

Policies and Practicalities: Focusing on the Patient, Not the Opioid

Jennifer Hah, MD, MS

#### Disclosures

Nothing to disclose

#### Painweek.

#### Learning Objectives

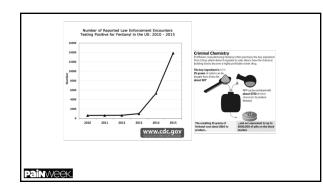
 Demonstrate knowledge of current legislation and guidelines regarding opioid prescribing and opioid tapering in the context of chronic noncancer pain
 Review current evidence-based approaches to opioid tapering in chronic

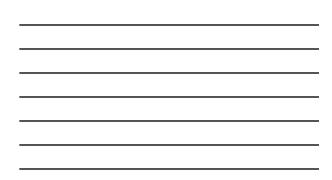
- noncancer pain

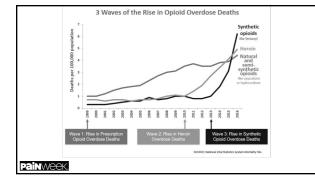
  Explain the benefits of opioid tapering in terms of improvements in pain,
- function, and mood Identify the role of behavioral interventions in the management of pain and the data supporting their use

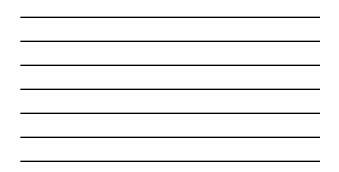


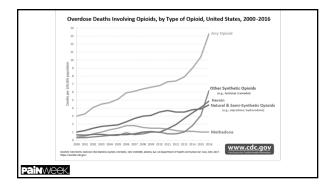
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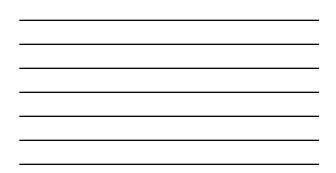


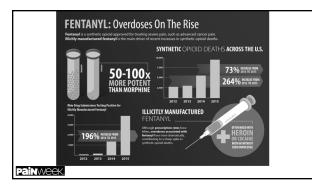














#### Akron Beacon Journal/Ohio.com Ohio is hardest hit by Chinese carfentanil trade, logging 343 of more than 400 seizures in U.S.

s not being diverted from legal domestic supplies "The carrientanii that has been seized in multiple U.S. states is believed to be arriving from foreign sources via illicit networks," Russell Baer, a DEA special agent in Washington,

> The man geographic cluster centers on Ohio, which has been harden Li aly who S43 confirmed carbrania securacy. The drug has also goread through the surrounding states of <u>Ferritory Indiana</u>, Michigan and Illinois, Cardenani ha been sized at least 34 times in fjored. Une second-harders hit stata, and has been identified in <u>Econdent and Perspective</u> and the state of the form cases in west Virginia, New York and Pennsylvania.

The resulting wave of human misery has been overwhelming. In just 21 days in July, paramedics in Akron logged 236 overdoses, including 14 fatalities, with suspected links to carfentanil, according to the DEA. In the first six months of

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# **Opioid Bills in Congress**

 H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act: bipartisan bill advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs like fentanyl

 Require all state Medicaid programs to have a beneficiary assignment program that identifies Medicaid beneficiaries at-risk for substance use disorder (SUD) and assigns them to a pharmaceutical home program, which must set reasonable limits on the number of prescribers and dispensers that beneficiaries may utilize (H.R. 5808)

 Require state Medicaid programs to have safety edits in place for opioid refills, monitor concurrent prescribing of opioids and certain other drugs, and monitor antipsychotic prescribing for children (H.R. 5799)

## **Opioid Bills in Congress (cont'd)**

 H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act:

 Add a review of current opioid prescriptions and, as appropriate, a screening for opioid use disorder (OUD) as part of the Welcome to Medicare initial examination (H.R. 5798)

 Incentivize post-surgical injections as a pain treatment alternative to opioids by reversing a reimbursement cut for these treatments in the Ambulatory Service Center setting, as well as collect data on a subset of codes related to these treatments (H.R. 5804)

 Require e-prescribing, with exceptions, for coverage of prescription drugs that are controlled substances under the Medicare Part D program (H.R. 3528)

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## **Opioid Bills in Congress (cont'd)**

 H.R.4275 - Empowering Pharmacists in the Fight Against Opioid Abuse Act: This bill requires the Department HHS to develop and disseminate training programs and materials on: (1) the circumstances under which a pharmacist may refuse to fill a controlled substance prescription suspected to be fraudulent, forged, or indicative of abuse or diversion; and (2) federal requirements related to such refusal.

