considered candidates for opioid therapy.

#5. One Prescriber

- Patients should receive chronic opioid therapy from one provider (or his/her associates) only
- Before prescribing, check to ensure that they do not have a pain contract elsewhere
- For acute pain requiring opioids:
  - During office hours: call primary prescriber for OK
  - After office hours: have patient call primary prescriber ASAP after office opens to notify of prescription

#5. No Early Refills

- Consider: how often do patients lose *non*-narcotic prescriptions?
- Of all prescriptions, which is most important to a chronic pain patient?
- WHY would they lose it, leave it somewhere, or make it available for theft??

"I swear, they fell down the drain!"

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Guideline #5

Patients should not receive opioid prescriptions from multiple physicians. There should be a dedicated provider such as a primary care or pain specialist to provide all opioids used in treating any patient's chronic pain, with existing pain contracts being honored. Physicians should avoid prescribing controlled substances for patients who have run out of previously prescribed medication or have had previous prescriptions lost or stolen.

#6. Treating Chronic Pain in an Acute Pain setting (ED, etc.)

- Chronic pain should be treated by the primary prescribing provider, with referrals as needed.
- Some chronic pain patients frequently go to acute care settings for additional opioids, often seeking IV hydromorphone.
- Avoid parenteral opioids for claims of acute exacerbations of chronic pain. It is much better to refer back to the primary prescriber.

Interesting Fact

Heroin addicts commonly prefer IV hydromorphone to heroin!

Makes you wonder why heroin is the Category I drug…

Guideline #6

Physicians should avoid using intravenous or intramuscular opioid injections for patients with exacerbations of chronic non-cancer pain in the emergency department or urgent care setting.

The PDMP is Important

http://165.189.64.111/pdmp/access

- Checking the PDMP before writing any prescription for a controlled substance is mandated by law as of April 1, 2017.

Look for:

- Patient actually on doses claimed
- Multiple/overlapping prescriptions from multiple providers
- Dramatic changes in dose
- Frequent early refills
- Opioids + benzodiazepines or other sedatives

Guideline #7

Physicians are encouraged to review the patient's history of controlled substance prescriptions using the Wisconsin 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. As of April, 2017, Wisconsin state law requires prescribers to review the PDMP before prescribing any controlled substance for greater than a three-day supply.

#8. Try to Avoid Pre-op Opioids

Do everything possible to avoid starting opioids preoperatively. Associated with:

1. Higher complication rates
2. Significant ↑ rate of chronic use postop
3. Lower satisfaction scores

Maximize non-narcotic treatments instead

(See Guideline #4)

Guideline #8

Pain from acute trauma or chronic degenerative diseases can oftentimes be managed without opioids prior to surgery. Surgical patients using opioids preoperatively have higher complication rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery.

#9. Avoid Opioids + Benzodiazepines

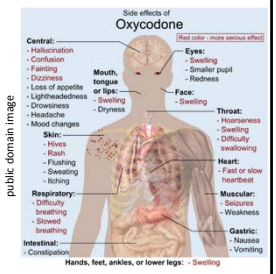
- Neither opioids nor benzodiazepines have good evidence for use longer than 2 months; in fact, both can worsen symptoms
- Dramatic increase in mortality when co-prescribed

Treatment	Annualized ↑ in mortality
100 MME/d	880%
+ BZDP	2640%
200 MME/d	2400%
+ BZDP	7200%

Guideline #9

Prescribing of opioids is strongly discouraged in patients taking benzodiazepines or other respiratory depressants. Benzodiazepines triple the already high increases in annual mortality rates from opioids. If they are used concurrently, clear clinical rationale must exist.

#10. Avoid Oxycodone



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- Oxycodone is intensely rewarding
- It is no more effective than other opioids
- Studies show it is twice as euphoric at equianalgesic doses as morphine, hydrocodone, and oxymorphone
- Oxycodone and its metabolite, oxymorphone, are the two most sought-after oral drugs by prescription opioid abusers, giving it much higher street value

  ($1.00/mg if pure, only $0.15 if w/ APAP)
- It is MUCH easier to discontinue treatment with other opioids

Guideline #10

The use of oxycodone is discouraged. There is no evidence to support that oxycodone is more effective than other oral opioids, while there are multiple studies indicating that oxycodone is more abused and has qualities that would promote addiction to a greater degree than other opioids. As a result, oxycodone should not be considered first-line and should be used only in patients who cannot tolerate other opioids and who have been evaluated for and found not to demonstrate increased risk of abuse.

