ADDRESSING THE OPIOID CRISIS

A Call to Save Our Communities

Supported by an educational grant from Johnson & Johnson

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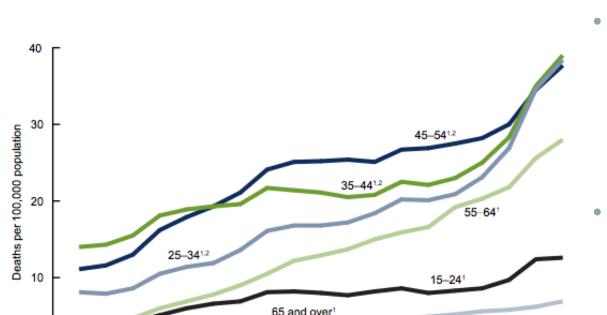
STEVEN P. STANOS, DO

Medical Director,
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LEARNING OBJECTIVES

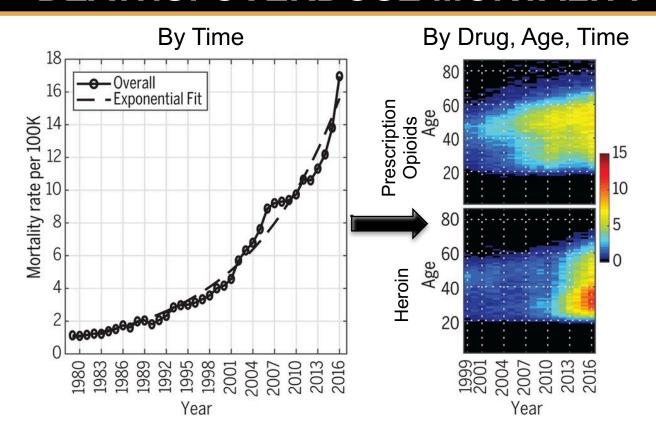
- Recognize the growing burden of the opioid epidemic and the role of all stakeholders in the community
- Apply knowledge of acute and chronic pain pathways and underlying mechanisms to clinical assessment and appropriate management
- Upon evaluation of current clinical workflow for opioid prescribing, 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

DRUG OVERDOSE DEATH RATES, BY SELECTED AGE GROUP: UNITED STATES, 1999–2017

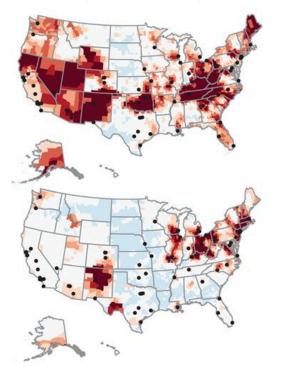


- In 2017, rates were significantly higher for age groups 25-34 (38.4 per 100,000), 35-44 (39.0), and 45-54 (37.7) than for those aged 15-24 (12.6), 55-64 (28.0), & 65+ (6.9)
- From 1999 to 2017, the greatest % change in drug overdose death rates occurred among adults aged 55–64, increasing from 4.2 per 100,000 in 1999 to 28.0 in 2017, a more than 6-fold increase

EXPONENTIAL GROWTH IN OVERDOSE DEATHS: OVERDOSE MORTALITY RATE

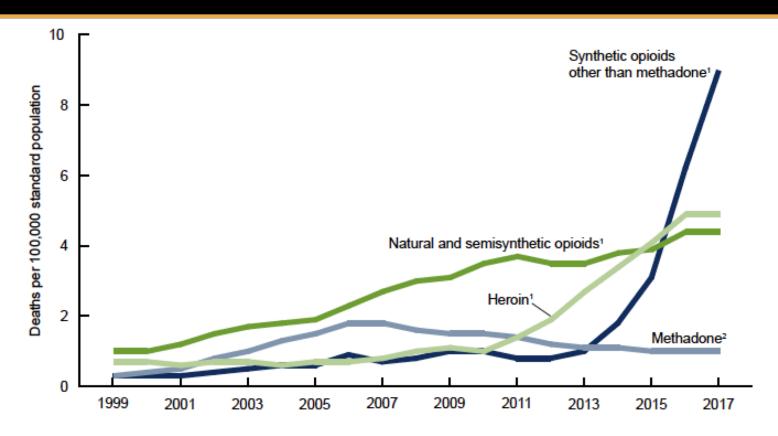


By Drug and Geography



Jalal H, et al. Science. 2018;361(6408). pii: eaau1184. doi: 10.1126/science.aau1184.

