Prescribing Opioids & Obvious Pitfalls Thereof (Taking Into Consideration CDC Guideline for Prescribing Opioids for Chronic Pain – 2016)

JUNE 17, 2016

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Course Objectives

- Education of prescribers about responsibilities, obligations, and management of prescribing controlled substances.
- Education of prescribers about the New Guidelines from the CDC about prescribing opioids for chronic pain.
- Provide a framework for approaching this controversial area.
- To minimize the risk of prescribing addictive substances for chronic conditions.
Scope of the Problem

- Americans consumed 80% of the global supply of prescription opioids from 1997 to 2007.
- Average sales per person increased 402%.
- Opioid analgesics are the most misused class after marijuana.
- 20% of patients presenting with noncancer pain receive an opioid Rx. For their pain.
- In 2012 there were 259 million opioid prescriptions.

Scope of the Problem

- Overall cost of the opioid prescription problem is probably in the 500 to 600 Billion dollar range.
- Opioid related ER visits increased 111% from 2004 to 2008.
- 14.6% of adults in the US have widespread or localized pain greater than 3 months.
- Deaths involving opioid analgesics quadrupled from 1999 to 2008.
- This year deaths from overdoses from drugs is greater than highway accident deaths.
- From 1999 to 2014, there were 165,000 overdoses involving pain prescriptions.
Scope of the Problem

- In 2013, DSM IV noted that there were 1.9 million abusers or dependent people
- In 2011 there were greater than 420,000 ER visits involving opioids.
- Therefore the CDC has reviewed the evidence regarding this problem, and has released a Guideline for Prescribing Opioids for Non-cancer pain.

Primary Clinical Questions

- 1. What is the effectiveness of long-term opioid therapy, or non-opioid therapy for long-term outcomes?
- 2. What are the risks of opioids vs. no opioids?
- 3. What are the effective opioid dosing strategies?
- 4. What is the accuracy of instruments for predicting risk for opioid overdoses?
- 5. What are the effects of prescribing opioid therapy versus not prescribing opioid therapy for acute pain or long term use?
Key Question 1 – What is the effectiveness of long-term opioids?

- There is no evidence on the effectiveness of long term opioid treatments.
- There were no studies that evaluated outcomes related to pain, function, or quality of life.
- The body of evidence is insufficient.

Key Question 2 – What are the risks of prescribing opioids?

- In the general population there are between 3-26% of the patients having the DSM IV criteria for addiction.
- In pain clinics this ranges from 2-14%.
- Recent opioid use is associated with increased risk for any overdose events.
- Higher doses are associated with higher risk.
- There is increased fracture risk for concurrent opioid use.
- There is also evidence the opioid dosages greater than 20 MME/day are associated with increased odds of road trauma among drivers.
Key Question 3 – What is the evidence for dosing strategies?

- The initiation of the use of ER/LA opioids is associated with greater risk for nonfatal overdose vs. initiation with a short acting opioid.
- There is no evidence for comparisons related to dosing strategies.

Key Question 4 – What is the accuracy of assessment tools?

- 4 studies have shown that the accuracy of assessment instruments for predicting opioid abuse or misuse are inaccurate.
- There are no studies evaluating the effectiveness of risk mitigation strategies.
- These include risk assessments, opioid management plans, patient education, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations for improving outcomes related to overdose, addiction, abuse or misuse.
Key Question 5 – What are the effects of opioid therapy for acute pain on long term use?

- Use of opioids within 7 days of surgery for opioid-naïve patients who had undergone low risk surgery was associated with increased risk for use of opioids for one year following.
- Early use of opioids for back pain within 2 weeks of the injury leads to an increased risk of receiving 5 or more prescriptions within 2 years.

The New Recommendations

- 1. Determining when to initiate or continue opioids for chronic pain.
- 2. Opioid selection, dosage, duration, follow-up, and discontinuation.
- 3. Assessing the risk and addressing the harms of opioid use.
Determining When to Initiate or Continue Opioids for Chronic Pain

1. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.

2. You should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.

3. If opioids are used, they should be combined with non-pharmacological therapy and non-opioid pharmacologic therapy as appropriate.

4. Before starting opioid therapy for chronic pain, you must establish treatment goals with all patients. This should include realistic goals for pain and function. It will be discontinued if benefits do not outweigh risks.

