



Trainwreck: Addressing Complex Pharmacotherapy With the Inherited Pain Patient

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Disclosures

- Nothing to disclose

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Learning Objectives

- Assess the prescription drug problem in America
- Discuss the CDC guidelines on opioids in chronic pain
- Appraise what is pharmacological instability?
- Judge the importance of documentation

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PainWeek

The Prescription Drug Problem in America

- The “givens” of this session
 - If you aren’t sure there is a prescription drug problem in America, this session is probably not for you
 - We can debate the magnitude/solutions
 - If you don’t think prescribers have a role to play in either the problem or the solution, this session is probably not for you
 - For some patients, their pain medications are both the problem and the solution at the same time—these are often complex issues

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PainWeek

The Prescription Drug Problem in America (cont'd)

- The “givens” of this session
 - If you think that the answer to the prescription drug problem is to simply stop writing opioid prescriptions, this session may (or may not) be for you
 - Contrary to popular belief, most chronic opioid users do not stop using opioids easily
 - You need a rational plan that considers the general pharmacological issues as well as individual patient issues

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PainWeek

The Prescription Drug Problem in America (cont'd)

- Key elements of this program are
 - Distinguishing between rational and irrational pharmacotherapy
 - Approaching the problematic medication user
 - Problems of pattern of use?
 - Problems with simple per diem dose
 - Iatrogenic vs patient-driven aberrant behavior
 - Developing a rational approach to medication rotation and taper/discontinuation

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PainWeek

CDC Guidelines Summary

- Nonpharmacotherapy/nonopioid therapy preferred
- Before opioids, establish realistic treatment goals (pain/function)
- Risk/benefits assessment/discussion with patient
- Begin with IR rather than SR opioid preparations
- Start at lowest effective dose (avoid doses >90 MME/day)
- Acute pain <3 days (rarely >7 days)

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CDC Guidelines Summary (cont'd)

- Evaluate benefits/harms after 1-4 weeks after starting opioid therapy (then q 3/12 or more frequently as needed)
- Evaluate risk factors—including possible naloxone rescue
- Review the PDMP program, if it exists in your state
- Patient UDT—frequency?
- Avoid concurrent prescription of sedatives, eg, benzodiazepines
- Offer/obtain evidence based assessment/treatment of patients with opioid SUD

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PainWeek

Where Is the Controversy?

- Well, most of the CDC Guidelines are pretty straightforward
 - The really contentious point is the arbitrary “line in the sand” drawn at 90 MME/day
 - Is it even useful to “compare” different members of the opioid class of drug in terms of equivalency to morphine?

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PainWeek

Where Is the Controversy? (cont'd)

- Why 90? Why not 120 mg morphine equivalents per day? Why not 200 mg MME/day?
 - Well, all those numbers have been proposed at some point as being the “line in the sand” that should be drawn

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PainWeek

Where Is the Controversy? (cont'd)

- What we know is
 - 1) As MME dose rises, risk increases—100 mg MME seems to be a dose where this increase becomes problematic
 - 2) As doses become excessive, the likelihood of achieving acceptable treatment outcomes in terms of pain relief and function decrease
 - Much more likely to be “desperation” pharmacotherapy than “rational” pharmacotherapy
 - 3) Polypharmacy, especially with sedative class of drugs increases risk
 - Multiple agents from same class appears to be problematic

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PainWeek

What's Missing from the CDC Guidelines?

- The guideline is clearly oriented toward “new” patients, rather than giving guidance to clinicians as to what to do with patients who were placed on opioids prior to our awareness of these risks
 - What do you do with the “inherited pain patient” who is already on doses well in excess of the 90 MME/day dose recommendations?

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PainWeek

What's Missing from the CDC Guidelines? (cont'd)

- How do you determine who might be “exceptions” to these guidelines?
 - How do you document these exceptions?
- How do you take a patient “from where they are to where they need to be?” in terms of medication management?
 - Concept of readiness to change—both for the patient AND for the prescriber
 - Optimizing pharmacotherapy, including taper/discontinuation
 - The stalled taper
 - Minimizing physiologic/pharmacologic consequences of withdrawal

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PainWeek

Documentation Requirements

- The importance of documentation can't be overstated
 - Your medical record must clearly establish the thought process used to come to the proposed treatment plan
 - Detox ≠ Tapering as a legal concept

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PainWeek

Documentation Requirements (cont'd)

- If your treatment plan departs from currently accepted guidelines, it must be clear WHY this departure is appropriate or if this departure is part of a longer term plan to bring the patient into compliance
 - Many of these cases are going to be “inherited,” ie, initiated under the old model of “no ceiling means no limit” in terms of acceptable agonist dose

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PainWeek

Clinical Concerns

- Boundaries and limits
 - Pill loads
 - Interval/contingency prescribing
 - Eg, “do not fill until...”
 - The “assessment of stability”
 - Some people are deemed stable based more on a hope than objective evidence
 - » ? UDT
 - » ? Running out of medication early
 - » ? Willingness to participate in nonpharmacologic therapies

