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Evolution, Not Revolution: Opioid Safety in 2021

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Disclosure

- No relevant financial disclosures
- The views expressed are those of the speakers alone and due not reflect the views or beliefs of the Department of Veterans Affairs or the Department of Defense

Learning Objectives

- Discuss at least two best practices for institutional pain care transformation and opioid stewardship
- Name two strategies VA has adopted to address the opioid epidemic
- Name a life saving treatment that should be considered when managing chronic opioid therapy

Background

- What actually is the Opioid Safety Initiative (OSI)?
  - A mechanism to assess and manage risk
  - It provides clinicians:
    - Education to weigh risks/benefits/alternatives
    - Guidelines that improve risk mitigation strategies
    - Awareness of integrative treatments to manage pain
  - It provides the healthcare system:
    - A mechanism to audit and improve
    - A mechanism to share best practices
    - A mechanism to identify areas of risk

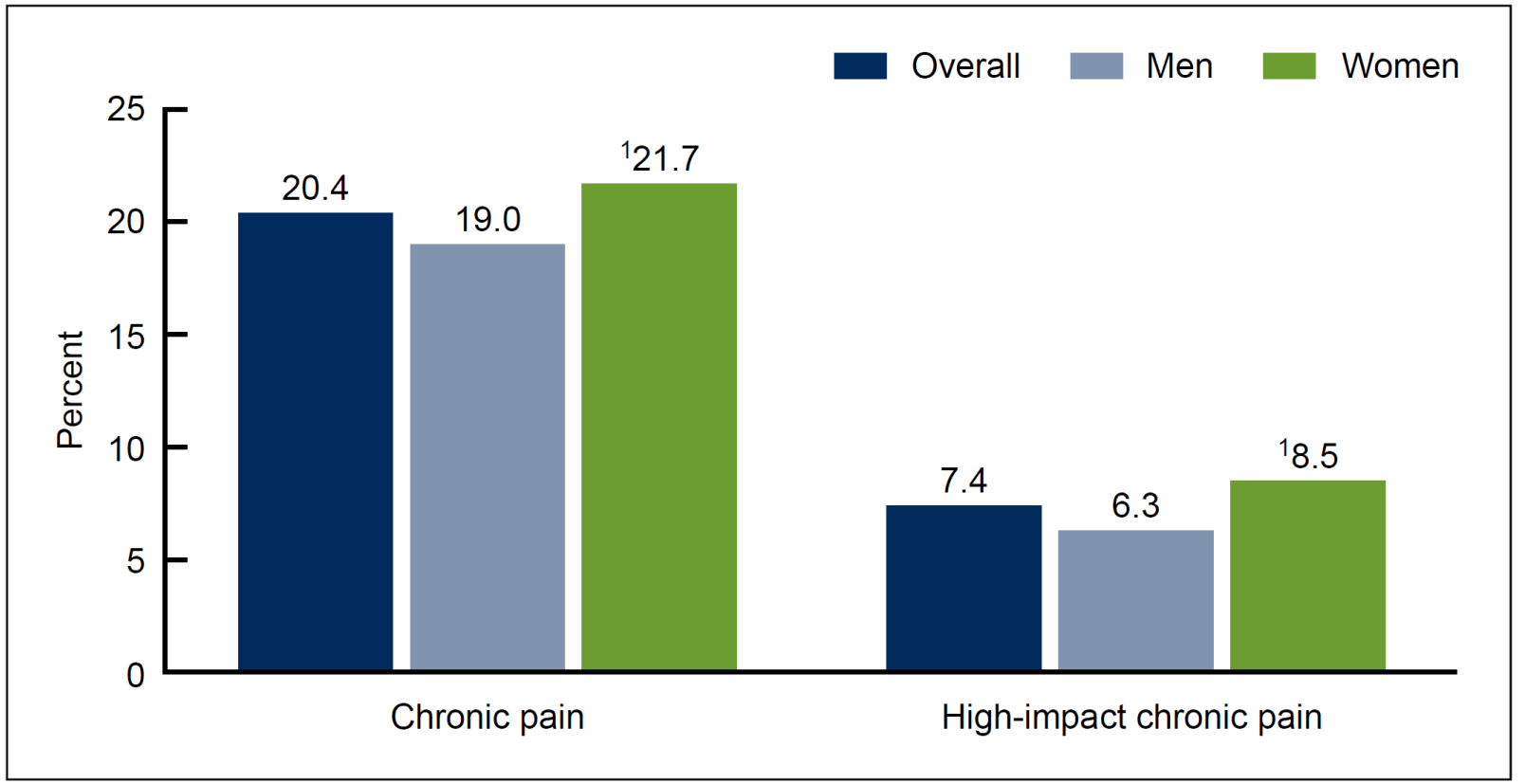
Background

- Addressing the opioid crisis requires us to move beyond focusing solely on opioids
- The factors that increase risk for prescribing opioids are also associated with risk when opioids are no longer a part of the treatment plan (i.e. Mental health disorders, medical complexity, medications)
- The OSI dashboard, STORM, and PDMP, can identify and stratify patients by risk
- For those identified at risk, OSI helps with mitigation (i.e. Tapering, OEND, M-OUD)
- Process improvement helps guide, evaluate, and redesign care to improve safety

Oliva EM, Bowe T, Manhapra A, Kertesz S, Hah JM, Henderson P, Robinson A, Paik M, Sandbrink F, Gordon AJ, Trafton JA. Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation. BMJ. 2020 Mar 4;368:m283

Is Chronic Pain Still an Issue?

Figure 1. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, overall and by sex: United States, 2019



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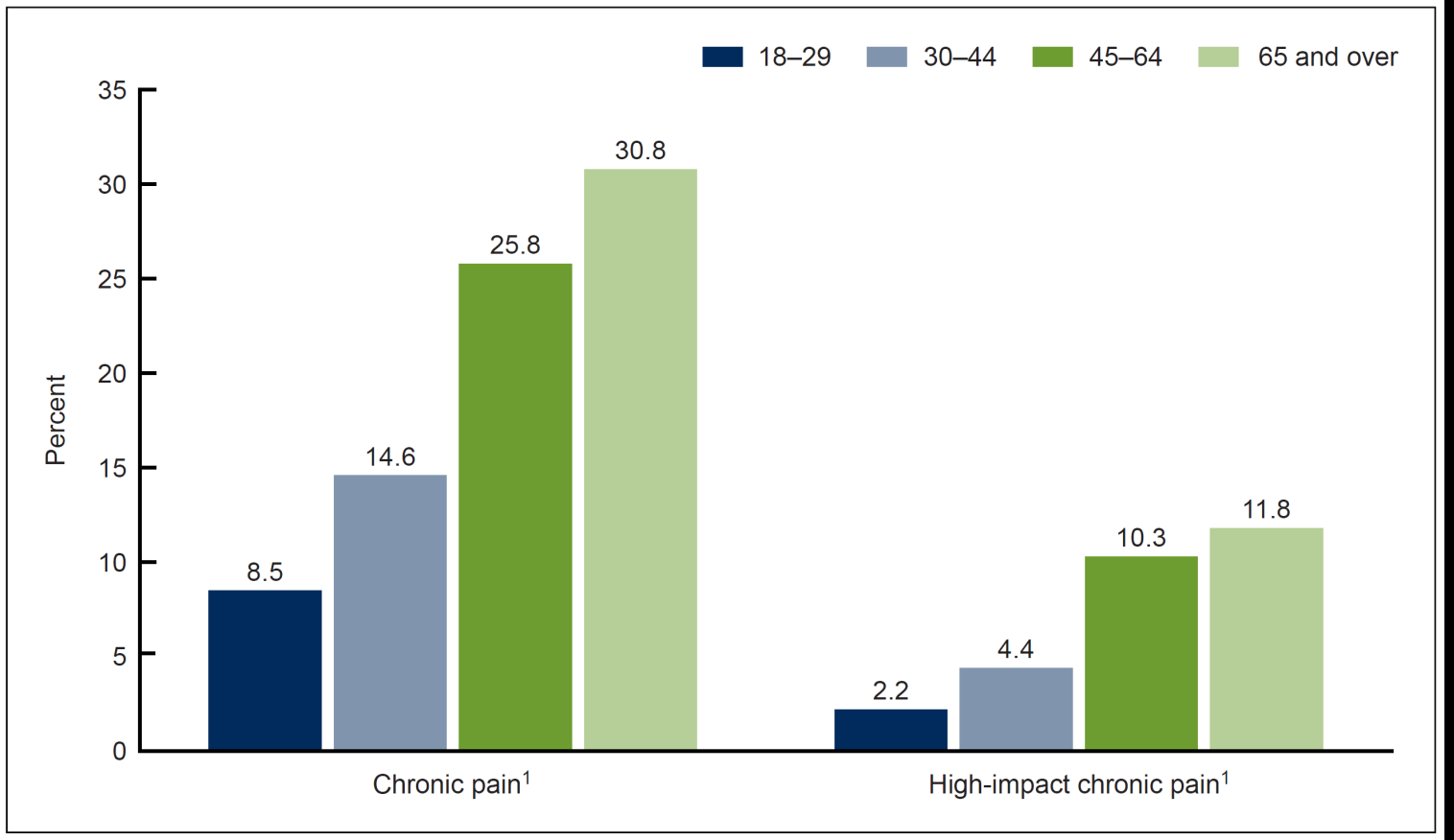
Zelaya CE, Dahlhamer JM, Lucas JW, Connor EM. Chronic pain and high-impact chronic pain among U.S. adults, 2019. NCHS Data Brief, no 390. Hyattsville, MD: National Center for Health Statistics. 2020

Does Age Matter?

