The CDC Crisis: The Ignored Component – The Patient.

John F. Peppin, DO, FACP

Introduction

- CDC Guidelines
  - Majority of state Medicaid agencies have "implemented" the guidelines.
  - Guideline rated "high quality" by ECRI Guidelines Trust Scorecard.
  - But should they be and are they?

Introduction

- "The guideline was not intended to be mandatory; yet, as I predicted in a previous roundtable discussion, the stature of the CDC appears to have resulted in it being viewed by many as more than a guideline." (Webster, 2016)

Introduction

- The CDC Guideline focus exclusively on opioids and opioid doses.
  - No mention of the withdrawal risks. (Dubin, 2019)
- The Guidelines have resulted in:
  - Overzealous Tapering.
  - Abrupt discontinuation.
  - Refusal to prescribe or to continue prescribing.
  - Refusal to see or continue to see chronic pain patients.

Introduction

- CDC Advises Against Misapplication of the *Guideline for Prescribing Opioids for Chronic Pain*
  - Misapplication of recommendations to populations outside of the Guideline's scope.
    - Examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain.
  - Misapplication of the Guideline's dosage recommendation that results in hard limits or "cutting off" opioids.
    - The recommendation statement does not suggest discontinuation of opioids already prescribed at higher dosages.

Introduction

- The Guideline does not support abrupt tapering or sudden discontinuation of opioids.
  - These practices can result in severe opioid withdrawal symptoms including pain and psychological distress, and some patients might seek other sources of opioids … policies that mandate hard limits conflict with the Guideline's emphasis on individualized assessment and treatment.
- Misapplication of the Guideline's dosage recommendation to patients receiving or starting medication-assisted treatment for opioid use disorder.

Introduction

- Patient Experience and Suffering:
  - Pain News Network reported in 2016 (Anson, 2016).
    - Dozens of patients contacted the Network after the CDC Guidelines went into effect.
      - Doctors have fired them on "flimsy excuses"
      - Suddenly weaning off opioids
      - Abruptly cutting off opioids.
      - Refusing to continue opioids.
      - Refusing to see patients with chronic pain.

Introduction

- "In December, Human Rights Watch documented how some physicians were involuntarily reducing opioid medication dosages for chronic pain patients because they feared liability or scrutiny from law enforcement, state medical boards, and insurance providers." (Human Rights Watch, 2019)
- Are restrictions on opioids a threat to human rights. (Washington Post, 2019).

Introduction

- "In particular the CDC's 2016 guidelines for opioid prescribing came under heavy fire, as even a self-described supporter of its recommendations admitted the evidence base was week." (Firth, 2019)
- "But in a letter sent to the CDC more than 300 medical experts, including three former White House drug czars, contend that the guidelines are harming one group of vulnerable patients: those with severe chronic pain, who may have been taking high doses of opioids for years without becoming addicted." (Hoffman, 2019)

Oregon Health Authority

- Due to the CDC Guidelines
  - Proposed:
    - Forced reduced opioid dosages.
    - Forced Discontinuation and abrupt stoppage of opioids.
  - Due to intense patient and pain physician expert comment
    - Have held off implementation.
  - Current revised version: Patients with fibromyalgia and some other conditions will still be forced to taper.

Introduction

- AAPM Consensus Panel
  - Inflexible application of recommended doses and duration
    - Limits-used as "hard limits".
  - Involuntary abrupt or cessation of opioids.
  - Lack of availability and coverage for multimodal pain care.
  - Difficulty of OUD diagnosis/Barriers to OUD treatment
  - Incomplete data in reporting of overdose death statistics.
  - Lack of emphasis on risks of withdrawal
  - Lack of evidence for specific tapering schedules.

Introduction

- To add to the issue:
  - Lack of clear definitions of misuse, abuse, addiction.
  - Also "doctor shopper", misprescribing, overprescribing, etc …
  - No universally accepted definitions
- "The lack of shared definitions is problematic for formulating and evaluating opioid policy." (Dineen, 2018)

Introduction

- Patients are intensely fearful concerning (Henry, 2019);
  - Re-emergence of pain
  - Pain of withdrawal
  - No access to proper care of their pain.
- "Fears emerged as a uniquely powerful emotion affecting both patients' willingness to taper and their overall tapering experience. Most patient fears involved the possibility of worse pain and withdrawal owing to decreased opioids" (Henry, 2019)

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Tapering and Withdrawals

- "The FDA last month said it had received reports of patients taken off their pain medicines who were suffering "serious withdrawal symptoms, uncontrolled pain, psychological distress and suicide." (Talbot, 2019)

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Tapering and Withdrawal

- Goesling, 2019
  - US Study, patient interviews
  - 150 patients who formerly used opioids for chronic pain, were forcefully tapered.
  - 46.9% felt their pain, function and psychological state worse
  - 53% felt their pain was better.
- The claim that tapering and withdrawal from opioids universally improves chronic pain is without evidentiary support.

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Tapering and Withdrawal

- "Though many studies reported positive dose reduction outcomes, the overall quality of the evidence for effectiveness of all strategies to reduce for discontinue LTOT was very low due to methodological limitions across studies and an absence of adequately powered randomized trials." (Frank, 2017)
- "Unfortunately, the literature as a whole is limited. This limitation is due to tapering strategies being founded almost completely on clinical experience." (Suttner, 2013)

Tapering and Withdrawal

- "Prescribers should never initiate any pharmacological therapy without knowing how and when to discontinue it." (Pergolizzi, 2018)
- Tapers should involve shared decision-making
- Close supervision should always be initiated during any taper
  - Patients are vulnerable during weaning for withdrawals and side effects
  - Supervision for increased pain, psychological distress and suicidality.