H.R.5473 - Better Pain Management Through Better Data Act of 2018
 H.R.5811 - Long-Term Opioid Efficacy Act of 2018

- This of the Long-Term Opioid Enleady Act

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#### 2019 Medicare Advantage and Part D Rate Announcement and Call Letter 4.2.18

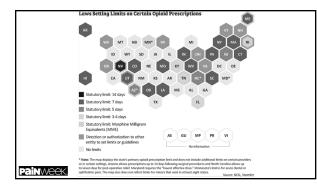
 Opioid naïve patients: To reduce the potential for chronic opioid use or misuse, we expect all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days' supply.

 High risk opioid users: We are building upon and expanding the Overutilization Monitoring System (OMS), which has already significantly reduced the number of high risk beneficiaries. The OMS retrospectively identifies those beneficiaries we consider at significant risk (using high levels of opioids from multiple prescribers and pharmacies). Sponsors review these cases and perform case management with the beneficiaries' prescribers.

#### 2019 Medicare Advantage and Part D Rate Announcement and Call Letter 4.2.18 (cont'd)

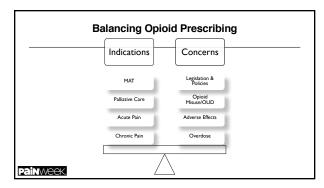
- Chronic opioid users: We expect all sponsors to implement real-time safety alerts at the time of dispensing as a proactive step to engage both patients and prescribers about overdose risk and prevention.
- We expect all sponsors to implement an opioid care coordination edit at 90 morphine milligram equivalent (MME) per day. This formulary-level safety edit should trigger when a beneficiary's cumulative MME per day across their opioid prescriptions reaches or exceeds 90 MME. In implementing this edit, sponsors should instruct the pharmacist to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that specifically states that the prescriber and/or pharmacy count in the opioid care coordination edit. Sponsors will also have the flexibility to implement hard safety edits (which can only be overridden by the sponsor) and set the threshold at 200 MME or more and may include prescriber/pharmacy counts.

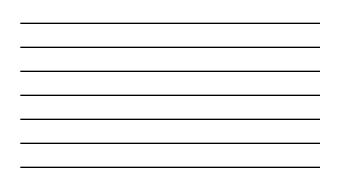
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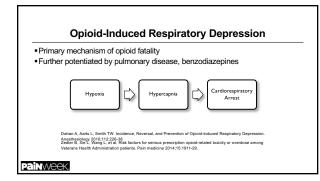


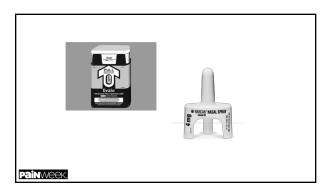
#### State Legislation

- Most legislation limits initial opioid prescribing to a certain number of days, 7 days is most commons (or 3, 5, or 14 days)
- In a few cases, states also set dosage limits (morphine milligram equivalents, or MMEs)
- Nearly half the states with limits specify that they apply to treating acute pain, and most states set exceptions for chronic pain treatment, palliative care, cancer pain treatment, MAT, or provider judgement
- Many laws stipulate that any exceptions must be documented in the patient's medical record
- Certain states authorize other entities (eg, provider regulatory boards, commercial insurers, state Medicaid programs) to implement policies for prescribing certain controlled substances









## **Risk Factors for Prescription Opioid Overdose**

es. J Pain 2016;17(4):406-44

Mean OME >50 mg/d (OR = 1.986 [95% Cl, 1.509-2.614)
Methadone use (OR = 7.230 [95% Cl, 2.346-22.286)
Drug/alcohol abuse (OR = 3.104 [95% Cl, 2.195-4.388])
Other psychiatric illness (OR = 1.730 [95% Cl, 1.307-2.291])
Benzodiazepine use (OR = 2.005 [95% Cl, 1.516-2.652]) • Multiple pharmacies (OR = 1.514 [95% CI, 1.003-2.286])

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#### **Overdose Deaths and Chronic Pain**

61.5% of overdose decedents received a chronic noncancer pain diagnosis in the last year of life

Those with chronic pain were more likely to have filled opioid and benzodiazepine prescriptions during the last 30 days of life
Only 4% of all decedents had a diagnoses of opioid use disorder

Higher incidence of depression and anxiety amongst those with chronic pain

Wall M. Wang S. Crystal S. Blanco C. Service Use Preceding Opioid-Related Fatality. Am J Psychiatry. 2017;appiaip201717070808.

