Safe Opioid Prescribing

A Patient-Centered Approach to the FDA Blueprint

Holy Scoliosis! by Kristen McLaren

Part 3: Topics in Long-Term Opioid Treatment

Wednesday December 8, 2021
6:00 – 7:00 PM

Charles E. Argoff, MD
Albany Medical College

Marc R. Gerber, MD
MRG Rehabilitation & Pain Medicine
University of Central Florida

Bill H. McCarberg, MD
Kaiser Permanente San Diego

Introduction

Charles E. Argoff, MD
Professor of Neurology, Albany Medical College
Vice Chair, Department of Neurology
Director, Comprehensive Pain Center
Director, Pain Management Fellowship
Albany Medical Center
Albany, New York

Program and presenters

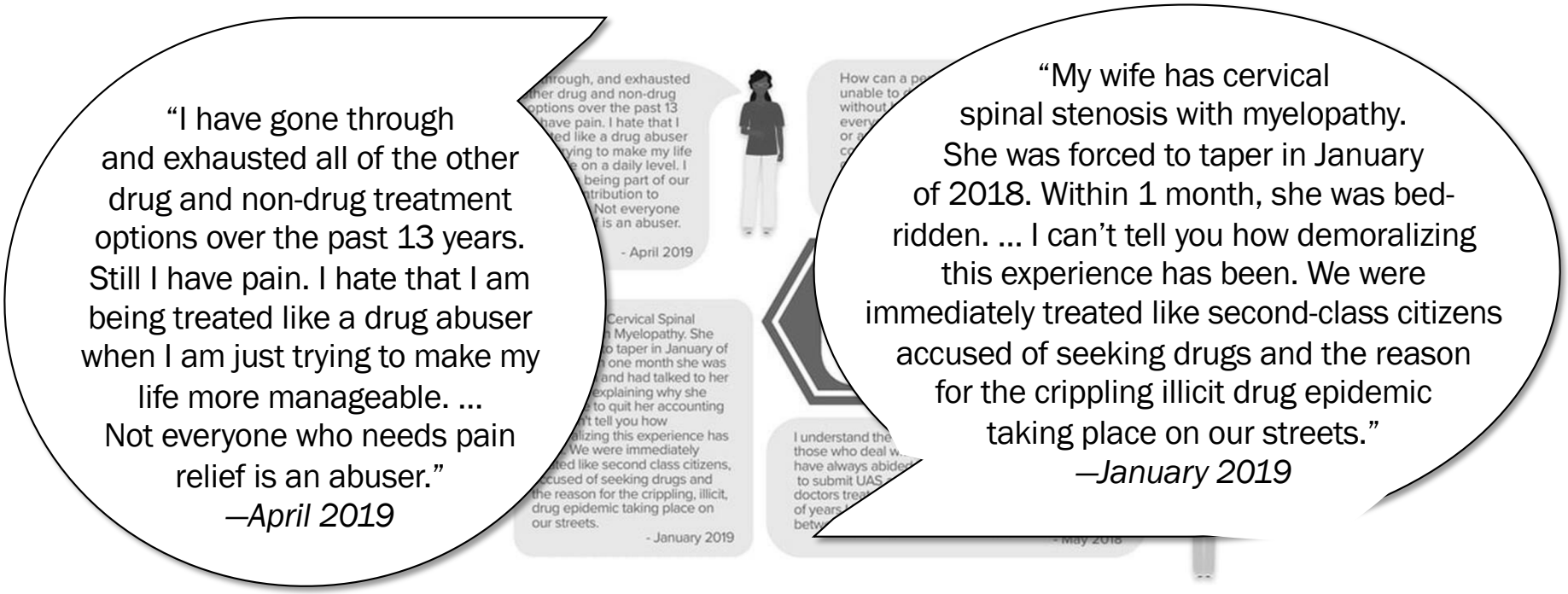
Topic	Presenter	Time
Introduction	Dr. Argoff	5 minutes
	Dr. Gerber	20 minutes
	Dr. McCarberg	20 minutes
Conclusion	Dr. Argoff	5 minutes
Live Q&A	Panel	10 minutes

Disclosures

- Charles E. Argoff, MD: Consulting fees (eg, advisory boards): Amgen, BDSI, Collegium, Grünenthal, Lilly, Lundbeck, Neumentum, RedHill Biopharma, Teva, Vertex; contracted research (principal investigators must provide information, even if received by the institution): AbbVie, Amgen, Lilly, Teva; speakers' bureaus: AbbVie, Amgen, Biohaven, Grünenthal, Lilly, Lundbeck, Red Hill Biopharma, Teva
- Marc R. Gerber, MD: Nothing to disclose
- Bill H. McCarberg, MD, FABM: Consulting fees (eg, advisory boards): Averitas, Lilly, Silex; speakers' bureaus: Adapt, Silex; stock shareholder (individual stocks/stock options, diversified mutual funds do not need to be disclosed): Johnson and Johnson

- **Learning objectives**
  - Review how to safely and effectively manage patients on opioid analgesics, including dose titration, opioid rotation, and taper
  - Specify when referral to a pain specialist is appropriate
  - Identify and manage patients with opioid use disorder
  - List the fundamental elements of addition medicine
  - Discuss how to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal

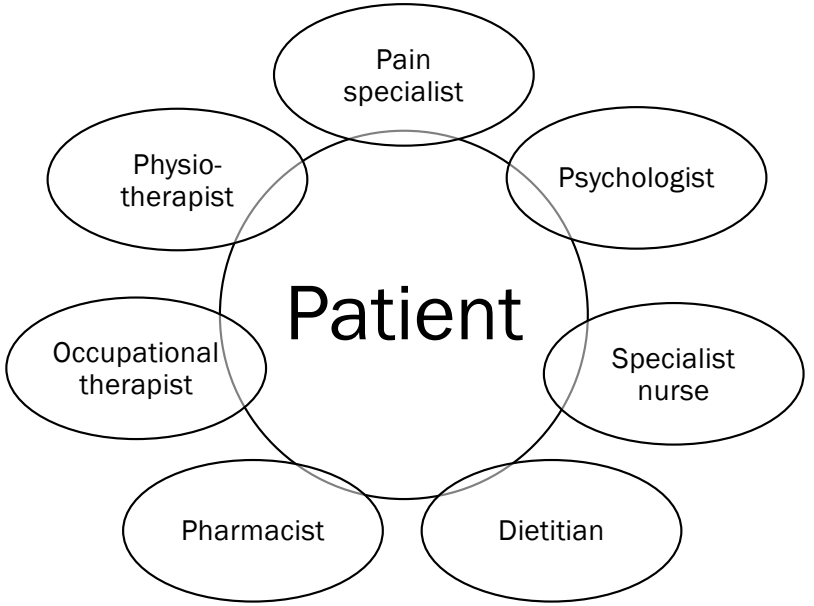
Combating stigma: Real-world examples



US Department of Health and Human Services. www.hhs.gov/sites/default/files/pain-mgmt-best-practices-draft-final-report-05062019.pdf.

Parts 1 and 2 of this activity presented the selection and initiation of opioid therapy

- Chronic pain is optimally treated in a multidisciplinary fashion
  - Patient-focused
  - Evidence-based
  - Art and science
- Opioid medications can play a role in this care in appropriately selected patients
  - Agent selection
  - Dosing, titration, conversion
  - Warnings and precautions, AEs
  - Special populations
- Risk mitigation is an important element
  - Multistep process
  - Ongoing



AE, adverse event.

What does successful opioid therapy look like?

Desired outcomes	
Patient	Provider
• Participates in and contributes to treatment decision-making process • Sufficiently informed about need for, and anticipated benefits and risks of, treatment • Understands treatment decisions • Knows what to do/not to do while on treatment • Confident in ability to minimize risks • Understands need to periodically reassess treatment experience	• Able to elicit information necessary to assess and counsel patients • Confident that patients understand the benefits and risks of treatment, as well as instructions and precautions, and are able to adhere to safe use conditions • Confident that treatment decisions are appropriate for each patient • Able to obtain reliable patient feedback to adjust treatment and counsel as needed

FDA. www.fda.gov/files/about%20fda/published/A-Framework-for-Benefit-Risk-Counseling-to-Patients-About-Drugs-with-a-REMS.pdf.

