HOW TO MANAGE CHRONIC PAIN IN THE MIDDLE OF AN OPIOID EPIDEMIC

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OBJECTIVES

- Review policies and action plans to combat the opioid crisis
- Determine our role in the opioid epidemic
- Analyze the current literature to determine best practices for chronic pain treatment

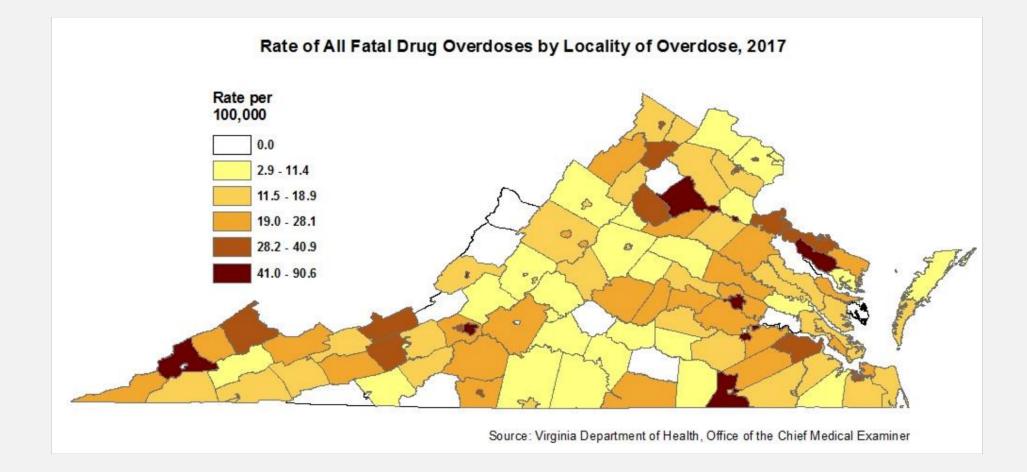
DISCLOSURES

I have no financial relationships or conflicts of interest to disclose

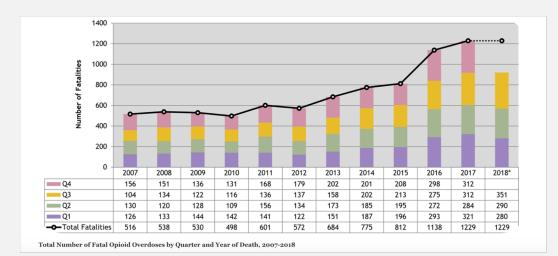
176 Americans died each day from an opioid overdose in 2016 40% of opioid overdoses involve a prescription opioid

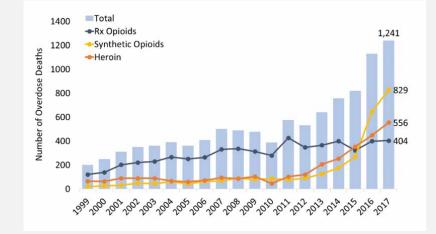


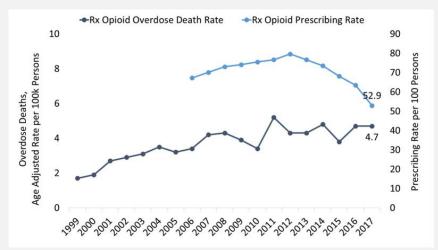
WHAT DOES THE OPIOID CRISIS LOOK LIKE IN VIRGINIA?



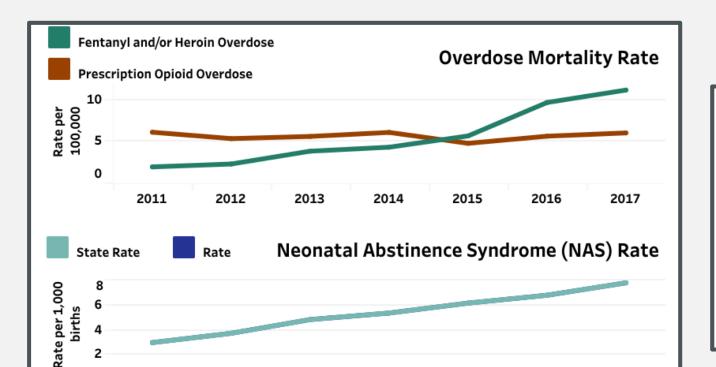
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WHAT DOES THE OPIOID CRISIS LOOK LIKE IN VIRGINIA?



