U.S. Department of Veterans Affairs

The VA Opioid Safety Initiative – how did we get here and what is ahead?

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No relevant financial relationships or conflicts of interest.
No discussion of off label use of drugs 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.

Objectives/Overview

- **Introduction**
- **Risk factors for Overdose/Suicide and OUD**
- **Opioid Safety Initiative in VHA**
- **Federal Initiatives and the Comprehensive Addiction and Recovery Act (2016)**
- **OSI components:**
  - Opioid Safety Initiative/Opioid Risk Mitigation
  - Dashboards
  - VA-DoD Clinical Practice Guideline
  - Provider Education
  - Complementary and integrative health (CIH)
  - Stepped Care Model and Pain Management Teams
- **OSI patient care reviews**
- **Pain, MH and SUD cooperation**

Pain Management and Opioid Safety as Foundational Services in VHA

- **Chronic pain is more common in Veterans than in the non-veteran US population, more often severe and in the context of comorbidities**.
- Pain severity and co-concurrence with mental health comorbidities result in high impact pain (i.e. associated with substantial restriction of participation in work, social, and self-care activities).
- Behavioral Health Autopsy report (2015) *"The most frequently identified risk factor among Veterans who died by suicide was pain".*
- Pain, medical and/or mental comorbidities are often related to military service and/or require Veteran-specific expertise.
- Veterans are at high risk for harms from opioid medication.
- Integrated care: systematic coordination of medical, psychological and social aspects of health care is required for high quality pain care.

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

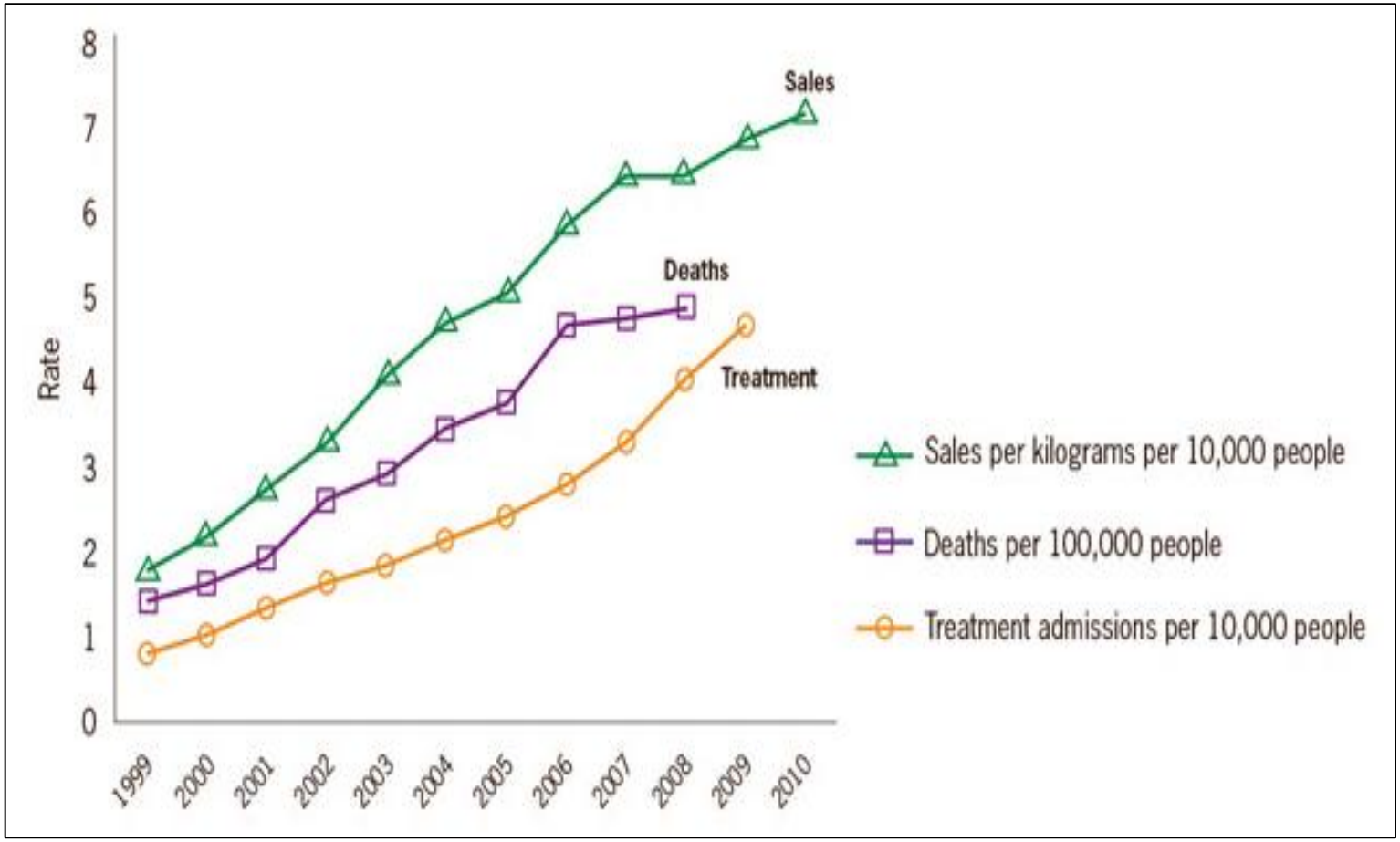
Patient Robert B.*

32 y/o OEF/OIF Veteran recently transitioned to care in VHA
CC of low back pain

* Case study includes minor modifications to protect anonymity

- Pain condition: low back pain with axial and radicular features, with significant degenerative disk disease on his spine by MRI; not surgical candidate.
- Comorbidities: PTSD (severe), TBI (mild)
- No illicit drug use
- Longstanding high dose opioid therapy that was already initiated during active military service, with Morphine SR 45 mg TID.
- At VA: Morphine dosage was gradually reduced over several months to 30 mg TID and then kept stable per patient request.
- Patient is on time with refills, not early. UDS as expected.
- The day after one of his opioid medication renewals, he was found by his father unresponsive in his bed at home.
- Review of chart: about 2 weeks prior to his last opioid renewal, he was seen by his Mental Health provider where he complained about poor sleep and also reported worsened anxiety. He had received a new diazepam prescription at that time.
- Accidental or suicidal overdose of multiple CNS depressant medications/substances.

Prescription Opioid Sales, Opioid Overdose Deaths and Opioid Use Disorder



SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009; http://www.cdc.gov/vitalsigns/painkilleroverdoses/infographic.html

The Opioid Overdose Challenge in VHA

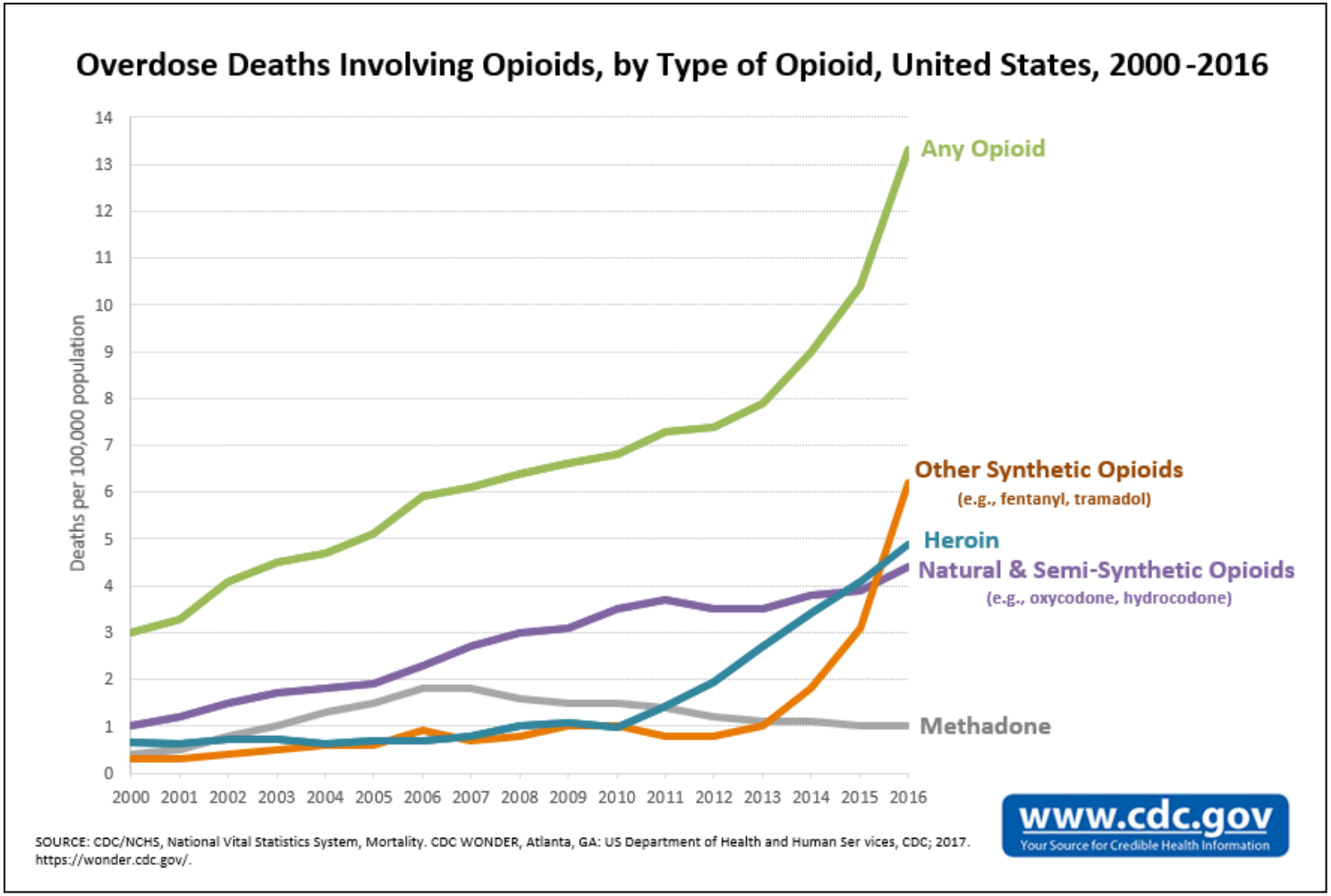
Accidental Poisoning Mortality Among Patients in the Department of Veterans Affairs Health System.
Bohnert, Ilgen, Galea et al. Med Care 2011

- Study of all 5,567,621 Veterans in VHA in FY 2004/05 alive at start of FY 2005
- 1,013 died of accidental poisoning in FY 2005.

	U.S. 2005		V.H.A. FY2005			
Gender/ Age Group	Accidental Poisonings	Crude Rate per 100,000 person-years	Accidental Poisonings	Crude Rate per 100,000 person-years	Standardized Mortality Ratio[b]	95% Confidence Interval
Males	15,679	14.51	960	20.62	1.98	**1.85, 2.10**
18-29 yrs	3,390	13.45	28	21.86	1.62	**1.02, 2.23**
30-64 yrs	11,826	17.53	841	36.81	2.10	**1.96, 2.24**
65+ yrs	463	3.01	91	4.06	1.35	**1.07, 1.63**
Females	7,647	6.68	53	11.82	1.61	**1.18, 2.04**
18-29 yrs	1,024	4.28	1	1.70	n/a	**n/a**
30-64 yrs	6,155	8.91	50	15.34	1.72	**1.24, 2.20**
65+ yrs	468	2.19	2	3.14	n/a	**n/a**
Total	**23,326**	**10.49**	**1,013**	**19.85**	**1.96**	**1.83, 2.08**

- Opioid medication 32.3% (incl. methadone 13.8%), cocaine 23.3%, other/unspecified narcotics 8.5%, antidepressants 8.1%, benzos 7.55, synthetic heroin 6.3%, psychostimulants 4.4%, synthetic narcotics 4.3%
- **"VHA patients had nearly twice the rate of fatal accidental poisoning compared with adults in the general US population."**

Overdose Deaths Involving Opioids 2016



64,070 Americans died from drug overdoses in 2016, including illicit drugs and prescription opioids – nearly double in a decade. For comparison: cocaine: 10,619; methamphetamine 7,663

https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

Opioid Use Disorder (OUD) Epidemic

- **Anyone who takes prescription opioids can become addicted to them.**
- In 2014, nearly two million Americans either abused or were dependent on prescription opioid pain relievers.
- 25-41% of patients on prescription opioids meet criteria for OUD (DSM-5).
- Heroin-related deaths more than tripled between 2010 and 2014.
- Among new heroin users entering treatment programs, ¾ report initiating misuse with prescription opioids.

Why America Can't Kick Its Painkiller Problem, TIME Magazine June 4, 2015

Risk Factors for Overdose and OUD

Risk factors are related to:

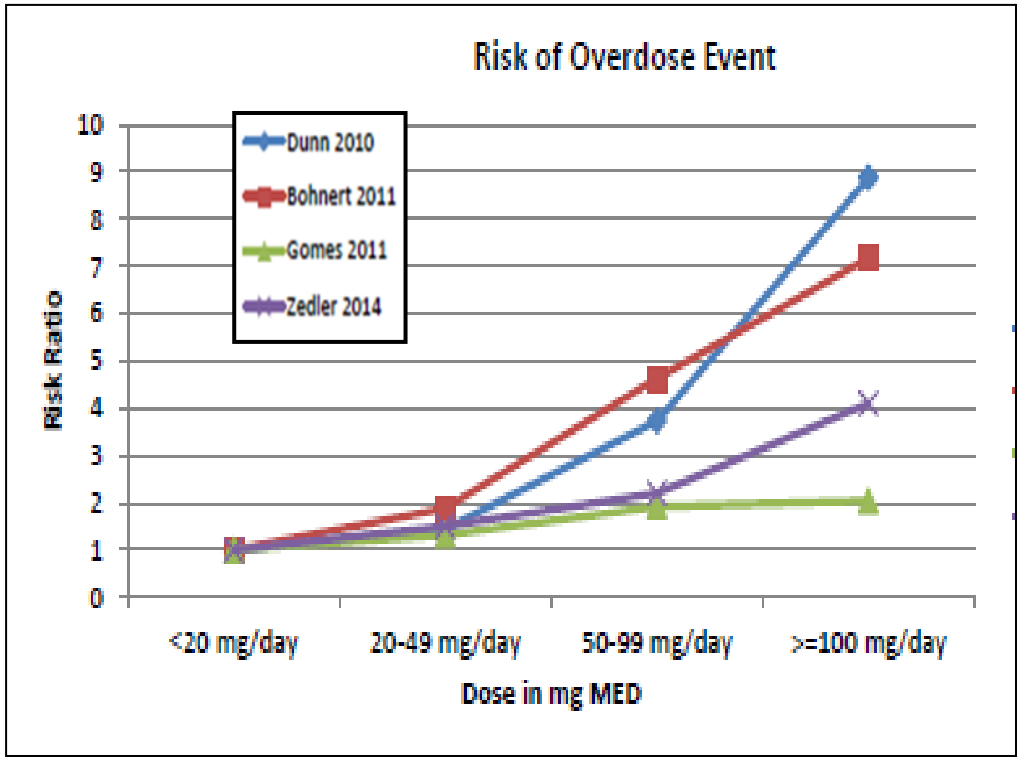
- Opioid prescribing
- Interaction with other medication/drugs
- Medical comorbidities
- Mental health comorbidities

"**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.