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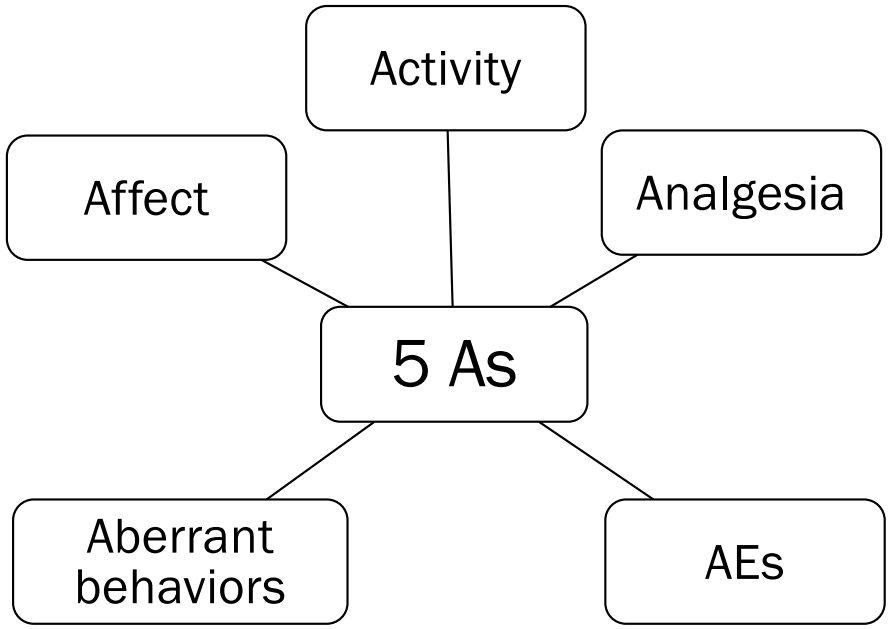
Opioid Titration, Rotation, and Taper

Marc R. Gerber, MD
MRG Rehabilitation & Pain Medicine
Assistant Clinical Professor
University of Central Florida
College of Medicine
Orlando, Florida

Periodic monitoring is important for all patients on long-term opioid therapy

- Recommended frequency: **every 3 months**
- At each visit:
  - Review pain levels and functional goals
    - PEG, BPI, other tools
  - Assess underlying conditions
  - Review AEs
  - Check PDMP, UDT
  - Elicit signs or symptoms of opioid abuse
  - Conduct medication reconciliation
- Tailor therapy and monitoring based on the information learned
- **DOCUMENTATION**



BPI, Brief Pain Inventory; **PDMP,** prescription drug monitoring program; **PEG,** Pain, Enjoyment, General Activity; **UDT,** urine drug testing.

American College of Physicians. www.acponline.org/system/files/documents/about_acp/chapters/ut/17mtg/anisman1.pdf.

Opioid AEs can vary significantly among patients and over time

Analgesic tolerance	Development is variable, occurring at different rates and times
Sedation	Indicator of respiratory depression
Cardiovascular effects	QT prolongation with methadone: ECG monitoring
Constipation	First-line treatment: traditional laxatives; second-line: PAMORAs
Rash/Pruritus	Antihistamines may be necessary
Adrenal insufficiency/ Sexual dysfunction	Androgen-replacement therapy (men)

ECG, electrocardiogram; **PAMORA,** peripherally acting mu-opioid receptor antagonist.

Chou R, et al. *J Pain*. 2014;15(4):321-337. Crockett SD, et al. *Gastroenterology*. 2019;156(1):218-226. Yaksh T, Wallace M. In: Brunton LL, et al, eds. *Goodman & Gilman's: the pharmacological basis of therapeutics*. 13th ed. New York, NY: McGraw-Hill Education; 2018.

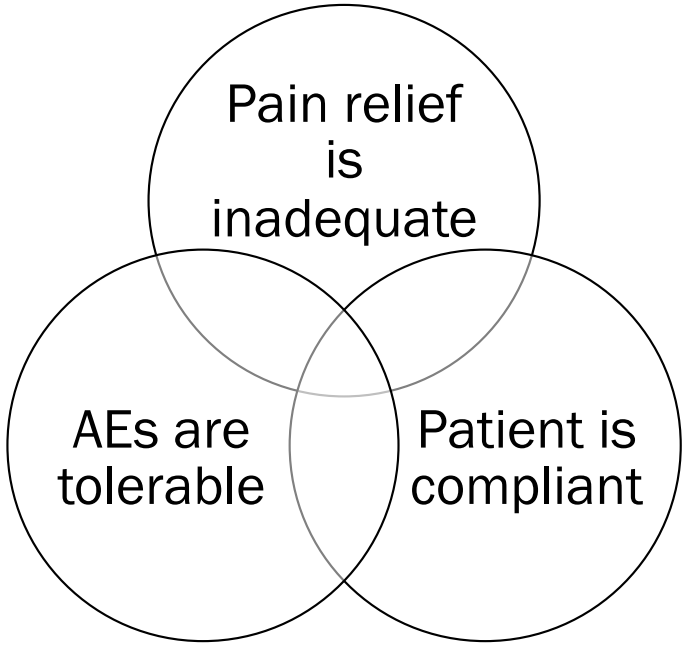
Reporting adverse drug effects

- Why is it important?
  - Ethical and professional obligations to patients and the wider public
  - Not legally obligated
- What should you report?
  - Unexpected side effects or AEs
  - Product quality problems
  - Preventable medication errors
    - Look-alikes/Sound-alikes
    - Device controls/Displays
    - Instructions for use
  - Therapeutic failures

- What are the mechanisms?
  - Medwatch
    - www.fda.gov/Safety/MedWatch
    - 1-800-FDA-1088
  - Contacting the manufacturer
  - Publishing case reports

Klein E, Bourdette D. *Neurol Clin Pract*. 2013;3(4):288-294. FDA. https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.

Opioid titration: When to escalate doses



Brooks A, et al. *Med Clin North Am*. 2016;100(1):81-102. Chou R, et al. *J Pain*. 2009;10:113-130. Centers for Disease Control and Prevention. www.cdc.gov/drugoverdose/training/dosing/.

Opioid titration: Use lowest effective dose, base on ongoing assessment

- Optimal method unknown
  - Titrate slowly to reduce AE risk
  - Assess after 5 half-lives (steady state)
  - Smaller dose increases in patients with organ dysfunction
- Scrutinize carefully
  - Patients with no relief after 1 month are unlikely to achieve relief after 6 months
- May be constrained by formulation/dose

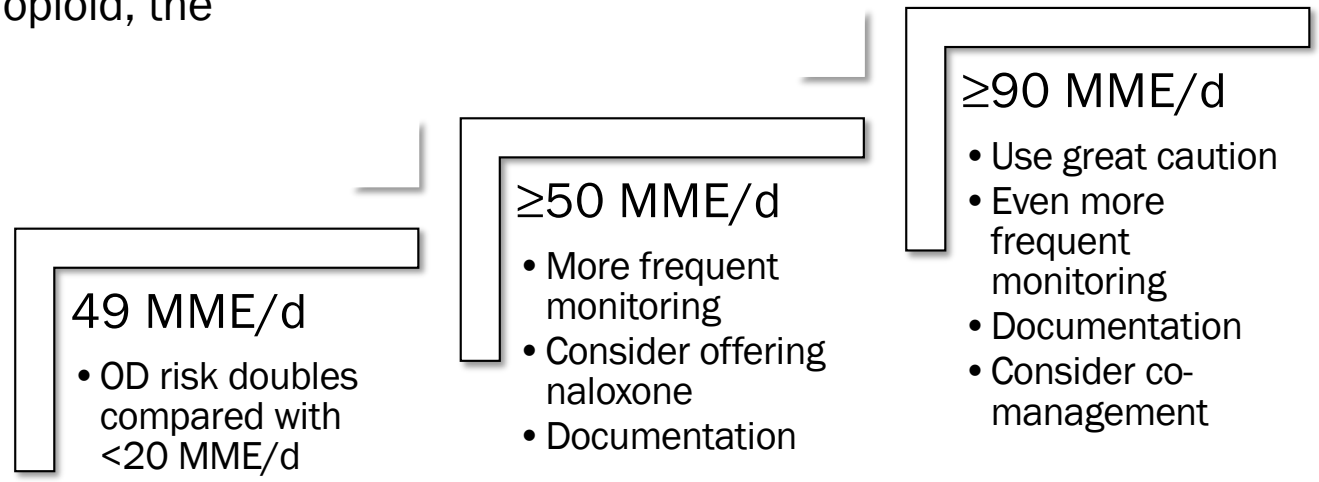
- Unresolved pain
  - Use clinical judgment
  - Generally, ↑ TDD by 25%-50%
- Exclusions
  - Multicomponent products
  - Methadone
  - TD fentanyl/buprenorphine

TD, transdermal; **TDD,** total daily dose.

Brooks A, et al. *Med Clin North Am*. 2016;100(1):81-102. Chou R, et al. *J Pain*. 2009;10:113-130. Centers for Disease Control and Prevention. www.cdc.gov/drugoverdose/training/dosing. McPherson ML. *Demystifying opioid conversion calculations: a guide for effective dosing*. Bethesda, MD: American Society of Health-System Pharmacists; 2018.

Dose matters

- The higher the dose of opioid, the greater the risk for AEs

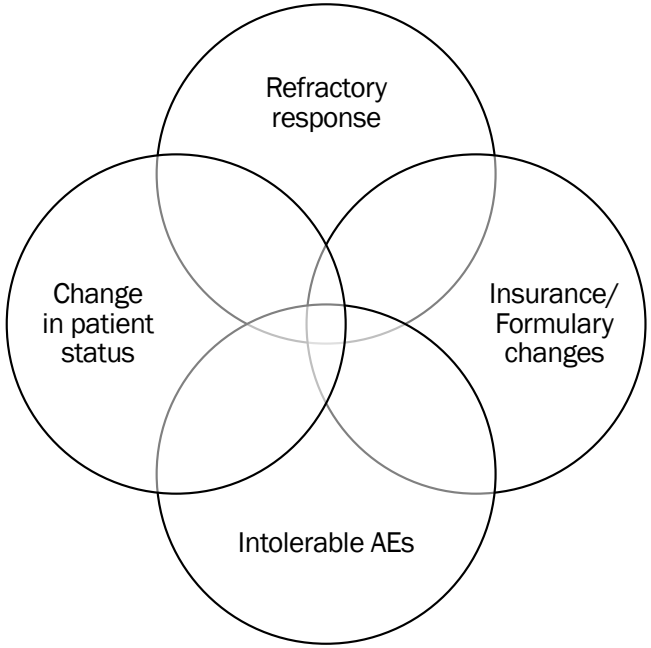


MME, morphine milligram equivalent; **OD,** overdose.