2018 Virginia Summary

ED Heroin Overdose	ED Opioid Overdose	EMS Narcan		
Visits	Visits	Administrations		
1,301	7,323	7,775		
Visit Rate	Visit Rate	Administration Rate		
15.4	86.5	89.5		

FOSTER CARE SYSTEM

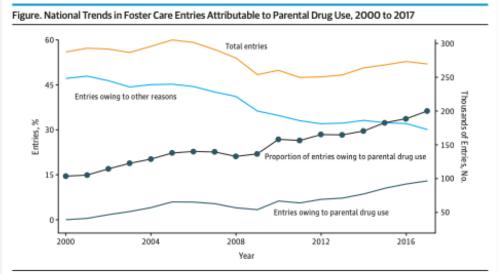




Heleen Zeegers/Getty Images

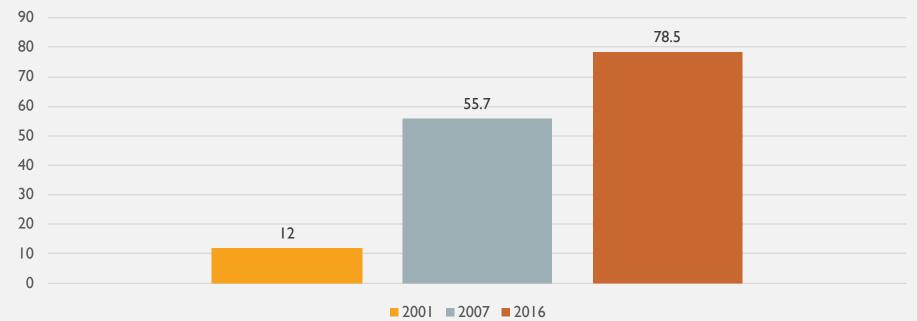
https://www.npr.org/sections/health-shots/2019/07/15/741790195/more-kids-are-getting-placed-in-foster-carebecause-of-parents-drug-use JAMA Pediatr. 2019;173(9):881-883

- 8% increase in the number of children entering the foster care system between 2012 – 2017
 - "Parental Drug Use" was the reason in:
 - 14.5% of cases in 2000
 - 36% of cases in 2017
- Other causes (such as abuse) have decreased and policy changes confound these results



FINANCIAL IMPACT

Societal Costs (in billions)



Annu Rev Public Health. 2015 Mar 18;36:559-74.

VIRGINIA'S RESPONSE

Encourage appropriate prescribing Increase education and awareness Expand access to treatment and harm-reduction services

Respond to Overdoses Penalties for traffickers

Civil litigation

PHYSICIAN DIRECTED STRATEGIES

- VA Board of Medicine increased regulations on the prescribing of opioids
- Last revised August 2018
- Provides regulations for the management of acute pain, chronic pain, and buprenorphine for addiction management
- Chronic Pain requirements listed by:
 - Prior to initiating
 - Initiating
 - Monitoring and treatment plan

PHYSICIAN DIRECTED STRATEGIES

Prior to initiating

- Drug Screen
- Query the prescription drug monitoring program
- Patient history and assessment of risk
- Discuss risks and benefits with the patient

Initiating

- Non-opioid and nonpharmacologic treatments are first line
- If a patient requires > 50 MME/day, reason must be recorded
- Prescribe naloxone when indicated
- Document rationale to continued treatment every 3 months
- Document if co-prescribing with other opioids, benzodiazepines, sedatives, carisoprodol, and tramadol
- Regular evaluation for opioid use disorder

Monitoring and treatment plan

- Medical record shall include a treatment plan
- Review the treatment plan every at least every three months
- Query the Prescription Monitoring Program at least every three months
- Review urine drug screen or medication levels at least once a year

*This list is NOT an exhaustive list. Please consult the Board or Medicine or Board of pharmacy for a complete list of regulations

VIRGINIA OPIOID PRESCRIBING REQUIREMENTS

Clinical DO's

- Co-prescribe naloxone based on specific risk factors
 - Prior overdose
 - Substance abuse
 - Dose in excess of I20 MME/day
 - Concomitant benzodiazepine use



Clinical DON'Ts

- Don't co-prescribe an opioid with the following medications
 - Benzodiazepines
 - Sedative hypnotics
 - Carisoprodol
 - Tramadol
 - Can be allowed in extenuating circumstances but documentation and tapering plan is required



https://virginiapharmacists.org/resources/board-medicine-regulations/

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RECENT REQUE	ESTS				Exciting changes are coming to 09/20/2017	
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DELEGATES						
Delegate Name Status			Status	Request Date		
um James Delegate		pending	12/01/2017			
Jordan Delegate		approved 04/25/2017				

PRESCRIPTION DRUG MONITORING

- Online program
- Report shows the following information for each patients
 - Fill history of controlled substance prescriptions (CII CIV, CV if RX required)
 - Who prescribed
 - Who dispensed
- Health Care providers have ability and responsibility to look up this information for each patient that they prescribe or dispense controlled substances