Higher Dosage Increases Risks from Opioids



Hazard Ratios(HR):

Mortality (all causes):

HR 1.64 for LA opioids

Overdose deaths (unintentional)

HR 7.18-8.9 for MME > 100 mg/d

Opioid use disorder

on long-term opioids (> 90 d)

HR 15 for 1-36 mg/d MME

HR 29 for 36-120 mg/d MME

HR 122 for > 120 mg/d MME

Edlund et al 2014

Dosage and Risk of Overdose from Opioids

"Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths"

Bohnert et al, JAMA 2011

Risk of Opioid Overdose Death, HR (95% CI)

	Chronic Pain (n = 111 759)
Maximum prescribed daily opioid dose, mg/d	
1-<20	1 [Reference]
20-<50	1.88 (1.33-2.67)
50-<100	4.63 (3.18-6.74)
≥100	7.18 (4.85-10.65)
Pain-related diagnoses	
Cancer	0.99 (0.72-1.36)
Chronic bodily pains	0.69 (0.35-1.33)
Headache	1.02 (0.74-1.41)
Neuropathy	0.64 (0.38-1.08)
Injuries and acute pain	1.37 (1.08-1.74)
Other diagnoses	
Substance use disorders	2.53 (1.99-3.22)
Other psychiatric disorders	1.87 (1.48-2.38)
COPD, CVD, and sleep apnea	0.63 (0.50-0.80)

- Case-cohort study
- All FY2004/05 VHA pts who died of opioid overdose by FY2008
- Random sample for comparison

Opioid OD deaths:
Total 750 cases
296 cases
498 cases

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Dosage and Risk of Overdose from Opioids

"Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths"

Bohnert et al, JAMA 2011

Table 2. Unadjusted Rate of Prescription Opioid Overdose Death by Opioid Dose and Fill Type

	Overdose Deaths, No.	Person-Months	Overdose Death Rate per 1000 Person-Months (95% CI)
Patients With Chronic Noncancer Pain Diagnoses			
Maximum prescribed daily opioid dose, mg/d			
0	243	2 729 022.7	0.09 (0.08-0.10)
1-<20	44	395 205.0	0.11 (0.08-0.15)
20-<50	108	458 296.2	0.24 (0.19-0.28)
50-<100	86	129 491.6	0.66 (0.53-0.82)
≥100	125	100 479.3	1.24 (1.04-1.48)
Fill types			
Regularly scheduled only	115	323 304.7	0.36 (0.29-0.43)
As needed only	152	672 276.0	0.23 (0.19-0.27)
Simultaneous as needed and regularly scheduled	96	87 891.5	1.09 (0.88-1.33)

- Chronic non-cancer pain were 606 of the 750 total cases
- The vast majority of overdoses happened in pts with no or lower dose opioids

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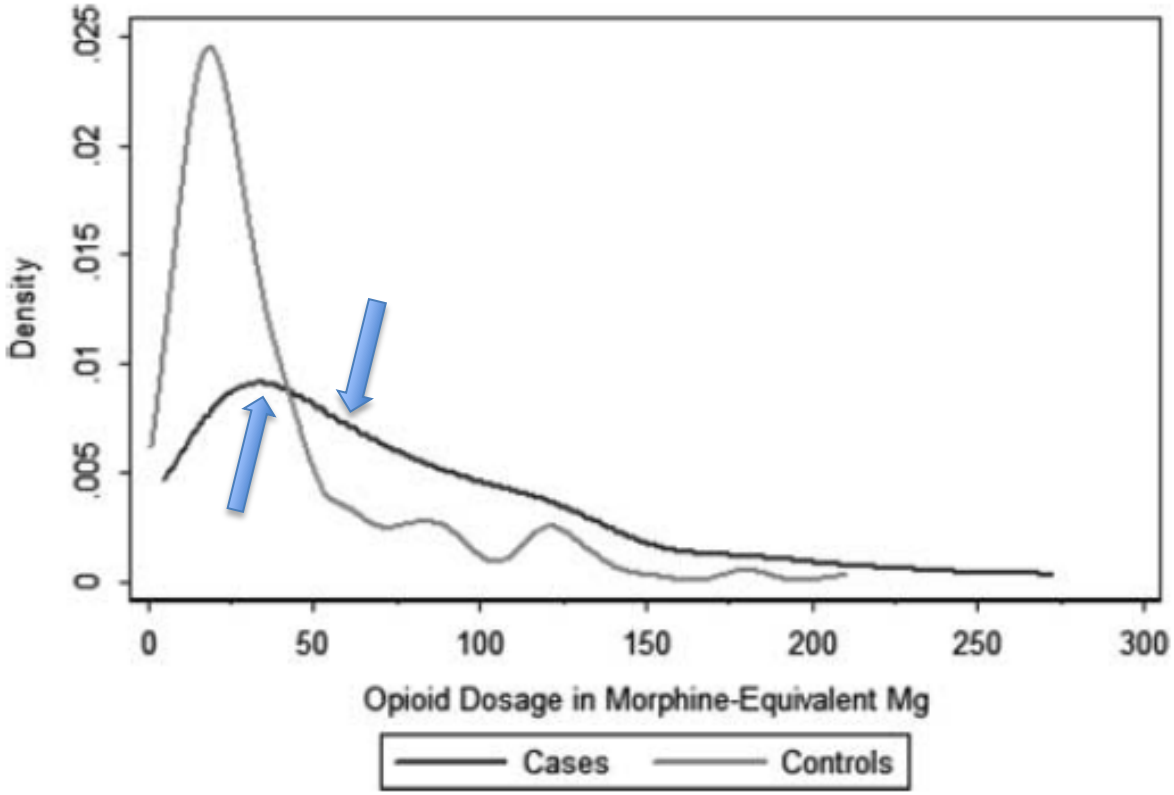
Dosage and Risk of Overdose from Opioids

"A Detailed Exploration Into the Association of Prescribed Opioid Dosage and Overdose Deaths Among Patients With Chronic Pain" Bohnert et al, Med Care 2016



2004-2009 study

- Nested case control design
- New starts of opioids for pts with chronic pain (excluding tramadol and buprenorphine)

Average opioid dosages

Cases (overdose deaths):
98.1 MEDD (SD 112.7)

Controls:
47.7 MEDD (SD 65.2)

- No clear cut-point in opioid dosage to distinguish between OD cases and controls.
- Median dosage for pts with OD was 60 mg; i.e. vast majority below 100 mg MEDD.

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Patient Risk Factors for Harm from Opioids

- **Psychiatric disorders**, including anxiety or depression.
- Personal or family history of **substance use disorder.**
- History of aberrant behavior/non-compliance.
- Age 65 or older.
- Young age (below 30).
- COPD or other underlying respiratory conditions.
- Renal or hepatic insufficiency.
- Pregnancy.

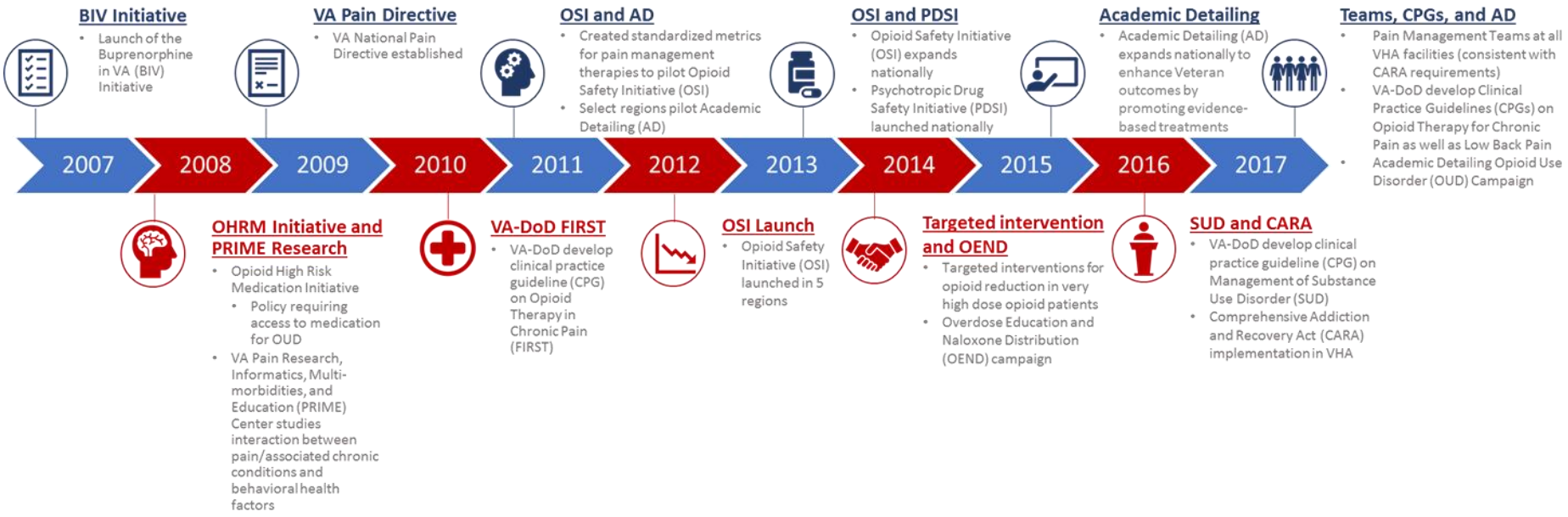
Every patient is at risk

http://www.cdc.gov/drugoverdose/opioids/prescribed.html

The VA Opioid Safety Initiative (OSI)

- **Opioid Safety Initiative (OSI)** expanded nationally in FY 2013
- The OSI aims to **reduce over-reliance on opioid analgesics for pain management and to promote safe and effective use of opioid therapy when clinically indicated**.
- Comprehensive OSI strategy that includes **education of providers** and **expanded access to non-pharmacological treatment options**, in particular behavioral and complementary integrative health modalities.
- **OSI Dashboard** makes the totality of opioid use visible within VA and provides feedback to stakeholders at VA facilities regarding key parameters of opioid prescribing.

The VA Opioid Safety Initiative (OSI) Timeline



The Opioid Crisis - Nationally

- **Presidential Memorandum: Addressing Prescription Drug Abuse and Heroin Use (Oct. 2015)**
  - Training of all federal prescribers
  - Patients with OUD require access to addiction treatment incl. MAT
- **CDC Opioid Prescribing Guidelines (March 2016)**
  - Guidance for primary care providers
  - Recommendations includes non-opioid therapy as first line therapy for pain, limit opioid therapy to short duration/low dosage if possible, and specific dosage limits (50/90 mg MEDD)
- **Comprehensive Addiction and Recovery Act (CARA) (July 2016)**
  - Title IX: Jason Simcakoski Memorial Act with specific VHA mandates
- **Presidential Opioid Commission Report (November 2017)**
  - 56 recommendations

Comprehensive Addiction and Recovery Act (CARA)

PUBLIC LAW 114–198—JULY 22, 2016

- **Community interactions**: 90-day regular meetings.
- Expanded **VA Patient Advocacy program**.
- VA/DoD **Health Executive Committee Pain Management Workgroup.**
- System-wide implementation of the **Opioid Safety Initiative.**
  - Opioid risk mitigation strategies: PDMP, UDS, informed consent.
  - Opioid Overdose Education and Naloxone Distribution (OEND)
- **Dashboards** to assess risk and monitoring opioid/pain care
- **VA-DoD Clinical Practice Guideline** for Opioid Therapy of Chronic Pain.
- **Provider education** in VA-DoD CPG and evidence based pain care
- Reporting of providers/facilities in conflict with care standards
- Expanded **complementary and integrative health** modalities.
- Full compliance with **Stepped Care Model of Pain Management**
- **Pain Management Teams** at all VA facilities.

VIEWPOINT

Addressing the Opioid Epidemic in the United States

Lessons From the Department of Veterans Affairs

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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 Department of Veterans Affairs (VA) are part of this epidemic. C… half of veterans using the VA, com… morbidities suc… stress … office … tices, opio… near… VA …

address op… ment's data capabilities and … tives reduced the use of opioid medication… proved the safety of opioid prescribing, while expanding alternative pain therapies (**Figure**). By mid-2016 compared with mid-2012, the number of veterans dispensed an opioid each quarter had decreased by 172 000, or about 25%. Moreover, there were 57 000 (47%) fewer patients receiving concomitant opioids and benzodiazepines and 22 000 (36%) fewer patients receiving daily opioid dosages of more than 100 morphine-milligram equivalents, both measures of potentially unsafe opioid use. Between 2010 and 2015, the rate of

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 detailing, the VA developed an overdose education and naloxone distribution system that has distributed tens of thousands of naloxone doses and developed stan… patient and provider education to comple… efforts outside of the VA that …macologic (eg, acu… expanded mini-residency programs … consult capabilities for primary care clinicians to im… prove their management of pain.

Risk Mitigation

The VA implemented several strategies to support and track risk mitigation activities for opioid therapy (eTable in the Supplement). A key component of the Opioid

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).

VA Opioid Data

https://www.data.va.gov/story/department-veterans-affairs-opioid-prescribing-data

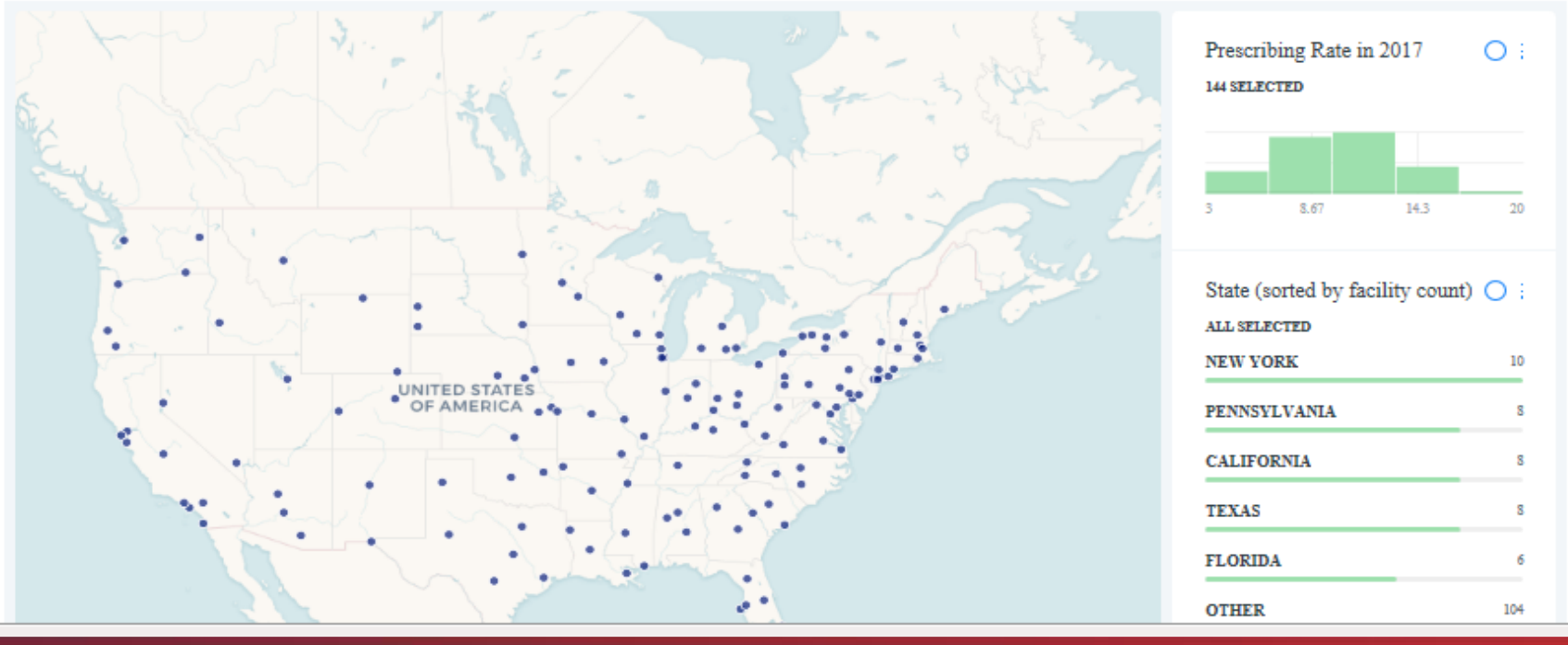
Department of Veterans Affairs Opioid Prescribing Data

In keeping with the Department of Veterans Affairs' effort to be the most transparent agency in government, VA will begin posting information publicly on opioids dispensed from VA pharmacies, along with VA's strategies to prescribe these pain medications appropriately and safely.

The interactive map shows data over a five-year period (2012-2017) and does not include Veterans' personal information. The posted information shows opioid-dispensing rates for each facility and how much those rates have decreased over time. It is important to note that because the needs and conditions of Veterans may be different at each facility, the rates of the use of opioids may also be different for that reason, and cannot be compared directly.

The prescribing rate information will be updated semi-annually, on January 15 and July 15 of each year.

If you are having issues viewing the map please click here.



VA Opioid Data Description and Example

The Opioid Safety Initiative (OSI) is the coordinating center for all of VA's efforts to promote safe prescribing practices and to address the broader opioid epidemic in the United States.

Prescribing Rates

Opioid prescribing rates are calculated by dividing the number of Veterans who received any opioid prescription by the total number of Veterans who received a prescription from that pharmacy within the specified time period.

Percent Change

The percent change represents the relative decrease (or increase) in opioid prescribing rates between 2012 and 2017. Overall, 99% of VA facilities have decreased prescribing rates since 2012.

Regional Non-VA Prescribing Rate

It is well-established that opioid prescribing rates and abuse vary across different parts of the country. Regional comparison categories were generated using publicly available data from the Centers for Medicare & Medicaid Services (CMS). CMS reports opioid prescribing rates by state, which are calculated by dividing the number of Medicare Part D claims for opioid medications by the total number of prescription claims.

Data for states are aggregated in to 5 groups by CMS. The "Low" Regional Non-VA comparison category represents the 40% of states with the lowest prescribing rates for Medicare beneficiaries. The "High" Regional Non-VA comparison category represents the 40% of states with the highest prescribing rates. The "Average" Regional Non-VA comparison category represents the 20% of states in the middle. The most current available comparison data is from 2015.

Search...