Centers for Disease Control and Prevention. www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf.

Rotating opioids can be necessary and helpful under certain conditions

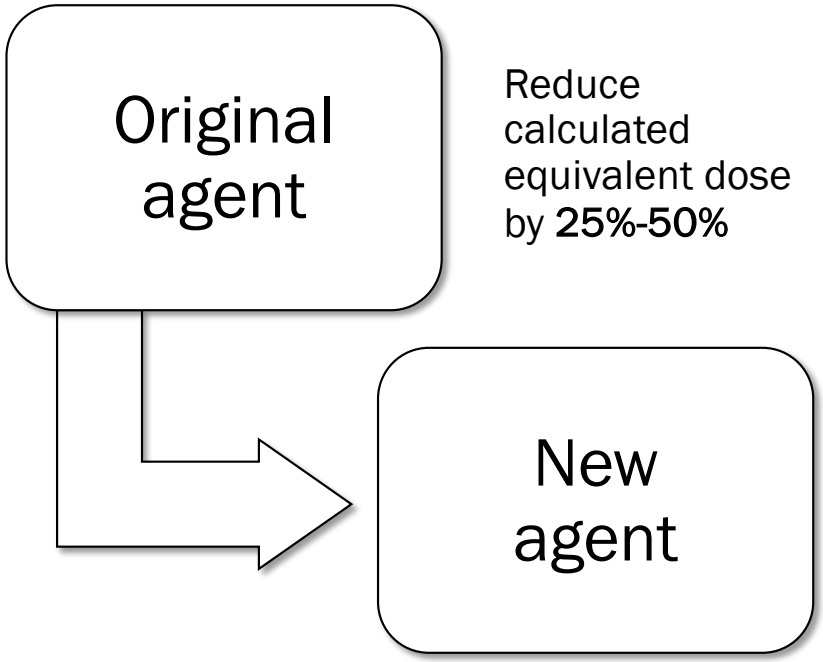
- Requires dosing conversion
  - Complicated
  - Inconsistent from one patient to the next
- Issues
  - Incomplete cross-tolerance
  - Relative potency
  - Equianalgesic dosing tables can be problematic



McPherson ML. *Demystifying opioid conversion calculations: a guide for effective dosing*. Bethesda, MD: American Society of Health-System Pharmacists; 2018.

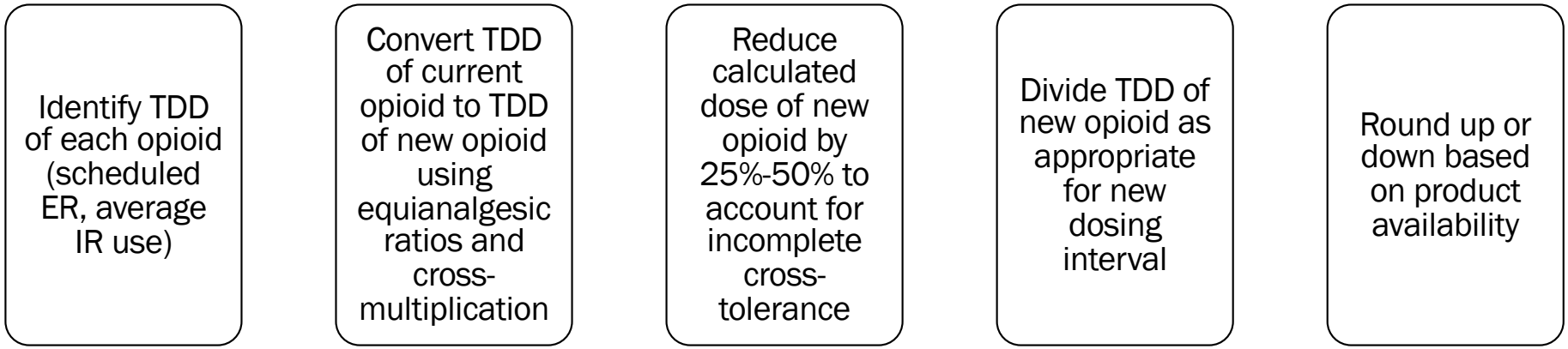
Incomplete cross-tolerance to AEs

- Development of tolerance to one agent does not guarantee the same level of tolerance to another
  - Differences between opioids in affinity for receptor subtypes
  - Interpatient pharmacokinetic/ pharmacodynamic variability
- Caution is warranted
- Methadone conversion factors increase as doses increase
- To calculate actual TDD, check PDMP, not just heath records



Koyyalagunta D, Waldman SD. In: Waldman SD, ed. *Opioid analgesics*. 2nd ed. Philadelphia, PA: Elsevier; 2011;890-912.
McPherson ML. *Demystifying opioid conversion calculations: a guide for effective dosing.* Bethesda, MD: American Society of Health-System Pharmacists; 2018.

Stages of opioid conversion



ER, extended-release; **IR,** immediate-release.

McPherson ML. *Demystifying opioid conversion calculations: a guide for effective dosing*. Bethesda, MD: American Society of Health-System Pharmacists; 2018.

Opioid dose conversion table from AAFP

Calculating MME[a]			
Opioid	Conversion factor, MMEs	Duration, h	Dose equivalent morphine sulfate
Codeine	0.15	4-6	200 mg
Fentanyl (mcg/h)	2.4	--	12.5 mcg/h[b]
Hydrocodone	1	3-6	30 mg
Hydromorphone	4	4-5	7.5 mg
Morphine	1	3-6	30 mg
Oxycodone	1.5	4-6	20 mg
Oxymorphone	3	3-6	10 mg
Methadone	4	--	
	8	--	7.5 mg
	10	--	3.75 mg
	12	--	3 mg

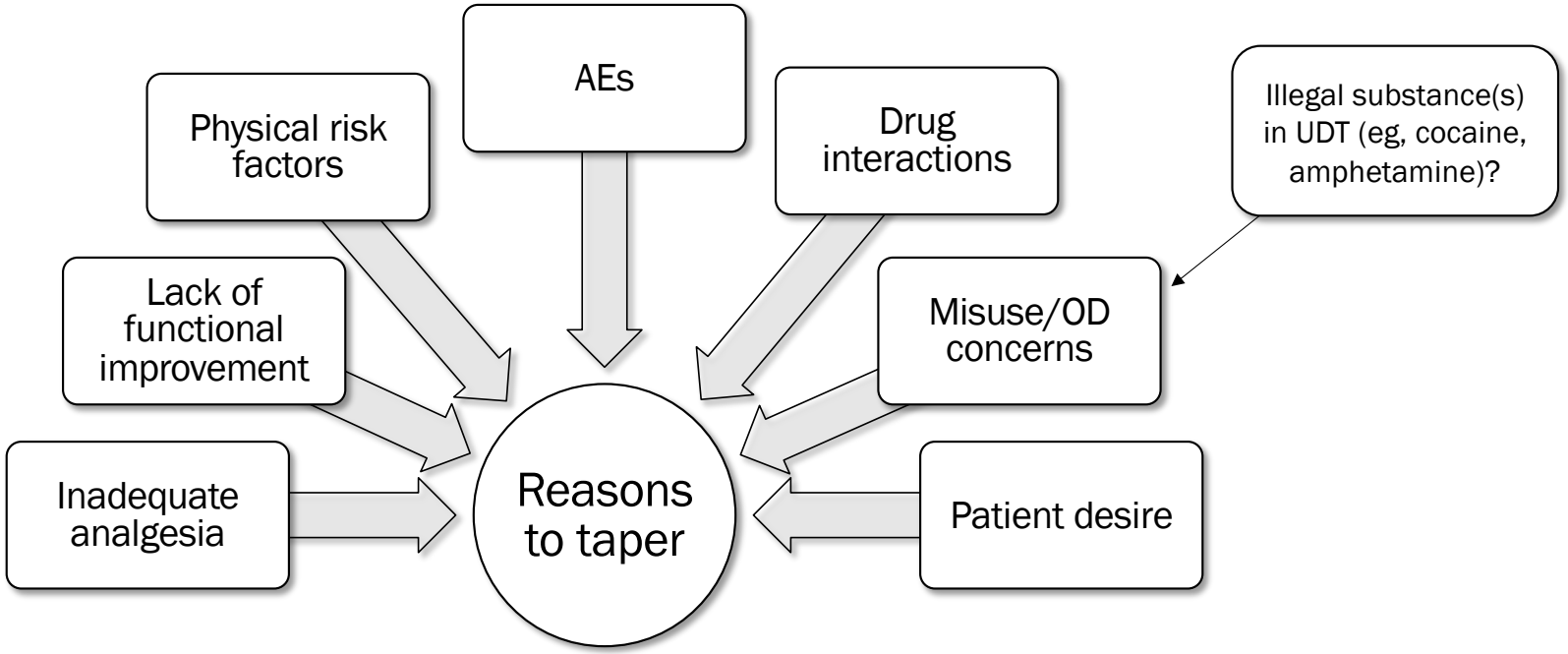
- Sample chronic pain case: 45-year-old man taking oxymorphone 10 mg 4 times daily; transitioning to ER oxycodone
  1. Oxymorphone TDD = 40 mg/d
  2. Convert to MME, using oxymorphone conversion factor of 3 = 120 MME
  3. Determine MME of oxycodone, using conversion factor of 1.5 = 80
  4. Decrease dose by 25% = 60
  5. Divide by interval of 12 h = 30
- Starting dose of ER oxycodone for this patient = 30 mg q12h

AAFP, American Academy of Family Physicians.

