Community Forum on Opioid Use and Addiction

October 21, 2016

David Tauben, MD | Chief, Division of Pain Medicine, University of Washington Todd Korthuis, MD | Associate Professor of Medicine, Program Director of Addiction Medicine, Oregon Health Sciences University

Frances Gough, MD | CMO, Molina Healthcare of WA



Agenda:

Session A

7:30am - Welcome & Introductions

7:35am - David Tauben, MD Chief, University of Washington Division of Pain Medicine

Assessment, Treatment, and the Challenge of Opioids:

Overcoming Barriers to SAFE & EFFECTIVE Pain Care Delivery

8:15am - Todd Korthuis, MD, MPH, Associate Professor of Medicine, Program Director of Addiction Medicine, Oregon Health Sciences University

*Recognition and Treatment of Opioid Use Disorder in Patients with Chronic Pain

9:00am - Panel Q&A: Audience Case Discussion

Session B

12:00pm - Welcome & Introductions

12:05pm - David Tauben, MD, FAPC, Chief, University of Washington Division of Pain Medicine Assessment, Treatment, and the Challenge of Opioids:

Overcoming Barriers to **SAFE & EFFECTIVE** Pain Care Delivery

12:50pm - Todd Korthuis, MD, MPH, Associate Professor of Medicine, Program Director of Addiction Medicine, Oregon Health Sciences University

*Recognition and Treatment of Opioid Use Disorder in Patients with Chronic Pain

1:30pm - Panel Q&A: Audience Case Discussion





Clinical Presentation

- RJ*
- Lives in Western Washington
- Diagnoses: complex medical and behavioral health conditions including chronic pain due to traumatic brain injury, PTSD and depression

Areas of Concern

- RJ needed help getting procedures and medications approved,
 specifically for pain management
- In-home assistance was needed and connections to community resources



Molina Intervention

- Located a provider willing to prescribe pain medication
- Facilitated further medical assessments to update her diagnosis
- Identified resources for caregiving assistance
- Helped RJ better understand her condition and direct her to community resources



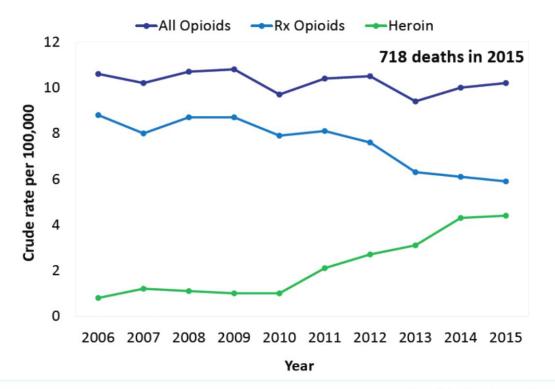
Outcomes

- RJ has a PCP willing to help manage her pain
- She has received updated diagnosis
- In-home care assistance has been secured
- She is attending a support group



Rx opioid deaths are decreasing while heroin overdoses have risen sharply

Trends in WA state 2006-15, excluding falls



Source: Department of Health death certificates

Overall WA Mortality Rates*:

- 164 firearm homicides
- 633 motor vehicle deaths

^{*}Source: Washington State Department of Health 2014 Mortality Tables



Seattle Pain Center (SPC)







FUNDAMENTALS AND CORE COMPETENCIES OF PAIN MANAGEMENT

Pain:

Assessment, Treatment, and the Challenge of Opioids

Overcoming Barriers to **SAFE & EFFECTIVE** Pain Care Delivery

David J. Tauben, MD, FACP

Chief, UW Division of Pain Medicine
Hughes M & Katherine G Blake Endowed Professor
Clinical Associate Professor
Depts of Medicine and Anesthesia & Pain Medicine
University of Washington, Seattle WA







DISCLOSURES

Drs. Korthuis & Tauben report: No financial conflicts of interest.





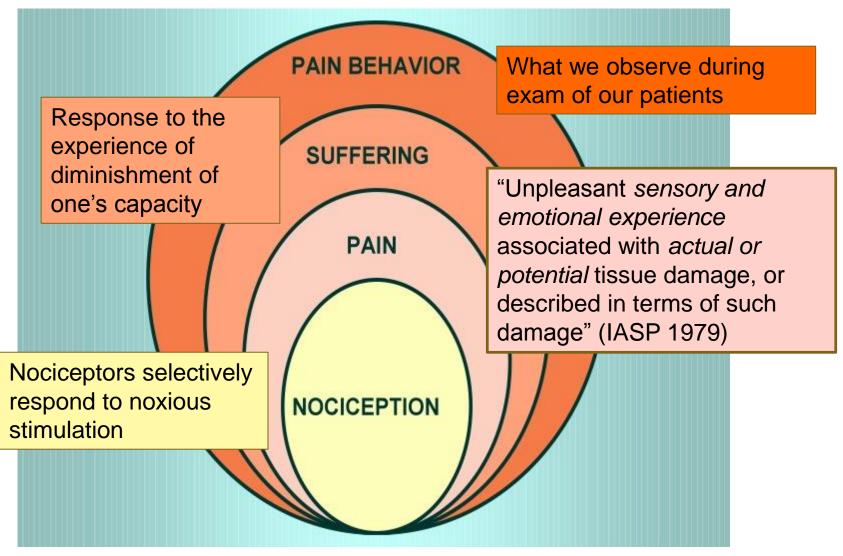
Course Learning Objectives

- 1. Understand challenges of opioid-centric treatment paradigm & limits to effectiveness for chronic pain
- 2. Understand & implement evidence-based, guideline compliant care (including guidelines for opioid prescribing in the setting of acute pain management)
- 3. Access expert resources and education to support practice-based chronic pain management
- 4. Diagnosis, treatment, and referral of opioid use disorder in a patient with chronic pain





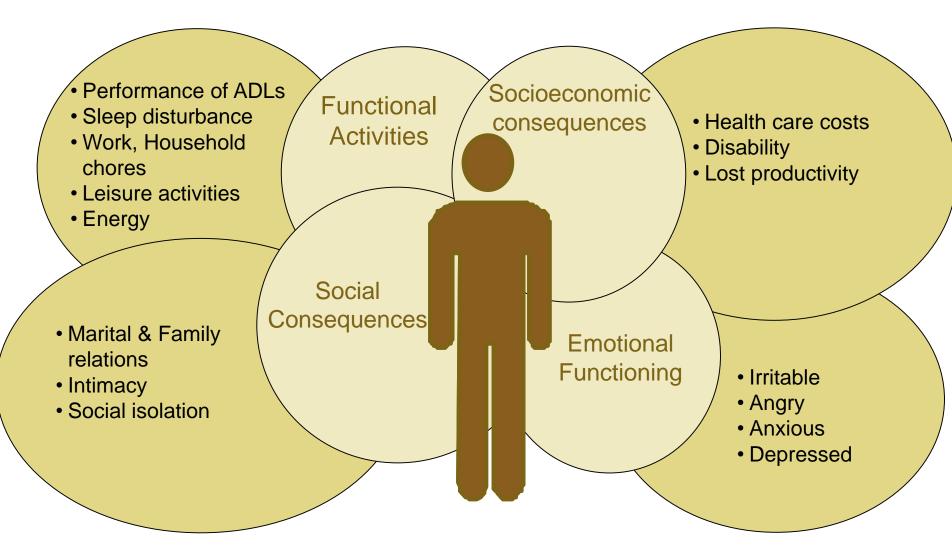
Pain is NOT Nociception







Multidimensional Burden of Chronic Pain

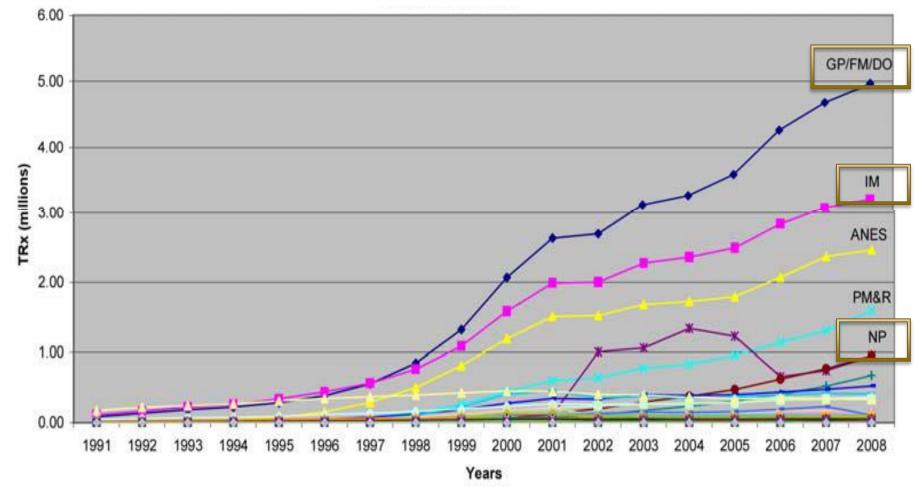






Total Outpatient Prescriptions of ER Opioids, (by Medical Specialty)

SDI, Vector One: Nationale. Extracted 12/2009







Written for Clinicians who Care for People with Pain 3rd Edition, June 2015

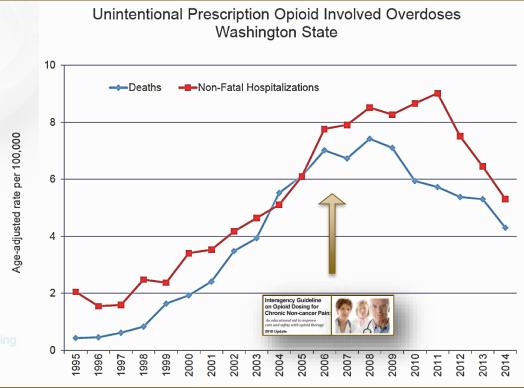
Guidelines Work! Bending the Curve"



Interagency Guideline on Prescribing Opioids for Pain

Developed by the Washington State Agency Medical Directors' Group (AMDG) in collaboration with an Expert Advisory Panel, Actively Practic Providers, Public Stakeholders, and Senior State Officials.

www.agencymeddirectors.wa.gov





improve health care quality for Washington State citizens.

