Guidelines for Appropriate Opioid Prescribing in Non-cancer Patients

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Disclosure

• Dr. Munzing has no relevant financial interests to disclose

Goals & Objectives: Participants will be able to:

- Analyze the 2022 CDC Opioid Prescribing Guidelines – compare with 2016 guidelines
- Discuss Risks / Benefits of Opioid Medications / Risks of Dangerous Combinations
- Incorporate standard of care elements and patient safety when managing pain

Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain (Dr. Tim Munzing SCPMG) May 1, 2017

ORIGINAL RESEARCH & CONTRIBUTIONS

Special Report

Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain

Timothy Munzing, MD, FAAFP	Perm J 2017;21:16-169
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ABSTRACT

Prescription opioid use for relief of noncancer pain has risen dramatically in the last 15 years, contributing to a quadrupling of opioid overdoses and prescription opioid-related deaths. This crisis is resulting in heightened attention by health care professionals and organizations, law enforcement, and the government. In this article, I highlight key topics in the management of patients using opioids (or potentially needing opioids) in outpatient clinical practice; federal and state law enforcement actions regarding physicians' illegal prescribing of opioids; multimodal approaches to pain control; nonmedication management of pain; response strategies when suspecting a patient of diverting or misusing opioids; and warning signs for abuse or diversion. For those patients for whom opioids are appropriate, I describe key elements for prescribing, including documentation of a detailed history and examination, appropriate evaluation to arrive at a specific diagnosis, individualizing management, and ongoing monitoring (including the use of urine drug screening and a prescription drug monitoring program). In addition to individual action, when possible, the initiation of systemwide and clinicwide safe prescribing practices supports the physician and patient such that the patient's well-being is at the heart of all pain management decisions. Physicians are encouraged to further educate themselves to treat pain safely and effectively; to screen patients for opioid use disorder and, when diagnosed, to connect them with evidence-based treatment; and to follow Centers for Disease Control and Prevention guidelines whenever possible.

INTRODUCTION

Opioids are just one of a large armament of tools to treat acute (days to weeks) and chronic (months to years) pain, to relieve the physical distress of patients, and to maximize their quality of life. Physicians wield the power to heal and relieve pain. However, the same power has the potential to contribute to harm, especially in the case of prescribed opioids.

Current prescribing patterns by many have contributed to large increases in abuse, drug overdoses, and deaths. More than 50 people die of opioid overdoses each day in the US,¹ surpassing overdose deaths owing to all illicit drugs and motor vehicle crashes. Careless or criminal physicians are being investigated and prosecuted in increasing numbers by local, state, and federal law enforcement.

To accentuate the severity of the crisis, new action is occurring at the state and federal levels. Last year, the Centers for Disease Control and Prevention (CDC) released new opioid prescribing guidelines³; the Food and Drug Administration (FDA) added a black box warning for prescribing opioids and benzodiazepines³; US Surgeon General Vivek Murthy sent a letter to all US physicians asking them for commitment to "Turn the Tide" on the opioid crisis⁴; and the White House convened a summit of national leaders on this subject.

Causes of the Crisis

Efforts to increase prescribing for pain were intense in the 1990s and early 2000s. Regulatory bodies, including The Joint Commission, called on pain to be "made visible,"⁵ resulting in many calls to implement pain as the fifth vital sign. National groups unrealistically recommended "getting pain to zero." In addition, pharmaceutical companies developed stronger and long-acting opioids, with aggressive marketing to physicians, while minimizing potential risks.6 Nonlegitimate users found that short-acting opioids (hydromorphone, oxycodone) and long-acting opioids (when "broken" of their time-release coatings) may result in enhanced euphoria and potentiation of their addictive nature.7 "Pill mill" practices sprang up across the US.6,8 Many wellmeaning physicians prescribed high-dose opioids because of a lack of, or erroneous, education and experience, being naïve or exceedingly busy, or not recognizing the dangers that existed. Sadly, some patients who were started on opioid therapy for pain ultimately abused these medications. Tragic for far too many, this resulted in drug overdoses and death. A very small proportion of patients began selling their prescribed opioid medications for profit ("diversion" of medications).68

From 2000 to 2014 the rates of opioid sales greatly increased, resulting in a quadrupling of opioid overdoses* and a similar rise in opioid prescription-related deaths.¹ The Sidebar: Potential Side Effects of Opioid Medications lists serious and common potential side effects of opioid use.

