MMS Webinar

Incorporating the New Opioid Prescribing Guidelines into Practice

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Summary of Disclosure Information

The Department of Continuing Education and Certification (DCEC) of the Massachusetts Medical Society has determined that none of the individuals in control of this CME activity including faculty speakers, planners, and reviewers have any relevant financial relationships with commercial interests to disclose.
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Chronic Pain in Perspective

- 100 million in U.S. with chronic pain
  - 25 million have moderate to severe chronic pain
- Chronic pain can be a disease in itself

**Significant barriers to adequate pain care include:**
- Negative attitudes and disparities in pain care
- Lack of decision support for chronic pain management
- Financial misalignment favoring use of medications
- Poor support for team-based care and specialty clinics
- Over-burdened primary care providers

Institute of Medicine. 2011 Relieving Pain in America. Washington DC
Dzau VJ, Pizzo PA. *JAMA* 2014
Opioid Prescribing

Kilograms of opioids sold (per 10,000)

Over-Prescribing Opioids
Confluence of Factors

• Lack of training in pain and addiction
• Societal medication mania, fast relief attitude
• Patients (families) overly focused on opioids
• Pain as the 5th vital sign
• Pharma over-marketing
• Provider’s eagerness to relieve pain and suffering
• Provider’s confrontation phobia
• Lack of pain specialists offering comprehensive pain management
• Reimbursement system favors the use of medications alone, despite evidence supporting multimodal care
Trends & Worrisome Associations

- Kilograms of opioids sold (per 10,000)
- Deaths due to opioid overdose (per 100,000)
- Admissions for opioid-abuse treatment (per 10,000)


Opioid Dose & Overdose Risk

![Graph showing the relationship between opioid dosage (mg/d) and percent of person years, with a linear increase in percentage as the dosage increases.](image)

- 1-19 mg/d: 78.3%
- 20-49 mg/d: 13.1%
- 50-99 mg/d: 5.0%
- 100+ mg/d: 3.5%

Odds Ratio and Percent Use.
Governor Baker convened a task force and propose legislation to stem the overdose epidemic.
Opioid Efficacy for Chronic Pain
Inadequately Studied

- Most literature: surveys and uncontrolled case series
- RCTs are short duration (<8 months) with small samples (<300 patients)
- Mostly pharmaceutical company sponsored
- Outcomes
  - Better analgesia with opioids vs. placebo
  - Pain relief modest
  - Mixed reports on function
  - Addiction not assessed

Problematic Opioid Use in Chronic Pain

• Systematic review from 38 studies (26% primary care settings, 53% pain clinics)

**Misuse** rates: 21% - 29% ([95%CI]: 13%-38%)

**Misuse**: Opioid use contrary to the directed or prescribed pattern of use, regardless of the presence or absence of harm or adverse effects.

**Addiction** rates: 8% - 12% ([95% CI]: 3%-17%)

**Addiction**: Pattern of continued use with experience of, or demonstrated potential for, harm (eg, “impaired control over drug use, compulsive use, continued use despite harm, and craving”).

Collateral Opioid Risk

• **Risks**
  - Young children’s ingestion and overdose
  - Adolescent experimentation leading to overdose and addiction

• **Mitigating risk**
  - Safe disposal and storage (i.e., lock box)
  - Educate family members
  - Have poison control number handy
  - Naloxone distribution (if available)*

* www.prescribetoprevent.org

* Beletsky L, Rich JD, Walley AY. *JAMA* 2012
* SAMHSA Overdose Toolkit http://store.samhsa.gov/shin/content/SMA13-4742/Toolkit_Patients.pdf)
Safe Opioid Prescribing
a primer
It is more than about opioids...

**Self-Care**

- **Physical**
  - Exercise
  - Manual therapies
  - Acupuncture
  - Orthotics
  - TENS
  - Other modalities *(heat, cold, stretch)*

- **Psycho-behavioral**
  - CBT/ACT
  - Tx mood/trauma issues
  - Address substances
  - Meditation

- **Medication**
  - NSAIDS
  - Anticonvulsants
  - Antidepressants
  - Topical agents
  - Opioids
  - Others

- **Procedural**
  - Nerve blocks
  - Steroid injections
  - Trigger point injections
  - Stimulators
  - Pumps

**Cultivate Well-being**

- **Reduce Pain**

**Restore Function**

- **Improve Quality of Life**

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TENS  Transcutaneous Electrical Nerve Stim
CBT  Cognitive Behavioral Therapy
ACT  Acceptance and Commitment Therapy
When Are Opioids Indicated?