Figure 2. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, by age group: United States, 2019



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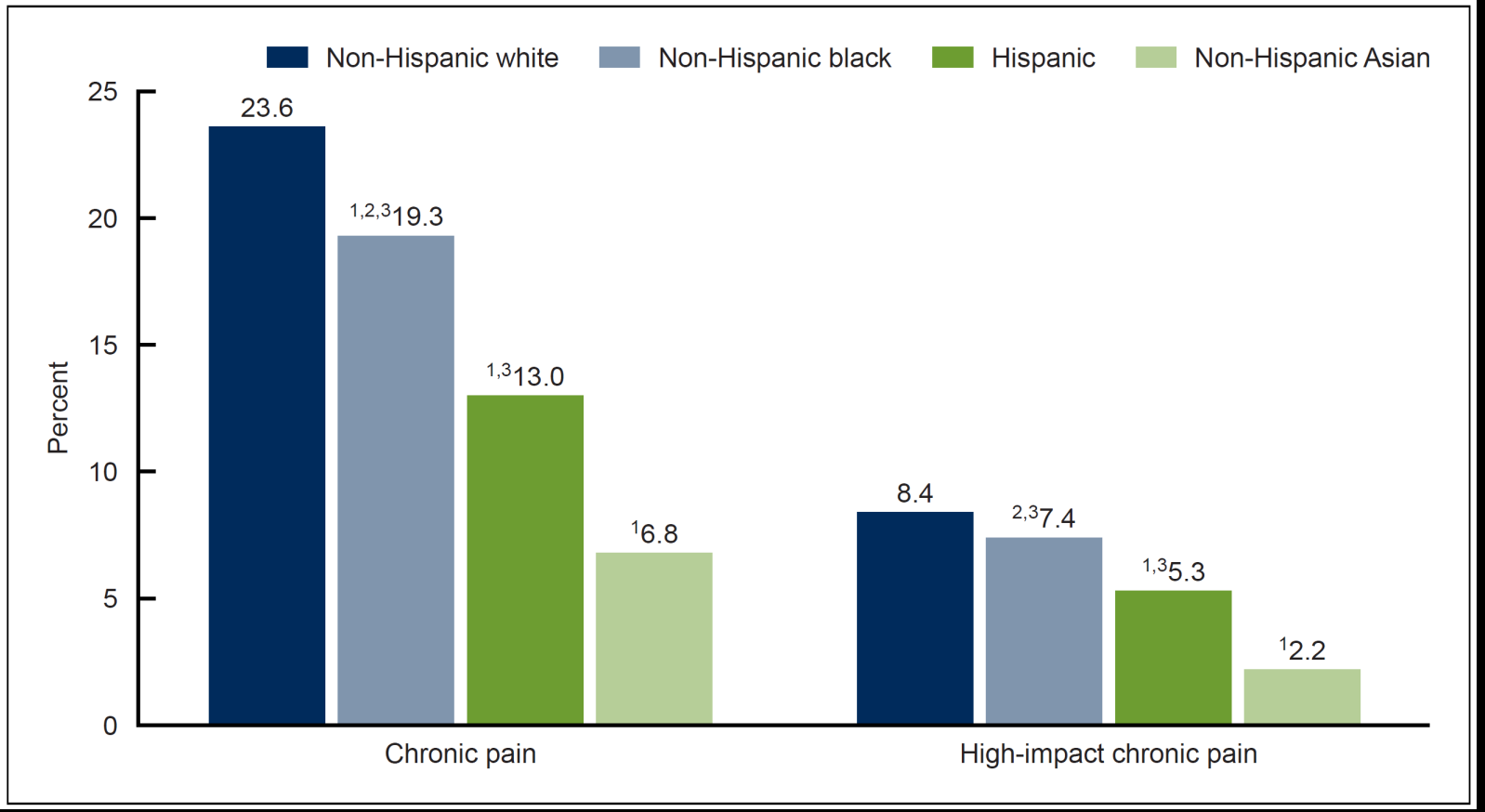
Zelaya CE, Dahlhamer JM, Lucas JW, Connor EM. Chronic pain and high-impact chronic pain among U.S. adults, 2019. NCHS Data Brief, no 390. Hyattsville, MD: National Center for Health Statistics. 2020

Which Groups are Affected?

Figure 3. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, by race and Hispanic origin: United States, 2019



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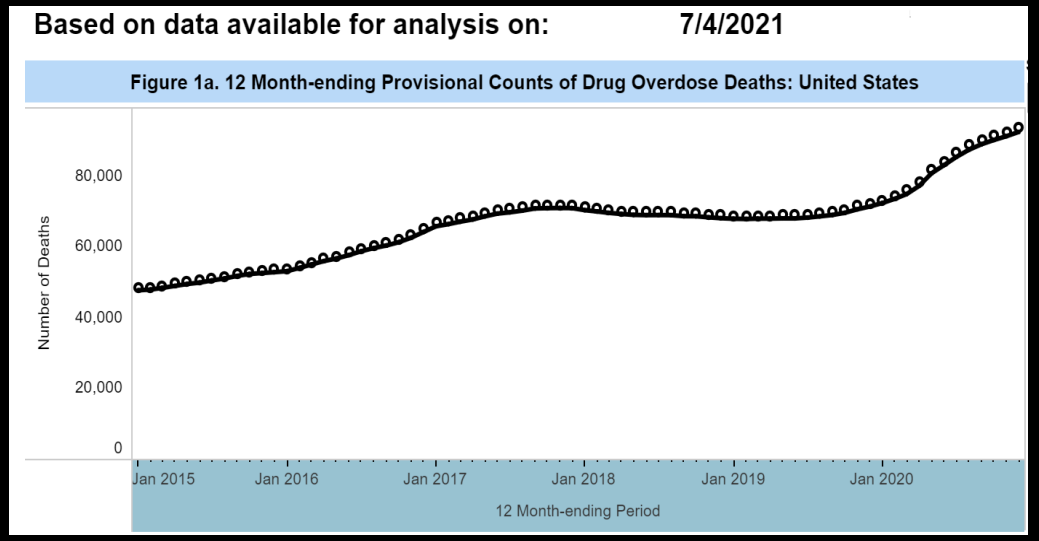
Zelaya CE, Dahlhamer JM, Lucas JW, Connor EM. Chronic pain and high-impact chronic pain among U.S. adults, 2019. NCHS Data Brief, no 390. Hyattsville, MD: National Center for Health Statistics. 2020

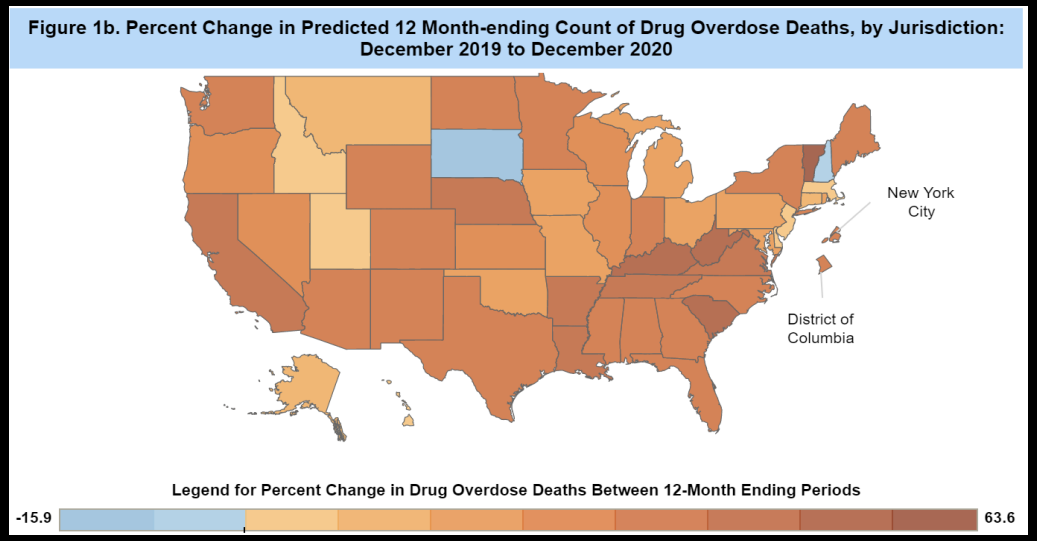
What constitutes Opioid Safety?

- Universal precautions
  - Informed consent for opioid management
  - Management of morphine equivalent dose
  - Urine toxicology screens
  - Routine surveillance of PDMP
- Added elements
  - Opioid Education Naloxone Distribution (OEND)
  - Prescription Drug Monitoring Program Solution (PDMP button)
  - Stratification Tool for Opioid Risk Mitigation (STORM)
  - Medication for Opioid Use Disorder (m-OUD)
  - Opioid tapering strategies

Centers for Disease Control and Prevention

- The most drug overdose deaths in a year
- The most deaths from opioid overdoses
- The most overdose deaths from stimulants (i.e. methamphetamine)
- The most deaths from fentanyls