[a]Dose conversions are estimates; cannot account for individual patient genetics and pharmacokinetics.
[b]Fentanyl is dosed in mcg/h instead of mg/d; absorption is affected by heat and other factors.

www.aafp.org/dam/AAFP/documents/patient_care/pain_management/conversion-table.pdf.

If harms outweigh benefits, medically directed opioid tapering may be necessary

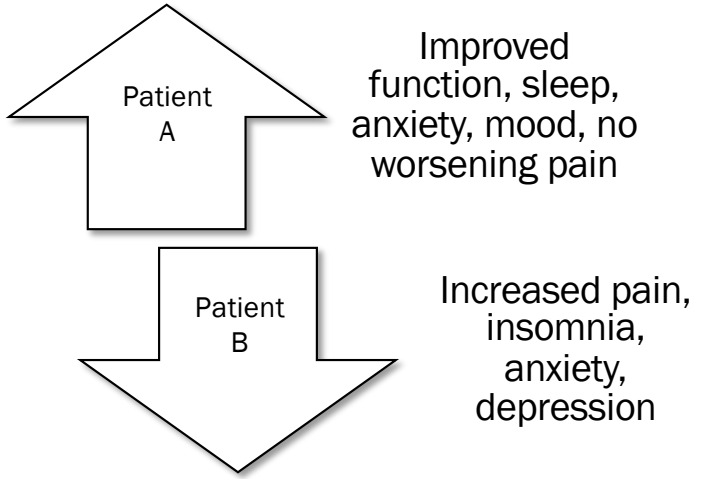


Lembke A. *Am Fam Physician*. 2020;101(1):49-52. Mendoza M, Russell HA. *J Fam Pract*. 2019;68(6):324-331. US Department of Health and Human Services. www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.

Considerations and cautions for opioid taper

- Opioids should not be tapered rapidly or discontinued suddenly
  - Risk for significant, acute withdrawal symptoms, exacerbation of pain, serious psychological distress, suicidality
  - Particularly in patients who have developed physical dependence or are taking high doses
  - Particular risks during pregnancy
  - Patients may seek other, potentially illicit, sources opioids to treat pain and/or withdrawal symptoms

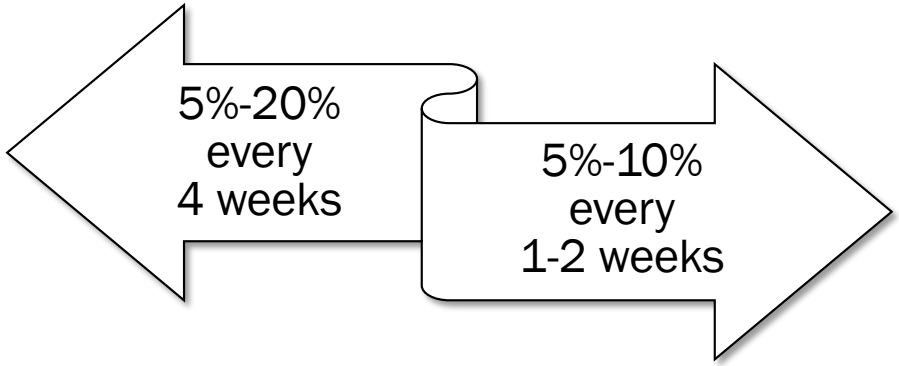
- Response to taper can be unpredictable



US Department of Health and Human Services. www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.

Strategies for opioid taper

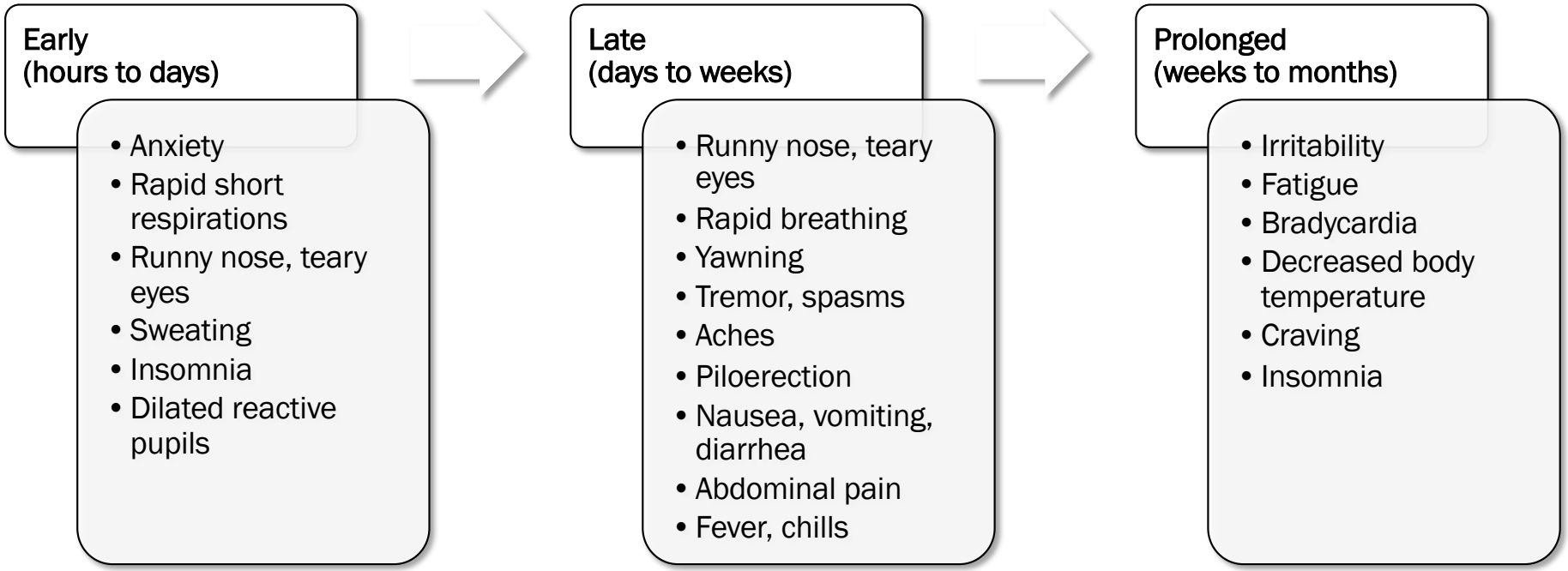
- Individualize; no single optimal regimen
  - Consider maintaining frequency but at lower doses, as patients may be accustomed to receiving opioids at specific times of day
- Collaborative approach may be beneficial
  - Patient engagement in decisions
  - Multiple coordinated providers, modalities
- Patience during taper is essential
  - Tapers may need to be slowed or even paused and restarted at a later date
- Manage withdrawal symptoms
- Avoid dismissing patients from care
- Advise patients of rapid loss of tolerance



Range of recommended opioid dose decreases

Lembke A. *Am Fam Physician*. 2020;101(1):49-52. Mendoza M, Russell HA. *J Fam Pract*. 2019;68(6):324-331. US Department of Health and Human Services. www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.

Symptoms of opioid withdrawal



Mendoza M, Russell HA. *J Fam Pract*. 2019;68(6):324-331. US Department of Health and Human Services. www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf; US Department of Veterans Affairs. www.pbm.va.gov/AcademicDetailingService/Documents/Pain_Opioid_Taper_Tool_IB_10_939_P96820.pdf.

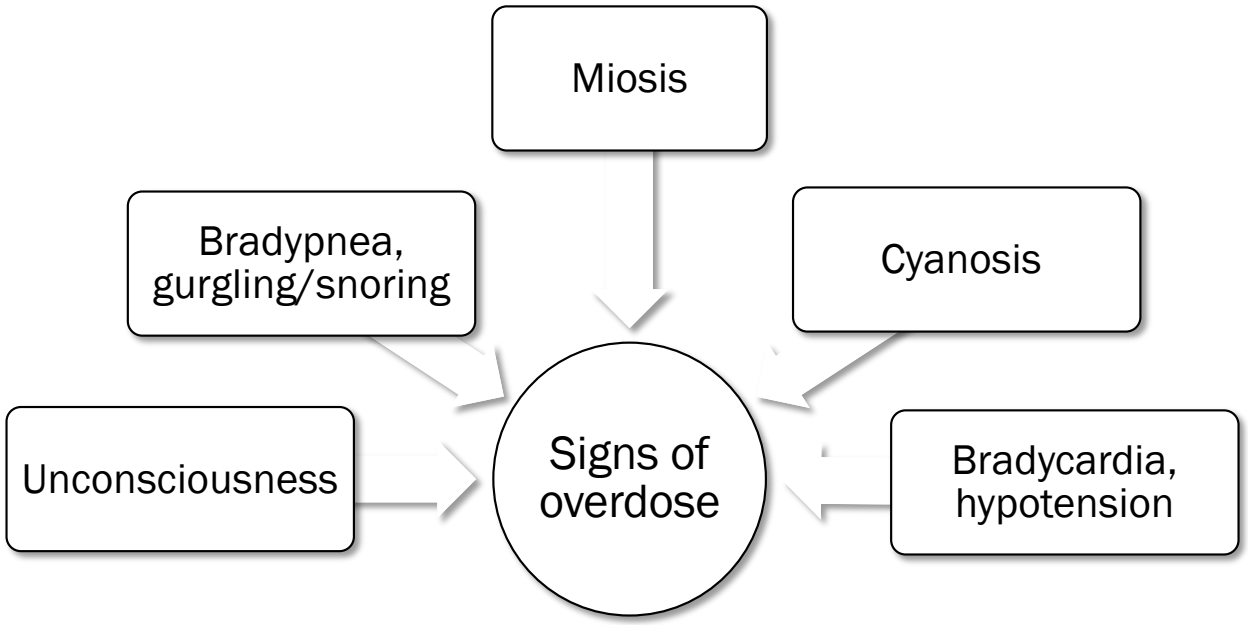
Reducing opioid withdrawal symptoms

Symptom	Treatment options
Autonomic symptoms: sweating, tachycardia, myoclonus	First-line: clonidine Alternatives: baclofen, gabapentin, tizanidine
Anxiety, dysphoria, lacrimation, rhinorrhea	Hydroxyzine, diphenhydramine
Myalgias	NSAIDs, acetaminophen, topical analgesics
Sleep disturbances	Trazodone
Nausea	Prochlorperazine, promethazine, ondansetron
Abdominal cramping	Dicyclomine
Diarrhea	Loperamide, bismuth subsalicylate
“Opioid withdrawal symptoms”	Lofexidine

NSAID, nonsteroidal anti-inflammatory drug.

