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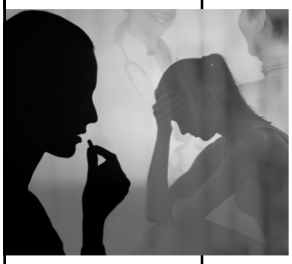

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2

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Disclosures

- ***Research Support*:** Flowonix Medical Inc.; Medtronic; TerSera; Nevro; Biotronik; Saluda; Stimguard
- ***Consultant:*** Flowonix Medical Inc.; Medtronic, TerSera; Stimwave;

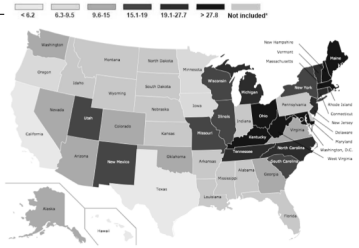
3

LEARNING OBJECTIVES

- Apply knowledge of acute and chronic pain pathways and underlying mechanisms to clinical assessment and appropriate management
- Upon evaluation of current clinical workflow for opioid prescribing, incorporate two best practice strategies to optimize safe and competent prescribing and minimize potential for abuse and diversion
- Educate patients about their pain to optimize safe and effective multimodal treatment plans

4

2017 OPIOID-INVOLVED OVERDOSE DEATHS RATES 100,000 PEOPLE



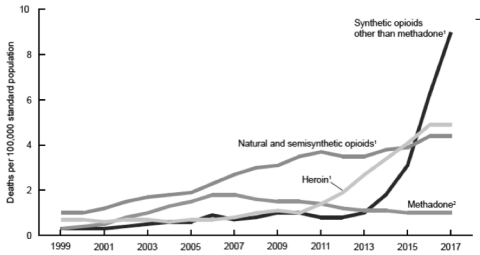
Highest

Kentucky
Maryland
Maine
New Hampshire
Ohio
Rhode Island
West Virginia

National Institute on Drug Abuse. The original source of the opioid prescribing rates is *IQVIA Xponent 2006–2017*. Available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state. Accessed May 28, 2019.

5

DEATHS BY OPIOID CATEGORY



https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf#4.

6

NHIS ESTIMATES OF CHRONIC PAIN AND HIGH IMPACT CHRONIC PAIN[1,2]

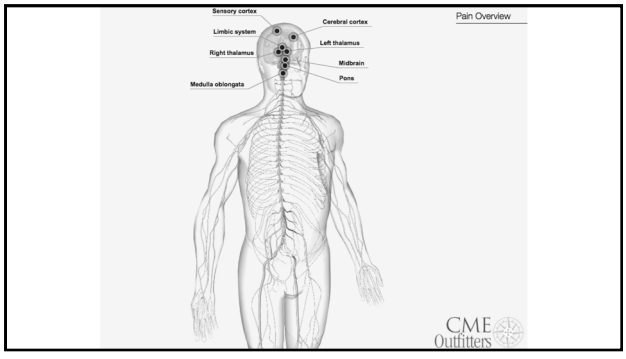
- Chronic pain: 50 million people[2]
  - Pain most days or every day in past 6 months
- High impact chronic pain: 20 million people
  - Chronic pain limited life or work activities on most days or every day during past 6 months

NHIS = National Health Interview Survey
1. Nahin RL. *Journal of Pain*. 2015;16(8):769-780.; 2. Dahlhamer J, et al. *MMWR* 2018;67:1001-1006.

7

PAIN 3-D ANIMATION

8



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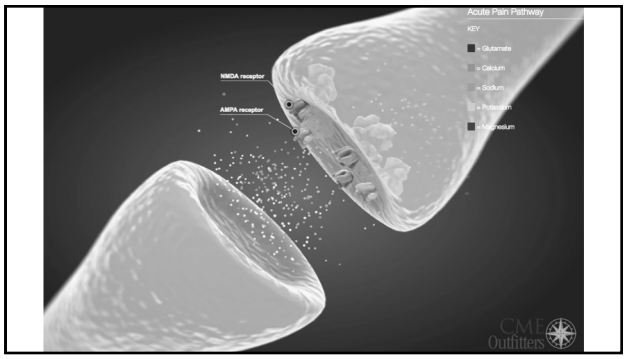