Guideline #11a

Patients presenting for chronic pain treatment should have a thorough evaluation, which may include the following:

a. Medical history and physical examination targeted to the pain condition

There are 2 reasons:

1. To ensure that there is a valid pain condition present
2. To ensure that there is no evidence for substance abuse

Suspicious Physical Exam Findings

- Objective evidence validating painful condition
  - Evidence of factitious complaints
  - Exam not compatible with complaints
  - Marked difference in SLR lying and sitting (examine foot)
  - Waddel's, McBride's, Mankopf's not supported by literature

(Evidence level C) J Fam Prac. 2005 August;54(8):711-728.

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- Evidence of drug abuse:
  - Track marks, possibly covered with tattoos (injectors)
  - Pulmonic valve murmur (injectors; due to impurities)
  - Nasal septal perforation (cocaine)
  - Very bad dentition for age (crystal methamphetamine)
  - Hepatomegaly (alcohol)

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#11b. Initial evaluation to include:

Nature and intensity of the pain

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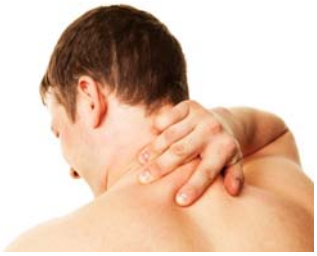
Key Benefits:

1. Helps guide diagnosis
2. May help target treatment
3. Provides a baseline to show benefits of treatment
4. May challenge credibility (i.e., nonanatomic, chronic pain at site of every surgery, etc.)



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#11c. Initial evaluation to include:

Current and past treatments, with response to each treatment

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- Ensures not exposing patient to ineffective treatment
- Maximize effective treatment (i.e., epidurals, PT, etc.)
- If multiple similar meds cause same ADR, avoid
- May challenge credibility (multiple atypical ADRs, "only oxycodone works," "no Tylenol,"…)

#11d. Initial evaluation to include:

Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e., renal or hepatic disease, sleep apnea, COPD, etc.)

COPD puts patients at much higher opioid risk

Sleep apnea same (opioids make it deeper, longer)

Renal disease affects dosing of multiple pain meds; some opioids should be avoided (i.e., morphine)

If Stage III or worse: consider fentanyl or buprenorphine

Liver disease may also affect dosing (titrate slowly)

#11e. Initial evaluation to include:

Effect of pain on physical and psychological functioning

- Baseline functioning measured for later comparison
- Opioid treatment should improve both pain and function
- If function not affected, credibility of severe pain complaints called into question

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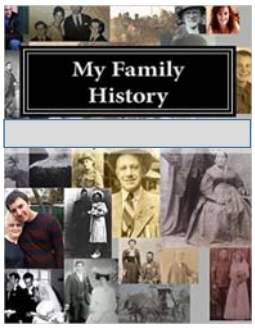
#11f. Initial evaluation to include:

Personal and family history of substance abuse

- Opioids should be avoided in current drug abusers
- Past drug abuse a relative contraindication, perhaps absolute if it was with opioids (esp. if required rehab)
- Addiction is heavily influenced by genetics: a strong family history strongly indicates risk
- SOAPP very helpful re: risk



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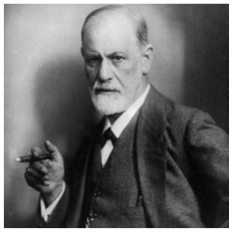
#11g. Initial evaluation to include:

History of psychiatric disorders associated with opioid abuse



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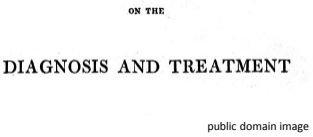
- Bipolar, ADD/ADHD: disproportionate reward effect
- Sociopathic/Antisocial: do what they want regardless of what you say
- Borderline: Drug abuse commonly part of syndrome
- Depression: Drugs a "recess" from psychological pain
  - Also true if history of emotional trauma, PTSD
- Anxiety: often on benzodiazepines

#11h. Initial evaluation to include:

Medical indication(s) for use of opioids.



