

Action Collaborative on Countering the U.S. Opioid Epidemic



Tapering Guidance for Opioids: Existing Best Practices and Evidence Standards

July 22, 2019
3:00 – 4:30 pm EST



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Agenda

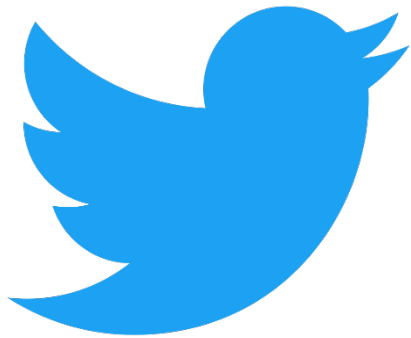
3:00-3:05pm	Overview and Introduction
3:05-3:55pm	Panel Presentations
3:55-4:15pm	Panel Discussion
4:15-4:30pm	Q&A

Questions

Questions are welcome throughout the webinar and will be addressed at the end of the presentation.

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Overview and Introductions

Roger Chou, Panel Moderator

Presenters



Roger Chou

Oregon Health and Science University



Chad Brummett

University of Michigan Medical School



Erin E. Krebs

Minneapolis Veterans Affairs Health Care System
University of Minnesota Medical School



Anna Lembke

Stanford University Medical Center



Anne L. Burns

American Pharmacists Association



Kate Nicholson

Chronic Pain/Opioids Task Force for
the National Centers on Independent Living

Panelist Presentations

Post-Surgical Cases

Chad Brummett

Postoperative Opioid Weaning

**Chad M.
Brummett, M.D.**

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michigan-OPEN.org

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Case review: Planned Surgical Intervention

- 48 year old woman presents for evaluation an laparoscopic abdominal hysterectomy for uterine fibroids
- PMH: Chronic low back pain, depression, anxiety, GERD, and tobacco dependence (1/2 ppd)
- Home medications: Citalopram, alprazolam 0.5mg prn
- SH: No alcohol or illicit drug use
- FH: Chronic pain, deceased father with history of alcoholism

Perioperative Course

- Preop management: Patient given a prescription for 30 tablets of 5mg hydrocodone with acetaminophen in the preop visit 7 days before surgery
- Surgery: Uneventful laparoscopic hysterectomy under general anesthesia
 - Local anesthetic used at port sites (0.5% bupivacaine)
 - Postoperative intravenous and oral opioids for the inpatient stay
 - Schedule oral acetaminophen
- Discharge: Discharged late morning postoperative day 1
 - Patient state that she used half of the hydrocodone prescribed in the preop visit
 - Prescribed an additional 60 tablets of 5mg hydrocodone
 - Told to use acetaminophen and ibuprofen regularly for the first 3 days then as needed

Post-discharge Course

- Two weeks after surgery, the patient calls for a refill of her hydrocodone
 - Prescribed an additional 45 tablets
- Calls again 5 weeks after surgery again requesting refill; however, cross-covering surgeon denies the refill
- Patient seeks care in the ER multiple times and is administered intravenous opioids and given a prescription for 30 tabs 5mg oxycodone and told to follow up with primary care (PCP)

New Persistent Opioid Use



6%

Brummett CM et al. *JAMA Surg.* 2017; 152(6).



8%

Goesling J et al. *Pain.* 2016;157(6).



13% Johnson SP et al. *JHS.* 2016;41(10).



13% Deyo RA et al. *Pain.* 2018. Epub.



5%

Harbaugh CM et al. *Pediatrics.* 2017. Epub.