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#### **Prescription Opioids**

Increased rates of substance abuse and depression exist in long-term prescription opioid users compared to nonusers with chronic pain

· Pain intensity does not predict treatment with opioids vs nonopioid analgesics Depression and anxiety contribute to substance use disorders amongst long-term opioid users

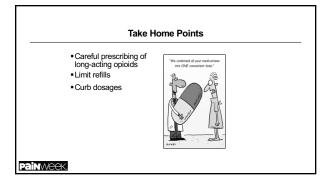
ridge J, Clark JD. Patient characteristics associated with opioid versus nonsteroidal anti-Inflammatory drug management of chronic low back pain. J Pain 2003;4(6):344-30. MJ, Sullwan M, Steffick D, Hamis KM, Wells KB. Do users of regularly prescribed opioids have higher rates of substance use problems than nonsers? Pain Med. 2007;4(8):647-56.

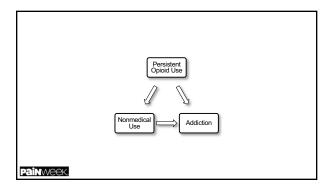
## **Prescribing Patterns**

- Statewide retrospective cohort study
   26,785 (5.0 %) of 536,767 opioid naive patients who filled an opioid
   prescription became long-term users
- Numbers of fills, cumulative MMEs during the initiation month were associated with long-term use

Deyo RA, Halvik SE, Hilsebran C, et al. Association Between Initial Opioid Preaching Patients and Subsequent Long-Term Use Among Opioid Naive Patients: A Statewide Retrospective Cohort Study. J Gen Initian Med. Jan 2017 23(1):21-07.

Initiating with long-acting opioids had a higher risk of long-term use





## **Nonmedical Prescription Opioid Use**

- Prospective, multisite, observational study
- 3396 HV/sinfected and uninfected patients enrolled into the Veterans Aging Cohort Study, followed from 2002-2012

Nonmedical use of prescription opioids was associated positively and independently with heroin initiation [adjusted hazard ratio (AHR) = 5.43, 95% CI = 4.01, 7.35]

cohort study. Addiction. Nov 2016:11

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#### **Opioid Tapering**

- Opioid detoxification as outpatient vs inpatient is comparable
- Successful opioid tapering in intensive outpatient and inpatient pain rehabilitation programs (♥pain, ★functioning, ♥depression, ♥catastrophizing)
- Patients with comorbid chronic pain and opioid misuse can undergo tapering without ↑pain or ↓QOL

#### Fors EA. evink PC. Patients with pro Nilsen HK, Stiles TC, Lan

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## **Guidelines for Opioid Therapy**

cian. 2014;17:401-14

Thorough patient evaluation (eg, psychological and psychosocial factors to identify potential drug misuse and abuse)

- Adequate risks vs benefits discussion (informed consent)
- Begin with a trial of opioid therapy
- Conservative, individualized opioid regimen
- · Continued patient monitoring (loss of response, AEs, aberrant behaviors)

ing CW, Qiu Q, Chol SW, Moore B, Goucke R. Invin M. Chronic opioid therapy for chronic non-cancer pain: a review and comparison of treatment guidelines. Pain Phys

#### American Pain Society-American Academy of Pain Medicine

\*6.2 Clinicians should evaluate patients engaging in aberrant drug-related behaviors for appropriateness of COT or need for restructuring of therapy, referral for assistance in management, or discontinuation of COT\*

Restructuring of therapy: more frequent monitoring, temporary or permanent opioid tapering, or the addition of psychological therapies or other non-opioid treatments

GJ, Fine PG, et al. Cl ines for the use of chronic opioid therapy in chronic noncancer pain. J Pain. 2009;10: 113-30.

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#### American Pain Society-American Academy of Pain Medicine (cont'd)

ancer pain. J Pain. 2009:10: 113-30

"7.4 Clinicians should taper or wean patients off COT who engage in repeated aberrant drug-related behaviors or drug abuse/diversion, experience no progress toward meeting therapeutic goals, or experience intolerable adverse effects."

or the use of chronic opioid th

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#### American Pain Society-American Academy of Pain Medicine (cont'd)

ancer pain. J Pain. 2009;10: 113-30

Opioid taper can occur in outpatient setting without severe medical or psychiatric comorbidities

Opioid detoxification in a rehabilitation setting (outpatient or inpatient)
 Enforced weaning and referral to an addiction specialist may be necessary with aberrant drug-related behaviors

s for the use of chronic opioid therapy in chronic no

o GJ, Fine PG, et al. Clin Painweek.

