TAKING AIM AT PAIN

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The I Love Me Slide:

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- 15 years private practice, board certified in pain medicine and addiction medicine, Certified Medical Review Officer
- Current Chair, American Osteopathic Pain Medicine Conjoint Exam Committee
- Extensive experience in that time treating not just chronic pain but also the unintended consequence of addiction
- Leadership Council, Long Island Council on Alcoholism and Drug Dependence (LICADD)
- Medical Director, LICADD Opioid Overdose Prevention Program
- Member, Nassau County, NY, County Executive's task force on Heroin and Prescription drug abuse

Disclosures:

- Speaker Bureau, Alkermes, Inc., Vivitrol
- Treatment Advocate, Reckitt Benckiser, Suboxone
Objectives

- How did we get into this predicament
- Non-opioid treatment of pain
- When is a good time to consider opioid therapy
- When does it become “Chronic Opioid Therapy”
- How can identify the high risk patients and offer them help
- Appropriate titration of opioid medications and/or changing to a different opioid
- Monitoring for compliance and preventing diversion
How did we get here?

1997 - The AMA passes H-120.960

“Protection for Physicians Who Prescribe Pain Medication”

This is effectively the first time the AMA specifically affirms the obligation of the physician to treat pain but also advocates protection for those physicians that do treat pain.
A Reality Check from CDC Director Thomas Frieden, MD, MPH:

- "The rise in abuse of and deaths from prescription opioid narcotics has reached epidemic proportions...."
- "There were more than 27,000 deaths from prescription drug overdoses in 2007, a number that has risen five-fold since 1990...."
- "...overdose deaths from prescription opioids are exceeding deaths from heroin and cocaine overdoses combined...."
- "Also, the overall number of drug-induced deaths -- which includes all drugs, not just prescription painkillers, although it is attributable in large part to those -- is approaching the number of deaths from motor vehicle crashes."
- "Drug abuse deaths have also surpassed the number of deaths from suicide, homicide, and fire arms...."

“Deaths from Rx Painkillers Still Rising, CDC Says”; Med Page Today, 17 Feb. 2011
In 2009 the APS and the AAPM commissioned a “Blue Ribbon” panel to establish:

Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain

Roger Chou,1 Gilbert J. Fanciullo,2 Perry G. Fine, et. al.
FOR THE AMERICAN PAIN SOCIETY–AMERICAN ACADEMY OF PAIN MEDICINE OPIOIDS GUIDELINES PANEL
The Journal of Pain, Volume 10 Issue 2, Pages 113-130.e22, February 2009
1. Patient Selection and Risk Stratification

Recommendations

1.1. Before initiating COT, clinicians should conduct a history, physical examination and appropriate testing, including an assessment of risk of substance abuse, misuse, or addiction (strong recommendation, low-quality evidence).

1.2. Clinicians may consider a trial of COT as an option if CNCP is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harms (strong recommendation, low-quality evidence).

1.3. A benefit-to-harm evaluation including a history, physical examination, and appropriate diagnostic testing, should be performed and documented before and on an ongoing basis during COT (strong recommendation, low-quality evidence).
2. Informed Consent and Opioid Management Plans

Recommendations

- 2.1. When starting COT, informed consent should be obtained. A continuing discussion with the patient regarding COT should include goals, expectations, potential risks, and alternatives to COT (strong recommendation, low-quality evidence).

- 2.2. Clinicians may consider using a written COT management plan to document patient and clinician responsibilities and expectations and assist in patient education (weak recommendation, low-quality evidence).

2. Medication Management Agreement

- The purpose of this Agreement is to prevent misunderstandings about certain medicines you will be taking for pain management. This is to help both you and your doctor to comply with the law regarding controlled pharmaceuticals.
- I understand that this Agreement is essential to the trust and confidence necessary in a doctor/patient relationship and that my doctor undertakes to treat me based on this Agreement.
- I understand that if I break this Agreement, my doctor may stop prescribing these pain-control medicines.
- In this case, my doctor may taper me off the medicine over a period of several days, as necessary, to avoid withdrawal symptoms or switch me to a different medication. Also, a drug-dependence treatment program may be recommended.
- I will communicate fully with my doctor about the character and intensity of my pain, the effect of the pain on my daily life, and how well the medicine is helping to relieve the pain.
- I will not use any illegal controlled substances, including marijuana, cocaine, etc.
- I will not share, sell or trade my medication with anyone.
2. Medication Management Agreement (Cont’d)

