PainWeek®

Jagged Little Pill

VHA Opioid Safety Initiative

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Disclosure

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- No relevant financial disclosures

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- No relevant financial disclosures

- No discussion of off-label medication use or devices
- The presentation is the personal opinion of the presenters and does not reflect the official views of the Department of Veterans Affairs or any other Federal Agency

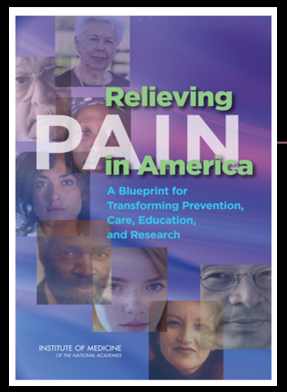
Learning Objectives

- Describe factors that increase risk for adverse event for those on long-term opioid therapy (LTOT)
- Cite the appropriate precautions for patients on opioid maintenance therapy
- Summarize the steps taken by VA to improve patient safety
- List the key tenants of VA/DoD guidelines for safe opioid prescribing

Overview

- Background
  - Chronic Pain as Public Health Problem
  - Opioid Crisis
- VA Opioid Safety Initiative
  - Clinical Practice Guidelines
  - Opioid risk mitigation
- Overdose and Suicide risk
- Opioid Tapering
- Opioid Use Disorder
- Pain Management in VHA

Chronic Pain as a Major Public Health Problem



Institute of Medicine 2011

(now: National Academy of Medicine)

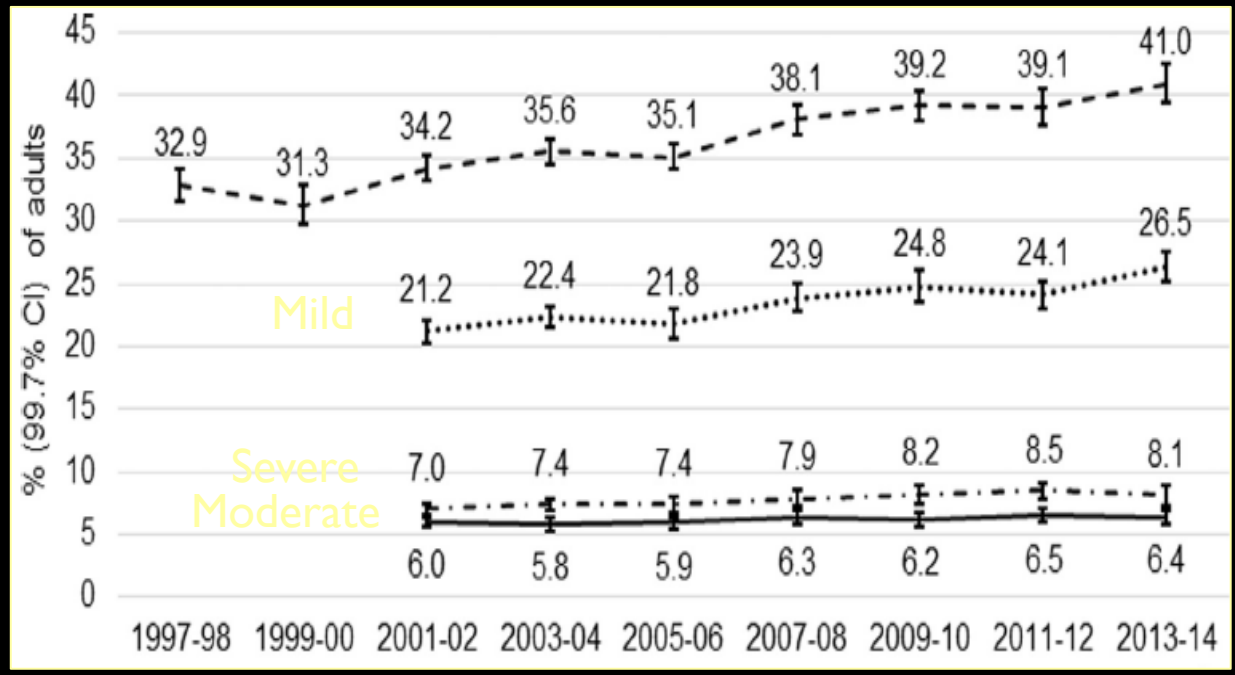
Relieving Pain in America

- **> 100 Mil in U.S. with chronic pain (30% of adults)**
- **Cost greater than cancer and heart disease combined**

Prevalence Noncancer Pain

United States

1997 to 2014



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http://www.ncbi.nlm.nih.gov/books/NBK91497/

Nahin RL et al. J Pain. 2019 Jan 15. [Epub ahead of print]

Chronic Pain as a Major Public Health Problem

- Chronic pain that frequently limits life or work activities
- 20.4% (50 million) of U.S. adults had chronic pain
- 8% of U.S. adults (19.6 million) had high-impact chronic pain
- High prevalence groups:
  - Women
  - Older adults
  - Previously but not currently employed adults
  - Living in poverty
  - Public health insurance
  - Rural residents.

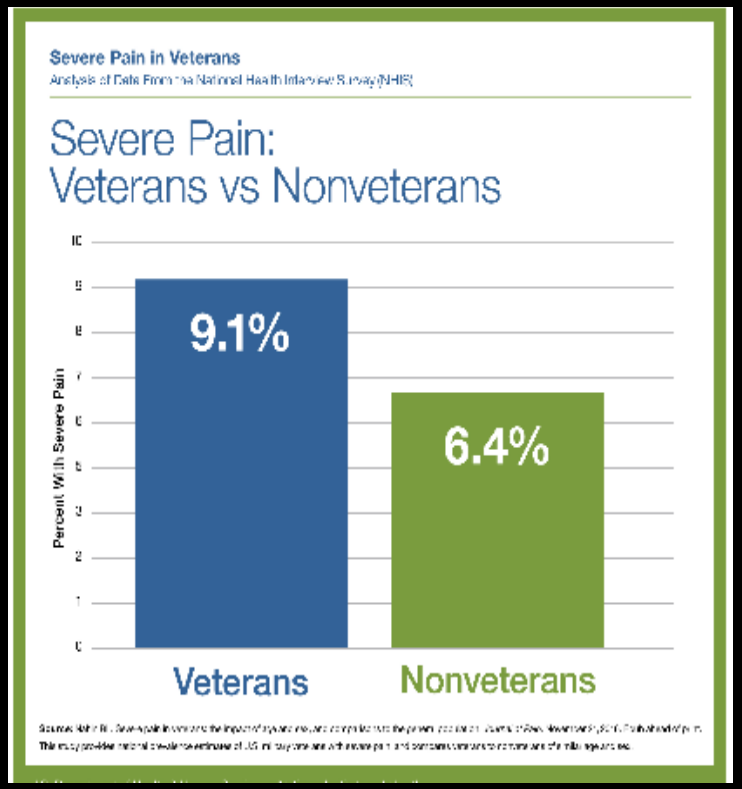

Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016

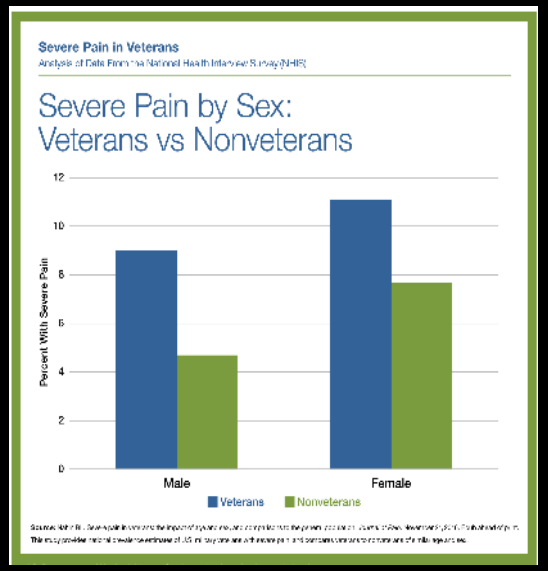
James Dahlhamer, PhD[1]; Jacqueline Lucas, MPH[1]; Carla Zelaya, PhD[1]; Richard Nahin, PhD[2]; Sean Mackey, MD, PhD[3]; Lynn DeBar, PhD[4]; Robert Kerns, PhD[5]; Michael Von Korff, ScD[4]; Linda Porter, PhD[6]; Charles Helmick, MD[7]

Prevalence of Pain in Veterans – All Veterans in US

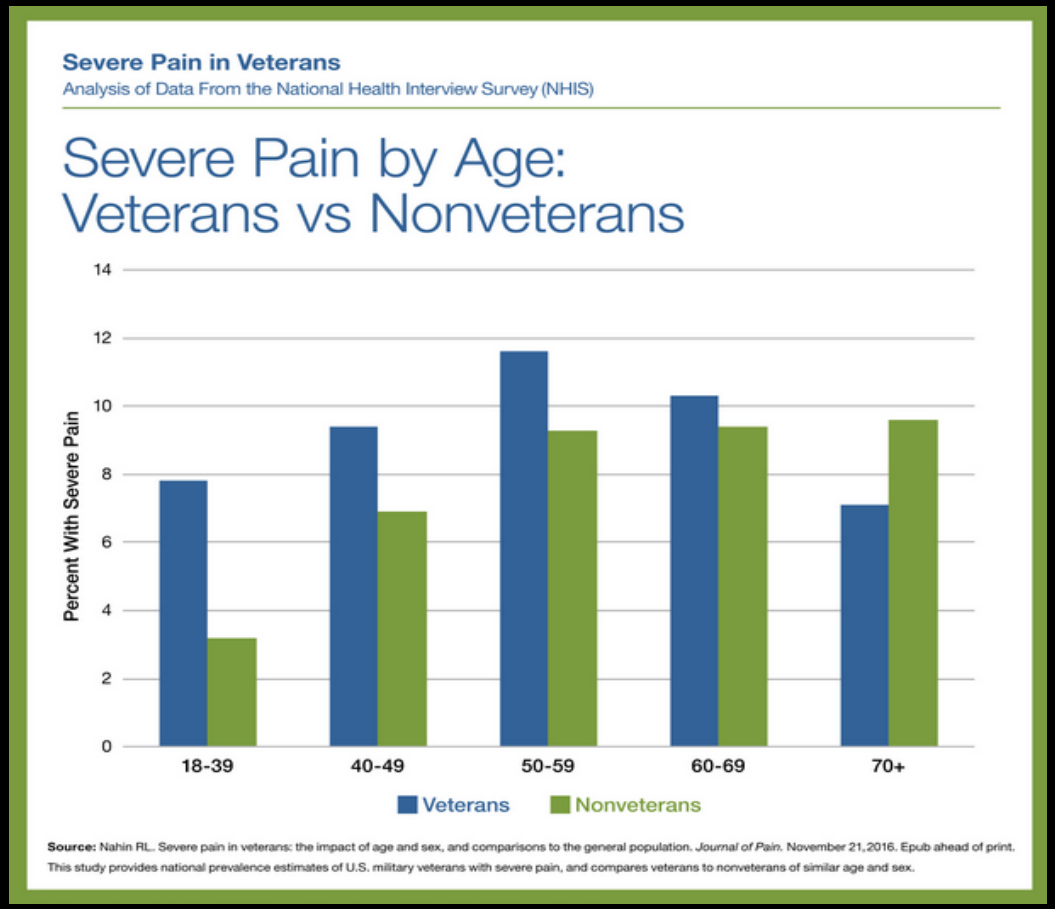
Chronic pain more common in Veterans and often severe

Severe pain in Veterans is 40% more common





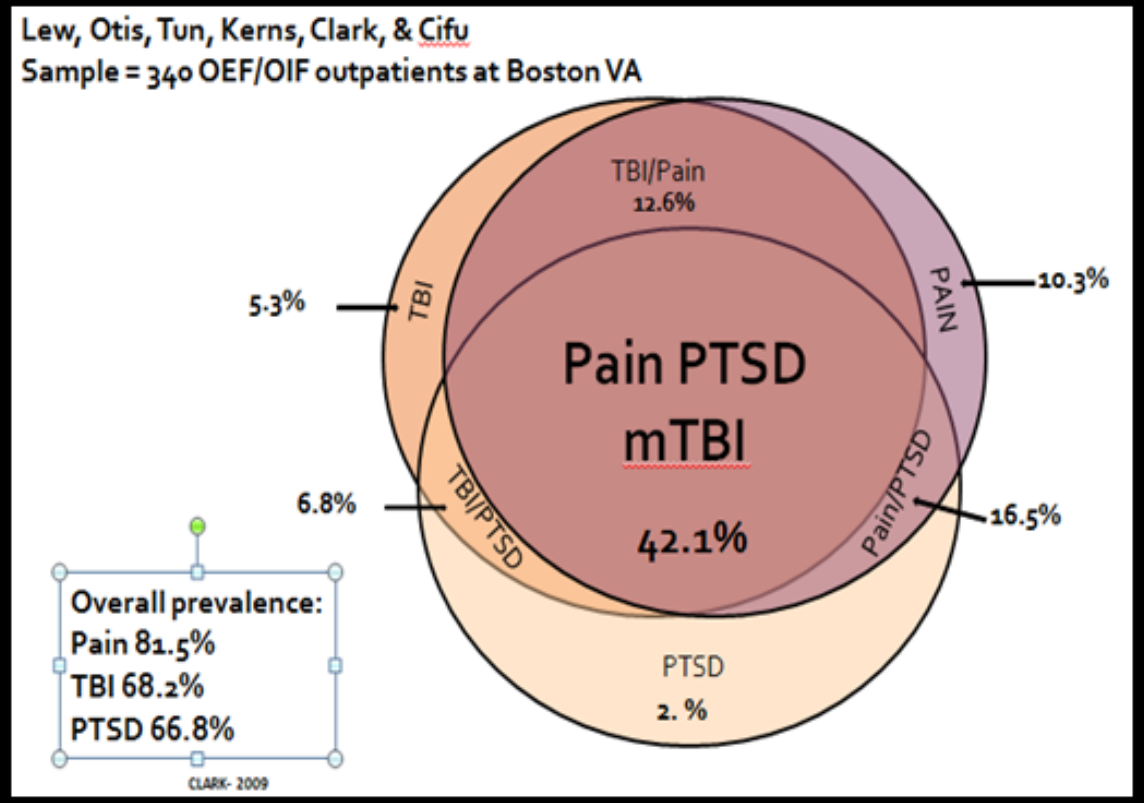
Severe Pain



The Pain Challenge in VHA

Chronic pain in VHA Veterans is often severe and in the context of mental health comorbidities