# American Pain Society— American Academy of Pain Medicine (cont'd)

• 10% dose reduction weekly

10% cose reduction weekiy
25% to 50% dose reduction every few days
At greater than 200mg/day MEQ initial wean can be more rapid
At doses of 60-80 mg/day MEQ slower tapers may be required
Improved well-being and function vs. pain hypersensitivity during opioid withdrawal

Chou R, Fancialo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncanoer pain. J Pain. 2009;10: 113-30.

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SOAPP-R	
<ul> <li>Cutoff score of ≥18, sensitivity was 0.80 (95% CI, 0.70 to 0.89) and specificity was 0.68 (95% CI, 0.60 to 0.75) for identification of any aberrant drug-related behavior</li> <li>Each item scored from 0 to 4, maximum score 96</li> </ul>	Pipers 1. Lead SSMP 4 question: 1. Sum of the second seco

(	ORT			
aximum score=26 errant drug-related behaviors were identified in 6% ( mpared with 28% (35/123) of patients categorized a tegorized as high risk (score ≥8) after 12 months				
Mark each box that applies	Female	Male	Sensing (Bisk)	
Mark each box that applies 1. Family the d'autorates above The property of the	Female	Male	Scoting (Risk) 0-3 Low Risk 4-7 Moderate Risk a 8 High Risk	
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1. Family five of substance abuse Acceld ingul Origin Prescription Rougin Prescription Rougin Regularity		1 2 4 3 4 5 5	0-3 Low Risk 4-7 Moderate Fink	

11

#### COMM

 17-items Self-report

 Sein-report
 A score of 9 or higher on the COMM has 94% sensitivity and 73% specificity to identify opioid misuse among patients prescribed opioids for pain Assesses behaviors within the past 30 days

C, et al. C ure. Pain 2007;130:144-55.1950245

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#### American Society of Interventional Pain Physicians

2012;15:

"It is essential to monitor for side effects and manage them appropriately including discontinuation of opioids if indicated"

- 10% of the original dose weekly
- Tapering over 6-8 weeks

Abdi S, Atluri S, et al. A

 Clonidine 0.1-0.2mg PO q6hrs or clonidine 0.1mg/24 hrs TD weekly Mild opioid withdrawal symptoms up to 6 months after discontinuation

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Manchill 547-11

## American Society of Interventional Pain Physicians (cont'd)

"Discontinue opioid therapy for lack of response, adverse consequences, and abuse with rehabilitation."

- Tapering or weaning is not necessary for patients who have not taken medication on a long-term basis
  Consider adjuvant treatment for continued opioid withdrawal symptoms
- -Antidepressants -Antineuropathics
- -Counseling

Manchikanti L, Kaye AM, Knezevic NN, et al. Re. Physician. Feb 2017;20(25):52-592.

#### GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

 7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (recommendation category: A, evidence type: 4).

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#### GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

# Opioid Discontinuation/Tapering

- No improvements in pain and function
- High-risk regimens (eg, dosages ≥50 MME/day, opioids combined with benzodiazepines) without evidence of benefit
- Patients believe benefits no longer outweigh risks or if they request dosage reduction or discontinuation
- Overdose or other serious adverse events (eg, an event leading to hospitalization or disability) or warning signs of serious adverse events

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#### GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Opioid Discontinuation/Tapering (cont'd)

Reducing weekly dosage by 10%-50% of the original dosage

Overdose: rapid taper over 2-3 weeks

Slower tapers may be appropriate with longer durations of opioid use
 Pregnancy: risk of spontaneous abortion and premature labor

#### GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

#### **Opioid Discontinuation/Tapering (cont'd)**

Minimize opioid withdrawal symptoms (drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection)

Discontinue when taken less than once a day
 Ultrarapid detoxification under anesthesia is associated with substantial risks, including death

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#### Health Plan Driven Opioid Tapering

 Oregon Health Authority and the Health Evidence Review Commission implemented guidance for Oregon Medicaid members who were taking opioids for chronic pain (back and spine) in 2016.