THREE PHASES OF THE OPIOID EPIDEMIC AND DEATHS BY OPIOID CATEGORY



DRUG ABUSE AND INFECTIOUS DISEASE CONSEQUENCES



People who inject drugs are a high-risk subgroup of endocarditis patients²



Viral hepatitis is increasing at concerning rates: new hepatitis B infections rose 20% from 2014-2015, and new hepatitis C infections increased 233% from 2010-2016



1 of every 10 new HIV infections is among people who inject drugs



The rate of infants born to hepatitis C-infected mothers increased by 68% nationally from 2011-2014, primarily due to the nation's opioid crisis

People who inject drugs are at elevated risk for unsafe sexual practices, such as having sex without a condom, having sex partners who are injection drug users, or engaging in sex work. Such high-risk behavior puts injectable drug users at elevated risk for acquiring and transmitting a sexually transmitted disease.

\$100 MILLION IN MEDICAL COSTS





The result of a 2015 outbreak of disease linked to opioid use in Indiana



225 people were diagnosed with HIV >90% were co-infected with hepatitis C

^{1.} Addressing the Infectious Consequences of the U.S. Opioid Crisis. Centers for Disease Control. Available at https://www.cdc.gov/nchhstp/budget/infographics/opioids.html. Accessed January 15, 2019.; 2. Elbatarny M, et al. *Gen Hosp Psychiatry.* 2019;57:44-49.



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

- Chronic pain: 50 million individuals
 - Pain on most days or every day in past 6 months
- High impact chronic pain: 20 million individuals
 - Chronic pain limited life or work activities on most days or every day during past 6 months
- 91 million individuals prescribed opioids
- 2 million individuals with OUD^{3,4}

PATIENT-CENTERED CONSIDERATIONS



"Pain"

 Threat to the biological integrity of an individual

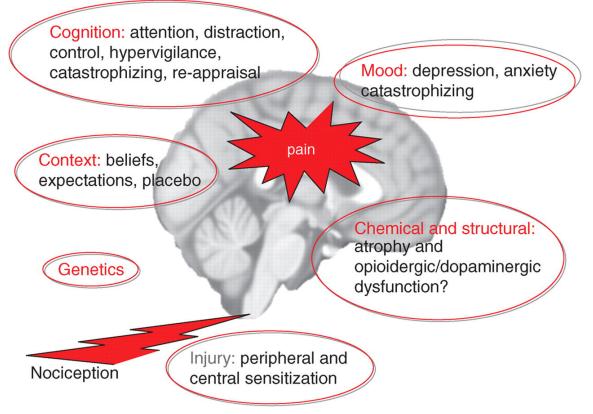
"Suffering"

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

PAIN CATASTROPHIZING

- Tendency to ruminate and focus excessively on pain and exaggerate its threat value
- Consistently associated with health-related outcomes
 - Interference of pain with patients' life, physical disability, and mental well-being
- Key target in psychological interventions such as cognitive behavioral therapy (CBT) and mindfulness stress reduction
 - Goal is to identify poor coping strategies and provide patients with better tools

FACTORS THAT INFLUENCE NOCICEPTIVE INPUTS AFFECTING PAIN PERCEPTION





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

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 <u>without</u> structural pathology

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- Painful diabetic peripheral neuropathy Chemotherapy-induced neuropathy
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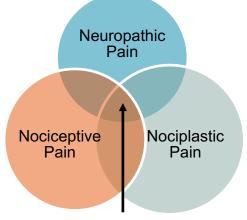
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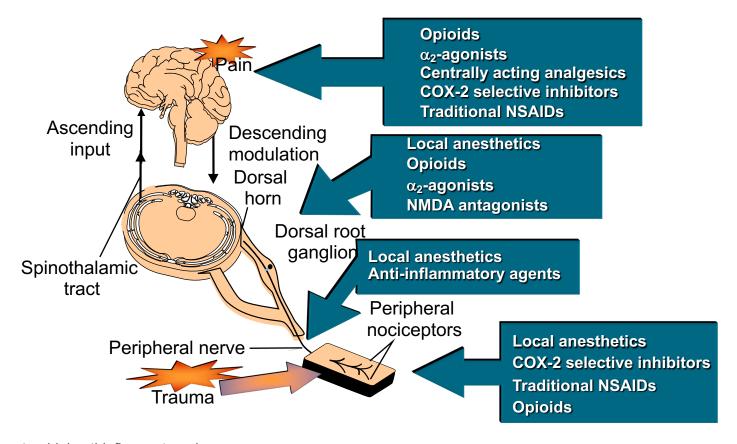
Mixed pain conditions are frequently associated with multiple pain pathophysiologies once pain becomes chronic

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

MECHANISM-BASED APPROACH



NSAIDs = nonsteroidal anti-inflammatory drugs. Adapted from Gottschalk A, Smith DS. *Am Fam Physician*. 2001;63(10):1979-1984.