10%

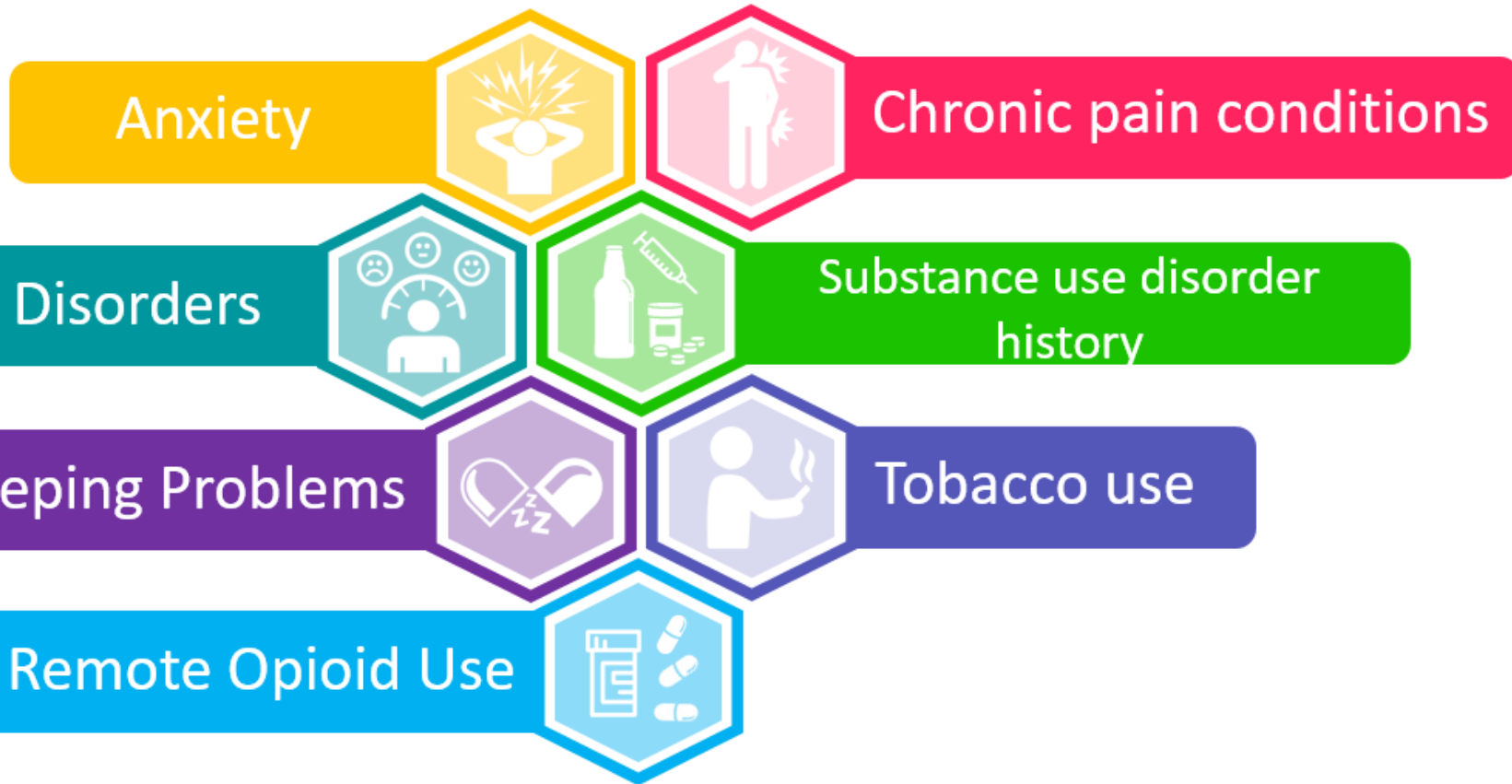
Lee JS et al. *JCO.* 2017. Epub



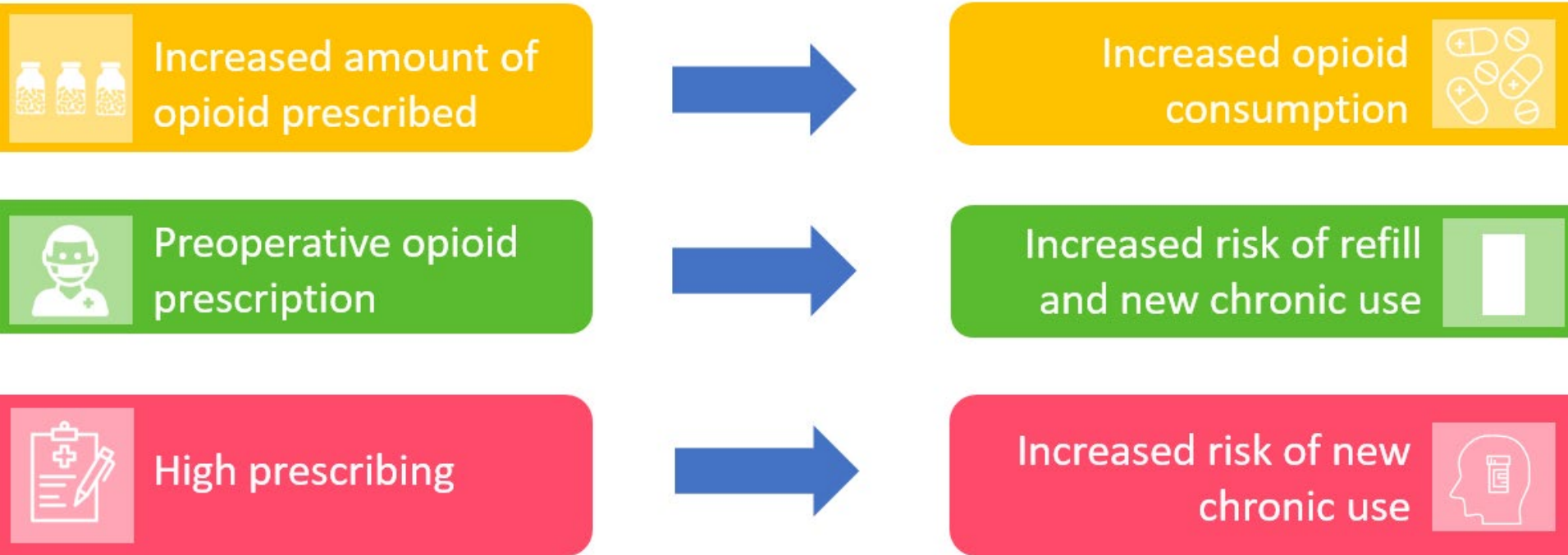
19%

Marcusa D et al. *PRS.* 2017;140(6).

Who is at risk for New Chronic Opioid Use?



Postoperative Prescribing Practices Influence Outcomes



Bicket MC, et al. Am J Surg 2019; Brummett CM, et al. JAMA Surg 2017; Gil JA, et al. Am J Sports Med 2019; Larach DB, et al. Annals Surg 2019

The amount of opioid prescribed after surgery was not associated with patient satisfaction or refill rate



Bateman BT, et al. Obstet Gyn 2017; Howard R, et al. JAMA Surg 2018; Lee JS, et al. JAMA 2017; Sekhri S, et al. Ann Surg 2017

Prescribing Recommendations

UPDATED 2019

Procedure	Oxycodone* 5mg tablets	Procedure	Oxycodone* 5mg tablets
Dental Extraction	0	Carotid Endarterectomy	0 - 10
Thyroidectomy	0 - 5	Cardiac Surgery via Median Sternotomy	0 - 15
Laparoscopic Anti-reflux (Nissen)	0 - 10	Cesarean Section	0 - 15
Appendectomy – Lap or Open	0 - 10	Hysterectomy – Vaginal, Lap/Robotic, or Abdominal	0 - 15
Laparoscopic Donor Nephrectomy	0 - 10	Breast Biopsy or Lumpectomy	0 - 5
Hernia Repair – Major or Minor	0 - 10	Lumpectomy + Sentinel Lymph Node Biopsy	0 - 5
Sleeve Gastrectomy	0 - 10	Sentinel Lymph Node Biopsy Only	0 - 5
Laparoscopic Cholecystectomy	0 - 10	Wide Local Excision ± Sentinel Lymph Node Biopsy	0 - 20
Open Cholecystectomy	0 - 15	Simple Mastectomy ± Sentinel Lymph Node Biopsy	0 - 20
Colectomy – Lap or Open	0 - 15	Modified Radical Mastectomy or Axillary Lymph Node Dissection	0 - 30
Ileostomy/Colostomy Creation, Re-siting, or Closure	0 - 15	Total Hip Arthroplasty	0 - 30
Open Small Bowel Resection or Enterolysis	0 - 20	Total Knee Arthroplasty	0 - 50
Prostatectomy	0 - 10		

*If prescribing hydrocodone 5mg, the number of tablets remains the same as listed above.



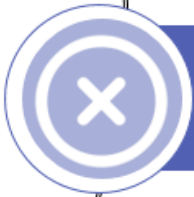
Opioid Prescribing for Opioid Naïve Patients