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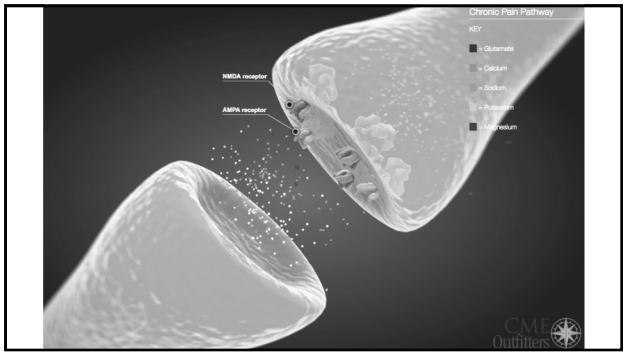


11

PATIENT-CENTERED CONSIDERATIONS

"Pain"

- Threat to the biological integrity of an individual

"Suffering"

- A threat to that person that is affecting who they are
  - Anxiety, depression
  - Distress, hopelessness
  - Change in function

Fishbain D. et al. *Pain Medicine* 2015:6:1057-72.

12

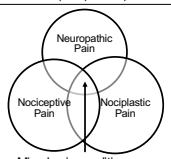
CHRONIC PAIN PRESENTATIONS

Predominantly Neuropathic

- Postherpetic neuralgia
- Painful diabetic peripheral neuropathy
- Lumbar or cervical radiculopathy
- Stenosis
- Tumor-related neuropathy
- Chemotherapy-induced neuropathy
- Small fiber neuropathy
- Persistent postoperative pain
- Multiple sclerosis pain
- Post-stroke pain
- Pain associated with spinal cord injury

Predominantly Nociceptive

- Osteoarthritis
- Rheumatoid arthritis
- Tendonitis, bursitis
- Ankylosing spondylitis
- Gout
- Neck and back pain with structural pathology
- Tumor-related nociceptive pain
- Sickle-cell disease
- Inflammatory bowel disease



Mixed pain conditions are frequently associated with multiple pain pathophysiologies once pain becomes chronic

Predominantly Nociplastic

- Fibromyalgia
- Irritable bowel syndrome
- Tension-type pain
- Interstitial cystitis/pelvic pain syndrome
- Tempo-mandibular joint disorder
- Chronic fatigue syndrome
- Restless leg syndrome
- Neck and back pain without structural pathology

Adapted from Stanos S, et al. *Postgrad Med* 2016;128(5):502-515.

13

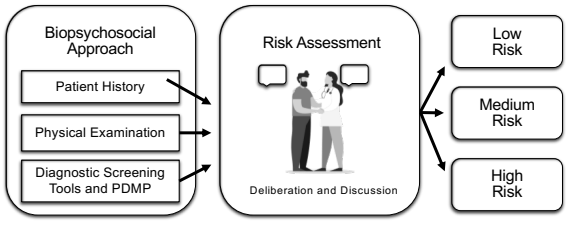
UNITED STATES PREVENTIVE SERVICES TASK FORCE (USPSTF)

- Recommendation that all adults be screened for illicit drug use, including nonmedical use of prescription drugs

U.S. Preventive Services Task Force. Available at https://www.uspreventiveservicestaskforce.org/Page/Document/draft-evidence-review-screening/drug-use-in-adolescents-and-adults-including-pregnant-women-screening. Accessed August 30, 2019.

14

A RISK ASSESSMENT IS CRITICAL TO PROVIDING THE BEST POSSIBLE PATIENT-CENTERED OUTCOME WHILE MITIGATING UNNECESSARY OPIOID EXPOSURE



U.S. Department of Health and Human Services. Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Published May 9, 2019. Available at https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf. Accessed June 1, 2019.

