PainWeek

Involuntary Tapers: Ethical, Legal, and Clinical Concerns

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Disclosures

- Nothing to disclose

PainWeek

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LEARNING OBJECTIVES

- Summarize the CDC Guideline for Prescribing Opioids for Chronic Pain (in general)
- Summarize several key recommendations in the Guideline that relate to tapering
- Describe the ethical, legal, and clinical concerns involving involuntary tapers
  - In some clinical situations, w/patient buy-in & support, [+] outcomes possible

PainWeek

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Recent Survey Respondent

- "My wife went from being on a dose of 120 [MED] a day to 10
- Then none within two months
- Doc said: it's not up to me, it's up to the CDC and the FDA [and] I won't lose my license because of your wife's pain"
- She committed suicide ("She died by her own hand")
  - https://twitter.com/tal7291/status/998558947828101120

PainWeek 4

Befehl ist Befehl – "an order is an order"

- "Based on fear, [physicians] cite non-facts routinely."
- 'I am stopping opioids because it's required by CDC'
- [or required] 'by DEA' etc
- all this stuff is written in the charts I review."
  - Stefan Kertesz, MD (@StefanKertesz)
  - But…. Is this *de jure* or *de facto*? (ie, the law or 'true in practice')

PainWeek 5

What do they say? Summary of Rx Guideline (3/15/16)

- "The recommendations in the guideline are voluntary, rather than prescriptive standards. . . . Clinicians should consider the circumstances and unique needs of each patient when providing care."
  - Easier said than done
- Quality/Strength of the evidence to support the recommendation (Types 1-4; 1=Very strong, 4=Very weak)

PainWeek 6

Some Relevant Specifics (Excerpts)

- Rec #1: Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain [Weak evidence, Type 3]
- Rec #5: Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day. [Weak evidence, Type 3]

PainWeek 7

Rec #7: Very Weak Evidence [Type 4]

- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. . . .
- If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. [emphasis not in original]

PainWeek 8

Some Relevant Specifics (Excerpts)

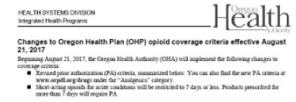
- "evidence on the comparative effectiveness of opioid tapering or discontinuation versus maintenance, and of different opioid tapering strategies, was limited to small, poor-quality studies"

PainWeek 9

Does the CDC support involuntary tapers?

- "this review . . . nor CDC's guideline provides support for involuntary or precipitous tapering."
- "Such practice could be associated with withdrawal symptoms, damage to the clinician–patient relationship, and patients obtaining opioids from other sources."
  - Deborah Dowell, MD, MPH & Tamara M. Haegerich, PhD of the CDC
    - "Changing the Conversation About Opioid Tapering," Annals of Internal Medicine, 167 (3), August 2017
- "Disclaimer: The conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention."

Reality: Involuntary Tapers Occurring



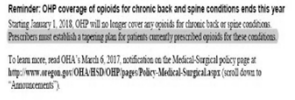
HEALTH SYSTEMS DIVISION
Integrated Health Programs

Oregon Health Authority

Changes to Oregon Health Plan (OHP) opioid coverage criteria effective August 21, 2017

Beginning August 21, 2017, the Oregon Health Authority (OHA) will implement the following changes to coverage criteria:

- Revised prior authorization (PA) criteria, summarized below. You can also find the new PA criteria at www.orpdl.org/drugs under the "Analgesics" category.
- Short-acting opioids for acute conditions will be restricted to 7 days or less. Products prescribed for more than 7 days will require PA.

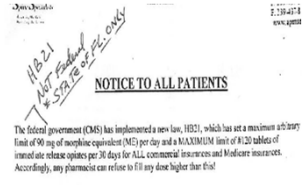


Reminder: OHP coverage of opioids for chronic back and spine conditions ends this year

Starting January 1, 2018, OHP will no longer cover any opioids for chronic back or spine conditions. Prescribers must establish a tapering plan for patients currently prescribed opioids for these conditions.

To learn more, read OHA's March 6, 2017, notification on the Medical-Surgical policy page at http://www.oregon.gov/OHA/HSD/OHP/pages/Policy-Medical-Surgical.aspx (scroll down to "Announcements").

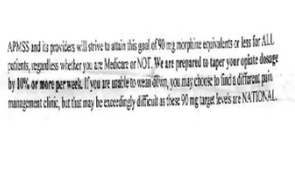
The devil made me do it



HB 21
Not Federal
* STATE OF FL ONLY

NOTICE TO ALL PATIENTS

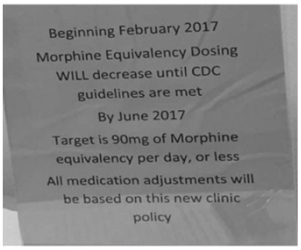
The federal government (CMS) has implemented a new law, HB21, which has set a maximum arbitrary limit of 90 mg of morphine equivalent (ME) per day and a MAXIMUM limit of #120 tablets of immediate release opiates per 30 days for ALL commercial insurances and Medicare insurances. Accordingly, any pharmacist can refuse to fill any dose higher than this!