Facility	State	Rate in 2012	Rate in 2017	Percent Cha...	Non-VA Rate
Louis Stokes Cleveland VA Medical Center	Ohio	5%	3%	-41%	Low
San Juan VA Medical Center	Puerto Rico	5%	3%	-34%	n/a
Edith Nourse Rogers Memorial Veterans' Hospital	Massachusetts	6%	4%	-34%	Low
East Orange VA Medical Center	New Jersey	6%	4%	-27%	Low
Manhattan VA Medical Center	New York	8%	4%	-49%	Low

https://www.data.va.gov/story/department-veterans-affairs-opioid-prescribing-data

OSI Parameters

OSI Dashboard (PBM) – quarterly updated

1. **Opioid use overall**, and Long-term opioid use
2. **Opioid and Benzo co-prescribing**
3. **High dose >100 MEDD**
4. **UDS** in Veterans on long-term opioid therapy within the last 12 months

- Report for **provider specialty**
- Report of all **providers with high opioid prescribing / Outliers**

- **Informed consent** policy issued 2014, for all pts on LTOT (90 d)
- **PDMP checks** policy issued 10/2016, at least annually, for > 5 d supply
- **OEND – Overdose Education and Naloxone Distribution**
  Naloxone prescribed for all pts at risk, broad inclusion, no cost to Veteran
- Timely f/u with prescriber at least q3 months

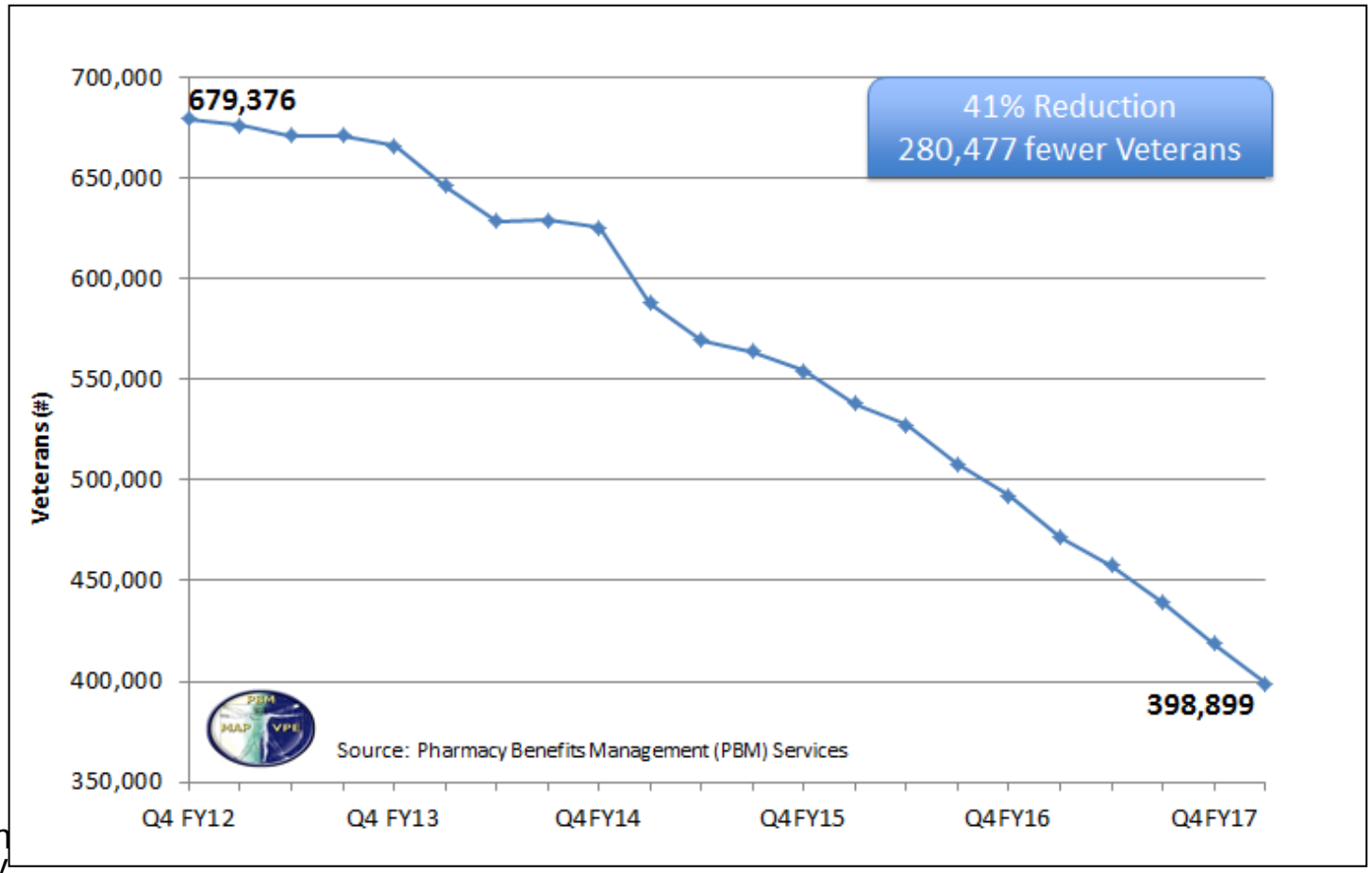
Veterans with Dispensed Opioid Medication

Q4 FY2012 to Q1 FY2018

17.2%

9.7%

of pts with pharmacy activity



Opioid patients (excludes tramadol)

Patients with opioid dispensed as percentage of all patients with pharmacy activity (excludes tramadol)

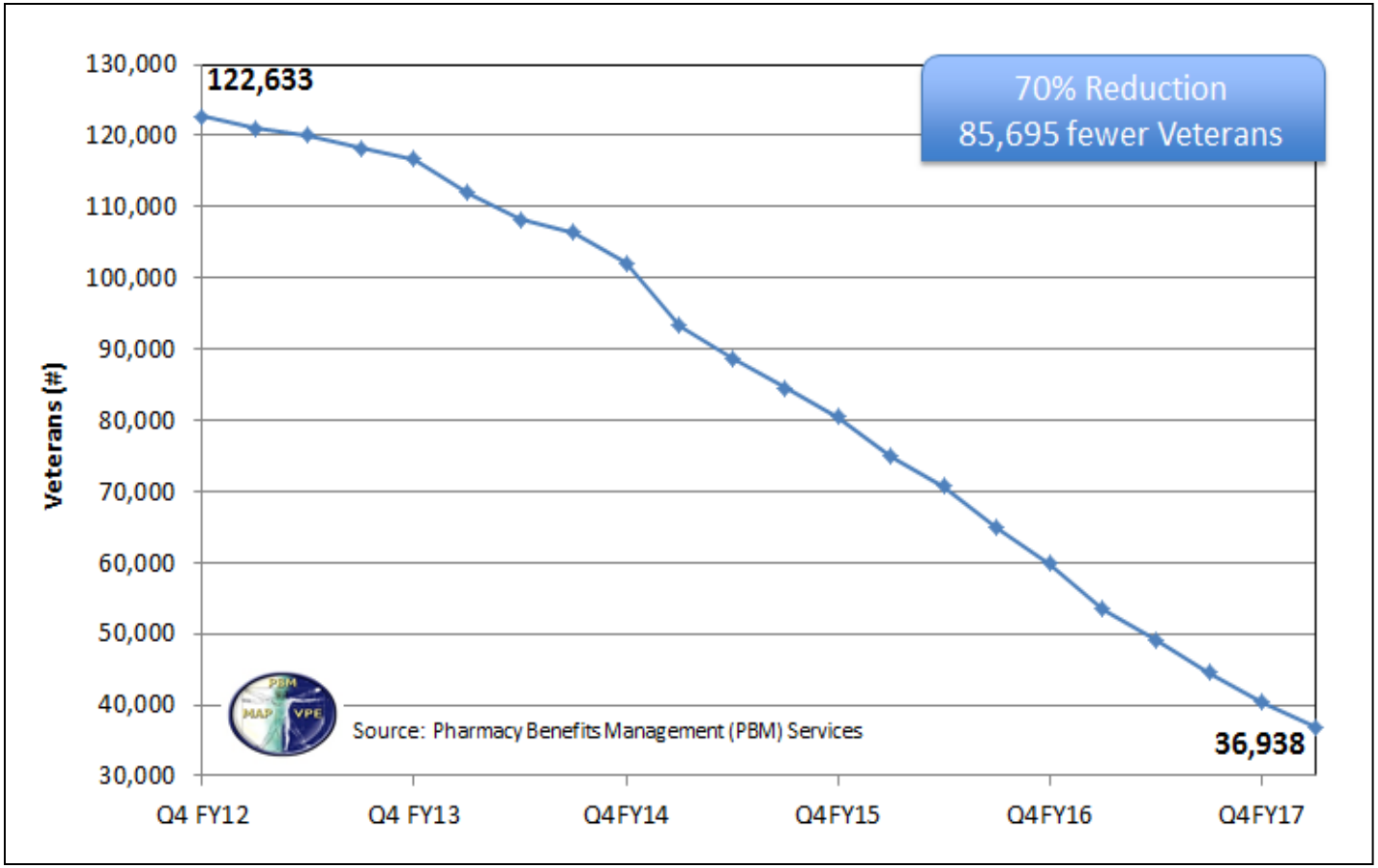
Veterans with Opioid and Benzodiazepine

Q4 FY2012 to Q1 FY2018

13.9%

6.6%

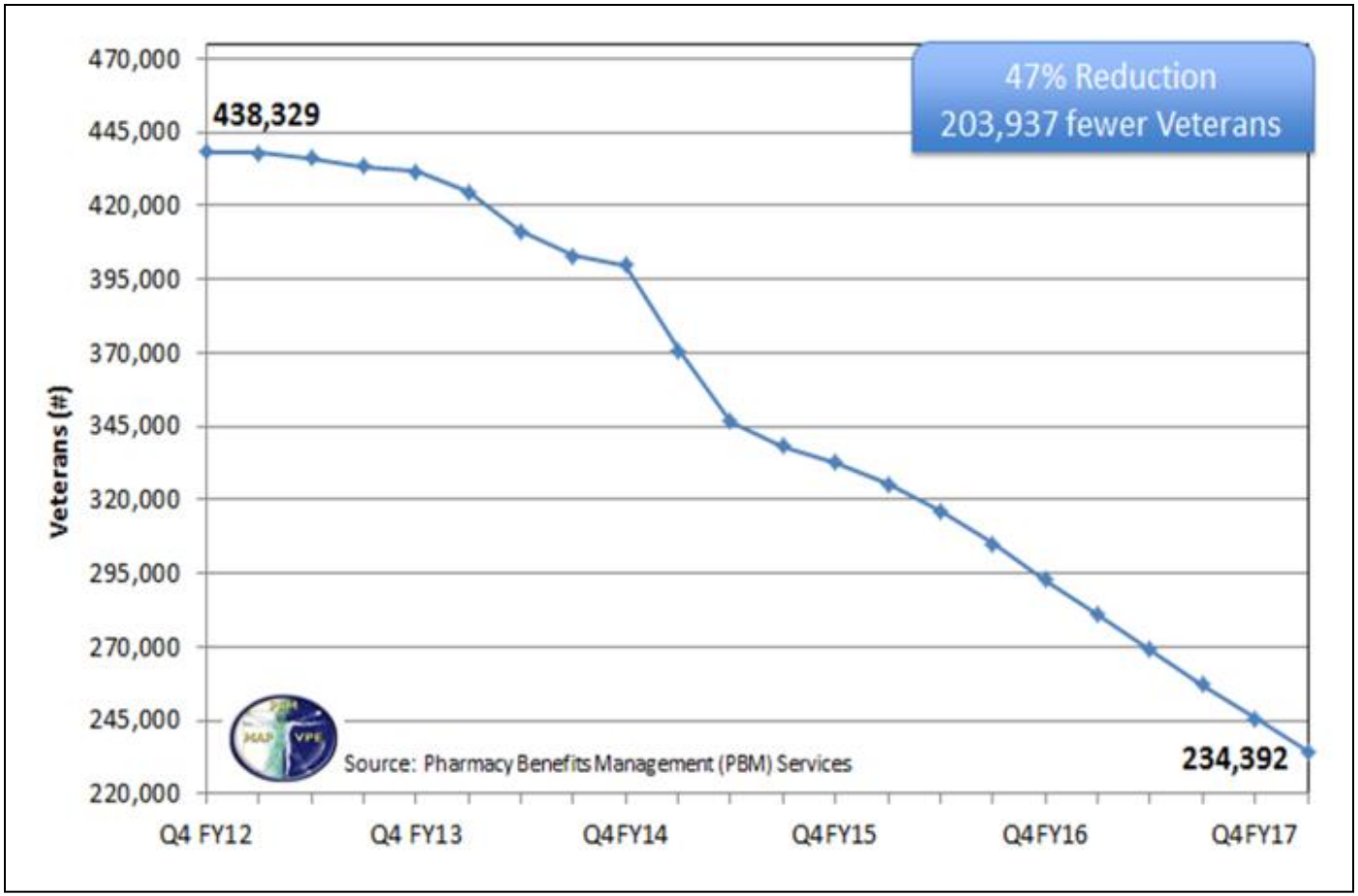
of opioid patients



Opioid data include patients on tramadol

Veterans on Long-Term Opioid Therapy

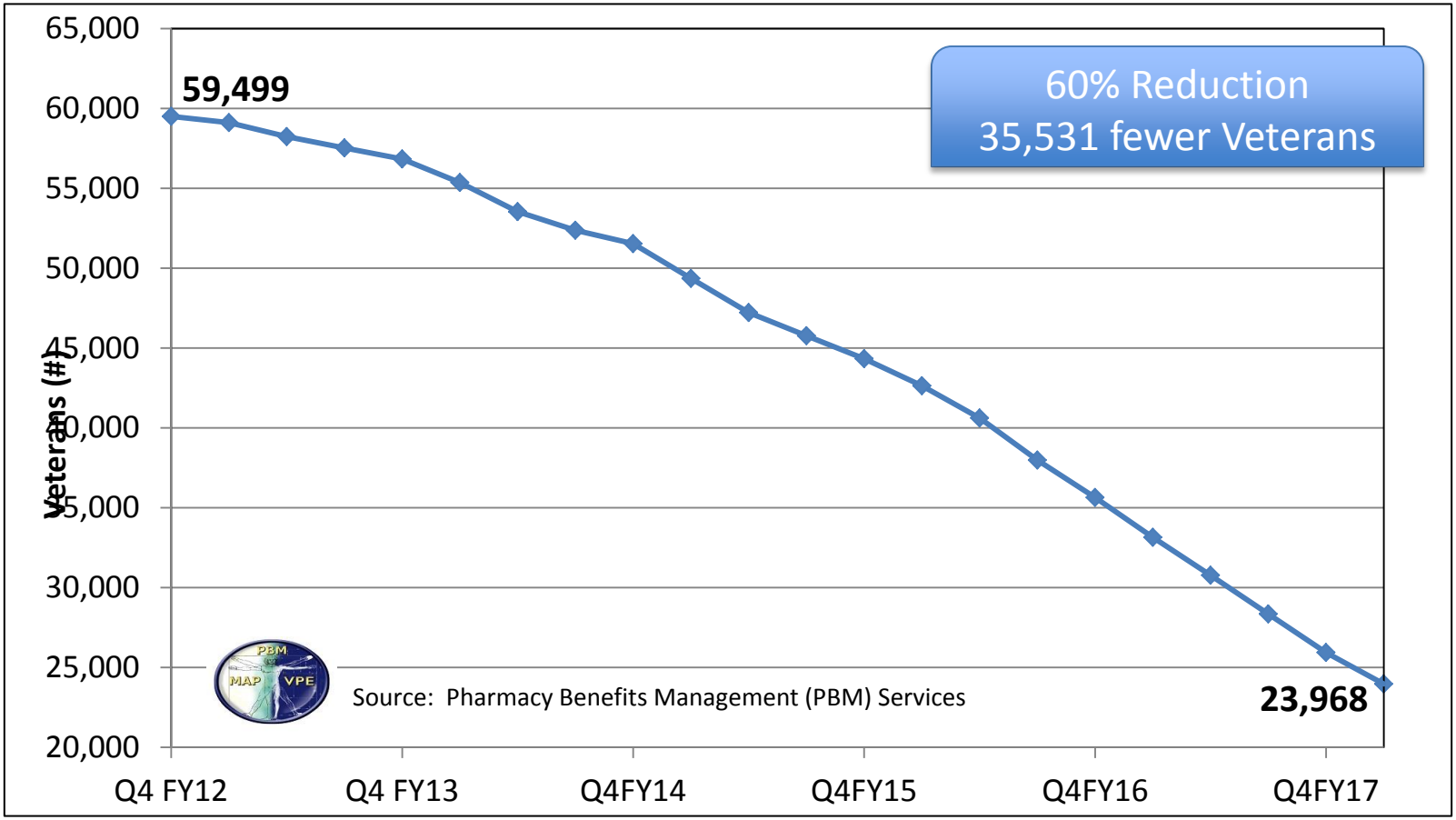
Q4 FY2012 to Q1 FY2018



Q3FY17

Patients on opioid therapy (excluding tramadol) dispensed in the selected quarter and ≥90 days total cumulative supply of opioid medications in the last two quarters.