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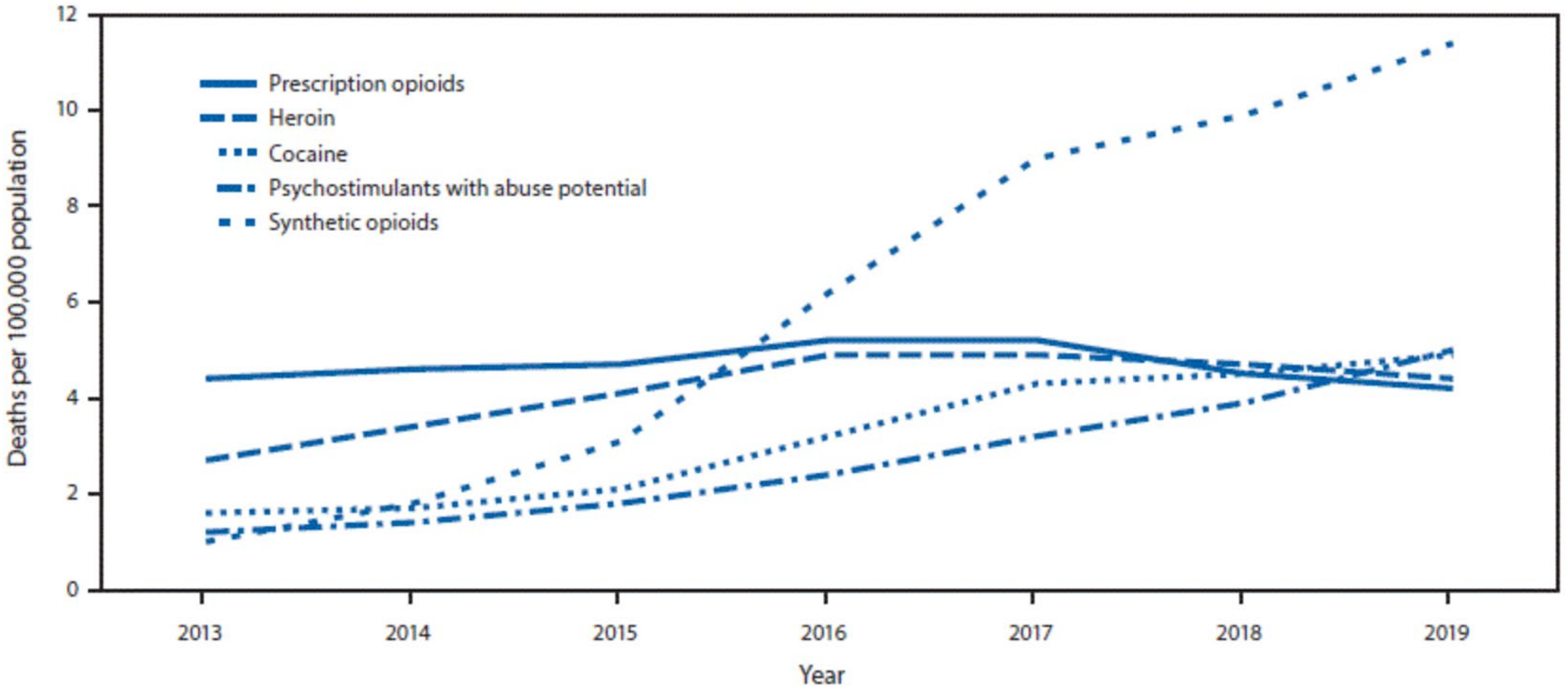
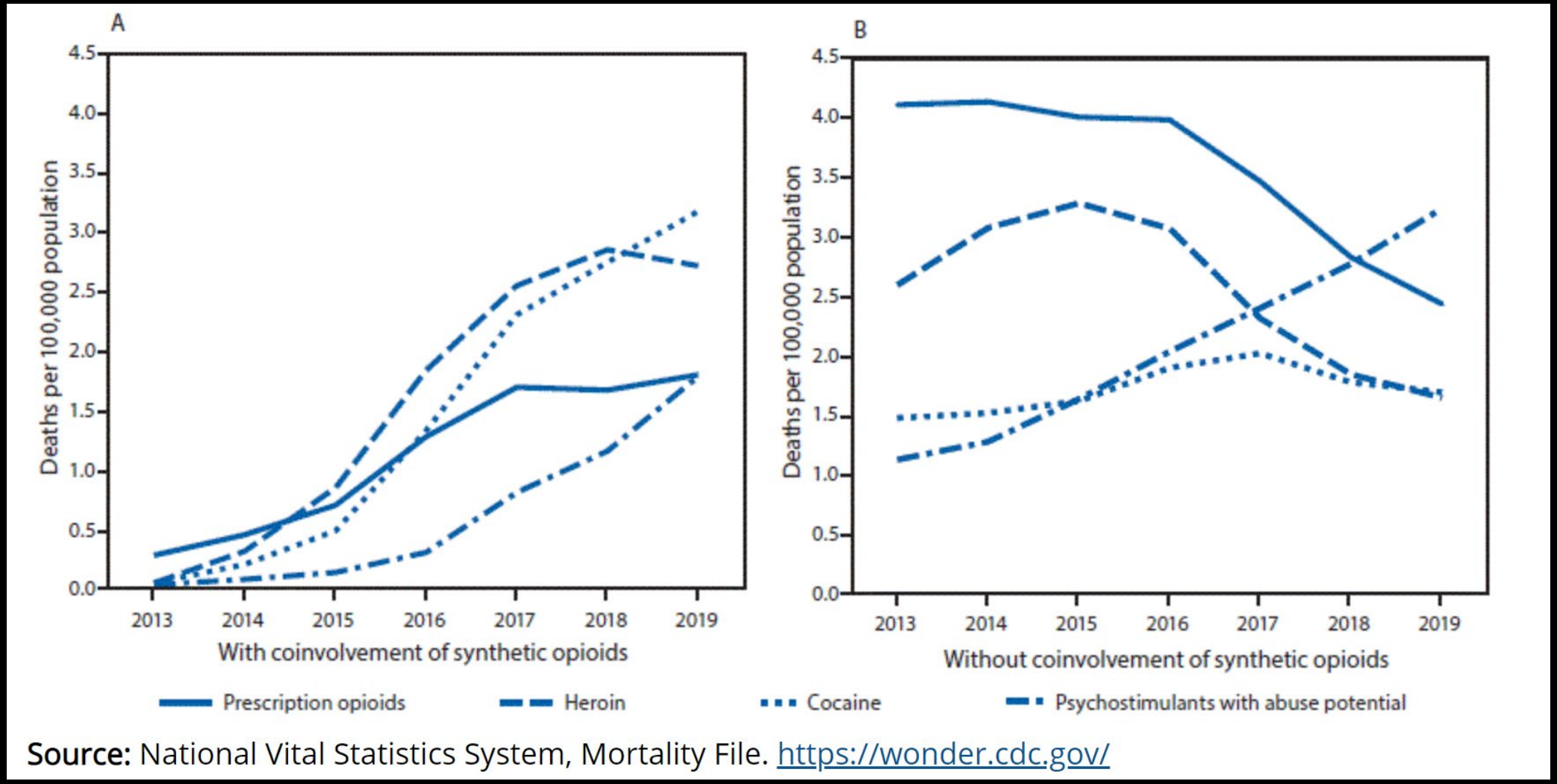
Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2021



Source: National Vital Statistics System, Mortality File. https://wonder.cdc.gov/

FIGURE 1. Age-adjusted rates* of drug overdose deaths† involving prescription opioids, heroin, cocaine, psychostimulants with abuse potential, and synthetic opioids other than methadone, — United States, 2013–2019



Source: National Vital Statistics System, Mortality File. https://wonder.cdc.gov/

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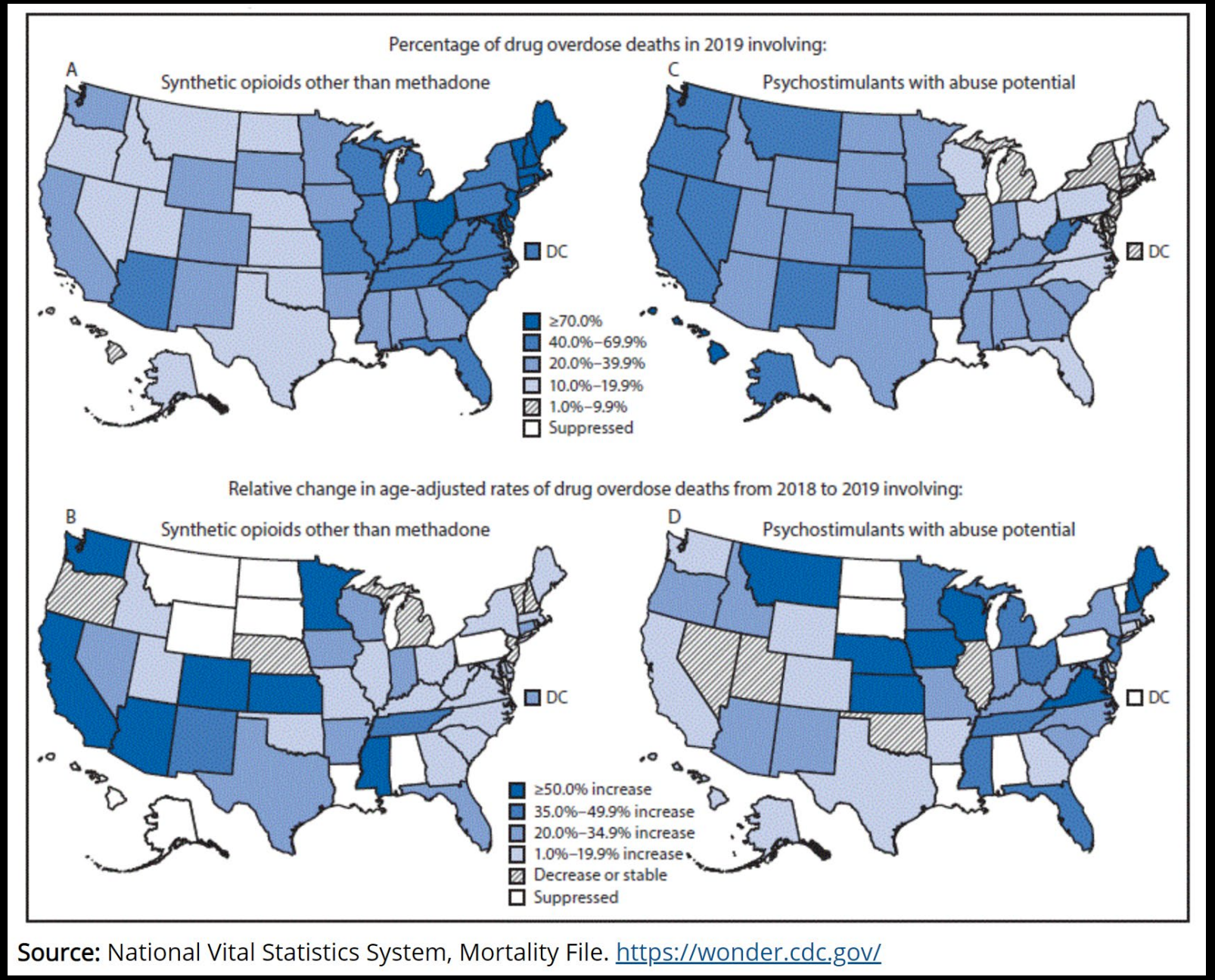
FIGURE 2. Age-adjusted rates of drug overdose deaths involving prescription opioids, heroin, cocaine, and psychostimulants with abuse potential, with (A) and without (B) synthetic opioids other than methadone, United States, 2013–2019



Source: National Vital Statistics System, Mortality File. https://wonder.cdc.gov/