• Pain is severe and has significant impact on function and quality of life
• Non-opioid treatments have been tried and failed
• **Patient agreeable to...**
  • **take opioids exactly as prescribed**
    • e.g., no unsanctioned dose escalation
  • **have opioid use closely monitored**
    • e.g. pill counts, urine drug testing
• Should be a test or trial and modified or discontinued based on ongoing risk-benefit
• **Start low and go slow**
For each opioid prescription, the decision to continue, modify or discontinue the opioid should be based on a risk benefit clinical assessment.
## Assessing Benefit in Primary Care – PEG scale

1. What number best describes your pain on average in the past week:

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<tr>
<td>No pain</td>
<td>Pain as bad as you can imagine</td>
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2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?

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<tr>
<td>Does not interfere</td>
<td>Completely interferes</td>
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3. What number best describes how, during the past week, pain has interfered with your general activity?

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“Universal Precautions”

(not evidence-based but has become “standard” of care*)

• Misuse risk assessment
  • ORT - Opioid Risk Tool
  • SOAPP - The Screener and Opioid Assessment for Patients with Pain
• Patient Provider Agreements
  • Informed consent (risks and benefits)
  • Plan of care
• Frequent face-to-face visits
• Monitor for adherence, addiction and diversion
  • Urine drug testing
  • Pill counts
  • Prescription Drug Monitoring Program data
  • COMM - Current Opioid Misuse Measure

Gourlay DL Pain Med 2005

American Pain Society/
American Academy of Pain Medicine
American Society of Interventional Pain Physicians

American Academy of Neurology
Federation of State Medical Boards
Canadian National Pain Centre
Safe Opioid Prescribing... is a lot of Work

Develop and implement:

• Office controlled substance policies, reflected in Patient-Provider Agreement (PPA)
• Management flow sheet
• Patient registry
• Utilize other staff (nurses, medical assistants, pharmacist, social workers, psychologists, front desk staff)
• Lists of referral and support resources (pain, mental health, addiction)
Documentation
Rationale for all Decisions

• Subjective reports *(patient, family, co-care providers)*
• Standardized screens and assessments (PEG)
• Objective information *(observations, drug tests, pill counts, PMP)*
• Clinical and diagnostic impressions/assessment and plan


-six A’s-

- Analgesia
- Activities
- Adverse effects
- Aberrant behaviors
- Affect
- Adherence
Patient Education

• Effects of opioid therapy including the risks and warning signs of physical dependence and addiction
• Warnings especially of patient’s cognition and performance including risks to self and others i.e. driving, operating machinery
• Warn against using alcohol and other sedatives such as benzodiazepines
• Discuss safe storage, disposal when no longer taking medication, including dangers of sharing medication
• Women should be counseled on the risks associated with opioid therapy during pregnancy
When to Seek Pain Consultations

• Unsure of pain diagnosis
• Patients with complex pain conditions
• Unsure of other treatment options
• Long-term opioid therapy*
  • Decision to continue opioid therapy after 60 days
  • Patients have been receiving opioids for more than 90 days

*MMS Guidelines
Potential Resources
Academic Medical Centers with Pain Programs

• Boston Medical Center
• Massachusetts General Hospital
• Brigham and Women’s Hospital
• Beth Israel Deaconess Medical Center
• UMASS Medical Center
• Baystate Medical Center
• Others??
Physicians and patients have a meaningful opportunity to reduce the abuse of prescription drugs in Massachusetts. Patients can limit the supply of drugs by safely storing and disposing of their prescription medications, and physicians can follow safe, effective and responsible prescribing practices.

**Medication Storage**
How to safely store your medications and prevent drug abuse.

**Medication Disposal**
How to dispose of your medications safely and properly.

**Prescriber Education**
Free CME programs, prescribing guidelines, and more information for prescribers.

**Patient Information**
Resources for patients, parents and grandparents about safe handling of prescription medications.
• Boston University SCOPE of Pain scopeofpain.org
  – Education videos, faculty toolkit
  – Prescribe to prevent
  – Acute Dental Pain
• TOPCARE (Transforming Opioid Prescribing in Primary Care) mytopcare.org
• Inflexxion painedu.org
• American Academy of Pain Medicine painmed.org
• Provider’s Clinical Support System Opioid Therapies pcss-o.org
• MA Board of Registration in Medicine mass.gov
• NIH CoE Pain Education painconsortium.nih.gov
• American Chronic Pain Association theacpa.org
• MADPH Bureau of Substance Abuse Services mass.gov
• SAMHSA Treatment Locator findtreatment.samhsa.gov
Review of the New Opioid Prescribing Guidelines
MMS Prescribing Guidelines

- Developed by the MMS Opioid Task Force: physician-primary care, pain management, addiction medicine, emergency medicine, anesthesiology, and more.
- Consulted many resources
  - Other state-based guidelines including those from Indiana, Oklahoma and Washington
  - Other pain management guidelines such as those from the VA and the Federation of State Medical Boards
  - Specialty-society guidelines including those from American Pain Society, American Academy of Pediatrics, American College of Environmental and Occupational Medicine
  - Original research and reports including those from the Institute of Medicine
• The MMS Guidelines were developed to help inform physicians of best practices for general applicability. The guidelines are not intended to replace or supersede independent clinical judgment.