15

PSYCHOSOCIAL ASSESSMENT TOOLS

- 4 A's
  - **A**nalgesia
  - **A**ctivities of daily living
  - **A**dverse effect
  - **A**berrant behavior
- Opioid Risk Tool
- Tools such as GAD-7, PHQ-9 to assess anxiety and depression
- PEG: **P**ain, **E**njoyment of life and **G**eneral activity


Opioid Risk Tool

MARK EACH BOX THAT APPLIES:	FEMALE	MALE
1. Family history of substance abuse		
Alcohol	❑ 1	❑ 3
Illegal drugs	❑ 2	❑ 3
Prescription drugs	❑ 4	❑ 4
2. Personal history of substance abuse		
Alcohol	❑ 3	❑ 3
Illegal drugs	❑ 4	❑ 4
Prescription drugs	❑ 5	❑ 5
3. Age (mark box if between 16 and 45 years)	❑ 1	❑ 1
4. History of preadolescent sexual abuse	❑ 3	❑ 0
5. Psychological disease		
ADD, OCD, bipolar disorder, schizophrenia	❑ 2	❑ 2
Depression	❑ 1	❑ 1
SCORING TOTALS:		

ADMINISTRATION: • On initial visit • Prior to opioid therapy

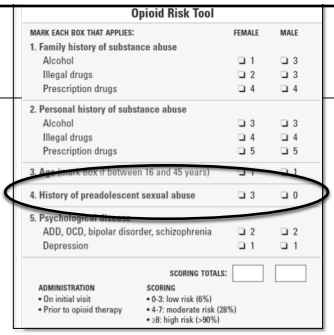
SCORING: • 0-3: low risk (6%) • 4-7: moderate risk (28%) • ≥8: high risk (>90%)

1. Webster LR, Webster RM. *Pain Med* 2005;6:432-442.

16

USE RISK ASSESSMENT TOOL[1]

A study of 295 patients in an outpatient treatment setting for substance use disorders or depression, substance use was **4x higher among victims of emotional and sexual abuse** than those in the control group.[2]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Alcohol	❑ 3	❑ 3
Illegal drugs	❑ 4	❑ 4
Prescription drugs	❑ 5	❑ 5
3. Age (mark box if between 16 and 45 years)	❑ 1	❑ 1
4. History of preadolescent sexual abuse	❑ 3	❑ 0
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ADD, OCD, bipolar disorder, schizophrenia	❑ 2	❑ 2
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1. Webster LR, Webster RM. *Pain Med* 2005;6:432-442.
2. Tucci AM, et al. *Child Abuse & Neglect*. 2010;34:95-104.

17

PAIN MANAGEMENT TOOLS

Medications	• Use multimodal analgesia NSAIDs, acetaminophen, AEDs, gabapentanoids, immediate-release (IR) opioids • Prescribe lowest effective IR opioids for shortest period possible • Minimize use of ER opioids, Never first line therapy
Behavioral Medicine	• Cognitive behavioral therapy, acceptance, and mindfulness approaches • Relaxation training (biofeedback, deep breathing) and counseling • Pain education, motivational interviewing techniques
Physical Modalities and Interventions	• Use appropriate immobilization, ice, and elevation • Physical and occupational therapy, exercise, and movement-based approaches • Interventional procedures, injections
Monitoring and Education	• Assess pain regularly with short validated tools • Patient education

AED = anti-epileptic drug

18

APPROPRIATE STEPS

- Discuss risks and benefits of use of controlled substances with the patient
- Secure documentation
- Periodically review treatment for efficacy and tolerability[1]
- Re-evaluate the patient
  - Is pain controlled?
  - Are physical and psychological functioning improved?
  - Patient quality of life
- Adjust plan to optimize analgesia and function

1. Federation of State Medical Boards of the United States, Inc Web site. Model policy for the use of controlled substances for the treatment of pain. http://www.painpolicy.wisc.edu/domestic/model.htm.

19

BEST PRACTICES FOR CHRONIC PAIN MANAGEMENT

20

CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Determining need for opioids
• Opioids are not first-line or routine therapy for chronic pain. • Establish and measure goals for pain and function. • Discuss benefits and risks of opioid therapy and availability of nonopioid therapies.
Opioid selection, dosage, and duration of therapy
• Use immediate-release opioids when starting. • Use caution at any dose. Reassess benefits and risk when dose reaches >50 mg MED and avoid increasing dose to > 90 mg MED without carefully justifying decision. • Long-term use begins with treatment of acute pain. 3 days or less often sufficient. • Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed.
Assessing risk and addressing harm
• Evaluate risk factors for opioid-related harms. • Check PDMP for high dosages and prescriptions from other providers. • Use urine drug testing to identify prescribed substances and undisclosed use. • Avoid concurrent benzodiazepine and opioid prescribing. • Arrange treatment for OUD if needed.