NALOXONE

• Virginia Standing order for Naloxone

 Allows pharmacists to dispense Naloxone to those they believe are at risk of opioid overdose

• **REVIVE!**

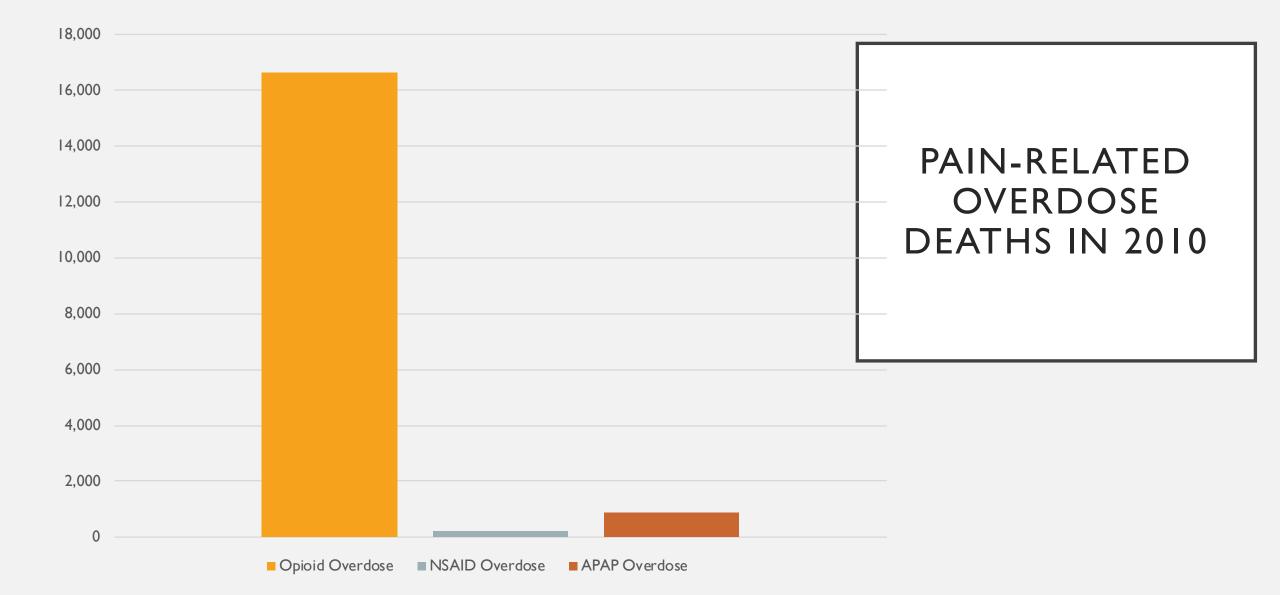
- Virginia's opioid overdose and naloxone education program
- Train's individuals, most often laypersons, to recognize signs of opioid overdose and treat with naloxone
- Provides educational documents

OPIOID BASED PAIN MANAGEMENT

OPIOID-BASED PAIN MANAGEMENT

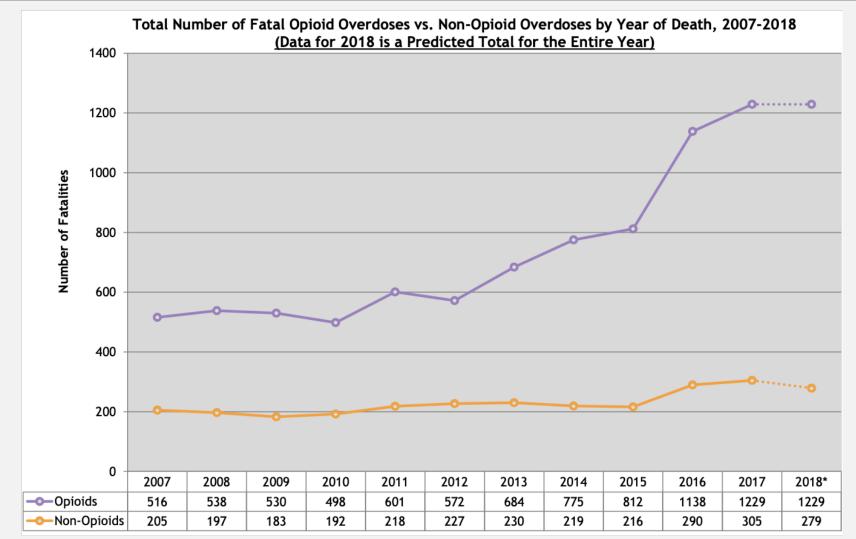
"We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