Prescribe only 1 short-acting opioid



No long-acting opioids



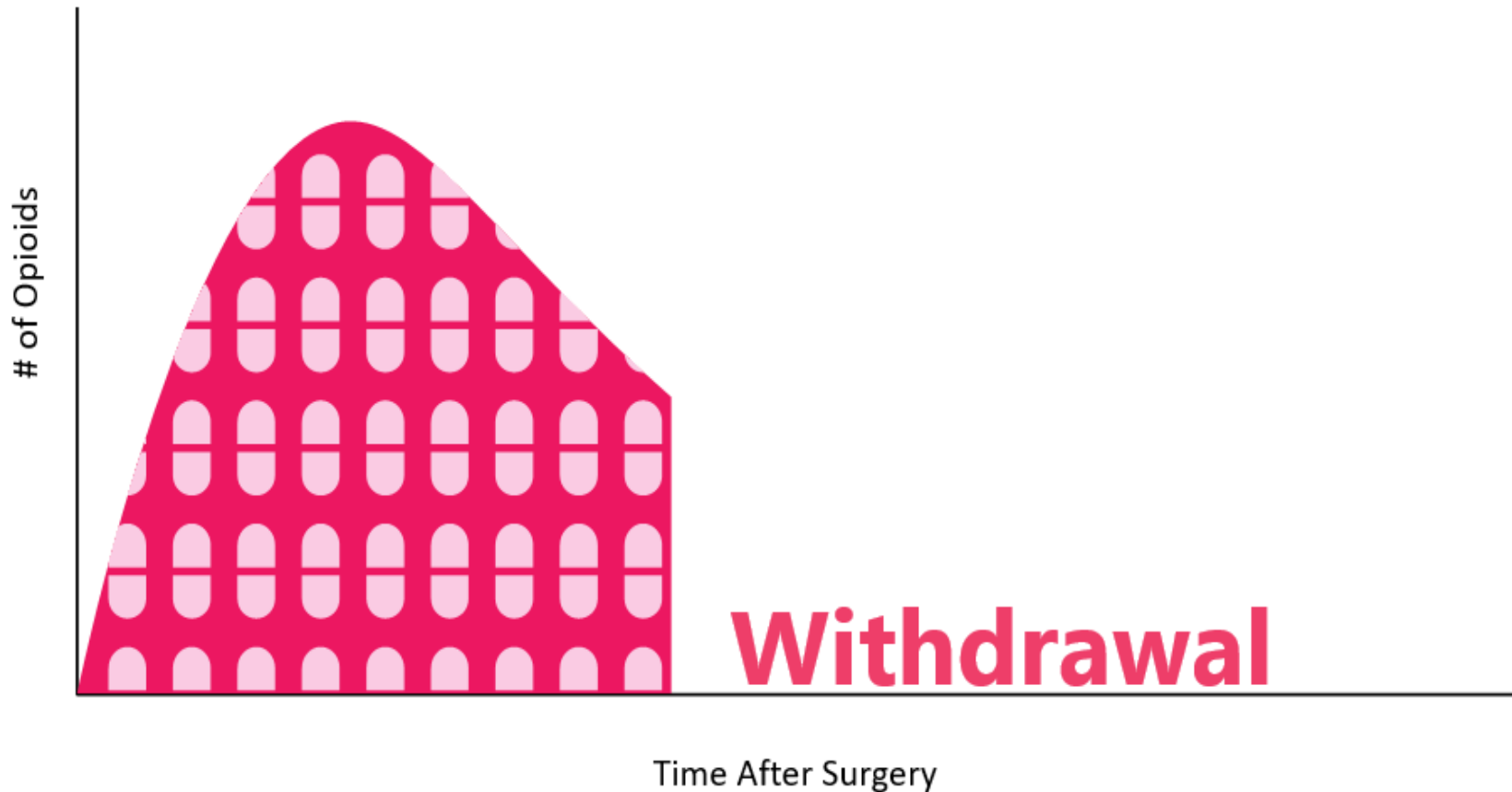
Avoid pre-op opioid prescription



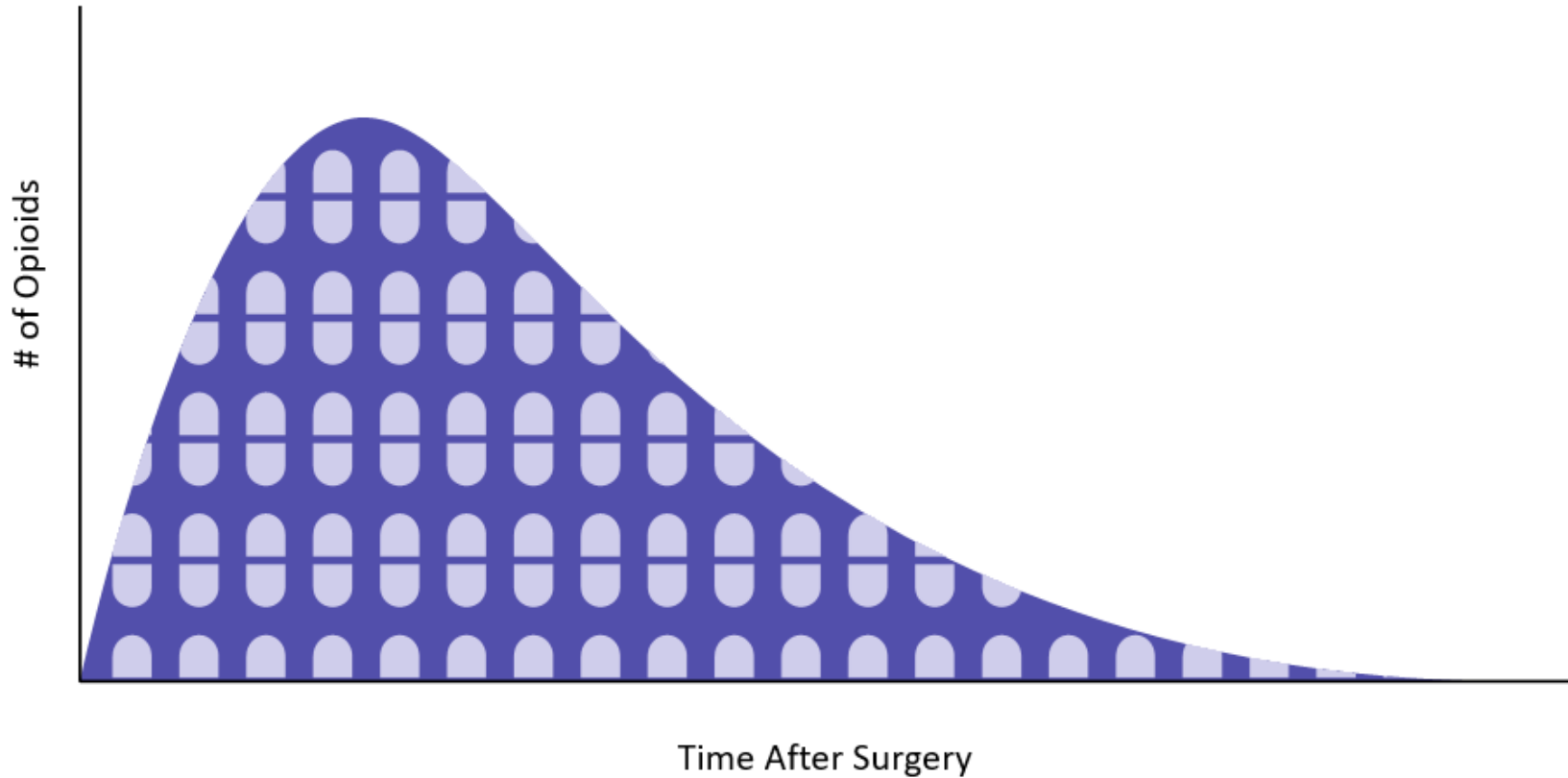
Prescribe naloxone in high-risk patients

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Abrupt Discontinuation Leads to Withdrawal



Weaning Plan Needed With Prolonged Use



Case Resolution

- PCP visit 10 weeks after surgery. Patient notes 4-6 tabs of oxycodone/day and acknowledges withdrawal symptoms between doses.
 - Notes reason for opioid use as preoperative pelvic and low back pain and states that incisional pain has long resolved.
- Slow taper plan written by PCP and successfully weaned weeks later.
- Referred to pain medicine for management of her preoperative chronic and low back pain.