Dowell D, et al. *MMWR Recomm Rep* 2016;65(1):1-49.

21

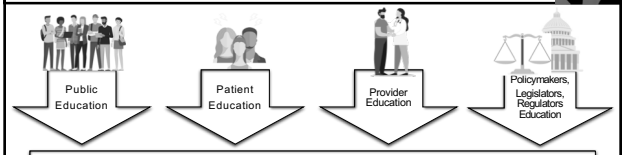
UNINTENDED CONSEQUENCES: NO SHORTCUTS TO OPIOID PRESCRIBING

- Although not intended to be model legislation, 28 states have enacted legislation related to opioid prescription limits
- Has been used to override medical decisions
- Patients on high dose opioids discontinued or dismissed from care
- Universally stop prescribing opioids even when benefits outweigh risks

Dowell D, et al. *N Engl J Med*. 2019 Apr 24. doi: 10.1056/NEJMp1904190.

22

EDUCATION IS CRITICAL TO THE DELIVERY OF EFFECTIVE PATIENT-CENTERED PAIN CARE AND REDUCING THE RISK ASSOCIATED WITH PRESCRIPTION OPIOIDS



+ Effective, patient-centered care
+ Optimize patient functional outcomes
+ Appropriate use of pain medication
+ Reduced risk through risk-benefit assessment

U.S. Department of Health and Human Services. Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Published May 9, 2019. Available at https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf. Accessed June 1, 2019.

23

HAVE AN EXIT STRATEGY

- Taper opioids appropriately and optimize non-opioid pain management and psychosocial support
  - Collaborate with the patient using motivational interviewing skills
- Patient-centered opioid taper
  - If no sustained improvement in pain and/or function
  - Patient side effects, frequent unscheduled requests, overdose, warning signs, concurrent benzodiazepines
  - Avoid abrupt discontinuation
  - Taper slowly, pause and adjust as needed
  - Decrease dose by 10%/week or by 25% at a time, in monthly steps
  - Assess and manage opioid withdrawal signs and symptoms

1. Kroenke K, et al. *Pain Med*. 2019 Jan 25. doi:10.1093/pm/pny/307. 2. www.cdc.gov/drugoverdose/prescribing/guideline.html.

24

BEST PRACTICES FOR ACUTE PAIN MANAGEMENT

25

DO ALL SURGICAL PROCEDURES REQUIRE OPIOIDS?

- ~~1 in 16 surgical patients prescribed opioids becomes a long-term user~~[1]
- 190 patients undergoing 6 procedures offered the opportunity to participate in opioid-sparing management[2]
- Advised to use acetaminophen and ibuprofen and given a small "rescue" opioid prescription for breakthrough pain
  - 52% used NO opioids after procedures
  - Patients report high level of satisfaction and pain control
  - 91% of patient agreed their pain was manageable
- Results demonstrate effectiveness and acceptability of reduction and/or elimination of opioids after discharge from minor surgery

1. Overton HN, et al. *J Am Coll Surg*. 2018;227(4):411-418.; 2. Hallway A, et al. *J Am Coll Surg*. 2019 Apr 26 S1072-7515(19)30295-9. doi: 10.1016/j.jamcollsurg.2019.04.020. [Epub ahead of print].

26

ORTHOPAEDIC TRAUMA ASSOCIATION (OTA) RECOMMENDATIONS FOR PAIN MEDICATION TAPER FOLLOWING MAJOR MUSCULOSKELETAL INJURY PROCEDURE

