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The Opioid Caper Taper: Deciphering and Deflating Daily Dilemmas

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Financial Disclosures

- Dr. Fudin: See next slide
- Dr. Schatman has no conflicts of interest relevant to this presentation.
- Dr. Bettinger has no conflicts of interest relevant to this presentation.



Disclosures

Affiliation	Role/Activities				
Abbott Laboratories	Speaking, non-speakers bureau				
AcelRx Pharmaceuticals	Acute perioperative pain (speakers bureau, consulting, advisory boards)				
BioDelivery Sciences	Collaborative publications, consulting, advisory boards				
International					
Firstox Laboratories	Micro serum testing for substances of abuse (consulting)				
GlaxoSmithKline (GSK)	Collaborative non-paid poster presentations				
Medscape/WebMD	Presentations / webinars on medication assisted treatment (MAT) for opioid-use disorder				
Pharmacy Times	Webinars, writing/publishing				
Practical Pain Management	Co-Editor-At-Large, writing, and editing				
Rockpointe, Inc	REMS opioid presentation/lecture (a continuing education company)				
Scilex Pharmaceuticals	Collaborative non-paid publications				
Salix Pharmaceuticals	Speakers bureau, consultant, advisory boards				
Trnity Health, Inc.	Direct patient care, virtual consultations for pain management akin to a virtual private medical practice				

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Learning Objectives

- Identify situations where tapering is appropriate versus inappropriate
- Delineate between appropriate forced tapering versus shared-decision making tapering
- Demonstrate proper communication techniques when discussing potential tapers with patients
- Recognize effective approaches and responses to minimize psychological consequences when tapering



Pretest Question #1

Online opioid conversion calculators are most inaccurate for...

- A. Hydrocodone and oxycodone
- B. Hydromorphone and oxymorphone
- C. Methadone and fentanyl
- D. None of the above



Pretest Question #2

In which case would an initiation of an opioid taper be appropriate for a patient maintained on extended-release morphine 60mg PO TID?

- A. Abnormal urine drug screen
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- C. The 2016 CDC Guidelines recommended a daily dose limit below 90mg morphine equivalence
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Pretest Question #3

The candidate for an involuntary taper least likely to be successful would be:

- A. A patient with a rigid personality style
- B. A patient diagnosed with a Borderline Personality Disorder
- C. A patient with insurance that won't cover other treatments
- D. All of the above represent poor candidates



Introduction on Tapering Why all the buzz?



Changes in Annual Opioid Prescriptions Compared to Overdose Death Rates From Different Types of Opioids: 2006-2017

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U.S. Opioid prescribing rate maps . CDC, 2018, <u>https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html</u>; Data Brief 329 . Drug overdose deaths in the United States, 1999–2017. CDC, 2019, <u>https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf</u>; Warner, M, et al. Natl Vital Stat Rep 2016; 65(10): 1–15

Why the Conversation Matters

As shown in the prior graph, there have been marked reductions in total opioid prescriptions since 2012

Tapering recommendations and de facto dose ceilings have been enacted by several states and private insurers, driving this trend^{1,2}

• Ultimately can lead to unintended consequences...

1. Kertesz SG, et al. Addiction. 2019;114(1):169-80.





Why are We Tapering?



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Persico AL, Bettinger JJ, Wegrzyn E, Fudin J, Strassels S.. Variability in opioid dose tapers among clinicians. Poster presentation at the American Society of Health-System Pharmacists Midyear Meeting; December 2-6, 2018; Anaheim, CA

Background on Morphine Equivalent Daily Dose What does it all mean and why should we taper? Or should we?



How Have Clinicians and Patients Responded?

Providers

- Rapid tapers or discontinuation
- PCPs cannot find specialists to evaluate appropriateness for continued or new COT
 - including prescribing or RX guidance for continuation or taper
- Clinicians are fearful of regulatory agencies
- Cut off patients due to inadequate training in UDM interpretation
- Third Party Payers
 - Insist on failure of more dangerous alternatives (traditional IR opioids) first
 - -Limited payment for ADFs
- Poor understanding of BUPE p-cology, x-waiver, etc.

Patients

- Increased suicidality
- Increased use of potentially dangerous alternatives
 - -Cannabinoids (CBD v THC) UDS??
 - -Kratom
 - Street opioids (possible risk of fentanyl analogue exposure)
- Blog posts (thousands of comments)
- Decreased / increased QOL, employability
- False accusations in medical record
- BUPE-associated mislabeling (friends, family, ER, etc.)