CDC DIRECTOR TOM FRIEDEN



https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf

OVERDOSE-RELATED DEATHS IN VIRGINIA



http://www.vdh.virginia.gov/content/uploads/sites/18/2019/01/Quarterly-Drug-Death-Report-FINAL-Q3-2018.pdf

CHRONIC PAIN

- Often combination of nociceptive, neuropathic, and centralized pain
- Can present with symptoms similar to acute pain but does not occur in temporal relation with noxious stimuli
- Long-term experience that is often more subjective than objective
- Often exists with other co-morbid conditions such as diabetes or history of stroke

TERMINOLOGY

Opiate

- Derived from the opium poppy, papaver somniferum
- Natural plant alkaloids
 - Morphine
 - Codeine

Opioid

 Has functional and pharmacologic properties of an opiate

OPIOID RECEPTORS

- What
 - Mu (μ), Kappa (K), & Delta (Δ) opioid receptors
 - All are G-Protein Coupled Receptors
- Where
 - Throughout the central and peripheral nervous system on neuronal cells
 - Are also located on macrophage cell types, astrocytes, and in the enteric nervous system of the GI tract
- Agonists vs Partial Agonist vs Antagonist
 - Agonists: Highly selective for opioid receptors, particularly Mu Opioid Receptors
 - Partial Agonist: bind specifically to opioid receptors but have limited activity

Raynor K et al. Pharmacological characterization of the cloned kappa-, delta-, and mu-opioid receptors. *Mol Pharmacol*, **1994**;45:330–334

OPIOID RECEPTORS

Opioid Receptor	Effects	Medications			
M ()	Mu ₁ – Euphoria, supraspinal analgesia, confusion, dizziness, nausea	Fentanyl***, Hydromorphone***, Methadone***, Morphine***, Sufentanil***			
Mu (μ)	Mu ₂ – Respiratory depression, cardiovascular and GI effects, miosis, urinary retention	Naloxone			
Delta (∆)	Spinal analgesia, cardiovascular depression, decreased brain and myocardial oxygen demand	Sufentanil* Naloxone			
Карра (К)	Spinal analgesia, dysphoria, psychomimetic effects, feedback inhibition of endorphin system	Hydromorphone*, Morphine*, Sufentanil* Naloxone			
In potency: * < ** < *** Antagonist: (-) Agonist: *					

Terrie. Pharmacy Times, 2011; *Mol Pharmacol*, **1994**;45:330–334.

OPIOID SIDE EFFECTS

- Antitussive
 - Inhibits cough reflex
- Nausea & vomiting
 - Impact on medulla
- Impaired stress response and reduced libido
 - Inhibits the release of several pituitary hormones
 - This reduces the level of cortisol and sex hormones
 - Increased prolactin (reduces sex drive in males)
- Respiratory depression
 - Brainstem becomes insensitive to increases in carbon dioxide
 - All patients should be co-prescribed naloxone

- Reduces gut motility
 - Causes nausea, constipation, and anorexia with weight loss
 - Can cause severe constipation and toxic megacolon
 - All patients should be co-prescribed stool softener and/or stimulant
- Orthostatic Hypotension
 - Due to histamine release and peripheral blood vessel dilation
- Sedation and slowed mentation
- Urinary Retention

OPIOID SIDE EFFECTS

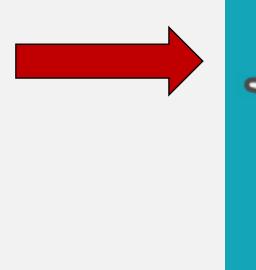
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OPIOID OVERDOSE

Signs & Symptoms of Overdose

- Shallow, slow respirations
- Pupillary miosis
- Bradycardia
- Hypothermia
- Stupor/coma/unresponsiveness



Reverse opioid overdose with Naloxone



OPIOID OVERDOSE

Reverse opioid overdose with Naloxone

Naloxone is...

- Opioid Antagonist
- Administration can precipitate opioid withdrawal
- Available in different formulations
 - Intravenous for in-hospital use
 - Nasal spray for community
- Co-prescribe with opioids if patient is at risk for overdose



OPIOID SIDE EFFECTS

- Desensitization
 - Acute tolerance that occurs at the specific receptor and then disappears when the drug is cleared
- Tolerance
 - Decrease in the apparent effectiveness
 - Occurs with repeated or continuous administration
 - Can occur over days to weeks
 - Tolerance occurs at different rates for different effects
 - CNS effects vs GI effects
- Cross-tolerance
 - Reduced response to another agent of the same class
 - Never complete between opioids
- Dependence
 - When cessation of the drug results in withdrawal

Pain Management. In: Wells BG, DiPiro JT, Schwinghammer TL, DiPiro CV. eds. *Pharmacotherapy Quick Guide* New York, NY: McGraw-Hill