US Department of Veterans Affairs.
www.pbm.va.gov/AcademicDetailingService/Documents/Pain_Opioid_Taper_Tool_IB_10_939_P96820.pdf.

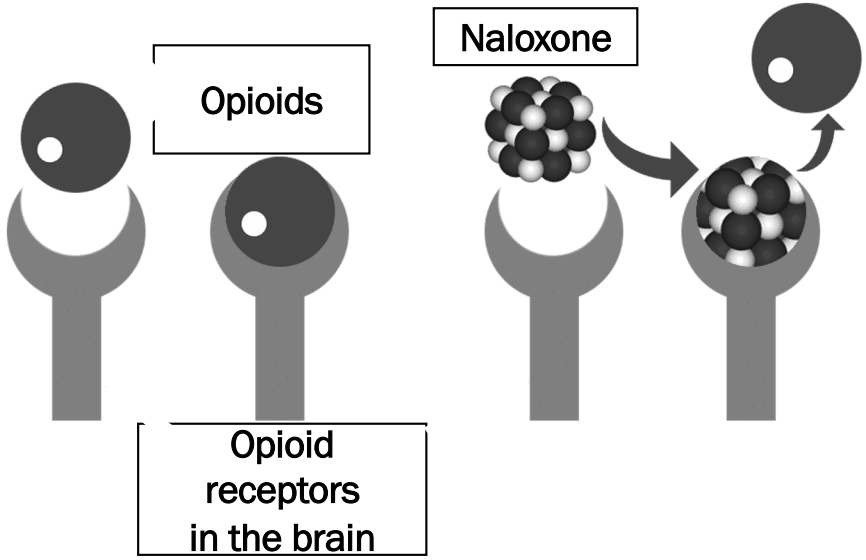
Signs of opioid overdose



SAMHSA. https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742.
Schiller, EY et al. Opioid overdose. 2021 update. https:// www.ncbi.nlm.nih.gov/books/NBK470415.

Naloxone can be used for OD reversal and taper

- Opioid mu receptor antagonist[1]
  - Has stronger affinity to receptor than opioid drugs themselves
  - Blocks and reverses opioid effects
  - Historically used to reverse opioid-induced respiratory depression during surgery
- 2 FDA-approved formulations[1]
  - Prepackaged nasal spray (can be given by bystanders)
  - Injectable device for IV, intramuscular, or subcutaneous delivery (only professionals can administer)
- May need multiple doses of naloxone to counteract powerful opioids like fentanyl[2]



1. Schiller EY, et al. *Opioid overdose*. 2021 update. https:// www.ncbi.nlm.nih.gov/books/NBK470415.
2. Comer S, et al. *Neurosci Biobehav Res*. 2019;109:49-57.

When and how to consult with a pain specialist

- Patients unable to achieve adequate pain management
- Patients at high risk for OUD
- Prior OD
- If provider is uncomfortable with the patient, including aberrant behavior
- Comanagement depends on the practice setting
  - Patient could be stabilized by the specialist then returned to primary care
  - Patient could see the specialist on every other visit
  - In rural areas, consultation and comanagement by telehealth

OUD, opioid use disorder.

Opioid Use Disorder, Addiction, and Patient Counseling: Sending the Right Messages

Bill H. McCarberg, MD, FABM
Kaiser Permanente San Diego
(retired)
Adjunct Assistant Clinical Professor
University of California
San Diego, California

Key definitions

Physical dependence

- Occurrence of withdrawal symptoms with discontinuation of substance use
- Body is adjusting its normal functioning around regular opioid use

Tolerance

- Reduced effect of a drug after repeated use
- Applies to desired effects and AEs; highly variable

Misuse

- Use of a prescribed substance in a manner other than as directed by a provider

Addiction (more on this later)

- Chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences
- Compulsive use of substances
- Continued use despite harmful consequences
  - When referring to opioids, preferred term is ***opioid use disorder***
  - When referring to other substances (eg, alcohol), preferred term is ***substance abuse disorder***

More simply, a chronic, relapsing disorder characterized by compulsive drug seeking and use despite adverse consequences

American Society of Addiction Medicine. www.asam.org/Quality-Science/definition-of-addiction.
Centers for Disease Control and Prevention. www.cdc.gov/drugoverdose/opioids/terms.html.

Be aware of red flags for OUD

- Patient requests early refill due to lost or stolen pills
- Concurrent use of multiple pharmacies
- Concurrent prescriptions from ≥1 physician (doctor shopping)
- Use of drug culture street language
- Failure to improve but no desire to change management plan
- Drug overdose

Advice from pain specialist about handling an OUD patient case

"You can be sympathetic in your approach with her, but be firm. You can no longer prescribe opioid medication for her because you feel that she likely has an addiction problem, and that her health and safety is at risk if you keep prescribing."[3]

1. Munzing M, et al. *Perm J.* 2017;21:16-169. **2.** Mendoza M, et al. *J Fam Pract*. 2019;68(6):324-331.
3. Liddy C, et al. *J Am Board Fam Med*. 2017;30(6):766-774.

Diagnostic criteria for OUD

- **Mild:** 2-3 criteria
- **Moderate:** 4-5 criteria
- **Severe:** ≥6 criteria

- Opioids taken in larger amounts or over longer period than intended
- Persistent desire or unsuccessful efforts to reduce or control usage
- Great deal of time spent obtaining, using, or recovering from opioids
- Craving or strong desire to use opioids
- Recurrent use causing a failure to fulfill major obligations at work, school, or home
- Continued use despite persistent or recurrent social or interpersonal problems associated with opioid effects
- Important activities given up or reduced due to use
- Recurrent use in physically hazardous situations
- Continued use despite knowledge of persistent or recurrent physical or psychological problems likely caused or exacerbated by the substance
- Tolerance
- Withdrawal

} Only in individuals taking opioids outside appropriate medical supervision

American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013.

Treatment for OUD

Nonmedication treatment	MAT	Benefits

• Also called abstinence-based treatment
• Typically consists of multiple psychosocial services
• Considered inferior to MAT for most patients
• Not a suggested first-line option
	• Used in conjunction with counseling and behavioral therapies
	• Often underutilized, underdosed, or not administered for an appropriate duration
	• Agent selection, setting are patient-specific
	• Methadone, naltrexone, buprenorphine approved
		• Reduction in:
		  • Risk for relapse, OD
		  • Infectious disease transmission
		  • Illicit drug use
		• Longer treatment increases likelihood of continued abstinence

MAT, medication-assisted treatment.

Crowley R, et al. *Ann Intern Med*. 2017;166(10):733-736. Substance Abuse and Mental Health Services Administration. www.ncbi.nlm.nih.gov/books/NBK535268/. Volkow ND, et al. *JAMA Psychiatry*. 2019;76(2):208-216. Saxon AJ, et al. Approach to treating opioid use disorder. www.uptodate.com.

MAT in OUD is highly patient-specific

	Methadone	Buprenorphine	Naltrexone
Dispensing restrictions	• SAMHSA-certified treatment programs only, for OUD • *Legal to prescribe for pain without special license*	Prescribers with Drug Abuse Treatment Act 2000 waiver	No license or waiver required
Addiction potential	Compared with heroin or fentanyl, mu opioid receptor binding is slower and of longer duration	Binding to mu opioid receptor is slow and acts as a partial agonist, so less reward stimulating	Inhibits binding of opioids
Selected AEs	QT prolongation, constipation, drowsiness, death from OD	Constipation, headache, elevated transaminases	Nausea (often resolves after a few days), hepatotoxicity (rare), injection-site reactions

SAMHSA, Substance Abuse and Mental Health Services Administration.

Kampman K, et al. *J Addict Med*. 2015;9(5):358-367. Substance Abuse and Mental Health Services Administration. www.ncbi.nlm.nih.gov/books/NBK535268/.

A difficult clinical question: Are these patients using their opioid medications properly?