Data from the CDC document that more than 47,000 people in the US died of drug overdose in 2014, of which 60.9% involved an opioid.⁹ According to the CDC, approximately 44 people per day die in the US of opioid prescription overdoses, resulting in more than 16,000 deaths annually, with benzodiazepine overdoses contributing another 8000 deaths.¹⁰ In addition, drug use and misuse annually result in more than 2.5 million Emergency Department visits, of which 56% are for prescription

Soaring Towards Improved Outcomes and Patient Safety





Avoiding Falling off the Cliff: Potential Consequences

- Patients
 - Addiction (Substance Use Disorder)
 - Overdose
 - Death
- Physicians
 - Loss of Medical License
 - Prison

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

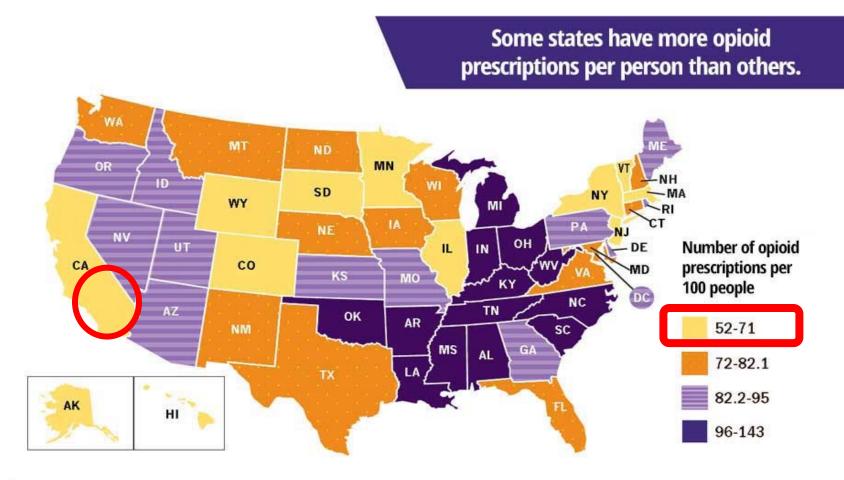
To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients' who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare inmedical patients with no history of addiction.

JANE PORTER HERSHEL JICK, M.D. Boston Collaborative Drug Surveillance Program Waltham, MA 02154 Boston University Medical Center

 Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
 Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

Outdated Information is Wrong

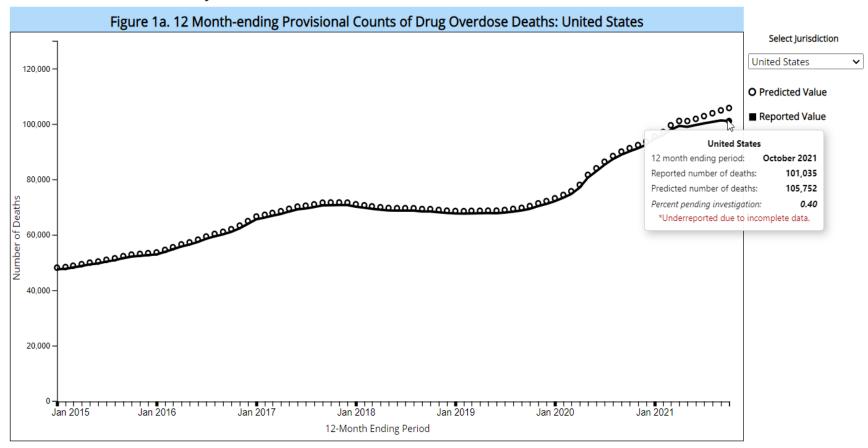
- "The risk of addiction is much less than 1%"
- Porter J, Jick H. Addiction rare in pain patients treated with narcotics. New Eng J Med. 1980 Jan 10;302(2):123
- Pain 5th Vital Sign
- 1990's Physicians encouraged to treat pain aggressively (assumed no harm)



SOURCE: IMS, National Prescription Audit (NPA™), 2012.