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- This is the conclusion resulting from the evaluation.
- Different acute pain conditions take different times to resolve; this may determine length of treatment
- The condition should justify the opioids
- The condition also guides non-narcotic treatment

  (i.e., radicular pain often responds to epidurals)

#12. It's a trial, not a commitment

- Opioids must help both symptoms and function
- If both don't improve at least 30%, wean
- Agree on specific, achievable goals before treatment (back to work, pick up baby, walk a mile, get groceries)
- If tolerance causes goals to no longer be met, then wean

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Guideline #12

Initiation of opioids for chronic pain should be considered on a trial basis. Prior to starting opioids, objective symptomatic and functional goals should be established with the patient. If after a reasonable trial these goals are not met, then opioids should be weaned or discontinued.

#13. Risk Assessment

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- Chronic opioid therapy (COT) has minimal benefits and very high risks
- It's important to discuss risks/benefits when prescribing, particularly chronically *(NOTE: starting new patients on COT is not recommended.)*
- A formal informed consent document very desirable
- Need to continually re-assess; if problems, wean
- If serious problems, discontinue and treat withdrawal
  - Exceptions: unstable angina, 3rd trimester pregnancy
  - These may require admission for rapid detox

Monitoring - PDMP

WI PRESCRIPTION DRUG MONITORING PROGRAM

http://165.189.64.111/pdmp/access

- Review before each controlled substance prescription is *mandated by law* as of APRIL 1, 2017.
- The new PDMP is much easier/better than previous
- Look for:
  - Overlapping prescriptionss from different doctors
  - Early refills
  - Opioids + benzodiazepines/barbiturates/soma/etc.
  - Discrepancies with what patient claims to be taking
  - Rapidly escalating dosing

Monitoring – Urine Drug Testing (UDS)

- If sophisticated testing, >60% show aberrant behavior
- Do yearly if low risk, 2/yr if high, more if very high
  - If significant concern, call mid-month and give24 hrs. to give UDS/pill count
- ELISA testing highly unreliable; many false + and –
  "Opioid detected" could be prescribed med, could be heroin
- Chromatography highly desirable to identify exact medication
- If at high risk, check quantitative levels
- Important to know what is a metabolite of which medication
- "I can't pee" is very suspicious. Check salivary test.
- Often good to do pill counts with UDS's

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Monitoring – UDS Interpretation

- Medication not present:
  - Overtook and ran out
  - Diverting
- Medication present, metabolites not present:
  - Suggests diversion
  - May be a metabolic abnormality (esp. if by CyP2D6)
- Another opioid: make sure it's not a metabolite
- False +: poppy seeds (morphine), Inca Tea (cocaine)
- Always check temp, creatinine, specific gravity
  - If urine tampered with, get them off opioids

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Monitoring – Pill Counts

Consider periodic pill counts either with or at separate times from UDS's

- If pills accumulating, cut dose
- If pills too few, probably overtaking
- If unable to provide pills, probable diversion
  - Be aware; some dealers "lease" pills to patients for counts. Be sure to check to ensure they're the right meds, dose, etc.

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Monitoring - Rechecks

At least q 1-2 mo. for Category II's, q 3 mo. for Cat III, more frequently if high risk

Should include:

- H+P to confirm that condition warrants ongoing use
- Assessment of progress toward symptom/functional goals
- Evidence of aberrant behaviors
  1. Frequent calls
  2. Atypical frequency/character ADRs to non-opiate treatment
  3. Visits to other docs/EDs with intent to get opioids
  4. Frequent requests for ↑ opiates (1 request doubles risk)
  5. PDMP aberrancies
  6. UDS aberrancies
  7. Other violations of pain agreement
- Assessment of whether treatment plan should be continued/changed

Monitoring – Rechecks Consider Making a Documentation Template

1. Has the patient's condition changed significantly since their last visit?
2. Has the patient been compliant with treatments, including non-opioid treatments?
3. Has there been any aberrant opioid behavior since the last visit?
4. Is the total opioid dose less than 90 morphine equivalents?
5. Is there reasonable progress toward meeting established functional goals?
6. Was the last drug test consistent with prescribed medications?
7. Is another drug test due on this visit?
8. Has the PDMP been reviewed?
9. Is the patient complying with their signed Opioid Agreement?
10. Based on all the above, is the patient still a candidate for chronic opioid therapy?

