The CDC Guideline Itself or Its Weaponization?

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Disclosure

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Efforts to Curb the Prescription Opioid Crisis

- The 2016 CDC Guideline is constantly criticized
- But its primary problems related to process, not substance
- The process of developing the guideline was problematic
  - ❖Secretive
  - ❖Non-responsive to stakeholders
  - ❖Committee dominated by PROP

Schatman ME, Ziegler SJ. J Pain Res. 2017;10:2489-2495.

- And the process is reflected in current prescribing realities…

Efforts to Curb the Prescription Opioid Crisis

- Yet, many of us who see ourselves as patient advocates note that the guideline itself has its strengths
  - ❖Should prescribers not think twice prior to increasing dosages beyond 90 MEDD?
  - ❖The recommendations are presented as "voluntary, rather than prescriptive standards"

Dowell D, et al. MMWR Recomm Rep. 2016;65(1):1–49.

  - ❖Recently, referred to as a "nuanced, patient-centric view on opioid prescribing"

Cohen J. The importance of patient-centric opioid prescribing guidelines. Forbes, January 23, 2019.

Efforts to Curb the Prescription Opioid Crisis

- Is the guideline the problem, or is it the weaponization of the guideline?
- AMA's 2016 response:
  - ❖"The CDC recommendations also have the potential to cause confusion in light of institutional or state policies….. We are concerned that insurers and other payers will use the recommendations to deny or impose new hurdles to coverage of any dose that exceeds the CDC's recommended thresholds. We are concerned that pharmacies will be under pressure to deny prescriptions that exceed those thresholds…"

Harris PA. Am Fam Physician. 2016;93(12):975.

Efforts to Curb the Prescription Opioid Crisis

- And so it has come to pass….
- State medical board opioid guidelines discourage clinicians from prescribing opioid dosages higher than the CDC guideline thresholds

Federation of State Medical Boards Guidelines for the Chronic Use of Opioid Analgesics. 2017. Available at: https://www.fsmb.org/globalassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf.

- And the results?
  - ❖Recent study – Internet-based survey found that CPPs tapered (involuntarily) from ER/LA opioids reported decreased pain control and diminished function

Twillman RK, et al. J Pain Res. 2018;11:2769-2779.

Efforts to Curb the Prescription Opioid Crisis

- ❖Internet-based studies of CPPs from a patient-advocacy group are likely to be rife with selection bias issues…
- 2018 study of patients on high-dosage opioids voluntarily tapered from a median of 288 mg to 150 mg in 4 months demonstrated no increase in pain levels
  - ❖That the drop out rate was 38% needs to be considered

Darnall BD, et al. JAMA Intern Med. 2018;178(5):707-708.

- 2019 study of patients tapered ≥20% (primarily voluntarily, but with psych assist) - reported no increase in pain or decrease in function

DiBenedetto DJ, et al. Pain Med. 2019[Epub ahead of print].

Efforts to Curb the Prescription Opioid Crisis

- So, whom to believe?
- Populations varied from study to study
- Approaches to tapering varied as well
- Methodologies inconsistent between studies
- What about "outliers"?
- Likely answer – Those CPPs tapered in a patient-centered manner (e.g. voluntarily, with psychological assistance) are likely to fare better than those rapidly tapered involuntarily
- The former approach is consistent with the CDC Guideline

But the CDC Guideline Has Been Bastardized…..

Examples of Draconian State Laws

- By the end of 2017, twenty-six states had passed laws that impose mandatory limits on initial prescriptions for acute pain

Davis CS, et al. Drug Alcohol Depend. 2019;194:166-172.

- 2018 Florida law – limits prescription for acute pain to 3-day supply

Controlled Substances, Florida HB 21 (2018), 2018-13. Available at: http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=60136.

- Similar law in place in Kentucky

201 KAR 9:260. Professional standards for prescribing and dispensing controlled substances. Available at: http://www.lrc.state.ky.us/kar/201/009/260.pdf.

Draconian State Laws

- Ohio and Rhode Island – 30 MEDD maximum for acute pain

State of Ohio Board of Pharmacy. For Prescribers - New Limits on Prescription Opioids for Acute Pain. Available at: https://www.pharmacy.ohio.gov/Documents/Pubs/Special/ControlledSubstances/For%20Prescribers%20-%20New%20Limits%20on%20Prescription%20Opioids%20for%20Acute%20Pain.pdf.