APWSS and its providers will strive to attain this goal of 90 mg morphine equivalents or less for ALL patients, regardless whether you are Medicare or NOT. We are prepared to taper your opiate dosage by **10% or more per week**. If you are unable to wean down, you may choose to find a different pain management clinic, but that may be exceedingly difficult as these 90 mg target levels are NATIONAL.

What happened to individualized treatment?

- Maine (across the board)
- VA
- Self-medication
- OD (intentional & unintentional)
- Suicide



PainWeek

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Intersection of law & ethics: mutually exclusive?

- A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient (AMA)
  - College of Physicians and Surgeons of British Columbia 2018

PainWeek

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Intersection of law & ethics: mutually exclusive?

- College of Physicians and Surgeons of British Columbia 2018 recent reform:
- "Physicians cannot exclude or dismiss patients from their practice because they have used or are currently using opioids. It's really a violation of the human rights code and it's certainly discrimination and that's not acceptable or ethical practice."
  - Bains (June, 2018), quoting Oetter from CPS, BC (https://tgam.ca/2JpDL1n)

PainWeek

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Ethical & Legal Concerns

- Classic 4 principals to guide ethical decision making
  - Respect for patient autonomy [Informed consent issue];
  - Do no harm (Non-maleficence);
  - Beneficence (what is in the patient's best interest)
  - Justice (fairness)
    - *Human Rights violation & Human Rights Watch (HRW)

PainWeek 16

Clinical Concerns

- So, what's a clinician supposed to do?
  - Are the CDC guidelines a problem or a fact?
    - If a fact, we better accept it as a fact
    - If a problem, we need to find a solution
  - Can they be both?

PainWeek 17

Clinical Concerns

- This is a multilevel problem
  - Regulators
    - State Medical Boards
  - Governmental
  - Payors
    - Insurance Limits
- Can a problem become so big that it comes a fact justifying blind adherence to non-evidence based solutions?

PainWeek 18

Clinical Case

- Is this really an involuntary taper?
  - ie, You insist while the patient refuses your medical advice
- Or, is it a 'readiness to change' issue
  - ie, helping the patient "get from where they are to where they need to be"
  - How you document these issues can take you from a defensible position (medicolegally) to one of significant legal exposure
    - ie, "this is the law!" vs "in the interest of safety, based on what we now know… your current dose is unacceptable"

PainWeek 19

Case I "It's the LAW!"

- 34 yo male, on LTOT for past 5 years for Dx Failed Back Syndrome
  - Currently using 120mg of CR Oxycodone (40mg po q 8hr)
  - Patient has not been able to return to work as a computer programmer
  - Does not run out of medications early
    - Urine drug screen has been appropriate on all occasions
  - Pt would like to have better function but does not want to change his opioid use

PainWeek 20

Case I

- Is this patient within CDC Guidelines?
  - No
    - 1.5-2.0x factor so 180-240mg MMED – well outside guidelines
- Is the patient willing to change their dose?
  - No
    - Pt states "not the best, but I can at least make it through the day!"
    - "oxycodone is the only thing that makes my life worth living!"
- New Clinic Policy is "As a result of recent changes to the law – all long term opioid patients will be reduced to a dose that is within the currently acceptable limit of 90mg Morphine/Day"

PainWeek 21

Case I

- Patient comes in for routine monthly prescription appointment and is advised that in keeping with CDC regulations:
- 1) "your new prescription will be 20mg CR oxycodone q8hr"
- 2) "We'll review in one month to see if the dose needs to be reduced further"
- Is this a reasonable approach?

PainWeek 22

Case I

- Pt returns in 2 weeks concerned that he will be out of medication in a few days
  - "borrowing from tomorrow to pay for today"
- Pt states that he wants to be back on his usual dose of oxycodone
  - "I'm going to find a new doctor!"
    - You give him a "final" prescription for 30 days at 40mg q8hr advising him that you will send his chart to his new doctor
      - You hand him a copy of your 1 month termination of care letter – wishing him well!