For patients with chronic pain from diagnoses on these lines currently treated with long term opicid therapy, opicids must be tapered off using an individual treatment plan developed by January 1, 2017 with a quit date no later than January 1, 2018. Taper plans must include romptamacological treatment strategies for managing the patient's pain based on Guideline Note 56 NOLHAITERVENTIONAL TREATINENTS FOR MONITORIO FOT HER ACM AND SPIRE. The patient has developed dependence and/or addiction related to their opicids, treatment is available on Line 4 SUBSTANCE USE DISORDER.

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#### Health Plan Driven Opioid Tapering (cont'd)

Provider Outreach (Introductory Letter, Summary Letter—an example 10% taper plan, a nonopioid analgesic therapy resource, a noninterventional therapy resource, and an "Opioid Tapering FAQ" patient handout)

16 members (14.2%) had a decrease in MEDD
23 members (20.4%) had no change in MEDD

• 72 members (63.7%) had an increase in MEDD

 2 members (1.8%) were unable to be analyzed because of lapsed CCO coverage Page J, Traver R, Patel S, Salba C. Implementat J Manag Care Spec Pharm 2018 24(2):191-195.

#### Voluntary Patient-Centered Opioid Tapering

- Patients with CNCP prescribed long-term opioids at a community pain clinic
- Provided education about the benefits of opioid reduction
- $\bullet$  Physicians offered to partner with patients to slowly reduce their opioid dosages over 4 months
- 51 of 83 patient completed the 4-month follow-up
  Baseline median MEDD 288 (153-587)
- Baseline median MEDD 288 (153-587)
   Follow-up median MEDD 150 (IQR, 54-248) mg (P = .002)
- No increase in pain intensity or interference
- Darnal BD, Zadni MS, Sleg RL, Mackey KJ, Kao MC, Riod P. Patien-Centered Prescription Opiola Tapering in Community Outpatients With Chronic Pain. JAMA Intern Med. 2018

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#### **Facilitators of Opioid Tapering**

vider Experiences Tapering Long-term Opioid Medications. Pain

- Empathizing with the patient's experience
- Preparing patients for opioid tapering
- Individualizing implementation of opioid tapering
   Supportive guidelines and policies

ranger IA, Mueller SR, et al. "Those Conversations in My Experience Don't Go Well": A Qualitative Study of P

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Kennedy L

#### Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy

- 67 studies (11 randomized trials and 56 observational studies)
  Interdisciplinary pain programs, behavioral interventions
- Most studies report dose reduction but discontinuation rates were highly variable
- Improvements in pain severity, function, and quality of life

#### Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy (cont'd)

- 4-month interactive voice response intervention vs usual care among patients with chronic pain (n = 51)
- Optional opioid dose reduction
- Reduced mean opioid dose significantly at 4-months (P = 0.04) and 8-months (P = 0.004) follow-up

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#### Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy (cont'd)

- 8-week group intervention based on mindfulness meditation and cognitive behavioral therapy with usual care among patients receiving LTOT (n=35)

Did not explicitly encourage dose reduction

• The mean change in the daily opioid dose from baseline to 26 weeks was -10.1 mg MED in the intervention group compared with -0.2 mg MED in the control group (P = 0.8)

of Long-Term Opiold Therapy: A Systematic Review. Ann Intern Med. 2017;167(2):181-191

tion of Long-Term Opioid Therapy: A Systematic Review. Ann Intern Med. 2017;167(2):181-191.

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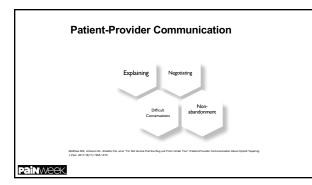
Frank JW, Lovejoy TI, Becker WC, et al. Patien

#### Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy (cont'd)

- Patient barriers to opioid tapering
- · Strategies to enhance patients engagement
- · Less resource intensive models of opioid tapering No studies address mandatory opioid tapering
- Need for long-term surveillance regarding adverse events (overdose, suicide)

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Frank JW, Lovejoy TI, Becker WC, et al. Patient





#### **MI-Based Interventions**

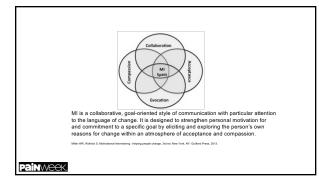
 Pilot RCT of taper support intervention (psychiatric consultation, opioid dose tapering, and 18 weekly meetings with a physician assistant to explore motivation for tapering and learn pain self-management skills) vs usual care • Lower opioid doses and pain severity ratings in both groups