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@drchadb



Simple Legacy Cases

Erin Krebs

Case: New patient to your clinic

- 60 y/o man seeking new primary care physician
- CC: "I need my pain meds refilled."
- Problem list: Chronic back pain (on opioids >15 years), depression, anxiety, type 2 diabetes with kidney disease, obesity, sleep apnea, tobacco dependence (1 pack/day)
- Medications include: morphine SR 60 mg 3x/day, oxycodone/APAP 8 tabs/day, clonazepam 2 mg 3x/day
- She reports no alcohol, illicit drugs, or opioid use problems
 - *Chart review shows adherence with visits and refill requests, PDMP consistent with report, urine drug test results consistent with prescribed meds*

Patient-centered opioid management

- Patient-centered care is “respectful of and responsive to individual patient preferences, needs, and values”
 - *Is not a customer service activity*
 - *Is not an alternative to evidence-based care*
- Patient-centered pain care considers evidence of treatments’ potential benefits and harms in context of patient goals and values

Institute of Medicine. Crossing the quality chasm. National Academies Press, 2001

Two types of goals

- Functional goals should be mostly within patient control
- “Big picture”/life goals
 - *Linked to values and aspirations*
 - *Not usually achievable in the short term*
 - *Important for grounding treatment decisions and generating short-term goals*
- Short-term goals
 - *Linked to “big picture”/life goals*
 - *Should be achievable in short term*
 - *May be SMART (Specific, Measurable, Achievable, Relevant, Time-bound)*
 - *Helpful for reframing pain conversation and promoting behavior change*

Questions to Ask

- What/who is important to you?
- What is a typical day for you?
 - *Tell me about yesterday.*
- How does pain affect your life?
 - *Is there anything you would like to do that you can't do because of pain?*
 - *How would your life be different if your pain was well controlled?*
- How are the medications working for your pain?
 - *What do you mean by ...? How can you tell ... ?*

Case: Additional Information

- 60 y/o man with chronic back pain on long-term opioids
- Values: family, independence, reliability as “go to” person
- Current reality: most days spent in bed, pain prevents valued activities, not trusted to be alone with young grandchildren, unable to attend important family events, no travel in past five years
- Perceived opioid effects: “take the edge off,” “the only way I can function”
- Big picture goals: being an involved grandparent, traveling, taking care of household and family

Key tasks for successful tapering

- Provide individualized rationale for dose reduction
 - *Patients (unlike clinicians) may fear uncontrolled pain and suffering more than overdose, death, or addiction*
 - *Most patients perceive personal risk of overdose as low*
 - *Most patients have priorities for pain treatment (emotional well-being, physical activity, sleep, participation) beyond simple pain relief*
- Elicit and address concerns about uncontrolled pain, withdrawal, abandonment, and loss of control
- Involve patients in developing tapering plan

Frank J et al. Pain Med 2016;17:1838-1845; Henry GS et al. J Pain 2019;20(2):181-191; Kennedy LC et al, Pain Med 2018;19:2201-2211; Matthias MS et al. J Pain 2017;18(11):1365-1373; Wilder CM, et al. J Addict Dis 2016

Shared decision-making

- Involves patient and physician sharing information (both directions), deliberating about options, and agreeing to a course of action
- Does not require physician to give up prescribing decision authority
 - *You don't have to put every decision on the table*

Charles C et al. Social Sci Med 1999;49:651-61; Makoul and Clayman. Patient Educ Couns 2006;60(3):301-12.

Degree of decision sharing

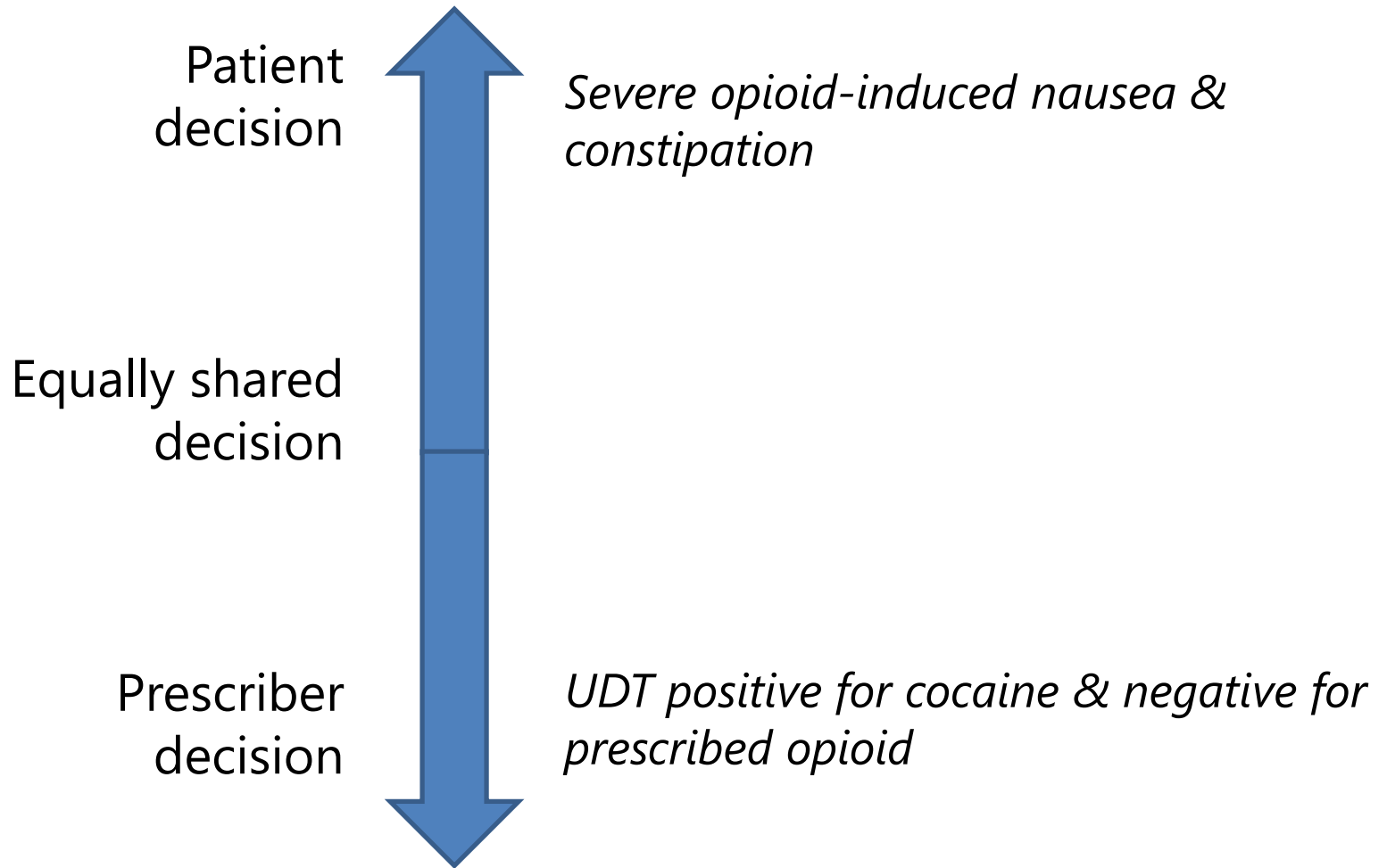
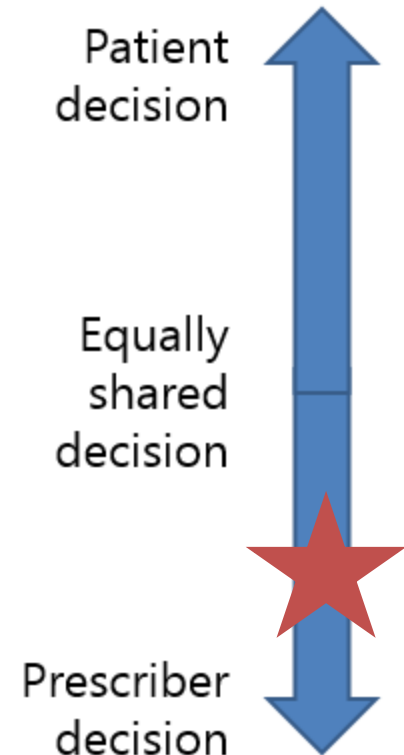