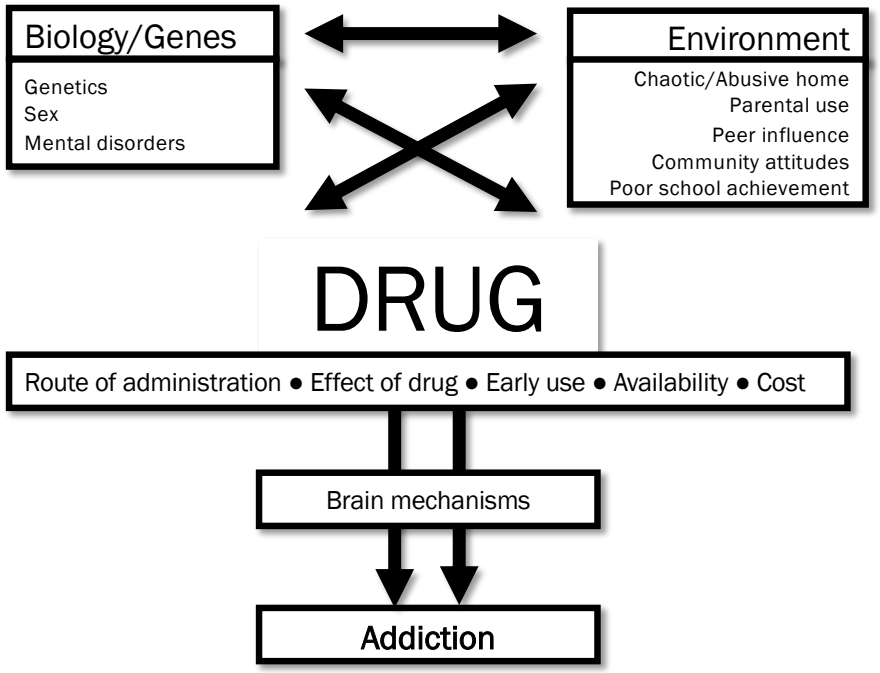
- Has been doing well but now running out of opioids early
- UDT shows no opioid in the urine
- UDT shows an opioid but not the prescribed opioid
- Spouse or friend reports that the patient takes all the medication in the first 2 weeks and goes without for the rest of the 30-day prescription
- Spouse or friend reports that the patient is overly sleepy and not attending work or school regularly

If you think a patient is "getting in trouble" with their opioid medication:

- Bring the patient in
- Ask how they are doing with the treatment
- Review the rules
- Determine whether more intervention, including opioid taper, is warranted

When OUD worsens

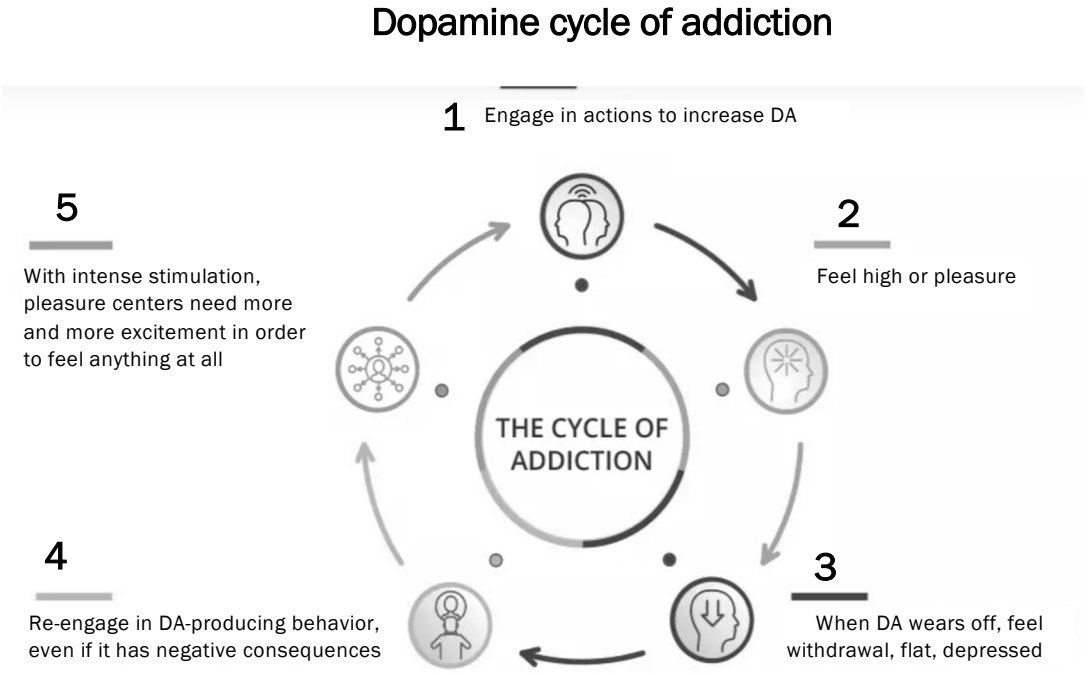
- Biological factors account for ~50% of addiction risk
  - Genes influence biological response to substances of abuse or their metabolism
  - Environmental factors affect gene expression (epigenetics)
  - Teens are at greater risk
- Environmental factors
  - Exposure to home use of drugs by family
  - Peer/Community pressure
- Psychological traits
  - Impulsivity
  - Novelty and sensation seeking
  - Stress reactivity
- **Untreated mental health issues**



National Institute on Drug Abuse. www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-misuse-addiction. Volkow ND, et al. *Am J Psych*. 2018;175:729-740.

Opioids and the dopamine cycle of addiction

- MORs are concentrated in brain regions that control pain and reward[1,2]
  - Nucleus accumbens, PFC, amygdala
  - Also located in the brainstem (respiration) and gut (constipation)
- Stimulation of MORs in the VTA causes DA production[2,3]
  - Creates feelings of pleasure, euphoria
  - Reinforces repetition of pleasurable activities
- Eventual decrease in DA binding correlates with increased impulsivity, and impaired self-control[4]

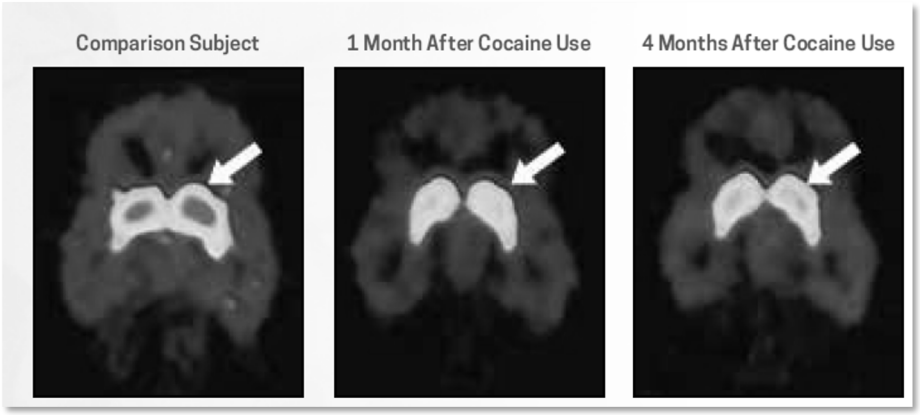


DA, dopamine; **MOR,** mu opioid receptor; **PFC,** prefrontal cortex; **VTA,** ventral trigeminal area.

1. Volkow N, et al. *Mol Psychiatry*. 2021;26(1):218-233. **2.** NIH. https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/soa.pdf.
3. Le Merrer, et al. *J Physiol Rev*. 2009;89(4):1379-1412. **4.** Trifilieff P, Martinez D. *Neuropharmacology*. 2014;76:498-509.

Addiction changes the structure of the brain

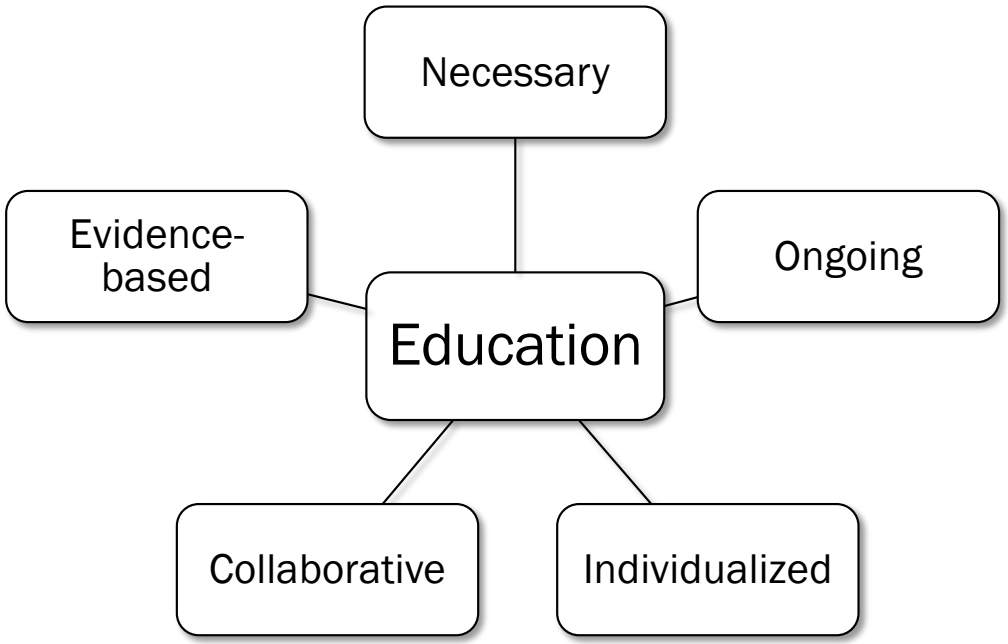
- Comparing functional MRI brain images
  - (**A**) An individual with no history of cocaine use
  - (**B**) and (**C**) Individuals with history of cocaine use disorder
- Lower levels of D_2 DA receptors (in red) even after stopping cocaine use for 1 month and 4 months
- After 4 months of abstinence, D_2 receptors start to recover but have not been restored to normal levels



MRI, magnetic resonance imaging.