State of Rhode Island Department of Health. Safe Opioid Prescribing. Available at: http://health.ri.gov/healthcare/medicine/about/safeopioidprescribing/#apain.

- ❖ A regulatory approach that takes into account prescriber intent and patient-specific factors that influence prescribing is likely more effective than a strict limitation on the amount or duration of opioid prescribing

Mundkur ML, et al. Subst Abuse 2017;38:239-238.

Samet JH, Kertesz SG. JAMA Network Open 2018;1(2):e180218.

Draconian State Laws

- ❖Unintended consequences for low income patients – transportation issues, more frequent office visits resulting in additional co-pays

Grol-Prokopczyk H. Pain 2017;158:313-322.

- ❖Potential to drive some patients to the black market – illicit fentanyl and its analogues

Barnett ML, et al. N Engl J Med. 2017;377:2306-2309.

- ❖Is there any evidence that the beneifits of such policies justify the potential risks and consequences?

Draconian State Laws

- Nevada – If a patient needs more than 90 days of opioid therapy, he/she must undergo blood and radiology tests to determine the cause of the pain
  - ❖"Conduct an investigation, including, without limitation, appropriate hematological and radiological studies, to determine an evidence-based diagnosis for the cause of the pain"

NV Assembly Bill No. 474–Committee on Health and Human Services. Available at: https://nvdoctors.org/wp-content/uploads/AB474_Bill-FINAL.pdf.

- If most chronic pain is maldynic, such testing is going to tell us what?!?!?!
  - ❖Seems like an invitation to create a false narrative…
- And the list goes on and on….

Insurers and Pain Management

- Insurers' "about face" regarding opioids is laughable
  - ❖Was it about "concern" for the well-being of pain patients?
  - ❖Was it about cost-containment and profitability associated with the high costs of insuring patients on opioids?

Kern DM, et al. Am J Manag Care. 2015;21(3):e222-234.

  - ❖Recent study demonstrates that insurers are still "inconsistent" in coverage for nonpharmacologic therapies

Heyward J, et al. JAMA Netw Open. 2018;1(6):e183044.

  - ❖If they're not paying for opioids and not paying for nonpharmacologic, evidence-based treatments, for what **ARE** they paying?!?!

Insurers and Pain Management

  - ❖This in light of data demonstrating that early PT is associated with less long-term opioid dependence

Sun E, et al. AMA Netw Open. 2018;1(8):e185909.

- And its not just the for-profit private insurers…
  - ❖Medicare's 90 MED hard limit almost became a reality
  - ❖Currently surpassing 90 MED requires a consult between the pharmacist and the prescriber
  - ❖Likely to have a "chilling effect"
    - ❑Potentially puts the pharmacist and the prescriber in a confrontational situation

Sullum J. Practical Pain Manage. January 14, 2018. Available at: https://www.practicalpainmanagement.com/patient/resource-centers/chronic-pain-management-guide/medicare-rule-will-create-new-challenges.

What Was CDC's Intent?

- So many of these draconian laws and policies make reference to the CDC Guideline
  - ❖Anecdotal reports on involuntary tapers with physicians telling patients that it's the new CDC law
- What was the Guideline's intent?
  - ❖States that CDC is committed to "evaluating the guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted"

Dowell D, Haegerich TM, Chou R. MMWR Recomm Rep 2016;65(1):1–49.

What Was CDC's Intent?

- Any evidence of efforts by CDC to halt the weaponization?
- "The period following guideline release has seen clinical and policy issues that may have gone beyond what was originally intended by developers of the guideline"

Kroenke K, et al. Pain Med. 2019;20(4):724-735.

- MAY HAVE?!?!?!
  - ❖Even the PROP-heavy AAPM panel that reviewed the challenges to implementing the guideline were able to elucidate numerous examples of how to guideline was misapplied

Kroenke et al Findings

- Inflexible application of recommended ceiling doses or prescription durations as hard limits;
- Abrupt opioid taper or cessation in physically dependent, opioid treated patients without regard for CDC emphasis on empathically reviewing benefits and risks of continued high-dosage therapy and working collaboratively with patients on a tapering plan;
- Lack of availability and coverage for recommended comprehensive, multimodal pain care;
- Difficulty of OUD diagnosis and barriers to accessing evidence based OUD treatment;
- Underutilization of naloxone;
- Incomplete data in reporting of overdose death statistics

What Was CDC's Intent?