OPIOID SIDE EFFECTS

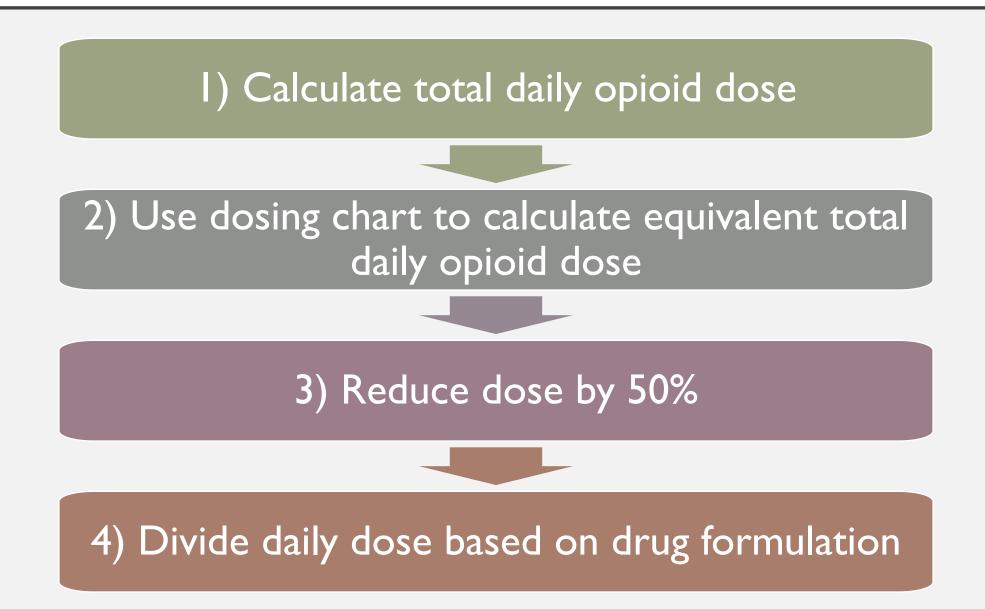
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- Reduced response (pain control, side effects) between agents
- Can use this effect to your patients benefit by switching between agents
 - Never transition to equal doses, instead reduce dose by ~50% when transitioning

CONVERTING BETWEEN OPIOIDS



CDC RECOMMENDATIONS FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

When to initiate or continue opioids for chronic pain

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

Assessing risk and addressing harm

https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf

CDC RECOMMENDATIONS FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

When to initiate or continue opioids for chronic pain

- <u>Opioids are not first line for</u> <u>chronic pain</u>
- Establish and measure goals for pain and function
- Discuss risks, benefits, and nonopioid therapies with patients

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

- Use immediate-release opioids when initiating
- Start low and go slow
- Start at the lowest effective dose
- Reassess benefit and risk when dosage increases to > 50 MME/day
- Avoid > 90 MME/day must have careful justification
- Follow-up and re-evaluate risk of harm

Assessing risk and addressing harm

- <u>Evaluate risk factors for</u> <u>opioid-related harm</u>
- <u>Check PDMP</u>
- Use urine drug testing
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder

OPIOIDS ARE NOT FIRST LINE



- Physical Options
 - Physical manipulation
 - Heat or Ice
 - Massage
 - Acupuncture
 - Exercise
- Psychologic Options
 - Biofeedback
 - Cognitive behavioral therapy
 - Relaxation

- Exercise therapy and Physical therapy
 - Immediate and sustained improvement in function
 - Helpful for hip and knee osteoarthritis, low back pain, fibromyalgia
 - Can include aerobic, aquatic, and resistance exercises
- Multimodal therapies
 - Combines physical therapy with psychological therapy
- Transcutaneous electrical nerve stimulation (TENS)



usual care, placebo, sham, attention control, or waitlist						
Intervention	Function Short-Term	Function Intermediate- Term	Function Long-Term	Pain Short-Term	Pain Intermediate- Term	Pain Long-Term
	Effect Size SOE	Effect Size SOE	Effect Size SOE	Effect Size SOE	Effect Size SOE	Effect Size SOE
Exercise	slight +	none +	none +	slight ++	moderate +	moderate +
Psychological Therapies: CBT primarily	slight ++	slight ++	slight ++	slight ++	slight ++	slight ++
Modalities: Short- Wave Diathermy	insufficient evidence	no evidence	no evidence	insufficient evidence	no evidence	no evidence
Physical Modalities: Ultrasound	insufficient evidence	no evidence	no evidence	none +	no evidence	no evidence
Physical Modalities: Low- Level Laser Therapy	slight +	none +	no evidence	moderate +	none +	no evidence
Manual Therapies Spinal Manipulatio		slight +	no evidence	none +	slight ++	no evidence
Manual Therapies Massage	s: slight ++	none +	no evidence	slight ++	none +	no evidence
Manual Therapies Traction	s: none +	no evidence	no evidence	none +	no evidence	no evidence
Mindfulness Practices: MBSR	none +	none +	none +	slight ++	slight +	none +
Mind-B∖ody Practices: Yoga	slight ++	slight +	no evidence	moderate +	moderate ++	no evidence
Acupuncture	slight +	none +	none +	slight ++	none +	slight +
Multidisciplinary Rehabilitation	slight +	slight +	none +	slight ++	slight ++	none +