% of Veterans from Middle East conflicts with chronic pain, up to 75% in women Veterans



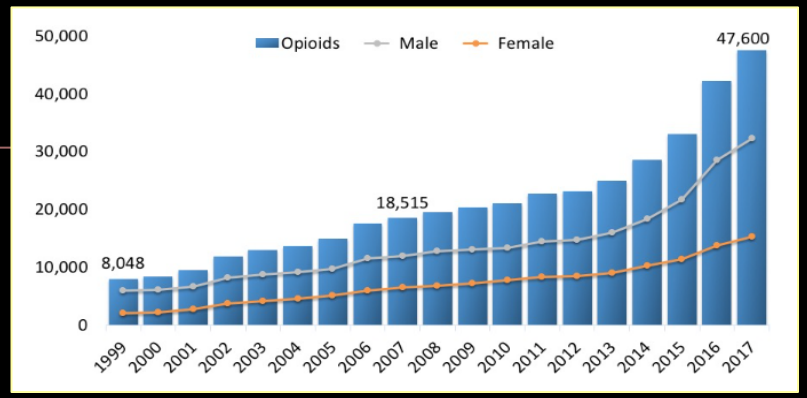
- MH and Pain conditions increased in prevalence from 2008 to 2015
  - Increase in pain scores/pain severity

Pain in Veterans (in VHA):
1 in 3 with chronic pain diagnosis
1 in 5 with persistent pain
1 in 10 with severe persistent pain

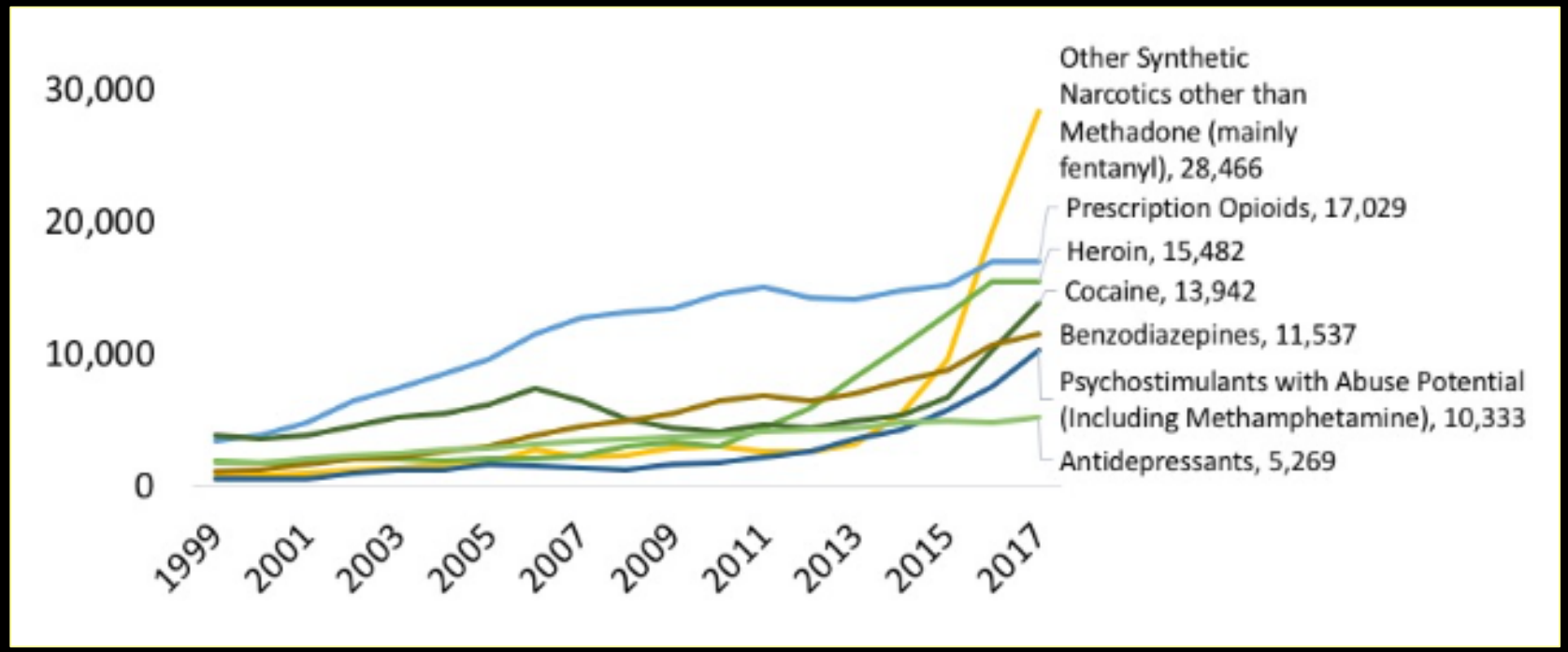
National Drug Overdose Deaths

1) Natural and semi-synthetic opioid deaths increased 4-fold from 1999 to 2011
2) Heroin death rate increased over 5-fold since 2011
3) Synthetic opioid (excluding methadone) death rate increased more than 6-fold from 2013 to 2016
4) Methamphetamines and other stimulants continue to increase

Any Opioid, All Ages

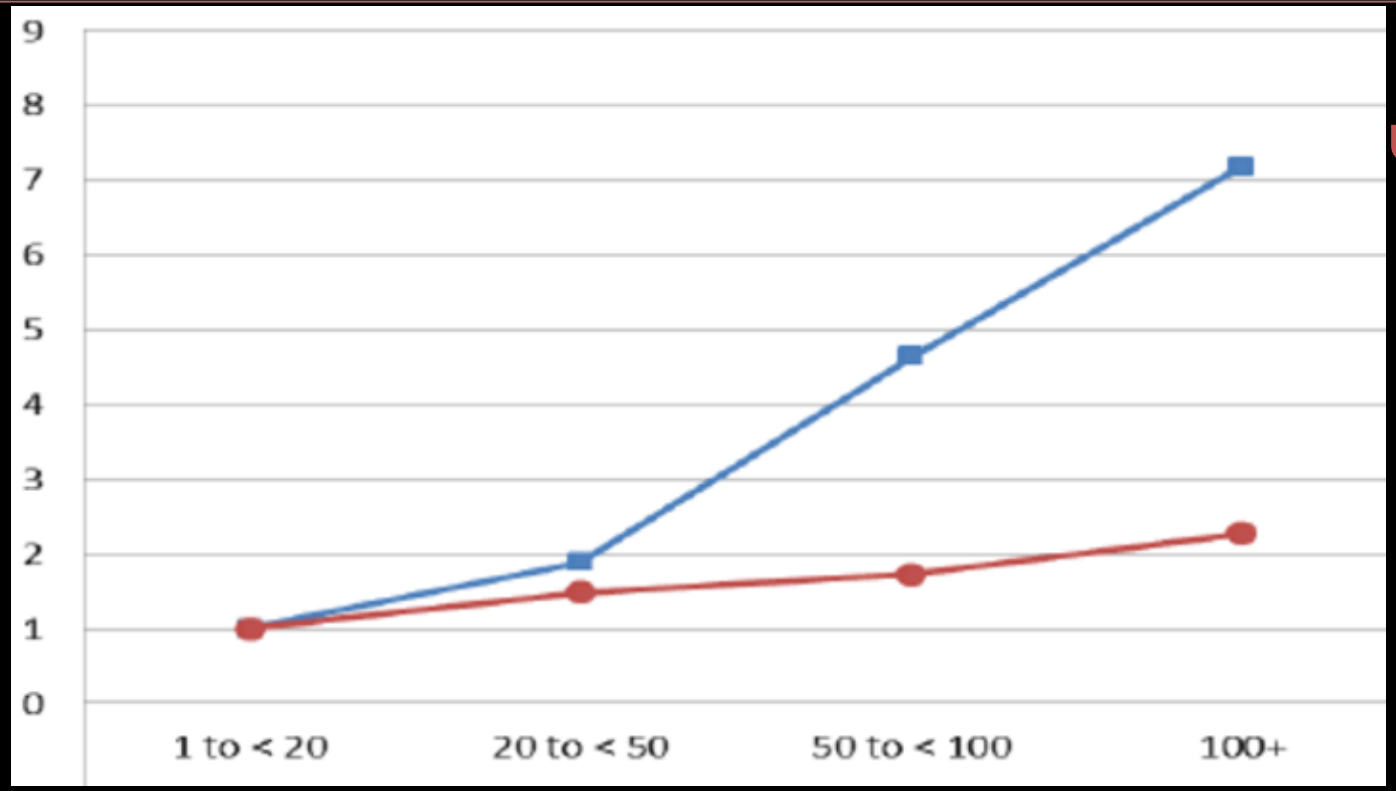


Overdose by Drug



Dosage and Risk of Overdose and Suicide from Opioids

Opioid Dose and Risk of Death (Patients with Chronic Pain)



Unintentional Overdose

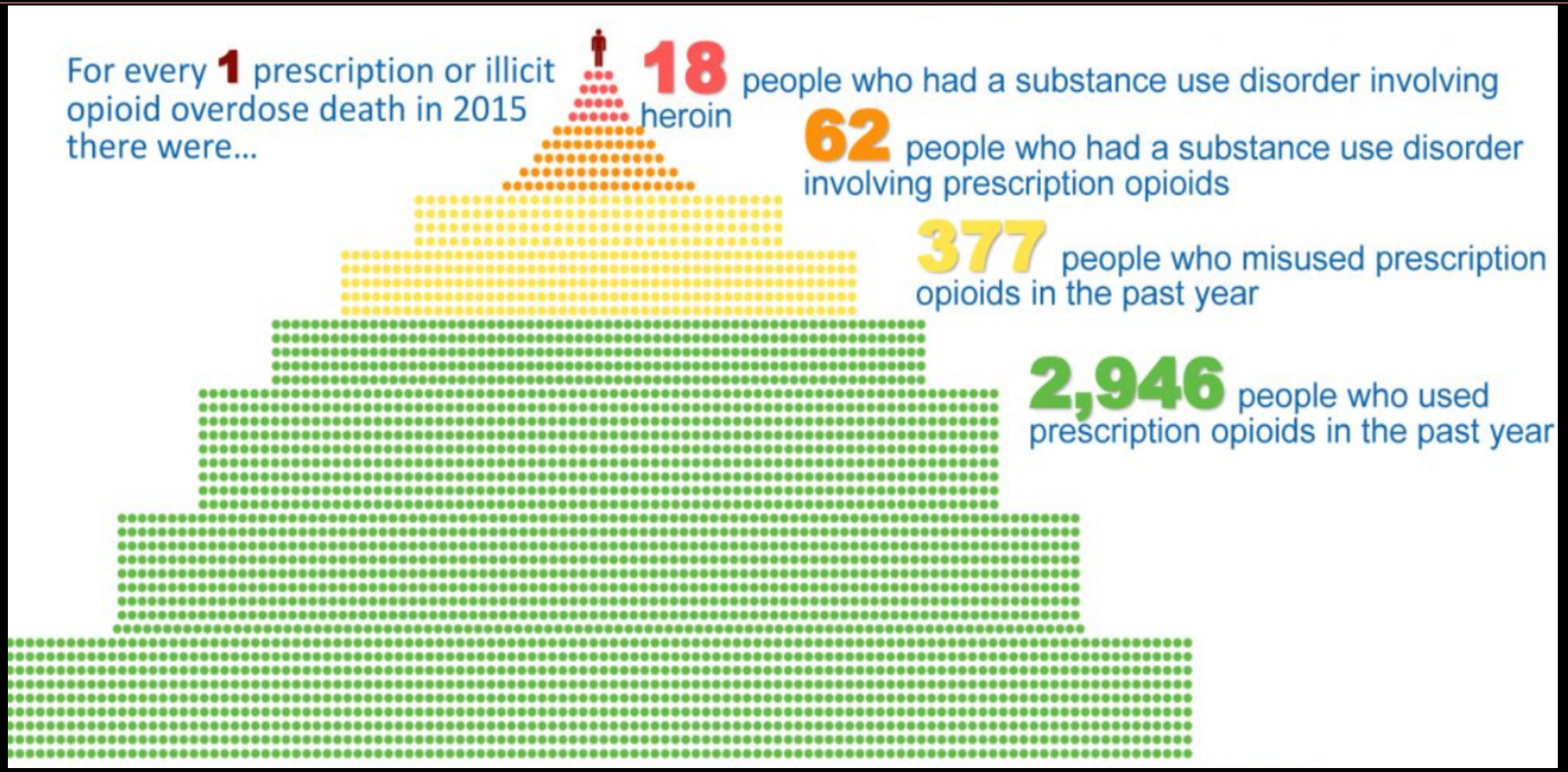
Suicide

Patients with prescribed opioids in FY 2004 or 2005. These were followed until end of 2008 unintentional OD) or 2009 (suicide).

Nested case control design.

