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

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Disclosures

- NIH NIDA R01 DA045027: Psychological Risk Factors for Persistent Opioid Use and Prevention of Chronic Opioid Use and Misuse After Surgery: Postoperative Motivational Interviewing and Guided Opioid Weaning
Learning Objectives

- Demonstrate knowledge of current legislation and guidelines regarding opioid prescribing and opioid tapering in the context of chronic non-cancer pain.
- Review current evidence-based approaches to opioid tapering in chronic non-cancer pain.
- Understand the benefits of opioid tapering in terms of improvements in pain, function, and mood.
- Develop an understanding of the role of behavioral interventions in the management of pain and the data supporting their use.
3 Waves of the Rise in Opioid Overdose Deaths

- **Wave 1:** Rise in Prescription Opioid Overdose Deaths
- **Wave 2:** Rise in Heroin Overdose Deaths
- **Wave 3:** Rise in Synthetic Opioid Overdose Deaths


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Number of Reported Law Enforcement Encounters Testing Positive for Fentanyl in the US: 2010 - 2015

**Criminal Chemistry**
- Fentanyl is often sold on the dark web.
- The key ingredient is **N-Phenylallylnitromethane**.
- A 25 gram bag of fentanyl can be bought for about $87.
- The resulting 25 grams of fentanyl cost about $500 to produce.
- And are equivalent to up to 500,000 pills on the black market.

*Source: www.cdc.gov*
Akron Beacon Journal/Ohio.com
Ohio is hardest hit by Chinese carfentanil trade, logging 343 of more than 400 seizures in U.S.

The DEA says the carfentanil spreading through illicit drug markets in the U.S. is not being diverted from legal domestic supplies. "The carfentanil 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, said by email.

The main geographic cluster centers on Ohio, which has been hardest hit with 343 confirmed carfentanil seizures. The drug has also spread through the surrounding states of Kentucky, Indiana, Michigan and Illinois. Carfentanil has been seized at least 34 times in Florida, the second-hardest hit state, and has been identified in Georgia and Rhode Island. DEA is waiting on confirmation from 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
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).

- **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).**
Opioid Bills in Congress

- 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

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

- 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 has been consulted. Sponsors will have the flexibility to include a 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.
State Legislation

- Most legislation limits initial opioid prescribing to a certain number of days, 7 days is most common (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 (e.g. provider regulatory boards, commercial insurers, state Medicaid programs) to implement policies for prescribing certain controlled substances

Balancing Opioid Prescribing

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<th>Indications</th>
<th>Concerns</th>
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<tr>
<td>MAT</td>
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<td>Adverse Effects</td>
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<td>Chronic Pain</td>
<td>Overdose</td>
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Opioid-Induced Respiratory Depression

- Primary mechanism of opioid fatality
- Further potentiated by pulmonary disease, benzodiazepines

Risk Factors for Prescription Opioid Overdose

- Mean OME >50mg/d (OR = 1.986 [95% CI, 1.509-2.614])
- Methadone Use (OR = 7.230 [95% CI, 2.346-22.286])
- Drug/Alcohol Abuse (OR = 3.104 [95% CI, 2.195-4.388])
- Other Psychiatric Illness (OR = 1.730 [95% CI, 1.307-2.291])
- Benzodiazepine Use (OR = 2.005 [95% CI, 1.516-2.652])
- Multiple Pharmacies (OR = 1.514 [95% CI, 1.003-2.286])


Overdose Deaths and Chronic Pain

- 61.5% of overdose decedents received a chronic noncancer pain diagnoses 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

Prescription Opioids

- Increased rates of substance abuse and depression exist in long-term prescription opioid users compared to non-users with chronic pain
- Pain intensity does not predict treatment with opioids vs. non-opioid analgesics
- Depression and anxiety contribute to substance use disorders amongst long-term opioid users


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

Take Home Points

- Careful prescribing of long-acting opioids
- Limit refills
- Curb dosages

"We combined all your medications into ONE convenient dose."
Non-Medical Prescription Opioid Use

- Prospective, multi-site, observational study
- 3396 HIV-infected and uninfected patients enrolled into the Veterans Aging Cohort Study, followed from 2002-2012
- Non-medical use of prescription opioids was associated positively and independently with heroin initiation [adjusted hazard ratio (AHR) = 5.43, 95% CI = 4.01, 7.35]

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

Guidelines for Opioid Therapy

- Thorough patient evaluation (e.g., 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)


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

American Pain Society- American Academy of Pain Medicine

“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.”


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

American Pain Society- American Academy of Pain Medicine

- 10% dose reduction weekly
- 25-50% 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


SOAPP-R

- 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
- Each item scored from 0 to 4, maximum score 96

ORT

- Maximum score = 26
- Aberrant drug-related behaviors were identified in 6% of patients categorized as low risk, 28% of patients categorized as moderate risk, and 91% of those categorized as high risk.
- Aberrant drug-related behaviors were identified in 6% (1/18) of patients categorized as low risk (score, 0 to 3), compared with 28% (35/123) of patients categorized as moderate risk (score, 4 to 7) and 91% (41/44) of those categorized as high risk (score ≥8) after 12 months.

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<td>4-7 Moderate Risk</td>
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Scoring totals:

COMM

- 17-items
- Self-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.

American Society of Interventional Pain Physicians

“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
- 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


American Society of Interventional Pain Physicians

“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
  - Anti-neuropathics
  - Counseling

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).