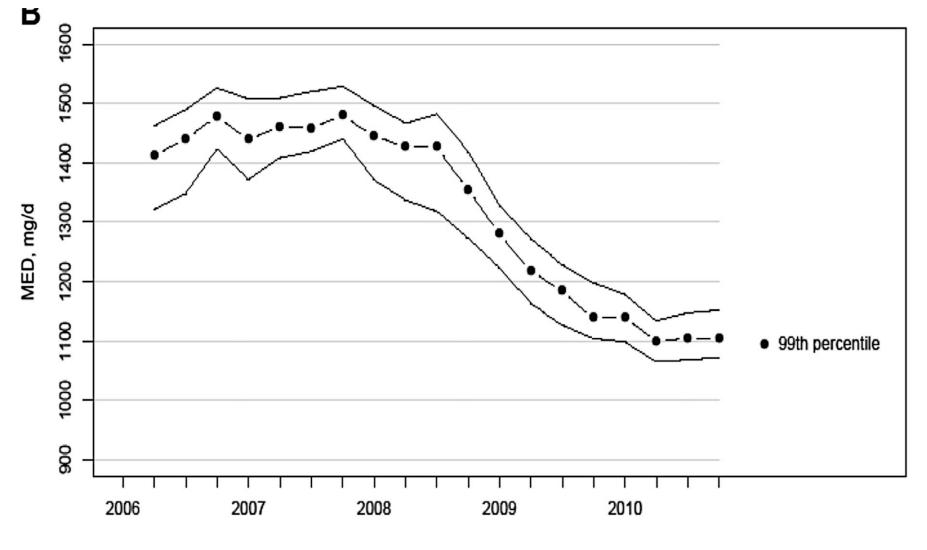
Written for Clinicians who Care for People with Pain 3rd Edition, June 2015

Achieving Guideline Compliant Care





Reduced High Dose Prescribing in WA Medicaid Post-dosing Guideline









Summary of

2015 Interagency Guideline on Prescribing Opioids for Pain



See full guideline at www.AgencyMedDirectors.wa.gov



All pain phases

- Use non-opioid therapies, such as behavioral intervention, physical activity and non-opioid analgesics.
- Avoid opioids if the patient has significant respiratory depression, current substance use disorder, history of prior opioid overdose or a pattern of aberrant behaviors.
- Assess and document function and pain using a validated tool at each visit where opioids are prescribed.
- Don't prescribe opioids with benzodiazepines, carisoprodol, or sedative-hypnotics.

Acute phase (0-6 weeks)

- Check the state's Prescription Monitoring Program (PMP) before prescribing.
- Don't prescribe opioids for non-specific back pain, headaches, or fibromyalgia.
- Prescribe the lowest necessary dose for the shortest duration.
- Opioid use beyond the acute phase is rarely indicated.

Perioperative pain

- Evaluate thoroughly preoperatively: check the PMP and assess risk for over-sedation and difficultto-control pain.
- Discharge with acetaminophen, NSAIDs, or very limited supply (2–3 days) of short-acting opioids for some minor surgeries.
- For patients on chronic opioids, taper to preoperative doses or lower within 6 weeks following major surgery.

Subacute phase (6–12 weeks)

- Don't continue opioids without clinically meaningful improvement in function (CMIF) and pain.
- Screen for comorbid mental health conditions and risk for opioid misuse using validated tools.
- Recheck the PMP and administer a baseline urine drug test (UDT) if you plan to prescribe opioids beyond 6 weeks.

Chronic phase (>12 weeks)

- Continue to prescribe opioids only if there is sustained CMIF and no serious adverse events, risk factors, or contraindications.
- Repeat PMP check and UDT at frequency determined by the patient's risk category.
- Prescribe in 7-day multiples to avoid ending supply on a weekend.
- Don't exceed 120 mg/day MED without a pain management consultation.

When to discontinue

- At the patient's request
- No CMIF
- Risks outweigh benefits
- Severe adverse outcome or overdose event
- Substance use disorder identified (except tobacco)
- Aberrant behaviors exhibited
- To maintain compliance with DOH rules or consistency with AMDG guideline

Considerations prior to taper

- Help the patient understand that chronic pain is complex and opioids cannot eliminate pain.
- Consider an outpatient taper if the patient isn't on high-dose opioids or doesn't have comorbid substance use disorder or other active mental health disorder.
- Seek consultation if the patient failed previous taper or is at greater risk for failure due to high-dose opioids, concurrent benzodiazepine use, comorbid substance use disorder or other active mental health disorder.

How to discontinue

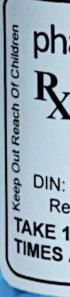
- Taper opioids first if patients are also on benzodiazepines.
- Unless safety considerations require a more rapid taper, start with 10% per week and adjust based on the patient's response.
- Don't reverse the taper; it can be slowed or paused while managing withdrawal symptoms.
- Watch for unmasked mental health disorders, especially in patients on prolonged or high-dose opioids.

Recognizing and treating opioid use disorder

- Assess for opioid use disorder and/or refer for a consultation if the patient exhibits aberrant behaviors.
- Help patients get medication-assisted treatment along with behavioral therapies.
- Prescribe naloxone (especially if you suspect heroin use) and educate patient's contacts on how to use it.

Special populations

- Counsel women before and during pregnancy about maternal, fetal, and neonatal risks.
- For children and adolescents, avoid prescribing opioids for most chronic pain problems.
- In older adults, initiate opioids at 25–50% lower dose than for younger adults.
- For cancer survivors, rule out recurrence or secondary malignancy for any new or worsening pain.



Check out the resources at www.AgencyMedDirectors.wa.gov

- Free online CME
- Opioid Dose Calculator
- Videos from Primary Pain Care Conference

Opioid R_x After Surgery Can Lead to Long-term Use (1)

Retrospective studies 1-year post surgery¹:

- Approximately one-third of all patients were still using opioids
- 18% of patients who did not use opioids before surgery were still using opioids
- older patients (>65 years of age) undergoing low-risk surgery and receiving an opioid prescription²:
 - 10.3% were still taking opioids a year later
 - There was a 44% increase in likelihood that they would become long-term opioid users, compared to patients not receiving a prescription

"...initiation of short-term opioid therapy may lead to their longer-term use"³

1. Wang M et al. Spine J. 2013;13:S6-S7. 2. Alam A et al. Arch Intern Med. 2012;172:425-430. 3. Katz MH. Arch Intern Med. 2012;172:430.



Acute and Sub-acute Pain Phases



Pain: Acute Phase:

- ≤ 6 weeks post episode of pain or surgery
- For severe injuries or medical conditions, surgical procedures, or when alternative non-opioid options are ineffective or contraindicated.
- If opioids are prescribed, should be for the shortest duration and at the lowest necessary dose (usually less than 14 days).

NOTE per CDC Guideline for Prescribing Opioids for Chronic Pain:

"3 days or less will often be sufficient; > than 7 days will rarely be needed."

Use of opioids for non-specific low back pain, headaches, and fibromyalgia is not supported by evidence.



WA State AMDG Guidelines Opioids in the Acute Pain Phase

- Explore non-opioid alternatives
- Set reasonable expectations; educate risks & side effects.
- Provide patient education on safekeeping of opioids.
- Expect improvement in days to weeks:

RE-EVALUATION FOR THOSE WHO DO NOT FOLLOW THE NORMAL COURSE OF RECOVERY.

- Check the Prescription Monitoring Program (PMP)
- Assess FUNCTION & PAIN AT BASELINE AND WITH EACH FOLLOW-UP visit when opioids are prescribed.
- Document clinically meaningful improvement in function and pain using validated tools for every opioid refill visit.
 - Taper patient by 6 weeks if clinically meaningful improvement in function and pain has not occurred.





Treatment Adherence Monitoring Prescription Drug Monitoring Program

- 49 of 50 States capture all scheduled medication dispensed, even mail order or cash purchased
- Requires prescriber registration; can delegate proxy access to any number of licensed health care assistants
- Can seek registration from neighboring states
- Possible error with name entered by pharmacists:
 - call to verify when unexpected result
- VA/DoD and methadone programs don't report



WA State AMDG Guidelines Opioids in the Peri-Operative Phase

Preoperative Period

Thorough pre-op, risk screening, develop/inform patient of treatment plan (incl. who will prescribe at discharge), no new sedating Rx, <u>avoid</u> dose escalation

Intraoperative Period: Multimodal analgesia

Immediate Postoperative Period

Multimodal analgesia, monitor sedation/respiratory suppression, PCA early then PO Rx immediate release opioids

Don't add or raise dose of ER/LA opioids

At the Time of Hospital Discharge

No new benzos/sedatives; avoid alcohol

Introduce taper timeline: plan/schedule





Sub-Acute Phase

(6 -12 Weeks Post Episode Of Pain Or Surgery)

- Discontinuation of opioids unless:
 - Clinically meaningfully improvement in function, (pain interference with function level of ≤4/10)
- Discontinuation of opioids if:
 - has led to a severe adverse outcome.
- Screen for depression, anxiety, (possibly PTSD), opioid misuse risk using validated tools before embarking onto COAT*.

*COAT = Chronic Opioid Analgesic Therapy

 Avoid new prescriptions of benzodiazepines/sedative-hypnotics.





Opioids In Chronic Non-cancer Pain

>12 Weeks After an Episode of Pain or Surgery

Needs sustained clinically meaningful improvement in function AND no serious adverse outcomes or contraindications.

- Extreme caution/consider consultation with comorbid mental health disorder, family/personal history of substance use disorder, medical condition ..., or concurrent use of benzodiazepines.
- Routinely assess and document FUNCTION, MOOD, PAIN, RISK.

Seek pain expertise if dose ESCALATES ≥120 MED and/or RISKS

Know special METHADONE precautions





Opioid Prescribing in Dental Care



- Strong evidence that a combination of NSAIDs and acetaminophen is as effective as opioids
 - •At least two state dental bodies (Pennsylvania and New Hampshire) recommend using these drugs as first line therapy.
- Avoid opioids in persons < 20 years undergoing dental extractions.
- If opioids are indicated, prescription should be limited to 3 days or 10 tabs of 5 mg hydrocodone.

Moore PA, Hersh EV. Combining ibuprofen and acetaminophen for acute pain management after third-molar extractions. Translating clinical research to dental practice. JADA 2013; 144: 898-908.



Prevention of prescription opioid abuse

The role of the dentist

Richard C. Denisco, MD, MPH; George A. Kenna, PhD, RPh; Michael G. O'Neil, PharmD; Ronald J. Kulich, PhD; Paul A. Moore, DMD, PhD, MPH; William T. Kane, DDS, MBA; Noshir R. Mehta, DMD, MDS, MS; Elliot V. Hersh, DMD, MS, PhD; Nathaniel P. Katz, MD, MS

Dentists prescribe 12% of IR opioids in the U.S.

2nd only to family physicians, who prescribe 15 percent of IR opioids

~3.5 million young people (avg age 20 y.o.) exposed to opioids for 3rd molar extractions

Ibuprofen is the preferred postoperative analgesic (74%) for oral/maxillofacial surgeons

YET, 85% still prescribed opioids!