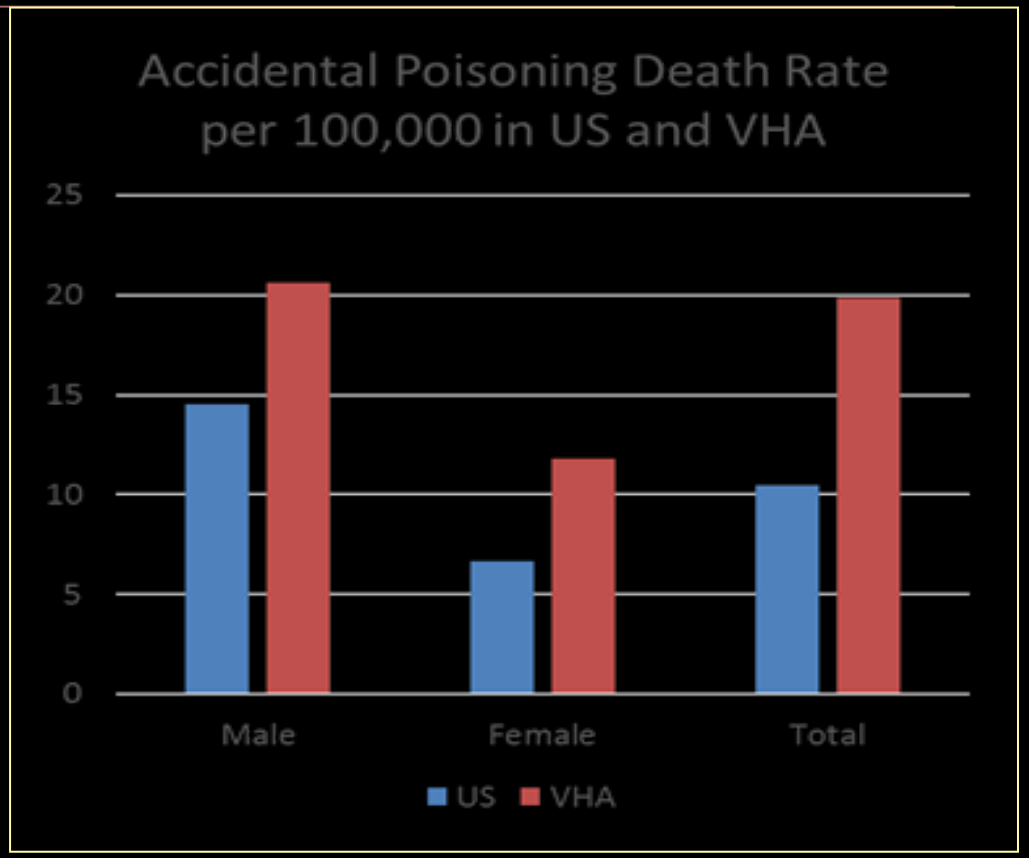
Bohnert AS et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*. 2011.
Ilgen MA et al. Opioid Dose and Risk of Suicide. Pain. 2016;157(5):1079-1084

Opioid Overdoses as the Tip of the Iceberg



Pain Management and Opioid Safety

- Pain severity and co-occurrence with mental health comorbidities result in high impact pain
- Pain, medical and/or mental comorbidities are often related to military service and/or require Veteran-specific expertise
- Veterans are at higher risk for harms from opioids/accidental poisoning than non-veterans
- *"The most frequently identified risk factor among Veterans who died by suicide was pain"* (2015, 2017)
- Systematic coordination of medical, psychological and social aspects of health care (integrated care)



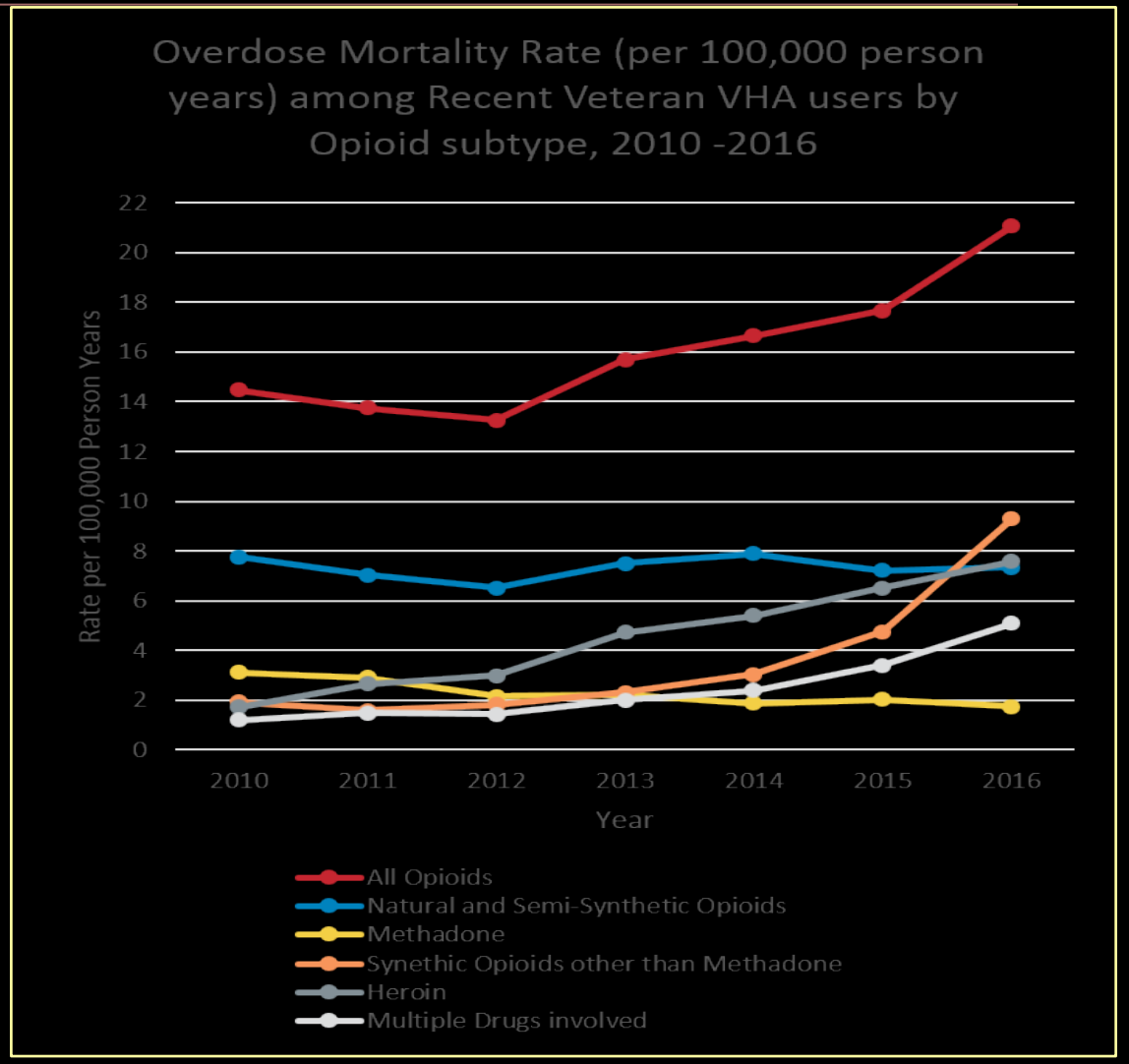
VHA: Pain Management and Opioid Safety was included in the list of "Foundational Services"

Opioid Overdoses in Veterans

- From 2010 to 2016, there were 6,485 VHA Veterans who died from any opioid overdose, with increasing trend over time
- 2016 opioid overdose deaths:
  62% of all Veteran overdoses included opioids
  Veterans in VHA
  1,271 deaths
  3.5/day
  21.1/100,000

Comparison: US population rate 13.3/100,000 (in 2016, CDC)

- Increase in opioid overdose is primarily due to overdose on heroin and synthetic opioids
- Overdose deaths from prescription opioids (other than methadone) have not changed significantly since 2010 for both groups



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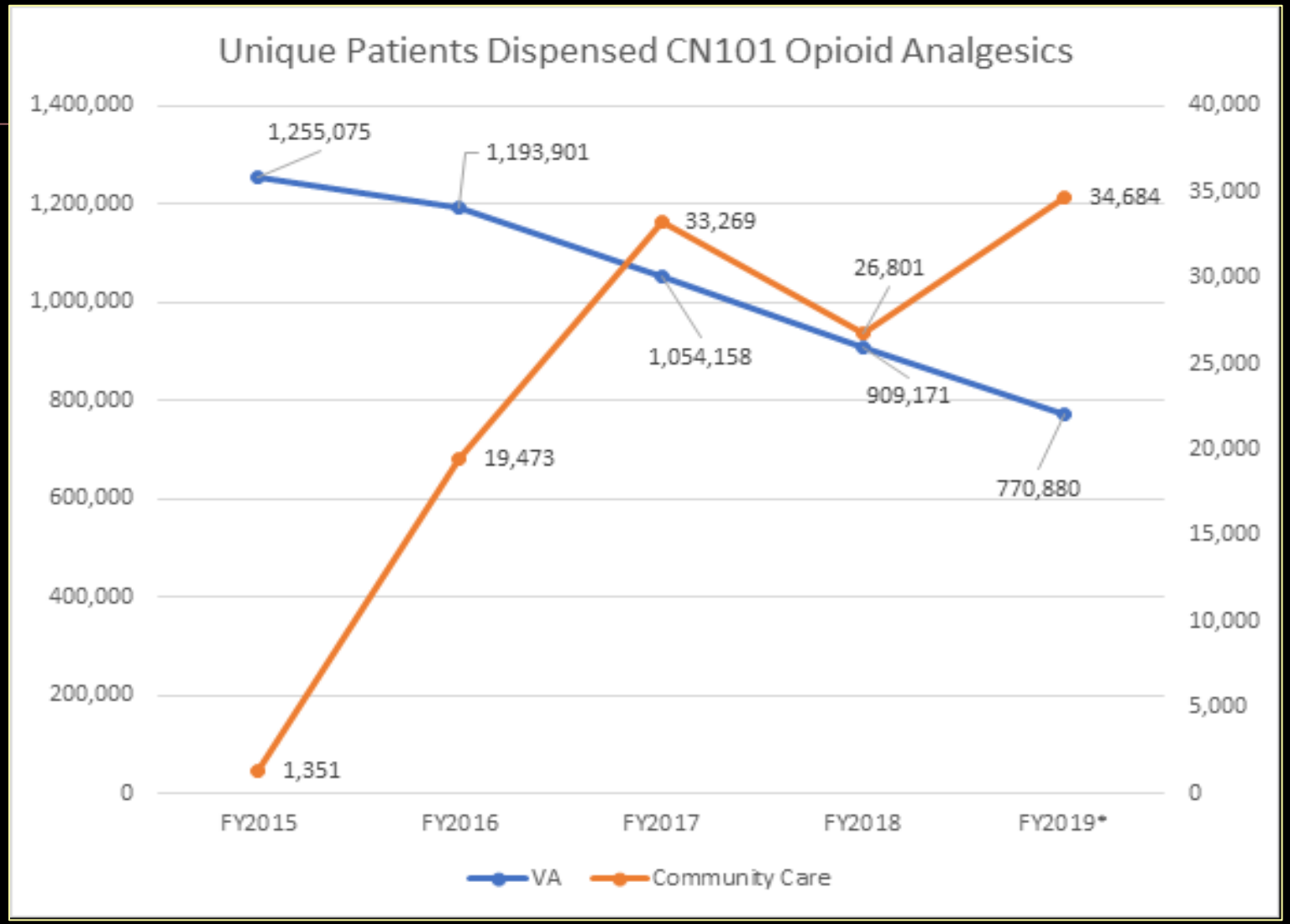
VHA Opioid Dispensing

- All CN101 opioids, including tramadol and buprenorphine for pain

- **VHA internal providers**
- **Community Care providers**

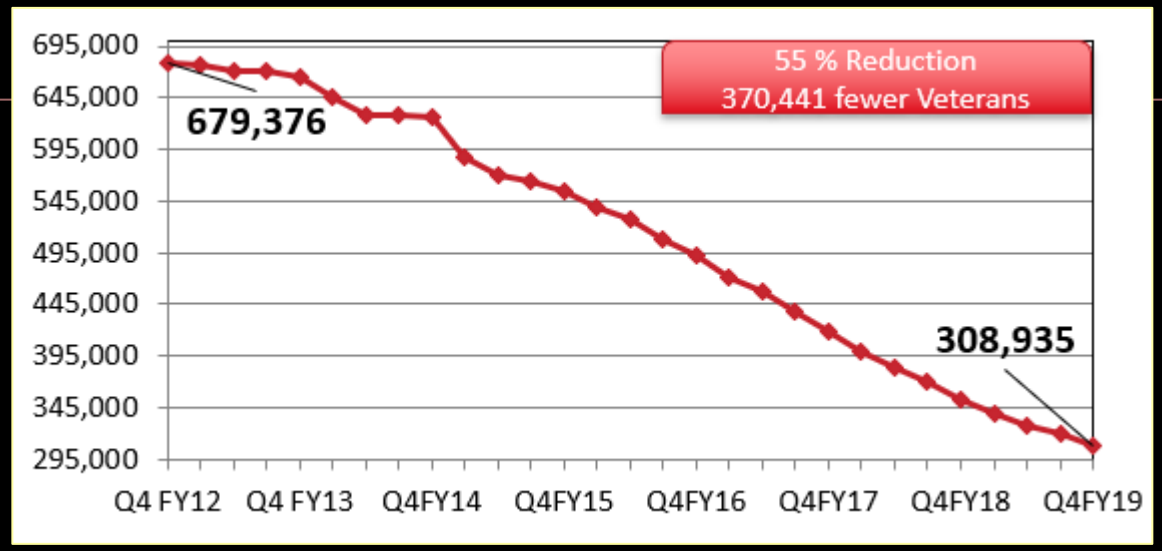


PAINWEEK

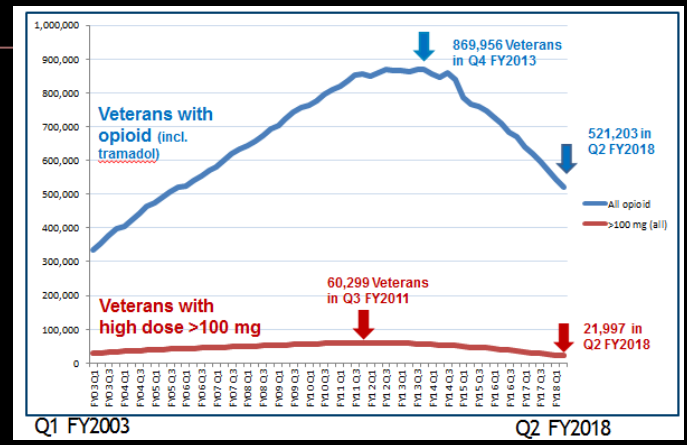
Opioid Safety – Veterans Opioid Dispensing Over Time