Veterans Dispensed Greater Than Or Equal to 100 MEDD*

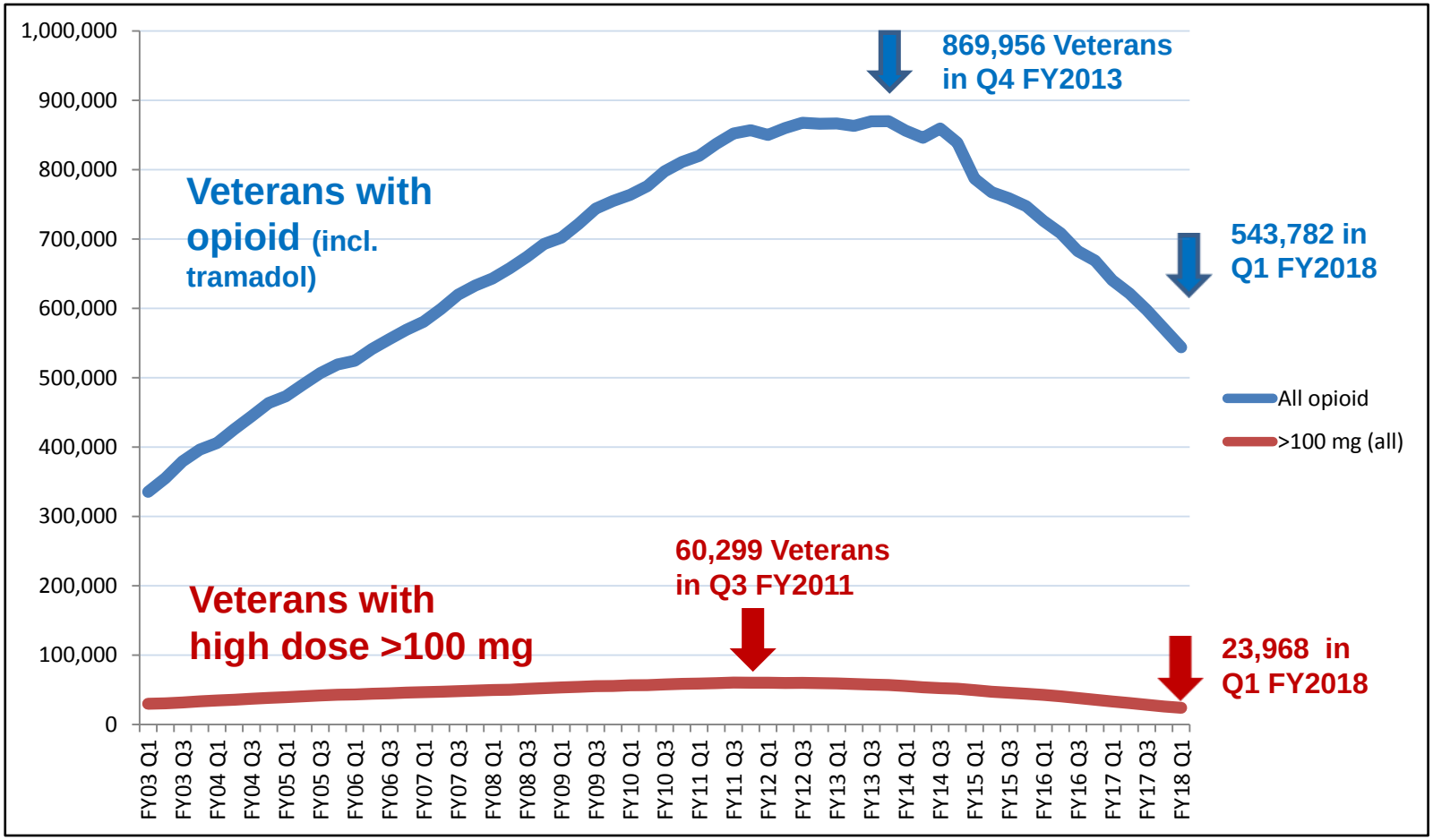


*MEDD = Morphine Equivalent Daily Dose

All Opioid and High Dose Opioid Therapy

Q1 FY2003 to Q4 FY2017

Veterans

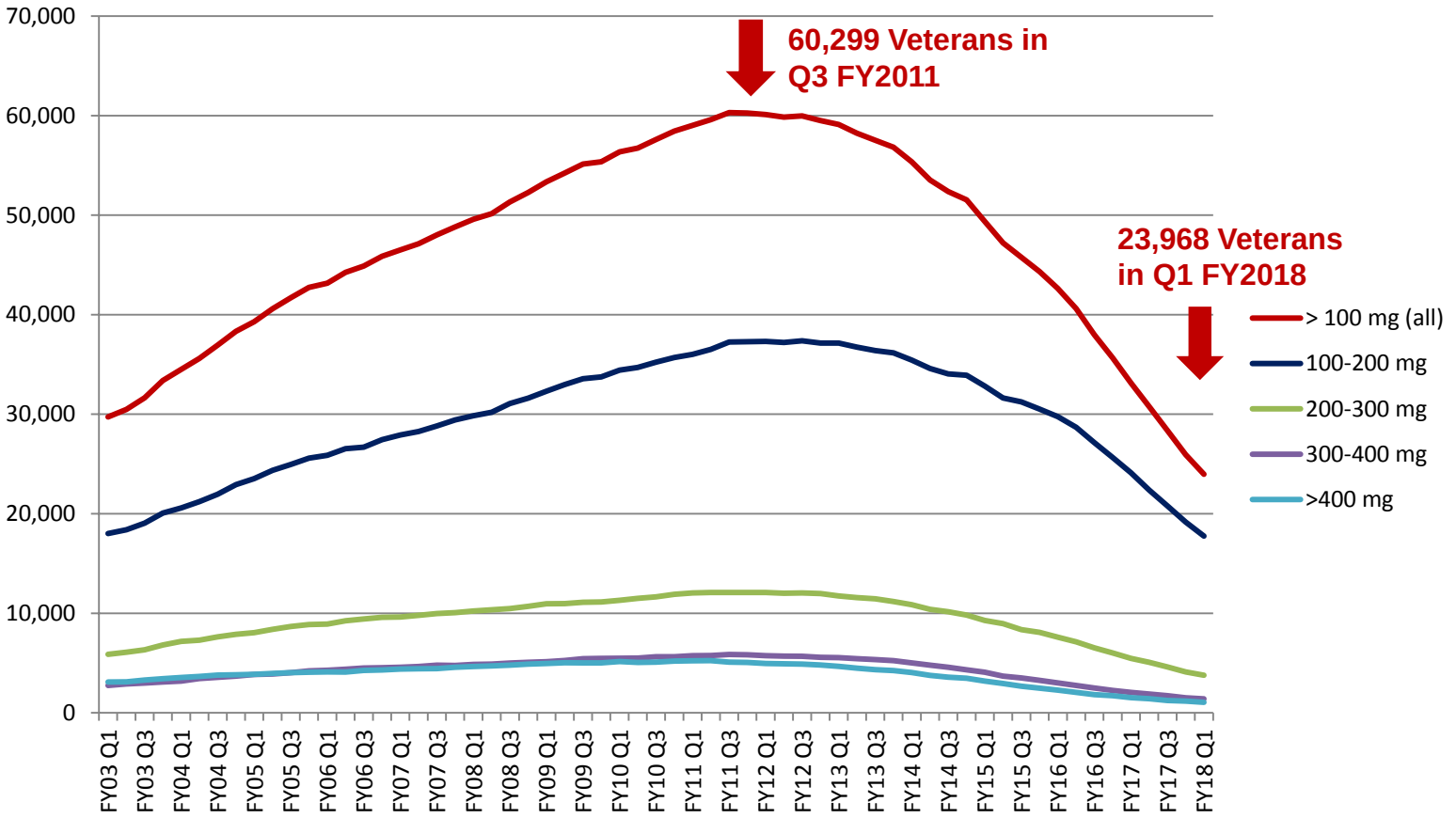


Q1 FY2003 Q1 FY2018

High Dose Opioid Therapy

Q1 FY2003 to Q1 FY2018

Veterans



Q1 FY2003

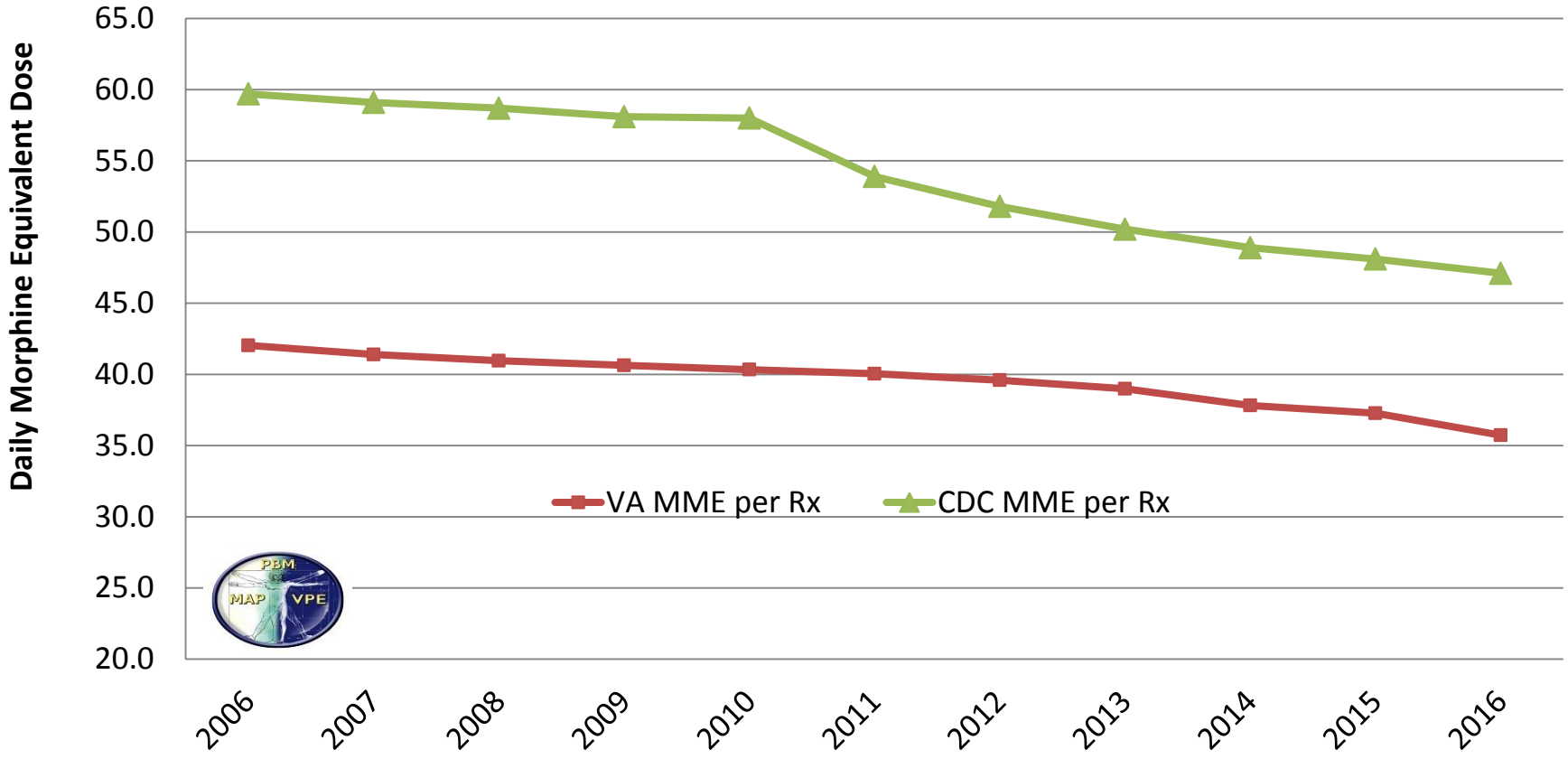
Q1 FY2018

Q1FY18: Top 10 Prescriber Specialties*

Specialty	Count (#)
Physician**	10,562
Internal Medicine	4,145
Nurse Practitioner**	3,528
Primary Care	2,428
Physician Assistant**	2,049
Surgery	1,922
Dentist	1,509
Emergency Medicine	1,330
Podiatrist	678

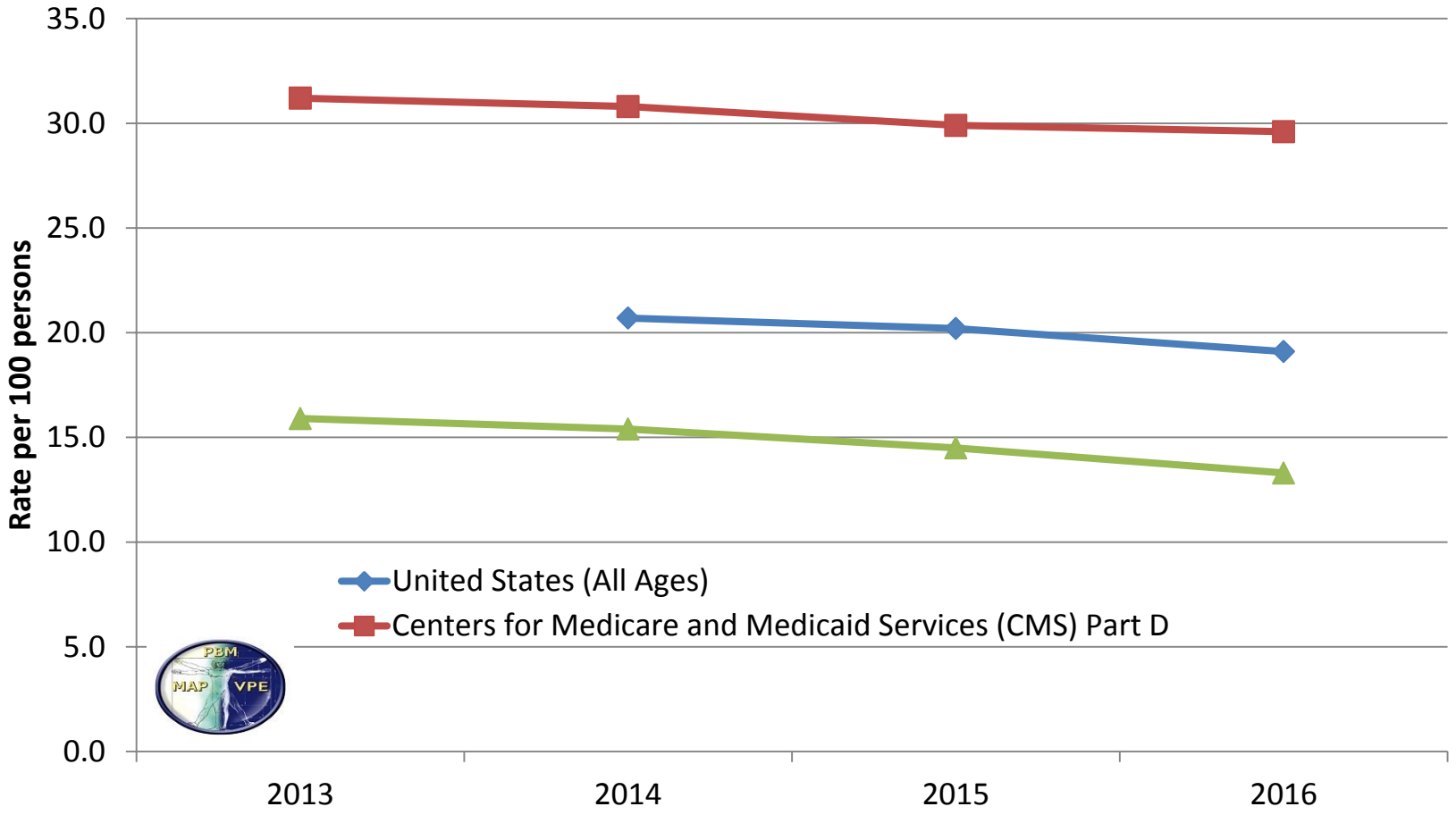
*Prescribers must have prescribed at least one opioid to be included in the count.
**Specialty was not defined in administrative data.

Average Daily Morphine Milligram Equivalent (MME)



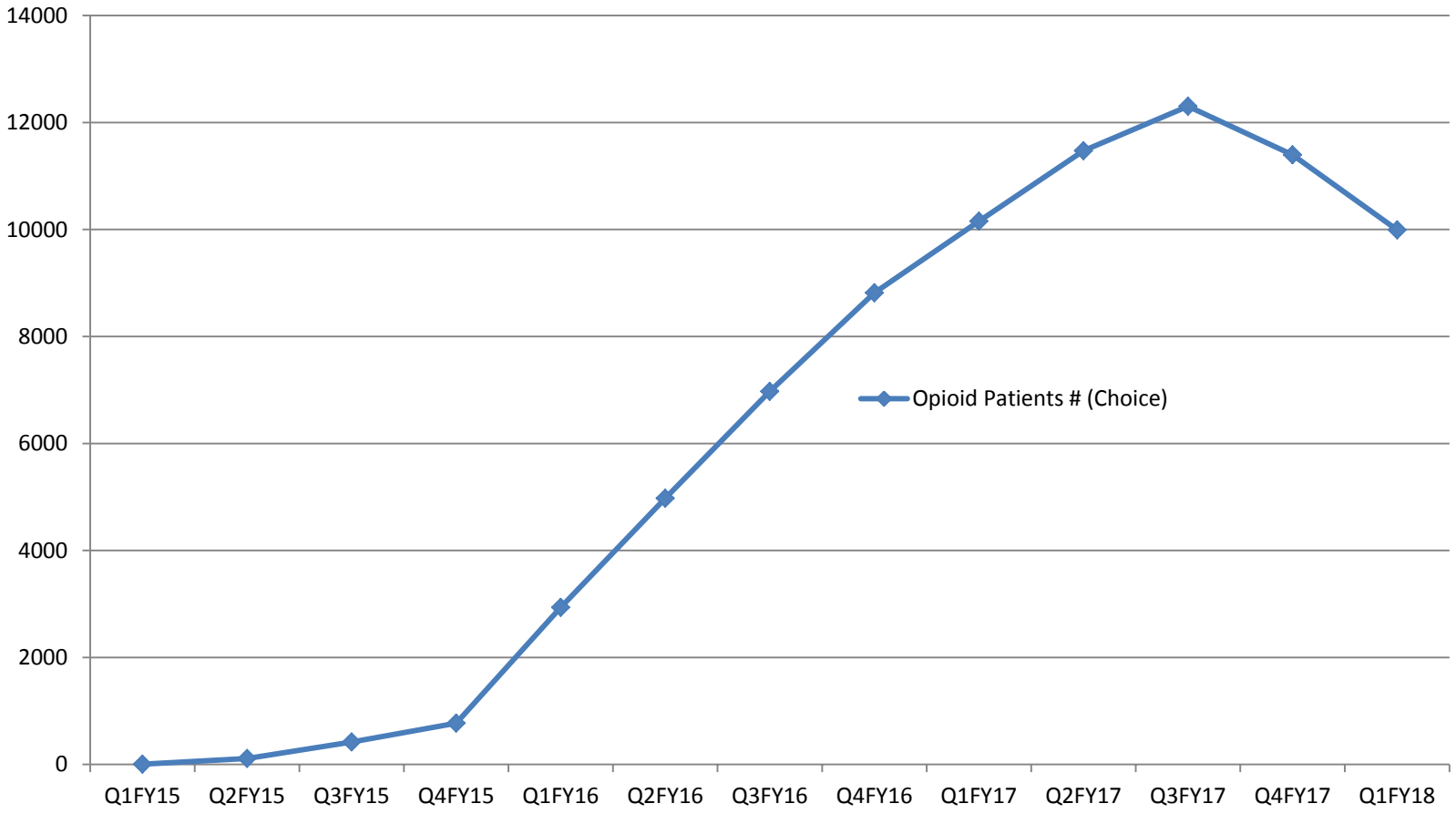
CDC: https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf
https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm#T1_down
VA: Pharmacy Benefits Management (PBM) Services
*NOTE: VA data is Fiscal Year (October to September) and CDC is Calendar Year

Opioid Utilization Rates, 2013-2016*



CDC: https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf
CMS: https://www.cms.gov/Medicare/HealthPlans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf
VA: Pharmacy Benefits Management (PBM) Services.
*NOTE: VA data is Fiscal Year (October to September) and CDC and CMS is Calendar Year

Community Care/Choice: Veterans Dispensed an Opioid



Community Care/Choice – OIG Report 2017

VA Office of Inspector General report on opioid prescribing, dated Aug 1, 2017

"Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care"

- Veterans receiving opioid prescriptions from VA-referred clinical settings may be at greater risk for overdose and other harm because medication information is not being consistently shared.
- **"Healthcare providers serving veterans should be following consistent guidelines for prescribing opioids and sharing information that ensures quality care for high-risk veterans."**
- OIG recommendations:
  - Non-VA providers to review the evidence-based guidelines for prescribing opioids in the OSI.
  - Include in care consults an updated list of the patient's medications and medical history.
  - Require non-VA providers to submit opioid prescriptions directly to VA pharmacies
  - If opioid prescribing in conflict with OSI guidelines: facility must taken action to ensure safety.
- Letter was sent out by facilities to all Non-VA providers by January 8, 2018.
- https://www.va.gov/oig/pubs/VAOIG-17-01846-316.pdf

Opioid Therapy Risk Mitigation

- Patients receiving long-term opioid therapy should be monitored and **reassessed at least every 3 months, with greater frequency based on risk**.
- Always maintain vigilance for sedation, declining function, evidence of opioid use disorder or other opioid related harms.
- 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.
- **Essential components of Opioid Safety include:**

  (1) An informed consent for long-term opioid therapy.

