An Overview of
Controlled Substance Stewardship

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Disclosures

- I do not accept any money from pharmaceutical companies/ commercial interests.
- Speakers and planners have no significant or relevant financial relationships to disclose.

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Goals for Our Time Today

1. Describe the Controlled Substance Stewardship Program
2. Introduce the Foundation for Controlled Substance Stewardship and Compassionate Tapering
3. Understand the Role of Pharmacists in Improving Opioid Stewardship

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CDC Guidelines

2016	2022
Start with lowest effective dose. Extra precautions > 50 MME, avoid > 90 MME	Start with lowest effective dose. Avoid increasing dosage above levels “likely to yield diminishing returns” (clearly identified as >50 MME in main body).
3-7 days usually sufficient for acute pain.	Only consider for acute pain if benefit exceeds risk. No greater quantity than needed for the expected duration of pain severe enough to require opioid.
Reevaluate every 3 months. Taper if benefits do not exceed risks.	Reevaluate every 3 months. For those already receiving high doses, consider tapering, but do not discontinue abruptly.

OUD vs. CPOD

OUD	CPOD
Use related to social, occupational and behavioral issues	Poor pain control and function, psychiatric instability, aberrant behavior.
Illicit or iatrogenic initiation	Iatrogenic initiation
Patient goal of intoxication or euphoria	Rare goal of intoxication/ euphoria
Classic withdrawal symptoms	Worsening pain and declining function are predominant withdrawal symptoms

Reference: Manhapra A, Sullivan MD, Ballantyne JC, MacLean RR, Becker WC. Complex Persistent Opioid Dependence with Long-term Opioids: a Gray Area That Needs Definition, Better Understanding, Treatment Guidance, and Policy Changes. J Gen Intern Med. 2020 Dec;35(Suppl 3):964-971. doi: 10.1007/s11606-020-06251-w. Epub 2020 Nov 6. PMID: 33159241; PMCID: PMC7728942.

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Controlled Substance Stewardship:

Community Care Partnership of Maine's Program

The CCPM CSS Model

- Began in 2013, with case reviews completed by Psychiatrist and Family Physicians.
- Now a **full interdisciplinary team of providers** reviews the cases, including:
  - Family Physician*
  - Psychiatrist*
  - Family Nurse Practitioner – Pain Specialist*
  - Clinical Pharmacists*
  - Licensed Clinical Professional Counselor
  - Peer Advocate

**Provide treatment for use disorder*

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CSS Case Review Process

Patient Identification → Chart Review → Presentation to Committee by Pharmacist → Development of Recommend-ations for Care Team → Communicati on of Recommend-ations to Care Team → Follow Up Case Reviews

Engagement with the Care Team

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Patient Identification

- Direct provider referral
- Report based referral
- Reports used
  - Opioid and benzodiazepine combination
    - Also, opioid +Z-drug or barbiturate
  - MME Threshold Reports – >50 MME
  - Methadone for pain
  - Multiple opioids
  - Panel reports for outlier prescribers
  - Opioids in patients with diagnosed use disorders
  - Premature Death Reviews

Pharmacist Chart Review

- Current pharmacotherapy (controlled and non-controlled)
- Relevant disease states
  - What is being treated with the controlled substances
  - Psychiatric comorbidities
  - Conditions that an opioid or benzodiazepine may worsen or increase a patient's risk with treatment(respiratory conditions, cardiovascular disease)
- Red flags or Concerning Findings
  - Requests for early refills
  - Frequent early fills (PMP findings)
  - Documentation of a use disorder
  - History of falls
  - Inconsistent drug screens or pill counts
  - Other indicators of misuse or diversion

Pharmacist Chart Review

- PMP Patterns
- Relevant screenings
  - PHQ-9
  - Trauma
  - Suicide risk assessment
- Other providers involved in care
  - Counselors or mental health providers
  - Specialists
- Relevant Office Visit Notes