Veterans with Opioid prescription: 55%
(excludes tramadol).
Veterans with opioid **percentage of all** Veterans with

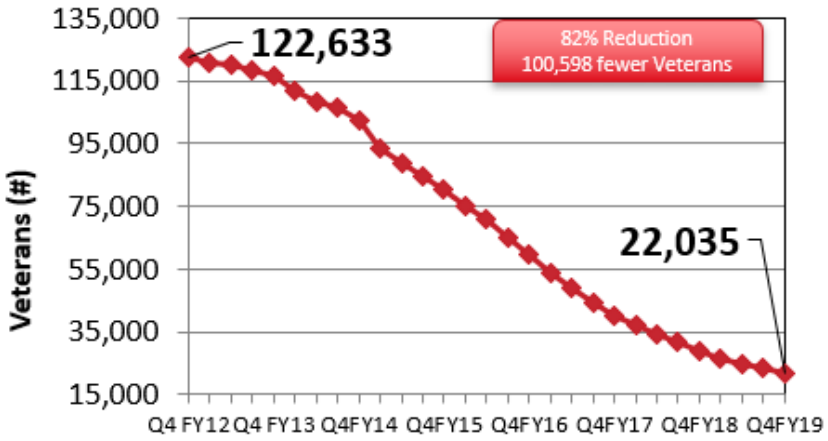
Source: Pharmacy Benefits Management (PBM) Services

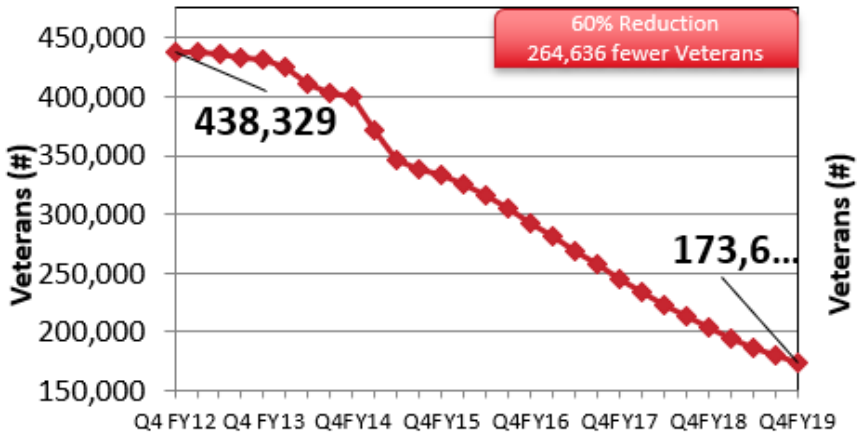


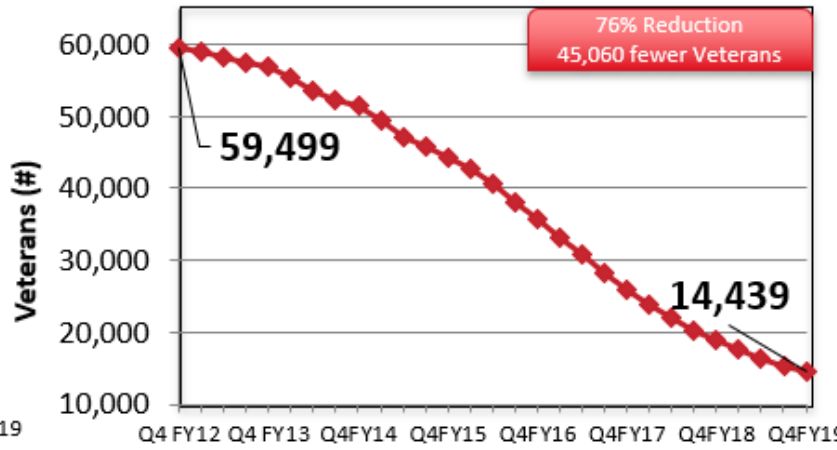
High Dose Prescribing
2003 to 2018



Opioid High Dose: 76%







Risk Factors for Overdose and OUD

Risk factors are related to:

- **Opioid prescribing**
- **Interaction with other medication/drugs**

- **Medical comorbidities**
- **Mental health comorbidities**

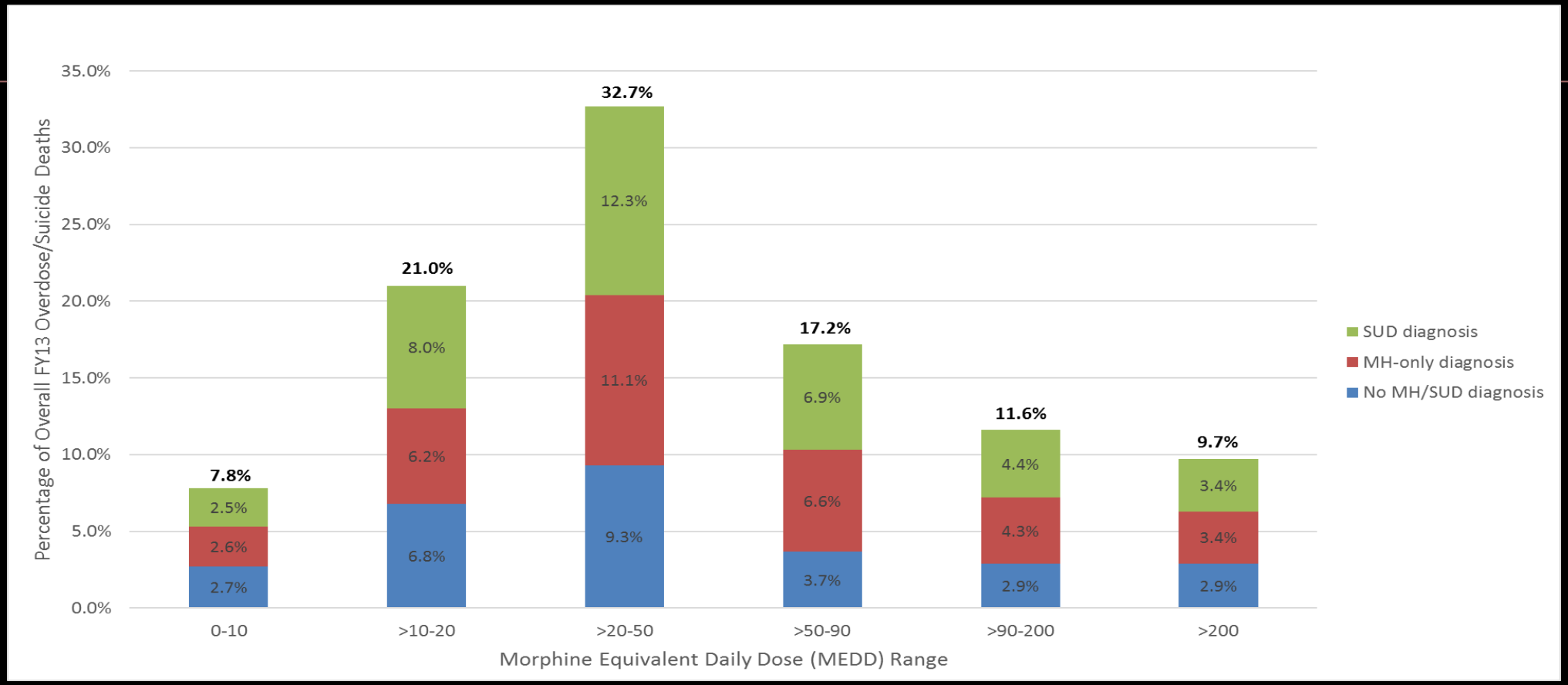
Prescribing
Patient factors

"**Opioid dosage** was the factor most consistently analyzed and also associated with increased risk of overdose. Other risk factors include **concurrent use of sedative hypnotics**, use of **extended-release/long-acting opioids**, and the presence of **substance use and other mental health disorder comorbidities**."

Park et al. J Addict Med 2016

Review of 15 articles published between 2007 and 2015 that examined risk factors for fatal and nonfatal overdose in patients receiving opioid analgesics.

FY2013/14 Overdose/Suicide Mortality - VHA



- Almost 4 out of every 5 patients who died from overdose/suicide were prescribed doses < 90 MEDD
- Almost 3 out of every 4 overdose/suicide deaths were among patients with MH/SUD diagnoses
- More than 1 out of every 2 deaths were among patients with MH/SUD diagnoses prescribed < 90 MEDD

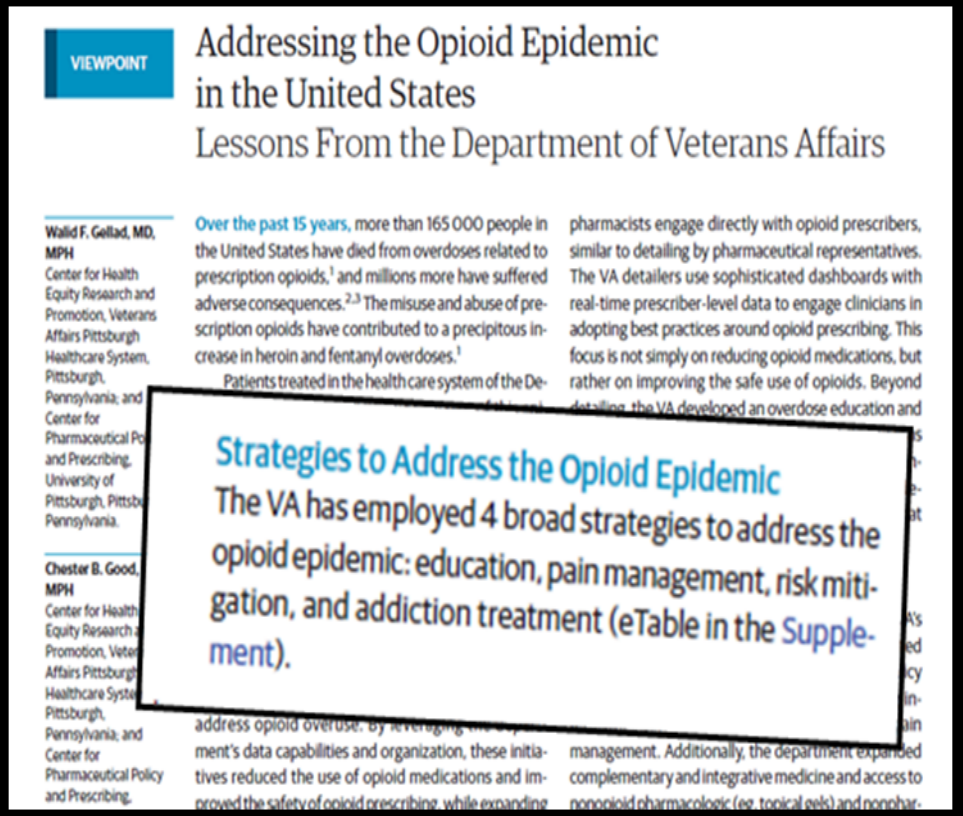
Paradigm Shift in Pain Care

- ***Paradigm shift away from opioid therapy*** *for non-end-of-life pain management.*
- There is no completely safe opioid dose threshold below which there are no risks for adverse outcomes.
  - Even a short-term use of low dose opioids may result in addiction.
  - Realization that any initial, short-term functional benefit will likely not be sustained in most patients.
  - Prolonged use of opioids, especially in higher doses, may lead to central sensitization and increase in pain over time (*Opioid Induced Hyperalgesia*)
  - Patients on opioids may actually experience a functional decline in the long term, measured by factors like returning to employment.
- ***Paradigm shift towards multimodal and integrated team-based pain care***
  - ***(biopsychosocial interdisciplinary care)***

The VA Opioid Safety Initiative (OSI)

Opioid Safety Initiative (OSI) National Expansion FY 2013

- **OSI Aims**
  - Reduce over-reliance on opioid analgesics for pain management
  - Safe and effective use of opioid therapy when clinically indicated
- **Comprehensive OSI strategy includes**
  - Provider education; Academic Detailing
  - Access to non-pharmacological modalities, incl. behavioral and CIH modalities
- **OSI Dashboard**
  - Totality of opioid use visible within VA
  - Provides feedback to stakeholders at VA facilities regarding key opioid parameters


VIEWPOINT

Addressing the Opioid Epidemic in the United States
Lessons From the Department of Veterans Affairs

Walid F. Gellad, MD, MPH
Center for Health Equity Research and Promotion, Veterans Affairs Pittsburgh Healthcare System, Pittsburgh, Pennsylvania; and Center for Pharmaceutical Policy and Prescribing, University of Pittsburgh, Pittsburgh, Pennsylvania.