- I will not attempt to obtain any controlled medicines, including opioid pain medicines, controlled stimulants, or antianxiety medicines from any other doctor.
- I will safeguard my pain medicine from loss or theft. Lost or stolen medicines will not be replaced.
- I agree that refills of my prescriptions for pain medicine will be made only at the time of an office visit or during regular office hours. No refills will be available during evenings or on weekends.
- I agree to use ____________Pharmacy, located at _________________, telephone number ____________, for filling prescriptions for all of my pain medicine.
- I authorize the doctor and my pharmacy to cooperate fully with any city, state or federal law enforcement agency, including this state's Board of Pharmacy, in the investigation of any possible misuse, sale, or other diversion of my pain medicine. I authorize my doctor to provide a copy of this Agreement to my pharmacy. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations.
- I agree that I will submit to a blood or urine test if requested by my doctor to determine my compliance with my program of pain control medicine.
- I agree that I will use my medicine at a rate no greater than the prescribed rate and that use of my medicine at a greater rate may result in my being without medication for a period of time.
- I will bring all unused pain medicine to every office visit.
- I understand that if I am being prescribed controlled substances on a daily basis and they are not present when tested for compliance, I will be immediately discharged and I may be reported to law enforcement for possible diversion.
- I agree to follow these guidelines that have been fully explained to me. All of my questions and concerns regarding treatment have been adequately answered. A copy of this document has been given to me.
2. Opioid Informed Consent

- Dr. Jan is prescribing opioid medicine, sometimes called narcotic analgesics, to me for a diagnosis of chronic pain secondary to _________________________________.

- This decision was made because my condition is serious or other treatments have not helped my pain. I am aware that the use of such medicine has certain risks associated with it, including, but not limited to: sleepiness or drowsiness, constipation, nausea, itching, vomiting, dizziness, allergic reaction, slowing of breathing rate, slowing of reflexes or reaction time, physical dependence, tolerance to analgesia, addiction and possibility that the medicine will not provide complete pain relief.

- I am aware about the possible risks and benefits of other types of treatments that do not involve the use of opioids. I will tell my doctor about all other medicines and treatments that I am receiving.

- I will not be involved in any activity that may be dangerous to me or someone else if I feel drowsy or am not thinking clearly. I am aware that even if I do not notice it, my reflexes and reaction time might still be slowed. Such activities include, but are not limited to: using heavy equipment or a motor vehicle, working in unprotected heights or being responsible for another individual who is unable to care for himself or herself.

- I am aware that certain other medicines such as nalbuphine (Nubain™), pentazocine (Talwin™), buprenorphine (Buprenex™), and butorphanol (Stadol™), may reverse the action of the medicine I am using for pain control. Taking any of these other medicines while I am taking my pain medicines can cause symptoms like a bad flu, called a withdrawal syndrome. I agree not to take any of these medicines and to tell any other doctors that I am taking an opioid as my pain medicine and cannot take any of the medicines listed above.

- I am aware that addiction is defined as the continued use of a substance despite adverse psychological, social and/or physical consequences. I am aware that the chance of becoming addicted to my pain medicine is very low if I follow the treatment protocol as prescribed. I am aware that the development of addiction has been reported rarely in medical journals and is much more common in a person who has a family or personal history of addiction. I agree to tell my doctor my complete and honest personal drug history and that of my family to the best of my knowledge.
I understand that physical dependence is a normal, expected result of using these medicines for a long time. I understand that **physical dependence is not the same as addiction**. I am aware physical dependence means that if my pain medicine use is markedly decreased, stopped or reversed by some of the agents mentioned above, I will experience a withdrawal syndrome. This means I may have any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawal is uncomfortable but not life threatening.

I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief. I am aware that tolerance to analgesia does not seem to be a big problem for most patients with chronic pain, however, it has been seen and may occur to me. If it occurs, increasing doses may not always help and may cause unacceptable side effects. Tolerance or failure to respond well to opioids may cause my doctor to choose another form of treatment.

(Males only) I am aware that chronic opioid use has been associated with low testosterone levels in males. This may affect my mood, stamina, sexual desire and physical and sexual performance. I understand that my doctor may check my blood to see if my testosterone level is normal.

(Females Only) If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to delivery while taking these medicines, the baby will be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that my child will have a birth defect while I am taking an opioid.

I have read this form or have it read to me. I understand all of it. I have had a chance to have all of my questions regarding this treatment answered to my satisfaction.