PainWeek 23

Case I

- 4 days later, his wife calls to advise that her husband was found dead yesterday morning
  - The coroner is awaiting toxicology results but says the circumstances are suggestive of opioid overdose
    - The prescription you had written had only 10 tablets remaining
- Problems with this case: *many!*

PainWeek 24

Case I

- Problems with this case:
  - 50% dose reduction might be considered excessive
    - Might have been accomplished by a more gradual dose reduction
      - (10-20% reduction every 1-2 weeks until bottom 30% of taper – then 5-10% reduction every 2-4 weeks)
  - Running out of medications at 2/52
    - Clearly had overused his meds vs the prescription as written
      - Loss of tolerance or uncertain tolerance?
  - Writing a 30 day prescription at original dose (which was clearly in excess of CDC Guidelines) – "one last 'script for the road"

PainWeek

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Case I

- Alternative Strategies
  - Dose drop might have been in the 10-20% range
    - Can be challenging with CR medications
  - Follow up appointment in 1 or 2 weeks for moral support for this patient who is obviously uncomfortable with the taper
  - Don't give a final 'big bottle of pills' to someone you know can't control them
  - DON'T call the CDC Guidelines "the law"
    - These guidelines are NOT legal lines that must not be crossed, even if that's how a lot of organizations/practitioners think of them

PainWeek

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Case Ib – An Alternative Approach

- Same case with different treatment options
  - Detailed discussion of 'safety issues' related to higher dose of opioids in light of new awareness of opioid-related risk
    - This is not an issue of trust – it's a duty of care to do the best for your patient, given your current and often evolving knowledge
  - Do NOT misstate the CDC Guidelines as "The Law"
    - Revise clinic policy statement to reflect this
  - Write for smaller quantities of drug – easier to stay within bounds with 1 week of medications vs 1 month

PainWeek

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Case Ib

- Change the script from 40mg tablets to 20mg tablets and reduce the dose by 1 tablet each week
  - ie, 5 tablets per day total, 1 tablet q AM and 2 tablets q8hrs
  - Total pills on first script = 35 tablets
- Consider introducing w/d mitigating agents (NSAID's/α2-agonists)
  - Avoid sedatives/anxiolytics
  - Caution with rebound hypertension/bradycardia
  - Possible role of buprenorphine in terms of analgesia AND exit

PainWeek 28

Can we use buprenorphine to convert from full agonists? YES!

- Several studies have shown improved pain scores and improved function comparing full mu agonist treatment to buprenorphine (Daitch et al, Webster et al)
  - [ND2]
  - Various methods of conversion
  - Some do not entail discontinuation of full agonist before introducing buprenorphine

PainWeek 29

Precipitated Withdrawal

- Withdrawal is NOT generally a function of opioid level, but rather rate of change of opioid level
  - 400ng/dL methadone falls to 200ng/dL over 24hrs…. Generally no withdrawal
  - 400ng/dL methadone falls to 395ng/dL over 5 minutes (ie, with antagonist use)…. Severe withdrawal
- Taper rate is a tedious balance between slow enough to effect optimum neuroadaptation but not so slow as to prolong misery!

PainWeek 30

Slide 29

ND2 Switching from high doses of pure μ-opioid agonists to transdermal buprenorphine in patients with cancer: a feasibility study.

Nitrous Dude, 3/4/2019

Precipitated Withdrawal

- In fully mu dependent patient, addition of 8mg of SL buprenorphine is likely to ppt withdrawal
  - Big dose – rapid route of administration
  - BUT
    - Using transdermal or buccal sub mg doses, risk is minimal

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Practical Conversion

- First – get the patient onto the lowest practical dose of full agonist
- Second – induce an opioid debt
  - ie, reduce incumbent opioid by 1/3
- Third – introduce buprenorphine and further reduce full agonist

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Starting Dose

- How do you determine what is the 'right' dose for the buprenorphine?
  - First, we don't want a therapeutic equivalency
    - Why would you try and convert to an arguably excessive dose of full agonist?
    - Goal is to mitigate (not necessarily eliminate) significant withdrawal NOT to achieve equivalence in the new molecule
  - Second, we want to manage expectations carefully
    - Buprenorphine is a more subtle drug – pts often describe much clearer head
    - The should not be "dose until pain is eliminated"

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Clinical Conclusions

- As time goes on, we learn new things to improve patient treatment and reduce risk
  - To imagine that most patients (especially those who are on excessively high doses of opioids) started on opioid therapy 20 years ago can't be improved is naïve
    - That doesn't mean it will be easy but the rewards can be huge!
- Status quo is rarely an optimum course of therapy for your LTOT patient and certainly can present considerable risk to you!

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Question 1

- To create an opioid debt, you should:
  1. Stop the incumbent opioid abruptly
  2. **Reduce the incumbent opioid by 1/3**
  3. Add a potent antagonist such as naloxone
  4. Switch to a less potent opioid

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Question 2

- The following are all true with respect to the CDC guidelines on the use of chronic opioids ***EXCEPT:***
  1. Other options besides opioids should be tried first
  2. Clinicians should evaluate benefits and harms within 1-4 weeks when deciding to continue with opioid therapy
  3. Chronic opioid therapy doses **must never** exceed 90MME/day
  4. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients…

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Question 3

- In the context of excessively high doses of an opioid medication, the first goal in an opioid rotation is not therapeutic equivalency, it is:
  1. Patient satisfaction
  2. CDC guidelines
  3. Gut feeling
  4. **Withdrawal mitigation**

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