NIH. https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/soa.pdf.

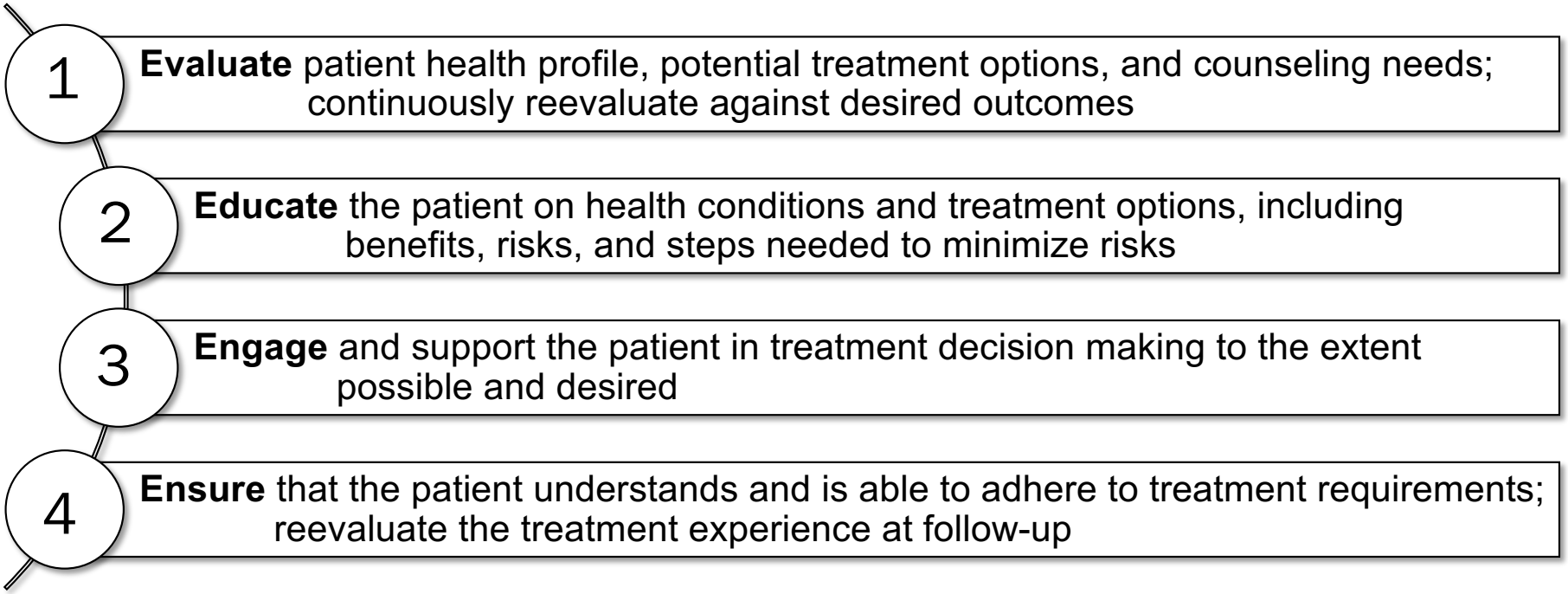
Characteristics of effective patient education around opioid management



- Avoids stigmatizing or blaming language
- Acknowledges that addiction is a disease
- Includes goal-setting
  - Reasonable
  - Incremental
  - Attainable

FDA. www.fda.gov/files/about%20fda/published/A-Framework-for-Benefit-Risk-Counseling-to-Patients-About-Drugs-with-a-REMS.pdf.

The 4 E's can help guide patient counseling

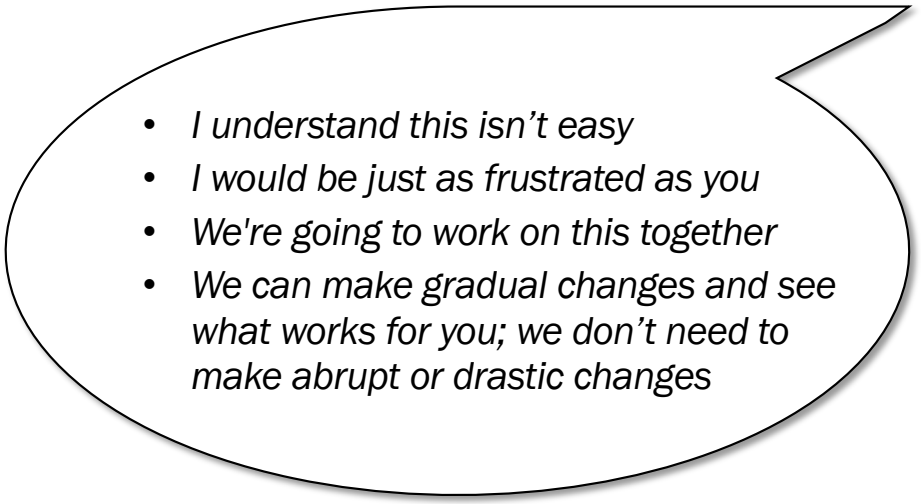


FDA. www.fda.gov/files/about%20fda/published/A-Framework-for-Benefit-Risk-Counseling-to-Patients-About-Drugs-with-a-REMS.pdf.

Patient communication principles

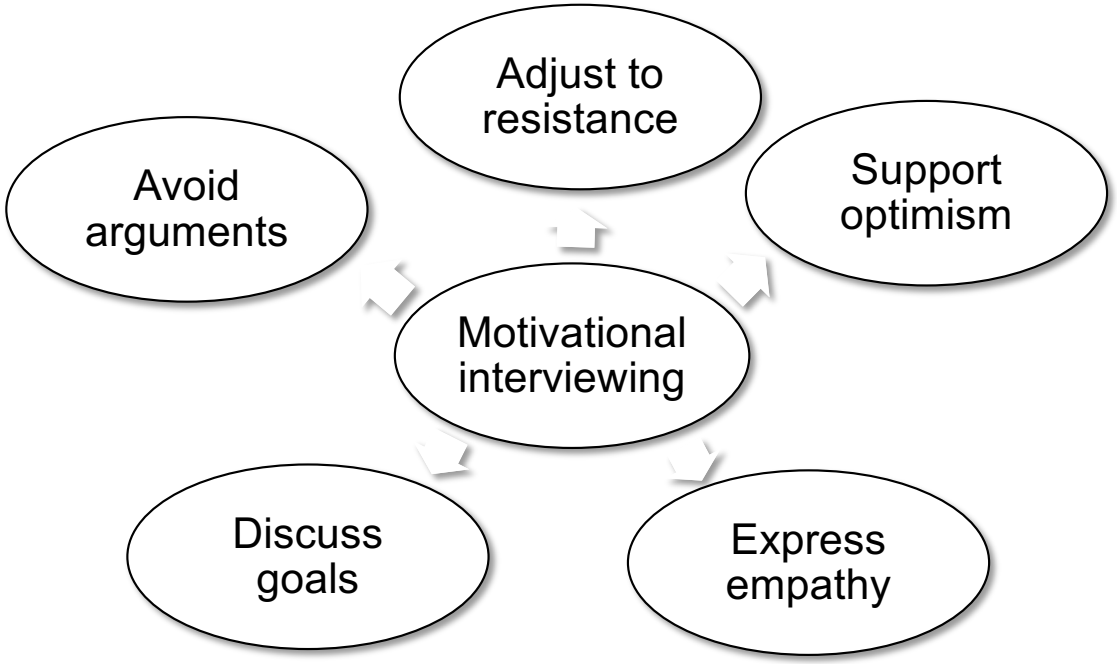
- Take time to listen reflectively
  - Demonstrate interest in collaborating to find a safe, effective solution
  - Frequently relay information back to the patient in their own words to confirm understanding
  - Allow time to correct misunderstandings and answer questions
- Recognize each patient's uniqueness
  - Address the patient by name
  - Consider culture, experience, and social influences
- Show empathy

- Consider nonverbal communication
  - Eye contact, body posture
  - Appropriate, caring facial expressions
  - Caring tone and pace



CDC. www.cdc.gov/drugoverdose/training/communicating/accessible/training.html.

Motivational interviewing



CDC. www.cdc.gov/drugoverdose/training/communicating/accessible/training.html.

Addressing conflict

- Understand patient concerns and expectations
- Validate concerns and emotions
- Reassure with positive information
- Explain recommendations
- Negotiate alternatives to meet goals
- Explore residual concerns

CDC. www.cdc.gov/drugoverdose/training/communicating/accessible/training.html.

Patient counseling topics: Key issues

What are opioids?

- Strong prescription medicines used to manage severe pain

What are the serious risks of using opioids?

- Addiction and OD
- Respiratory depression and death

What are the risk factors for opioid abuse?

- Personal or family history of addiction
- Concurrent use of medications for mental health issues
- Age ≤65 years

Risk evaluation tools will be used at initiation and throughout treatment with opioids

Opioid Analgesic REMS. https://opioidanalgesicrems.com/RpcUI/rems/pdf/resources/patient_counseling_document.pdf.

Patient counseling topics: Addiction

What is addiction?

- Taking/Craving drugs to feel high
- Persistent use despite awareness of harm
- Brain disease that may require ongoing treatment
- More common with with longer duration of treatment
- If patients suspect they are addicted, they should contact their provider immediately

Addiction can occur even if patients take opioids exactly as prescribed

What is physical dependence?