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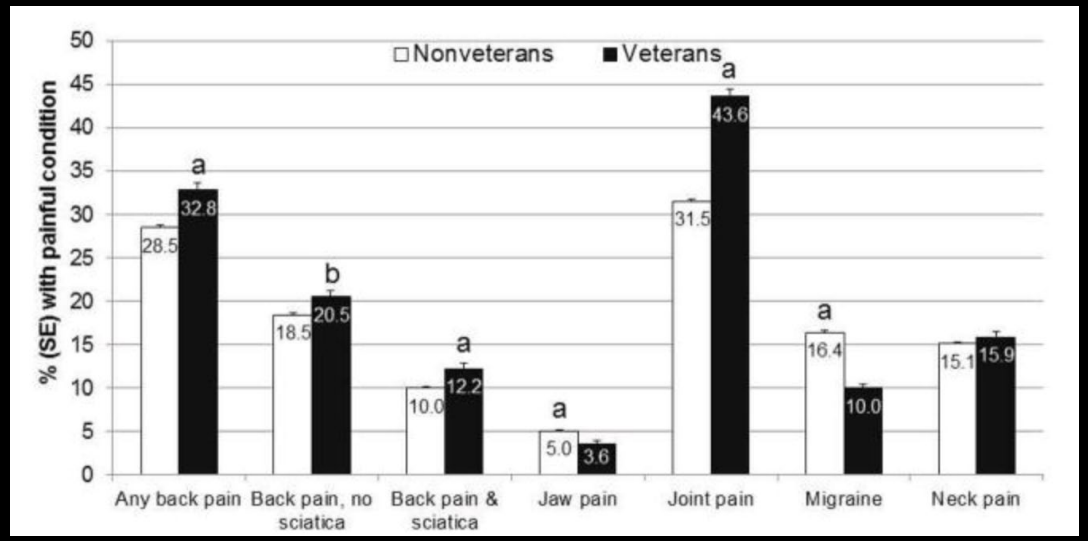
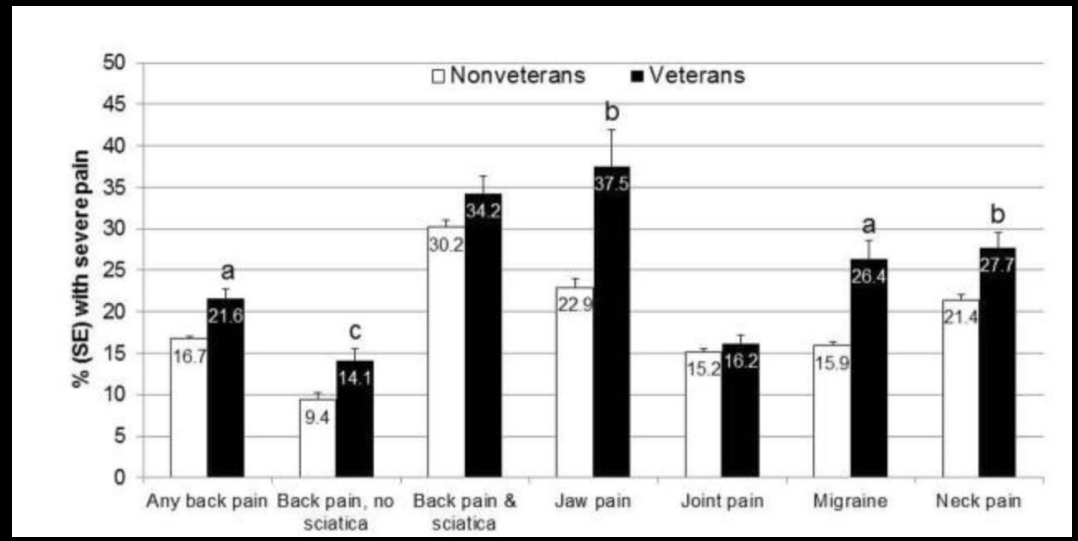
FIGURE 3. Percentage and relative change in age-adjusted rates, of drug overdose deaths involving synthetic opioids other than methadone (A, B) and psychostimulants with abuse potential (C, D)— United States, 2018–2019

What about Veterans?

- Chronic pain is more common and more severe in Veterans
- Pain is the most common factor among Veterans who die by suicide
- Veterans are 1.5x more likely to die of OD compared to the general population
- Mental health comorbidities often result in high impact and severe pain





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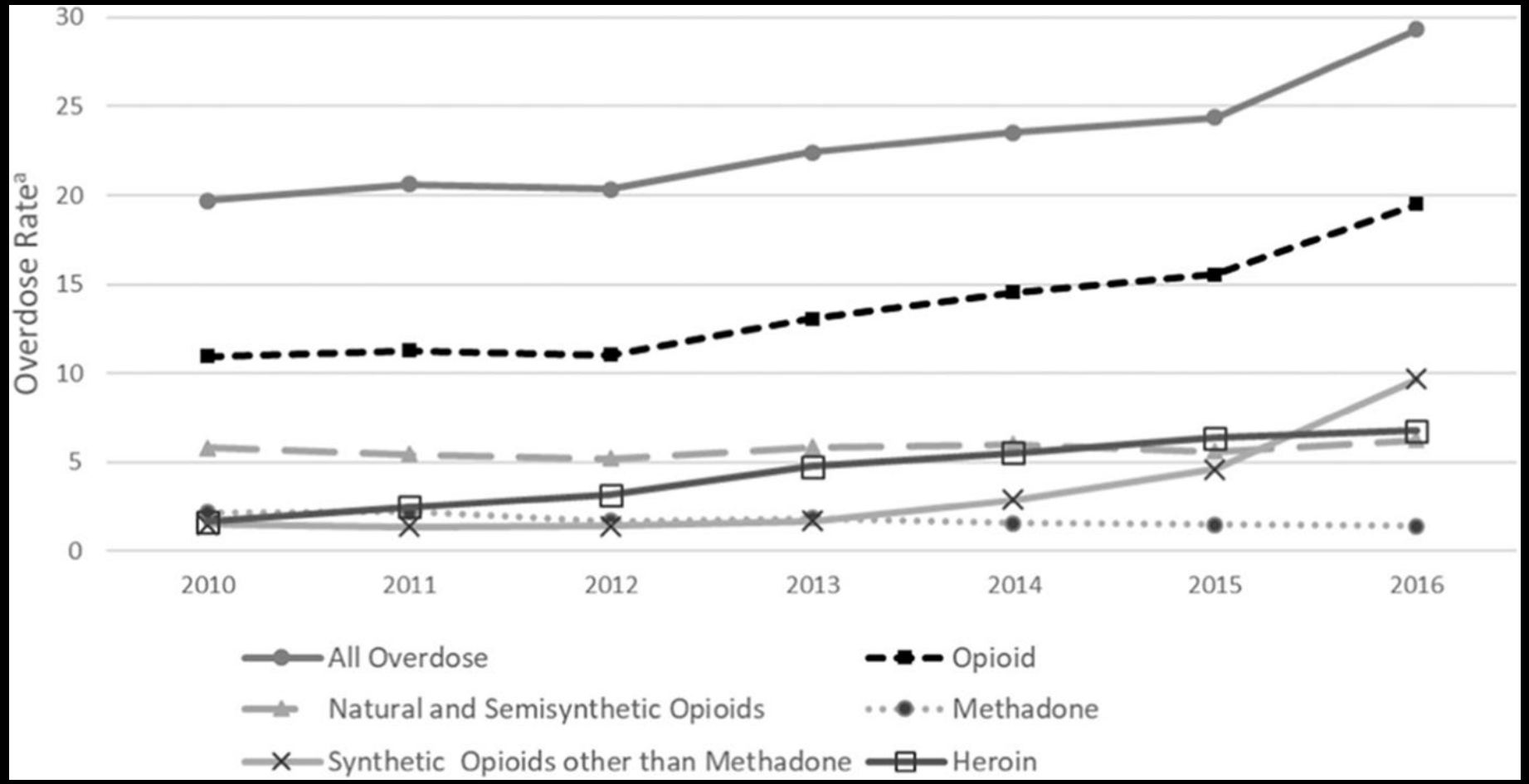
Nahin RL. Severe Pain in Veterans: The Effect of Age and Sex, and Comparisons With the General Population. J Pain. 2017;18(3):247-254.

What about Veterans?



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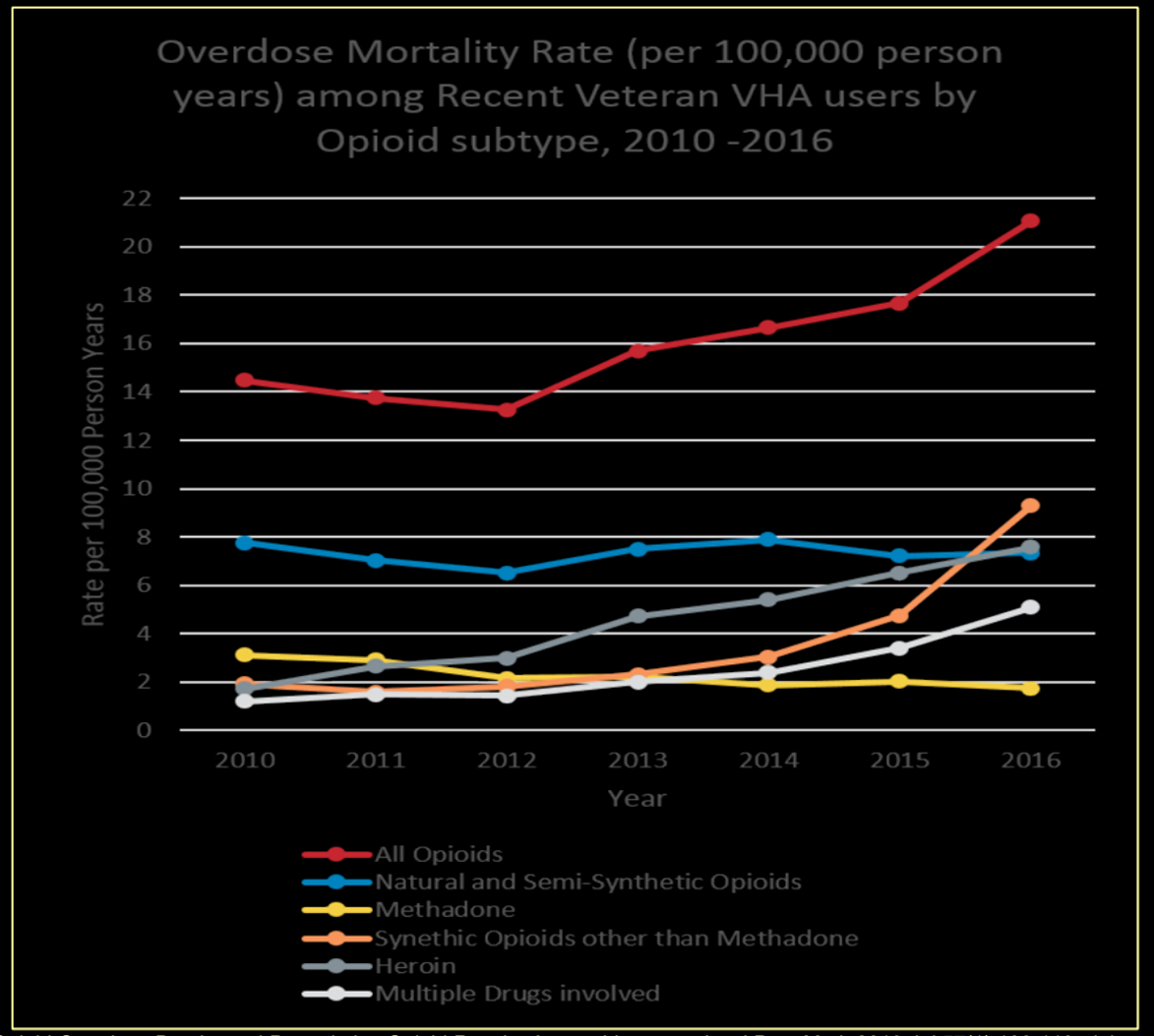
Peltzman, T., Ravindran, C., Schoen, P.M., Morley, S.W., Drexler, K., Katz, I.R. and McCarthy, J.F. (2020), Brief Report: Opioid-Involved Overdose Mortality in United States Veterans. Am J Addict, 29: 340-344

What about Veterans?