5. Continue therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patients safety.

6. Before starting therapy and intermittently, clinicians should discuss with patients the known risks and realistic benefits of opioid therapy.
Opioid Selection, Dosage, Duration, Follow-up and Discontinuation.

1. Clinicians should use immediate release opioids instead of extended-release/long acting opioids.
2. Clinicians should prescribe the lowest effective dosage and reassess if increasing the dosage over 50 MME/day.
3. Avoid over 90 MME/day.
4. When prescribing for short term use, use less than 7 days supply.
5. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy. Re-evaluate every 3 months. If benefits do not overcome harms, taper to a lower dose.

Assessing Risk and Addressing Harms of Opioid Use.

1. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid harms.
2. Clinicians should incorporate into the management of opioid therapy, strategies to minimize risk.
3. Minimize benzodiazepine use.
4. Review the patient’s PMP data, to determine his MME’s.
5. Clinicians should use urine drug testing.
6. Avoid concurrent opioids and benzodiazepines.
7. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with Suboxone for patients with opioid use disorder.)
How to Approach Before Treatment?

- Conduct a thorough history, including substances.
- Consider using empiric screening tools.
- Evaluate known risk factors.
- Consider non-opioid treatment first.
- Enhance monitoring for patients.
- Set treatment goals and discuss expectations with the patient before starting opioid therapy.

Before Prescribing

- 1. There needs to be comprehensive documentation of patient’s pain condition, general medical condition, psychosocial history, psychiatric status, and substance use history of patient and patient’s family.
- 2. Use a screening tool for opioid addiction.
- 3. UDS
- 4. Informed consent.
- 5. Taper benzodiazepines first.
- 6. Obtain PMP.
During Treatment

1. Begin opioid trial. Reassess within 1-4 weeks.
2. Routinely reassess the patient every 3 months. Document opioid therapy, efficacy, adverse effects, evidence of misuse, and evidence of benefits overshadowing risks.
3. Obtain PMP.
4. UDS.
5. Address, evaluate and respond to questionable use, per policy.
6. Discontinue use of opioids if no benefit or risks overshadow benefits.
7. Evaluate behavior and determine course of action, if questionable use occurs.
8. Address questionable use with patient.
9. Re-evaluate benefits and risks.
10. Consider referral to an addiction specialist for consultation.
11. Initiate opioid taper if discontinuing; consider addiction consult if SUD is present.
History and Physical

- Should include the cause and the nature of the pain, past treatments, tests, medication trials.
- Estimate the pain level and the intensity.
- Psychological history, includes living arrangement, family/social support, work status, family obligations.
- The psychiatric status should include psychiatric disorders and treatments and family history of psychiatric disorders.
- Substance Use History - current, past, and family history of substance use and abuse, addiction, and treatment for addiction.
- Documentation.

SOAPP - SF

- 0 - NEVER  1- SELDOM  2- SOMETIMES  3- OFTEN  4- VERY OFTEN
- 1. How often do you have mood swings?
- 2. How often do you smoke a cigarette within an hour after you wake up?
- 3. How often have you taken medication other than the way it was prescribed?
- 4. How often have you used illegal drugs in the last 5 years?
- 5. How often, in your lifetime have you had legal problems or been arrested?
- 6. Have you ever overdosed?
When Are Opioids Indicated?

- 1. Pain is moderate to severe.
- 2. Pain has significant impact on function.
- 3. Pain has significant impact on quality of life.
- 4. Non-opioid therapy and other therapies have failed.
- 5. Patient is agreeable to have opioid use closely monitored, and understands the risks and the benefits.
- 6. You, the prescriber determine that the risk is not elevated!!!!

Evidence of CNCP Efficacy

- Tramadol – fibromyalgia
- Opioids
  - Diabetic neuropathy
  - Peripheral neuropathy
  - Post-herpetic neuralgia
  - Phantom Limb Pain
  - Spinal cord injury with pain below level of injury
  - Lumbar radiculopathy
  - Osteoarthritis and Rheumatoid Arthritis
  - Low back pain
  - Neck pain
Opioid Prescribing Guidelines

- Medical Practice Act of Mississippi
- Mississippi Code 1972
- MSBML website- Outlined in the Jurisprudence Handbook
- Http://www.msbml.ms.gov/msbml/web.nsf

Patient Record

- H&P – Good faith
- Evaluation
- Treatment
- Documented diagnosis
- Reason for prescribing
- Date
- Name, dose, strength, and quantity of drug and refills
- Patient record maintained 7 years
Lack of “Good Faith”

- Physician allows the patient to “name the desired drug.”
- Dispensing drugs “when the physician knew or should have known the patients were addicts.”
- Repeated refills, despite non-compliance (failure to take correct dosage).
- Physician endorses non-therapeutic uses of drugs.
- Physician prescribes contradicted medicines, resulting in therapeutic conflicts.