- Even if not de jure law, few deny that the guideline is being interpreted as defacto regulation

Jay GW, et al. Pain Ther. 2019[Epub ahead of print].

- ❖Clearly contradicts the 2017 Federation of State Medical Board guidelines, which emphasize clinical judgment on a case-by-case basis

Guidelines for the Chronic use of Opioid Analgesics. 2017, Federation of State Medical Boards.

- Yet, we knew this would happen before the guideline was released
  - ❖ "In fact, the CDC imprimatur makes it more likely that these guidelines become de facto requirements through adoption by state health departments, professional licensing bodies or insurers"

Hansen CW. American cancer Society cancer action network letter to the United States Centers for Disease Control and Prevention. Oct 1, 2015. Available at: https://www.fightcancer.org/sites/default/files/ACSCAN_Comments_CDC_Opioid_Guidelines_Final.pdf.

Perpetuating CDC's Twisted Goal

- CDC is invested in exaggeration of prescription opioid OD death figures
  - ❖Claim that in 2017, there were 17,029 "prescription opioid deaths"

Scholl L, et al. MMWR Morb Mortal Wkly Rep. 2019;67(5152):1419–1427.

- ❖Represents evidence that CDC is "mathematically challenged"
- ❖So let's look at state data
- ❖Particularly that from NH's DOJ
- ❖Opioid mortality is counted objectively and accurately

ATTORNEY GENERAL
DEPARTMENT OF JUSTICE
GORDON MACDONALD
ATTORNEY GENERAL
JANE YOUNG
DEPUTY ATTORNEY GENERAL

Drug Death Data

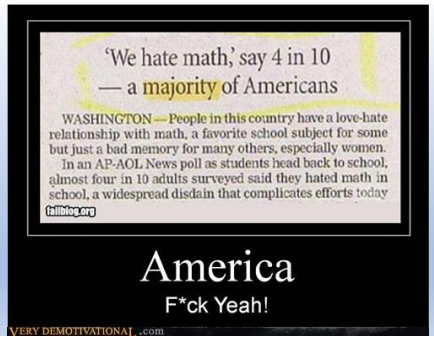
2018 Drug Death Data as of 3/18/2019

OPIATES/OPIOIDS	# OF DEATHS
Fentanyl (no other drugs)	192
Fentanyl and Other Drugs (excluding heroin)	171
Heroin (no other drugs)	1
Heroin and Other Drugs (excluding fentanyl)	0
Heroin and Fentanyl	3
Other Opiates/Opioids	29
Unknown Opioids	1
Total Deaths Caused By Opiates/Opioids	**397**
Other drugs	47
Unknown Drugs	2
Total Drug Deaths	**446**

There are 24 cases from 2018 that are "pending toxicology". It can take 2 to 3 months to receive toxicology results and for our pathologist to review them and determine the cause of death.

NH 2018 Opioid Mortality Data

- Only 29 of 397 (7%) of opioid deaths were determined to be the result of drugs other than heroin and/or fentanyl
- Extrapolating, these data suggest that of the 47,600 total opioid deaths in the US in 2017, 7% would suggest 2842 died of prescription opioid ODs, not 17,029
- Exaggerated the numbers 6-fold!



Summary and Conclusions

- The process of writing the 2016 CDC Opioid Guideline left much to be desired
  - ❖Yet, the final product, at face value, is generally reasonable
- However, the weaponization of the Guideline has been an abomination – against patients, those who treat them, and society generally
- State legislatures, medical boards, and insurers have had their misguided agendas
  - ❖"Ignorance" has been bliss for some, painful and deadly for others

Summary and Conclusions

- Many predicted that it would be CDC's intent to bastardize the guidelines…with horrific consequences
  - ❖They've stood by idly as draconian involuntary tapers became commonplace
  - ❖Let us pray that FDA's April 9th 2019 warning will stop this practice
- CDC's worst crime against humanity is not the Guideline, but their perpetuation of the myth of an ongoing "prescription opioid crisis"
- Some of us are fighting to right this narrative….
- Let us each do this in our own way – as we owe it to our patients

THANK YOU