= 56 million tabs hydrocodone/year

72% patient prescribed an opioid had leftover medication, and 71% of those with leftover medication kept it



Impact of Mandatory Prescription Drug Monitoring Program on Opioid Prescription By Dentists

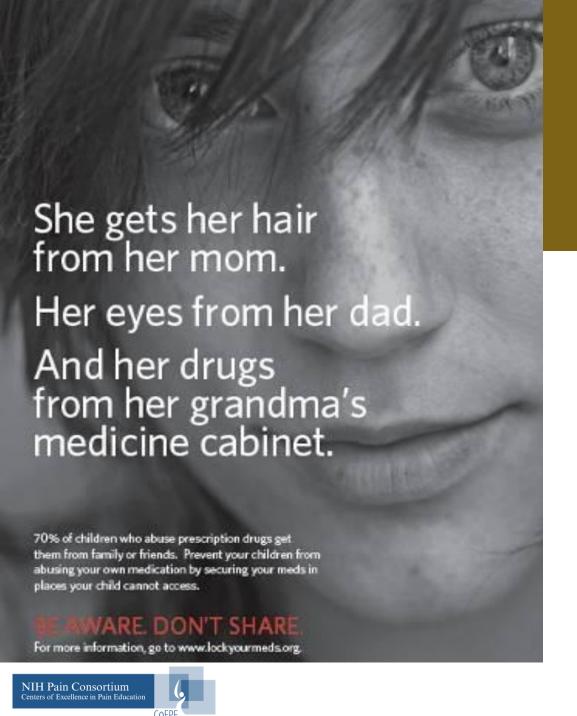
- Total numbers of prescribed opioid pills in a 3month period decreased 78% in absolute quantity.
- Prescriptions for non-opioid analgesics acetaminophen increased during the same periods.

Conclusion

Mandatory PDMP significantly affected the prescription pattern for pain medications by dentists.

Such change in prescription pattern represents a shift towards the evidence-based prescription practices for acute postoperative pain.





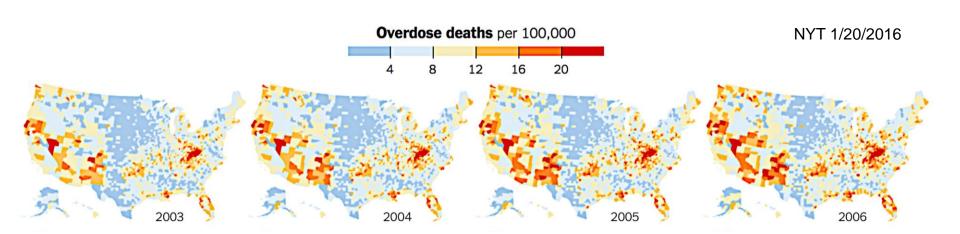
Storage and Disposal:

"the danger is in your home"

Opioids may fatal with just one dose, and so must be disposed of quickly through a medicine take-back program or by transferring them to a DEA-authorized collector.



OD DEATHS Ripple Across America







Chronic Pain Treatment

"Comparing" Effectiveness

Extrapolated averages of reduction in *Pain Intensity*

PAIN MEDICINE

Opioids: ≤ 30%

Tricyclics/SNRIs: 30%

Anticonvulsants: 30%

Acupuncture: ≥ 10+%

Cannabis: ?10-30%

CBT/Mindfulness: ≥ 30-50%

Graded Exercise Therapy: variable

Sleep restoration: ≥ 40%

Hypnosis, Manipulations, Yoga: "+ effect"

Turk, D. et al. Lancet 2011; Davies KA, et al. Rheum. 2008; Kroenke K. et al. Gen Hosp Psych. 2009; Morley S Pain 2011; Moore R, et al. Cochrane 2012; Elkins G, et al. Int J Clin Exp Hypnosis 2007.



Are CPPs Treatment Cost-effective? EVIDENCE OVERWHELMINGLY YES!

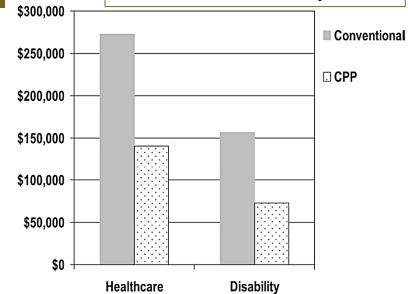
ence-Based Scientific Data Documenting the Treatment and -Effectiveness of Comprehensive Pain Programs for Chronic malignant Pain

t J. Gatchel* and Akiko Okifuji[†]

J Pain 2006

"This review clearly demonstrates that CPPs offer the most efficacious and cost effective, evidence-based treatment for persons with chronic pain."

"Unfortunately, such programs are not being taken advantage of because of short-sighted costcontainment policies of third-party payers." 70% reduced direct costs, 40% reduced disability costs.



AND:

Deschner & Polatin (2000); Feuerstein & Zostowny (1996); Gatchel &Turk (1999); Okifuji et al (1999); Turk & Burwinkle (2005); Turk & Gatchel (1999); Wright & Gatchel (2002); Sanders et al (2005).





Non-drug Pain Treatment Approaches

Physical and Occupational Therapies

- Functional activation
- Assistive devices
- Massage/Manipulation

Psychological: Cognitive Behavioral Therapy

- Cognitive reframing
- Behavior change
- Relaxation; MBSR
- Biofeedback techniques

Integrative Medicine ("CAM")

- Dietary hygiene
- Acupuncture, Acupressure, Massage, Biofeedback...

Spiritual Counseling

Finding meaning and purpose





"Multimodal Analgesia"

Summary of Major Pain R_x Indications

NSAIDs

 Acute nociceptive pain (inflammation, trauma, perioperative)

Antidepressants (TCA/SNRIs)

- Neuropathic pain
- "Pain Hypersensitivity"
- Also helps sleep & mood

Anticonvulsants

- Neuropathic pain
- "Pain Hypersensitivity"
- Also helps sleep & mood

Opioids

- Acute moderate or severe pain
- For carefully selected chronic pain conditions
- And only after other chronic pain treatments fail

Local anesthetics

- Acute pain in a regional distribution
- Transient relief for some chronic pain related to local nerve injury





98% Of Pain Care by Non-specialists

Chronic pain is mostly cared for and best managed in the primary care "medical home" setting, but when PCP's need help:

Access to multidisciplinary pain consultation is both scarce and difficult to access, especially so for non-metropolitan, rural, and remote communities; and very often for minorities and those reliant upon government sponsored health care.

Daubresse Med Care 2013; Bodenheimer JAMA 2002; Tait Am Psychologist 2014





UW TelePain Multidisciplinary Team

- 1. Primary care internal medicine or family medicine
- 2. Anesthesiologist
- 3. Physical Medicine & Rehabilitation/Psychology
- 4. Psychiatry
- 5. Addiction Medicine



Tele-mentoring primary care providers has been demonstrated to improve approach and treatment of chronic pain and so is expected to rapidly reduce costs in outpatient and/or post-acute settings.

 UW's TelePain service offers self-directed training link available on UW TelePain's main site to video series describing the why and how to connect and present cases.

http://depts.washington.edu/anesth/education/pain/telepain_videos.shtml

Eaton LH, Gordon DB, Wyant S, Theodore BR, Meins AR, Rue T, Towle, Tauben D,. Doorenbos A. Development and implementation of a telehealth-enhanced intervention for pain and symptom management. Contemp Clinic Trials. 2014;38:213-220.

"Clinically Meaningful Improvement in Function"

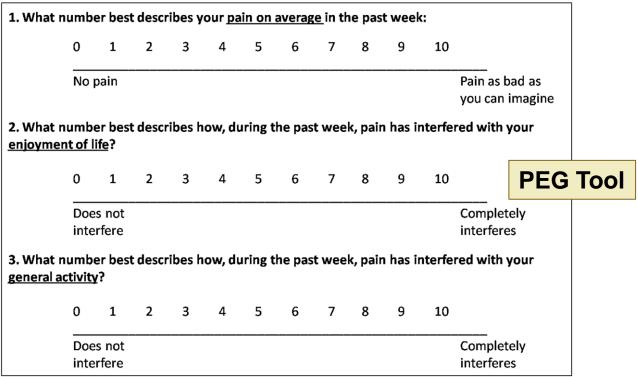
"Continuing to prescribe opioids in the absence of clinically meaningful improvement in function and pain, or after the development of a severe adverse outcome is not considered appropriate care."

Pain intensity

Pain interference with:

Enjoyment of life

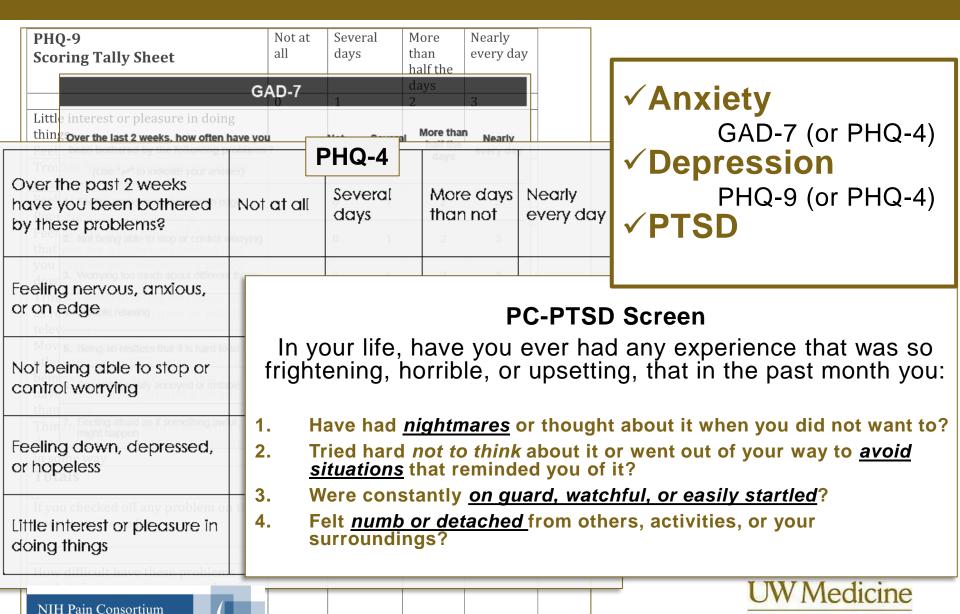
General activity







Identifying Co-occurring Mood Diagnoses



PAIN MEDICINE

Centers of Excellence in Pain Education

COFPF

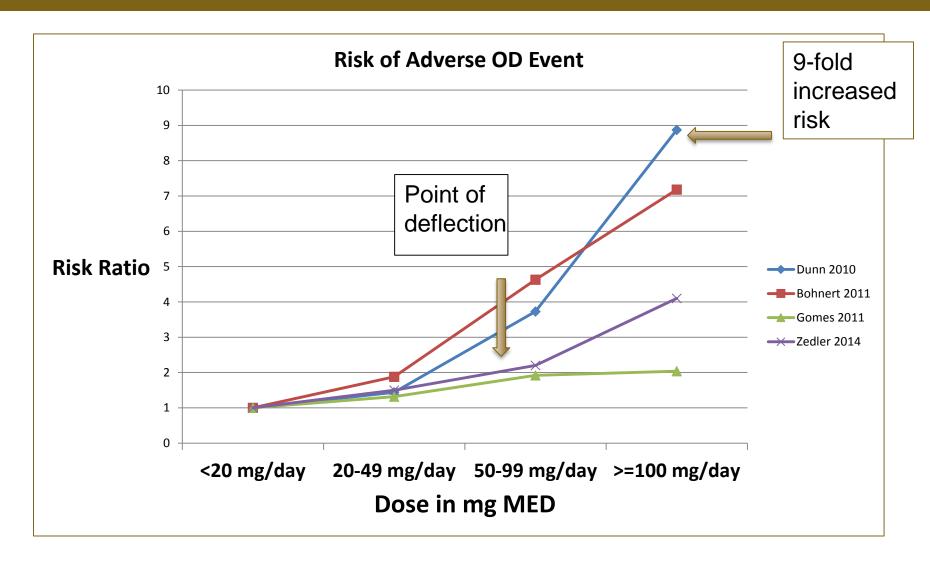
The Allure of Opioids

- ✓ They make patients happy (at least initially).
- ✓ They are very portable and available in the most remote sites.
- ✓ Insurance covers them better than any other pain treatment.
- ✓ The signed prescription closes the visit.