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2016 MME thresholds by state...



2016 MME and Opioid Deaths Data					
	States with MME Cut-	States with MME Cut-offs			
	offs LESS than 90MME	GREATER than 90MME			
Number of States	6	6			
MME Range	30-80	100-300			
Range of Opioid Deaths per 100,000 persons	8.0 to 37.3	15.1 to 32.7			
Average Opioid Deaths per 100,000	21.9	25.3			

Opioid Dosage and Morphine Equivalency: Implications for Meeting the Standard of Care when Comparing CDC Recommendations to State Policies. State Pain Policy Advocacy Network (SPPAN). August 2016. Available at http://blog.aapainmanage.org/wp-content/uploads/Opioid-Dosage-and-Morphine-Equivalency.pdf

• Gawdat M, Gawdat M, Bettinger JJ, Cleary JH, Fudin J. Analysis of variable morphine milligram equivalent (MME) threshold trends by state. Poster: (8-223). December 5, 2018. American Society of Health-System Pharmacists (ASHP) December 5, 2018. Midyear Clinical Meeting and Exhibition in Anaheim CA.



REACTIONS as of September 2019: Commercial Insurance



Plus

33 States

have enacted some type of legislation related to prescription limits, according to the National Conference of State Legislators.



Issues with MEDD & Opioid Conversion1-4

- Pharmacogenetic variability
- Drug interactions
- Lack of universal morphine equivalence
- Specific opioids that should never have an MEDD
 - -Methadone, Buprenorphine, Tapentadol, Tramadol

- 1. Fudin J, Marcoux MD, Fudin JA. Mathematical Model For Methadone Conversion Examined. Practical Pain Management. Sept. 2012. 46-51.
- 2. Donner B, et al. Direct conversion from oral morphine to transdermal fentanyl: a multicenter study in patients with cancer pain. Pain. 1996;64:527-534.
- 3. Breitbart W, Chandler S, Eagel B, et al. An alternative algorithm for dosing transdermal fentanyl for cancer-related pain. Oncology. 2000;14:695–705.
- 4. Shaw K, Fudin J. Evaluation and Comparison of Online Equianalgesic Opioid Dose Conversion Calculators. Practical Pain Management. 2013 August; 13(7):61-66.

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A Rose By Any Other Name...

DDD

-defined daily dose

OMEQ

-oral morphine equivalent dose

MEDD

-morphine equivalent daily dose

Or more accurately, perhaps we need a...

- -MAE (morphine analgesic equivalent)
- -MTE (morphine toxic equivalent)



EDITORIAL

The MEDD myth: the impact of pseudoscience on pain research and prescribing-guideline development

This article was published in the following Dove Press journal: Journal of Pain Research 23 March 2016 Number of times this article has been viewed

Jeffrey Fudin¹ Jacqueline Pratt Cleary² Michael E Schatman³

¹Western New England University College of Pharmacy, Springfield, MA, ²Stratton VA Medical Center, Albany, NY, ³US Pain Foundation, Bellevue, WA, USA With the opioid-misuse and -abuse problem on the rise, pain practitioners and lawmakers are scrambling for strategies to help mitigate opioid risks. Approaches include opioid-treatment agreements, urine drug testing, prescription-monitoring programs, assorted validated risk-assessment tools for abuse/misuse and opioid-induced respiratory depression (OIRD), biopsychosocial support, and other strategies.^{1–3} Nonopioid pain therapies should be considered and maximized prior to initiating opioid treatment; however, in some cases opioids are the optimal choice for both noncancer

Fudin J, Pratt Cleary J, Schatman ME. The MEDD myth: the impact of pseudoscience on pain research and prescribing-guideline development. Journal of Pain Research. 2016 March; 9:153-156.

Variability in Opioid Equivalence Survey

- Sept 13 thru December 31, 2013.
- 411 Respondents, adjusted after stats to 319
- RPhs, MD/DOs, NPs, PAs
- Convert to Daily MEQ:
 - Hydrocodone 80mg; Fentanyl 75mcg/hr; Methadone 40mg; Oxycodone 120mg;
 Hydromorphone 48mg

Rennick A, Atkinson TJ, Cimino NM, Strassels SA, McPherson ML, Fudin J. Variability in Opioid Equivalence Calculations. Pain Medicine. 2016;17: 892–898.