Chester B. Good, MPH
Center for Health Equity Research and Promotion, Veterans Affairs Pittsburgh Healthcare System, Pittsburgh, Pennsylvania; and Center for Pharmaceutical Policy and Prescribing,

Over the past 15 years, more than 165 000 people in the United States have died from overdoses related to prescription opioids,[1] and millions more have suffered adverse consequences.[2,3] The misuse and abuse of prescription opioids have contributed to a precipitous increase in heroin and fentanyl overdoses.[1]

Patients treated in the health care system of the De-

pharmacists engage directly with opioid prescribers, similar to detailing by pharmaceutical representatives. The VA detailers use sophisticated dashboards with real-time prescriber-level data to engage clinicians in adopting best practices around opioid prescribing. This focus is not simply on reducing opioid medications, but rather on improving the safe use of opioids. Beyond

Strategies to Address the Opioid Epidemic
The VA has employed 4 broad strategies to address the opioid epidemic: education, pain management, risk mitigation, and addiction treatment (eTable in the Supplement).

address opioid overuse. By leveraging the Department's data capabilities and organization, these initiatives reduced the use of opioid medications and improved the safety of opioid prescribing, while expanding

management. Additionally, the department expanded complementary and integrative medicine and access to

VHA Opioid Safety Initiative (OSI)

OSI Parameters and Policies (selected)

Dashboard

1. **Opioid use overall**, and long-term opioid use
2. **Opioid and Benzo co-prescribing**
3. **High dose >100 MEDD**
4. **Urine Drug Testing**

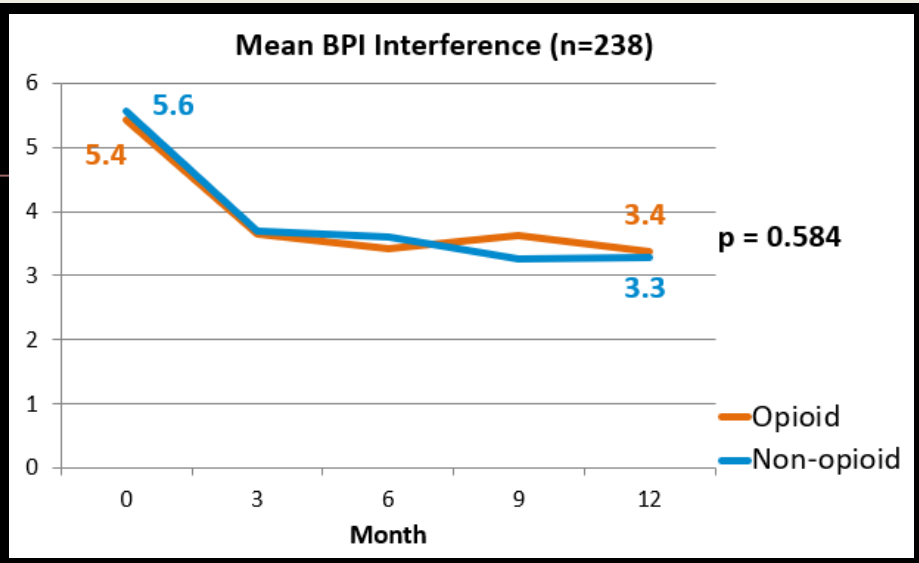
Other OSI parameters/risk mitigation strategies:

- **Informed consent** (2014) for pts on LTOT (90 d)
- **PDMP checks** (2016) annually or more often per state, for all controlled medications if > 5 d supply
- **Overdose Education and Naloxone Distribution** broad inclusion, no cost to Veterans
- **Timely f/u** within 1-4 weeks after dosage change, and at least q3 months to review care
- **OSI Risk Reviews based on STORM** (2018) optimize care of pts with very high risk for OD/suicide, and assess risk prior to initiation of opioid therapy

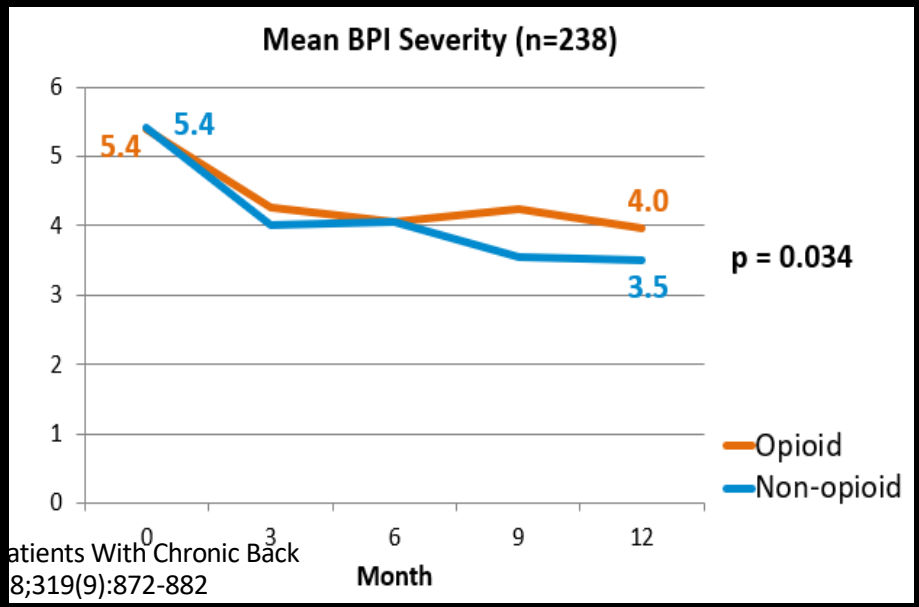
Long-Term Opioid Therapy – No Evidence of Benefit (SPACE Trial)

Opioid vs. Nonopioid Medications for chronic back pain or hip or knee osteoarthritis pain. Krebs et al. JAMA 2018

- Strategies for Prescribing Analgesics Comparative Effectiveness (SPACE) trial
- Pragmatic, 12-month, randomized trial with masked outcome assessment.
- Primary care clinics at the Minneapolis VAMC, from June 2013 through December 2015
- Moderate to severe chronic back pain or hip or knee osteoarthritis pain despite analgesic use.
- 240 patients were randomized.



- Opioid therapy and non-opioid medication resulted in similar pain related function (pain interference) over 12 months.
- Opioid therapy had worse pain intensity at 12 months, but the magnitude was small.
- Opioids had more medication-related adverse effects.



atients With Chronic Back
8;319(9):872-882

PAINWEEK

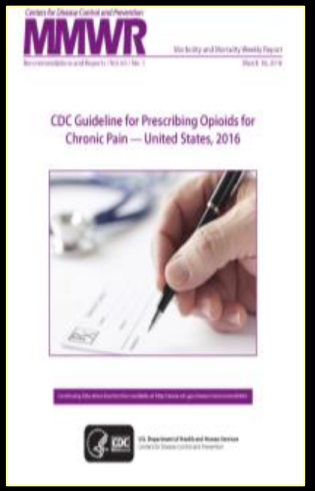
Evidence: CDC Opioid Prescribing Guideline (2016)

Summary of the Evidence

Evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited:

- insufficient evidence to determine long-term benefits versus no opioid therapy
- Though evidence suggests risk for serious harms that appears to be dose-dependent.

- **Primary Care Provider**
- Purpose:
  - **Improve communication between clinicians and patients** about the risks and benefits of opioid therapy for chronic pain
  - Improve the safety and effectiveness of pain treatment
  - Reduce the risks associated with long-term therapy including opioid use disorder

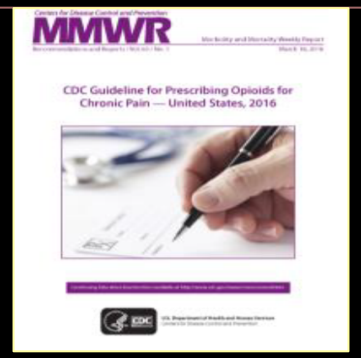


https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

Evidence: CDC Opioid Prescribing Guideline (2016)

12 Recommendations (abbreviated)

- Opioids not 1st line or routine therapy for chronic pain.
- Goals of improved pain and function
- Begin with immediate release opioids
- Use caution when increasing dosages, especially >50 MME/d; avoid or justify escalating to >90 MME/d
- Close f/u within 1-4 weeks; reevaluate for harms/risk with patients every 3 months or more frequently
- If benefits do not outweigh harms, work with patients to taper
- No more than needed for acute pain; 3-7 days usually enough
- Risk mitigation: naloxone, PDMP checks, urine drug testing.
- Avoid concurrent benzos and opioids "whenever possible"
- Offer/arrange medication-assisted treatment for OUD

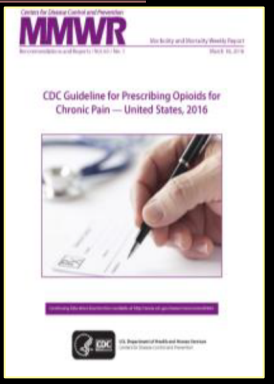


"Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context."

CDC Guideline – Follow-up 2019

NEJM April 24, 2019 **No Shortcuts to Safer Opioid Prescribing**

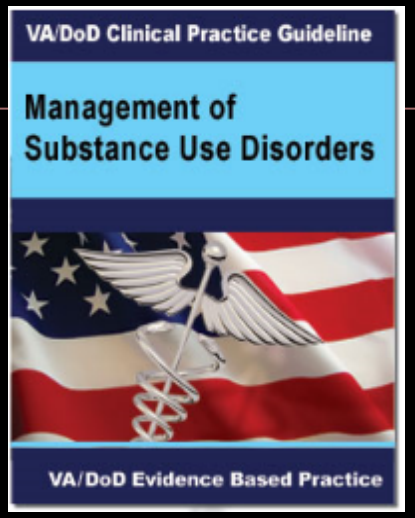
Dowell D, Haegerich T and Chou R.

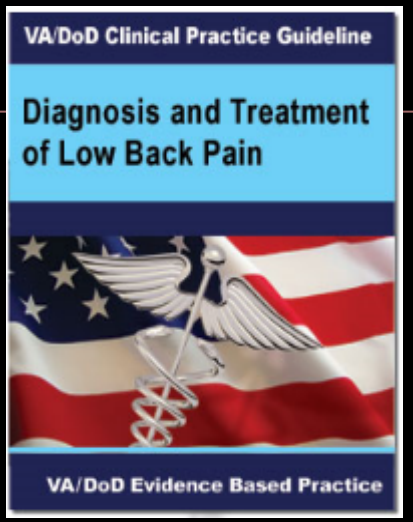


- "Unfortunately, **some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations**. … inconsistencies, which include **inflexible application of recommended dosage and duration thresholds and policies that encourage hard limits and abrupt tapering** of drug dosages, resulting in sudden opioid discontinuation or dismissal of patients from a physician's practice. … Such actions are likely to **result in harm to patients**."
- "**Starting fewer patients on opioid treatment and not escalating to high dosages** in the first place will reduce the numbers of patients prescribed high dosages in the long term.
- In the meantime, clinicians can maximize use of nonopioid treatments, review with patients the benefits and risks of continuing opioid treatment, **provide interested and motivated patients with support to slowly taper opioid dosages**, closely monitor and mitigate overdose risk for patients who continue to take high-dose opioids, and offer or arrange medication-assisted treatment when opioid use disorder is identified."
- Patients exposed to high dosages for years may need slower tapers (e.g., **10% per month, though the pace of tapering may be individualized**). Success might require months to years.

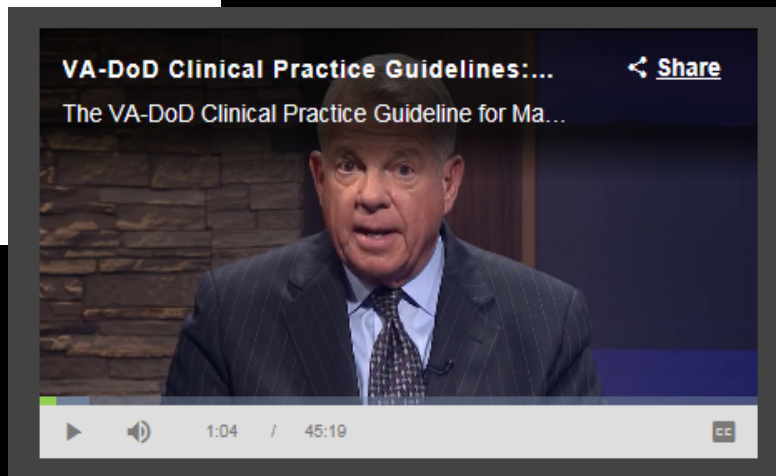
VA/DoD Clinical Practice Guidelines

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.





About the CPG	Guideline Links	Patient-Provider Tools	Related Guidelines
The guideline is formatted as a single algorithm with annotations. Questions about the OT Guideline	OT Full Guideline (2017) OT Provider Summary (2017) OT Pocket Card (2017)	OT Patient Summary (2017) Managing Side Effects Fact Sheet (2017) Patient Information Guide (2017) Opioid Therapy Provider Guide (2017) Tapering and Discontinuing Opioids (2017)	Substance Use Disorder (SUD)



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VA/DoD Clinical Practice Guideline: Opioid Therapy (2017)

– VA/DoD CPG includes 18 recommendations, organized in 4 topic areas

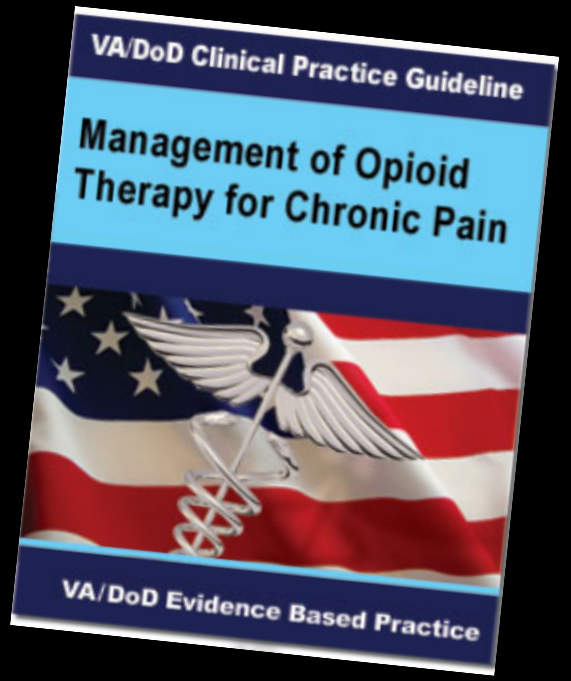
- Initiation and Continuation of Opioids

Recommendation 1:

"We recommend against initiation of long-term opioid therapy.

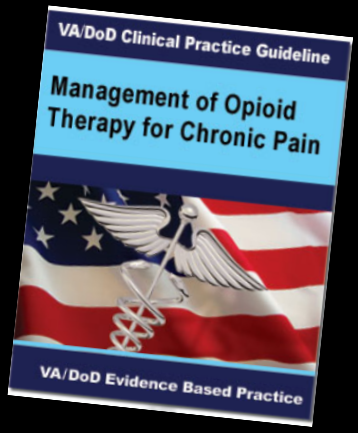
We recommend **alternatives to opioid therapy** such as self-management strategies and other non-pharmacological treatments.