By signing this form voluntarily, I give my consent for the treatment of my pain with opioid pain medicines.
3. Initiation and titration of COT

Recommendations

3.1. Clinicians and patients should regard initial treatment with opioids as a therapeutic trial to determine whether COT is appropriate (strong recommendation, low-quality evidence).

3.2. Opioid selection, initial dosing, and titration should be individualized according to the patient’s health status, previous exposure to opioids, attainment of therapeutic goals, and predicted or observed harms (strong recommendation, low-quality evidence). There is insufficient evidence to recommend short-acting versus long-acting opioids, or as-needed versus around-the-clock dosing of opioids.

4. Methadone

Recommendation

4.1. Methadone is characterized by complicated and variable pharmacokinetics and pharmacodynamics and should be initiated and titrated cautiously, by clinicians familiar with its use and risks (strong recommendation, moderate-quality evidence).

5. Monitoring

Recommendations

5.1. Clinicians should reassess patients on COT periodically and as warranted by changing circumstances. Monitoring should include documentation of pain intensity and level of functioning, assessments of progress toward achieving therapeutic goals, presence of adverse events, and adherence to prescribed therapies (strong recommendation, low-quality evidence).

5.2. In patients on COT who are at high risk or who have engaged in aberrant drug-related behaviors, clinicians should periodically obtain urine drug screens or other information to confirm adherence to the COT plan of care (strong recommendation, low-quality evidence).

5.3. In patients on COT not at high risk and not known to have engaged in aberrant drug-related behaviors, clinicians should consider periodically obtaining urine drug screens or other information to confirm adherence to the COT plan of care (weak recommendation, low-quality evidence).
“Reliance on aberrant behavior to trigger a UDT will miss more than 50% of those individuals using un-prescribed or illicit drugs.”

IT IS NOT ALWAYS THAT EASY TO TELL...
6. High-Risk Patients

Recommendations

6.1. Clinicians may consider COT for patients with CNCP and history of drug abuse, psychiatric issues, or serious aberrant drug-related behaviors only if they are able to implement more frequent and stringent monitoring parameters. In such situations, clinicians should strongly consider consultation with a mental health or addiction specialist (strong recommendation, low-quality evidence).

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 (strong recommendation, low-quality evidence).
6. High-Risk Patients, evaluation tools

- **SOAPP-R:** Screener to predict Opioid misuse Among chronic Pain Patients - Revised
- **ORT:** Opioid Risk Tool
- **DIRE:** Diagnosis, Intractability, Risk, Efficacy
- **COMM:** Current Opioid Misuse Measure

6. High-Risk Patients, evaluation tools

SOAPP-R

- **Purpose:** Patients at high risk for opioid abuse

  **Questions:** Ten questions cover the following topics:
  - Mood swings
  - Smoking upon waking
  - Family substance abuse
  - Personal or close friend substance abuse
  - Others viewing substance use as a problem
  - Attending AA or NA
  - Substance use treatment
  - Medications lost or stolen
  - Others express concern over you substance use
  - Non-prescribed use of medications
  - We do not have permission to reproduce this test, so please visit the external link to view questions.

- **Evidence**
  - Preliminary studies show internal reliability and predictive validity of the SOAPP (Akbik et al. 2006)
  - High scores on the SOAPP correlate with increased likelihood of future aberrant drug behavior (Chou et al. 2009).

- **Test features:**
  - Time: 5-10 minutes to administer and score
  - Length: Short and Long-item formats are available, including three formats of 5, 14 and 24 items. A revised version (SOAPP-R) includes a toxicology report.
  - Administered by: Patient self-administration
  - Target Population: Adults
  - Intended Settings: Primary care

- **Scoring and interpretation:**
  - The SOAPP can be scored by the health professional by adding the ratings for 14 of the 24 questions. A score of 7 or above indicates increased risk for abuse.
6. High-Risk Patients, evaluation tools

ORT

- **Questions**: The questions asks whether there is
  - Family history of substance abuse with alcohol, illegal drugs, or prescription drugs
  - Personal history of substance abuse with alcohol, illegal drugs, or prescription drugs
  - History of preadolescent sexual abuse (only statistically significant for females, as a group)
  - Psychiatric disorder

- **Purpose**: Assesses risk of aberrant behaviors when patients are prescribed opioid medication for chronic pain
  - **Evidence**
    - Provides excellent discrimination between high risk and low risk patients (Passik et al. 2008).
    - Exhibited a high degree of sensitivity and specificity for determining which individuals are at risk for opioid abuse (Webster & Webster 2005).
    - Patients categorized as high-risk on the ORT have an increased likelihood of future abusive drug-related behavior (Chou et al. 2009).