Opioid Overdose Risk by MED



"MED": Morphine Equivalent Dose



Calculate the MED



Patient's Name:

Today's Date: July 31, 2013

	_	_	
Opioid	Doco		-

Instructions: Fill in the mg per day* for whichever opioids your patient is taking. The web page will automatically calculate the total morphine equivalents per day. Learn how to add this calculator to your smart phone or tablet home screen here: Android or iPhone/iPad.					
Opioid (oral or transdermal):	mg per day: *	Morphine equivalents:			
Codeine	• 0				
Fentanyl transdermal (in mcg/hr)	€ 0	AMDG on-line calculator			
Hydrocodone	€ 0	AMDG OII-IIITE Calculator			
Hydromorphone	€ 0	www.agencymeddirectors.wa.gov			
Methadone	€ 0				
Morphine	€ 0	Methadone Methadone			
Oxycodone	€ 0	<20 mg 4x			
Oxymorphone	€ 0				
Tapentadol	€ 0	>20-40 mg 8x			
Tramadol	• 0	>60-80 mg 10x			
TOTAL daily morphine equivalent dose (M	ED) = 0	>80 mg 12x			

CAUTION: This calculator should **NOT** be used to determine doses when converting a patient from one opioid to another. This is especially important for fentanyl and methadone conversions. Equianalgesic dose ratios are only approximations and do not account for genetic factors, incomplete cross-tolerance, and pharmacokinetics.

Print

Reset

Calculate

*NOTE: All doses expressed in mg per day with exception of fentanyl transdermal, which is expressed in mcg per hour

Sleep Disorders Risk

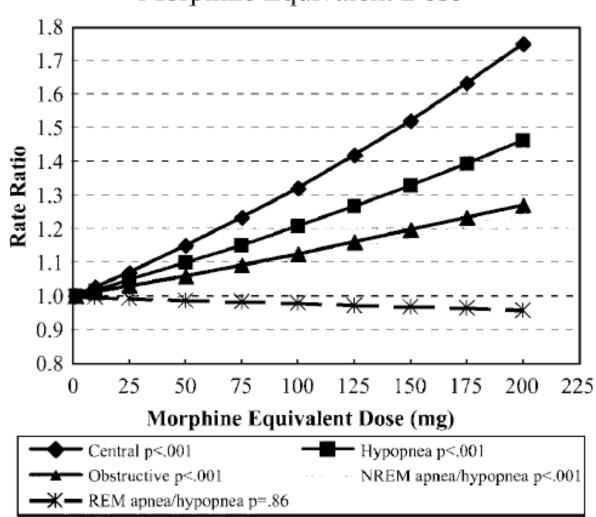
Rate Ratios by Increase of Morphine Equivalent Dose

EXTREME CAUTION:

- ✓ High dose Opioids
- ✓ Opioids <u>plus</u> Sedatives

Walker JM., et al. *J Clin* Sleep Med 2007





Role of Opioids for Chronic Pain?

REVIEW

Annals of Internal Medicine

The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop

Roger Chou, MD; Judith A. Turner, PhD; Emily B. Devine, PharmD, PhD, MBA; Ryan N. Hansen, PharmD, PhD; Sean D. Sullivan, PhD; Ian Blazina, MPH; Tracy Dana, MLS; Christina Bougatsos, MPH; and Richard A. Deyo, MD, MPH

Conclusion: Evidence is insufficient to determine the effectiveness of long-term opioid therapy for improving chronic pain and function. Evidence supports a dose-dependent risk for serious harms.

Annals of Internal Medicine • Vol. 162 No. 4 • 17 February 2015







Morbidity and Mortality Weekly Report

March 15, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016



12 Recommendations 3 Topic Areas

- 1. When to initiate or continue
- 2. Selection, dosage, duration, follow-up, and discontinuation
- 3. Assessing risk and addressing harms



CDC Recommendations: 4-7(1)

"Opioid selection, dosage, duration, follow-up, and discontinuation"

- 4. When starting...prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
- 4. When opioids are started... lowest effective dosage. Clinicians should use *caution when prescribing opioids at any dosage*, ... carefully *reassess evidence of individual benefits and risks when increasing dosage to...*

≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify decision to titrate dosage to ≥90 MME/day.



"Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians..."

Centers for Disease Control and Prevention MMWR March 15, 2016; 65:p23

- "...tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence."
- Offer in a "nonjudgmental manner"... "the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk."
- "empathically review benefits and risks of continued highdosage opioid therapy" and "offer to work with the patient to taper opioids to safer dosages"
- "very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages."
- Be aware that anxiety, depression, and opioid use disorder "might be unmasked by an opioid taper"
 UW Medicine



PAIN MEDICINE

CDC Recommendations: 4-7₍₂₎

"Opioid selection, dosage, duration, follow-up, and discontinuation"

- 6. ...for acute pain, ...prescribe the *lowest effective* dose of immediate-release opioids ... no greater quantity than needed for the expected duration of pain severe enough to require opioids.
 - 3 days or less will often be sufficient; > than 7 days will rarely be needed.
- 6. ...evaluate benefits and harms ...within 1 to 4 weeks of starting ...evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
- ...If benefits do not outweigh harms ...optimize other therapies
 - ...and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.



Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

- Set realistic goals for pain and function based on diagnosis (eg. walk around the block).
- Check that non-opioid therapies tried and optimized.
- □ Discuss benefits and risks (eg. addiction, overdose) with patient.
- Evaluate risk of harm or misuse.
 - · Discuss risk factors with patient.
 - . Check prescription drug monitoring program (PDMP) data.
 - · Check urine drug screen.
- Set criteria for stopping or continuing opioids.
- Assess baseline pain and function (eg, PEG scale).
- □ Schedule initial reassessment within 1-4 weeks.
- Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If RENEWING without patient visit

□ Check that return visit is scheduled ≤3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- Assess pain and function (eg, PEG); compare results to baseline.
- □ Evaluate risk of harm or misuse:
 - Observe patient for signs of over-sedation or overdose risk.
 - If yes: Taper dose.
 - · Check PDMP.
 - Check for opioid use disorder if indicated (eg, difficulty controlling use).
 - If yes: Refer for treatment.
- Check that non-opioid therapies optimized.
- Determine whether to continue, adjust, taper, or stop opioids.
- Calculate opioid dosage morphine milligram equivalent (MME).
 - If ≥50 MME/day total (≥50 mg hydrocodone; ≥33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
 - Avoid ≥ 90 MME/day total (≥ 90 mg hydrocodone; ≥ 60 mg oxycodone), or carefully justify; consider specialist referral.
- □ Schedule reassessment at regular intervals (≤3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- Benefits of long-term opioid therapy for chronic pain not well supported by evidence.
- Short-term benefits small to moderate for pain; inconsistent for function.
- Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- . Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- . Mental health conditions (eg, depression, anxiety).
- · Sleep-disordered breathing.
- · Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores (30% Improvement from baseline is clinically meaningful)

- Q1: What number from 0-10 best describes your pain in the past week? 0="no pain". 10="worst you can imagine"
- Q2: What number from 0-10 describes how, during the past week, pain has interfered with your enjoyment of life?
 - 0="not at all", 10="complete interference"
- Q3: What number from 0-10 describes how, during the past week, pain has interfered with your general activity?
 - 0="not at all", 10="complete interference"

March 2016







www.cdc.goV/dtUgoVerdose/prescribing/gUidelihe.html



HOW?

Understand Safe & Effective Chronic Pain Treatments

1. For Clinicians

- CDC Guidelines, & your state's guidelines
- UW's "COPE REMS" <u>www.coperems.org</u>



2. For Patients and Families

- YouTube: "Understand Pain", "Brainman Stops His Opioids"
- Stanford's: Chronic Pain Self Management Program
- U. Michigan's: fibroguide.com
- American Chronic Pain Association

3. For Policymakers and Payers

- National Pain Strategy
- IOM 2011 Report: Relieving Pain in America









HOW?

Step 2: Assess Your Practice:

- ✓ Do you have (or do you do?)
- Registries and regular review based on dose (MME)
- ☐ Measure and track function (e.g. PEG) and mood (e.g. PHQ's, GAD, PC-PTSD) when prescribing chronic opioids
- Misuse/Abuse Risk screening: ORT, COMM, SOAP, DIRE, etc.
- ☐ Adherence monitoring policies and procedures: PMP, UDT
- ☐ Care agreements & Informed Consent re benefits & harms
- ☐ Medical Risk screening: e.g. sleep apnea
- ☐ Protocols for OD high risk/naloxone prescribing
- Buprenorphine licensees? And actually prescribe?
- □ Process for interprofessional referrals? (CBT, PT/OT, Rehab, Addiction)

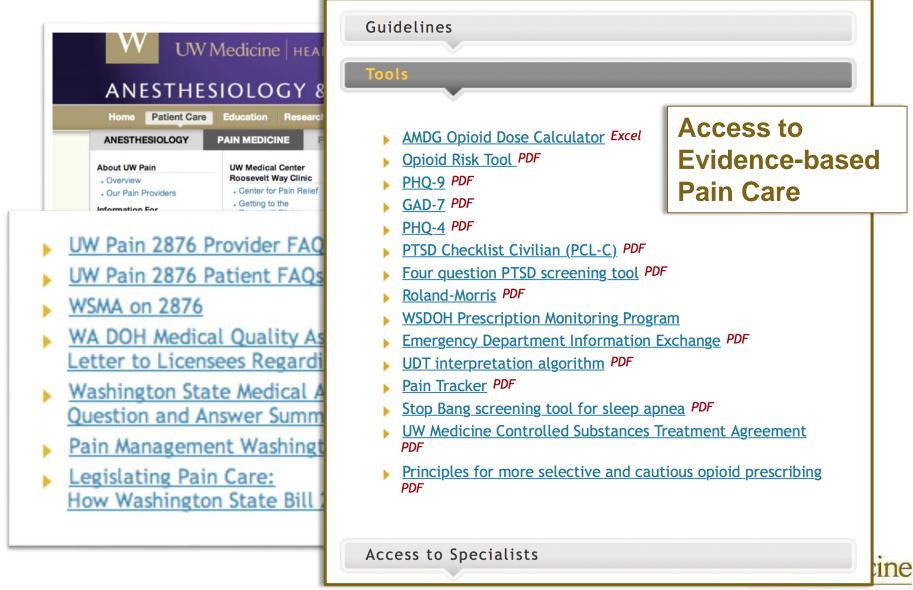






UNIVERSITY OF WASHINGTON

"Pain Medicine Provider Toolkit"



http://depts.washington.edu/anesth/care/pain/index.shtml

PAIN MEDICINE

Recognition and Treatment of Opioid Use Disorder in Patients with Chronic Pain

MOLINA Pain Management Provider Forum October 21, 2016

P. Todd Korthuis, MD, MPH Oregon Health & Science University

What Could Possibly Go Wrong?