- 6,485 Veterans receiving care in VHA died from an opioid overdose between 2010 and 2016, with increasing rate over that time period

- In 2016 there were 1,271 deaths of Veterans in VHA, or 3.5 per day
  - This is 1.5x greater than the general population opioid overdose mortality rate
  - 62% of VHA Veteran overdoses involved opioids



Lin LA, Peltzman T, McCarthy JF, Oliva EM, Trafton JA, Bohnert ASB. Changing Trends in Opioid Overdose Deaths and Prescription Opioid Receipt Among Veterans. Am J Prev Med. 2019 Jul;57(1):106-110. doi: 10.1016/j.amepre.2019.01.016. Epub 2019 May 22. PMID: 31128955.

Risk factors for OD and OUD

- Opioid prescription, including:
  - Dose and Duration
  - Type (Extended-Release/Long-Acting forms)
- Interaction with other medication/drugs, such as sedative hypnotics

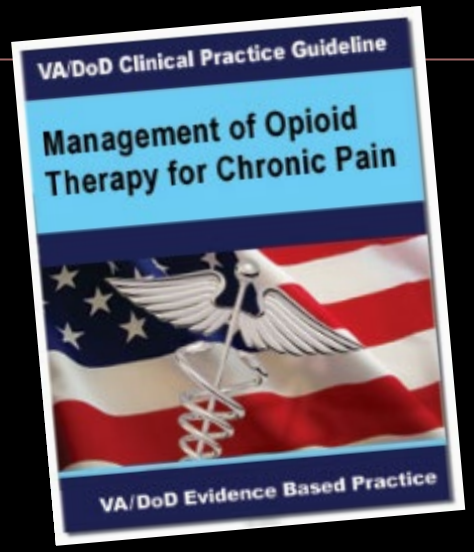
Prescribing factors

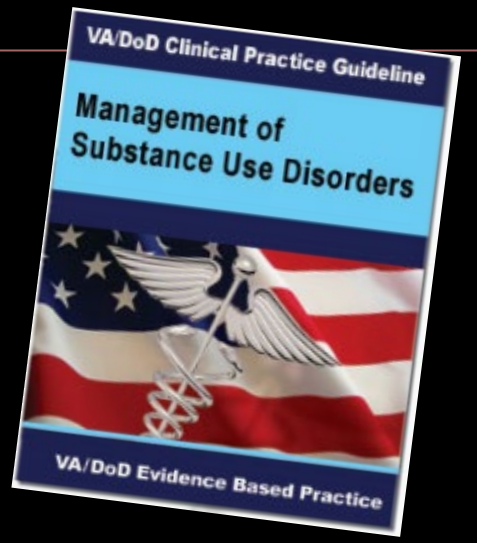
- Medical comorbidities (e.g., chronic pulm. disease, sleep apnea)
- Mental health comorbidities (e.g., depression, bipolar disorder)
- Substance Use

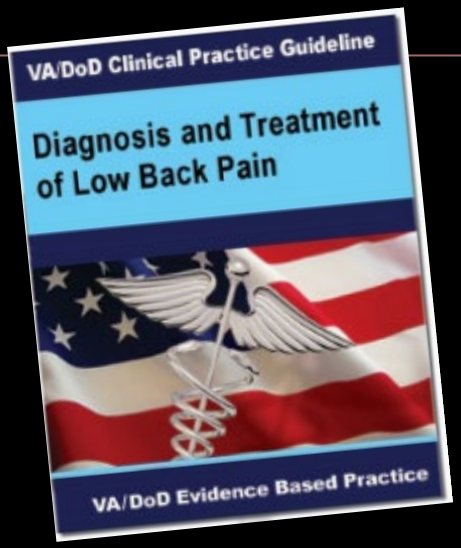
Patient factors

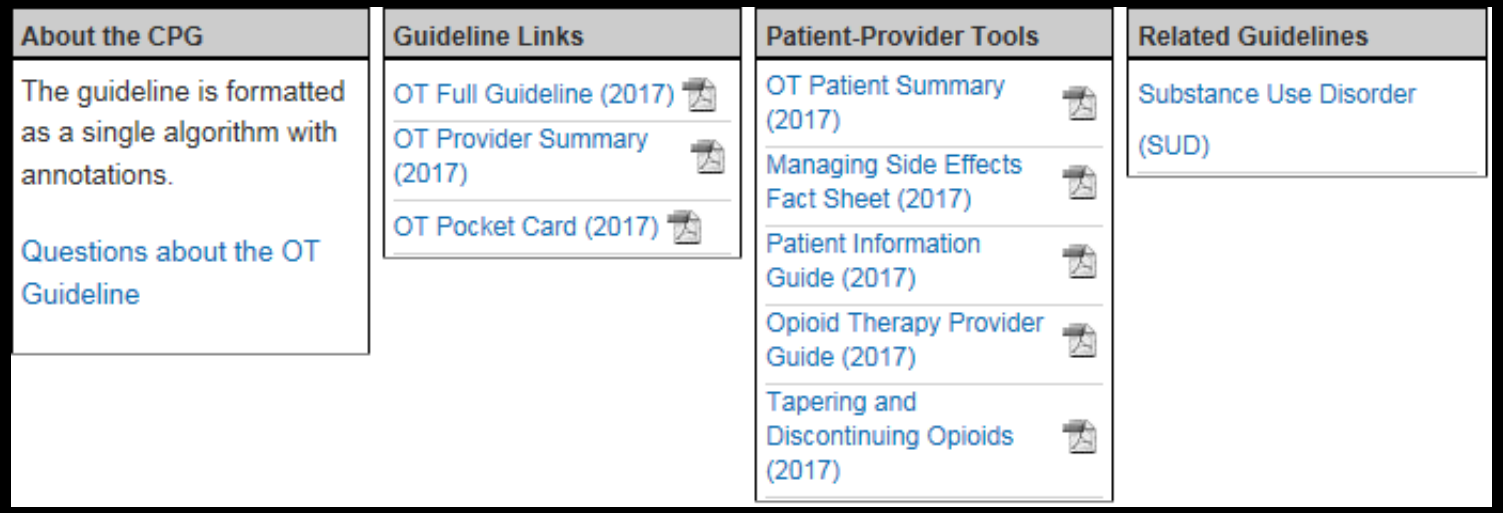
VA/DoD Clinical Practice Guidelines

VA Office of Health Integrity collaborates with the Department of Defense, VA and DoD clinicians and clinical researchers, and experts in systematic review of the literature to create evidence-based guidance for common medical problems.





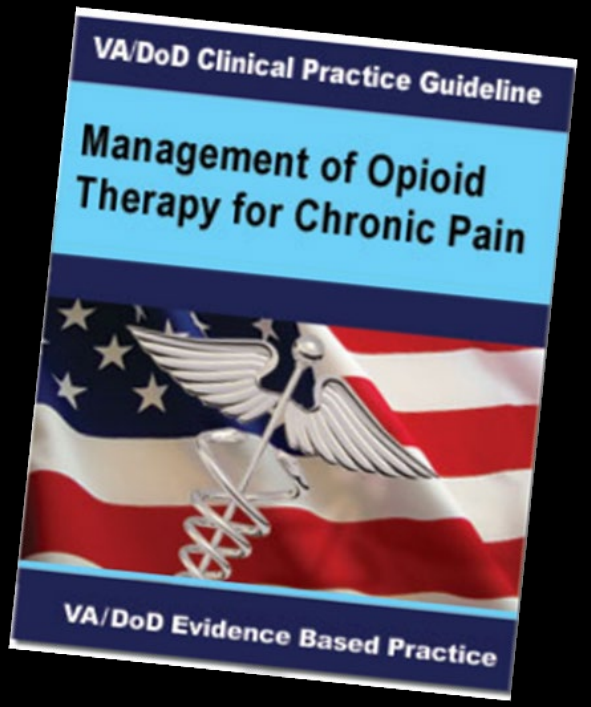




https://www.healthquality.va.gov/index.asp

VA/DoD Clinical Practice Guidelines

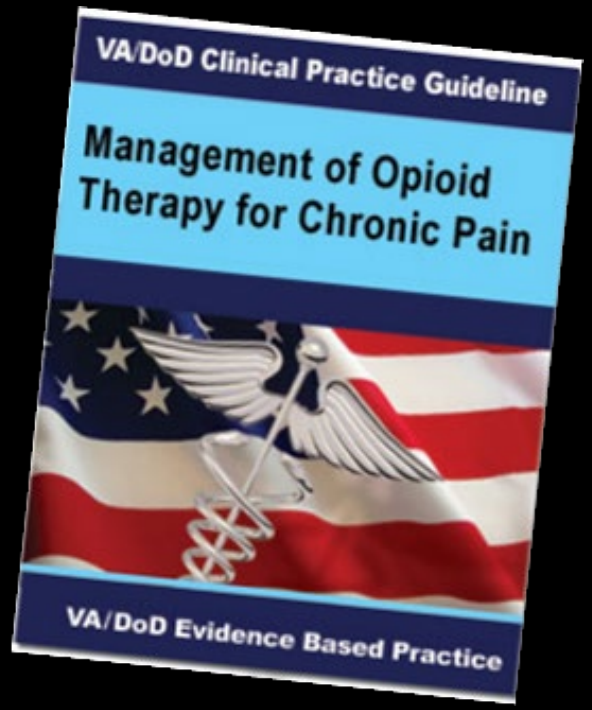
- Recommendation 1
  - We recommend against initiation of long-term opioid therapy
  - When pharmacologic therapies are used, we recommend non-opioids over opioids
  - We recommend alternatives to opioid therapy such as self-management strategies and other non-pharmacological treatments



https://www.healthquality.va.gov/guidelines/Pain/cot/

VA/DoD Clinical Practice Guidelines

- Initiation or continuation of opioids
  - Recommendation against use of opioids in patients < 30 years of age, those with active substance abuse, and when combined with benzodiazepines
- Risk Mitigation
  - Informed consent
  - Urine drug screen
  - PDMP checks
  - Opioid education/naloxone prescribing
  - Assess for suicide risk
  - Evaluate risks and benefits q 3 months