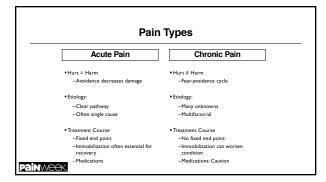
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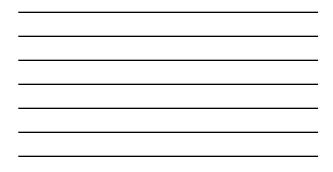
#### **MI-Based Interventions (cont'd)**

MI-based session concerning opioid tapering that included:

- Eliciting the patient's history related to pain, opioid therapy, and related difficulties
- Eliciting change talk related to tapering
- Education about dose-related health risks
- Identifying practical and psychological barriers to tapering opioid dose and problem-solving ways to overcome these; and developing a commitment to change with respect to opioid therapy
- Significant improvements in pain interference, pain self-efficacy, and perceived Opioid problems
   Superior MD, Turre JA, Diudokico C, et al. Prescription Quiod Taper Support for Outpatients With Chronic Pain: A Rendomized Controlled Trial. J Pain. Mer
   Str. 11:863, 368-11







#### **Chronic Pain Management**

Development of <u>active</u> self-management tools

 $\bullet$  Goals focus on functional improvement and increasing self-efficacy rather than pain reduction

## Chronic Pain Management (cont'd)

 Medical optimization —Physician, NP, PA

Physical reconditioning
 –Rehabilitation provider (PT, OT)

Behavioral/lifestyle modification

 Pain psychologist

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Chronic Pain Management Dilemma

Medical optimization
 Physician, NP, PA

Physical reconditioning. —Rehabilitation provider (PT, OT).

Behavioral/lifestyle modificati —Pain psychologist

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Stanford Comprehensive Interdisciplinary Pain Program (SCIPP)

Typical patient

Pain conditions accepted

Admission criteria

## Interdisciplinary Treatment

- Physical therapy
- Occupational therapy
- Medication optimization (cocktail)
- Lifestyle/behavioral modification

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#### Scheduled Activities

AM rounds

Physical therapy

Occupational therapy

Pain coping skills class

Individual provider visits

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#### **Unscheduled Activities**

Independent practice

Walking

Activity tracking log

## **Behaviors Reinforced**

- Consistent across all team members, including nursing
- Application of self-management skills
- Increased activity levels
- Focus on functioning

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## **Behaviors Not Reinforced**

Pain behavior

Medication focus

Somatic complaints

Inactivity

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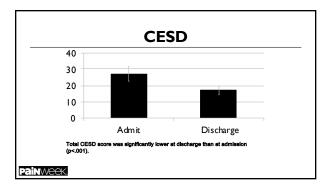
#### **SCIPP Outcomes**

n = 44 (19 male, 25 female)

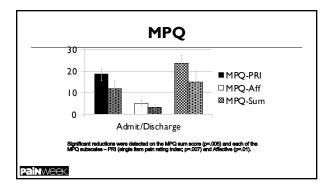
- Minimum of 1 pain diagnosis

- Assessments:
   -Center for Epidemiologic Study of Diseases –
   Depression Scale (CESD)
   -McGill Pain Questionnaire (MPQ)
   -McGill Pain Questionnaire-Visual-Analog Scale (MPQ-VAS)
   -Profile of Mood States (POMS)

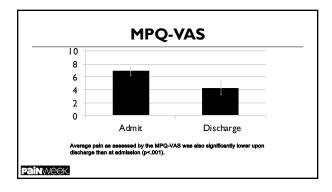
Administered within 24 hours of admission and discharge



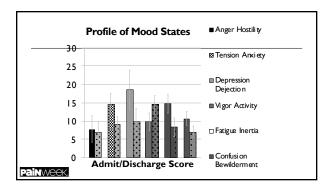


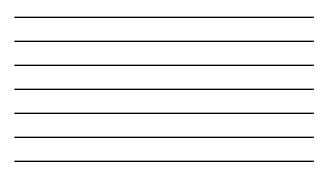












#### SCIPP Outcomes

- Significant changes on CESD (p<001) MPO VARSer (p<001) MPO Assist (p<001) MPO assist (p<001) MPO assist (p<001) MPO assist (p<001) POMS Testion-Arrively (p<005) POMS Depression-Dejection (p=001) POMS Faigue-Inertia (p=002) POMS Faigue-Inertia (p=002) POMS Total Mood Disturbance (p=01)

No significant difference on – POMS Anger-Hostility

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#### **Outpatient Application**

Participation in CBT-based coping skills class

Concurrent medication reduction

Consider joint psych-MD appointments