Case

- 45 y.o. gentleman with chronic lower back and bilateral shoulder DJD pain transfers to your practice for pain management requesting narcotic refills. Transferring due to disagreements about medicine refills with prior doctor (frequent early refills)
- Currently taking:
 - 135mg MED oxycontin,
 - 32mg MED hydromorphine daily (breakthrough)
 - Zolpidem 10mg as needed for sleep
 - Sertraline+ clonazepam as needed

PMHx

- Depression/anxiety, Hepatitis C
- DUI with outpatient rehab in 20's (no longer drinks)
- Strong family h/o alcohol use disorder
- PDMP and UDS: as expected

Risk Factors for Opioid Use Disorder Development

- Published rates of abuse and/or addiction in chronic pain populations are 4-26%
- Suggests that <u>known risk factors</u> for opioid use disorder in the general population would be <u>good predictors</u> for problematic prescription opioid use
 - Lifetime history of substance use disorder²
 - -Past alcohol, tobacco⁴, cocaine, or cannabis use¹
 - Family history of substance use disorder, a history of legal problems³
 - Heavy tobacco use⁴
 - History of severe depression, anxiety, or PTSD⁴

^{2.} Reid MC et al JGIM 2002

^{3.} Michna E el al. J Pain and Symptom Management 2004

Principle Risk Factors for Opioid Use Disorder Development

- Younger age, 13-45 years of age
- Previous substance use disorder
- Back pain, headache
- High dose chronic opioid dose
 - > 90 mg morphine equivalents/day

Recognizing Opioid Use Disorder Before prescribing

- Screening Instruments
 - Opioid Risk Tool (ORT)
 - Provider administered
 - 5 items
 - Screen and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)
 - Patient administered
 - 24 items
- Point of care urine toxicology screens
- PDMP

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol Illegal Drugs Prescription Drugs		1 2 4	3 4
2. Personal History of Substance Abuse	Alcohol Illegal Drugs Prescription Drugs		3 4 5	3 4 5
3. Age (Mark box if 16 – 45)			1	
4. History of Preadolescent Sexual Abuse	e	[]	3	0
5. Psychological Disease	Attention Deficit Disorder, Obsessive Compuls Disorder, Bipolar, Schizophrenia	[]	2	2
	Depression		1	
		TOTAL		

Total Score Risk Category

Low Risk 0-3Moderate Risk 4-7High Risk ≥ 8

When to say 'no' to a request for long-term opioid therapy

Definite No

- <u>Untreated</u>, current substance use or serious mental health disorders
- Benzodiazepine use, alcohol use disorder, opioid use disorder, other substance use disorder

Proceed with caution

- Cannabis, tobacco, alcohol use
- Strong family or personal history of substance use disorder
- Mental illness, history of trauma, young age

Saying 'no' to a request for opioids

- Offer alternative evaluation, therapies
- Continue regular patient visits to reevaluate goals of care and treatment

Use a Risk-Benefit Framework

NOT...

- Is the patient good or bad?
- Does the patient deserve opioids?
- Should this patient be punished or rewarded?
- Should I trust the patient?

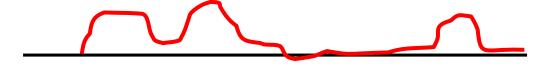


Do the benefits of opioid treatment outweigh the untoward effects and risks for this patient (or society)?

Judge the opioid *treatment*not the patient

Substance Use Disorder: A Chronic Illness

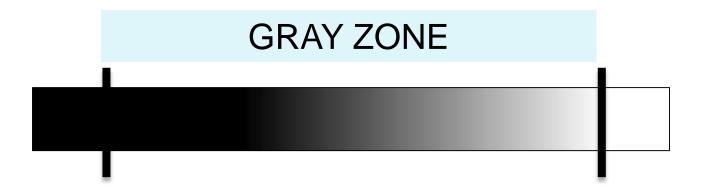
Asthma, Diabetes, HIV, etc.



Substance Use Disorder



Time



ADDICTED

Meets DSM criteria for opioid use disorder

NOT ADDICTED

- No lost prescriptions
- No ER visits
- No early prescriptions
- No requests for dose escalation
- No UDT aberrancies
- No doctor shopping (PMP)

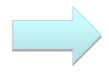
Continuum of Problematic Opioid Use



Mild indiscretion



Repeated misuse



Opioid use disorder



Severe Opioid Use Disorder (i.e. addiction)

Recognizing Opioid Use Disorder In Someone Already Prescribed Opioids

- Screening Tools
 - Current Opioid Misuse Measure (COMM™)
 - Self-report
 - Identifies high risk for current aberrant medication-taking behavior, but not diagnostic
 - Screening Tool for Addiction Risk (STAR)
 - Self-report
 - Corresponds to DSM-IV criteria
- Random Urine Drug Testing
 - Consider alcohol use (ethyl glucuronide)
- Random Pill Counts
- Prescription Drug Monitoring Data (PDMP)
- Review of medical records for new patients
- Discussions with other prescribers, family members

Concerning Behaviors for Opioid Use Disorder

Spectrum: Yellow to Red Flags

- O Requests for increase opioid dose
- O Requests for specific opioid by name, "brand name only"
- O Non-adherence w/other recommended therapies (e.g., PT)
- O Running out early (i.e., unsanctioned dose escalation)
- O Resistance to change therapy despite AE (e.g. over-sedation)
- O Deterioration in function at home and work
 - Non-adherence with monitoring (e.g. pill counts, UDT)
 - Multiple "lost" or "stolen" opioid prescriptions
 - Illegal activities forging scripts, selling opioid prescription

Opioid Use Disorder in Clinical Practice

- The 4 C's
 - Control, loss of
 - Compulsive use
 - Continued use despite harms
 - Craving

From: DSM-5 Criteria for Substance Use Disorders (SUD): Recommendations and Rationale

Am J Psychiatry. 2013;170(8):834-851. doi:10.1176/appi.ajp.2013.12060782

	DSM-IV Abuse ^a		DSM-IV Dependence ^b		DSM-5 Substance Use Disorders ^c	
Hazardous use	X)	-		X	1
Social/interpersonal problems related to use	X] ≥1	-		X	
Neglected major roles to use	X	criterion	_		X	
Legal problems	X	J	-		-	
Withdrawald	_	-	X	ı	X	
Tolerance	-		х		X	≥2
Used larger amounts/longer	-		х		X	criteria
Repeated attempts to quit/control use	-		X	≥3 criteria	X	
Much time spent using	-		X	Criteria	X	
Physical/psychological problems related to use	-		X		X	
Activities given up to use	_		x	J	х	
Craving	-		-		X	J

DSM-5 Criteria: 2-3 = mild SUD, 4-5 = moderate SUD, >6 severe SUD

Diagnosis of Prescription Drug Use Disorder

- No one test or questionnaire that can confirm prescription opioid use disorder
- PCP must determine risk/benefit
- Consider referral for diagnosis of an OUD if you do not feel comfortable making it
- DSM-5 criteria defines OUD
 - Tolerance and withdrawal criteria don't count
 - Sometimes becomes apparent over time

Pain Treatment in Opioid Use Disorder General Principles

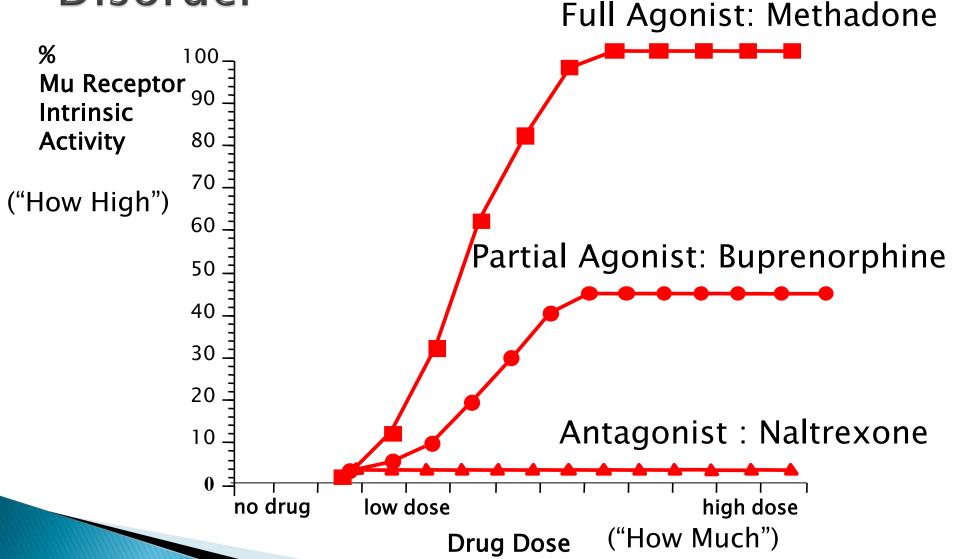
- Engage patient
- Treat pain safely and effectively
- Address opioid use disorder
 - Treatment including medication (methadone or buprenorphine) and counseling is needed
- Address pain facilitators including substance withdrawal

Pharmacotherapy for Opioid Use Disorder

- Methadone
 - OTP Referral
- Buprenorphine
 - Office-based
- Naltrexone
 - Office-based

Also potent analgesics!