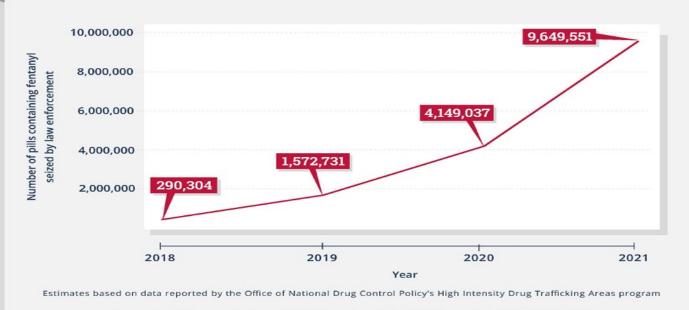
CDC Data: National Vital Statistics Rapid Release

Based on data available for analysis on: 06-Mar-22



Fentanyl Seizures

Number of Pills Containing Fentanyl Seized by Law Enforcement in the United States, 2018 – 2021



Reference: JJ Palamar, et al. Drug and Alcohol Dependence. DOI: 10.1016/j.drugalcdep.2022.109398 (2022)

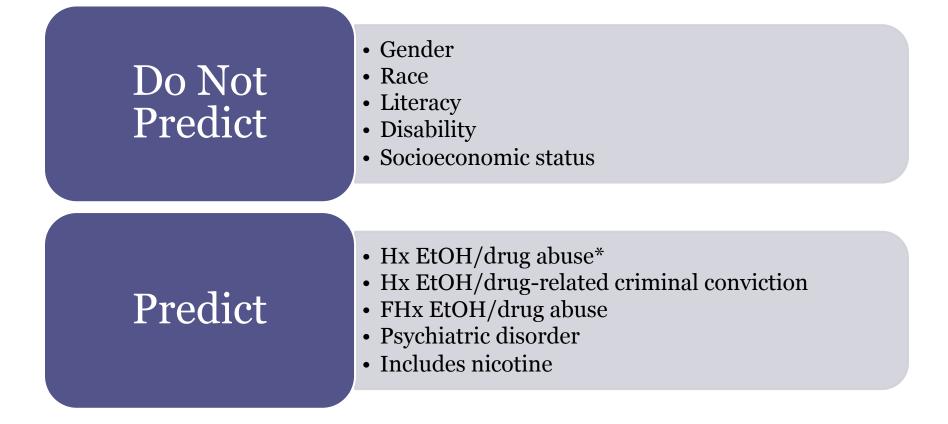


nida.nih.gov

Question: Which of the following predict misuse of prescription opioids?

- A. Race
- B. Literacy
- C. Disability
- D. Socioeconomic status
- E. All of the Above
- F. None of the Above

Cultural Competence



Opioid Risk Tool - Questionnaire developed by Lynn R. Webster, MD to asses risk of opioid addiction. Webster LR, Webster R. Predicting aberrant behaviors in Opioid-treated patients: preliminary validation of the Opioid risk too. Pain Med. 2005; 6 (6) : 432

Universal Precautions for Opioid Prescribing

- Evaluate the need
- Assess risk
- Select the specific opioid treatment
- Discuss informed consent written agreement
- Monitor closely
- Document thoroughly

2016 CDC Guidelines for Controlled Substances

- Audience Primary care
- Avoid benzodiazepines with opioids [increases risk of overdose death up to ten-fold versus only opioid use]
- **Periodic monitoring**, including PDMP and Urine Drug Screen
- Non-pharmacologic and non-opioid treatment first line
- Chronic pain avoid opioids if possible risk outweighs benefits for most
- **Discuss risk / benefits** with patients and document
- Establish realistic goals prior to opioid starts

2016 CDC Guidelines for Controlled Substances Continued

- Start immediate release avoid Methadone as first line – higher risk
- Additional precautions if dose exceeds 50 MME mg /day
- "Generally, avoid increasing the dosage >= 90 MME mg/day
- Should only give 3 days max for acute pain for most non-traumatic, non-surgical pain
- Avoid combinations short and long-acting opioids
- Concerns may limit opioids for some for whom they may benefit

2022 CDC Guidelines -

- Audience Primary care and anyone treating adult pain patients
- Eliminated mentioning the numbers (90 mg and 50 mg) in recommendation
- High dose >= 120 mg/day MME
- Encouraged <u>non-opioids</u> for pain when possible
- Risk vs benefit
- Mitigation of risk