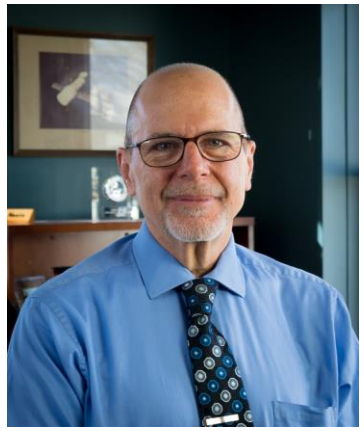
Case Presentation & Recommendation Development

- Pharmacist presents case to the interdisciplinary committee
- The committee provides recommendations focused on
  - Appropriateness of therapy
  - Taper plan recommendations
  - Alternative treatment options
  - Talking points for difficult conversations
  - Unaddressed or undertreated psychiatric comorbidities
  - Other areas of care that need to be addressed such as polypharmacy
- The pharmacist takes the recommendations and develops a response letter to the primary care provider with a detailed taper plan
- Complete follow up reviews every 3 months

Care Team Engagement

- Onboarding presentation for care teams
- Routine meetings with practice leadership
  - Discuss progress on tapers
  - Barriers to implementing recommendations
- Education for care teams
  - Inheriting patients from outlier prescribers
  - Specific patient discussions that have been challenging
- Prescribers join weekly CSS meeting to discuss their patients when requested

Controlled Substance Stewardship Team



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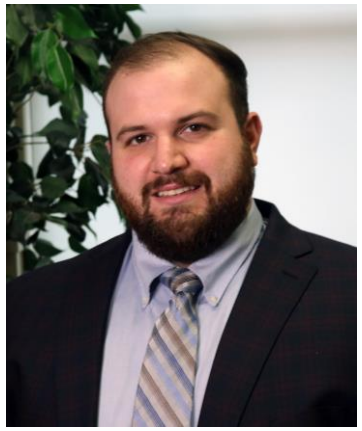

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CSS Program Outcomes to Date

2,394

Total cases reviewed completed since September 2019

15

Total organization clients engaged across Maine

21,838

Total MME reduction realized since September 2019

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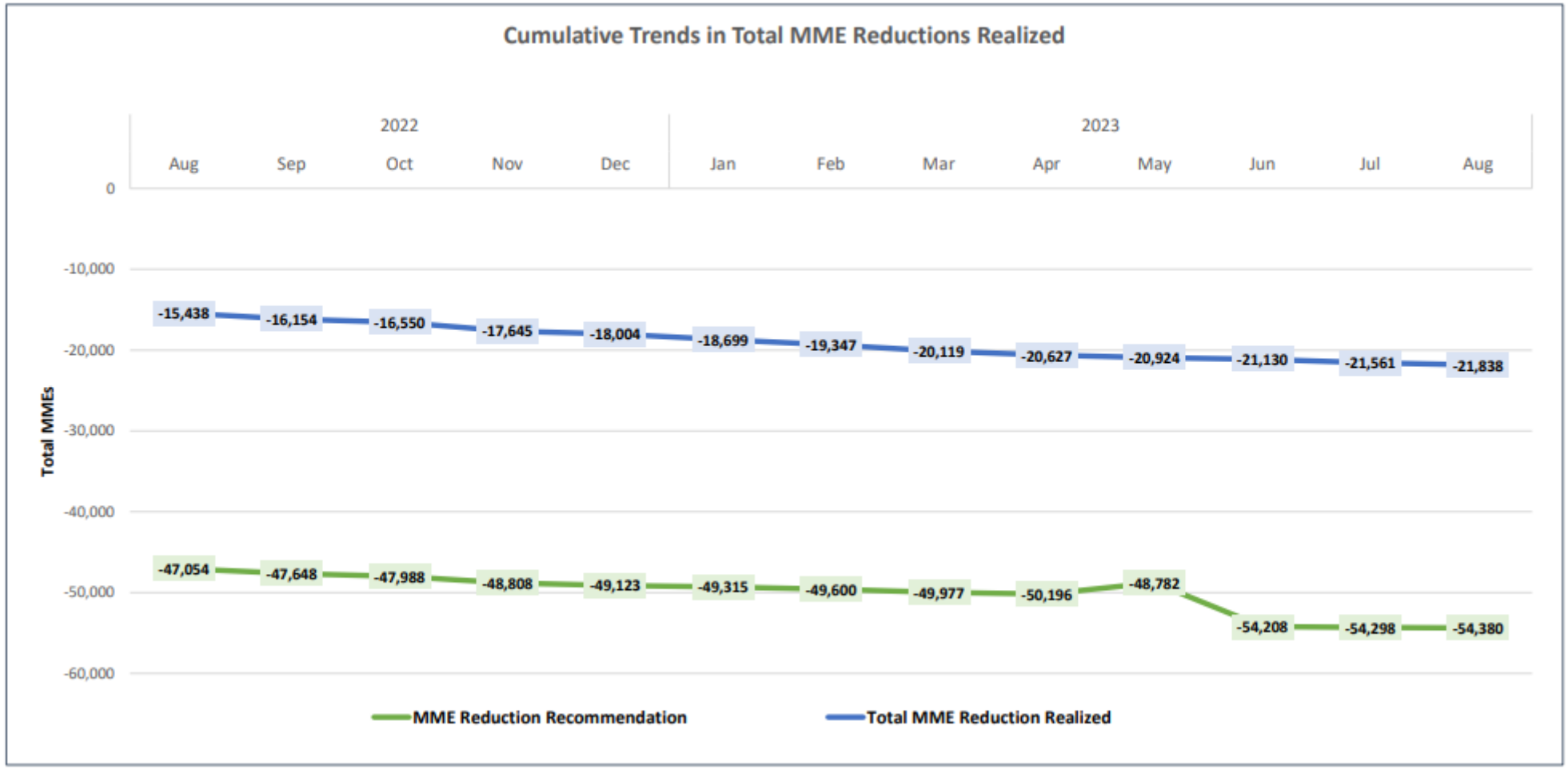
Cumulative Trends in Total MME Reductions Realized