#13. Noncompliance - Options

Minor – warning (everyone's human)

Significant/recurrent – weaning (10-25%/wk)

Illegal, or serious risk – Discontinue and treat withdrawal

Exceptions (these may require admission):

- 3rd trimester
- unstable angina

Guideline #13

Practitioners should always consider the risk-benefit ratio when deciding whether to start or continue opioids. Risks and benefits should be discussed with patients prior to initiating chronic opioid therapy, and continue to be reassessed during that therapy. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be discontinued and the patient should be treated for withdrawal, if needed.

a. Exceptions to this include patients with unstable angina and pregnant patients, especially in the 3rd trimester (withdrawal could precipitate pre-term labor).

b. Components of ongoing assessment of risk include:
   1. Review of the Prescription Drug Monitoring Program (PDMP) information
   2. Periodic urine drug testing (including chromatography)– at least yearly in low risk cases, more frequently with evidence of increased risk
   3. Periodic pill counts – at least yearly in low risk cases, more frequently if evidence of increased risk
   4. Violations of the opioid agreement

#14. Informed Consent/Agreement
Informed Consent - Rationale

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Opioids are very dangerous and provide very minor benefit if taken > 2 months.

Patients need to fully understand the extent of the risks they are taking by accepting opioids.

A formal informed consent detailing these risks should be utilized with patients if taking > 2 months

#14. Informed Consent/Agreement
Informed Consent – Suggested Contents

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- Risk of addiction
- Overdose/death
- Constipation
- Hypogonadism
- Loss of benefit/hyperalgesia
- Risk of birth defects/prematurity/NAS
- Cognitive dysfunction/driving

#14. Informed Consent/Agreement
Agreement – Suggested Contents #1

- The **informed consent** says what can happen to them
- The **agreement** is what we ask of them to keep them safe

Single prescriber

No early refills

Keep pills in safe place, preferably a fire safe

No dose increases without permission

No pill tampering

No sharing or selling pills

No taking pills from old prescription

#14. Informed Consent/Agreement
Agreement – Suggested Contents #2

No taking pills from others

Follow entire care plan until next appointment

Use recommended non-narcotic treatments

No alcohol or recreational/illicit drugs

(alcohol eliminates tolerance to respiratory effect)

Comply with UDS/pill count whenever asked

Follow up as requested

Allow practitioner to contact all other caregivers as needed

Guideline #14

All patients on chronic opioid therapy should have informed consent consisting of:

a. Specifically detailing significant possible adverse effects of opioids, including (but not limited to) addiction, overdose, and death

b. Treatment agreement, documenting the behaviors required of the patient by the prescribing practitioner to ensure that they are remaining safe from these adverse effects

#15. Starting Opioids

- Titration should use immediate-release (IR) opioids only
- Sensitivity varies widely – long acting (LA) opioids can cause prolonged OD in highly sensitive patients
- LA opioids should only be started after target dose reached
- Goal for COT – at least 2/3 LA, 1/3 IR

Guideline #15

Initial dose titration for both acute and chronic pain should be with short-acting opioids. For chronic therapy, it would be appropriate once an effective dose is established to consider long acting agents for a majority of the daily dose.

#16. Minimizing Prescriptions

- Remember the slide about 9 billion pills/year, with only 1/3-2/3 taken
- Prescribe the lowest effective dose
- Prescribe the fewest pills reasonable
- We don't want them showing up at skittle parties!

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#16. Minimizing Dose

- There is no evidence for high-dose chronic opioid treatment, with more than linear increase in risk
- In fact, high doses accelerate conversion of the mu receptor from inhibiting pain to amplifying it
- Therefore, if > 50 MME/day, use extra precautions
- Avoid dosing >90 MME/d (even at this dose, increases mortality/year 9 times!)