  (2) Prescription drug monitoring programs (PDMPs).

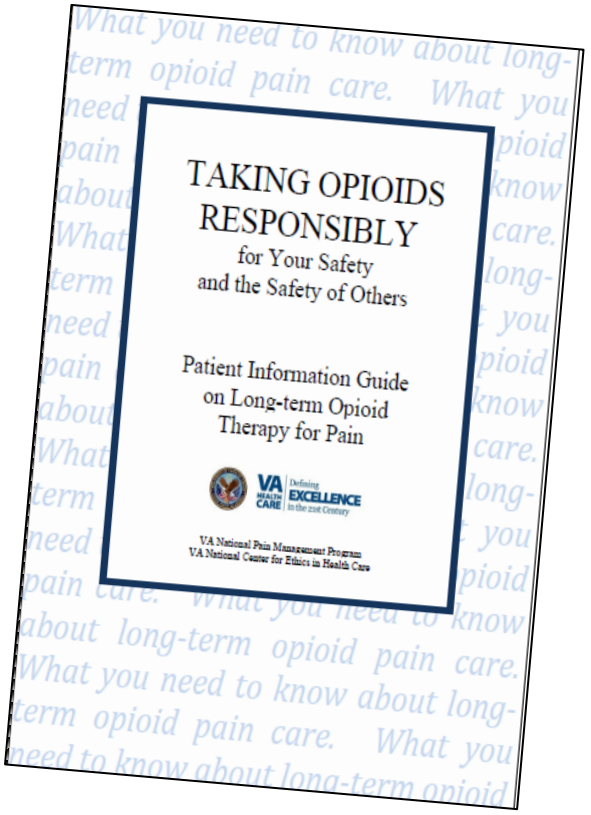
  (3) Random urine drug testing.

  (4) Overdose education, and naloxone distribution as appropriate (OEND).

Informed Consent for Long-Term Opioid Therapy

- **Informed consent (via I-Med) is required for all patients on Long Term Opioid Therapy (LTOT)**, defined as > 90 days (excluding patients enrolled in hospice, on opioids for cancer pain, when oral consent is sufficient)

- 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.
- Brochure "Taking Opioids Responsibly" should given to the patient.
- Currently being updated.

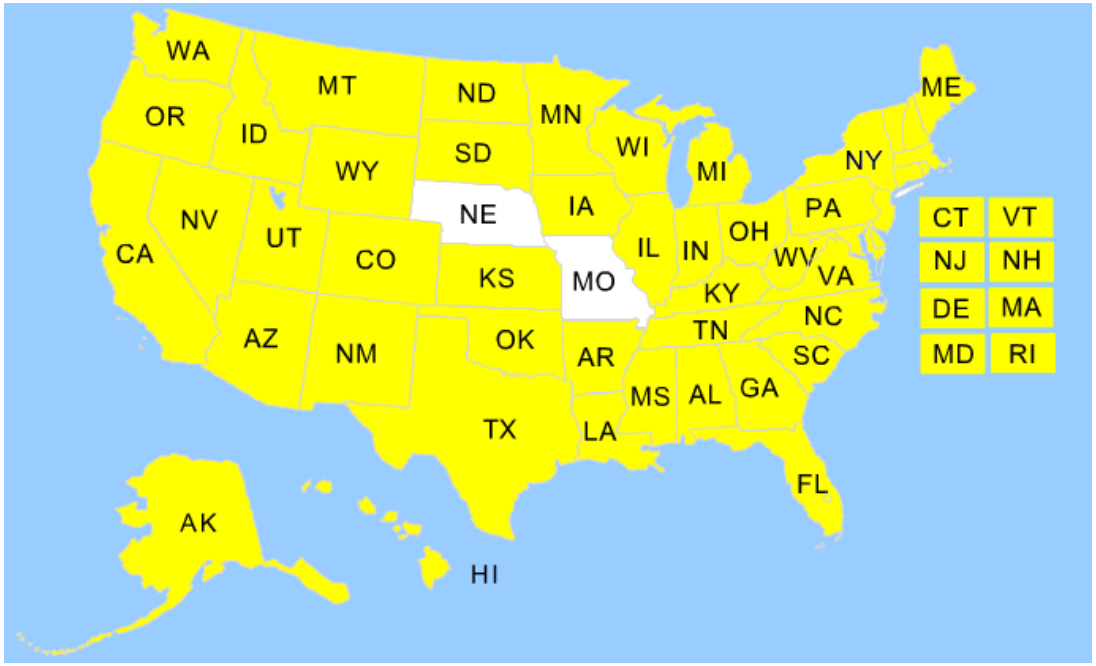


January 05, 2018 report:

- **National Score: 89.7%**

VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain. May 6, 2014

Prescription Drug Monitoring Programs (PDMP)



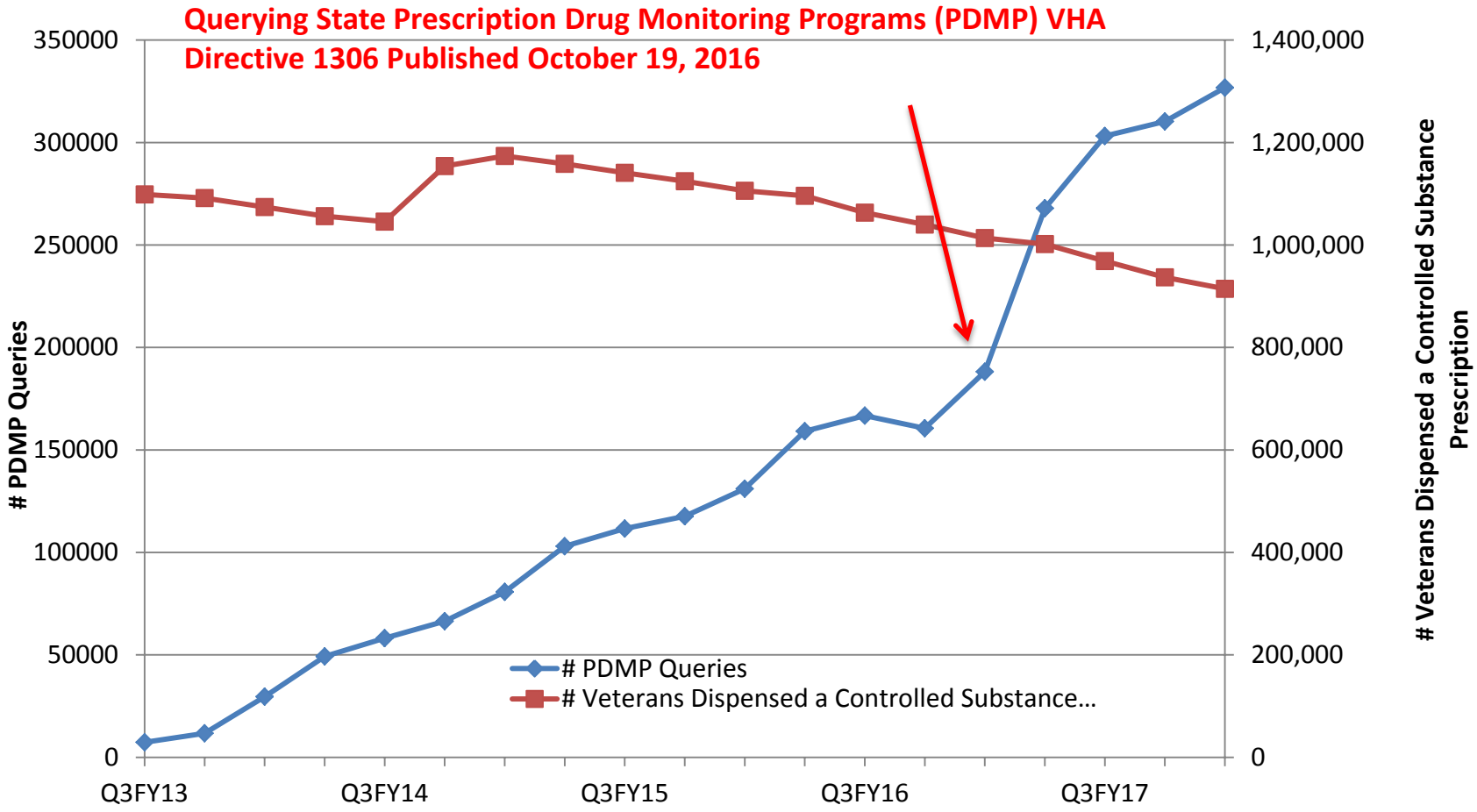
As of January 2018, 48 states and the District of Columbia are activated for PDMP data transmission.

States share data through PMP InterConnect

- Veterans in VHA: 23.9% received controlled substance, and 12% opioids
- From Q3 FY 2013 to Q4 FY 2017, VA providers documented > 2.3 million queries
- Long-Term Opioid Therapy Patients with a PDMP within the last 365 days: 70.2% (Jan. 2017)
- VHA Directive 1306, Querying State Prescription Drug Monitoring Programs (PMDP). Oct. 19, 2016

MO just recently established a statewide PDMP by executive order. NE's program has transitioned to Appriss AWARxE and work is underway to initiate transmissions; state working to implement FIPS 140-2 cryptography required for federal data sharing. VA-NSOC requires specific security documentation in order to open the firewall for outbound transmissions.

National: State Prescription Drug Monitoring Program (PDMP) Queries and the Number of Veterans Dispensed a Controlled Substance Prescription*



*Queries are underestimated because documentation was not standardized system-wide prior to publication of VHA Directive 1306

Source: Pharmacy Benefits Management (PBM) Services

Overdose Education and Naloxone Distribution - OEND

- **Overdose Education (OE)**
  - Education on how to *prevent, recognize, and respond* to an opioid overdose.
- **Naloxone Distribution (ND)**
  - FDA approved as **naloxone autoinjector and nasal spray.**
  - *Dispense and train* patient and caregiver/family.
- Target patient populations: OUD, and prescribed opioids.
- Highly successful: > 100,000 kits dispensed to > 70,000 Veterans
- From May 2014 to Jan 2016, 172 overdose reversals documented
- **Offer naloxone when factors that increase risk for opioid overdose are present: h/o overdose, h/o SUD, higher opioid dosages (≥50 MMED), or concurrent benzodiazepine use.**
- No cost to patients (elimination of copays for naloxone and training, as per CARA)

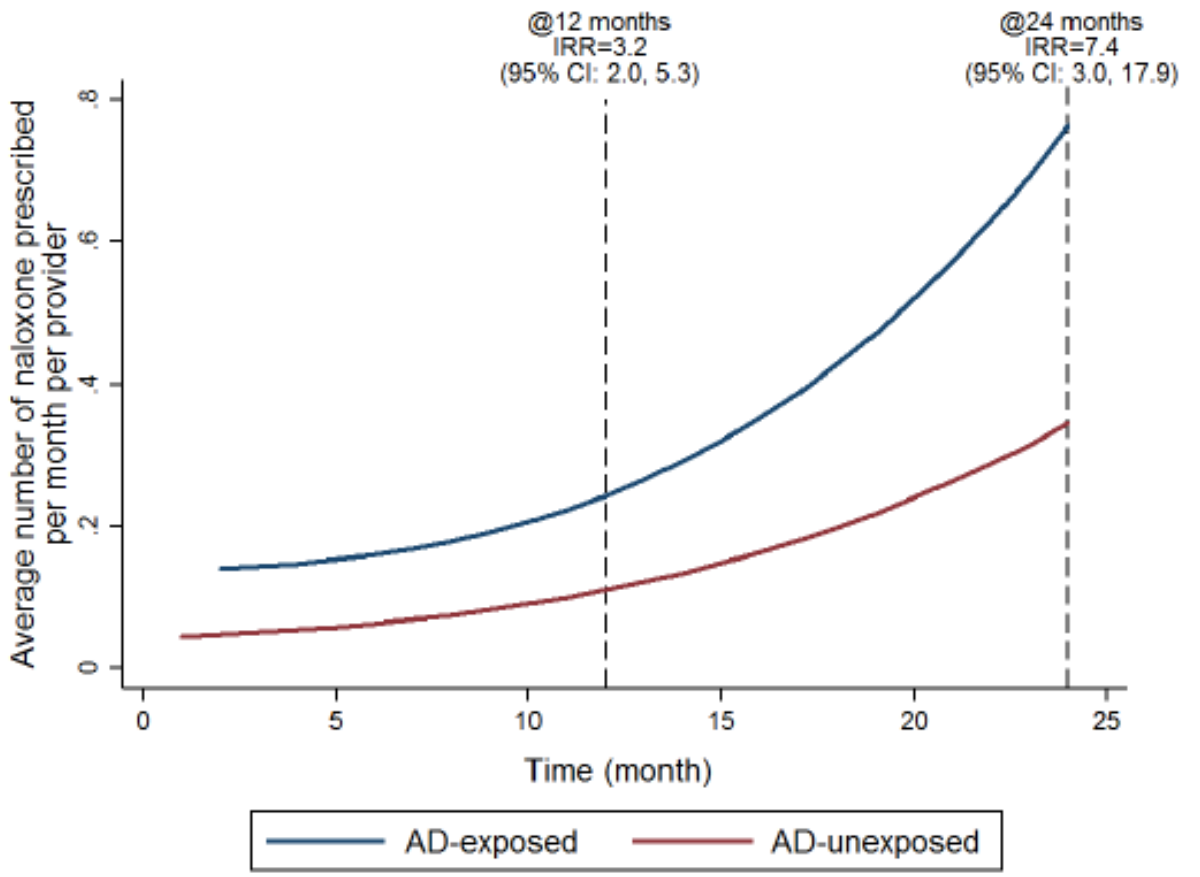
Education: Academic Detailing

Academic Detailing

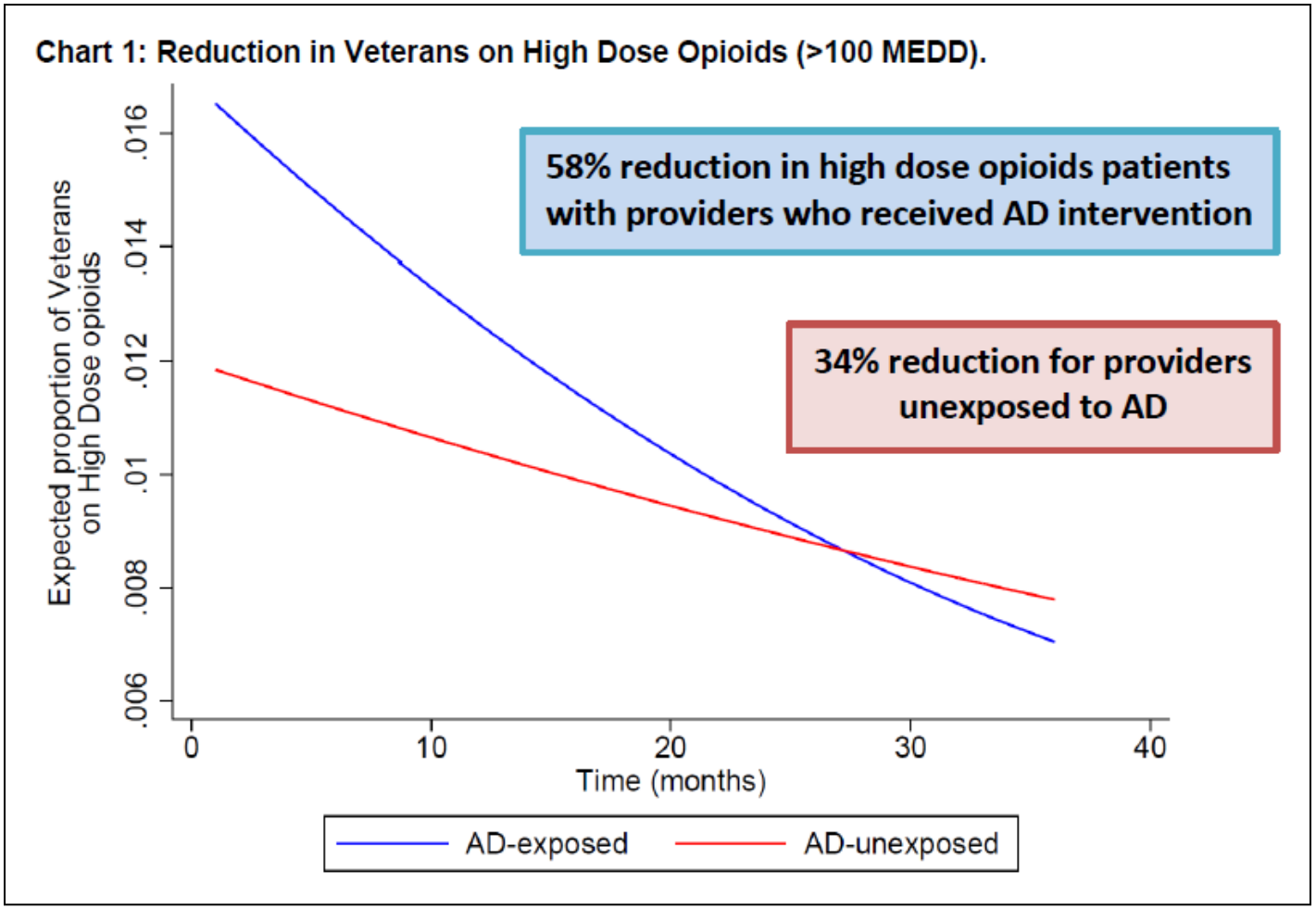
- ***In-person*** educational outreach
  - Information is provided ***interactively*** so the academic detailer can:
    - ***Understand*** where the provider is coming from in terms of knowledge, attitudes, and ***personal motivations*** for practice
    - ***Modify*** the interaction to meet the needs of the provider
    - ***Engage*** the provider by acknowledging their expertise and learning together rather than teaching
- Uses balanced evidence-based information and tools
- Delivered by a healthcare professional specially skilled in empathic persuasive communication
- Over time, the educator and provider develop a trusted and useful ***relationship***
- Multiple campaigns incl. Pain Management, Opioid Safety Initiative, Opioid Use Disorder (OUD), Insomnia; Psychotropic Drug Safety Initiative (PDSI), incl. benzodiazepines.
- http://www.pbm.va.gov/PBM/academicdetailingservicehome.asp