Statewide Expansion of the CSS Program

1. Establishment of Statewide Controlled Substance Stewardship and Prescribing Protocol Policies

CCPM has establish policy and procedure resources that providers can use to inform opioid prescribing and tapering practices.

2. CSS Case Reviews (by Interdisciplinary Committee)

CCPM's CSS Committee – an interdisciplinary team of providers with expertise in pharmacy, pain management, family medicine, psychiatry, and care management – will review individual cases at no cost to providers. These case reviews will include:

- Detailed medical record reviews by a clinical pharmacist, followed by presentation to the CSS Committee;
- Review of relevant cases by the CSS committee, followed by development of a recommended tapering plan that will be communicated to the provider;
- Follow-up reviews of each case, including secondary recommendations (as needed);
- Responses to written patient complaints that may result from implementation of the recommendations, on behalf of the provider.

3. CSS Resources and Training Sessions for Providers

CCPM has developed and provider training sessions offered throughout the State, covering resources and services available to providers, workflow and process summaries, and regionalized train-the-trainer models for new policies related to controlled substances and care delivery.

4. Development of Internal CSS Committee Structures for Interested Organizations

All CSS services are offered free of charge to organizations & providers statewide as part of a collaboration with the State of Maine Office of Behavioral Health.

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Controlled Substance Stewardship:

Compassionate Tapering

Four Principles of Opioid Stewardship

1. There is no evidence for benefit from opioids in the treatment of chronic pain for a population of people and for some of the most common conditions for which opioids are prescribed (back pain, headaches, fibromyalgia, neuropathic pain and chronic regional pain syndrome) there is evidence of no benefit.

2. For people on daily opioids for chronic pain the lifetime prevalence of opioid use disorder (using DSM V criteria) may be as high as 35%, so in the instance of a challenging tapering experience this must be part of the differential diagnosis.

3. Emotional trauma and significant mental illness are much more likely to be present in people with chronic pain and should always be assessed and addressed.

4. The best approach to the treatment of chronic pain is almost always multi-faceted and pharmacologic interventions are not the most important of those approaches.