	Opioid	Non-Opioid
Inpatient	• Moderate pain: Oxycodone/APAP 5mg/325mg 1 tab po q4 hrs PRN • Severe pain: Oxycodone/APAP 5mg/325 mg 2 tabs po q6 hrs PRN • ~~Hydromorphone 1mg IV q3 hrs PRN for severe breakthrough pain~~	• Ketorolac 15mg IV q6 hrs x 5 doses followed by ibuprofen 600mg po q8 hrs • ~~Gabapentin 100mg 1 tab po TID~~ • Scheduled APAP 500mg po q12 hrs
Week 1 at discharge	• Oxycodone/APAP 5mg/325 mg 1 tab po q4 hrs PRN. Dispense #42 (1 time Rx, no refills	• Ibuprofen 600mg po q8 hrs x 7 days (Rx given) • Gabapentin 100mg 1 tab po TID x 7 days (Rx given) • Scheduled APAP 500mg po q12 hrs x 7 days (can increase as combined opioid analgesic decreases)
	• Hydrocodone/APAP 5mg/325mg or tramadol 50mg (only if necessary, 3 Rx Max)	• NSAIDs PRN as directed • Gabapentin if necessary (up to 1800 mg/day)
Week 2	• 1 tab po q4 hrs PRN Dispense #42	• Scheduled APAP 500mg po q12 hrs (can increase as combined opioid analgesic decreases)
Week 3	• 1 tab po q6 hrs PRN Dispense #28	• Scheduled APAP 1000mg po q12 hrs (can increase as combined opioid analgesic decreases)
Week 4	• 1 tab po q8 hrs PRN Dispense #21	• Scheduled APAP 1000mg po q8 hrs (can increase as combined opioid analgesic decreases)
Week 5+		• NSAIDs PRN as directed • APAP PRN as directed • Gabapentin if necessary (then wean)

APAP = acetaminophen
Hsu JR, Mir H, et al. *J Orthop Trauma*. 2019;33(5):e158-e182.

27

OTA RECOMMENDATIONS FOR PAIN MEDICATION TAPER FOLLOWING MINOR MUSCULOSKELETAL INJURY PROCEDURE: POST-DISCHARGE

	Opioid	Non-Opioid
Week 1	• Hydrocodone/APAP 5mg/325mg or tramadol 50mg • 1 tab po q6 hrs PRN, Dispense #28 • 1 time Rx, No refills	• Ibuprofen 600mg po q8 hrs x 7 days (Rx given) • Gabapentin 100mg 1 tab po TID x 7 days (Rx given) • Scheduled APAP 500mg po q12 hrs x 7 days (can increase as combined opioid analgesic decreases)
Week 2	• Hydrocodone/APAP 5mg/325mg or tramadol 50mg • Only if necessary, 2 Rx Max • 1 tab po q8 hrs PRN Dispense #21	• NSAIDs PRN as directed • Gabapentin if necessary (up to 1800 mg/day) • Scheduled APAP 1000mg po q8 hrs (can increase as combined opioid analgesic decreases)
Week 3	• 1 tab po q12 hrs PRN Dispense #14	• NSAIDs PRN as directed • Gabapentin if necessary (up to 1800 mg/day) • Scheduled APAP 1000mg po q8 hrs (can increase as combined opioid analgesic decreases)
Week 4		• NSAIDs PRN as directed • APAP PRN as directed

Hsu JR, Mir H, et al. *J Orthop Trauma*. 2019;33(5):e158-e182.

28

OTA RECOMMENDATIONS FOR PAIN MEDICATION TAPER FOLLOWING NON-OPERATIVE MUSCULOSKELETAL INJURY

Injury Category	Opioid	Non-Opioid
Minor Injury (e.g. small bone fracture, sprain, laceration, etc.)	• Tramadol 50mg • Only if necessary, 2 Rx Max • 1 tab po q6 hrs PRN, Dispense #20, then #10	• NSAIDs PRN as directed • Scheduled APAP1000mg po q8 hrs, then PRN as directed
Major Injury (e.g. large bone fracture, rupture, etc.)	• Hydrocodone/APAP 5mg/325mg or tramadol 50mg • Only if necessary, 2 Rx Max • 1 tab po q6 hrs PRN • Dispense #20, then #10	• NSAIDs PRN as directed • Scheduled APAP 1000mg po q12 hrs, then PRN as directed

Hsu JR, Mir H, et al. *J Orthop Trauma*. 2019;33(5):e158-e182.