- **Advantages**
  - Brief, simple scoring tool that is validated in pain populations (Passik et al. 2008).
  - Validated for both male and female patients (Webster & Webster 2005).

- **Limitations**
  - One question on the ORT is limited by the patient's knowledge of family history of substance abuse (Passik et al. 2008).
  - Not validated in non-pain populations.

- **Test features**:
  - Time: Less than one minute to administer
  - Length: 5 items
  - Administered by: Patient self-administration
  - Target Population: Adults
  - Intended Settings: Primary care
  - Developed by: Lynn Webster, MD

- **Scoring and interpretation**:
  - The ORT can be scored by hand, either by the patient or the health professional. Each item that the patient answers positively is awarded a value; values for the entire assessment are added to obtain a patient's opioid risk score, which is broken down into low (0-3), moderate (4-7), and high (>7) risk.
6. High-Risk Patients, evaluation tools

**DIRE**

- **Purpose:** Assesses risk of opioid abuse and suitability of candidates for long-term opioid therapy
  - **Evidence**
    - Validated by six experts studying patient case vignettes (Passik et al. 2008).
    - Showed sensitivity, efficacy, specificity and high internal consistency (Belgrade et al. 2006)
- **Advantages**
  - Specifically designed for primary care use (Passik et al. 2008).
  - Patient's DIRE score correlates well with patient compliance and efficacy of long-term opioid therapy (Belgrade et al. 2006).
- **Limitations**
  - Prospective validation needed (Passik et al. 2008).
- **Test features:**
  - Time: less than 2 minutes to administer and score
  - Length: 7 items
  - Administered by: Patient interview
  - Target Population: Adults
  - Intended Settings: Primary care
  - Developed by: Dr. Miles J. Belgrade in 2005
- **Scoring and interpretation:**
  - Patient's score on the DIRE (between 7 and 21) correlates with efficacy of opioid therapy and compliance (Passik et al. 2008).
6. High-Risk Patients, evaluation tools

COMM

**Purpose:** The Current Opioid Misuse Measure (COMM) tool assesses aberrant medication-related behaviors of patients with chronic pain

**Target population:** Adults

**Validated in pain patients:**

**Evidence:**
- The COMM demonstrates excellent internal consistency, sensitivity and test–retest reliability (Butler et al. 2007)
- Increased score on the COMM correlates with a higher likelihood of current opioid-related aberrant behavior (Chou et al. 2009)

**Advantages**
- Useful in assessing adherence to an opioid treatment program and in reassessment
- Questionnaire is easy to understand and takes little effort to score

**Limitations**
- Currently in development
- Needs further study

**Test features:**
- **Estimated time:** 17 items
- **Length:** less than 10 minutes to administer and score
- **Administered by:** Self-report
- **Intended settings:** Primary Care
6. High-Risk Patients, evaluation tools

LOOK FOR PARENTEERAL DRUG USE IN ALL PATIENTS!!!

- Nasal
- Cutaneous
- Intravenous
7. Dose Escalations, High-Dose Opioid Therapy, Opioid Rotation, and Indications for Discontinuation of Therapy

Recommendations

- 7.1. When repeated dose escalations occur in patients on COT, clinicians should evaluate potential causes and reassess benefits relative to harms (strong recommendation, low-quality evidence).

- 7.2. In patients who require relatively high doses of COT, clinicians should evaluate for unique opioid-related adverse effects, changes in health status, and adherence to the COT treatment plan on an ongoing basis, and consider more frequent follow-up visits (strong recommendation, low-quality evidence).

- 7.3. Clinicians should consider opioid rotation when patients on COT experience intolerable adverse effects or inadequate benefit despite dose increases (weak recommendation, low-quality evidence).

- 7.4. Clinicians should taper or wean patients off of 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 (strong recommendation, low-quality evidence).
8. Opioid-Related Adverse Effects

Recommendation

8.1. Clinicians should anticipate, identify, and treat common opioid-associated adverse effects (strong recommendation, moderate-quality evidence).

- Physical dependence
- Nausea
- Constipation
- Sedation/clouded mentation
- Hypogonadism
- ADDICTION & PSUEDOADDICTION!!!
- Refer to your opioid consent

9. Use of Psychotherapeutic Cointerventions

Recommendation

9.1. As CNCP is often a complex biopsychosocial condition, clinicians who prescribe COT should routinely integrate psychotherapeutic interventions, functional restoration, interdisciplinary therapy, and other adjunctive nonopioid therapies (strong recommendation, moderate-quality evidence).