Why Consider Tapering?

- **Opioids are commonly used for indications which there is no evidence of benefit or evidence of no benefit**
  - Fibromyalgia
  - Complex regional pain syndrome
  - Chronic Back Pain
- **Reduction in pain severity is often seen following opioid tapers**
- **Similar to opioids, benzodiazepines are often used inappropriately for longer durations than appropriate**
- **Patients with psychiatric comorbidities are more likely to be prescribed opioids**
  - 18.7% of Americans with psychiatric conditions receive 51.4% of prescribed opioids
  - Higher risk for developing use disorder

Opioid Tapering Best Practices

- **10% - 15% reductions**
  - Pace is generally weekly to monthly reductions
    - Patient receptiveness
    - Tolerance to dose reductions
    - Presence of risk factors
- **Never reverse a taper**
- **Explore Opioid Use Disorder**
- **Leverage opioid rotations to expedite a taper when needed**
  - **Switch to another opioid and reduce dose by 25-50%**
- **Taper compassionately**

CCPM's CSS Model: Compassionate Tapering

Strategies Include:

- Put the plan in writing
- Frame the discussion around the patient and their safety
- Normalize the common reactions (i.e. anxiety, insomnia, achiness)
- Monitor while you taper (pill counts, UDS, PMP)
- Rate of taper can be customized but should be inexorable
- **Talk to the patient about the nature of addiction, repeatedly**
- Never reverse
- Rarely plateau
- No early refills, ever
- Constantly reassure
- Resist disparaging prior prescribers
- Use the force
- Maintain close contact, especially once taper is complete

CCPM's CSS Model: Compassionate Tapering

Risk Factors Driving Faster Tapering:

- COPD
- Sleep Apnea
- Heart disease
- On Benzodiazepines
- Suspicion of misuse or diversion
- Substance Use Disorder
- Trauma or PTSD
- Bipolar, depression, schizophrenia, other SPMI

Gabapentin & Overdose

- **Does have a role in treating neuropathic pain**
- **Is used illicitly to enhance the effects of opioids**
- **Growing rate of overdose deaths involving gabapentin**
  - Identified in 10% of overdose deaths reported to State Unintentional Drug Overdose Reporting System in (SUDORS) in 2019-2020
  - ~90% of cases involved opioids in addition to gabapentin

Benzodiazepine Tapering Pearls

- **Can use the benzodiazepine that patient is currently on**
  - May consider a switch to a longer acting benzodiazepine such as diazepam or chlordiazepoxide
- **Taper may be needed after as long as 2 weeks of continuous use**
- **Opioid and benzodiazepine tapers can occur concurrently**
- **Reductions of 10% every 2 to 4 weeks are often well tolerated**
  - Reduction percentage and taper speed will depend on patient dependent factors
- **Complicated cases involving high doses may require more supervised settings**

Withdrawal Symptoms: Abrupt Stopping

Opioids	Benzodiazepines
Abdominal cramping	Rebound anxiety
Nausea, vomiting	Rebound insomnia
Diarrhea	Headache
Body aches	Nausea
Muscle spasms	Joint and muscle pain
Lack of appetite	Seizure
Yawning	Psychosis
Runny eyes, runny nose	Hallucinations
Dysphoria	Jitters
Goose bumps	
Sweating	
Tachycardia	

Comfort Medications

Medication	Dose (Frequency)	Note
Clonidine	0.1 mg (TID)	Opioids & Benzos
Promethazine OR Hydroxyzine OR Diphenhydramine	25 mg OR 50-100 mg OR 25-50 mg (3-4x/day)	For nausea and vomiting, Opioids & Benzos only if GI issues
Loperamide	4 mg, then 2 mg after every loose stool (NTE 16 mg/ 24 hrs)	Opioids only
Cyclobenzaprine	5 mg (TID)	For aching, opioids only
Trazodone	50 mg (QHS)	For sleeping, opioids typically, can be used for benzos if difficulty sleeping
Ibuprofen & Acetaminophen	200 mg & 500 mg (3-4x/day)	Opioids only
Gabapentin		For restless legs, almost always for benzos

Tapering & Suicide

- Higher opioid doses are associated with higher suicide rates
- Lower doses are associated with lower suicide rates
- Suicide rates for those tapered off are the same as low daily doses (<20 MME) of opioids and lower than those receiving more than 20 MME

"The findings of this study are not suggestive of suicide-related harm from discontinuation."