Figure adapted from Makoul and Clayman. *Patient Educ Couns.* 2006;60(3):301-12.

Case: Individualized assessment

- Benefit from therapy: None apparent. Severe pain interferes with function and participation
- Risk factors for serious harm: high-dose, benzodiazepines, CKD (with morphine). No evidence of impending overdose. No evidence of misuse
- Adverse effects: sleep apnea, fatigue, low motivation, possible worsening of depression
- Plan: Non-urgent, doctor-led, patient-involved tapering



Questions to ask

- How ready are you to make a change in your pain meds?
- What are your concerns about reducing pain meds?
 - *Have you tried to reduce the dose before?*
 - *Have you run out of medication before?*
 - *Do you know anyone who's gone through this?*
- We can set a target for reducing the dose or just take it one step at a time. What do you prefer?
- I like to make one change at a time and we have options for where to start... What feels most comfortable to you?
- I like to schedule follow-up for when you've had a chance to get used to the change—maybe in 3-6 weeks—what do you prefer?

Case: Resolution

- Opioids tapered to lower daily dose
 - *Tapered off morphine SR over 24 months (15 mg at a time, alternating with reductions in oxycodone)*
 - *Reduced oxycodone/apap 5/325 mg to 3 tabs/day*
 - *Continues clonazepam 2x/day*
- Persistent moderate to severe pain
 - *Improved self-management*
- Dramatically improved physical & social function
 - *Resumed travel and activities, regularly cares for grandchildren*
 - *Daughter: "I got my dad back."*
- Moderate increase in PTSD symptoms midway through taper → taper pause, mental health referral

Alternative case resolution scenarios

- Rapid pain-free taper to discontinuation
 - *Yes, this does happen!*
- Major decompensation during tapering
 - *Reconsider approach... too fast? Not enough support?*
 - *Evaluate for re-emergent mental health problems*
 - *Evaluate for opioid use disorder*

Selected OUD criteria often applicable in long-term opioid therapy:

- *Unable to cut down or control opioid use*
- *Continued opioid use despite social/interpersonal problems*
- *Continued opioid use despite physical/psychological problems*
- *Activities given up or reduced due to opioid use*

Complex Legacy Cases

Anna Lembke

The BRAVO Protocol: A Biopsychosocial Approach to Opioid Tapers

Anna Lembke, MD
Associate Professor, Stanford
University School of Medicine
Stanford, CA

Disclosures

I have been retained as an expert witness on the plaintiff side in federal and state opioid litigation.



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Original Release Date:

08/02/18

Expiration Date: 08/02/21





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▲ **Tapering – Guidance & Tools**

Overview

Risk Benefit Assessment & Flowchart

Opioid Tapering Flowchart

BRAVO Overview

Tapering – Guidance & Tools

Clinical Update Dec. 2018

Overview

Over the last 20 years, the liberal prescribing of opioids for chronic pain has created a population of patients who been on long term opioid therapy (LTOT) for several years if not decades. Many patients are on doses well above the CDC recommended upper limit of 90 Morphine Equivalent Dose (MED) for new starts. Patients, however, may be reluctant to taper, fearing withdrawal and increased pain. Prescribers are also asking whether or not tapering is necessary if the patient is stable and compliant on their current dose. Yet, overdose rates continue to be high compared to historical standard and it is well established that patients on



B=Broaching the subject



Sherry's Story (Composite Case)

- At age 18, developed a mysterious pain in her abdomen that spread to her whole body.
- All medical work-up negative.
- Saw many doctors over time, and was diagnosed with fibromyalgia and rx'd opioids.
- By age 30 was taking ~800 MED's, prescribed by "the most compassionate doctor I ever saw."
- Sherry always took her opioids exactly as prescribed.

Sherry's Story

- Despite meds, pain no better, function worse.
- On high dose opioids, Sherry spent more time in bed.
- Her husband remarked she was "detached from family life." Sherry was not aware of being more detached.
- Her pain increased over time.

B=Broaching the subject

How to talk to patients

- Carefully Considered: "Sherry, I scheduled some extra time for us today because I want to discuss a very important topic with you. ***I've been thinking a lot about your chronic pain*** and how to help you with that."
- Gentle Introduction: "I would like to suggest that we taper you down and maybe even off your opioid medication."
- Anticipate Fear: "Now, I know the very thought of an opioid taper is terrifying for you, and you're not alone in that ... it's totally normal to feel afraid about going down on your dose, especially after you've been taking opioids for so long. But, please hear me out, and let me tell you the reasons why I think it's a good plan for you."