When pharmacologic therapies are used, we **recommend non-opioids over opioids**".



VA/DoD Clinical Practice Guideline: Opioid Therapy (2017)

- Initiation and Continuation of Opioids (cont'd)
  - Recommendation against opioid therapy in patients **< 30 years of age**, in patients with **active substance use disorder**, and in combination **with benzos**



- Risk Mitigation
  - Recommendation for risk mitigation strategies, including:
    - **Informed Consent, Urine Drug Testing, PDMP**
    - **Overdose Education and Naloxone prescribing.**
  - Assess for **Suicide risk**
  - Evaluate benefits and risks **at least every 3 months**

VA/DoD Clinical Practice Guideline: Opioid Therapy (2017)

- Type, Dose, Follow-up, and Taper of Opioids
  - If prescribing opioids: **short duration and lowest dosage**
  - **No dosage is safe**; Strong rec against of opioids to > 90 MEDD
  - **Avoid long-acting opioids for acute pain, as prn, or upon initiation** of opioid therapy
  - Opioid **dosage reduction should be individualized** to patient.

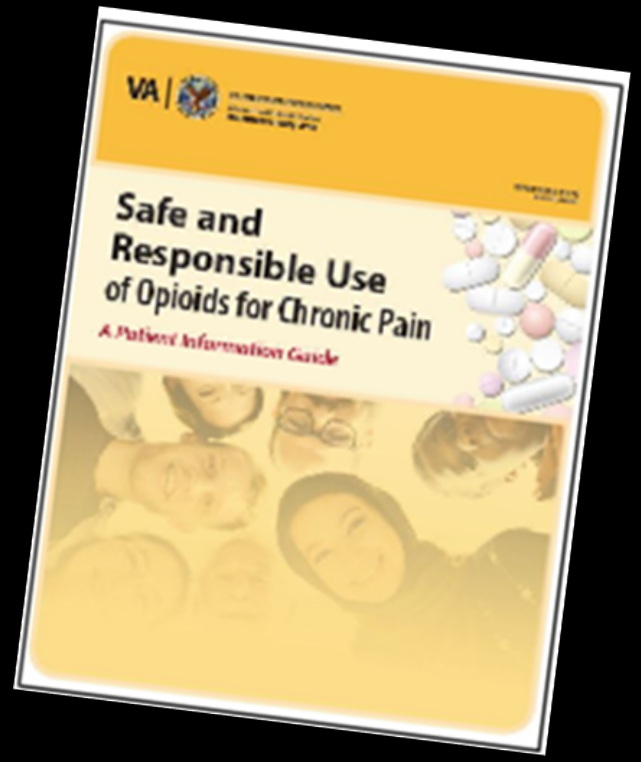
    Avoid sudden reductions; if opioid risk > benefit, taper slowly (!)
  - For **OUD**, offer medication opioid use disorder treatment (MOUD)

- Opioid Therapy for Acute Pain
  - **Acute pain:** use alternatives to opioids; use multimodal pain care, **if opioids prescribe for ≤ 3-5 days**

Informed Consent for Long-Term Opioid Therapy

- **VHA Policy: Informed consent (via I-Med)**
  - **Required for all patients on Long-term Opioid Therapy (LOT)**, defined as > 90 days
- **Excluded are:** patients enrolled in hospice, on opioids for cancer pain → oral consent

- **Opportunity to discuss risks of and alternatives to long-term opioid therapy with the veteran.**
- **Provides some protection to provider and facility in case of harm to the patient related to opioid therapy**.
- Updated in 2018, expanded are
  - Opioid risks, Opioid dosage reduction/tapering, and
  - Non-pharmacological strategies for pain care
- After education of patient and family and obtaining the signature informed consent, a copy of the signed document including the brochure "Taking Opioids Responsibly" is given to the patient.



Urine Drug Testing

- Random urine drug testing (UDT) prior to and routinely during long-term opioid prescribing.
- A **verbal consent** should be obtained and documented in the patient's medical record by the provider (may be done in advance, at least every 12 months).
- Frequency of UDT needs to be based on risk.
  - **at a minimum every 12 months for low risk** and
  - every 3 months or **more frequently for higher risk patients.**

- Correct interpretation of the result is imperative.
- Unexpected/abnormal results on urine drug screen must be confirmed by confirmatory testing.

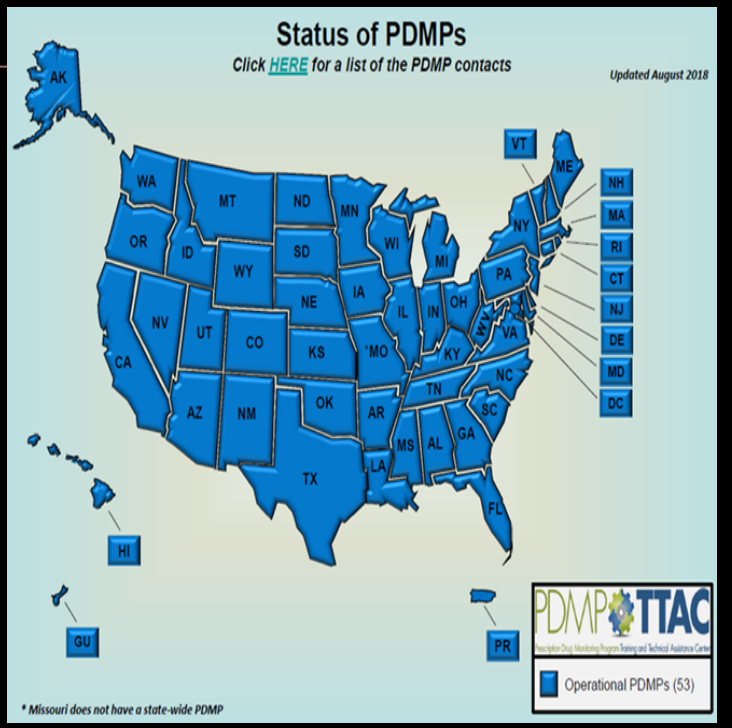
Prescription Drug Monitoring Programs (PDMPs)

- **VHA policy**:
  - PDMP queried for **all controlled substances** on annual basis at a minimum.
  - PDMP check prior to initiating therapy with a controlled substance.
  - When clinical indications and patient safety concerns warrant more frequently, at the discretion of the prescriber.
  - **Prescribers must conform to the policies of the state of their licensure**.
    - Relevant states: provider licensure, facility/practice location, Veteran residence
    - State policies vary greatly; several require PDMP check with each prescription.
  - CPRS **standard note title** for documentation.
  - **Exclusions**
    - Controlled substance prescription for ≤ 5-day supply without refills
    - Any patient enrolled in Hospice care

State Prescription Drug Monitoring Programs (PDMPs)

- VA has fully activated the PDMP data transmission capabilities to 49 states, Puerto Rico, and the District of Columbia.
  - Missouri does not currently have a statewide program.

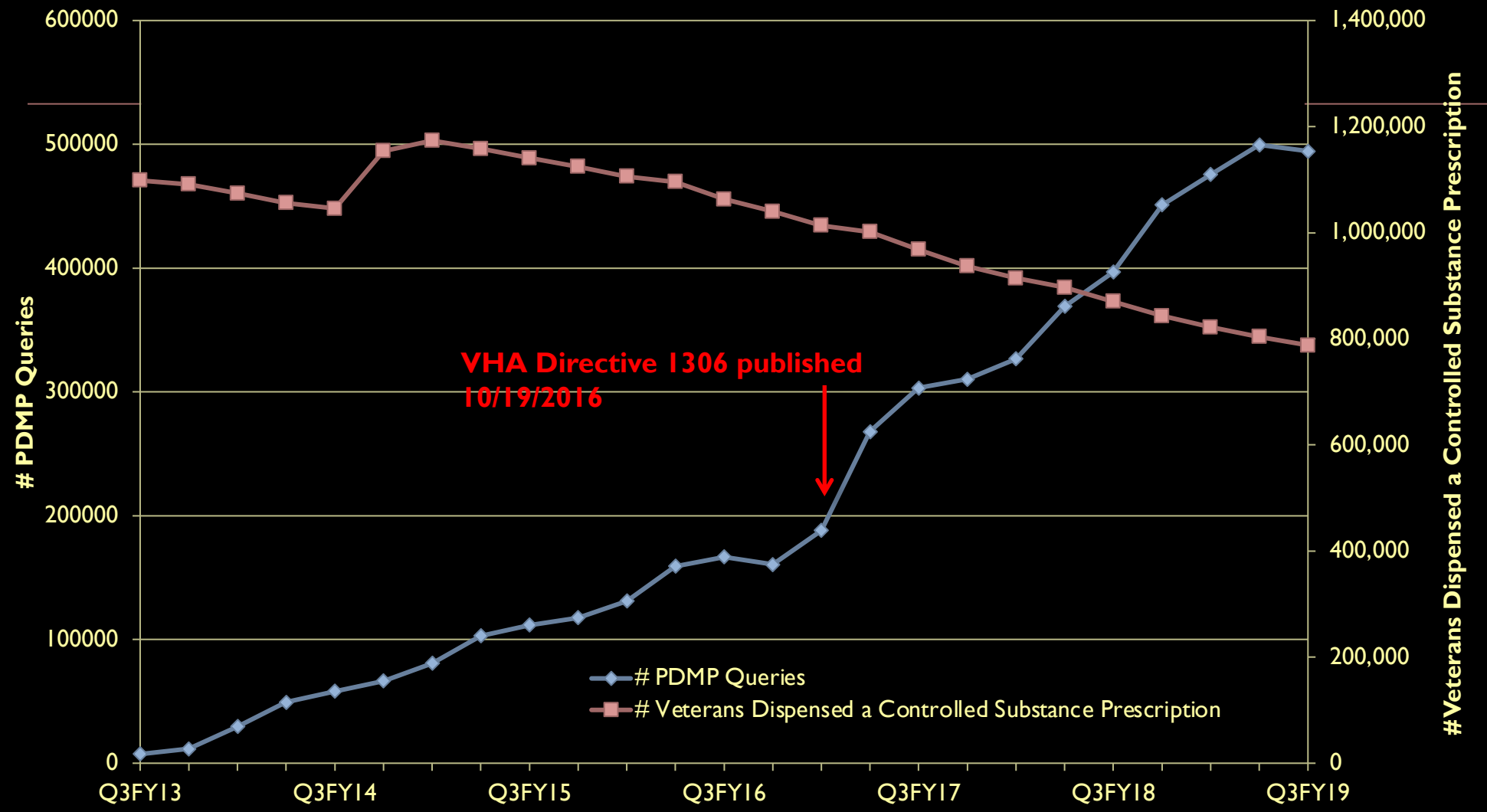
- **All prescribing providers should register and use the PDMPs regularly.**
- CDC recommendation: check PDMP prior to initiation of opioids and at least once every 3 months, consider check prior to every opioid prescription.
- MISSION Act Section 134 allows VA to develop a more seamless, comprehensive, and efficient query process of the State PDMP databases by leveraging Federal Supremacy.
  - Section 134: No state will be authorized to restrict the access of licensed health care providers or delegates from accessing that state's PDMP.
  - VA will implement IT solution for automated PDMP queries in 2020



http://www.pdmpassist.org/

VHA Directive 1306, Querying State Prescription Drug Monitoring Programs (PMDP). Oct. 19, 2016
VA Maintaining Systems and Stengthening Integrated Outside Netwworks (MISSION) Act June 2018

PDMP Queries and Dispensing of a Controlled Substance to Veterans (VHA)



- PDMP checks are continuing to increase
- Controlled Substance prescribing is decreasing
- Percent of patients continues to rise, approaching 90%

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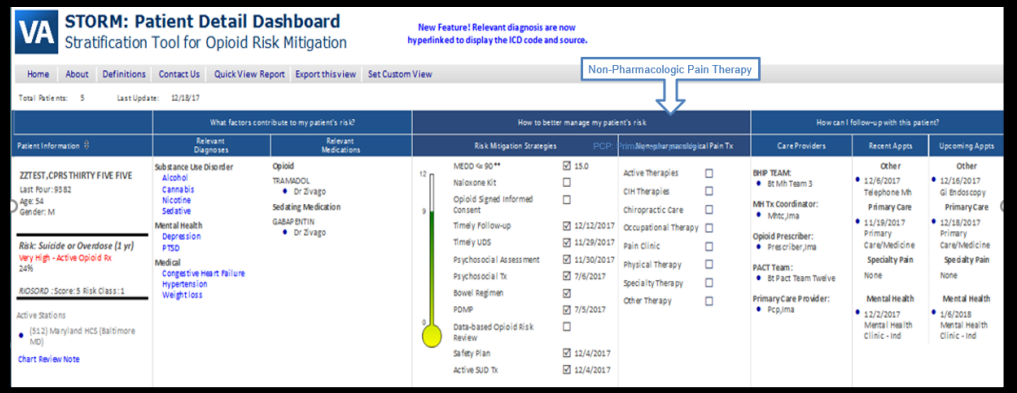
Opioid Risk Reviews (Data-based)

- 20-30% of patients with opioid overdoses are estimated to be intentional/suicidal
- STORM dashboard identifies Veterans at very high risk
- Other patients with high risk: dosage, opioid/benzo combination, etc.
- OSI review teams include Primary Care, Pain specialty, MH, SUD programs
- Care coordination across services
- Care recommendations entered into the EMR to assist clinical providers

Stratification Tool for Opioid Risk Mitigation (STORM)