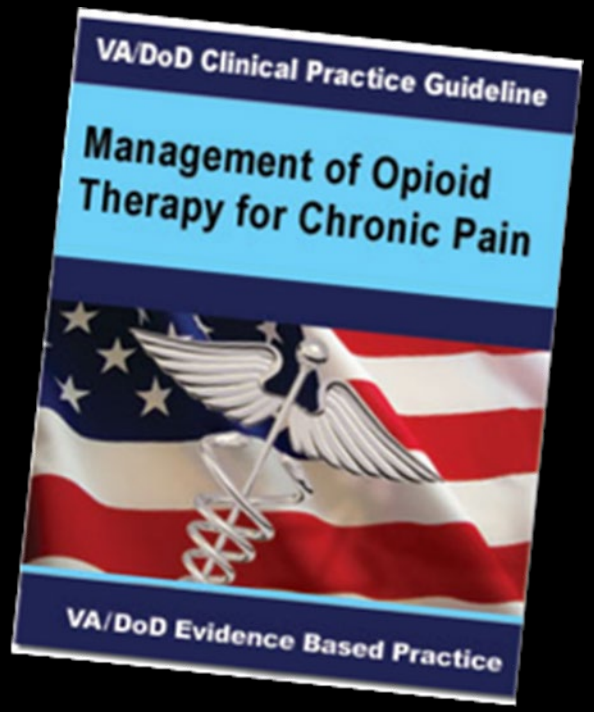


https://www.healthquality.va.gov/guidelines/Pain/cot/

VA/DoD Clinical Practice Guidelines

- Type, Dose, Follow up of Opioids
  - No dosage is safe, strong recommendation against > 90 MEDD
  - Avoid long-acting opioids for acute pain, PRN, or upon initiation of OT
  - Opioid dosage reduction should be individualized to the patient
  - Avoid sudden reductions: taper slowly if opioid risk > benefit

- Opioid therapy for acute pain
  - Acute pain: use alternatives to opioids, use multimodal pain care
  - If prescribing opioids, prescribe for </= 3-5 days



Dashboards

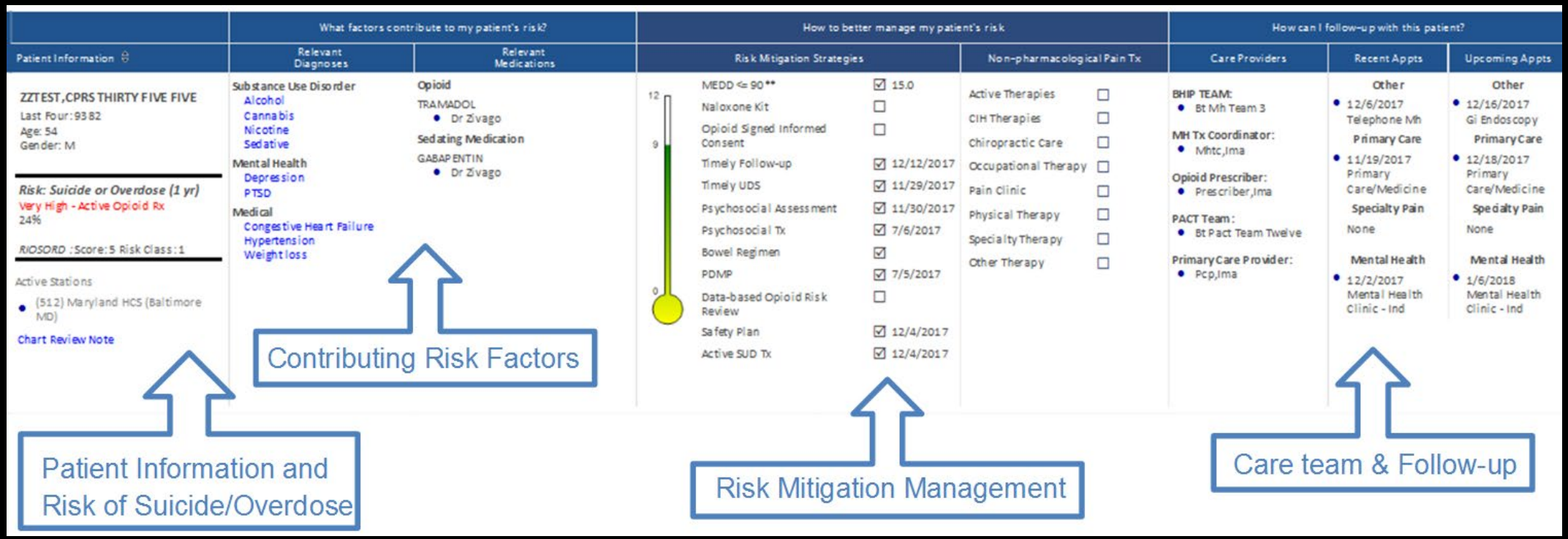
- Opioid Safety Initiative 2.0
  - Includes:
    - Opioid utilization (total opioid prescribing)
    - Opioid and Benzodiazepine co-prescribing
    - High-dose prescribing (defined now as ≥90 MEDD)
    - Long-Term Opioid Therapy (LTOT) (use of opioids for ≥ 90 days)
    - Urine Drug Screen (UDS) in LTOT
    - Newly started LTOT

Stratification Tool for Opioid Risk Mitigation (STORM)

- Opioid type
  - Patients on acute short-acting or chronic short-acting opioids were 1.1 times more likely to have an overdose/suicide-related event than those on tramadol.
  - Those on long-acting opioids were 1.5 times more likely.
  - For patients on chronic opioid therapy (LA and chronic SA opioids), the HR increased to 5.92.
- Risk increased slightly with increasing dose in MEDD
  - Model parameter =.003/MEDD
  - For example, 120 mg MEDD, would increase modeled risk by about as much as a PTSD or alcohol use disorder diagnosis
- Co-prescription of sedatives increased risk by 1.4 times
- Receiving prescriptions for other classes of evidence-based but sedating pain medications (i.e., SNRI, TCA, anticonvulsants) increased risk compared to those not receiving these medications:
  - 1 additional class = 2.1 times the risk
  - 2 additional classes = 3.6 times the risk
  - 3 additional classes – 6.1 times the risk
  - Association could be related to unmanaged pain or cumulative sedation or both

Stratification Tool for Opioid Risk Mitigation

- Predicts individual risk of overdose or suicide-related health events or death in the next year.
- For patients on opioids and when considering opioid therapy.
- Displays the Risk Index for Overdose or Severe Opioid-Induced Respiratory Depression (RIOSORD) score (Zedler et al. 2015, 2018)
- Identifies patients at-risk for opioid overdose-/suicide-related adverse events.
- Provides patient-centered opioid risk mitigation strategies, targeted at risk level.



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Tapering

- Several factors go into the speed of taper selected:
  - **Slower, more gradual tapers are often the most tolerable and can be completed over a several months to years based on the opioid dose**
  - The longer the duration of the opioid therapy, the longer the taper
  - CDC: "… patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages."
- **Most commonly, tapering will involve dose reduction of 5-20% every 4 weeks**
- More rapid tapers may be required in situations where the risks of continuing the opioid outweigh the risks of a rapid taper
- **Sudden interruption of opioid prescribing must be avoided** for opioid dependent patients with few exceptions (safety issues, diversion, etc.)
- Follow up is recommended within 1 to 4 weeks after dosage adjustment

Tapering

- Integrated approach with patient buy-in and active participation leads to improved pain control and enhanced quality of life.
- Goal is to improve function and long-term outcome while reducing risk.
- Provider approach: empathetic, personalized, building trust.
- Patients are often scared about opioid dosage reduction, and some are desperate, especially if they have features of opioid use disorder.
- Expectations should be clear and reasonable/achievable. The patient needs a clear plan that appears manageable and helps avoid or minimize fear or anxiety.
  - Close collaboration with mental health providers including addiction medicine is recommended for many patients – with evaluation for OUD
  - Caution: Involuntary tapers may carry significantly greater risk than voluntary tapers, and interfere with collaborative provider/patient relationship and shared decision making.

Tapering

- Patient outcomes in dose reduction or discontinuation of long-term opioid therapy
  - 11 trials, 56 observational studies, 8 types of intervention: low quality evidence
  - Voluntary programs
  - Dose reduction can be achieved for some patients, and some feel better when off.

Frank JW, Lovejoy TI, Becker WC, Morasco BJ, Koenig CJ, Hoffecker L, Dischinger HR, Dobscha SK, Krebs EE. Patient Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy: A Systematic Review. Ann Intern Med. 2017 Aug 1;167(3):181-191.

Tapering

- Reasons for discontinuations in patients on long-term opioid therapy (Lovejoy, 2017)
  - 7247 patients discontinued long-term opioid therapy (LTOT) in 2012
  - 1868 (26%) had SUD dx (of these 52% AUD, 29% OUD)
  - Sample N=600 with 300 with and 300 without SUD
  - Opioid reductions initiated by clinician (85%), with 64% due to aberrant behavior

- Changes in pain intensity after discontinuation of long-term opioid therapy for chronic non-cancer pain. (McPherson et al. 2017)
  - Same sample as above for Lovejoy et al.
  - After discontinuation, pain score does not, on average, worsen and may slightly improve particularly for patients with mild-to-moderate pain at the time of discontinuation

Lovejoy TI, Morasco BJ, Demidenko MI, Meath THA, Frank JW, Dobscha SK. Reasons for discontinuation of long-term opioid therapy in patients with and without substance use disorders. Pain. 2017 Mar;158(3):526-534

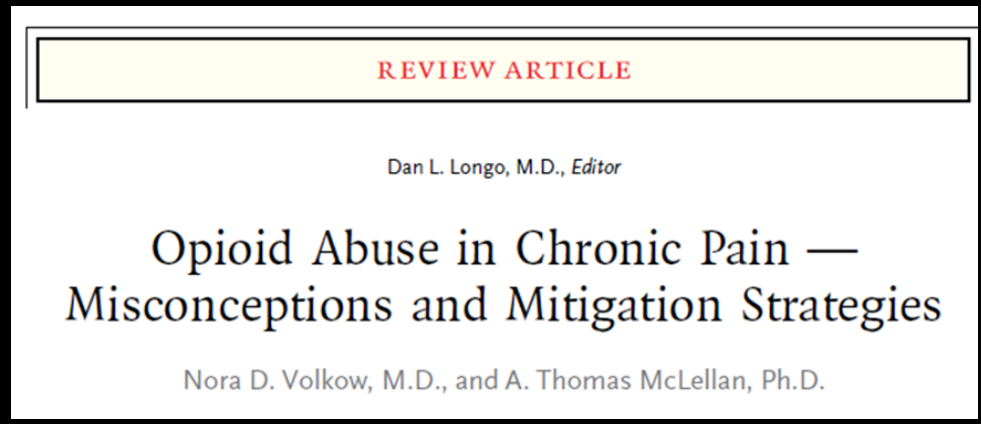
McPherson S, Lederhos Smith C, Dobscha SK, Morasco BJ, Demidenko MI, Meath THA, Lovejoy TI. Changes in pain intensity after discontinuation of long-term opioid therapy for chronic noncancer pain. Pain. 2018 Oct;159(10):2097-2104.