Medicolegal considerations and the inherited patient

- It's okay to continue the high dose at first, as long as you:
 - Demonstrate and document you are weighing the risks and benefits of continued opioid therapy
 - Check the PDMP, urine toxicology, and other collateral
 - Discuss overdose prevention and offer naloxone
 - Build a therapeutic alliance that anticipates the taper
 - Discuss the topic with the patient

R=Risk Benefit Calculator



R=Risk Benefit Calculator

How to talk to patients

- First Do No Harm: “I think we need to get you off opioids because they’re doing more harm than good. Your pain is no better than before you started on opioids, and may even be worse.”
- Functionality: “More importantly, you’re less functional than you used to be, spending most of the day in bed. Your husband reports you are detached from family life. Opioids can do that, even when we’re not aware of them doing that.”
- Medical Decision-Making: “For all of those reasons, we’re going to work together to slowly taper you off these medications.”

Tapering may improve pain



RESEARCH
EDUCATION
TREATMENT
ADVOCACY



The Journal of Pain, Vol ■, No ■ (■), 2016: pp 1-11
Available online at www.jpain.org and www.sciencedirect.com

Prescription Opioid Taper Support for Outpatients With Chronic Pain: A Randomized Controlled Trial

Mark D. Sullivan, Judith A. Turner, Cory DiLodovico, Angela D'Appolonio, Kari Stephens, and Ya-Fen Chan

Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle, Washington.

Abstract: Patients receiving long-term opioid therapy for chronic pain and interested in tapering their opioid dose were randomly assigned to a 22-week taper support intervention (psychiatric consultation, opioid dose tapering, and 18 weekly meetings with a physician assistant to explore motivation for tapering and learn pain self-management skills) or usual care (N = 35). Assessments were conducted at baseline and 22 and 34 weeks after randomization. Using an intention to treat approach, we constructed linear regression models to compare groups at each follow-up. At 22 weeks, adjusted mean daily morphine-equivalent opioid dose in the past week (primary outcome) was lower in the taper support group, but this difference was not statistically significant (adjusted mean difference = -42.9 mg; 95% confidence interval, -92.42 to 6.62; $P = .09$). Pain severity ratings (0-10 numeric rating scale) decreased in both groups at 22 weeks, with no significant difference between groups (adjusted mean difference = -.68; 95% confidence interval, -2.01 to .64; $P = .30$). The taper support group improved significantly more than the usual care group in self-reported pain interference, pain self-efficacy, and prescription opioid problems at 22 weeks (all P -values < .05). This taper support intervention is feasible and shows promise in reducing opioid dose while not increasing pain severity or interference.

Perspective: In a pilot randomized trial comparing a prescription opioid taper support intervention to usual care, lower opioid doses and pain severity ratings were observed at 22 weeks in both groups. The groups did not differ significantly at 22 weeks in opioid dose or pain severity, but the taper support group improved significantly more in pain interference, pain self-efficacy, and perceived opioid problems. These results support the feasibility and promise of this opioid taper support intervention.

© 2016 by the American Pain Society

Key words: Chronic opioid therapy, opioid dose taper, pain intensity, pain interference, pain self-management.

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A=Addiction Happens

How to talk to patients

- Mea Culpa: “When we [doctors] first started prescribing opioids more liberally for chronic pain in the 1980s, we believed the risk of becoming addicted, as long as we were prescribing them for a medical condition, was very low.”
- Pain Patients Get Addicted Too: “Since then, we have learned a lot and now know that even when patients are being prescribed opioids for a legitimate pain condition, and take them as prescribed, they can become addicted to those opioids.”
- Anticipation: “So, if in the process of a slow and medically supervised taper, you are unable to come off opioids, it is possible that you too have become addicted. If that’s true for you, you’re not alone. Millions of people have become addicted to prescription opioids through a doctors’ prescription.”
- Good Treatment: “The good news is there’s treatment for addiction, which may even help your pain.”

Risk of opioid misuse ~ 25%

Risk of opioid addiction ~ 12%

- Systematic review and meta-analysis from 38 studies. Across most calculations, **rates of misuse** averaged between **21% and 29%** (range, 95% confidence interval [CI]: 13%-38%). **Rates of addiction** averaged between **8% and 12%** (range, 95% CI: 3%-17%).
 - Used real world and population based studies.
 - Vowles, K.D. Pain, 2015.
-

Using the DSM-V criteria to diagnose “opioid use disorder” in the context of a medically managed opioid taper

- Tolerance and withdrawal: These criteria don't count when patients taking opioids as prescribed.
- DSM-V Criteria (need at least 2 beyond tolerance and withdrawal)
 - Control
 - Compulsions
 - Craving
 - Consequences

Sherry's story

- At 800 MED's, Sherry did not meet DSM-V criteria for opioid use disorder.
- But as we attempted to taper her over 18 months, it became apparent she had developed an opioid use disorder, based on:
 - She was unable to adhere to even minimal dose decrements (Control)
 - She was unable to taper despite ongoing serious medical consequences as a result of opioids, including hypoxemia, somnolence, depression, cognitive dysfunction (Consequences)

Sherry's story

- We transitioned her to buprenorphine
- She experienced improvements in mood, cognition, activity level, alertness, breathing
- Her pain did not improve, but also did not get worse

Sublingual Buprenorphine

- FDA approved treatment for opioid use disorder
- 3 unique properties
 - Long half life
 - High binding affinity
 - Ceiling effect on euphoria and respiratory depression



<https://doi.org/10.17226/25310>

V=Velocity and Validate



V=Velocity and Validate

How to talk to patients

- Validation: "I know this is scary, but we'll do this together, and I'll support you as much as I can."
- Autonomy: "Let's start wherever you feel comfortable. You want to taper your fentanyl before your oxycodone? That's fine."
- Velocity: "You'll get a say in how fast we taper. If you need to take breaks from going down, we can hang out at one dose for a couple of months, until you're ready to continue. The important thing is not to go backwards, because you'll lose all that hard work you put in."
- Expectations: "Every time you decrease your dose, your pain will increase. This isn't the pain you'll have to live with. This also isn't a sign of your underlying pain disorder getting worse. This is opioid-withdrawal-mediated pain. If you can just stick with it, you'll feel better in 2-4 weeks. If you don't, we'll slow down the taper."
- Outcomes: "There's a chance your pain may actually improve off of opioids. Opioids taken every day for a long period of time can make pain worse, by changing pain perception thresholds."