2022 CDC Opioid Prescribing Guidelines

Determining Whether or Not to Initiate Opioids for Pain (Recommendations 1 and 2)

1 – Maximize use of nonpharmacologic and nonopioid pharmacologic therapies

- Consider and discuss "realistic benefits and known risks" with patients

2 – Nonopioid therapies are preferred for subacute and chronic pain

- Consider how opioid therapy will be discontinued if benefits do not outweigh risks

2022 CDC Guidelines

Selecting Opioids and Determining Opioid Dosages (Recommendations 3, 4, and 5)

3 – When starting opioid therapy – prescribe immediate release opioids

4 – Opioid-naïve patients – use caution – any dosage, carefully evaluate risks / benefits prior to dosage increase
5 – Patients on opioids, carefully weight benefits vs risks, utilize other therapies and if taper – gradual, monitor for withdrawal side effects

2022 CDC Guidelines

Deciding Duration of Initial Opioid Prescription and Conducting Follow-Up (Recommendations 6 and 7)

- 6 Acute pain opioids prescribe no greater quantity than needed for expected duration
- 7 Evaluate benefits and risks within 1 4 weeks of starting opioid therapy or dose escalation regularly reevaluate the benefits and risks
- 8 Before starting opioids and periodic evaluate risks and discuss with patients. Mitigate risk, including offering Naloxone

2022 CDC Guidelines

9 – Initial and periodic – check PDMP [required at least every 6 months in California – CURES] 10 – Consider benefits and risks of toxicology testing [Urine drug screening] [*Generally advised 1 – 4 times* yearly depending on risk level of the patient] 11 – Use caution when prescribing opioids and benzodiazepines [or other CNS depressants] concurrently – weigh benefits and risks 12 – Offer or arrange treatment for opioid use disorder; detox without medications not recommended – more risky

FDA Black Box Warning-September 2016

 Avoid prescribing (or using) opioids and benzodiazepines concurrently

Significant risk of respiratory depression (difficulty / slower breathing)

• Higher risk of overdose death

Pain Management Basics

- Multiple strategies
 - Non-pharmacologic
 - Pharmacologic
 - Procedures
 - Opioids
 - Devices

Controlled Substance Prescribing Core Elements:

- Medical History- Thorough
- Physical Exam- Imaging
- Assessment- Specific
- Plan-Goals
- Informed Consent
- Periodic Review
- Consultation
- Records/Documentation
- Monitoring (PDMP, Urine drug testing, etc.)

Adapted from the Medical Board of California; American Academy of Pain Medicine; American Pain Society

The 5 A's Plus

- Analgesia: rating of average pain, worst pain, and pain relief
- Activity: progress in patient's functional goals
- Adverse Effects: nausea, dizziness, drowsiness, other forms of impairment, etc.
- Affect: impacts to mood, anxiety, depression, ability to be happy, etc.
- Aberrant behaviors: taking meds as prescribed, illicit drug use
- Prescription Drug Monitoring Program (PDMP)
- Urine Drug Screening (UDS)
- Updated History, Exam, and Assessment
- Taper medications when possible
- Include the Morphine Equiv Dosing Every visit

- Dr. Tim Munzing SCPMG
- Dr. Carol Forster MAPMG

Reference: 1. Executive Committee of the Federation of State Medical Boards of the United States, Inc. Model policy on the use of opioid analgesics in the treatment of chronic pain. July 2013. (Sourced 25/2/14) www.fsmb.org/pdf/pain policy july2013

Comparison of Guidelines

<u>KEY</u>	
FSMB	Federation of State Medical Boards
MBC	Medical Board of California
ASIPP	American Society of Interventional Pain Practitioners
AMDG	Agency Medical Directors Group - Washington
CDC	Centers for Disease Control and Prevention
AAPM	American Academy of Pain Medicine
CS	Controlled substance medications

	FSMB	MBC	ASIPP	AMDG	CDC - 2016	CDC - 2022	AAPM
Patient Evaluation							
Intended audience	All	All	All	All	Primary care	All	All
Pain history	Х	Х	Х	Х	Х	Х	Х
Pain / function assessment	Х	Х	Х	Х	Х	Х	Х
Mental health history	Х	Х	Х	Х			
Substance abuse history, opioid risk	Х	Х	Х	Х			
Chronic diseases	Х	Х		Х	Х		Х
Appropriate exam	Х	Х	Х	X	X	Х	Х