Medication for Opioid Use Disorder

- In 2019, about 1.6 million adults in the US had an opioid use disorder (OUD) *(SAMHSA, 2019)*

- Iatrogenic prevalence estimates for OUD in patients on prescription opioids vary greatly – anywhere from less than 1% to 26% although rates of carefully diagnosed iatrogenic addiction have averaged less than 8% *(Volkow and McLellan, 2016)*

- In a recent study from the Journal of Pain Research 26.5% of patients on opioid medication for non-cancer pain met DSM-5 criteria for OUD while 9% met criteria for moderate or severe OUD *(Boscarino et al., 2020)*. This is consistent with other studies that have reported the range of opioid addiction to be about 10 to 12% in this population *(Vowles et al., 2015)*


REVIEW ARTICLE

Dan L. Longo, M.D., *Editor*

Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies

Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D.

SAMHSA, 2019 https://www.samhsa.gov/data/release/2019-national-survey-drug-use-and-health-nsduh-releases; Volkow and McLellan, NEJM 2016;374:1253-62 https://pubmed.ncbi.nlm.nih.gov/27028915/; Boscarino et al., J Pain Res 2020;13:2697-2705 https://pubmed.ncbi.nlm.nih.gov/33122939/; Vowles et al., Pain 2015; 156(4):569–576

Medication for Opioid Use Disorder

- Improve patient survival.
- Increase retention in treatment.
- Increase patients' ability to gain and maintain employment.
- Improve birth outcomes among women who have substance use disorders and are pregnant.
- Decrease illicit opiate use and other criminal activity among people with substance use disorders.
- Contribute to lowering a person's risk of contracting HIV or hepatitis C by reducing the potential for relapse.

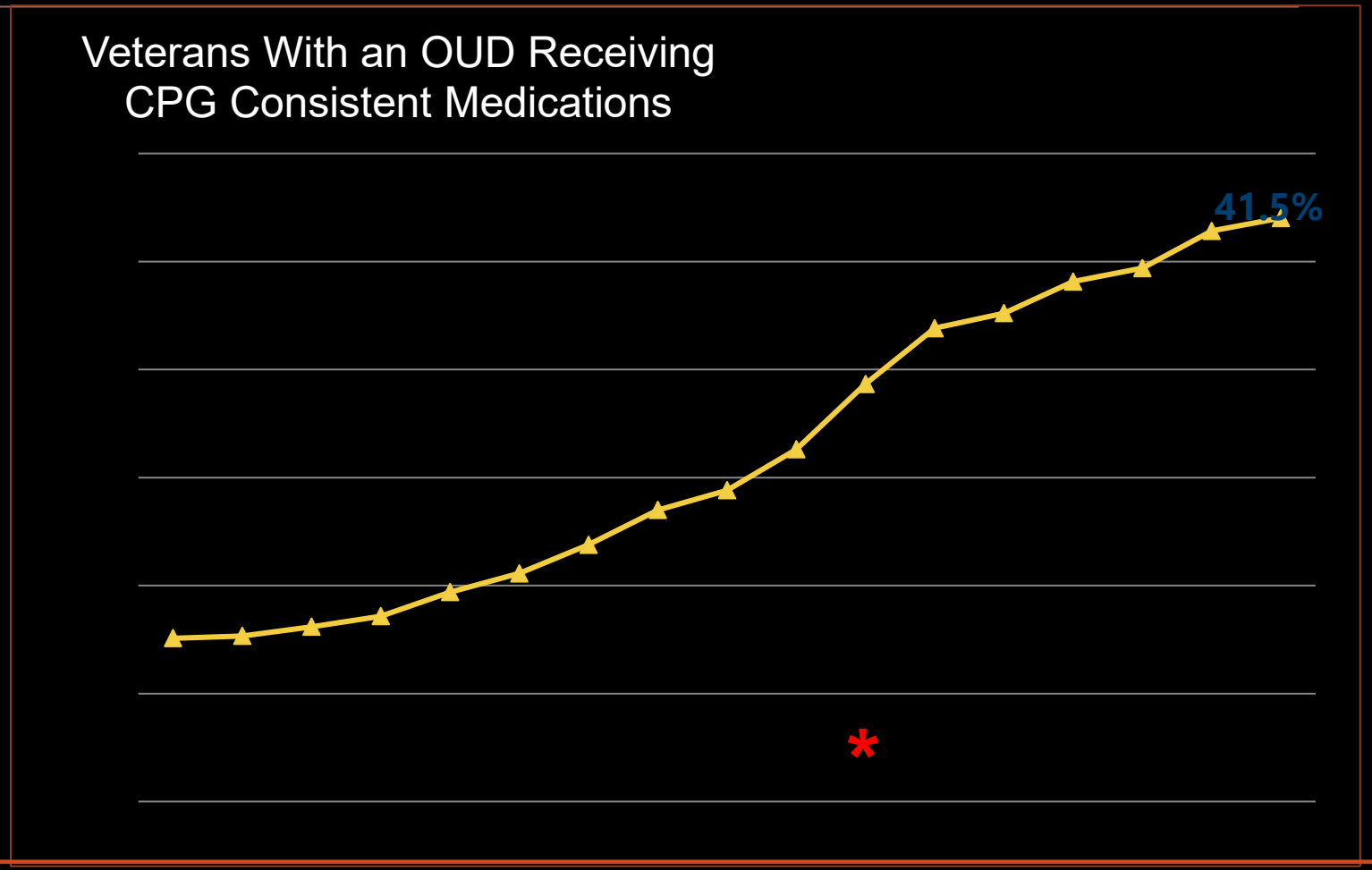
SAMHSA 2020, https://www.samhsa.gov/medication-assisted-treatment

Medication for Opioid Use Disorder (m-OUD) For Veterans Treated in VHA with an OUD

- M-OUD includes:
  - methadone,
  - buprenorphine, or
  - injectable naltrexone.

- During FY 2019, among Veterans with an OUD diagnosis 87% were seen in outpatient mental health clinics and 55% were seen in SUD Specialty Care.

- Most of this medication was provided in SUD specialty care settings.



* Starting in FY14, Extended-Release Naltrexone was counted as a medication for OUD.

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https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/3806-notes.pdf

Patients with OUD and Pain

AVOID:

Medications with Addiction Potential:

- Opioid analgesics
- Sedative-hypnotics
- Muscle relaxants

RECOMMENDED:

Nonpharmacological Therapies for Pain Care:

- As described in the previous section.

Non-Opioid Medications:

- Serotonin and Norepinephrine Reuptake Inhibitor (SNRI) or low dose Tricyclic Antidepressant (TCA)
- Gabapentin/Pregabalin
- Acetaminophen, NSAIDs
- Topicals (e.g., Lidocaine, Capsaicin)

Assessment for and treatment of co-morbid psychiatric conditions (e.g., PTSD, insomnia, anxiety).

Medications for Opioid Use Disorder (m-OUD):

- Buprenorphine/naloxone
- Methadone/Naltrexone (including injection)

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Lipari and Hughes SAMHSA. Jan. 12, 2017 https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html
Volkow and McLellan, NEJM 2016;374:1253-62 https://pubmed.ncbi.nlm.nih.gov/27028915/

Opioid Therapy: Clinical Practice Guidelines

"Pearls" or "Peril"

What's in Your Wallet?

Provider's Perspective, Agenda and implementation

"When Things Go South"

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Clinical Scenario:
Assume the patient does have severe Chronic (non-CA/non-end-of-life) Pain, has failed many standard treatment options but actively engaged with others as indicated, and is currently *stable but on high dose of opioids, of long duration with a documented hx of compliance with all aspects of the care plan

---

VA/DoD Clinical Practice Guidelines

- **Recommend against "initiation" of long-term opioid therapy.**

- **Recommendation** against **"increasing"** opioid dosage > 90 MEDD.

Provider's Interpretation, Implementation

Involuntary Taper To Discontinuance:

I am sorry Mr. Smith! The CDC and VA/DoD CPGs no longer allow providers to prescribe opioids long-term because of the epidemic.

I'm going to start the taper now. I placed a consult to pain management to "fix" your pain and complete the taper.

Involuntary Dose Reduction:

I'm sorry Mrs. Smith, I know you're angry but it's not my fault-I'm forced to do this!

The CDC, and VA Policy clearly mandate that you should not be on doses higher that 50 MEDD but certainly cannot be on doses > than 90mg/day MEDD.

I'm going to start the taper now.

VA/DoD Clinical Practice of Opioid Therapy for Chronic Pain

VA/DoD CPGs

Recommend against "initiation" of long-term opioid therapy.

Recommend against "**increasing**" dosage > 90 MEDD.

……..

CPGs

- Regardless of a given care recommendation
  - –Example: Opioids with Benzo
- Overarching clinical care message >

CPGs As Purposed

Optimal Word = *Initiation*

- **Does not say, OT should or must be discontinued for existing regimens…**

……..

Optimal Word = "Increasing"

Does not say, for those who are on ≥ amounts must should be tapered down…

……..

Purposed Message

A continued care plan with appropriate assessment, RMS, follow-up and any adjustments thereof as clinically indicated

- **–Sometimes regardless of care option choice, risk are withstanding**
- **– Clinical Discretion**
  - **Choose that of highest probability**
    - **–yields least harm / provides best outcome**

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CPGs, "Literature Says"

Opioid Therapy: Initiating, Continuing, or Tapering (Dose Reduction or to Discontinuance)

A Provider's Clinical Discretion: First To Do No Harm, "but"

Harm May Comes in Many Ways

- **Risks Support Medically Indicated Taper:**
- Patient may present with risks that compels a provider to taper as a dose reduction or to discontinuance as the associated risk (both apparent and/or that of perceived) is most concerning for the patient but too possibly for others (community)

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- **Literature details the Risks of Tapering**
- Potentially equally adverse outcome associated with opioid tapering:

- *Especially following the initiation and for the defined period follow discontinuance and thus the emphasis
  - Benefits of voluntary tapers with patient buy-
  - Very important

Provider to Patient Discussion & Relationship

- **Voluntary Taper:**
- Coveted Patient buy-n for a proposed taper as medical indicated.

- Likelihood is greater success of a taper with patient buy-n and lessened risk for potential SI or attempt or that of overdose

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- **Involuntary Taper**
- Patient Resistant to Taper, but strongly feels risks is simply too great to continue with this care plan

- Provider is now positioned two sets of Risks and subsequent responsibilities:

2017 VA/DoD CPGs for Opioid Therapy for Chronic Pain
II. How to use the Clinical Practice Guideline

Purposed Goal

- A healthcare system can use the CPG to assure that its clinicians and patients have the resources available to:
- compassionately, effectively, and safely evaluate and deliver LOT in a timely, culturally sensitive manner.

Purposed Goal

- CPG must always be considered as a recommendation, within the context of:
  - –Provider's clinical judgment
  - –Patient values and preferences,
  - –These in the care for an individual patient

Ultimate Judgement

The ultimate judgement regarding a particular clinical procedure or treatment course must be

- **Made by the individual clinician**
  - **–In-light of the patient's clinical presentation,**
  - **–With consideration of patient preferences, available diagnostic and treatment options**

Voluntary / Involuntary: To Taper or Not To Taper
Medically Indicated Taper: Associated Risks

What's a Provider to Do?