- Normal bodily adaptation to opioid medication
- Leads to need for slow taper to avoid withdrawal symptoms

Opioid Analgesic REMS. https://opioidanalgesicrems.com/RpcUI/rems/pdf/resources/patient_counseling_document.pdf.

Patient counseling topics: Safe use

How do I take opioids safely?

- Do not cut, break, chew, crush, or dissolve oral formulations
- Do not cut, tear, or damage TD formulations
- Take exactly as prescribed by your provider
- Do not increase dose for uncontrolled pain; contact your provider
- Do not share or give to anyone else
- Do not operate heavy machinery until you know how opioids affect you

Discuss ALL medicines, including vitamins, supplements, and OTC products

Driving

- Opioids can slow reaction time, cause drowsiness, or cloud judgment
- Permitted in patients in stable dose for ≥1 week without cognitive changes

Work safety

- Impaired employees can pose a safety hazard
- Employers have a role in managing risk
- Job-based regulations vary by state

OTC, over-the-counter.

Opioid Analgesic REMS. https://opioidanalgesicrems.com/RpcUI/rems/pdf/resources/patient_counseling_document.pdf. National Safety Council. www.nsc.org/Portals/0/Documents/RxDrugOverdoseDocuments/RxKit/2019/Opioids-in-the-Workplace.pdf?ver=2019-03-27-161805-350. Schisler RE, et al. *J Palliat Med*. 2012;15(4):484-485.

Patient counseling topics: Storage and disposal

Storage

- Keep opioids secured in a home safe or locked container or drawer
- Keep out of reach of family members, especially teens, and household visitors
- Keep track of the amount of medication you should have

Disposal

- Community drug take-back program
- DEA-authorized collection site/drop-box; find one: 1-800-882-9539
- Pharmacy mail-back program
- Flush down toilet
- TD fentanyl: fold in half with sticky sides together and flush

Deaths due to accidental exposure have been reported, particularly in children

DEA, Drug Enforcement Agency.

Opioid Analgesic REMS. https://opioidanalgesicrems.com/RpcUI/rems/pdf/resources/patient_counseling_document.pdf. CDC. www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf. FDA. www.fda.gov/consumers/consumer-updates/fentanyl-patch-can-be-deadly-children.

Steps for medication disposal at home

- >70% of people using opioid analgesics for nonmedical reasons get them from family or friends

MIX

- Mix medicines (do not crush tablets or capsules) with an unpalatable substance, such as dirt, cat litter, or used coffee grounds

PLACE

- Place the mixture in a container such as a sealed plastic bag

THROW

- Throw the container in your household trash

SCRATCH

- Scratch out personal information on the label of your empty pill bottle or packaging to make it unreadable, then dispose of the container

American Academy of Family Physicians. www.ama-assn.org/opioids-disposal.

Patient counseling topics: What to avoid or use?

Avoid: alcohol and certain medications

- Alcohol
- Benzodiazepines
- Muscle relaxants
- Sleep medications
- Other prescription opioids
- Medications prescribed to other people

What is your approach to treating patients prescribed cannabinoids?

Use: other pain-management modalities

- Nonpharmacologic therapies:
  - Physical therapy, exercise, rest
  - Acupuncture
  - Self-help techniques
  - Behavioral therapy
- Nonopioid analgesics: acetaminophen, NSAIDs, adjuvant analgesics

Opioid Analgesic REMS. https://opioidanalgesicrems.com/RpcUI/rems/pdf/resources/patient_counseling_document.pdf. CDC. www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf. FDA. www.fda.gov/consumers/consumer-updates/fentanyl-patch-can-be-deadly-children.

Patient counseling topics: Naloxone

What is naloxone?

- Medicine for the management of known or suspected opioid OD
- Sprayed inside the nose or injected into the body to reverse opioid effects
- Give if a patient taking opioids is having trouble breathing; is short of breath or unusually sleepy; or if a child has accidentally taken an opioid
- Always call 911 or seek emergency care when using naloxone

Availability

- Products for home use are available in pharmacies
- Some states may not require a prescription
- Tell your family about your naloxone and store it in a place where you or your family can retrieve it in an emergency

Naloxone is safe if given to someone who has *not* taken an opioid—even a child

Opioid Analgesic REMS. https://opioidanalgesicrems.com/RpcUI/rems/pdf/resources/patient_counseling_document.pdf.
CDC. www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf.

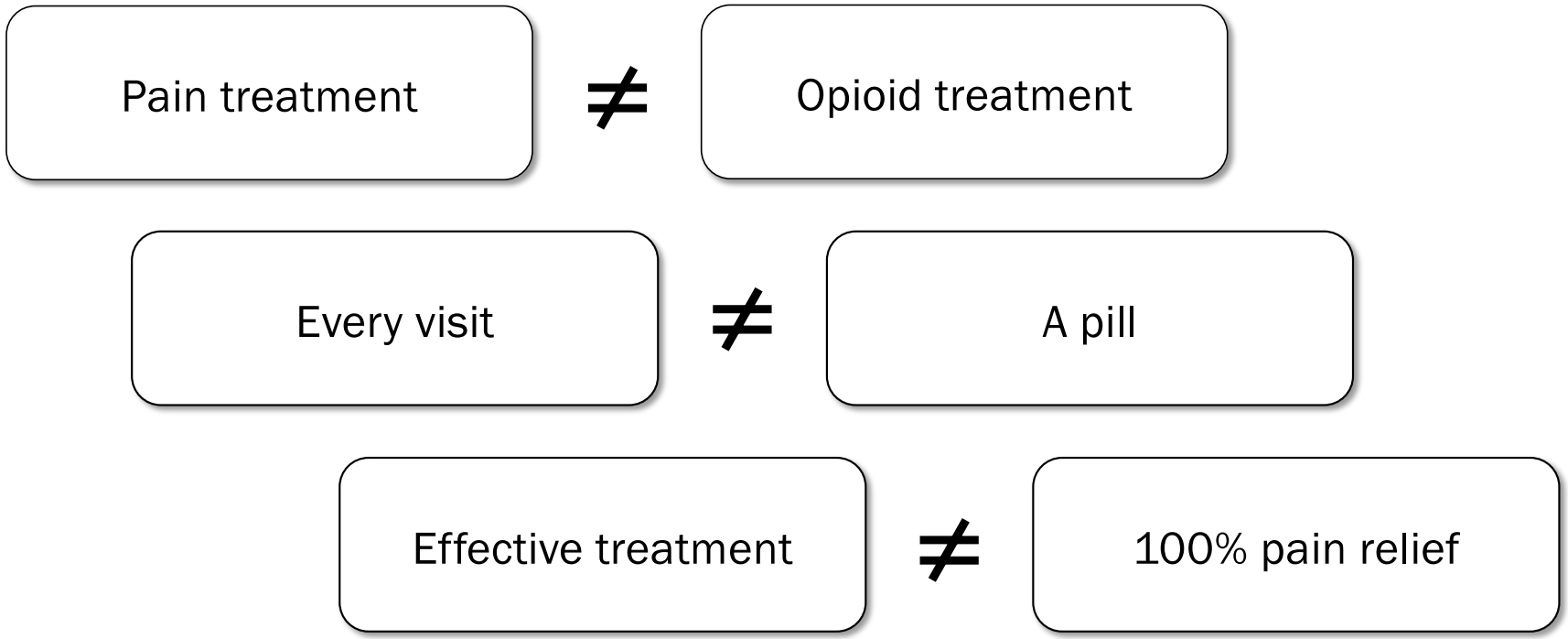
Patient counseling topics: AEs

Common AEs and how to manage them

- **Sedation:** naloxone
- **Nausea, vomiting:** opioid rotation, antiemetics, different route of administration
- **Constipation:** prophylactic stool softener and laxatives, opioid dose reduction or rotation
- **Cardiovascular effects:** ECG monitoring, opioid rotation or dose reduction
- **Sexual dysfunction:** androgen replacement therapy, opioid rotation, dose reduction
- **Rash/Pruritis:** Antihistamine therapy

Opioid Analgesic REMS. https://opioidanalgesicrems.com/RpcUI/rems/pdf/resources/patient_counseling_document.pdf. CDC. www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf. FDA. www.fda.gov/consumers/consumer-updates/fentanyl-patch-can-be-deadly-children.

What pain treatment is *not*



Drakulich A. www.practicepainmanagement.com/meeting-summary/worldwide-take-opioid-prescribing -access.
PBS News Hour. www.pbs.org/Newshour/science/brain-gets-hooked-opioids.

Conclusion

Charles E. Argoff, MD
Professor of Neurology, Albany Medical College
Vice Chair, Department of Neurology
Director, Comprehensive Pain Center
Director, Pain Management Fellowship
Albany Medical Center
Albany, New York

Key takeaways

- Successful opioid treatment requires informed decision making, patient engagement, and regular monitoring of analgesia, affect, activity, AEs, and aberrant behaviors
- Dose escalation or opioid rotation may be necessary; be aware of incomplete cross-tolerance and limitations of dose conversion charts
- If harms outweigh benefits, individualized opioid taper may be necessary
- Naloxone should be made available
- Providers should be aware of common red flags, diagnostic criteria, and treatments for OUD
- OUD can progress to addiction, which is influenced by biological, environmental, and psychological factors, as well as the dopamine cycle
- Effective patient counseling about the safe use, storage, and disposal of opioids is an important and ongoing process

Thank you!