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SETTING AND MANAGING EXPECTATIONS

30

PATIENT EDUCATION IS IMPORTANT

- Education to help patients better understand their pain is essential
- Setting clear goals and expectations is critical!
  - A reasonable goal is a 30% reduction in pain which is considered meaningful and improve daily functioning
- Provide education about what the patient can and should do to feel better and be more active
  - Non-pharmacological therapies: Cognitive behavioral therapy, relaxation training, mindfulness
  - Exercise and movement without significant pain increase
  - Discuss healthy self-care, necessity of taking an active role in treatment

31

NALOXONE

- Not a "cure" but reverses the dangers of an opioid overdose allowing medical treatment and hopefully prevent death
- Three FDA-approved formulations
  - Injectable
  - Autoinjectable
    - Prefilled autoinjection device
    - Once activated, device provides verbal instructions to user
  - Prepackaged nasal spray, no assembly
    - Prefilled, needle-free device
- All 50 states + DC have legislation increasing access
  - Naloxone distribution by pharmacists
  - Allows distribution beyond those at risk for overdose

[Package Insert]. Drugs@FDA Website

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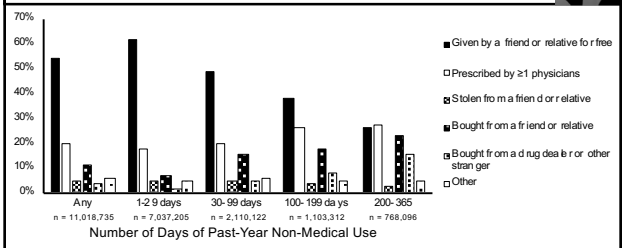
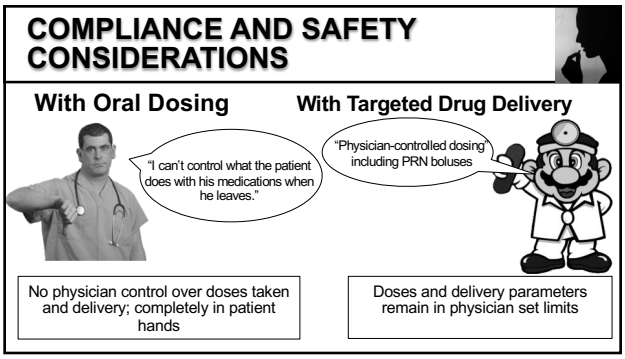
SOURCES OF OPIOID FOR NON-MEDICAL USE



Obtained from the US National Survey on Drug Use and Health, 2008-2011.; Estimate is statistically significantly different from that for highest-frequency users (200-365) ($p < .05$). Jones C, et al. *JAMA Intern Med.* 2014;174(5):802-803.

33

COMPLIANCE AND SAFETY CONSIDERATIONS



34

ROLE OF PRIMARY CARE PHYSICIANS IN INTRATHECAL PAIN MANAGEMENT: A NARRATIVE REVIEW OF THE LITERATURE.

McDowell GC 2nd, Winchell J. *Postgrad Med*. 2018;130(4):411-419.

35

EDUCATION ON SAFE STORAGE AND DISPOSAL OF UNUSED MEDS

- Opioids should be stored inside lockbox and/or secure location
- Medication take-back programs
  - DEA-registered collection sites at retail/hospital/clinic pharmacies and law enforcement
  - Check www.takebackmymeds.com for additional details
- Disposal in household trash
  - Mix (do not crush tablets or capsules) with an unpalatable substance such as dirt, cat litter, or used coffee grounds and seal in plastic bag
  - Delete personal information from the prescription label before disposing
- Disposal in a drug deactivation pouch that utilizes carbon to deactivate and dispose in household trash
- FDA endorses flushing, but many oppose due to concerns about aquatic life

US Food and Drug Administration (FDA). Disposal of Unused Medicines: What You Should Know. Available at: https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm

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SMART GOALS

Specific, Measurable, Attainable, Relevant, Timely

- Integrate risk assessment tools into clinical workflow
- Individualize multimodal treatment planning
- Educate patients about their pain to set appropriate expectations and treatment goals
- Provide patients at risk with access to naloxone

37

QUESTIONS & ANSWERS

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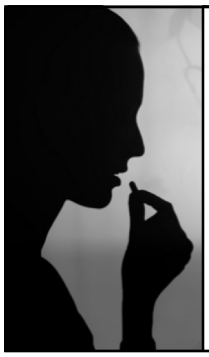

NEW FROM CME OUTFITTERS

OPIOID EDUCATION HUB

Free resources and education to educate both HCPs and patients on pain & appropriate pain management, substance use, and more.

See the handout at your seat to get access the Hub!

www.cmeoutfitters.com/RX4Pain

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