Academic Detailing : Impact on Naloxone Prescribing

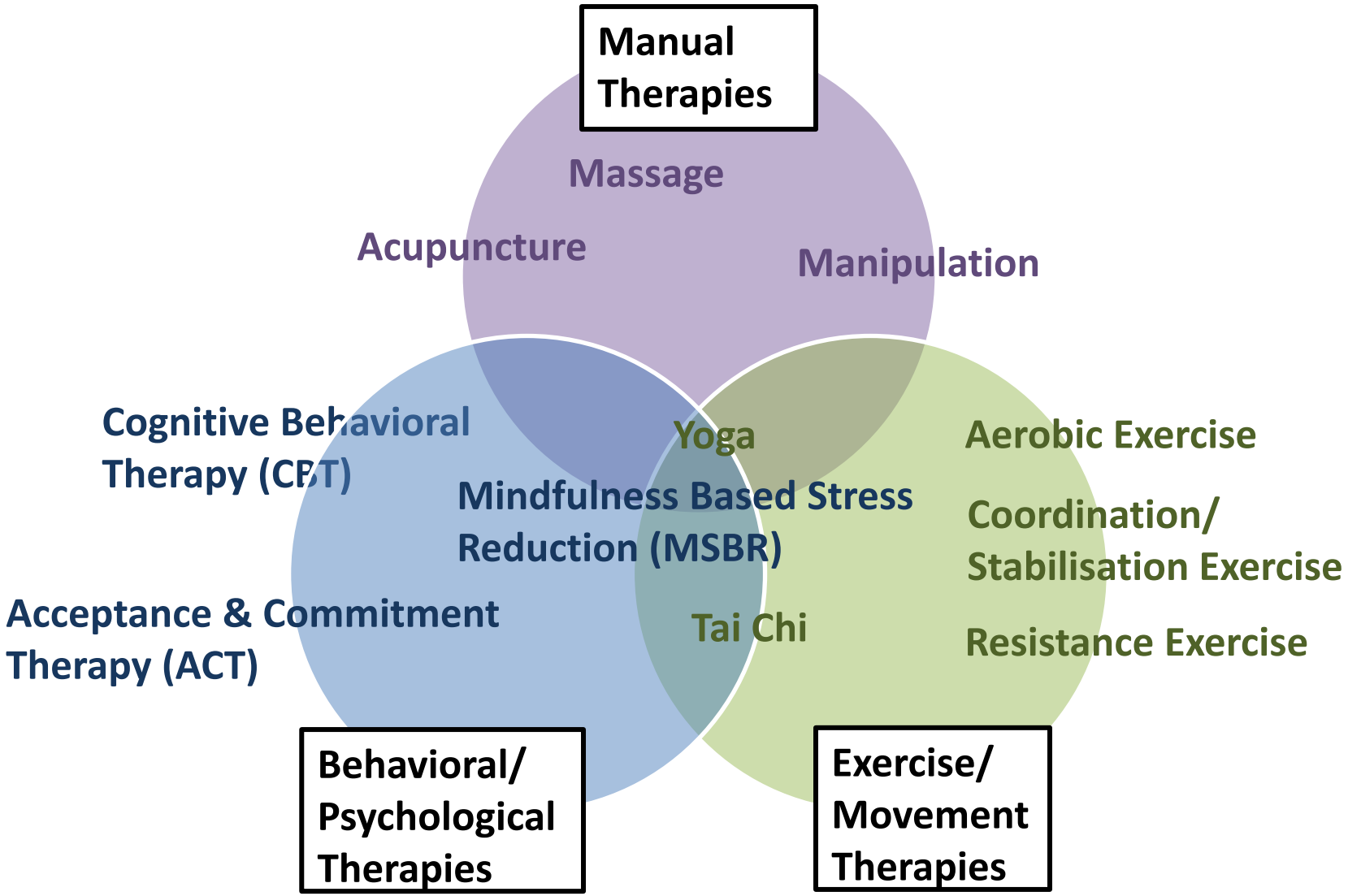
Chart 4. Academic Detailing's impact on naloxone distribution at the provider level.



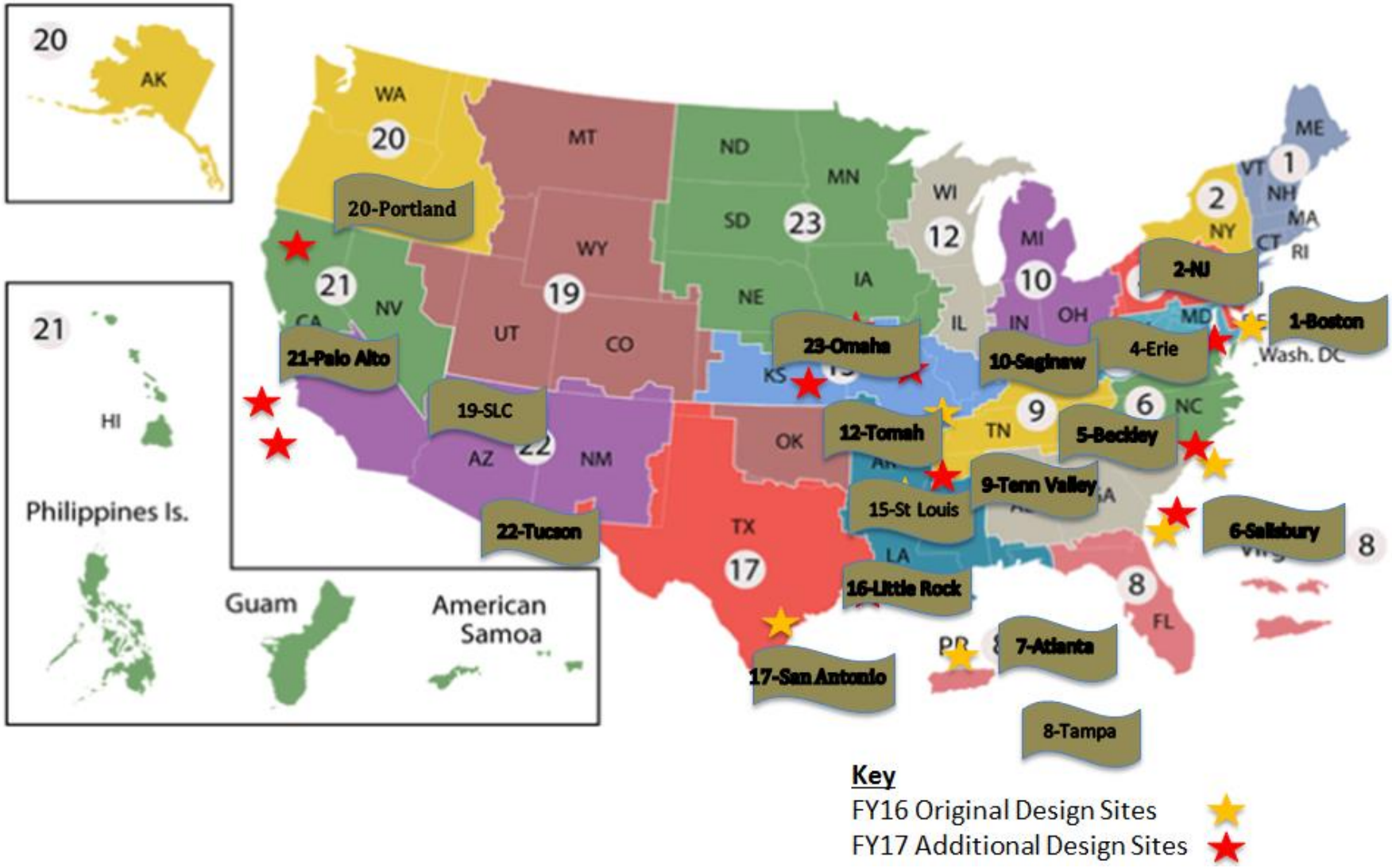
Academic Detailing : Impact on Veterans > 100 MEDD



Self Care/Active non-Pharmacologic Therapies
SOTA 2016

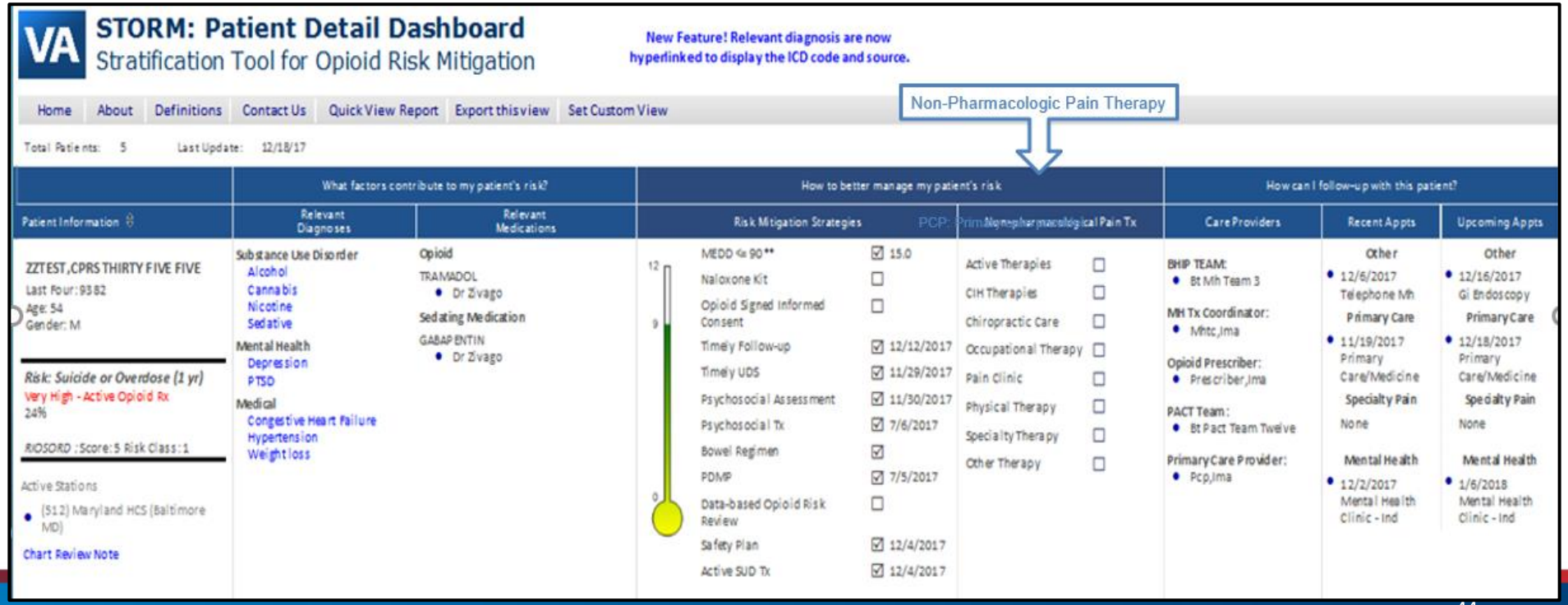


Whole Health System Flagship Sites



Stratification Tool for Opioid Risk Monitoring – 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.**
- Risk score is designed to support treatment planning. The goal should be to design a treatment plan that addresses risk factors and is appropriate for the patients risk level.
- https://spsites.cdw.va.gov/sites/OMHO_PsychPharm/Pages/Real-Time-STORM-Dashboard.aspx



Opioid Therapy Risk Report – OTRR

- Tool optimized for PACT: review their panel for all patients on long-term opioids
- Included in CPRS under Tools → Primary Care Almanac.
- Veteran lookup by SSN
- Multitude of factors that potentially increase risk incl. MH diagnoses

- Opioid risk mitigation parameters including last PDMP check
- Updated nightly
- Individual report includes Visual display
  - Opioid dosage
  - Pain score (severity)
- LTOT definition: opioid dispensed in the last 90 days *and* total days supply ≥ 90 days in the past 180 days

VA/DoD Opioid Therapy CPG

The guideline describes the critical decision points in the Management of Opioid Therapy (OT) for Chronic Pain and provides clear and comprehensive evidence based recommendations incorporating current information and practices for practitioners throughout the DoD and VA Health Care systems. The workgroup consensus statements are provided to minimize harm and increase patient safety in patients requiring opioid therapy.

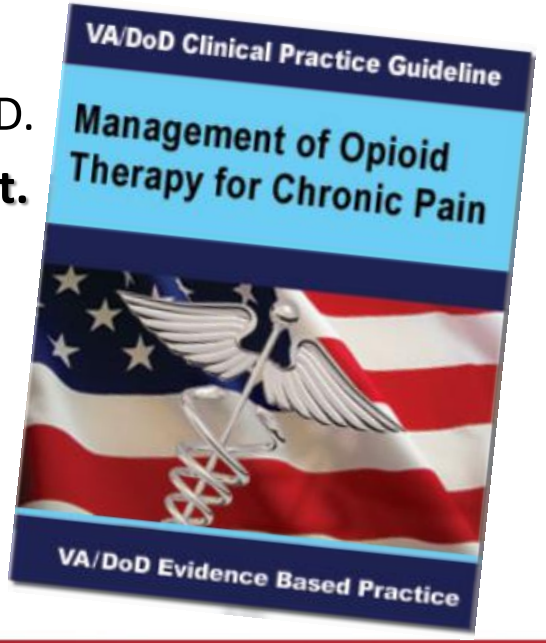
Disclaimer: This Clinical Practice Guideline is intended for use only as a tool to assist a clinician/healthcare professional and should not be used to replace clinical judgment.

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)	Substance Use Disorder (SUD)

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

VA/DoD Clinical Practice Guideline: Opioid Therapy

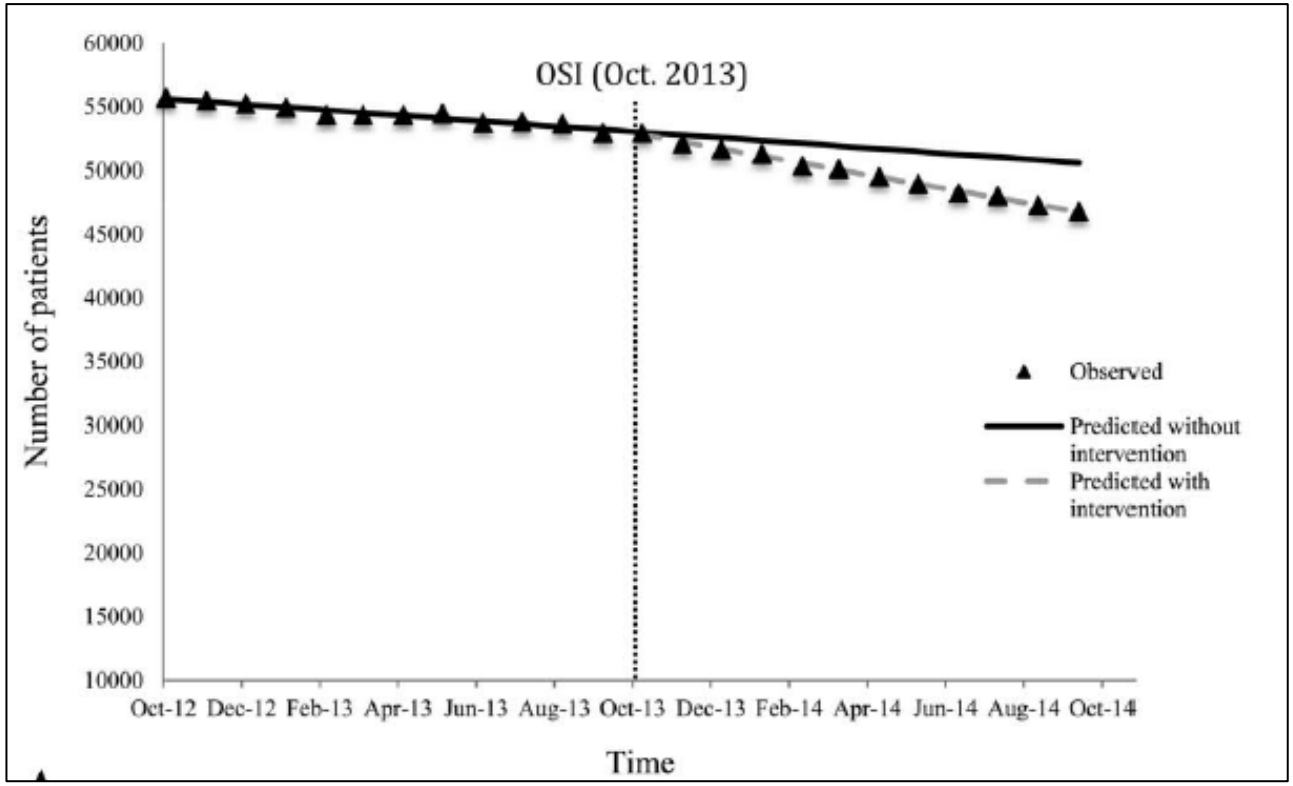
- **"We recommend against initiation of long-term opioid therapy".**
  "**We recommend alternatives to opioid therapy** such as self-management strategies and other non-pharmacological treatments. When pharmacologic therapies are used, we recommend non-opioids over opioids".
- Recommendation against opioid therapy in patients < 30 years of age, in patients with active substance use disorder, and in combination with benzos.
- Recommendation for risk mitigation strategies, including urine drug testing, PDMP, overdose education, naloxone distribution
- If prescribing opioids: short duration and lowest dosage
- **No dosage is safe**; Strong rec against of opioids to > 90 MEDD.
- **Opioid dosage reduction should be individualized to patient.**
  Avoid sudden reductions; taper slowly if opioid risk>benefit
- Suicide prevention in pain patients
- Use multimodal pain care
- Acute pain: use alternatives to opioids; if opioids ≤ 3-5 days
- For OUD, offer medication assisted treatment.
  https://www.healthquality.va.gov/guidelines/Pain/cot/