Tapering and Withdrawal

- "Opioid withdrawal isn't minor. It's not "just temporary" or "the price to be paid" for pain relief. It's not morally innocuous. The moment that I was in withdrawal - all of the thousands of moments of genuine suffering – were the worst of my life. That kind of suffering matters, and its seriousness needs to be reflected in the way we deal with prescription opioids." (Rieder, 2017).

Tapering and Withdrawal

"Taper is not a pain treatment."
(Kertesz, 2018)

Tapering and Withdrawal

- Cancer Pain
  - Frequently carved out apart from the concerns with opioids.
  - No difference in physiology, pathophysiology, in cancer or noncancer pain (Peppin, 2016).
- CDC guidelines have been used to block use of opioids in cancer patients. (Rubin, 2019)

Suicide

- Of the 5 subgroups at highest risk of suicide in prison, OUD was one. (Rivlin, 2013)
  - High rate of substance use disorder and opioid use disorder.
    - High rate of suicidal ideation and successful suicide.
    - Frequently related to withdrawal. (Center for Health and Justice, 2016).
- Opioid substitution therapy reduces suicide rates in opioid dependent prisoners. (Larney, 2013)

Suicide

- Suicide rates in the US have increased over the last 20 years.
- Opioids play a role in a number of ways:
  - "unintentional" overdose may be due to successful suicide (Cheatle, 2018; Bohert, 2019)
- 47,173 overall suicides in 2017 (AFSP, 2019)
  - > 2x the number of deaths from opioids."
  - "Anecdotal reports that chronic pain contributes greatly must not be dismissed." (Webster, 2016)
  - The role of abrupt tapering and withdrawal may also play a role (Darnell, 2019).

Suicide in Chronic Pain

- Pain is an independent risk factor for suicide. (Theodoulou, 2005; Hassett, 2014)
- Lifetime prevalence of suicidal ideation and attempts in chronic pain patients "significantly elevated". (Garland, 2017)
  - 5-14% for attempts, 20% for ideation (Tang, 2006)
  - Some studies 75% plan on suicide attempt using overdose (Smith, 2004)
- "We recommend assessing suicide risk when considering initiating or continuing long-term opioid therapy and intervening when necessary." (Rosenberg, 2018)

Suicide in Chronic Pain

- National Sample of VHA patients with SUD
  - Matched with patients without.
  - Both discontinued from long term opioids
  - Strongest predictors: depression and previous lifetime suicide attempt.
  - "Substance use in the absence of negative mood states may be insufficient to precipitate these suicidal thoughts and behaviors." (Demidenko, 2017)

Suicide

- "Rapid forced tapering can destabilize these patients, precipitating severe opioid withdrawal accompanied by worsening pain and profound loss of function. To escape the resultant suffering, some patients may seek relief from illicit (and inherently more dangerous) sources of opioids, whereas others may become acutely suicidal." (Darnall, 2019)

Conclusion

Conclusion

"Prescription opioid policies too often reflect over a century's worth of moralizing about the nature of opioid use disorder, the value of pain, and the meaning of suffering."
(Dineen, 2018)

Conclusion

- Complexity
  - One important issue the CDC Guidelines miss is the complexity of chronic pain.
    - Single answers are rarely effective in the chronic pain patient
      - Whether procedures or medications.
      - A patient focused and individualized approach

Conclusion

"We must acknowledge, to ourselves and our nonhospice/palliative care colleagues that providing optimal pain care is difficult … the trap … is to minimize how hard pain management truly is …"
(Weissman, 2004)

Conclusion

- "Oftentimes cases are complex with patients presenting with unique needs, co-occurring conditions, and exacerbation of their painful conditions. There, the guideline may not always be consistent with the standard of care. Blind adherence to the Guideline is not appropriate." (Stanton, 2017)

Conclusion

1) Medical co-morbidities
2) Other concomitant symptoms
3) Psychiatric and psychological co-morbidities
4) Risk for medication abuse and diversion
5) Number of pain problems
6) Number of past surgeries
7) Tobacco usage
8) Head trauma history
9) Body Mass Index
10) Sleep disorders
11) Goal setting
12) Educational level and employment status
13) Current pharmacotherapy regimen
14) Coping skills and social support
15) Physical conditioning
16) Current pain intensity

(Peppin, et, al. 2015)

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Conclusions

- Unintended consequences of policies, guidelines need to be measured, followed and understood
  - Evidenced based legislation and regulation development.
- In 2017, Lynch and Katz wrote, "the current harsh regulatory climate on prescribers is doing more harm to people with chronic pain." (Lynch, 2017)

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Prescriber Knowledge

- Prescriber Knowledge:
  - It has become apparent that:
    - Little training of FPs or others in identifying withdrawal
      - Little training in the risks of "adrenergic and autonomic overdrive in opioid withdrawal".
    - Little training in opioid taper or treatment of withdrawal.
    - Little training in pain management, substance use disorder and use of opioids.

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Conclusion

"The first thing we have to realize at this moment is that we must stop swinging the opioid pendulum. Each pole is easy … but neither is morally defensible."
(Rieder, 2018)

Conclusion

"Absence of evidence is not evidence of absence."
(Martin, 2007)

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Thank You.