Prescribed Daily Opioid Dose	Suicide, Any Mechanism Hazard Ratio (95% Confidence Interval)	Intentional Overdose Hazard Ratio (95% Confidence Interval)
1 to <20 mg per day	Reference	Reference
20 to <50 mg per day	1.48 (1.25, 1.75)	1.59 (1.12, 2.27)
50 to <100 mg per day	1.69 (1.33, 2.14)	1.74 (1.09, 2.76)
100 or more mg per day	2.15 (1.64, 2.81)	2.09 (1.22, 3.56)

Ilgen, *Pain* 2016; 157:1079-84.

Chronic Opioid Prescribing Often Includes Other Pharmacologic Concerns

- Anticholinergic use
- Chronic Proton Pump Inhibitor use without a reasonable indication
- Benzodiazepines and Z-Drugs with opioids
- SSRIs/SNRIs in patients with Bipolar Disorder without a mood stabilizer
- Stimulants without ADHD diagnosis confirmation or with multiple sedating medications
- Absence of naloxone

Health Systems Pharmacist Role in Controlled Substance Stewardship

- **Promotion of appropriate use of controlled substances**
- **Development of taper plans**
- **Pharmacotherapy considerations**
  - Patients on complex pharmacotherapy regimens
  - Polypharmacy
  - Anticholinergic burden
- **Chronic disease management**
  - Often undertreated in patients with chronic pain
- **Promotion of naloxone use**

Community Pharmacist Role in Controlled Substance Stewardship

- **Scrutinize all controlled prescriptions**
  - High doses
  - Dangerous combinations
  - Document communications
- **Identify behaviors that may be indicative of underlying use disorders**
- **Identify outlying prescribers and report to licensing boards**
- **Partner with your local health centers**
- **Promotion naloxone use**

Case Review

CD is a 56-year-old male presenting for a follow up visit with a new primary care provider. CD was in a MVA 20 years prior with back pain that has been managed poorly with chronic opioids ever since. CD smokes 1.5 packs per day and drinks 5 alcoholic beverages daily. CD's new provider approaches you, the primary care pharmacist at the clinic, asking for recommendations around CD's pharmacotherapy.

Comorbidities	Medications
- **Chronic back pain** - **Major Depressive Disorder (last PHQ-9 = 18)** - **PTSD** - **Alcohol Use Disorder** - **COPD** - **Sleep Apnea** - **Diabetes** - **GERD** - **Cyclical vomiting syndrome**	- Fentanyl 25 mcg/hr patch – Apply 1 patch every 72 hours - Oxycodone 10 mg – 1 tab every 6 hours as needed - Diazepam 10 mg – 1 tab twice daily - Metformin 1000 mg – 1 tablet twice daily - Duloxetine 30 mg – 1 cap daily - Acetaminophen 500 mg – 2 tabs three times daily as needed

Case Question #1

Which of the following interventions for CD's pharmacotherapy do you recommend?

A. Taper fentanyl and oxycodone

B. Taper diazepam

C. Provide patient with naloxone

D. Smoking cessation

E. Offer treatment for Alcohol Use Disorder

F. Increase dose of duloxetine

G. All the above

Case Question #2

Which of the following would be the most appropriate recommendation for the diazepam taper?

A. 10% reduction daily

B. 10% reduction every 2 weeks

C. No need for a taper, diazepam can just be discontinued

D. No need for a taper, diazepam is indicated

Case Question #3

Which of the following is a withdrawal symptom that may be associated with rapid opioid tapers?

A. Seizures

B. Psychosis

C. Nausea and Vomiting

D. Respiratory depression

Questions?

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