• The MMS Guidelines were adopted by the Massachusetts Board of Registration in Medicine into their prescribing guidelines. The guidelines can be used to inform the standards of care used by the board in its response to accusations of substandard care or inappropriate prescribing. While deviation from the guidelines is not necessarily a per se violation of the standard of care, physicians should be able to demonstrate, and ideally document, the safety and appropriateness of their clinical judgment.
As legislators consider measures to limit and change opioid prescribing, it is important prescribers utilize these guidelines so effective pain management is not compromised for those patients who are suffering with pain who truly need and benefit from opioids.
MMS Prescribing Guidelines

• Separate guidelines are needed for treatment of acute and chronic pain.
  • Chronic pain guidelines apply to patients who receive opioids for more than 90-day period, including transferred patients with opioid treatment histories and existing patients who reach a 90 day period of treatment.
  • Guidelines do NOT apply to patients with cancer, patients in hospice or palliative care, and inpatients of hospitals and nursing homes.

• Work is ongoing with appropriate specialists and specialty societies to review opioid prescribing issues and guidelines unique to specialties and practice settings. Physicians should review existing guidelines for their individual societies.
Acute Care:  
Initiation of Opioid Treatment 

11 Elements
1. Physicians must be familiar with and follow the requirements of the law and regulations on use of the prescription monitoring program (PMP) prior to initiating opioid treatment.

**Action:** Check the PMP prior to initiating opioid treatment
2. Patients should be screened or assessed for: pregnancy; personal or family histories of substance use disorder; mental health status; or, relevant behavioral issues.

**Action:** Assess for opioid risk and opioid misuse risk
3. Physicians prescribing opioids should inform their patients about the cognitive and performance effects of these prescriptions and warn them about the dangers to themselves and others in operating machinery, driving and related activities while under treatment.

**Action:** Educate patients on opioid risks
4. Patients with complex pain conditions, serious co-morbidities and mental illness, or a history or evidence of substance use disorder should be considered for consultation from a colleague or specialist referral.

**Action:** Seek consultation with pain specialist
5. When clinically indicated, opioids should be initiated as a short-term trial to assess the effects and safety of opioid treatment on pain intensity, function, and quality of life. In most instances, the trial should begin with a short-acting opioid medication.

**Action:** Initiate opioid as short term trial with short-acting medication
6. The starting dosage should be the minimum dosage necessary to achieve the desired level of pain control and to avoid excessive side effects.

**Action:** Prescribe minimum dose necessary
Opioid Initiation

7. Duration should be short term with possible partial fill prescriptions or short term, low dosage sequential prescription approaches considered.

**Action:** Prescribe short term with possible partial refill
Opioid Initiation

8. Physicians should be aware of published dosing guidelines for pediatric patients and consider body weight and age as a factor in treating pediatric patients.

Action: Use special consideration for pediatrics based on age and weight

9. Concurrent prescriptions should be reviewed, including paying close attention to benzodiazepines and other medications that may increase the risks of harm associated with opioid use.

**Action**: Obtain patient and medication history, medication reconciliation. Educate patients on risks of taking opioids with other medications, especially benzodiazepines.
10. Physicians must maintain records and engage in patient assessments consistent with prescribing guidelines of the Board of Registration in Medicine which are available on the Board’s website.

www.mass.gov/eohhs/gov/departments/borim/

**Action**: Follow guidelines on assessment, monitoring and clear documentation
11. Patients should be counseled to store the medications securely, never share with others, and properly dispose of unused and expired prescriptions.

**Action:** Educate patients about collateral risk mitigation
Common Elements of Best Practices for Ongoing Opioid Treatment of >60 Days Duration

2 Elements
Opioid Treatment >60 Days

1. There should be regular visits scheduled for evaluation of progress.

**Action:** Conduct face-to-face visits for monitoring
2. Evaluating Opioid Treatment

a. Continuing opioid treatment should be a deliberate decision that takes into consideration the risks and benefits of ongoing opioid treatment for that patient. Patients and health care providers should periodically reassess the need for continued opioid treatment, tapering whenever possible, as part of the comprehensive pain care plan. A second opinion or consultation from a colleague or specialist may be useful in making that decision.
2. Evaluating Opioid Treatment

b. Routinely assess function and pain status. An assessment of function and pain should consistently measure the same elements to determine the degree of progress.