Opioid Discontinuation/Tapering

- No improvements in pain and function
- High-risk regimens (e.g., 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 (e.g., an event leading to hospitalization or disability) or warning signs of serious adverse events
Opioid Discontinuation/Tapering

- 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

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Opioid Discontinuation/Tapering

- 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
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 opioid therapy, opioids 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 nonpharmacological treatment strategies for managing the patient's pain based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE. If a patient has developed dependence and/or addiction related to their opioids, treatment is available on Line 4 SUBSTANCE USE DISORDER.


Provider Outreach (Introductory Letter, Summary Letter—an example 10% taper plan, a nonopioid analgesic therapy resource, a non-interventional 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
**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
- 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)
- Follow-up median MEDD 150 (IQR, 54-248) mg ($P = .002$)
- No increase in pain intensity or interference


**Facilitators of Opioid Tapering**

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

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

- 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

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

- 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 ($P = 0.8$)


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

- 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)

Patient-Provider Communication

Explaining

Negotiating

Difficult Conversations

Non-abandonment

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

MI-Based Interventions

- 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


People are generally better persuaded by the reasons which they have themselves discovered than by those which have come into the mind of others.

-Blaise Pascal
MI is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person’s own reasons for change within an atmosphere of acceptance and compassion.

MI

- Improved Treatment Engagement
- Improved Treatment Outcomes
- Increased Medication Adherence
- Decreased Illicit Drug Use

Processes of MI

- Engaging
  - Establishing a connection and a working relationship

- Focusing
  - Deciding on a particular agenda

- Evoking
  - Eliciting client's own motivation for change

- Planning
  - Formulating a specific plan of action
Motivational Interviewing

**Tools**
- Open questions
- Affirmations
- Reflections
- Summary

**Change Talk**
- Desire- “I want to…”
- Ability- “I can…”
- Reasons- “I would probably feel better if…”
- Need- “I have to…”
- Commitment- “I will…”
- Activation- “I’m ready to…”
- Taking steps- “This week I started…”

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**Human motivation**

People generally resist being coerced

Everybody is motivated for something

*The point is not whether they’re motivated or not, but what they’re motivated for.*

Motivation for change is:
- malleable
- fluctuates over time and across situation
- a product of interaction between people, not within one person
Motivational model

- Perceived importance of change
- Readiness to make the change
- Self-efficacy for making the change

Stages of change

- Determine the patient’s current stage of change
- Intervention should match current stage of change
- Goal for visit is to move patient one stage forward.
Stages of change in opioid tapering

- **Pre-contemplative**: Opioid use is not a problem for me.
- **Contemplative**: I do have side effects from opioids like constipation and drowsiness, but nothing else helps my pain.
- **Preparation**: I know opioids are not a good long term solution, and I am looking for something else that works to manage my pain.

- **Action**: Active engagement with strategies to reduce opioid use, such as following tapering schedule and learning alternative coping strategies like distraction and relaxation
- **Maintenance**: I am using other medications and tools to manage pain instead of opioids.

Tipping the balance

Clinician’s tasks:

- Explore both positive and negative prospects of life with and without the proposed changes
- Help patient understand discrepancy between current behavior and long-term goals
MI Example

Patient says, “I can’t cut down. Norco is the only thing that help my pain.”

Assessment: (Stage of change)

Pros/Cons of using opiates:

How does behavior fit with long term goals?
**MI Example**

Patient says, “I can’t cut down. Norco is the only thing that help my pain.”

- **Open-ended questions:** What are some of the benefits of Norco? What are the drawbacks?
- **Affirmations:** Living with pain is difficult, and you’ve tried several ways of coping with it.
- **Reflective Listening:** You’ve tried not taking Norco but then you have more pain, and feel nauseous too.
- **Summary:** Norco takes the edge off, but you still have pain. When you run out early, you know it’s painful and you feel sick. There are some risks to long term opioid use, but nothing you’ve tried has been as effective. You’ve tried PT and a few other medications, but there are some medications you haven’t tried yet.

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**MI Example**

- Patient moved from **pre-contemplative** to **contemplative stage**
- Can take several sessions
- Include psychoeducation when appropriate
- Provide tools (stress management, CBT, etc.)
- On going assessment of stage of change and barriers to success including depression, anxiety, trauma history
Responding to Relapse

- Normalize relapse process
- Praise accomplishments
- Discuss what can be learned from relapse – accept it as opportunity to reengage, rethink, reemerge stronger.
- Reframe relapse as being one step closer to maintenance

**Relapse prevention plan**
- Review original motivations for tapering
- Identify potential triggers for relapse (pain flare, life stressor)
- Plan in advance how you will cope (behavioral and cognitive strategies)
- Identify support systems for returning to taper (MD, family, friends, groups)

SELF REGULATION

- Acupuncture
- Biofeedback
- Stretching
- Foam rolling
- Tai Chi
- Yoga
- Progressive Muscle Relaxation
- Diaphragmatic Breathing
- Guided Imagery
- Body Scan
- Meditation
- Mindfulness
- Prayer

*Present focus is mentally grounding & physically relaxing*
SELF REGULATION APPs

Summary of strategies

**MI**
- Assess stage of change
- OARS
- Pros/Cons
- Change talk
- Support active coping
- Ongoing re-assessment of stages of change
- Reframe relapse

**Tapering Strategies**
- Psychoeducation about long term opioid use and provide alternatives
- Tapering schedule
- Medication and behavioral management of withdrawal and cravings
- Relaxation training
- Cognitive-behavioral approaches
- Mindfulness and Acceptance-Based approaches