10. Driving and Work Safety

Recommendation

- 10.1. Clinicians should counsel patients on COT about transient or lasting cognitive impairment that may affect driving and work safety. Patients should be counseled not to drive or engage in potentially dangerous activities when impaired or if they describe or demonstrate signs of impairment (strong recommendation, low-quality evidence).

11. Identifying a Medical Home and When to Obtain Consultation

Recommendations

- 11.1. Patients on COT should identify a clinician who accepts primary responsibility for their overall medical care. This clinician may or may not prescribe COT, but should coordinate consultation and communication among all clinicians involved in the patient's care (strong recommendation, low-quality evidence).

- 11.2. Clinicians should pursue consultation, including interdisciplinary pain management, when patients with CNCP may benefit from additional skills or resources that they cannot provide (strong recommendation, moderate-quality evidence).

12. Breakthrough Pain

Recommendation

12.1. In patients on around-the-clock COT with breakthrough pain, clinicians may consider as-needed opioids based upon an initial and ongoing analysis of therapeutic benefit versus risk (weak recommendation, low-quality evidence).

13. Opioids in Pregnancy

Recommendation

13.1. Clinicians should counsel women of childbearing potential about the risks and benefits of COT during pregnancy and after delivery. Clinicians should encourage minimal or no use of COT during pregnancy, unless potential benefits outweigh risks. If COT is used during pregnancy, clinicians should be prepared to anticipate and manage risks to the patient and newborn (strong recommendation, low-quality evidence).

14. Opioid Policies

Recommendation

14.1. Clinicians should be aware of current federal and state laws, regulatory guidelines, and policy statements that govern the medical use of COT for CNCP (strong recommendation, low-quality evidence).

“This section is not intended to impose any limitations on a physician or authorized hospital staff … to administer or dispense narcotic drugs to persons with **intractable pain in which no relief or cure is possible or none has been found after reasonable efforts**”

Chronic Pain!!!
When federal regulations differ from state regulations, it is safer to adhere to the more stringent of the two.

- Howard Heit, Georgetown University
The *Controlled Substances Act* replaced all the previous regulations and classified controlled substances in five categories:

I. Substances that have no accepted medical use in the United States and have a high abuse potential (e.g. heroin, L.S.D., etc.)

II. Substances that have a high abuse potential with severe psychic or physical dependence liability but with an accepted medical use (e.g. Dilaudid, Morphine, Ritalin, etc.)

III. Substances that have an abuse potential less than those in Schedules I and II, and include compounds containing limited quantities of certain narcotic drugs and non-narcotic drugs (e.g. Tylenol #3, paregoric, Marinol, etc.)

IV. Substances that have an abuse potential less than those in Schedules I, II and III (e.g. Restoril, Darvocet, Ambien, etc.)

V. Substances that have a relatively low potential for abuse (e.g. Lyrica, Lomotil, Hycotuss, etc.)
The Uniform Controlled Substances Act is proposed and enacted by all 50 states.
Treatment Algorithm for Moderate to Severe Chronic, Non-Cancer Pain

- Full medical (including a physical examination) and psychosocial assessment including screen for addiction risk
- Pursue appropriate investigations
- Establish working diagnosis of the chronic pain
- Treatments for specific diseases where appropriate
- Overall pain management plan is established include active participatory strategies
- Analgesic medications are determined to be necessary

**Mild to Moderate Pain**
- Start a non-opioid analgesic such as acetaminophen or an NSAID
- Add codeine if necessary

**Moderate to Severe Pain**
- Nociceptive
  - Start an anticonvulsant (e.g., gabapentin or pregabalin) or specific tricyclic (e.g., amitriptyline, nortriptyline, desipramine)
  - Sleep disturbance present
    - Start a broad spectrum analgesic antidepressant
- Neuropathic
  - Both
  - Start an opioid analgesic (stronger than codeine)
    - Continuous release opioids preferred
    - Combination pharmacotherapy
      - If one agent is inadequate to control pain then it may be necessary to use a combination of two or more analgesic agents, using combinations with different mechanisms of action (e.g., a tricyclic antidepressant, an anticonvulsant and a stronger opioid)

[There is] “compelling evidence for the need to develop smart strategies to curtail abuse of opioid analgesics, without jeopardizing pain treatment.”

In conclusion:

- We have an obligation to treat pain but also an obligation to do so safely, minimizing harm.
- While there is a paucity of objective evidenced based studies, there is a relative consensus among the pain community as to how to do so safely.