Variability Survey Results

Morphine equivalent doses (mg) for each opioid medication by specialty

Specialty	Fentanyl	Hydrocodone	Hydromorphone	Methadone	Oxycodone
Pain Management	166 ± 115	85 ± 43	191 ± 68	162 ± 111	167 ± 45
(n=39)	(150)	(80)	(192)	(120)	(180)
Palliative Care	168 ± 57	84 ± 17	188 ± 67	251 ± 166	154 ± 38
(n=35)	(150)	(80)	(192)	(240)	(180)
None of the Above	177 ± 124	88 ± 43	191 ± 50	169 ± 115	177 ± 37
(n=247)	(150)	(80)	(192)	(160)	(180)

Rennick, A., Atkinson, T., Cimino, N. M., Strassels, S. A., McPherson, M. L., & Fudin, J. Variability in opioid equivalence calculations. Pain Medicine. 2016;17:5:892-898. PCINVEEK.

To Taper or Not to Taper?

And if so, what kind of taper should we consider?



To Taper or Not to Taper...

Appropriate Reasons to Taper	Inappropriate Reasons to Taper
Abnormal Urine/Serum Drug Screen	The CDC told me to!
Aberrant behaviors	Tolerance
Refusal to trial non-opioid medications/non- pharmacologic modalities	Stigma/stereotypes
Risks begin to outweigh benefits	Insurance/PBMs (can be tricky)
Lack of significant benefit	
Patient decision	



Major Types of Taper

- Forced Tapering:
 - -Tapering of an opioid in the setting where the patient does not agree with the taper, but must be done for an appropriate reason (generally to reduce harm)

VS

- Shared-decision making tapering:
 - -Tapering in the setting that the patient agrees upon, where there is no end goal or time limit to the taper



Forced Tapering



Forced or Involuntary Tapering

Most commonly in the setting of abnormal UDS/serum screens or aberrant behavior:

-Where continuing opioids could cause immediate harm

■ Specified time limit → HARM REDUCTION



Discussion Around Forced Tapers

- We are NOT police! Or Detectives! Or the FBI, CIA, etc, etc!
- We need to explain why we are tapering the patient off of an opioid:

 It is NOT a punishment, but a measure of safety that is imperative for the patient
 That continuing opioids in that setting would be more dangerous than potential consequences of a taper
- When necessary, refer to substance abuse or behavioral health if and when appropriate
 - Abnormal UDS's are often cries for help!

DO NOT JUST KICK OUT OF THE PRACTICE!



Shared-Decision Making Tapering



Shared-Decision Making Tapering

Most commonly in the setting of lack of response, prolonged period of use, patient desire to reduce, etc.

-Where continuing opioids will not necessarily cause additional harm

Does not need a goal dose

Does not need to have a specified time limit



Discussion Around Shared-Decision Making Tapers

- It is still equally important to discuss with the patient the reasons why tapering could be beneficial
- Patient understanding of the process and that there is a possibility to increase dose back up if not tolerating is imperative
- Cognitive Behavioral Therapy for chronic pain in the context of shareddecision making tapers have demonstrated efficacy in efficiently reducing opioid doses while also reducing pain



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Opioid Taper Caper: Psychological Issues

Michael E. Schatman, Ph.D. Department of Diagnostic Science Tufts University School of Dental Medicine &

Department of Public Health and Community Medicine Tufts University School of Medicine

Psychological Issues

Involuntary opioid tapers range from complete and abrupt to partial and gradual

Withdrawal can be an issue

Symptoms of withdrawal can range from mild to intolerable Darnall BD, Colloca L. Int Rev Neurobiol. 2018;139:129–157.

The symptom of anxiety is likely to be worst at the onset of tapers Darnall BD, et al. JAMA Intern Med. 2018;178(5):707–708.

Yet how many prescribers are willing to order anxiolytics when initiating a taper?

Opioids and benzodiazepines are being tapered concomitantly Austin RC, et al. Fam Med. 2019;51(5):434-437.



Patient Selection

 Historically, all guidelines have emphasized psychologically evaluating patients prior to INITIATING opioid therapy

Cheung CW, et al. Pain Physician. 2014;17:401-414.

- Perhaps it's time for a paradigmatic revision...
 - Should we not be evaluating prior to tapers to see which patients will survive it emotionally and behaviorally?!?!
 - How well will the psychologically inflexible fare?
 - What about the Borderline Personality Disorders?

And the "criminally poorly insured"?