Reduction in Opioid Prescribing in VHA

Impact of the Opioid Safety Initiative on opioid related prescribing in veterans

Lin et al, Pain 2018



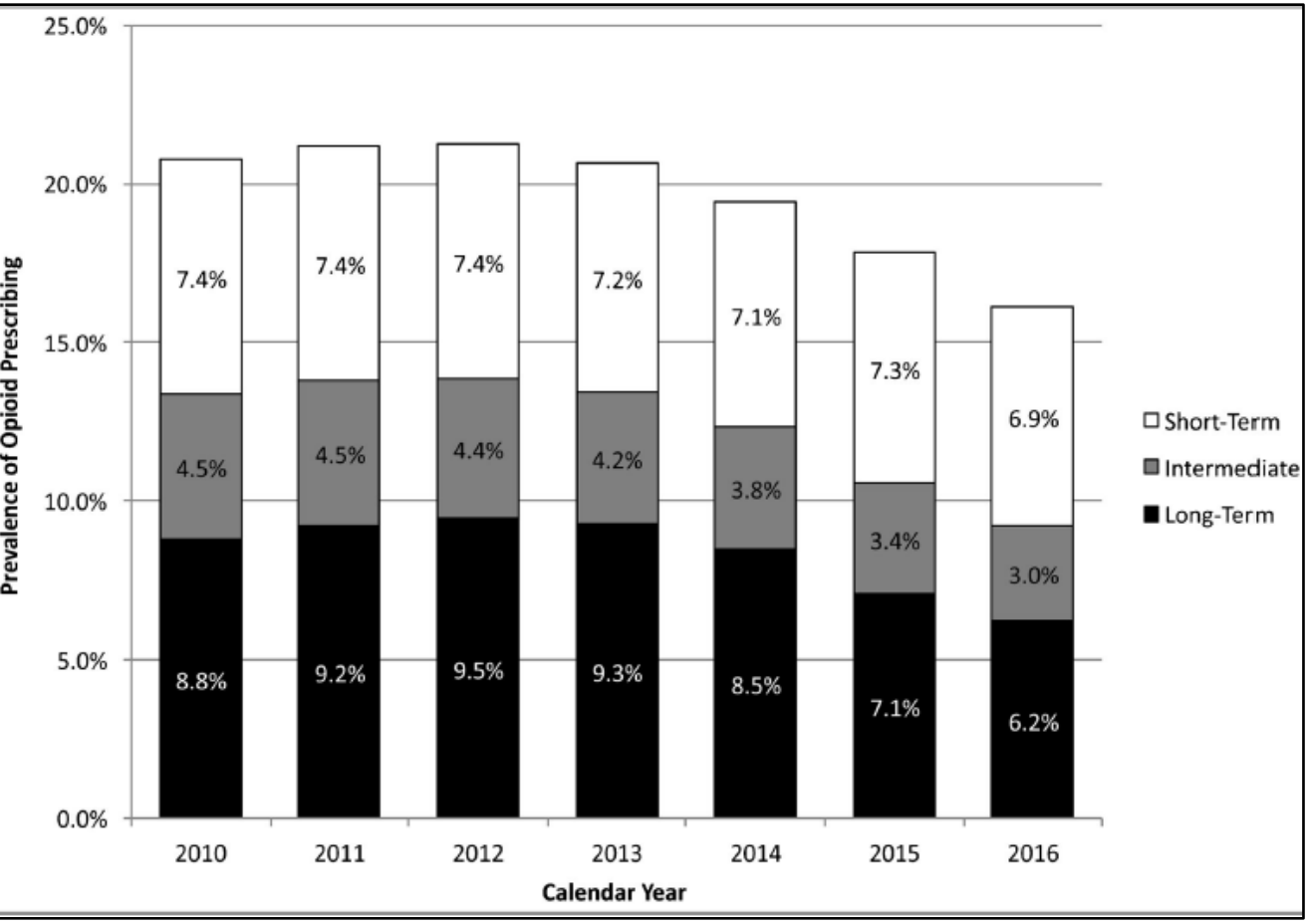
- Interrupted time series analyses
- October 2012 to September 2014

- High-dosage opioid >100 MME: 331 per month reduction due to OSI
- High dosage opioid > 200 MME: 164 per month reduction due to OSI
- Benzodiazepine coprescribing: 781 per month reduction due to OSI

Reduction in Opioid Prescribing in VHA

Decline in Prescription Opioids Attributable to Decreases in Long-Term Use: A Retrospective Study in the Veterans Health Administration 2010–2016

Hadlandsmyth et al, J Gen Intern Med 2018

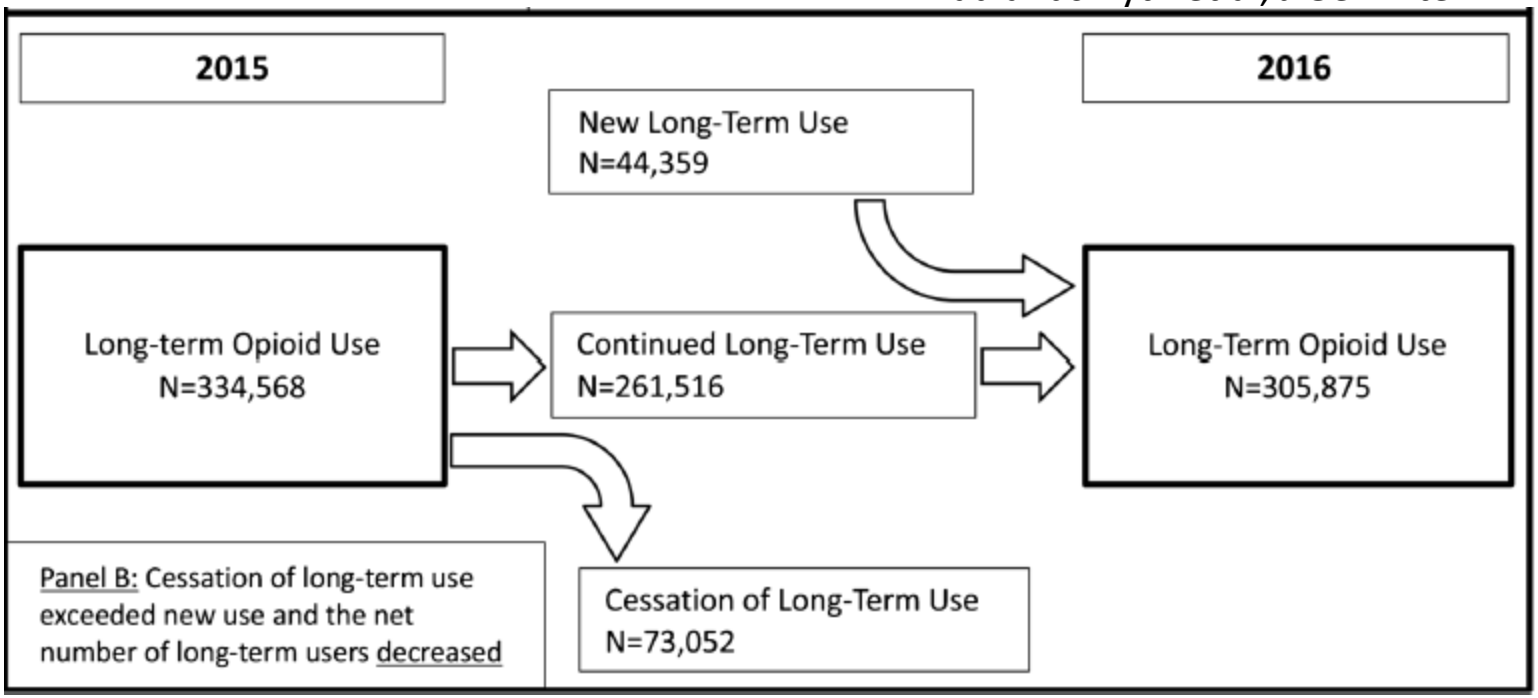


- 83% of decline in opioid scripts due to decreases in LOT.
- 90% of reduction from fewer new LOT prescription fills.
- < 10% from increases in cessation of existing LOT users

Reduction in Opioid Prescribing in VHA

Decline in Prescription Opioids Attributable to Decreases in Long-Term Use: A Retrospective Study in the Veterans Health Administration 2010–2016

Hadlandsmyth et al, J Gen Intern Med 2018



- 83% of decline in opioid scripts due to decreases in LOT.
- 90% of reduction from fewer new LOT prescription fills.
- <10% of reduction from increases in cessation of existing LOT users

Opioid Tapering Considerations

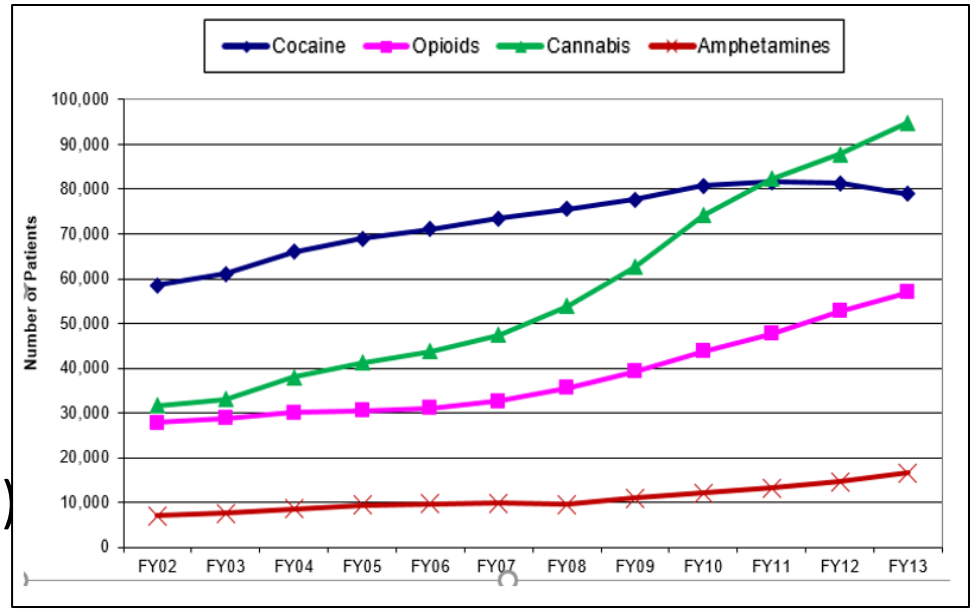
- Several factors go into the speed of taper selected:
  - **Slower, more gradual tapers are often the most tolerable and can be completed over a several months to years based on the opioid dose**
  - The longer the duration of the opioid therapy, the longer the taper
  - CDC: "… patients tapering opioids 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.)
- F/u is recommended within 1 to 4 weeks after dosage adjustment.

Approaching Opioid 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 - evaluation for OUD and, if present, referral to Medication-Assisted Treatment is usually indicated.
- Caution: Involuntary tapers may carry significantly greater risk than voluntary tapers, and interfere with collaborative provider/patient relationship and shared decision making.

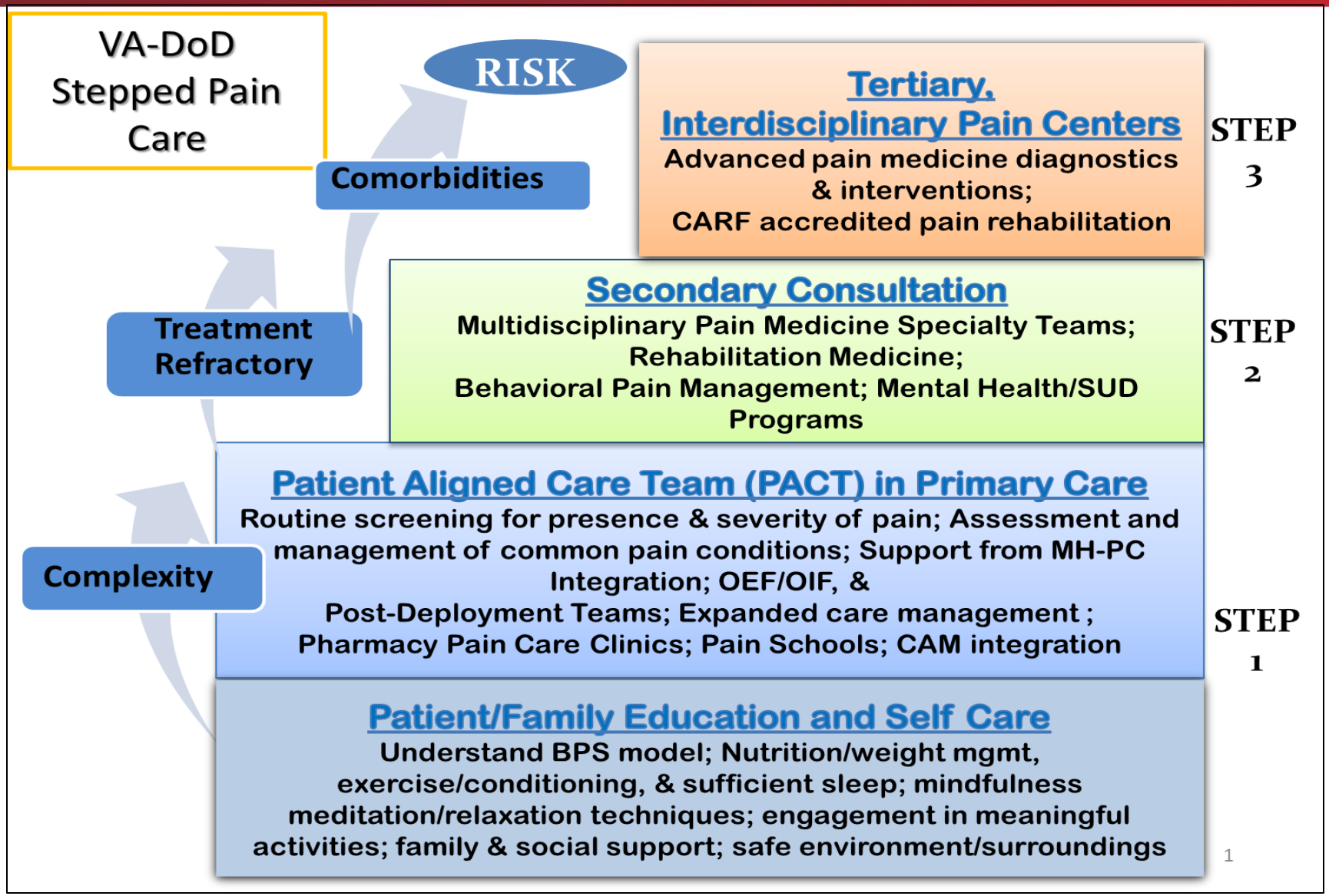
SUD and OUD in VHA

- **Prevalence of SUD in VHA –**
  - 10% of Veterans (600,000 in FY 2015)
  - AUD >> other SUD
- **"Diagnosed" OUD**
  - 1.1% of Veterans (FY 2015)
  - About 60,000 Veterans total
  - 23,000 Veterans on MAT (2016)



- **What is the Prevalence of OUD in Veterans on long-term opioids?**
  - Estimate of 25 to 40% of LOT patients?
  - How many truly have OUD? 10,000 to 100,000 Veterans?
  - How many need addiction medicine? MAT?

Stepped Care Model for Pain Management



CARA Pain Teams

- **CARA mandates designated Pain Management Teams** at all VA facilities
- Developed the Pain Management Team standards and provided the information to directors regarding reporting requirements.
- Veterans must have timely access to **specific components of pain care** that are available system-wide
- **Coordination between the different clinical areas is essential** to promote efficient use of resources and smooth transition of the Veteran between the care areas.
- Facility with higher complexity may be tasked to provide services to lower resourced facilities via tele-health/VA-ECHO, as **VISN-supported hubs**.
- Field Data call for the collection of the Facility Director Reports on Pain Management Teams is ongoing.