APPLYING A BIOPSYCHOSOCIAL MODEL TO ASSESSING PAIN

- Physical assessment
 - What is the underlying cause of pain?
 - What tools can be used to assess pain?
- Psychosocial assessment
 - Use of tools such as GAD-7, PHQ-9 to assess anxiety and depression
 - Pain catastrophizing tools
 - Tools to predict aberrant behaviors for medications
 - PEG: <u>Pain</u>, <u>Enjoyment of life and <u>General</u> activity
 </u>

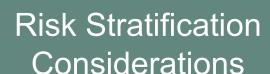
Comprehensive H&P and evaluation

Integrating risk assessment tools

Patient selection

COMPLEXITY OF ASSESSING RISKS





Acute to Chronic Pain

Aberrant Behaviors and Addiction

Medications and Medical Condition

USE RISK ASSESSMENT TOOL¹

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

- 1. Webster LR. Webster RM. Pain Med 2005:6:432-442
- 2. Tucci AM, et al. Child Abuse & Neglect. 2010;34:95-104.

Opioid Risk Tool					
FEMALE	MALE				
1. Family history of substance abuse					
□ 1	□ 3				
□ 2	□ 3				
4	□ 4				
2. Personal history of substance abuse					
□ 3	□ 3				
□ 4	□ 4				
□ 5	□ 5				
3. Age (mark box if between 16 and 45 years)					
buse 🔲 3	0				
5. Psychological disease					
ophrenia 🖵 2	□ 2				
□ 1	□ 1				
SCORING TOTALS:					
risk (6%)					
derate risk (28%) risk (>90%)					
	FEMALE 1 2 4 se 3 4 5 5 years) 1 ORING TOTALS: 7 risk (6%) derate risk (28%)				

PAIN MANAGEMENT TOOLS

Medications

- Use multimodal analgesia NSAIDs, acetaminophen, gabapentin, immediate-release (IR) opioids
- Prescribe lowest effective IR opioids for shortest period possible
- Do not use ER opioids

Behavioral Medicine

- Cognitive behavioral therapy, acceptance, and mindfulness approaches
- Relaxation training 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



MRS. JASPER

- 64-year-old administrative assistant
- Knee osteoarthritis
- Obese, cardiovascular disease
- Candidate for knee replacement, but surgeon would like her to try to lose weight first
- No improvement with NSAIDs or topical analgesics
- Knee injection provided transient relief



What would you recommend for Mrs. Jasper

- A. Oxycodone 5mg/acetaminophen 325 mg, 1 q4-6 hrs (3/day)
- B. Continue with knee injections every 3 months
- C. Prescribe gabapentin, NSAID, acetaminophen daily
- D. Continue on weight loss program
- E. I'm not sure

CDC GUIDELINE FOR PRESCRIBING

- OPIOIDS FOR CHRONIC PAIN¹
- CDC's recommendations are made on the basis of a systematic review of best available evidence.
- Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context.
- The recommendations in the guideline are voluntary, rather than prescriptive standards.
- Clinicians should consider the circumstances and unique needs of each patient when providing care.2

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 treatment.
- Start low and go slow.
- Reassess pain and function when doses reach >50 mg of morphine equivalents a day and avoid increasing doses to >90 mg a day.
- 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.

ESTABLISHED PATIENTS ALREADY

- TAKING HIGH DOSAGES OF OPIOIDS
- "...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 high-dosage 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."
 - Decrease dose by 10%/week or by 25% at a time, in monthly steps
- Be aware that anxiety, depression, and opioid use disorder "might be unmasked by an opioid taper"



MR. JAMES

- 42-year-old male technology salesman
- Presents to PCP complaining of 4 days of severe back and right leg pain after cleaning garage and lifting heavy boxes
- Severe lumbar pain, shooting down right buttock and right leg to heel
- Tried OTC ibuprofen, no change
- Unable to work, difficult to sit for more than 20 minutes due to severe leg pain
- Physical exam: Decreased Achilles reflex on right, decreased light touch calf and posterior upper leg



What would you recommend for Mr. James?

- A. Education material about low back pain and importance of staying active
- B. Steroid dose pack
- C. Prescription NSAID
- D. Tramadol 50 mg, 1-2 q4-6 hrs
- E. Send for lumbar MRI
- F. Oxycodone 5 mg every q4-6 hrs, max 4/day

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 directedAPAP PRN as directedGabapentin if necessary (then wean)

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

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

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
- 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 groups oppose due to concerns about aquatic life

MR. JAMES: A DIFFERENT LOOK

- 42-year-old male technology salesman
- Presents to PCP complaining of 4 days of severe back and right leg pain after cleaning garage and lifting heavy boxes
- Severe lumbar pain, shooting down right buttock and right leg to heel
- History of alcohol and prescription opioid abuse in early 20's. In recovery, attending AA meetings
- Unable to work, difficult to sit for more than 20 minutes due to severe leg pain
- Physical exam: Decreased Achilles reflex on right, decreased light touch calf and posterior upper leg



What would you recommend for Mr. James?