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PainWeek

Clinical Concerns (cont'd)

- Boundaries and limits
 - UDT ever been done?
 - Ever been abnormal? Finding things that shouldn't be there/not finding things that should be there
 - » Expected vs unexpected results
 - What is the one wrong answer in response to the unexpected results? "Do Nothing"
 - Presumptive vs definitive testing?
 - Often directed by the question you are trying to answer
 - Frequency of follow-up
 - As dose goes up, level of monitoring should likely go up

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The Signs of Pharmacological Instability

- Multiple members of the same class of drug
 - Polyopioids
 - Polybenzodiazepines
 - Addition of controlled substances to offset adverse effects of analgesics/sedatives
 - Stimulant class of drugs
- Excessive "pill loads" with each prescription written
 - Reliance on many tablets per day vs using a tablet strength to limit total number of tablets dispensed
 - With large number of daily unit doses, the total number of pills per prescription can become excessive—eg, 3 tablets per day q30 days = 90 tablets vs 10 tablets per day q30 days = 300 tablets per script

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The Signs of Pharmacological Instability (cont'd)

- Running out early
 - Failure to specify how long a prescription should last makes it very difficult to objectively assess “early refills”
- Excessive sedation/somnolence on current medication regimen
 - Consider 3rd party sources of information, eg, spouse/family
- Diminished rather than improved function
 - “continued use despite harm”
- Decreased duration of action +/- AM withdrawal symptoms associated with pharmacologic instability
 - Need to increase dosing frequency to achieve stability (eg, once daily medication taken BID; TID; even QID)

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Opioid Myths

- “Patients who no longer need opioids come off them easily” – NO
 - For the most part, this is nonsense
 - Physical dependency and accompanying withdrawal is largely person-specific but certain truths should be considered
 - As dose goes up and duration on the drug increases, the degree of withdrawal often increases (but not always the case)
 - The ease with which the taper goes at the beginning rarely predicts how easy/difficult the taper will be at the end (eg, when they are finally off the medication altogether)

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Opioid Myths (cont'd)

- “Patients who no longer need opioids come off them easily”
 - Any taper is a balance of tensions between time for optimal neuroadaptation to minimize withdrawal symptoms vs “prolonging the misery” of the process
 - Unfortunately, for some, even the slowest of tapers will not totally eliminate withdrawal symptoms—in these cases, simply pushing through the taper is often the necessary and “best” approach

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Practical Questions

- Should we taper the incumbent drug or substitute and taper?
 - Factors to consider
 - How long has the patient been on the drug to be tapered?
 - How many unsuccessful attempts have there been to taper this drug?
 - Does the patient feel, based on past history, beaten before they even start?

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Practical Questions (cont'd)

- Should we taper the incumbent drug or substitute and taper?
 - Factors to consider
 - How “malignant” has the relationship between the drug(s) and the patient been?
 - Frequently running out early?
 - Compromising the delivery system?
 - Multiple unsanctioned dose increases?
 - The nature of the drug
 - Is this a drug with a particularly bad reputation for withdrawal? Eg, fentanyl/alprazolam

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Conclusions

- Clearly, there are more questions than answers to this challenging topic
 - We hope that today’s session has expanded on some of these issues
- In the context of “desperation pharmacotherapy”
the *status quo* is rarely the correct answer
- QUESTIONS?



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References

- Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings.
- <http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.pdf>
- D Gourlay, HA Heit, A Almahrezi: Universal Precautions in Pain Medicine: A Rational Approach to the Treatment of Chronic Pain. *Pain Medicine*. 2005;6(2):107-12.
- DL Gourlay, HA Heit. Universal Precautions Revisited: Managing the Inherited Pain Patient. *Pain Medicine*. 2009; 10(S2):S115-S123.
- HA Heit, DL Gourlay. The Treatment of Chronic Pain in Patients with History of Substance Abuse. In S M Fishman, JC Ballantyne, JP Rathmell, (eds). *Bonica's Management of Pain*, Fourth Edition. Philadelphia: Lippincott Williams & Wilkins, 2010: 846- 854.

References (cont'd)

- Model Policy for the Use of Controlled Substances for the Treatment of Pain. Policy Statement: Federation of State Medical Boards of the United States, Inc; 2013.
- HA Heit, DL. Gourlay. Using Urine Drug Testing to Support Healthy Boundaries in Clinical Care. *Journal of Opioid Management*. 2015; 11(1): 7-12.
- DL Gourlay, HA Heit, YH Caplan. *Urine Drug Testing in Clinical Practice: The Art & Science of Patient Care*. Center for Independent Healthcare Education. <http://www.udtmonograph6.com>. 6th Edition. August 2015. Accessed April 4 2016.
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