	FSMB	MBC	ASIPP	AMDG	CDC - 2016	CDC - 2022	AAPM
Imaging, additional information considered		Х	Х	Х		Х	
Treatment goals for diagnosis	Х	Х	Х	Х	Х	Х	X
Risk stratification (assess risk)	Х	Х	Х	Х	Х	Х	X
Lowest dose possible	Х	Х	Х	Х	Х	Х	
Informed consent (risk / bnefits)	Х	Х	Х		Х	Х	X
Maximize / use of non-opioid treatments / multimodal	Х	Х	Х	Х	Х	Х	X
Opioid trial - new starts	Х	Х	Х	Х	Х	Х	X
Consults - referral - consider	Х	Х	Х	Х		Х	X
Opioid - benzo - sedatives - added risks - avoid if possible - caution	Х	Х	Х	Х	Х	Х	

	FSMB	MBC	ASIPP	AMDG	CDC - 2016	CDC - 2022	AAPM
Monitoring of CS							
Side effects - harm query / monitor	Х	X	Х	Х	Х	X	Х
Pain assessment - improvement (periodic assessment)	Х	X	Х	Х	Х	Х	Х
Periodic reassessment - History - exam updated	Х	Х	Х	Х	Х	Х	Х
Urine Drug Testing (UDT)	Х	X	Х	Х	Х	X	Х
Prescription Drug Monitoring Prog (PDMP) [CURES in California]	Х	X	Х	Х	X	Х	
Risk mitigation (e.g. tapering, discontinue as able)	Х	Х	Х	Х	Х	Х	Х
<u>Documentation</u>							
Detailed documentation	Х	Х	Х	Х	Х		Х
High dose opioid definition							
"High dose" opioid (mg/day)	Not defined	>=120	>91	>120	>=90	>=120	

Controlled Substance Medications: Drug Classes (Examples)

Drug – Generic	Brand Names	Schedule	Class
Hydrocodone	Norco, Vicodin	II	Opioid (pain)
Oxycodone	OxyContin, Percocet	II	Opioid
Morphine	MS Contin	II	Opioid
Methadone	Methadose	II	Opioid
Alprazolam	Xanax	IV	Benzodiazepine (anxiety, insomnia)
Lorazepam	Ativan	IV	Benzodiazepine
Carisoprodol	Soma	IV	Muscle Relaxant

Question: Red Flag(s) that confirm abuse / diversion include:

- A. Opioid MME > 250 mg/day
- B. Early refills of meds
- C. Using multiple doctors or pharmacies
- D. Driving a long distance to be seen
- E. All of the above
- F. None of the above

Potential Red Flags

- Requesting brand names
- Early Refills, lost or stolen Rx
- MME > 90 100 mg / day
- Multiple concurrent prescribers & pharmacies
- Combinations (e.g. opioid, benzodiazepine, carisoprodol)
- Escalating dosing by provider
- Escalating prescriptions by patient
- Inconsistent UDT results
- Too many tests (fraud???)
- Patients driving a long distance for care
- Multiple family members identical or similar meds
- Drug overdoses
- Buy/ give / sell meds
- Use of THC even with Marijuana Card



Common Drug Seeking Behavior

- Feigns illness.
- Complains of severe pain without basis.
- Repeated requests for replacement of "lost" prescriptions.
- Threatening behavior when denied drugs.
- Does not get appropriate treatment.
- Self-inflicted injury.
- Asks for <u>specific</u> controlled substance medication.

Common Drug Seeking Behavior

- Wants prescriptions to be filled at multiple pharmacies.
- Emails or calls for refills without periodic visits.
- Cancels follow-up appointments.
- Won't fill prescriptions for non-controlled substances.
- Frequent ED and urgent care visits.
- Yell or argumentative to office or pharmacy personnel.