O= Other Treatments for Pain (and ways to talk about pain)



O= Other ways to talk about pain

Summary points

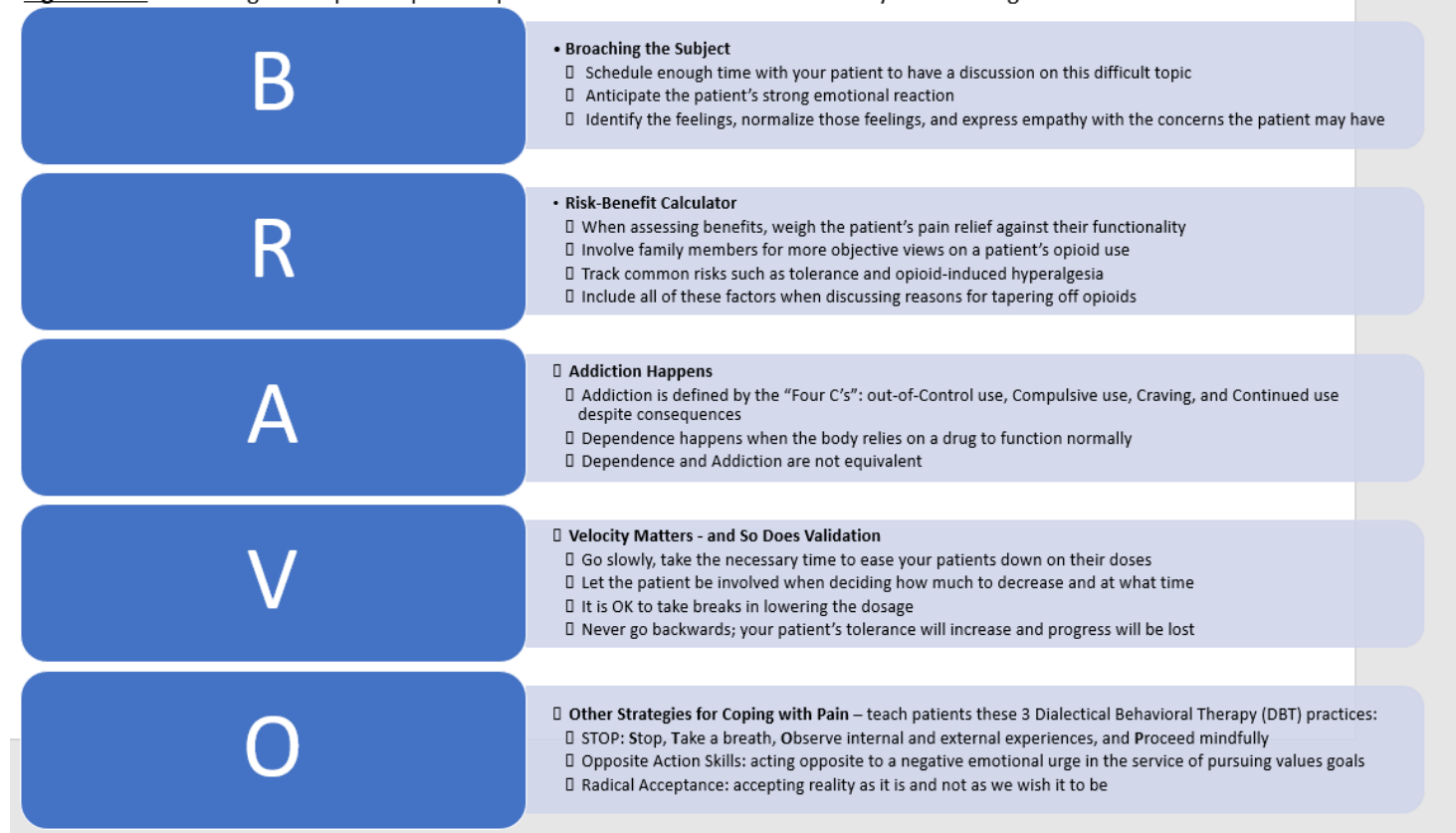
- Non-opioid medications
- Non medication treatments
- Mindfulness
- Opposite action
- Radical acceptance

Sherry's Story

- Sherry **continues on buprenorphine** SL 8 mg daily **two years later**
- Overall pain is slightly improved. Function is significantly improved.

BRAVO summarized

Figure 14-4: Discussing Prescription Opioid Dependence with Patients in the Primary Care Setting



<http://stan.md/taper-off-opioids>

Patient/Caregiver and Pharmacy Perspectives

Anne Burns

Objectives

- Discuss pharmacists' roles in pain management, including opioid tapering
- Describe caregiver perspective for patient with chronic pain

Pharmacist Accessibility to Assist with Opioid Tapering



Leveraging Pharmacists to Assist with Opioid Tapering

- Provide opioid dosage conversions
- Deliver tapering services in team-based care models
- Assist in monitoring patients' pain medications and other medications – collaborative care approach
 - How medications are working, side effects
 - Identify drug-drug interactions and other medication-related problems
 - Reinforce goals of therapy - *****sharing of information is critical**
 - Consult prescription drug monitoring programs (PDMPs) and communicate with prescribers
- Educate patients and caregivers about safe and effective use of opioids
 - Risks, storage and disposal, naloxone

Our Pain Journey

- Chronic pain since 2006
 - 2006 – spinal fusion L5/S1
 - 2013 – removal of benign tumor and ganglionectomy at T7
 - 2015 – spinal fusion at T7-T8
 - 2018 – nerve damage during neck lymph node biopsy – atrophied trapezius muscle
- Currently 6 physicians and 1 PT

Our Pain Journey

- Impact on daily living
 - Neuropathic pain significantly exacerbated by activity
 - Shoulder pain impacting daily functions like eating and writing
- Goals
 - ***Pain relief
 - Walk the dog
 - Play the guitar
 - Play with grandkids
 - Travel
- Experience with opioid tapers

From the Patient/Caregiver Perspective

- The data on opioids
 - 21-29% of patients on opioids misuse them
 - 8-12% of patients on opioids develop opioid use disorder
- OR
- **71-79%** of patients on opioids do not misuse them
- **88-92%** of patient on opioids do not develop opioid use disorder
- Living with pain is highly stressful – navigating the health care system in the midst of the opioid epidemic adds to the stress
 - Lack of objective measurement – validation concerns
 - Stigma
 - Lack of insurance coverage for some treatments

Vowles, KE, et.al. Pain. 2015;156(4):569-576.

From the Patient/Caregiver Perspective

- Integrated pain management programs are difficult to find
- Tapering questions:
 - What are the alternatives to opioids for managing pain (nonopioid medications and nonpharmacological therapies/treatments)?
 - How to find them?
 - Other specialists for medications- e.g., neurology, rheumatology
 - Behavioral health - e.g., Cognitive Behavioral Therapy
 - Restorative therapies – e.g. PT, OT
 - Interventional procedures – e.g. injections, neuromodulation
 - Complementary and Integrative Health – e.g., acupuncture, massage
 - Are they covered through insurance?