Pharmacotherapy for Opioid Use Disorder



Referral for Methadone

- Full opioid agonist
- > 40 years data support^{1,2}
 - Safety
 - Sustained abstinence
 - Reduced criminal behavior³



- But...
 - Requires careful monitoring in OTP
 - Prolongs QTc
 - 23% of patients by 16 weeks⁴
 - Many drug-drug interactions⁵



- ¹ Kreek Addict Dis 2010
- ² Mattick Cochrane Rev 2008
- ³ Marsh Addiction 1998
- ⁴ Wedam Arch Intern Med 2007
- ⁵ McCance-Katz Am J Addict 2009

Buprenorphine/naloxone

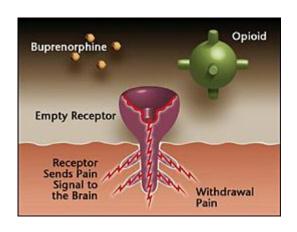
(4:1 combination)

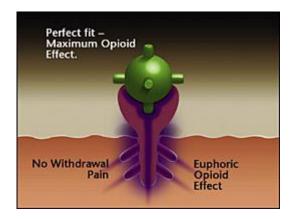
- Partial opioid agonist
 - Decreased overdose risk
- Naloxone inactive unless injected -then precipitates withdrawal
 - Decreased abuse risk
- Sublingual, once daily
 - Safe for flexible dosing

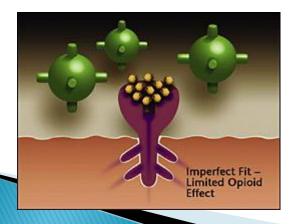


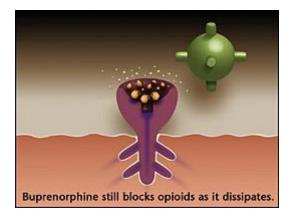


How Does Buprenorphine Work?









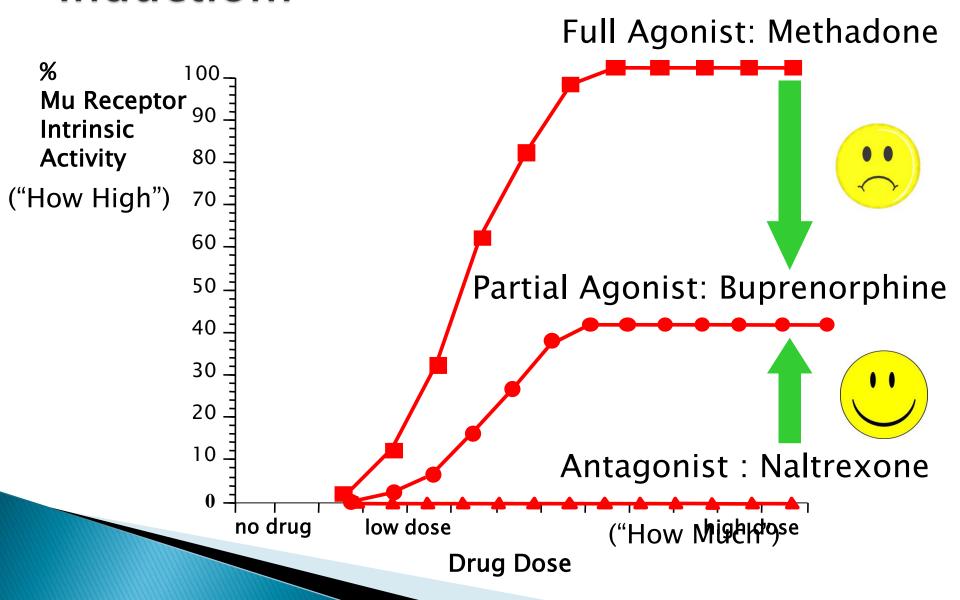
Buprenorphine for Treatment of Chronic Pain

- Ceiling effect for respiratory suppression
- Less of a ceiling for analgesia
- Analgesic effect 6-8 hours, so BID or TID dosing often helpful
- Partially blocks effect of other opioids
- DATA-2000 Waiver recommended

Starting Buprenorphine/Naloxone

- ▶ Induction (1–2 days)
 - Must be in moderate withdrawal
 - Clinical Opiate Withdrawal Scale (COWS)
 - Heroin/Hydromorphone: 12 hours
 - Methadone: 72+ hours
 - Start with 2mg and gradually increase
 - Titrate to effect (average dose 16mg)
- Stabilization/Maintenance
 - Combine with UDS & Counseling

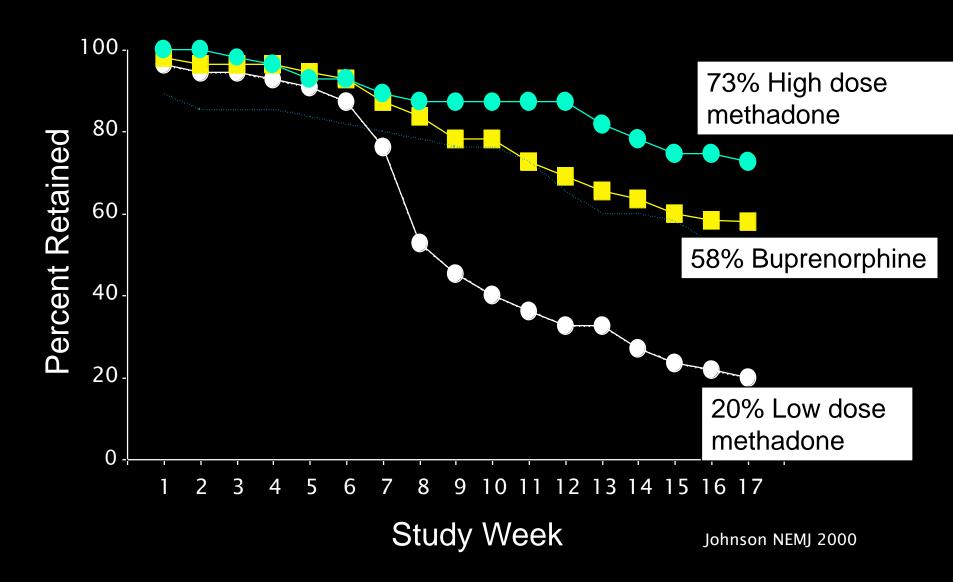
Why Is Withdrawal Required for Induction?



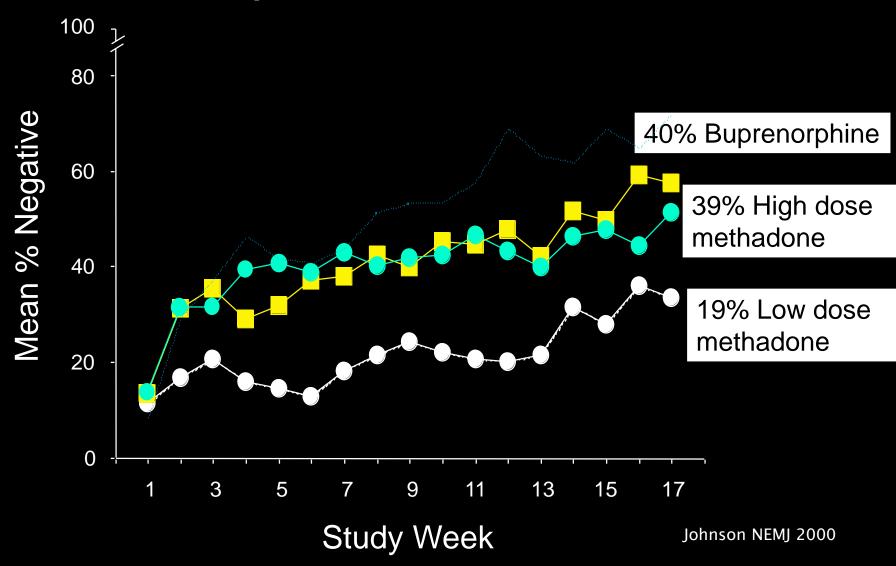
Buprenorphine vs. Methadone

- Design: 17 week outpatient randomized, double-blind clinical trial in heroin users (n=220)
 - 1. High dose methadone (60–100mg/day)
 - 2. Buprenorphine (16–32mg 3x/week)
 - 3. Low dose methadone (20mg/day)
- Outcomes
 - Treatment retention
 - Negative urine drug screens (%)

Buprenorphine vs. Methadone Treatment Retention

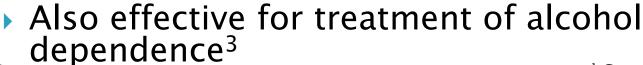


Buprenorphine vs. Methadone Opioid Urine Results



Naltrexone

- Oral Naltrexone
 - Opioid antagonist
 - May decrease pain hypersensitization
 - Decreased fibromyalgia pain in 1 study
- Extended-Release Naltrexone
 - Intramuscular injection lasts 28d
 - Efficacious compared to placebo:
 - Comer: 60 U.S. heroin users at 8 weeks¹
 - Krupitsky: 250 Russian heroin users at 24 wks²





¹ Comer Arch Gen Psych 2006

² Krupitsky Lancet 2011

³ Garbutt JAMA 2005

Buprenorphine Effectiveness for Chronic Pain

- No large-scale randomized trials
- Systematic Review of 10 studies (limited quality):
 - Increased efficacy in neuropathic pain
 - Ease of use for the elderly
 - Ceiling effect for respiratory depression
 - Less effect on hypogonadism
 - Antihyperalgesic effect
- All studies reported reduced pain intensity

Conclusions

- OK to say "no" to opioids
- Create a system to monitor for opioid use disorder in your practice
- Buprenorphine an option for office-based management of pain and opioid use disorder
- Refer when diagnosis or treatment in question

Additional Resources

- Providers Clinical Support Service
 - PCSS-Opioids
 - www.pcss-o.org
 - PCSS-Medication Assisted Treatment
 - www.pcssmat.org
- OHSU Addiction Medicine Consult Line
 - Call (800) 245–6478 or (503) 494–4567
 - Mon-Fri 8:00-5:00
- Oregon Addiction Prevention and Education Initiative
 - Buprenorphine waiver training and telementoring

Discussion

Supplemental Slides

What about Cannabis for Pain Relief?

- Narrow therapeutic window
- Cannabis with higher CBD content (vs THC) may be effective for some forms of pain, but few rigorous studies
 - Cannabis is not regulated, so label ingredients may be misleading
- Side effects: nausea, vomiting, paranoia, worsening of anxiety or depression, weight gain, reduced functional status, impaired driving

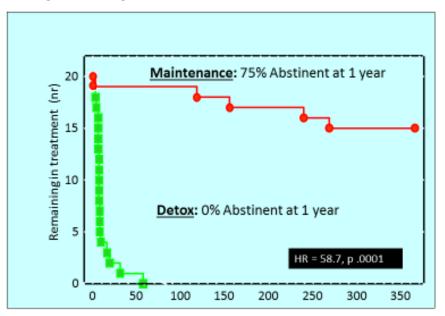
Detox vs. Maintenance: Which is Better?