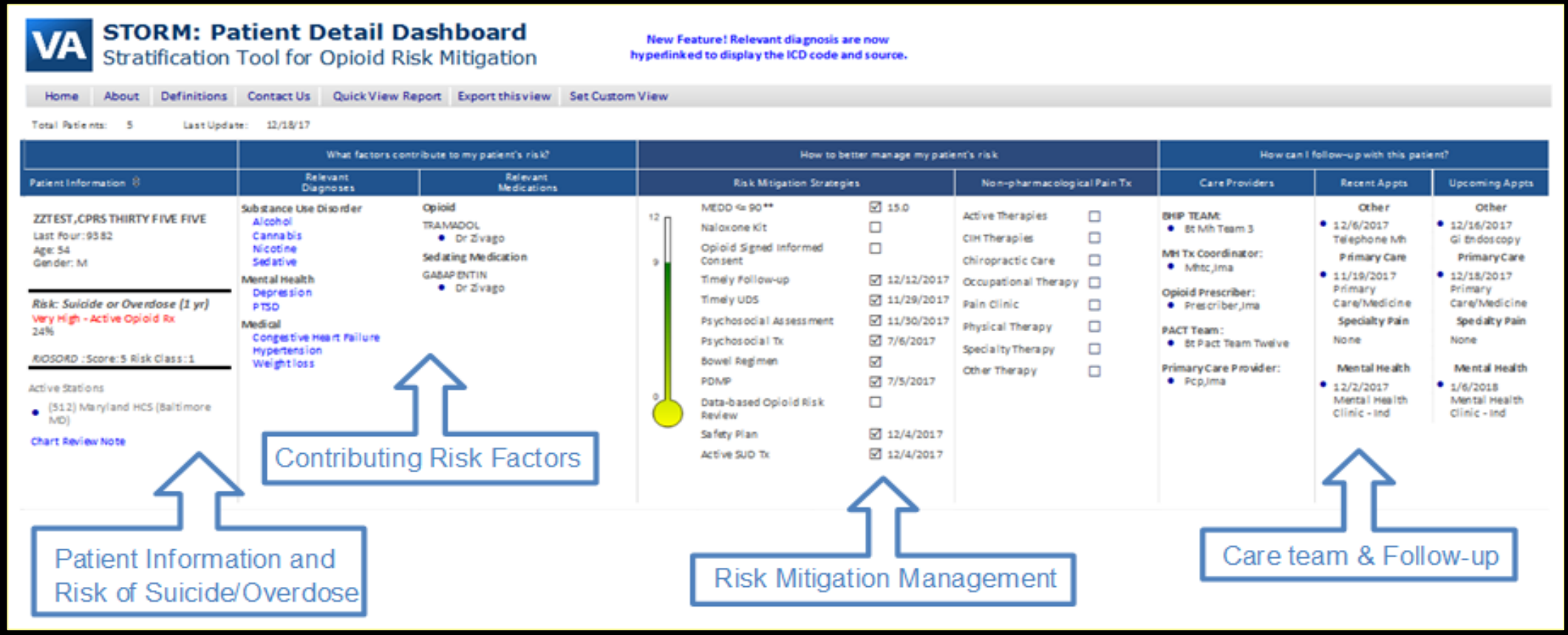


- **Field Guidelines updated in FY19**
- **Model for interdisciplinary case review forums** at facilities for patients with complex pain conditions
- **Routine screening for suicide risk** in Primary Care, Mental Health, Pain, and Sleep Clinics

Oliva et al. Psychol Serv. 2017;14:34-49

Stratification Tool for Opioid Risk Mitigation – STORM

- 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.
- ~~**Identifies patients at-risk for opioid overdose-/suicide-related adverse events.**~~
- **Provides patient-centered opioid risk mitigation strategies, targeted at risk level.**



Oliva et al. Psychol Serv. 2017;14:34-49

Overdose Education and Naloxone Distribution - OEND

- **Overdose Education (OE)**
  - How to prevent, recognize, and respond to an opioid overdose
- **Naloxone Distribution (ND)**
  - FDA approved as **naloxone auto injector and nasal spray**
  - Dispense and train patient and caregiver/family
- Target patient populations: OUD and prescribed opioids

- **Naloxone to be offered widely, low threshold for prescribing**
  - Factors that increase risk for opioid overdose include h/o overdose, h/o SUD, higher opioid dosages (≥50 MMED), or concurrent benzodiazepine use
  - Offer to patients with recent opioid discontinuations or during tapering of opioids

- No cost to patients (elimination of copays for naloxone and training, as per CARA)

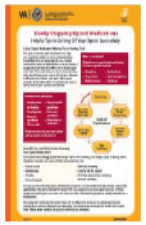
- **Rapid Naloxone initiative**: VA first responders and VA staff including deployment in automated external defibrillator (AED) cabinets and to VA police
  - More than 318,000 naloxone prescriptions dispensed with 780 overdose reversals (Sept. 30, 2019)

VA Academic Detailing Educational Materials

Pain/Opioid Safety Initiative

Marijuana: Natural = Safe, Right?

Classification: Patient Factsheet
File Name: Marijuana Use: Patient Discussion Tool
IB&P Number: IB 10-927; P96809



Slowly Stopping Opioid Medications
Helpful Tips to Getting Off Your Opioid Successfully

Classification: Patient Factsheet
File Name: Pain – Patient – Slowly Stopping Opioids
IB&P Number: IB 10-1016; P96884

Pain
New Ways to Treat a Common Problem

Classification: Patient Factsheet
File Name: Pain – Patient – Pain Information Guide
IB&P Number: IB 10-1017; P96885

Opioid Overdose Education and Naloxone Distribution

Provider Materials

VA OEND Program Quick Reference Guide

Classification: Provider Quick Reference Guide
File Name: OEND – Provider – Quick Reference Guide_V2
IB&P Number: IB 10-788; P96790

Provider DVD: VA Overdose Rescue with Naloxone

Classification: DVD
File Name: OEND – Patient – Provider DVD: VA Overdose Rescue with Naloxone
IB&P Number: IB 10-770; P96764

Patient Materials

Naloxone Instructions

Naloxone Nasal Spray 4 mg Instructions – Pocket Card

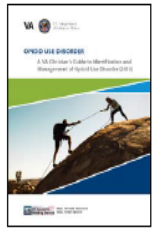
Classification: Patient Brochure
File Name: OEND – Patient – OEND Patient Brochure – Pocket Card
IB&P Number: IB 10-926; P96808

Opioid Overdose Rescue with Naloxone: Auto-Injector Kit Instructions_v2

Classification: Patient Brochure
File Name: OEND – Patient – Naloxone Kit Instructions – Auto-Injector_V2
IB&P Number: IB 10-780; P96782

Opioid Use Disorder

Provider Materials



Opioid Use Disorder
A VA Clinician's Guide to Identification and Management of Opioid Use Disorder (2016)

Classification: Provider Educational Guide
File Name: OUD – Provider AD – Educational Guide
IB&P Number: IB 10-933; P96813

Opioid Use Disorder
Identification and Management of Opioid Use Disorder

Classification: Provider Quick Reference Guide
File Name: OUD – Provider AD – Quick Reference Guide
IB&P Number: IB 10-932; P96812

Patient Materials

Opioids: Do You Know the Truth About Opioid Use Disorder?

Classification: Patient Brochure
File Name: OUD – Patient AD – Direct to Consumer Brochure
IB&P Number: IB 10-937; P96829

Approaching Opioid Tapering

- **Integrated approach with patient buy-in and active participation**
  - **Goal is to improve function and long-term outcome** while reducing risk
  - **Slower, more gradual tapers are often better tolerated**, may take months to years
  - **Sudden interruption of opioid prescribing must be avoided** with few safety exceptions
- **Provider approach: empathetic, personalized, building trust**
- **Assess and address patient needs/concerns incl. psychological factors**
- **Close collaboration with MH providers and integrated access to OUD treatment**
  - **Patients are often scared** about opioid dosage reduction
  - Expectations should be clear and **reasonable/achievable**
  - Assess patient preference regarding dosage changes (LA/IR opioid, timing)
  - **Evidence of OUD may manifest during opioid dosage reduction**
- **Patients are often at high risk for overdose after tapering**
  - **Protracted withdrawal and lowered tolerance** increase risk of OD **after** opioid discontinuation.
  - Follow-up within 1 to 4 weeks after dosage adjustments and continued follow-up after discontinuations.

Caution: **Involuntary tapers carry greater risk and interfere with provider/patient relationship**.

HHS Opioid Tapering Guide - Oct. 2019

- Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics – PDF (Oct. 2019)

HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics

This HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics provides advice to clinicians who are contemplating or initiating a reduction in opioid dosage or discontinuation of long-term opioid therapy for chronic pain. In each case the clinician should review the risks and benefits of the current therapy with the patient, and decide if tapering is appropriate based on individual circumstances.

After increasing every year for more than a decade, annual opioid prescriptions in the United States peaked at 255 million in 2012 and then decreased to 191 million in 2017.[1] More judicious opioid analgesic prescribing can benefit individual patients as well as public health when opioid analgesic use is limited to situations where benefits of opioids are likely to outweigh risks. At the same time opioid analgesic prescribing changes, such as dose escalation, dose reduction or discontinuation of long-term opioid analgesics, have potential to harm or put patients at risk if not made in a thoughtful, deliberative, collaborative, and measured manner.

Risks of rapid opioid taper

- Opioids should not be tapered rapidly or discontinued suddenly due to the risks of significant opioid withdrawal.
- Risks of rapid tapering or sudden discontinuation of opioids in physically dependent[a] patients include acute withdrawal symptoms, exacerbation of pain, serious psychological distress, and thoughts of suicide.[2] Patients may seek other sources of opioids, potentially including illicit opioids, as a way to treat their pain or withdrawal symptoms.[3]
- Unless there are indications of a life-threatening issue, such as warning signs of impending overdose, HHS does not recommend abrupt opioid dose reduction or discontinuation.

Whether or not opioids are tapered, safe and effective nonopioid treatments should be integrated into patients' pain management plans based on an individualized assessment of benefits and risks considering the patient's diagnosis, circumstances, and unique needs.[3,4,5] Coordination across the health care team is critical. Clinicians have a responsibility to provide or arrange for coordinated management of patients' pain and opioid-related problems, and they should never abandon patients.[3] More specific guidance follows, compiled from published guidelines (the CDC Guideline for Prescribing Opioids for Chronic Pain[3] and the VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain[4]) and from practices endorsed in the peer-reviewed literature.

Consider[a] tapering to a reduced opioid dosage, or tapering and discontinuing opioid therapy, when

- Pain improves[b]
- The patient requests dosage reduction or discontinuation[3,5]
- Pain and function are not meaningfully improved[2,3,5]
- The patient is receiving higher opioid doses without evidence of benefit from the higher dose[3,5]
- The patient has current evidence of opioid misuse[3,5]
- The patient experiences side effects[c] that diminish quality of life or impair function[3]
- The patient experiences an overdose or other serious event (e.g., hospitalization, injury),[2,3] or has warning signs for an impending event such as confusion, sedation, or slurred speech[3,5]
- The patient is receiving medications (e.g., benzodiazepines) or has medical conditions (e.g., lung disease, sleep apnea, liver disease, kidney disease, fall risk, advanced age) that increase risk for adverse outcomes[3,5]
- The patient has been treated with opioids for a prolonged period (e.g., years), and current benefit-harm balance is unclear

[1] https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html
[a] Physical dependence occurs with daily, around-the-clock use of opioids for more than a few days and means that the body has adapted to the drug, requiring more of it to achieve a certain effect (tolerance). Patients with physical dependence will experience physical and/or psychological symptoms if drug use is abruptly ceased (withdrawal).
[b] Additional tools to help weigh decisions about continuing opioid therapy are available: Assessing Benefits and Harms of Opioid Therapy, Pain Management Opioid Taper Decision Tool, and Tapering Opioids for Chronic Pain.
[c] e.g., drowsiness, constipation, depressed cognition

- *"More judicious opioid analgesic prescribing can benefit individual patients as well as public health when opioid analgesic use is limited to situations where benefits of opioids are likely to outweigh risks."*
- … once a patient is on opioids for a prolonged duration, any abrupt change in the patient's regimen may put the patient at risk of harm and should include a thorough, deliberative case review and discussion with the patient.
- Clinicians have a responsibility to coordinate patients' pain treatment and opioid-related problems. In certain situations, a reduced opioid dosage may be indicated, in joint consultation with the care team and the patient.
- HHS does not recommend opioids be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient.
- Slower tapers (e.g., ≤ 10% per month) are often better tolerated than more rapid tapers.

Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs of each patient" *Adm. Brett P. Giroir, M.D., Assistant Secretary for Health.*

Opioid Discontinuation and Suicide Risk

Opinion

When the Cure Is Worse Than the Disease

In an effort to reduce opioid addiction, doctors are cutting back on pain medication — and sometimes leaving patients to suffer.

By Maia Szalavitz

Ms. Szalavitz is the author of "Unbroken Brain: A Revolutionary New Way of Understanding Addiction."

The New York Times

Feb. 9, 2019

VA study (2017): Suicidal ideation and suicidal self-directed violence (SSV) following clinician-initiated prescription opioid discontinuation among long-term opioid users:

- 509 VHA Veterans and matched controls whose clinicians discontinued opioids, about 1/2 had SUD
- 9.2% had SI only, 2.3% had SSV
- Risk included h/o MH disorder with SI/SSV, in particular PTSD and psychotic disorder
  - but not SUD or pain dx, opioid dose or benzo script.