Administrative Code Definition of Chronic Pain

- Patients receiving controlled substances for more than six months. Three?
- Does not refer to Terminal Disease Pain, i.e., Those with life expectancy less than six months.
- Physicians may use controlled substances to treat chronic pain, with caution.
Requirements

- Conduct appropriate risk/benefit analysis.
- Review prior records and treatment.
- Proof of indicated need for long term therapy.
- Documentation of complete medical history, examination, and treatment plan.
- Review and documentation every 3 months or less, including modification of therapy dependent on completion of treatment objectives and referrals and consultations as necessary.

Written Treatment Plan

- Stated objectives as a measure of treatment.
- Planned diagnostic evaluations.
- Informed consent that details risks and benefits.
- Use of one physician and one pharmacy, if possible.
- Use of UDS when requested.
- PMP
- The four A’s of every visit:
  - Analgesia
  - Activity
  - Adverse events
  - Aberrant behavior
Aberrant Medication Behavior - Yellow Flags

- Complaints about the need for more medication
- Hoarding drugs
- Requesting specific medicine
- Openly acquiring medicines from other providers.
- Occasional unsanctioned dose escalation.
- Non-adherence to other recommendations.

Aberrant Medication Behavior - Red Flags

- Deterioration in functioning at work or socially
- Illegal activities - selling, forging, buying on street
- Injection or snorting drug
- Multiple episodes of “lost” or “stolen”
- Resistance to change therapy despite adverse effects
- Refusal to comply with random drug screens
- Concurrent use of alcohol or illicit drugs
- Use of multiple physicians and pharmacies.
- Using adulterants or someone else’s urine.
Monitor for Misuse

- Use Agreement
- Monitor Behavior
- Monitor for Adherence, Addiction, and Diversion
- Initially small quantities and frequent visits.
- PMP
- Discuss monitoring with family.

Pearls from Years of Practice

- People with pain who are treated with small amounts of narcotics get better quicker.
- People with addiction do not notice any small increase in amounts.
- If it looks like an addict, asks for more drugs, and even demands, it is an addict.
- If their dog ate the medicine ........did the dog die?
- Concurrent use of recreational drugs with pain meds is usually the mark of a polysubstance abuser.
- Anxiety is treated with anti-depressants, not benzos.
- The later in the day or closer to the weekend the patient calls for more, the more likely he is abusing.
- There are no shy bladders amongst drug abusers.
Pearls

- Lots of little old ladies make their living off the Rx. that you are writing them! Be suspicious.
- Excuses are what will get your DNA taken away.
- Do not write opioids for a patient after an overdose.
- Find a nurse who knows your patient base and has a nose for BS.
- Use your PMP and UDS.
- Patients who have received Suboxone are probably opioid addicts.

References

- Principles of Addiction Medicine – Fifth Edition
- Prescription Drug Abuse Crisis: Mississippi Prescriber’s Response - Dr. Scott Hamilton MD
- Utah Clinical Guidelines on Prescribing Opioids – Utah Dept. of Health
- FDA Blueprint for Prescriber Education for ER and LA Analgesics
- Prescribing for Pain – Daniel P. Alford MD. Boston University School of Medicine
- Substance Abuse – A Comprehensive Textbook – Fourth Edition
When Things Go Wrong

- Evaluate behavior and determine course of action if questionable use occurs
- Address questionable use with the patient
- Evaluated benefit of continuing opioid therapy
- Consider referral to an addiction specialist for consultation

Perspective

- No Evidence of Addiction  
  - Control over medication use  
  - Improved quality of life  
  - Concern about medical problems  
  - Adheres to treatment plan  
  - Concern of pain relief greater than opioids  
  - Some increase of tolerance

- Evidence of Addiction  
  - No control over medication  
  - Worsened quality of life  
  - Requests dose increase despite side effects  
  - Lack of concern about medical problems  
  - Non-adherence to tx. Plan  
  - Concern over opioids is greater than pain relief  
  - Increases in amounts