Question - MME Dosing

- Which oral opioid is strongest mg to mg?
- A. Oxycodone
- B. Hydrocodone
- C. Morphine
- D. Oxymorphone
- E. Methadone

Morphine Milligram Equivalence Dosing (mg/day) (Oral dosing except Fentanyl)

Drug	Brand	Relative Strength	100 mg/day MME Equiv
Morphine		1	100
Hydrocodone	Norco, Vicodin	1	100
Oxycodone	OxyCodone Roxycodone	1.5	66
Hydromorphone	Dilaudid	4	25
Oxymorphone	Opana	3	33
Methadone		4 to 12	
Fentanyl	Duragesic	100 (72 also used)	

Adapted from Opioid Calculator - Available at http://agencymeddirectors.wa.gov/mobile.html

Opioid Dosing Calculator -MME (mg/day) -(Oral dosing except Fentanyl)

Optional:	Patient name:				
	Today's date:	August 17, 2015			
Instructions:	Fill in the mg per day* for whichever opioids your patient				
		Isheet will automatically calculate the			
	total morphine equiva	-			
Opioid (oral or transdermal):	mg per day*:	Morphine equivalents:			
codeine	0	0			
fentanyl transdermal (in mcg/hr)	0	0			
hydrocodone	40 40				
hydromorphone	0 0				
methadone					
up to 20mg per day	0 0				
21 to 40mg per day	0 0				
41 to 60mg per day	0 0				
>60mg per day	0 0				
morphine	0	0			
oxycodone	30 45				
oxymorphone	0	0			
TOTAL daily morphine equival	ent dose (MED) =	85			

Available at http://agencymeddirectors.wa.gov/mobile.html

which is expressed in mcg per hour

Dangerous / Common Combinations

"Holy Trinity" –

Oxycodone, Benzodiazepine, Soma

"Houston Cocktail" –

Norco, Xanax, Soma

• "Sizzurp" –

Promethazine with codeine cough syrup, Jolly Ranchers candy, fruit flavored cola

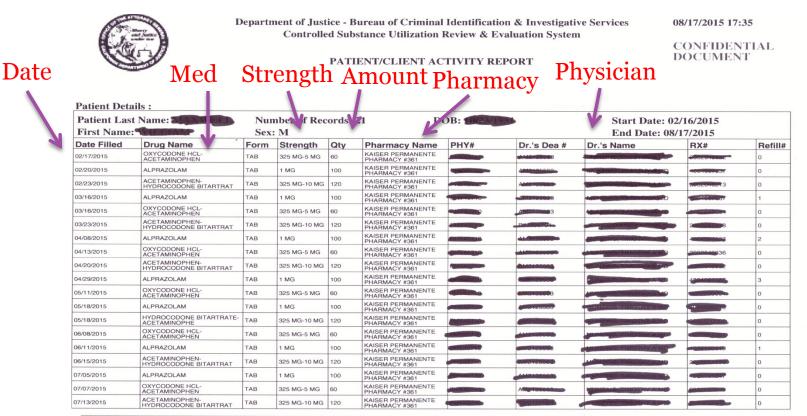
High Dose Opioids

- Dosing > 100 to 120 mg MME per day
 - Overdose increases up to 8-fold
 - Annual overdose risk ~ 2% per year
- Specific informed consent
- Close monitoring UDS, PDMP
- Subspecialty consultation
- Weigh potential benefit / risk ratio

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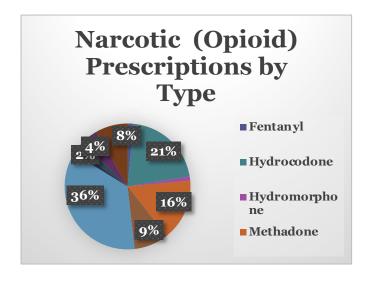
[•] Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study"; Annals of Internal Medicine, Kate Dunn, PhD, et al; January 19, 2010 [MED dosing information / risks]

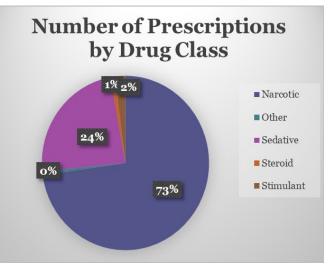
Physician Drug Monitoring Program (PDMP) -CURES in California [Example]