- Multi-site trial of buprenorphine/nx for 653 prescription opioid-dependent patients in 10 primary care clinics
- Detox phase followed by maintenance phase for those who relapse
- "Success" = minimal or no use on UDS & selfreport

Success at 12 Weeks:			
Detox Phase:	6.6%		
Maintenance Phase:	49.2%		

MAT Maintenance is Effective... Detox Is Not

Treatment Retention: Buprenorphine Detox vs. Maintenance



Deaths:

0% Maintenance

20% Detox

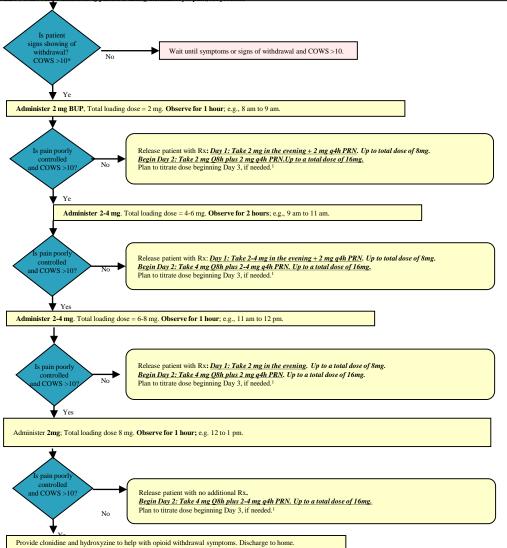
Kakko, Lancet 2003

Sublingual Buprenorphine-naloxone for Chronic Pain: Induction and Dosing Protocol

Patient with chronic pain undergoing transition to buprenorphine-naloxone for chronic pain.

- <u>Limit</u> patients to those taking a daily dose equivalent to ≥ 50 mg/day PO morphine and not prescribed benzodiazepines.
- Patients prescribed >30 mg/day PO methadone will need to first taper to 30mg of methadone.
- Patients prescribed >200 mg MED will need to first taper to <200 mg/day of PO morphine.
- · Schedule patient for 8 am buprenorphine (BUP) induction. Discontinue long acting opioids within 24 hours of induction appointment. Discontinue short acting opioids

At least 6 hours before induction. If patient is taking methadone for pain, see footnote*



^{*}Opioid withdrawal is measured by the Clinical Opioid Withdrawal Scale (COWS)

^{1.} Further increases in the scheduled Q8h dose can begin on Day 3; increase the scheduled dose no more frequently than every other day. Total dose of Day 3 is 20mg. Total dose of day 4 is 20mg. Total dose of day 5 is 24mg. Dose should be reduced for any signs of sedation. Doses will not exceed 24mg total. Doses will be prescribed daily, twice daily, or at most, three times day.

^{*}If patient is taking methadone ≥30 mg/day for pain: To reduce the risk of delayed precipitated withdrawal, consider stopping methadone 48 hours before induction and requiring a COWS >15 prior to the first dose. Alternatively, consider extending the BUP loading period on Day 1 by using smaller doses at the same intervals to titrate up to the desired level, e.g., 2 mg, 2 mg, 2-4 m

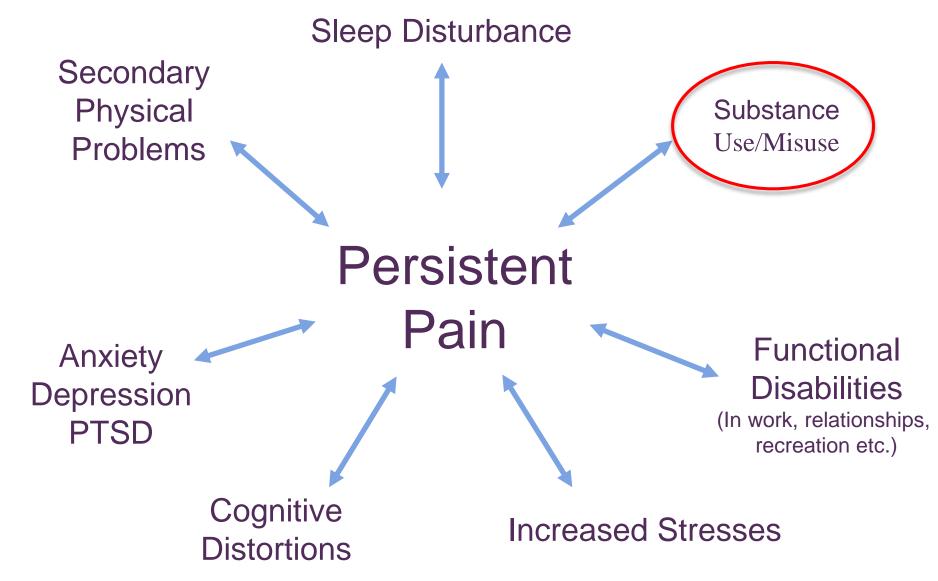
U.S. BHIVES 12-Month Results:

- Improved Drug Outcomes¹
 - Opioid use: 84% → 42%
- Improved HIV Outcomes²
 - Receipt of ART: 60% \longrightarrow 68%
- ▶ Improved quality of care, quality of life³
- Conclusion: Integrated buprenorphine and HIV Care feasible and safe

¹ Fiellin JAIDS 2011

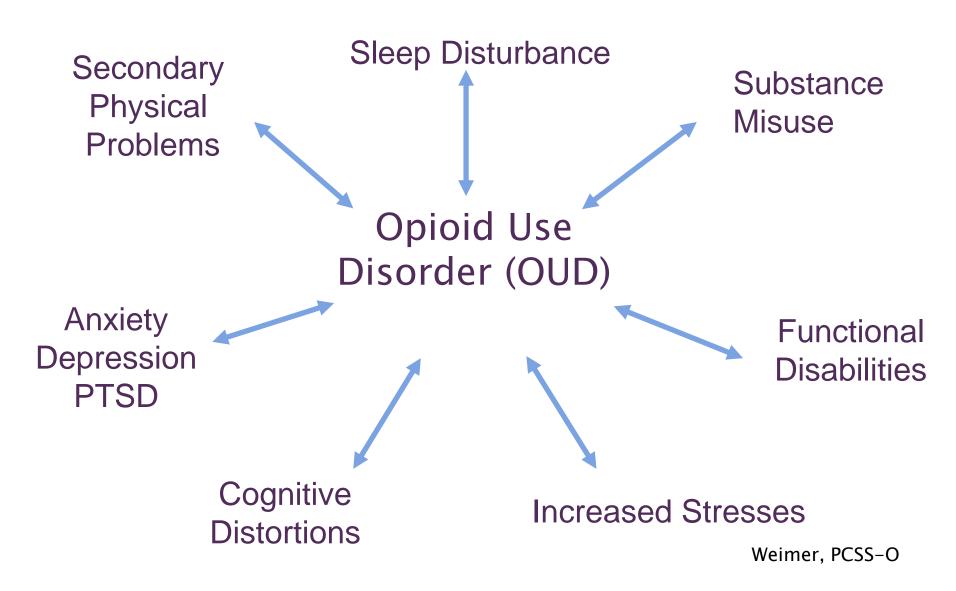
² Altice JAIDS 2011

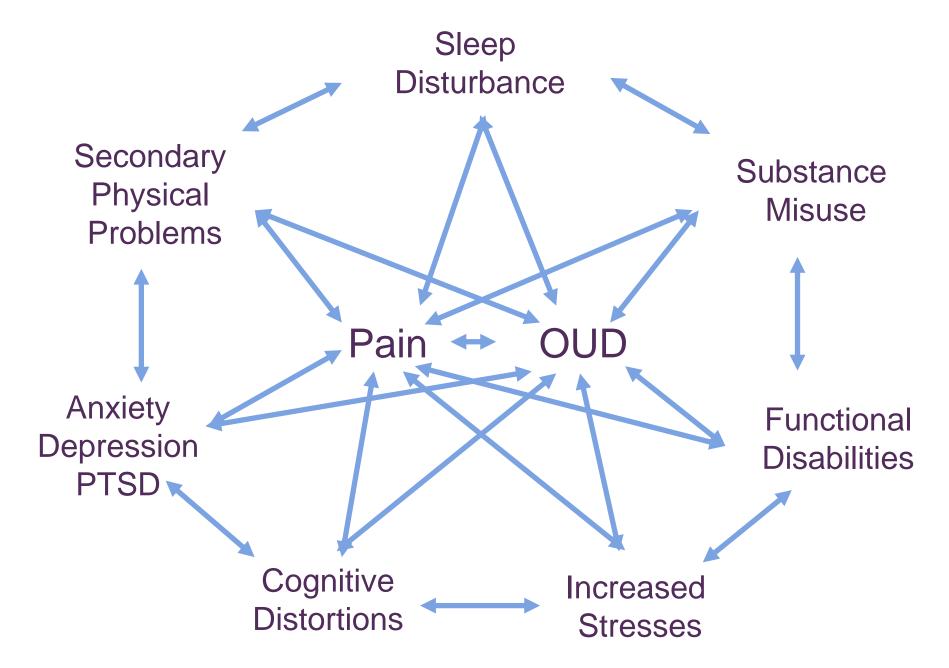
³ Korthuis JAIDS 2011



Whatever it's cause, when pain persists, it often causes secondary problems that can in turn facilitate distress and pain.

As a chronic condition, OUD shares similar challenges as persistent pain





When OUD and pain co-occur they may reinforce one Weimer, PCSS-O

Spectrum of Opioid Use Disorder

- Self medication (chemical coping)
 - Mood
 - Sleep
 - Traumatic memories
- Prevent withdrawal
- Reward (to get high)
- Opioid Use disorder
- Diversion for profit

Medication or substance misuse by persons with pain may occur for diverse reasons. Helps to identify and address the driver of misuse. Misuse may be selflimited or may be a sign of opioid use disorder in vulnerable people.

Does the patient with chronic pain who is prescribed opioids have an opioid use disorder?

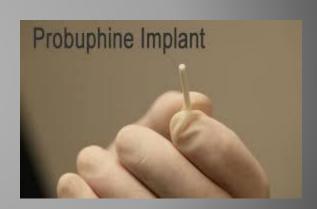
- 1. Unable to fulfill role obligations MAYBE
- 2. Social or interpersonal problems due to use MAYBE
- 3. Hazardous use MAYBE
- Tolerance DOES NOT APPLY*
- 5. Withdrawal/physical dependence **DOES NOT APPLY***
- 6. Taken in larger amounts or over longer period MAYBE
- 7. Unsuccessful efforts to cut down or control MAYBE
- 8. Great deal of time spent to obtain substance MAYBE
- 9. Important activities given up or reduced MAYBE
- 10. Continued use despite harm MAYBE
- 11. Craving MAYBE

*If opioids are prescribed, this criterion does not apply.