Table 47. Chronic low back pain: effects of nonpharmacological interventions compared with usual care, placebo, sham, attention control, or waitlist

Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review. Comparative Effectiveness Review No. 209. Short-Term: 1 to <6 months; Intermediate-Term: ≥6 to <12 months; Long-Term: ≥12 months Effect Size: none, slight/small, moderate, or large improvement

Strength of Evidence: + = low, ++ = moderate, +++ = high

CBT = cognitive-behavioral therapy; MBSR = mindfulness-based stress reduction; none = no effect/no statistically significant effect; SOE = strength of evidence.

EVALUATE FOR RISK

FOR USE IN PATIENTS THAT ARE BEING CONSIDERED FOR LONG-TERM OPIOID THERAPY

- ORT: Opioid risk tool
- SOAPP: Screener and opioid assessment for patients with pain
- SISAP: Screening instrument for substance abuse potential
- DIRE: Diagnosis, intractability, risk, and efficacy score
- SBST Risk with chronic low back pain

FOR USE TO ASSESS MISUSE ONCE OPIOID TREATMENT IS INITIATED

- PDUQ-p: Prescription drug use questionnaire-patient
- COMM: Current opioid misuse measure
- PMQ: Pain medication questionnaire
- PADT: Pain assessment and documentation tool
- ABD: Addiction behavior Checklist

OPIOID RISK TOOL

Item Description	Female	Male
 Family history of substance abuse Alcohol Illegal drugs Rx Drugs 	 2 4	3 3 4
 Personal history of substance abuse Alcohol Illegal drugs Rx Drugs 	3 4 5	3 4 5
Age between 16 – 45 years	I	I.
History of preadolescent sexual abuse	3	0
 Psychological disease ADD, OCD, Bipolar, Schizophrenia Depression 	2 I	2 I

- Tool to help physicians predict which patients may develop aberrant behaviors related to opioids for chronic pain
- Self-reported assessment
- Validated
 - 95% in the low risk category did not display aberrant behaviors
 - 91% in the high risk category did display aberrant behaviors
 - Good for use in both males in females
 - High specificity and sensitivity
- Scores
 - 0 3: Low risk
 - 4 7: Moderate risk
 - \geq 8: High risk

SCREENER AND OPIOID ASSESSMENT FOR PAIN PATIENTS- REVISED (SOAPP-R)

1. How often do you have mood swings?
2. How often have you felt a need for higher doses of medication to treat your pain?
3. How often have you felt impatient with your doctors?
4. How often have you felt that things are just too overwhelming that you can't handle them?
5. How often is there tension in the home?
6. How often have you counted pain pills to see how many are remaining?
7. How often have you been concerned that people will judge you for taking pain medication?
8. How often do you feel bored?
9. How often have you taken more pain medication than you were supposed to?
10. How often have you worried about being left alone?
11. How often have you felt a craving for medication?
12. How often have others expressed concern over your use of medication?
13. How often have any of your close friends had a problem with alcohol or drugs?
14. How often have others told you that you have a bad temper?
15. How often have you felt consumed by the need to get pain medication?
16. How often have you run out of pain medication early?
17. How often have others kept you from getting what you deserve?
18. How often, in your lifetime, have you had legal problems or been arrested?
19. How often have you attended an AA or NA meeting?
20. How often have you been in an argument that was so out of control that someone got hurt?
21. How often have you been sexually abused?
22. How often have others suggested that you have a drug or alcohol problem?
23. How often have you had to borrow pain medications from your family or friends?
24. How often have you been treated for an alcohol or drug problem?