Previous discussed strategies: "Approaching The Opioid Taper"

- Using CPGs, best clinical practices as guides

- **"BUT"> Ultimately using "objective" reasoning, best clinical "Judgment"**

- Do the Right Thing: For the Right Reason: For the Right Patient

Old Phrase but Withstanding

1. **Weigh the "Risk to Benefits" (one care plan to another)**
2. Bilateral open door of communication: provider/patient discussion
3. Execute the clinically appropriate, flexible supporting care plan, RMS and follow-up
4. In resistance, continue to seek buy-n and as with all, encourage engagement with treatment options offered

Truly It is a "Patient-Centric" Thing

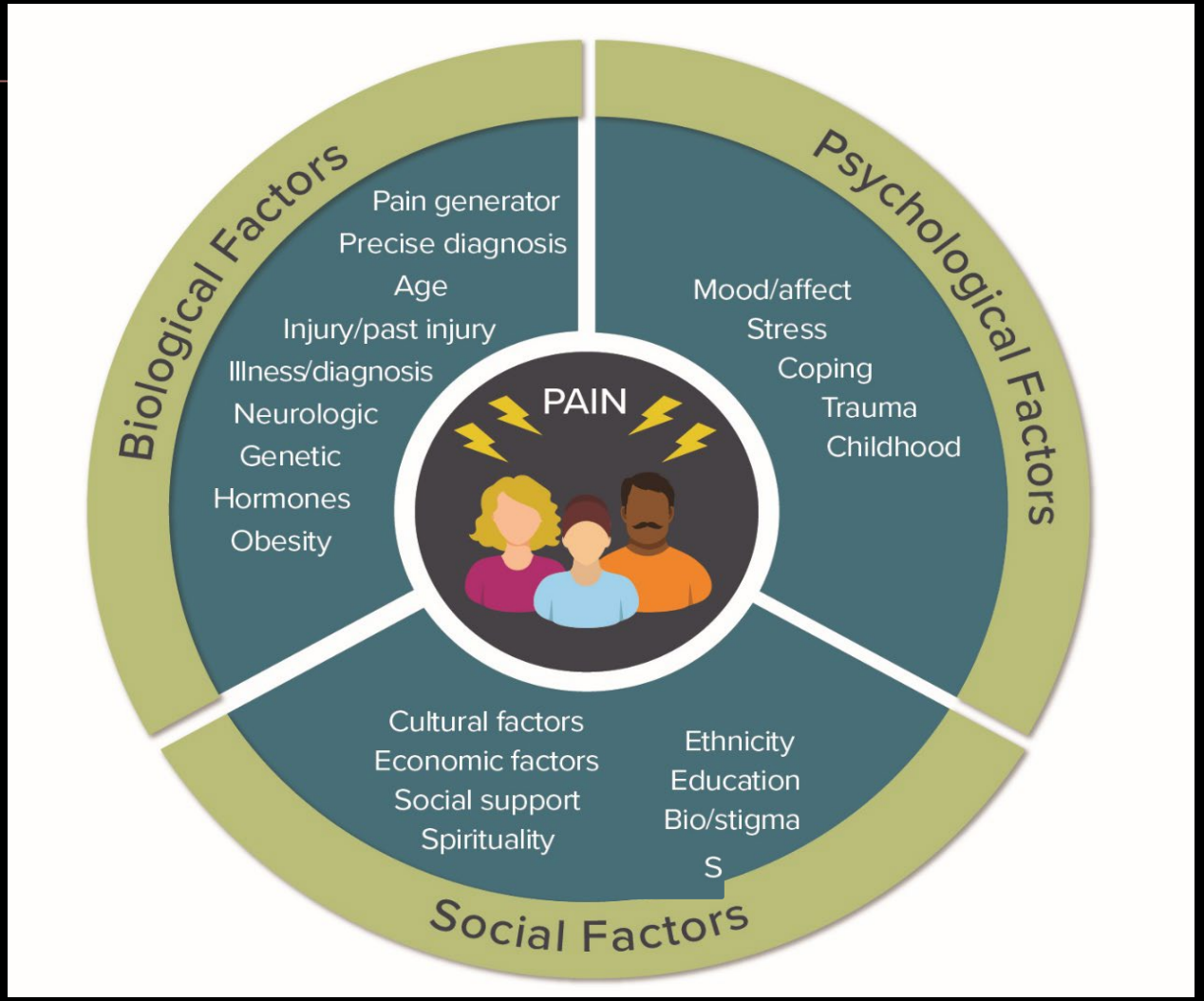
The Biopsychosocial Model Approach to Pain Management

- **Key Components:**

- Biological Factors (e.g., diagnosis, age)
- Psychological factors (e.g., mood, stress)
- Social factors (e.g., social support, spirituality)

- **Goals:**

- Improve the experience of pain
- Enhance physical functioning
- Promote activities of daily living
- Increase quality of life (QoL)



https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

Whole Health and CIH in VHA

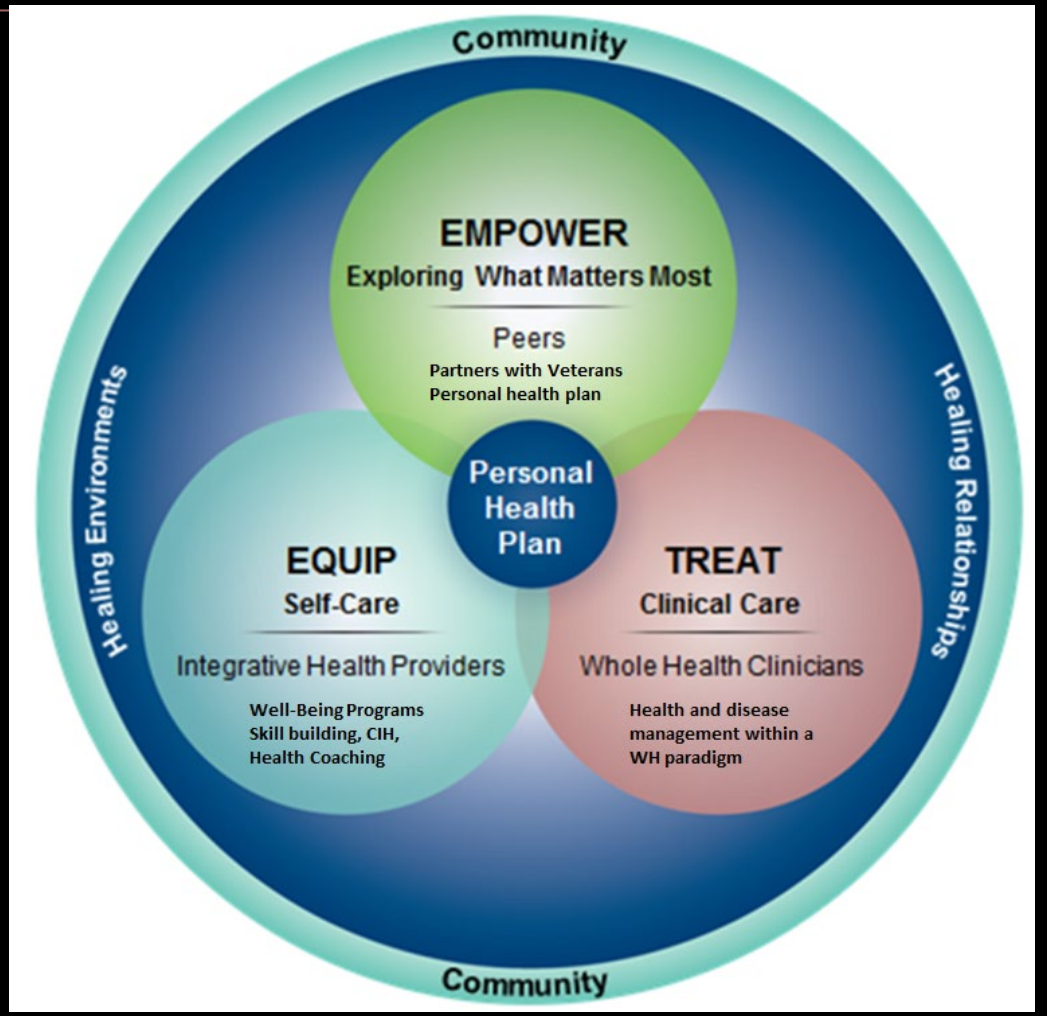
"Whole Health centers around what matters to you, not what is the matter with you."

Whole Health Approach

- **Empowers and equips people to take charge of their health and well-being**
- **to live their life to the fullest.**

Whole Health approach

- **reorientation of the Veteran's relationship with VA.**
- **combines conventional medicine with personalized health planning, CIH, and innovative self-care approaches.**



Summary: Recommended Treatments for Pain

- **Cognitive Behavioral Therapy for Chronic Pain (CBT-CP)** is the most empirically supported behavioral treatment and **recommended as a first line treatment for chronic pain**.

- **Physical Therapy may also be beneficial** for some Veterans with chronic pain.

- **Complementary and Integrative Health (CIH) treatments** are practices that are **not considered to be part of conventional or allopathic medicine**, some of which are currently recommended for chronic pain.
  - More up-to-date Integrative Health Coordinating Center (IHCC) website
  - The Comprehensive Addiction and Recovery Act (CARA) of 2016 mandates the evaluation and appropriate expansion of CIH treatment modalities within VHA.

- The **Whole Health approach** combines conventional medicine with personalized health planning, CIH, and innovative, self-care approaches

Summary: Opioid Safety Initiative (OSI) and Best Practices

1. The Opioid Crisis in the US has **shifted from overdoses to prescription opioids to illi** most recently synthetic opioids (e.g., fentanyl).

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2. Risk of prescription opioids is correlated with dose and duration.
3. Opioids in combination with sedating drugs are particularly dangerous.
4. Mental health/substance use disorders contribute greatly to increased risk.
5. The VA/DoD CPG for Opioid Therapy recommends against *initiation* of Long-Term Opioid Therapy (LTOT) for chronic pain.
6. Opioid risk mitigation strategies are available systemwide.
   - Overdose Education and widespread Naloxone Distribution (OEND).
   - Stratification Tool for Opioid Risk Mitigation (STORM).
   - Prescription Drug Monitoring Programs (PDMP).
   - Urine Drug Testing (UDT).
7. Opioid dose reduction (opioid tapering) must be patient-centered and individualized with the goal of maximizing function and safety.
8. Patients on long-term opioid therapy (LTOT) who fulfill the criteria for OUD must be offered access to evidence-based therapy, i.e., medication for Opioid Use

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Questions