Buprenorphine Implants

FDA advisory approval March 21st, 2013

- Slow-release (6 month)
 SQ implant
- 6 month RCT implantvs. placebo
- Supplemental SL buprenorphine allowed

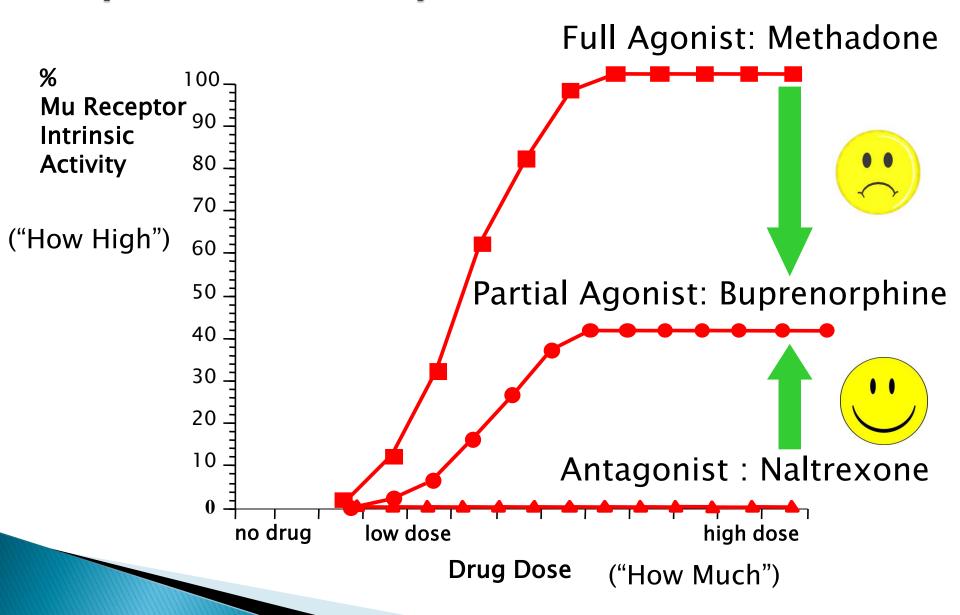


Buprenorphine Implant RCT

	Bup Implant (n=108)	Placebo Implant (n=55)	P-value
24-wk Retention	65.7%	30.9%	<.001
% UDS Negative: Weeks 1–16 Weeks 1–24	40.4% 36.6%	28.3% 22.4%	.04 .01
COWS	2.3	3.4	<.001
Subjective Withdrawal	4.1	6.5	.004
Opioid craving VAS	9.9	15.8	<.001

- ▶ 50% with mild implant irritation in both arms
- Conclusion: Improved retention & decreased opioid use

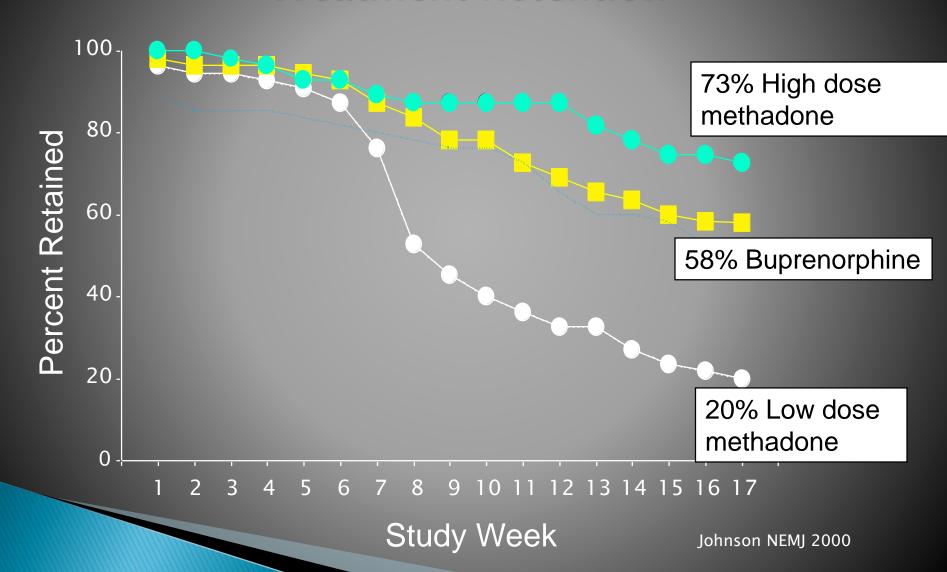
Opioid Activity Levels



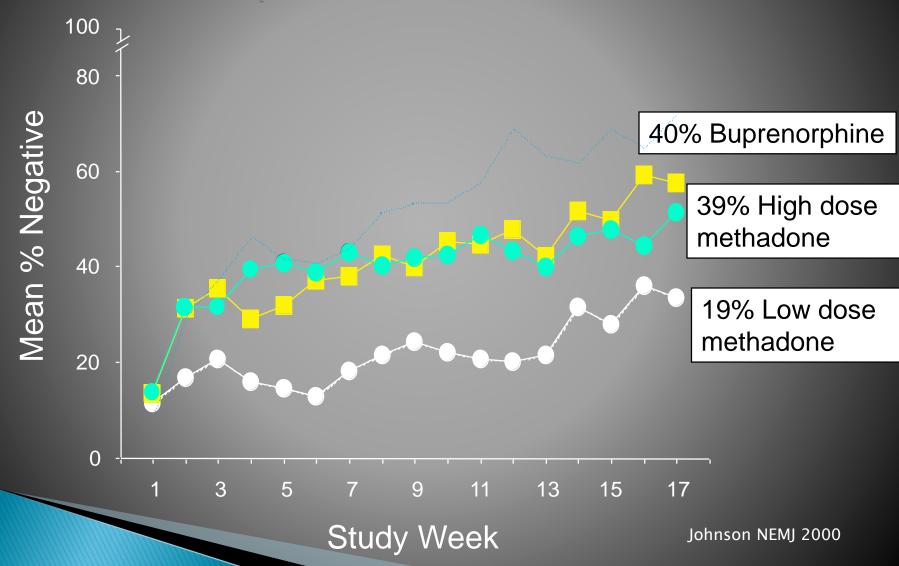
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Buprenorphine Drug Interactions

- Bup metabolized by CYP3A4, 2C8
- Fewer interactions than methadone

	Interaction	Clinical Management
Atazanavir	Buprenorphine levels 193%	May require bup dose
Rifampin	Buprenorphine levels 1 70%	May require bup dose
St Johns Wart	Buprenorphine levels	Alt. antidepressant
Benzodiazepines	Synergistic sedation	Avoid benzos + bup

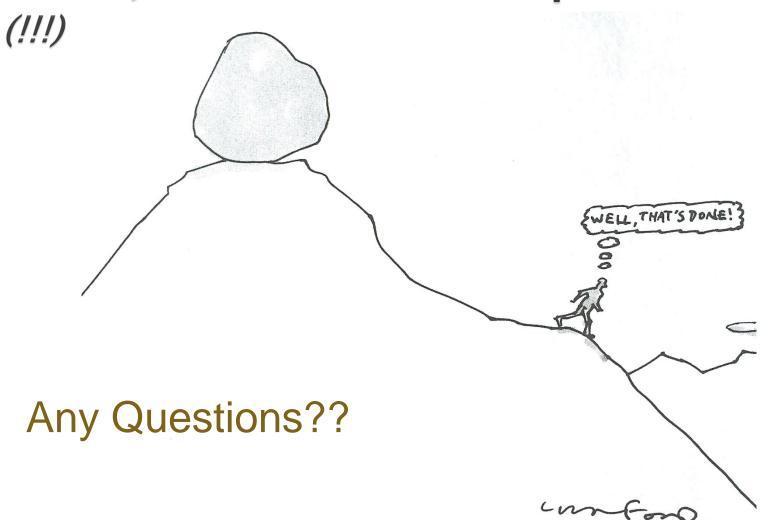
XR-NTX Induction with Recent Opioid Use (one example)

- ▶ Wait 1-3 days past last reported opioid use
- Assess UDS and repeat daily until negative for opioids and buprenorphine
- Perform naloxone challenge on first day UDS negative for opioids and buprenorphine
- When negative, administer XR-NTX same day.
- Prescribe non-opioid withdrawal treatment medications as needed, for up to 2 weeks

Treat Pain Safely and Effectively

- Untreated pain may drive opioid use disorder, self medication and misuse
- Reduce or resolve causes when possible
- Provide appropriate pain relief
 - Non-medication approaches when effective, safe, easily available and acceptable to patient
 - Less-rewarding meds when safe and effective
 - Potentially rewarding medications when needed with appropriate limits on use
- Plan treatment when pain anticipated (eg for elective procedures or surgery)

PAIN, at a Point of Equilibrium

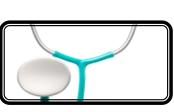


Proposed Washington State Action on Opioid Use



Goal 1: Prevent inappropriate opioid prescriptions and use

- CDC or Agency Medical Director Guidelines (AMDG); focus on limiting adolescent prescriptions
- · Prevention education targeting youth



<u>Goal 2</u>: Treat people with opioid use disorder and link them to support services, including housing

- BH integration strategies; improved screening, access to medication-assisted treatment
- · Ensure rapid, access to medical treatment



<u>Goal 3</u>: Save lives by intervening in overdoses

- · Education on overdose response and access to naloxone
- · Bulk purchasing of naloxone for public health use



Goal 4: Use Data to focus and improve our work

- Statewide measures to detect unsafe prescribing practices and identify high-risk patients
- Expand Prescription Drug Monitoring Program
- Improve provider notification of opioid overdose events

Source: WA Governor's Office Executive Order 16-09: Addressing the Opioid Use Public Health Crisis (October 7, 2016)

RESOURCES

Agency Medical Directors Group (AMDG) Guidelines summary:

http://www.agencymeddirectors.wa.gov/guidelines.asp

AMDG Guidelines (full version):

http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

CDC Guidelines:

http://www.cdc.gov/drugoverdose/prescribing/guideline.html

DOH general resources for opioid management:

http://www.doh.wa.gov/Emergencies/PainClinicClosures



Office Management of Chronic Pain: Overcoming Barriers to Safe and Effective Pain Care Delivery Friday, October 21st 2016

DISCLOSURE INFORMATION

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The following have indicated they do not have any relationships to disclose:

David Tauben, University of Washington - Speaker Todd Korthuis, Oregon Health Sciences University - Speaker Frances Gough, Molina Healthcare of Washington - Sponsor Whitney Howard, Molina Healthcare of Washington - Planner



Contact Information

David J. Tauben, MD, FACP

Chief, UW Division of Pain Medicine University of Washington, Seattle WA

Phone: (206) 616-0717 Email: tauben@uw.edu

P. Todd Korthuis, MD, MPH

Associate Professor of Medicine and Public Health-Preventive Medicine (joint) Oregon Health and Science University

3181 SW Sam Jackson Park Rd., L475

Portland, OR 97239-3098

Phone: (503) 494-8044

E-mail: korthuis@ohsu.edu

Frances Gough, MD, CMO

Chief Medical Officer

Molina Healthcare of Washington, Bothell WA

Phone: (425) 890-6012

Email: Frances.Gough@MolinaHealthCare.Com