Access to Pain Care, Opioid Tapering, and Suicide Risk

New York Times - July 31, 2018

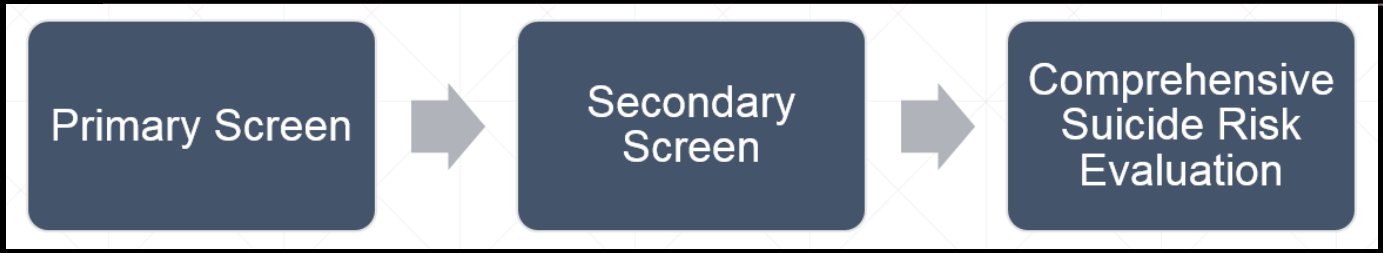
After Doctors Cut Their Opioids, Patients Turn to a Risky Treatment for Back Pain

By Sheila Kaplan

"Sherry Brandt said she was told she would be prescribed opioid painkillers for her chronic back pain only if she agreed to an epidural steroid injection."

PainWeek

Suicide Risk Screening



- Suicide screening for ALL patients newly evaluated in VHA Pain Clinics and at least annually upon follow-up
- **Primary**: Item #9 from the Patient Health Questionnaire-9 (PHQ-9), usually with PHQ-2
- **Secondary**: Columbia- Suicide Severity Rating Scale (C-SSRS) Screener

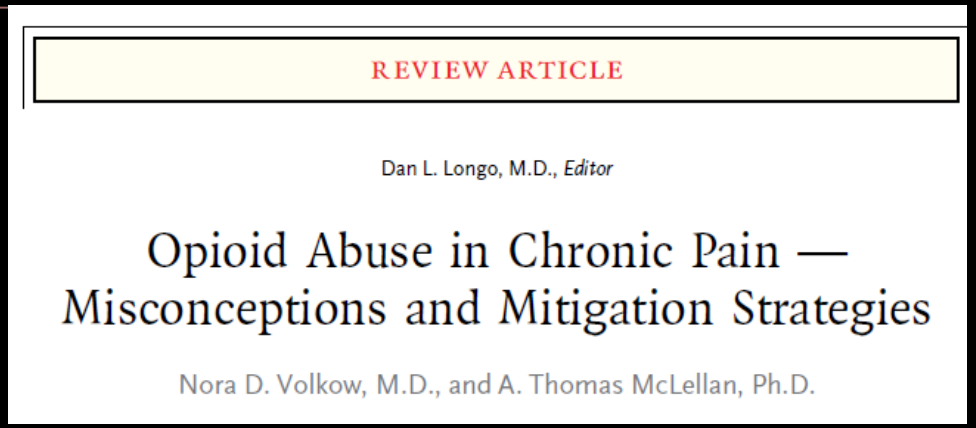
If you are a Veteran in crisis — or you're concerned about one — free, confidential support is available 24/7. Call the Veterans Crisis Line at 1-800-273-8255 and Press 1, send a text message to 838255, or chat online or at www.veteranscrisisline.net

Opioid Use Disorder (OUD) Epidemic: Misuse, Abuse and Addiction

- Prescription medication **misuse**: 2013/14 data

10.7 million people aged 12 or older misused prescription pain relievers in the past year.

- 50.5% obtained the prescription pain relievers from a friend or relative for free
- 22.1% from one doctor.


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.

- In 2014, **opioid addiction affected about 2.5 million adults in the US.**
- Prevalence estimates for OUD in pts on prescription opioids vary greatly – 1% to 41%
  - Probably less than 8%.
  - According to some studies, 25-41% of patients on prescription opioids meet DSM-5 criteria for OUD.
- Among new heroin users entering treatment programs, ¾ report initiating misuse with prescription opioids.

Lipari and Hughes: How people obtain the prescription pain relievers they misuse. 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

Diagnostic Criteria for Opioid Use Disorder

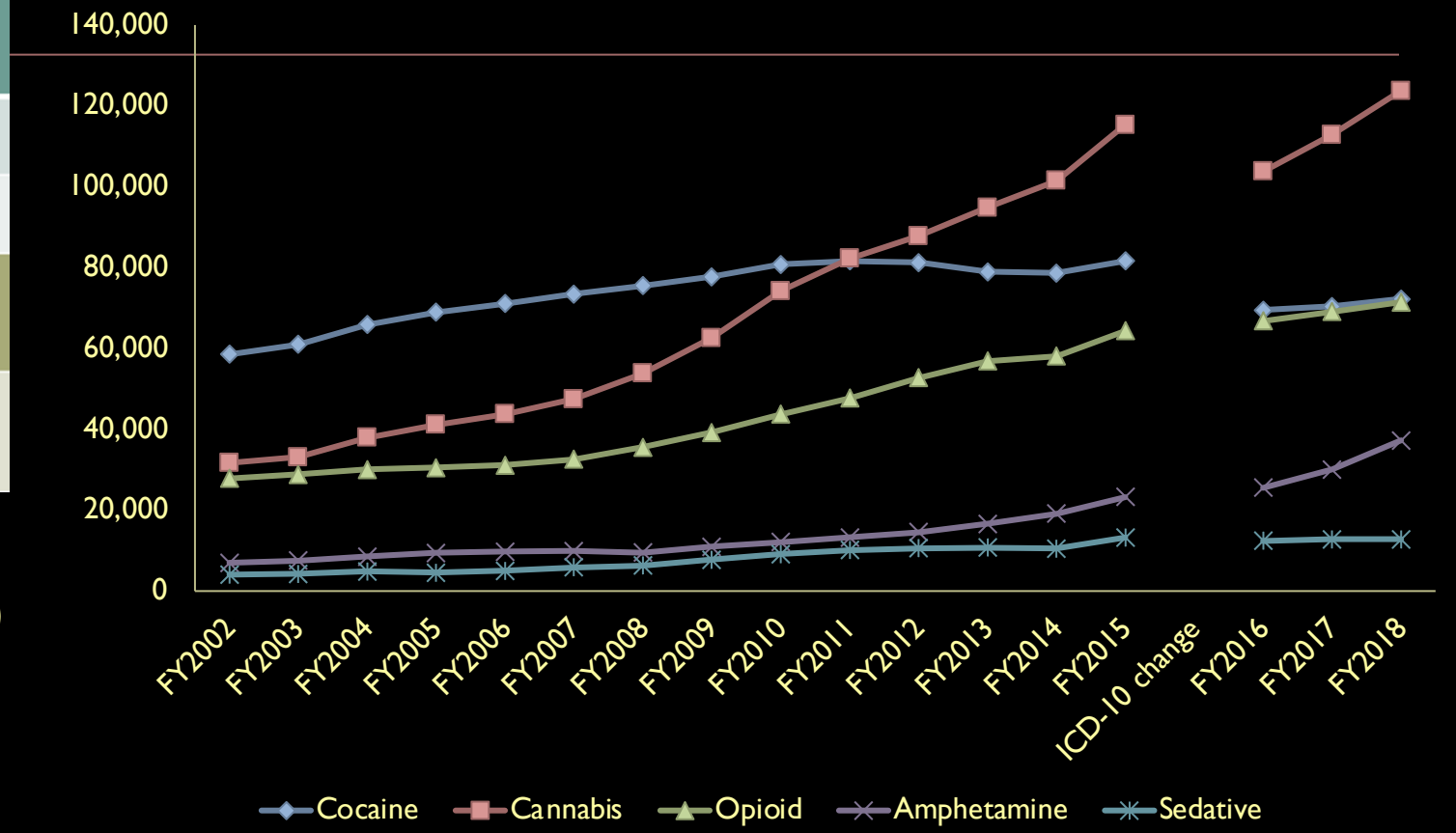
DSM-5 OUD / ICD-10 Opioid Dependence Criteria	Example signs and symptoms
1) Craving or strong desire to use opioids	Constantly thinking about next dose
2) Recurrent use in hazardous situations	Driving when impaired
3) Using more opioids than intended	Requests for early refills, multiple providers
4) Persistent desire or inability to reduce opioid use	Difficulty tapering from high risk pain opioids
5) Great deal of time spent to obtain, use, or recover	Driving to different doctor's offices to obtain opioids
6) Continued use despite knowing that opioids are causing medical or psychological problems	Requesting opioids after overdose, bowel obstruction
7) Continued use despite knowing that opioids are causing social or interpersonal problems	Continued use despite poor work performance or family requests to quit
8) Failure to fulfill obligations at home or work	Neglecting tasks- cleaning, gardening
9) Activities given up or reduced because of use	No longer playing softball, bridge
10) *Tolerance* – requiring 50% more to achieve effect*	**excluded by DSM-5 when opioids are taken under medical supervision*
11) *Withdrawal* – upon reduction or cessation of opioids*	**excluded by DSM-5 when opioids are taken under medical supervision*

DSM-5 severity: Mild 2-3 symptoms, Moderate 4-5 symptoms, Severe 6 or more symptoms

Substance Use Disorder (SUD) in Veterans

	Veterans	Non-Veterans
Alcohol use disorder	6.3%	6.8%
Illicit drug use disorders	1.5%	1.7%
Illicit drug use	8.4%*	10.5%*
Non-medical use of pain relievers	2.4%*	3.0%*

- **Prevalence of SUD in VHA**
  - 10% of Veterans (600,000 in FY15)
  - AUD >> other SUD
- **"Diagnosed" OUD**
  - 1.1% of Veterans, 71,000+ (FY 2018)
  - 24,696 Vets with OUD on MAT (FY2018)



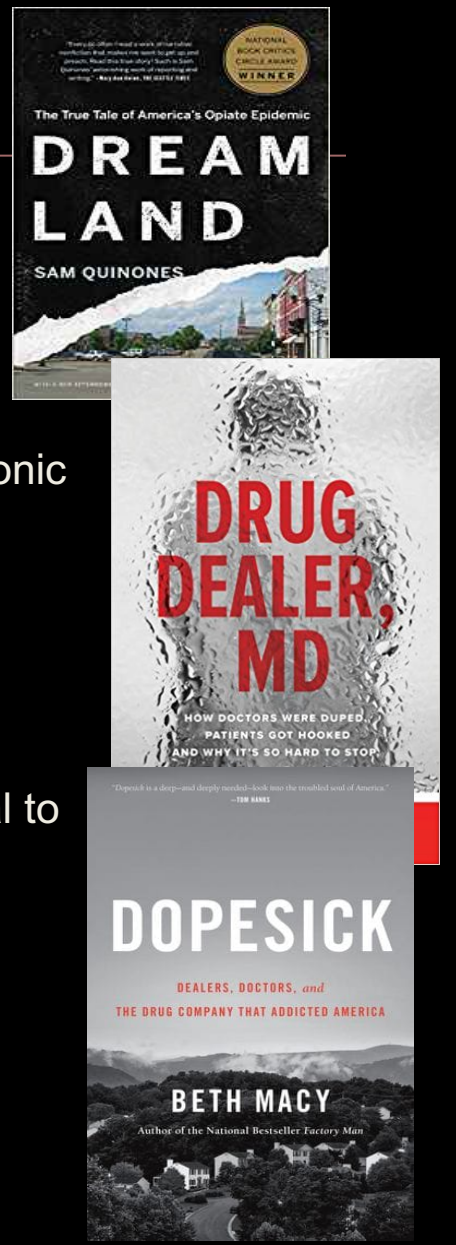
NOTE: Beginning in FY2016, VHA shifted from ICD-9 to ICD-10 diagnosis coding. Data from FY2016 onward should *not be compared* directly with those obtained in prior years using ICD-9 coding.

Lipari and Hughes: How people obtain the prescription pain relievers they misuse. 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

Summary: Opioid Safety Initiative in VHA

The Opioid Crisis Shift U.S. Overdose

1. **Overdoses from prescription opioids to illicit drugs**, most recently synthetic opioids (i.e. fentanyl).
2. Opioids in **combination with sedating drugs** are particularly dangerous.
3. **Mental health/substance use disorder contribute greatly** to risk.
4. VA/DoD CPG for Opioid Therapy **recommends against *initiation* of *long-term* opioid therapy** for chronic pain.
5. **Opioid risk mitigation strategies systemwide.**
6. Overdose education and widespread **naloxone distribution** (OEND).
7. **Opioid dosage reduction (opioid tapering) must be patient-centered** and individualized with the goal to maximize function and safety.
8. Patients with long-term opioid therapy who fulfill criteria for OUD must be offered **access to evidence-based therapy, i.e. medication for OUD (m-OUD).**



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Summary: Opioid Therapy Risk Mitigation

- Opioid therapy should only be prescribed at the lowest dose and shortest duration appropriate for the severity of the pain condition. Initiation of long-term opioid therapy is not recommended for chronic pain.
- Patients receiving opioid therapy require **timely follow-up**.
- Patients on long-term opioid therapy should be monitored and **reassessed at least every 3 months, with greater frequency based on risk**.
- **Essential components of Opioid Risk Mitigation:**
  (1) An informed consent for long-term opioid therapy.
  (2) Prescription drug monitoring programs (PDMPs).
  (3) Random urine drug testing.
  (4) Overdose education, and naloxone distribution as appropriate (OEND).
- **Always maintain vigilance** for sedation, declining function, evidence of opioid use disorder or other opioid related harms.
- All patients must be assessed for **suicide risk**.
- Each **follow-up interaction** with the patient is an opportunity to provide education about self-management strategies and the risks associated with opioid therapy while optimizing whole person approaches to pain care and treatment of comorbid health conditions.

Thank You!

THANKS TO:

- VA, VISN and Facility leadership
- VISN POCs and all facility POCs for PAIN
- OSI POCs and the OSI review committees
- Pain research community
- Pain Medicine Specialty Teams
- Pain Psychologists
- PACT Pain Champions, Primary Care
- PBM/Pharmacy
- Academic Detailing
- Mental Health
- Suicide Prevention
- Addiction Medicine
- Nursing Service
- Rehabilitation Medicine
- Integrative Health, IHCC and OPCC
- EES, Ethics
- Connected Care/Telehealth
- Patient Advocacy
- DoD partners/colleagues
- Patient Advocacy
- Community Care Program and providers
- **The Veterans and their families**

PAINWEEK®

www.va.gov/painmanagement