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Patient Selection

So many patients on high-dosage opioid therapy suffer from psychiatric comorbidities

Morasco BJ, et al. Pain. 2010;151:625–632. Kobus AM, et al. J Pain. 2012;13(11):1131-1138. Wasan AD, et al. Anesthesiology 2015;123(4):861-872.

The challenge of opioid tapers among these patients is great

Manhapra A, et al. Subst Abus. 2018;39(2):152-161.

Tapering them can result in activation of PTSD

SAMHSA. Protracted withdrawal. Substance abuse treatment advisory. 2010; 9(1):1-8.

And behaviors including suicide, violence, and going to the streets for opioids

Kertesz SG. Subst Abus. Turning the tide or riptide? The changing opioid epidemic. 2017;38(1):3-8.



Patient Selection

Yet when a hospital corporation wants its patients tapered...

 According to too many, the answer is switching patients to buprenorphine

Moryl N, et al. J Opioid Manag. 2020;16(2):111-118. Chou R, Ballantyne J, Lembke A. Ann Intern Med. 2019;171(6):427-429.

- Any long-term evidence-basis for such?
- Not even a modicum....
- Drs. Chou, Ballantyne & Lembke were unhappy with our response

Schatman ME, Shapiro H, DiBenedetto DJ. Buprenorphine for long-term chronic pain management: Still looking for the evidence. Ann Intern Med. 2020;172:293-294.



Patient Selection/Stigmatization

- Yet, without empirical backing, the anti-opioid crusaders speak "as if" there are supporting empirical data
- Stigmatization is associated with transitioning chronic pain sufferers to an addiction medication!

Schatman ME, et al. Ann Intern Med. 2020;172:293-294.

As was the case with methadone for chronic pain patients Macey TA, et al. J Opioid Manag. 2013;9(5):325-333.

 Stigmatization affects chronic pain severity and function, and is likely to be internalized by the sufferer

Penn TM, et al. Pain Med. 2020[Epub ahead of print].

Stigmatization

Empirically, stigmatization of CPPs has been linked to:

A sense of invalidation by significant others, friends and family

Monsivais DB. J Am Assoc Nurse Pract 2013;25(10):551-556.

A sense of devaluation and blame by others

Toye F, Barker K. Disabil Rehabil 2010;32(21):1722–1732.

Higher levels of catastrophization and depressive symptomatology

Waugh OC, et al. J Pain 2014;15(5):550 e1-10.

Anxiety

Van Brakel W. Psychol Health Med 2006;11:307–334.

Perceived sense of an assault on one's self-esteem and dignity

Werner A, Malterud K. Soc Sci Med 2003;57:1409-1419.



 Clinicians are reluctant to taper patients because they fear consequent dissatisfaction and anger

Kennedy LC, et al. Pain Med 2018;19:2201-2211.

 Without a credible alternative to pain medications, patients can feel abandoned

Matthias MS, et al. J Pain 2017;18:1365–1373.

 Data suggest that pts receiving CBT during tapers report less pain and higher psychosocial functioning than prior to taper

Townsend CO, et al. Pain 2008;140:177–189. Murphy JL, et al. Clin J Pain 2013;29:109–17.



Psychological Issues

- Of course these patients received treatment in full 4-6week interdisciplinary pain management programs
 - Selection bias runs rampant....
 - And try to find an interdisciplinary treatment program....
 - Are all chronic pain patients amenable to CBT?
- Apparently, only the psychologically-flexible ones Åkerblom S, et al. J Behav Med. 2020[Epub ahead of print].
- Lots of extrapolation....smoke and mirrors...

Are "real world" outcomes really rosy?

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Summary and Conclusions

- The consequences of abrupt draconian tapers are more than just physical
 - It's been too easy for the anti-opioid crusaders to ignore psychological response
 - This is critical, given that those chronic pain patients whose psychological sequelae are ignored DON'T get better
 - Perhaps our focus should be not just on who receives opioid therapy, but who are the ideal candidates for tapers, and who will be put at higher risk with involuntary tapers
 - And keep an eye on whether the extant research on "fixing" the damage that tapers can cause actually applies to the patients you treat



Post test Question #1

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Suggested Cases from the Audience

- Taper required because of
 - -PBM or Employer
 - -Patient is dose creeping
 - -PDMP mismatch
 - -Unexpected xyz in urine screen
 - Absence of prescribed xyz



What Questions Do You Have??