- 24 question assessment provided to patients to determine their risk for aberrant medication-related behavior
- Tool has been validated and crossvalidated in chronic pain patients
- Questions are ranked 0 (never) to 4 (very often) and the total score is tallied
- A score \geq 18 is considered positive
- SOAP-R is sensitive, better at identifying those who are at a high risk

EVALUATE

START BACK SCREENING TOOL (SBST)

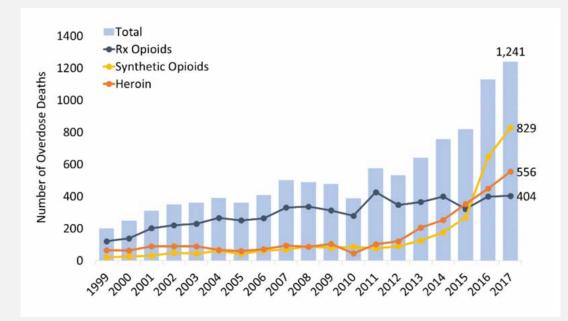
- 9-item questionnaire
- Groups patients into 3 categories of risk of poor outcome defined as persistent, disabling systems
- Scoring
 - 0 3: Low risk
 - 4 9: Medium risk
 - Distress subscale looks at just the last five items on the scale; Score of 4– 5 represents high risk

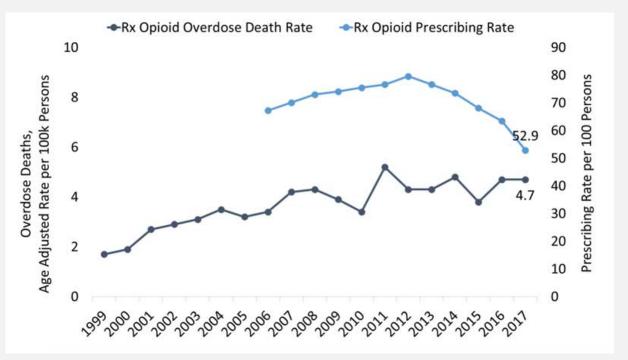
ASSESS PAIN AND FUNCTION (PEG SCORE)

- Three questions that are ranked on a scale of 0 10
 - What number from 0 10 best describes your pain in the past week?
 - What number from 0 10 describes how, during the past week, pain has interfered with your **enjoyment** of life?
 - What number from 0 10 describes how, during the past week, pain has interfered with your general activity?
- PEG Score = average of three scores
- 30% reduction in score is considered clinically meaningful
- Used to track improvement

OPIOID WITHDRAWAL & TAPERING

WHAT DOES THE OPIOID CRISIS LOOK LIKE IN VIRGINIA?





SHOULD WE THEN BE HELPING PATIENTS "GET OFF" OPIOIDS?

FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering

FDA Drug Safety Communication

f Share 🈏 Tweet 🛛 in Linkedin 🔄 Email 🔒 Print

Safety Announcement

~

[4-9-2019] The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

OPIOID WITHDRAWAL

Initial withdrawal symptoms

- Begins within 8 10 hours after last dose depending on medication and formulation
- Acute course has duration of 7 – 10 days

Protracted abstinence side effects

• Duration: 26 - 30 weeks

OPIOID WITHDRAWAL

Initial withdrawal symptoms

- Lacrimation
- Rhinorrhea
- Yawning
- Sweating

Symptoms increase to include

- Restless sleep
- Weakness
- Chills
- Gooseflesh
- Nausea and vomiting
- Muscle aches
- Involuntary movements
- Hyperpnea
- Hyperthermia
- Hypertension

Protracted abstinence side effects

- Hypotension
- Bradycardia
- Hypothermia
- Mydriasis
- Decreases responsiveness of respiratory center to carbon dioxide

WHEN TO CONSIDER TAPERING OPIOIDS TO A REDUCED DOSE OF DISCONTINUATION

Patient requests a dose reduction	Patient does not have clinically meaningful improvement in pain and function	Patient is on dosages of ≧ 50 MME/day without benefit
Patient is receiving both opioids and benzodiazepines	Patient displays signs of substance use disorder	Patient experiences an overdose or serious adverse event
Patient shows warning signs or risks for overdose https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf	 Adverse effects At minimum dose that also produces pain relief If opioid rotation not beneficial 	Impacts quality of life and daily functioning • Can be physical, emotional, or social

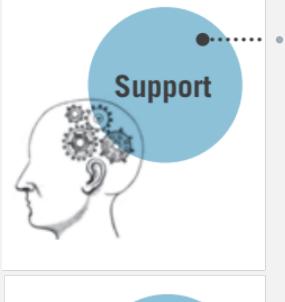
HOW TO TAPER OPIOIDS



• Decrease by 10% per week

- May consider slower reduction (10% per month) in patients who have been using opioids for an extended duration
- Increased risk of overdose if patients quickly return to previously higher dose
- Adjust rate and duration based on patient's response
 - Do not reverse the taper
 - Can pause the taper while managing withdrawal symptoms
 - Can stop the opioids when the dose is the smallest possible and taken less than once a day