- A. Education material about low back pain and importance of staying active
- B. Steroid dose pack
- C. Prescription NSAID
- D. Tramadol 50 mg, 1-2 q4-6 hrs
- E. Send for lumbar MRI
- F. Oxycodone 5 mg every q4-6 hrs, max 4/day



PATIENT EDUCATION IS IMPORTANT

- Education to help patients better understand their pain is essential
- Pain may not be 100% alleviated, but the intervention will reduce pain and improve daily functioning
- Clear expectations are critical!
- 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
- Establish common goals



40+ YEARS OF TRANSLATIONAL SCIENCE



Consumption of opioids to achieve high



Results in compulsive use despite adverse consequences

Increased exposure to drug cues



Triggers desire to continue to consume opioids



2016-2025: PROJECTED OPIOID DEATH TOLL



- No single policy is likely to substantially reduce deaths over 5 to 10 years
 - Wider availability of naloxone could reduce opioid-related deaths by 21,200 over 10 years
 - Medication-based treatments for opioid addiction like buprenorphine and methadone would reduce deaths by 12,500
 - Reductions in painkiller prescribing for acute pain would reduce deaths by 8,000

FDA-APPROVED MEDICATIONS TO TREAT OPIOID USE DISORDER



Medication	Receptor Pharmacology	Formulation
Methadone	Full mu opioid agonist	Oral solution, liquid concentrate, tablet/diskette, powder
Buprenorphine	Partial mu opioid agonist	Once monthly injection for subcutaneous use
Buprenorphine- naloxone	Partial mu opioid agonist/mu antagonist	Sublingual filmSublingual tablets
Naltrexone	Mu opioid antagonist	Extended release injectable suspension

Prescribing information available at https://www.accessdata.fda.gov

Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Rockville (MD): SAMSHA (US); 2005. (Treatment Improvement Protocol (TIP) Series, No. 43.) Chapter 3. Pharmacology of Medications Used to Treat Opioid Addiction. Available from: https://www.ncbi.nlm.nih.gov/books/NBK64158/

NALOXONE

- Not a "cure" but reverses the dangers of an opioid overdose allowing medical treatment and hopefully prevent death
- Three FDA-approved formulations¹
 - Injectable
 - Autoinjectable
 - Prefilled autoinjection device
 - Once activated, device provides verbal instructions to the user
 - Prepackaged nasal spray, no assembly
 - Prefilled, needle-free device requiring
 - Sprayed into one nostril while patients on their back
- Access to naloxone is expanding
- SAMHSA Opioid Overdose Prevention Toolkit²
- 1. https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio.;
- 2. https://store.samhsa.gov/shin/content//SMA18-4742/SMA18-4742.pdf



SUICIDE: A SILENT CONTRIBUTOR TO OPIOID OVERDOSE DEATHS



- Addressing the trajectory of opioid overdoses requires a better understanding between intentional (suicide) and unintentional (accidental) deaths
- Yet, most strategies to address overdose do not include screening for suicide or the need to tailor interventions for suicidal persons
- Classifying these deaths as "undetermined" if no documented history of depression hinders deployment of prevention services

SMART GOALS

Specific, Measurable, Attainable, Relevant, Timely

- Prescribe precisely! Individualize treatment planning based on mechanisms and treatment targets
- Screen patients with validated assessment tools to determine risk for addiction before prescribing opioids
 - GAD-7, PHQ-9, ORT
- Educate patients about their pain to appropriately set expectations and develop realistic treatment goals
- Educate patients about safe disposal of unused opioids
- Not one thing will change the course of the opioid epidemic
 - Reduction in prescribing, access to MAT, and availability of naloxone



DOWNLOADABLE RESOURCES



Today's presentation slides and resources will be available for download at:

www.cmeoutfitters.com/RX4painResources

Quality Payment Program (QPP)

How to Claim this Activity as a MIPS Improvement Activity



- Actively participate by responding to ARS and/or asking the faculty questions
- Complete your post-test and evaluation at the conclusion of the live meeting
- Over the next 90 days, actively work to incorporate improvements in your clinical practice from this presentation
- Complete the follow-up survey from CME Outfitters in approximately 3 months

CME Outfitters will send you confirmation of your participation to submit to CMS attesting to your completion of a MIPS Improvement Activity.



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 double-sided handout at your seat to get access the Hub!

www.cmeoutfitters.com/RX4Pain