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#16. Calculating MMEs

MME = Morphine Milligram Equivalent (the universal currency of opioids)

Hopweb.org
Opioid conversion program from Johns Hopkins University

OPIOID EQUIVALENCY TABLE

MEDICATION	Equianalgesic Doses (mg)	
	Parenteral	Oral
Morphine	10	30
Codeine	100-130	200
Tramadol	NA	200
Tapentadol	NA	32
Buprenorphine	0.3	0.4 (sl)
Hydrocodone	NA	30
Hydromorphone	1.5	7.5
Oxycodone	NA	20
Oxymorphone	1	10
Fentanyl*	0.1	NA

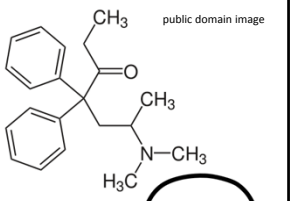
*** Morphine to Fentanyl Patch Conversion:** Each 2 mg PO morphine approximately equivalent to 1 mcg/hr fentanyl patch (e.g., morphine 100 mg/day → 50 mcg/hr patch applied q3days). Caution should be used in older adults or patients with cachexia—fentanyl is lipid soluble and requires subcutaneous fat for proper absorption.

Methadone to Morphine Conversion: Minimal data; often difficult given the multiple receptors that methadone affects.

Guideline #16

Opioids should be prescribed in the lowest effective dose. This includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely injured patients. If daily doses for chronic pain reach 50 morphine milligram equivalents(MMEs), additional precautions should be implemented (see #13.b. above). Given that there is no evidence base to support efficacy of doses over 90 MMEs, with dramatically increased risks, dosing above this level is strongly discouraged, and appropriate documentation to support such dosing should be present on the chart.

#17. Avoid Methadone Unless Trained in Its Use



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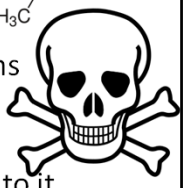

- Methadone is incredibly dangerous
  - Accounts for 5% of opioid prescriptions, 30% of deaths
  - Effect on breathing disproportionate to analgesia
    - Very easy to overdose on it
  - Wildly varying person-person variability in sensitivity to it
  - Weakly binds CyP-3A4 and -2D6, so drug interactions can ↑↑ blood levels
  - Prolongs QT, possibly dramatically
- As a result, avoid it unless extensively trained in use

Guideline #17

The use of methadone is not encouraged unless the practitioner has extensive training or experience in its use. Individual responses to methadone vary widely; a given dose may have no effect on one patient while causing overdose in another. Metabolism also varies widely and is highly sensitive to multiple drug interactions, which can cause accumulation in the body and overdose. For a given analgesic effect, the respiratory depressant effect is much stronger compared to other opioids. Finally, methadone can have a potent effect on prolonging the QTc, predisposing susceptible patients to potentially fatal arrhythmias.

#18. No Opioids for Drug Abusers

"No soup for you!"

iStock photo by Getty Images

- Patients illicitly abusing drugs are at extremely high risk of abusing opioids
- Risk to patient vastly outweighs their minimal benefit
- This includes taking family members' medications
- Also taking old prescriptions on top of current

#18. No Opioids for Drug Abusers
But How About Medical Marijuana?

- THC has been shown to help pain and is vastly safer than opioids for chronic pain
- Nevertheless, opioids should not be prescribed to drug abusers
- In states where it is approved, if a patient has a prescription for it, use isn't illicit, and opioids can be prescribed *cautiously*
- WI is ***not*** such a state, so even if they have a prescription from an adjacent state, use in WI is illicit – no opioid prescription

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Guideline #18

Prescribing of opioids is strongly discouraged for patients abusing illicit drugs. These patients are at extremely high risk for abuse, overdose, and death. If opioids are prescribed to such patients, a clear and compelling justification should be present.

Guideline #19

During initial opioid titration, practitioners should re-evaluate patients every 1-4 weeks.

During chronic therapy, patients should be seen at least every 3 months, more frequently if they demonstrate higher risk.

Guideline #20

Practitioners should consider prescribing naloxone for home use in case of overdose for patients at higher risk, including:

a. History of overdose (a relative contraindication to chronic opioid therapy)
b. Opioid doses over 50 MMEs/day
c. Clinical depression
d. Evidence of increased risk by other measures (behaviors, family history, PDMP, UDS, risk questionnaires, etc.)