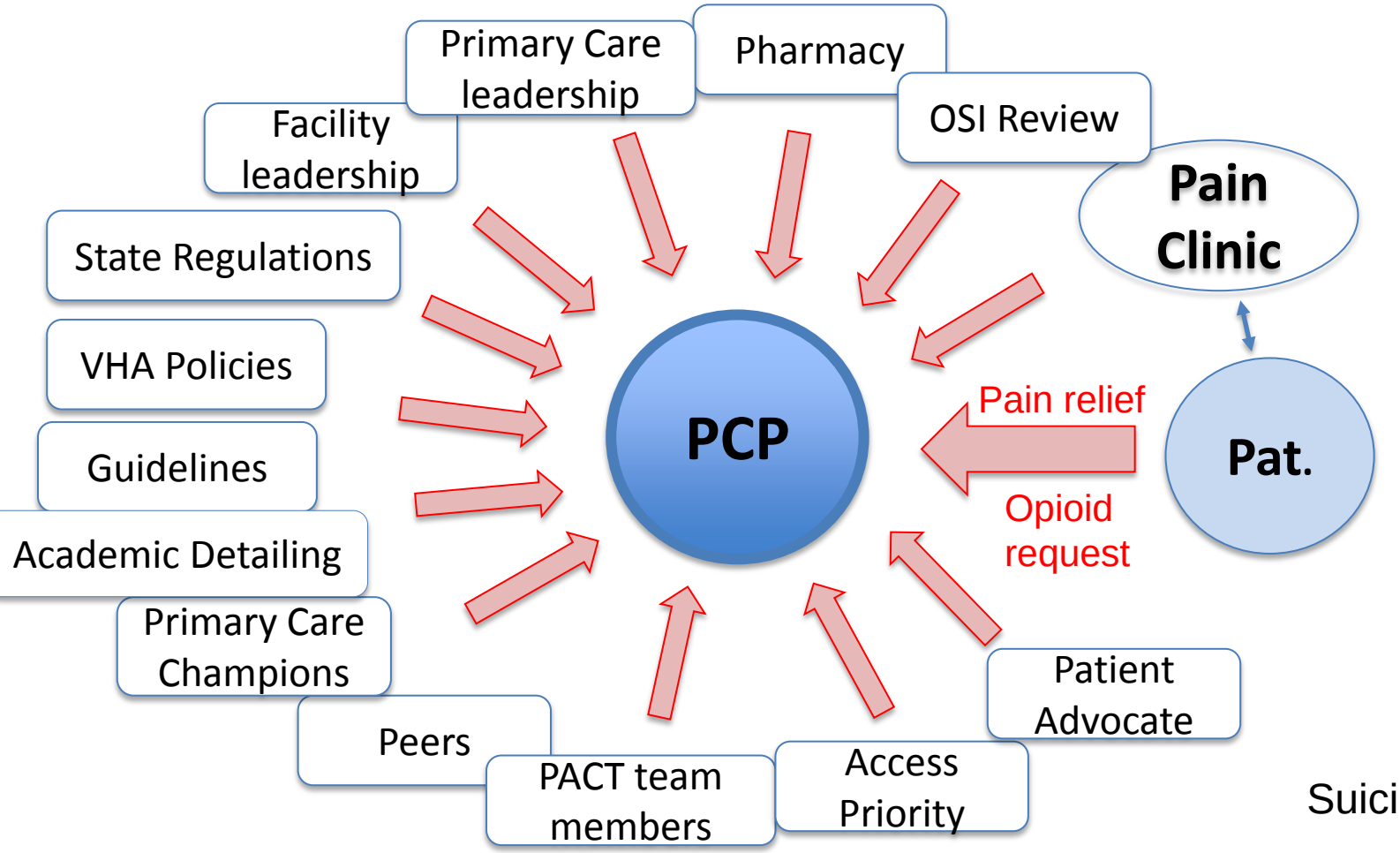
Pain Management Teams - Requirements

The functions of the Pain Management Team (PMT) include:

- **Evaluation and follow-up of pts with complex pain conditions**
- **Medication management and actual prescribing** of pain meds, as needed.
- **OSI Reviews**: Review of patients with high risk opioid prescriptions with provision of recommendations to clinical providers

- **At a minimum, the composition of the PMT must include:**
  - **Medical Provider with Pain Expertise**
  - **Addiction Medicine expertise** to provide evaluation for Opioid Use Disorder (OUD) and access to Medication-Assisted Treatment (MAT)
  - **Behavioral Medicine** with availability of at least one evidence-based behavioral therapy.
  - **Rehabilitation Medicine** discipline.

The PCP and the OSI…. ?



Integrative Health (CIH)

Whole Health

PCMHI

Mental Health

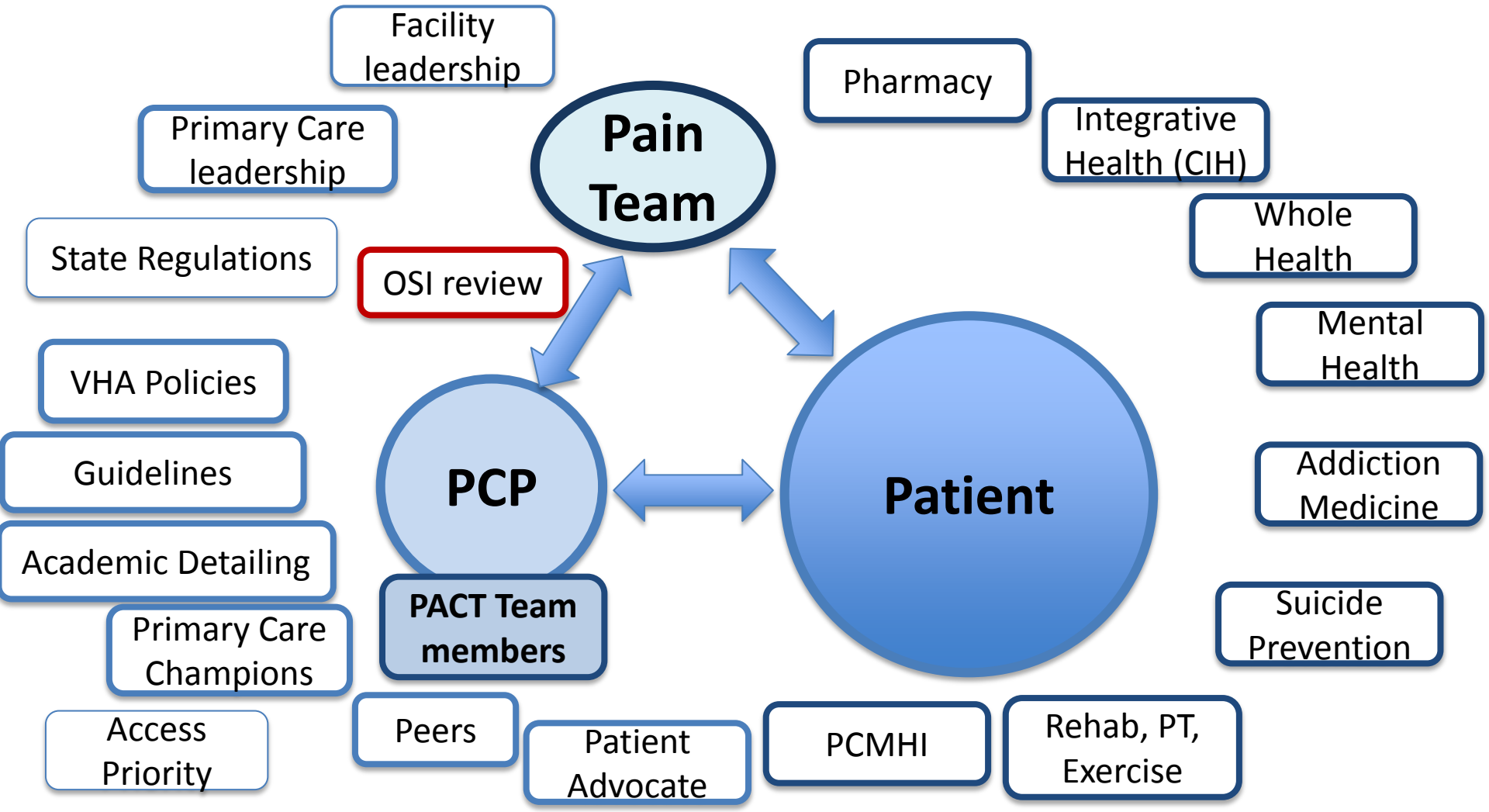
Addiction Medicine

Suicide Prevention

Rehab, PT, Exercise

Caution: Perceived Burden on the PCP

Integrated Pain Care in VHA



Collaborative Care that centers around the patient and supports the PCP/PACT team

STORM Risk Factors for Overdose/Suicide

"Development and Applications of the Veterans Health Administration's Stratification Tool for Opioid Risk Mitigation (STORM) to Improve Opioid Safety and Prevent Overdose and Suicide"

Oliva et al, Psych Serv 2016

Variable	Odds Ratio
Age (years)	
<=30	3.7
31–50	3.5
51–65	2.3
>=66 (reference)	1.0
Previous treatment risk indicators	
Previous overdose/suicide	23.1
Detoxification	18.5
Inpatient MH treatment	16.6
ER visit	3.4

Variable	Odds Ratio
Prescription related	
Opioid type, tramadol=reference	
Tier 1 (long acting)	1.5
Tier 2 (chronic, short acting)	1.1
Tier 3 (acute, short acting)	1.1
Coprescription with sedatives	1.4
# of classes other sedating	
1	2.1
2	3.6
3	6.1

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STORM Risk Factors for Overdose/Suicide

Variable	Odds Ratio
Substance use disorders	
Opioid use disorder	8.0
Alcohol use disorder	5.3
Tobacco use disorder	2.2
Sedative use disorder	11.2
Stimulant use disorder	8.1
Cannabis/hallucinogen use diso	5.9
Other substance use disorders	8.0
Mental Health disorders	
Posttraumatic stress disorder	2.6
Major depressive disorder	4.8
Bipolar disorder	5.8
Other mental health disorder	5.7

Variable	Odds Ratio
Medical comorbidities	
AIDS	2.2
Liver disease	2.2
Other neurological disorder	2.2
Electrolyte disorders	2.0
Weight loss	1.9
Coagulopathy	1.4
Paralysis	1.4
Chronic obstructive pulmonary	1.3
Metastatic cancer	1.3
Pulmonary circulation disorder	1.3
Sleep apnea	1.2
Deficiency anemia	1.2

Oliva et al, Psych Serv 2016

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Opioids and Suicide

Research Paper

PAIN

Opioid dose and risk of suicide

Mark A. Ilgen[a,b,*], Amy S.B. Bohnert[a,b], Dara Ganoczy[a], Matthew J. Bair[c,d], John F. McCarthy[a,b], Frederic C. Blow[a,b]

- VA patients with chronic pain receiving opioids in FY 2004-2005 (N=123,946).
- 2,601 patients died by suicide before the end of 2009.
- Controlling for demographic and clinical characteristics, higher prescribed opioid doses were associated with elevated suicide risk.
  - Compared with those receiving ≤20 mg/d
  - 20 to <50 mg/d HR 1.48 (95% CI, 1.25-1.75)
  - 50 to <100 mg/d HR 1.69 (95% CI, 1.33-2.14)
  - 100+ mg/d HR 2.15 (95% CI, 1.64-2.81)
- **Veterans receiving the highest doses of opioid painkillers were more than twice as likely to die by suicide**.
- The researchers could not tell, however, whether there was a direct causal link between the pain medications and suicide risk.
- → **High doses may be a marker for other factors that drive suicide,** including unresolved severe chronic pain.

Ilgen et al. Pain 2016

What is the Impact of Opioid Safety Policies?

Mandatory Provider Review And Pain Clinic Laws Reduce The Amounts Of Opioids Prescribed And Overdose Death Rates

Dowell et al, Health Affairs 2016

- IMS Health's National Prescription Audit and government mortality data to examine the effect of these policies on opioid prescribing and on prescription opioid and heroin overdose death rates in the United States during 2006 – 13.
- Combined implementation of mandated provider review of state-run prescription drug monitoring program data and pain clinic laws reduced opioid amounts prescribed by 8 percent and prescription opioid overdose death rates by 12 percent.
- We observed relatively large but statistically insignificant reductions in heroin overdose death rates after implementation of these policies.

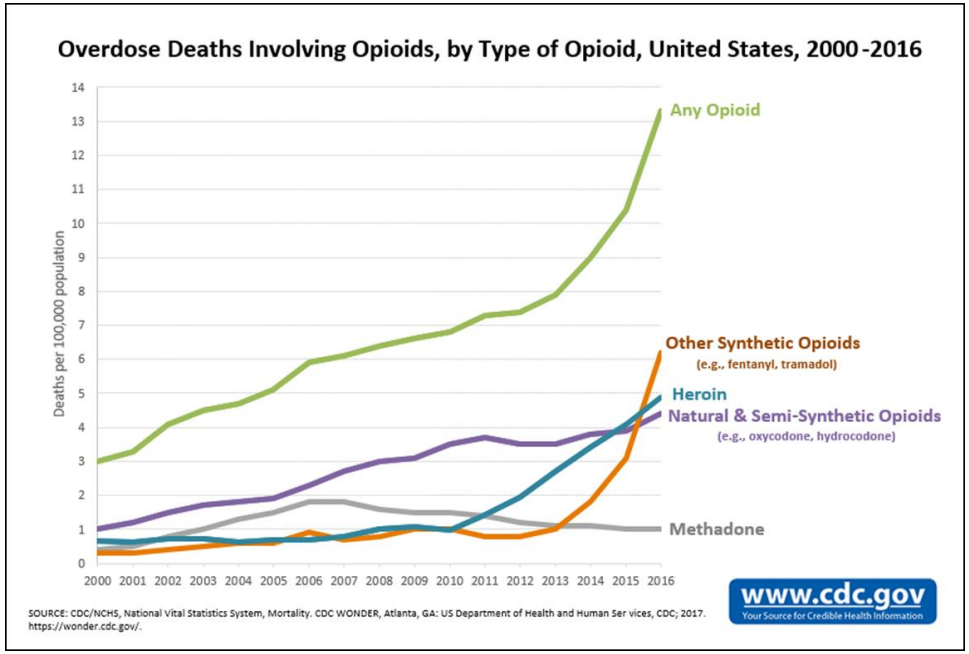
What is the Impact of Opioid Safety Policies?

Patient Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy: A Systematic Review

Frank et al, Ann Intern Med 2017

- 67 studies (11 randomized trials and 56 observational studies) examining 8 intervention categories, including interdisciplinary pain programs, buprenorphine-assisted dose reduction, and behavioral interventions, were found.
- Study quality good for 3 studies, fair for 13 studies, poor for 51 studies.
- Among 40 studies examining patient outcomes after dose reduction (very low overall quality of evidence), improvement was reported in pain severity (8 of 8 fair-quality studies), function (5 of 5 fair-quality studies), and quality of life (3 of 3 fair-quality studies).
- **Conclusion: Very low quality evidence suggests that several types of interventions may be effective to reduce or discontinue LTOT and that pain, function, and quality of life may improve with opioid reduction.**

The Opioid Crisis is Continuing in the US



- Opioid overdose deaths continue to climb
- Large number of the population that has been exposed to opioids
- Availability of illicit opioids
- Lethality of illicit substances

- High rate of OUD/complex dependence
- OUD/Addiction continues to be stigmatized
- Lack of resources for OUD care and challenges to enter treatment program
- High relapse/failure rate in patients with OUD, esp. if not on MAT
- Fragmented, poorly integrated care

Opioid Risk and STORM data

- Veterans on opioid medication in FY 2010 who had their opioid therapy *discontinued* by FY 2011 were compared with Veterans who stayed on opioids.
- Groups did not differ in opioid overdose rates.
- Evidence that **Veterans with opioid discontinuations had elevated suicide rates compared to Veterans who remained on opioid therapy**.
- Patients **with MH, and in particular SUD comorbidities, are highly vulnerable, especially if they were on high dose opioid medication**
- Veterans with opioid discontinuation may have greater behavioral or medical risks for OD/Suicide than patients remaining on opioid therapy.

- High risk on the STORM dashboard suggests the need for active risk management, such as close f/u and case management/care coordination.
- **Interdisciplinary OSI Reviews using STORM data can identify patients at very high risk for OD/Suicide**. These care reviews may allow the interdisciplinary OSI review team to focus resources on such patients including case management.
- MH and Addiction medicine providers must be part of the OSI review teams to maximize benefit and allow for care coordination.

Opioids and Mental Health

The missing 'P' in pain management: how the current opioid epidemic highlights the need for psychiatric services in chronic pain care

Howe CQ, Sullivan MD

Gen Hosp Psychiatry, 2014;36(1):99-104

"**The opioid epidemic thus reflects a serious unmet need for better recognition and treatment of common mental health problems in patients with chronic pain.** Psychiatry is the missing P in chronic pain care"

Rates and Correlates of Pain Specialty Clinic Use Nationally in the Veterans Health Administration.

Arout CA, Sofuoglu M, Rosenheck RA

Pain Med, 2017; 18(4):702-710

"Patients attending pain specialty clinics have more difficult-to-treat pain conditions and comorbid, psychiatric disorders (…), use more outpatient services, and receive a greater number of opioid prescriptions. These data support the **inclusion of mental health care in the specialized treatment of chronic pain**."

S.T.O.P. P.A.I.N. Toolbox

Toolbox available to the public on our website:

https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp

S	• Stepped care model
T	• Treatment alternatives/ complementary and integrative care
O	• Ongoing monitoring of usage
P	• Practice guidelines
P	• Prescription monitoring
A	• Academic detailing
I	• Informed consent for patients
N	• Naloxone distribution

Summary – VHA OSI and Pain Teams

1. In accordance with CARA, VHA is reducing reliance on opioid medication for chronic pain management, providing safer prescribing and monitoring practices, and Veteran-centric, biopsychosocial pain care.
2. The majority of Veterans with chronic pain conditions receive their care from Primary Care**. Well-trained PACT teams** must be supported with **access to patient education/self-care programs and non-pharmacological pain treatment modalities**. The PACT Pain Roadmap is a valuable tool.
3. Veterans with high impact/severe chronic pain benefit from biopsychosocial pain care by an **interdisciplinary Pain Team that works collaboratively** with Primary Care. Pain Management teams at all facilities to support PACT are legislatively mandated by CARA.
4. **Telehealth, E-consultation, VA-ECHO** are tools to maximize resources.
5. MH comorbidities are common in patients with chronic pain. **Integration of MH providers and access to OUD treatment** within Pain teams and Primary care are essential for success.
6. **Centralized pain care reviews** by interdisciplinary pain teams allow targeted interventions to minimize risk and optimize outcomes.

Thank You

Contact information:

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Phone 202-745-8145

www.va.gov/painmanagement

- VACO, 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
- The Veterans and their families

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