HHS Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. 2019. <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>

From the Patient/Caregiver Perspective

- Nonopioid medications
 - Consider side effects
 - Onset of full action for some medications can take 3-4 weeks
 - Formulary tiering/prior authorization impacts out of pocket costs and access



Patient/Caregiver Tapering Requests

- Patient-centered, compassionate care
- Change the dialogue from a one size fits all *tapering off opioids* to also include *tapering to safer levels*
 - Monitor for function improvements or worsening
- Recommend or refer for nonopioid alternative pain treatment options as part of tapering process
- Policymakers and providers:
 - Develop evidence-based policies and practice models that foster coordinated, multimodal care for patients with chronic pain
 - Continue to foster research on pain treatment, including the role of opioids in patients with diverse types of chronic pain

Key Messages

- Patients need an individualized, patient-centered approach to pain management, including for opioid tapering – function and quality of life are significant priorities for patients/caregivers
- Patients with chronic pain and their caregivers need assistance in navigating the health care system to find optimal, coordinated pain management services
- Pharmacists have medication expertise and patient access that can be better leveraged in pain management, including opioid tapering

Health Policy and Patient Perspectives

Kate Nicholson

My Story



Non-Ideal Tapering

- Where tapering is indicated, where risks > benefit, conversations about the subtleties of tapering are important because we need evidence-based, scalable protocols *but*
- In the current policy environment, poorly implemented, non-ideal tapering is occurring and it is causing desperation and harm.
- Policies arguably have incentivized abrupt tapers, forced tapers and actual and constructive patient abandonment.
- With pendulum swing of pressures to prescribe and then de-prescribe, many healthcare workers and patients are caught in the cross-hairs.

Oversight at Every Level of Healthcare

- State laws.
- Major pharmacy chains setting day/dosage limits.
- Private and public payers delaying or denying fills.
- DEA/DOJ surveillance of physicians.

Prosecutors notify 30 doctors about excessive opioid prescriptions



U.S. Attorney BJay Pak at news conference announcing indictment of former medical examiner Joe Burton. (Curtis

Patient Harms: An Unintended Effect

- Human Rights Watch Report:
 - Found that **clinicians were tapering involuntarily out of fear of liability even against their best medical judgment.**
 - **Diverse rationales** – DEA/law enforcement, generic fear of liability, state authority, pressure from payers.
 - “I turn away new patients if they are on a high dose. These are folks who **records checked out, they are good citizens. But I can’t afford to burn down my life and lose my license.**”
- Interagency Task Force had similar findings.
- **Recent JAMA study: 40% of primary care doctors refuse care for new chronic pain patients using opioids.**

I Hear of Tragic Outcomes - Daily

- PATIENTS WHO ARE ACUTELY SUICIDAL
 - “I am a pain patient who can no longer get treatment for my pain caused by a spinal cord injury. I do not want to [end] my life. I want to live. I want to see and hold my grandson. If I cannot get help from someone, somewhere, I will not be here next week.”
- FAMILIES WHO HAVE LOST LOVED ONES
 - “My brother passed away. Over the last year, his doctors began to significantly cut down his pain medication. He was truly at the end of his rope.”

Tragic Outcomes...

- PATIENTS WHOSE LIVES ARE SEVERELY DISRUPTED
 - “I was independent - now I have to get my kids to help me because I am bedridden ...so I get disability now and lost my house.”
 - “The tears, grieving, financial loss cannot be described [with] my husband bedridden in immense pain. I am so tired now and we are financially devastated.”

Stigma and Barriers to Care Arise from Laws and Policies

- There is sound evidence that systemic barriers to care and stigma arise from laws and policies.
- Given the breadth of the regulatory capture – this is a systemic problem.
- In some cases the policies themselves contain a mandate to taper across populations: Oregon Medicaid proposal.
- Recent disciplinary action: New Hampshire State Medical Board.

Emerging Evidence Requires Caution

- MEDICAID BENEFICIARIES IN VERMONT AT HIGH DAILY DOSES (120 MME for > 90 days)
 - **The median length of time to discontinuation was one day**
 - **49% had an opioid-related hospitalization or emergency department visit**
- KAISER COLORADO
 - Simply destabilizing dosage resulted in a **3-fold increased risk of opioid overdose** even after controlling for dose.
 - For those who make it through - the risks go down with discontinuation.

BOTH CONCLUDED THAT MORE RESEARCH IS NEEDED

KAISER STUDY URGES POLICYMAKERS TO CONSIDER RISKS BEFORE MAKING POLICY

Major Stakeholders Take Position Against Forced Opioid Tapering



FDA Response

- FDA Issued Warning and Label Change on April 9

FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering

FDA Drug Safety Communication

[4-9-2019] The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

CDC Clarification – Strict Application of Guideline May Cause Harm

NEJM: Strict or Hard Limits, Overreach to Unintended Populations

Director Redfield: The Relevant Calculus for LTOT Patients is **Benefit vs. Risk**, not a set MME.



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE
Apalutamide for Metastatic, Castration-Sensitive Prostate Cancer

Unlocking the Opportunities for Health Care Delivery Transformation

Perspective
No Shortcuts to Safer Opioid Prescribing

Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.

“The Guideline does not endorse mandated or abrupt dose reduction or discontinuation, as these actions can result in patient harm. The guideline includes recommendations for clinicians to work with patients to taper reduce dosage **only when patient harm outweighs patient benefits of opioid therapy. The recommendation on high-dose prescribing focuses on initiation. The Guideline offers **different** recommendations for patients already on opioid dosages greater than 90 morphine milligrams equivalent per day.”**

Should We Apply One-Size to All?

- Even in the best voluntary tapering studies, there are exemptions and outliers. Policy must leave room for a patient-centered approach and individual HCP treatment plans.
- Chronic pain is a very broad category – progressive illnesses other than cancer also cause serious pain and many people do well on opioid therapy.
- Palliation and functionality are both valid goals of opioid maintenance.
- **Be realistic about the environment.** Not everyone receives treatment at Stanford and Michigan – most don't. Many alternatives to treat pain remain poorly covered and/or inaccessible.
- We all need to interrogate our myopias in making policy (danger of story, case study).

A Prophylactic Approach is Needed

- Rather than press tapering as a policy matter– we need a prophylactic approach that protects patients.
- We need to implement the CDC clarifications. The misapplication has been so fast, and wide-reaching.
- We need evidence that the tapering protocols are scalable and successful before incentivizing them.
- We need to assure the absence of patient harm and have established and tested prescriber/patient infrastructures for safe monitoring in all opioid therapy.

Moderated Discussion



Q&A

Please use the comment box on your screen

Thank you

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