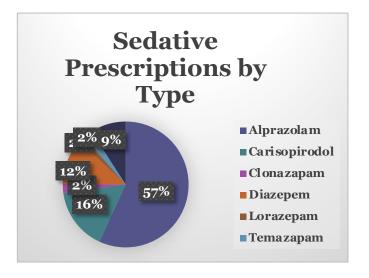


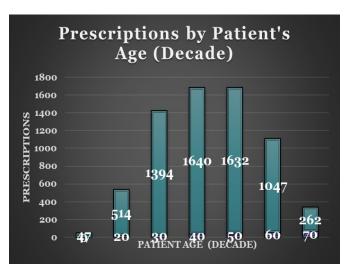
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What is Extracted from Prescription Drug Monitoring Programs (PDMP)









PDMP Analysis: Clues to the Story - Patterns

- Name
- DOB Age (younger?)
- Number of Prescriptions
- MME (mg/day) maximum
- Drug types prescribed; multiple drugs
- Multiple doctors or pharmacies
- Home addresses long distance
- Other suspicious patterns



Medications for Opiate Addiction (Medication Assisted Treatment (MAT)

- Suboxone (buprenorphine-naloxone): FDA approved ONLY for the treatment of opiate addiction, not pain; requires MD waiver to prescribe
- Methadone: If being prescribed for addiction, must come from free- standing methadone clinic only (not outpatient pharmacydispensed)
- Naltrexone: FDA approved for both alcohol and opiate cravings; Comes in daily oral form or every 4-week injectable form
- Nasal naloxone (NARCAN): Prescribe to prevent opioid overdose in high- risk patients; Discuss use with family members and caregivers; pharmacists can prescribe without MD order (standing order in VA and MD) (see pharmacy FAQ document)

Additional Issues and Questions???

- How to deal with early refills?
- Multiple prescribers physician generated?
- Are opioid medications really needed?
- How do I treat an addict in pain?
- Inheriting patients on high dose opioids?
- Do I refill when covering for a colleague?
- When do I refer to pain management?

Key Appropriate Prescribing Elements (Summary)

- Thorough evaluation prior to prescribing, including behavioral/mental health
- Current / past Alcohol & Drug use / abuse
- Opioid Risk Evaluation (Opioid Risk Tool)
- Assessment/Goals as specific as possible
- Individualize treatment Function > Pain Improvement – Multi-modal treatment
- Informed consent
- Start low and go slow up titrate and down titrate
- Trust <u>but verify</u> what your patients say
- Only one opioid at a time if at all possible
- Avoid opioid and benzodiazepine combination
- Long-acting opioids have lower addictive qualities
- Document MED, UDS, PDMP

Improving Patient Safety and Outcomes



References

- Medical Board of California Guidelines for Prescribing Controlled Substances for Pain – 1994, 2003, 2007, and 2014
- "Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain"; Permanente Journal, Timothy Munzing; 2017
- DEA Regulation 21 C.F.R. 1306.04 Purpose of issue of prescription
- "Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study"; Annals of Internal Medicine, Kate Dunn, PhD, et al; January 19, 2010 [MED dosing information / risks]
- "Use of Opioids for the Treatment of Chronic Pain" American Academy of Pain Medicine, <u>http://www.painmed.org/files/use-of-opioids-for-the-</u> <u>treatment-of-chronic-pain.pdf</u>
- Washington State Agency Medical Directors' Group in conjunction with the Interagency Guideline on Opioid Dosing for Non-cancer Pain

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- Drug Enforcement Administration
- Centers for Disease Control Overdose and Overdose death statistics; 2016 and 2022 Prescribing Guidelines
- "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain", American Pain Society – American Academy of Pain Medicine Opioids Guideline Panel – February 2009 – Journal of Pain - <u>http://www.jpain.org/article/S1526-5900(08)00831-6/fulltext</u>
- National Forensic Laboratory Information System (NFLIS) data found at:

http://www.deadiversion.usdoj.gov/mtgs/pharm_awaren ess/conf_2012/sept_2012/houston/drug_trends_1002.pdf

Books

- Dreamland: The True Talk of America's Opiate Epidemic; Author: Sam Quinones
- American Pain: How a Young Felon and His Ring of Doctors Unleashed America's Deadliest Epidemic; Author: John Temple
- Drug Dealer, MD: How Doctors were Duped, Patients Got Hooked, and Why It's So Hard to Stop; Author: Anna Lembke

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Opioid Prescribing Review

- "Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain", The Permanente Journal
- Author Timothy Munzing, MD
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