**Action:** Assess and document benefit and risk/harm. Consider second opinion.
Chronic Pain Guidelines
Threshold for Considering Pain Chronic

• The MMS supports a duration of treatment of 90 days consistent with the IOM’s definition in the 2011 report rather than morphine equivalents to trigger these guidelines.

• This time period should trigger a face-to-face reevaluation of the treatment provided to date, its long-term efficacy and risks of continued opioid therapy.

• Physicians should consider consulting with other physicians or referrals as part of the process in developing and implementing an ongoing treatment plan.
Chronic Pain: Common Elements of Best Practices when a 90-Day Treatment Threshold is Reached

To be implemented before continuing further opioid treatment

16 Elements
Chronic Opioid Therapy

1. A detailed reevaluation of the patient’s history and a physical should be done as soon as possible after the 90 day threshold is reached.

**Action:** Reassess history and physical examination
Chronic Opioid Therapy

2. The physician should have the patient complete an objective pain assessment tool.

**Action:** Reassess with pain assessment tool
3. The physician should do a risk of substance abuse assessment. The physician should consider the use of appropriate baseline urine drug testing if the risk assessment or other evidence indicates there may be issues with use of other drugs or with compliance with prescribed treatment.

**Action:** Conduct a substance misuse assessment and other monitoring tools ie. urine drug test
Chronic Opioid Therapy

4. The physician should tailor a diagnosis and treatment plan with functional goals at the initial 90 day threshold visit and every 60-90 days thereafter.

**Action:** Conduct regular assessment of diagnosis, treatment plan and functional goals
5. Chronic pain is multi-dimensional. Physicians should inform patient of the risks, benefits, and terms of continuation of opioid treatment. Alternative pain management options should be reviewed at the 90 day threshold visit and at subsequent 60-90 day follow-up visits.

**Action:** Educate patients regarding risks, benefits, and alternative treatments
6. Women should be counseled again on risks associated with opioid treatment and pregnancy.

**Action:** Educate patients
7. Physicians should be aware of published dosing guidelines for pediatric patients and consider body weight and age as a factor in treating pediatric patients.

**Action:** Follow dosing guidelines for pediatrics, consider age and weight
8. Physicians prescribing opioids should inform their patients about the cognitive and performance effects of these prescriptions and warn them about the dangers to themselves and others in operating machinery, driving and related activities while under treatment.

**Action:** Educate patients
9. The physician should review the patient’s current prescription monitoring program record at the 90 day threshold visits and at every 60-90 day follow-up visit thereafter. One goal of this review is to avoid duplicative or conflicting treatments from other providers.

**Action:** Check PMP regularly
Chronic Opioid Therapy

10. A treatment agreement plan should be established and incorporated into the medical record that includes measurable goals for reduction of pain, reduction in opioid therapy concomitant with reduction or resolution of the pain, and improvement of function. Goals should include improved function and quality of life as well as improved control of pain, and should be developed jointly by the patient and the physician. It should address what circumstances would allow a patient to receive prescriptions from other providers. It may be preferable for such a treatment agreement to be signed by the patient, with updated signature at least yearly.

**Action:** Use a treatment agreement
11. Physicians should discuss risks and warning signs of opioid dependence and addiction with their chronic pain patients.

**Action:** Educate patients
12. Physicians should discuss naloxone and its use to reverse overdoses. Physicians should offer to prescribe naloxone to their patients after such discussions.

**Action:** Consider co-prescribing naloxone for overdose reversal
13. Physicians who are not pain management specialists should not initiate treatment plans which call for in excess of 100 milligrams of morphine equivalent opioids per day without a documented consultation with a pain management specialist.

**Action:** Seek consultation with pain specialist before prescribing over 100mg morphine/day
14. If a patient is currently receiving > 100 mg morphine equivalent per day a plan should be instituted to begin tapering of the dose and, if not possible to do so, consultation with a pain management specialist should be obtained.

**Action:** Seek pain consultation if patient unable to taper when receiving > 100mg/day
15. When possible, physicians should preferentially select abuse resistant and abuse-deterrent medications when clinically indicated.

**Action:** Prescribe abuse deterrent opioids when indicated
16. If high risk or low benefit warrants a discontinuation of opioid therapy, physicians should prescribe non-opioid alternatives for continued pain management.

**Action:** Continue and initiate non opioid pain management when opioid therapy is discontinued
Questions?