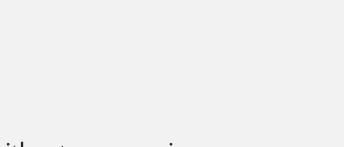
HOW TO TAPER OPIOIDS





Support

- Patients should received psychosocial support
 - Mental health providers
 - Naloxone for overdose prevention
- Coordinate with specialists as needed
 - Patients Patients at increased risk of harm should especially have multiple treatment experts on board
 - Pregnant women
 - Patients with opioid use disorder
- Encourage
 - Most patients have improved function without worse pain
 - Some patients even have improvement in pain after a taper
 - The pain can get worse briefly first



Consult



TE had a farming accident 6 months ago that resulted in the loss of his right lower leg (right below-the-knee amputation) in addition to a compound fracture in his left femur. He has been taking Oxycontin XR 40 mg BID plus Oxycodone IR 10 mg Q6h PRN which he usually takes twice daily between his long-acting tablets. He has expressed a desire to wean off his opioid pain therapy because he worries that is impedes his ability to participate in physical therapy. His pain is currently controlled.

Week	Total Daily Dose	Regimen
Week 0	100 mg of Oxycodone	Oxycontin XR 40 mg BID plus Oxycodone IR 10 mg Q6h PRN (usually takes twice daily)
Week I	90 mg of Oxycodone	Oxycontin XR 40 mg BID plus Oxycodone IR 10 mg Q24h PRN
Week 2	80 mg of Oxycodone	Oxycontin XR 40 mg BID
Week 3	70 mg of Oxycodone	Oxycontin XR 30 mg qAM and 40 mg qPM
Week 4	60 mg of Oxycodone	Oxycontin XR 30 mg BID
Week 5	50 mg of Oxycodone	Oxycontin XR 20 mg qAM and 30 mg qPM
Week 6	40 mg of Oxycodone	Oxycontin XR 20 mg BID
Week 7	30 mg of Oxycodone	Oxycontin XR 10 mg qAM and 20 mg qPM
Week 8	20 mg of Oxycodone	Oxycontin XR 10 mg BID
Week 9	10 mg of Oxycodone	Oxycontin XR 10 mg QD
Week 10	No Oxycodone	No Oxycodone

Week 3 of TE's opioid taper, he presents to your office with symptoms of withdrawal. He states that after he decreased last week, he had trouble sleeping, body aches, and nausea and vomiting. He says that they were starting to improve but then when he went dropped down to the next dose, the symptoms came back but now also include gooseflesh and sweating.

What options do you have to help TE continue in his taper?

- Do not increase his oxycodone back to a previous dose to increased risk of overdose
 - Can slow the taper to a reduction every 2-4 weeks rather than every week
- Limited data on the usefulness of alpha-2 adrenergic agonists such as clonidine or muscle relaxers such as tizanidine

Increased Pain

Dropout

Relapse

Increased Pain

- Hyperalgesia is brief and limited after opioid discontinuation
- Patients reported improved functioning and improved pain

Dropout

Relapse

Berna C, Kulich Rj, Rathmell JP. Tapering long-term opioid therapy in chronic noncancer pain. Mayo Clinic Proc, 2015; 90(6): 828-842.

Increased Pain

Dropout

- Symptoms of depression is a risk factor for drop out
- An option for opioid maintenance therapy may improve drop out rates
- Mandatory tapering may increase risk of dropout

Relapse

Increased Pain

Dropout

Relapse

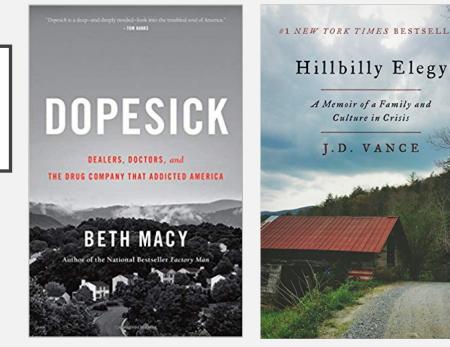
- Depressive symptoms and high pain scores are associated with an increased risk of relapse
- Posttreatment depression increases risk
- Low pain scores at the end of a taper is associated with continued abstinence

RESOURCES

- Books
 - Dopesick by Beth Macy
 - Hillbilly Elegy by J.D.Vance

Documentaries

- Do No Harm Media Policy Center and Physicians for responsible opioid prescribing
- Understanding the Opioid Epidemic PBS
- Warning: This Drug May Kill You HBO
- Recovery Boys Netflix







QUESTIONS?

Thank you!

HOW TO MANAGE CHRONIC PAIN IN THE MIDDLE OF AN OPIOID EPIDEMIC

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