The recommended dose is 0.4 mg for IM or 4.0 mg for intranasal use, with a second dose available if the first is ineffective or wears off before EMS arrives.

Family members can be prescribed naloxone for use with the patient.

#20. Other High-Risk Factors

- History of opioid use disorder (COT contraindicated)
- History of abuse of opioids or other substances*
- Benzodiazepine or significant alcohol use*
- COPD, severe asthma, sleep apnea*
- Significant liver or renal disease
- Starting/switching to methadone
- Schizophrenia, bipolar, ADD, borderline, sociopathic

* relative contraindications to chronic opioid therapy

Note: in WI, patients/loved ones can get naloxone without a prescription

#21. You Break It, You Fix It

- All practitioners are expected to assume responsibility for ADRs of their treatments
- Addiction is a possible ADR of opioid therapy
- Therefore, opioid prescribers must be capable of diagnosing opioid use disorder (OUD) and arranging medication-assisted treatment (MAT) for those patients who develop it.
- Terminating the patient from the practice is *not* considered acceptable.

#21. You Break It, You Fix It

Diagnosing OUD: DSM-V Criteria* (paraphrased)

Need at least 2 in 12 months for diagnosis:

- Opioid use longer/higher dose than intended.
- Persistent desire/unsuccessful efforts to cut down or quit
- Craving for opioids
- Inordinate time spent getting/using opioids
- Important social/work activities reduced because of use
- Ongoing use despite work/school/home problems
- Ongoing use despite causing significant interpersonal problems
- Ongoing use despite causing physical/psychological problems
- Recurrent use in hazardous situations
- Tolerance (doesn't apply if opioids prescribed)
- Withdrawal (doesn't apply if opioids prescribed)

❖ https://www.psychiatry.org/psychiatrists/practice/dsm/dsm-5

#21. You Break It, You Fix It

Treating OUD

- Can be by prescribing practitioner or referral
- Referral must be to a MAT program (methadone, buprenorphine, naltrexone LA) that will accept patient's insurance and can see them within several days

  (NOTE: Avoid "Suboxone mills" – charge a lot, never wean)

If none in area meet this criteria, burden is on the prescriber.

#21. You Break It, You Fix It
Provider-based OUD Treatment

Buprenorphine MAT (Suboxone, and others)
Training: 8 hours online, ~$200. For a list of options, go to:
http://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training

POCKET GUIDE MEDICATION-ASSISTED TREATMENT OF OPIOID USE DISORDER by SAMHSA
http://store.samhsa.gov/shin/content/SMA16-4892PG/SMA16-4892PG.pdf

LA Naltrexone (Vivitrol® – 30 day shot)

- No mandatory training, no special DEA #
- For clinical guidelines, search "SAMHSA SMA14-4892R"

MAT must include counseling by trained therapist, preferably, plus community self-help group

Guideline #21

All practitioners are expected to provide care for potential complications of the treatments they provide, including opioid use disorder. As a result, if a patient receiving opioids develops behaviors indicative of opioid use disorder, the practitioner, when possible, should assist the patient in obtaining addiction treatment, either by providing it directly (buprenorphine, naltrexone, etc. plus behavioral therapy) or referring them to an appropriate treatment center or provider willing to accept the patient. Discharging a patient from the provider's practice solely due to an opioid use disorder is not considered acceptable.

Guideline #22a
Weaning: Lack of Benefit

- If lack of efficacy of opioid therapy is determined discontinuation of therapy should be performed.
- Opioid weaning can be performed by reducing the MED by 10% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued
- Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.

Guideline #22b
Weaning or Discontinue: Evidence of ↑ Risk

B) If evidence of increased risk develops, weaning or discontinuation of opioid should be considered.

1. Opioid weaning can be performed by reducing the MED by 25% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued
2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.
3. Physicians can consider weekly or bi-monthly follow-up during the weaning process

Guideline #22c
Discontinue: Imminent Danger to Patient

If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be immediately discontinued and the patient should be treated for withdrawal, if needed.

1. Exceptions to abrupt opioid discontinuation include patients with unstable angina and pregnant patients. These patients should be weaned from the opioid medications in a gradual manner with close follow-up

Thank You For Your Time and Attention

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