Rethinking Opioids for Pain: Current Research and Considerations

ASAM Pain & Addiction: Common Threads

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Daniel Alford, MD, MPH **Disclosures**

 I serve as course director for safer opioid prescribing CME funded by an unrestricted educational grant awarded to Boston University by the REMS Program Companies as part of the FDA's Opioid Analgesic REMS program

I have not received any direct payment from industry for these activities

Roadmap

- Background
- Acute Pain and Opioids
- Chronic Pain and Opioids
- Safer Prescribing for Chronic Pain
- Opioid Discontinuation
- Mistrust and Patient Experience
- Putting it Together



Background

Looking Back to Move Forward

- Pain as the 5th vital sign, patient satisfaction surveys
- Opiophobia and pseudo-addiction
- Extended-release opioids, rate hypothesis, over-marketing as safe and effective
- Societal medication mania, unrealistic expectations "painkillers"
- Confrontation phobia, fear

JCAHO Pain Management Standards Are Unveiled

Donald M. Phillip Patient Satisfaction, Prescription Drug Abuse, and Potential Unintended Consequences

Aleksandra Zgierska, MD, PhD

boards can determine that care is substandard if clinicians se components. Before prescri **JAMA 2012** be expected to recommend

American Opiophobia: Customary Underutilization of Opioid Analgesics

John P. Morgan, MD

Opioid pseudoaddiction — an iatrogenic syndrome ¹

David E. Weissman *,2 and J. David Haddox **



ever invented

Not guilty plea in death of Ky. doctor CORNETTSVILLE, Ky. -Apatient who is charged with They're the most fatally shooting a popular compowerful munity doctor at a rural clinic a painkillers

few hours after being denied narcotics pleaded not guilty

medical chart.

"He was shot in the head." Perry County Coroner Jimmy Maggard said. "He had a pen in his hand."

Police don't yet have a motive.

Looking Back to Move Forward continued

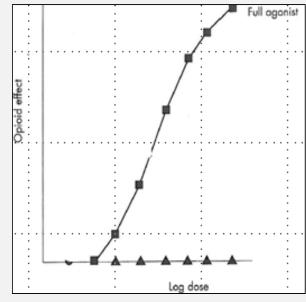
- Lack of training for all healthcare providers
- Financial misalignment favoring use of medications
- Lack of access to comprehensive, multimodal pain management services

Measuring and documenting subjective benefits (pain, function, quality of

life) and harms are challenging

Clinically it is difficult to distinguish...
inappropriate drug-seeking (i.e., misuse) from...
appropriate pain relief-seeking

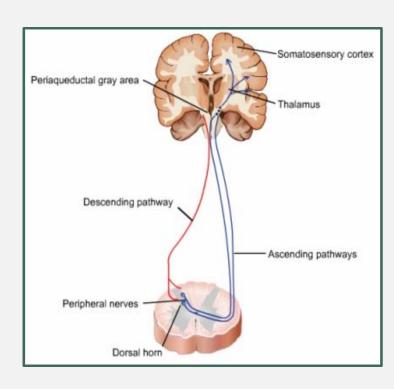
 Opioids as last choice with no analgesic ceiling effect led to high dose, high risk prescribing



Opioid Analgesics

Analgesia

- Turn on descending inhibitory systems
- Prevent ascending transmission of pain signal
- Inhibit terminals of C-fibers in the spinal cord
- Inhibit activation of peripheral nociceptors
- Variable response (not all patients respond to the same opioid in the same way)
 - >1000 polymorphisms in the human MOR gene
 - Single nucleotide polymorphisms (SNPs) affect opioid metabolism, and activity at receptors and ion channels
- Activate the reward pathway



McCleane G, Smith HS. *Med Clin N Am.* 2007 Smith HS. *Pain Physician*. 2008 Ren Z et al. *Pain Physician*. 2015

Opioid Prescribing Trends

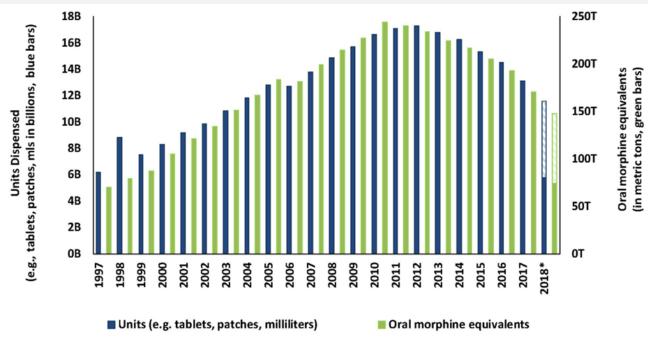


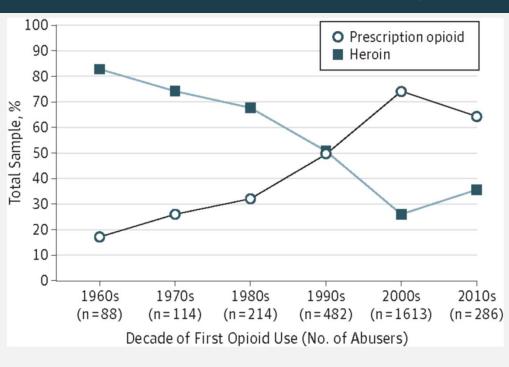
Figure 1: Estimated number of units (e.g., tablets, patches, milliliters) and calculated oral morphine equivalents (in metric tons) dispensed for opioid analgesic products from U.S. outpatient retail pharmacies, 1997 through projected year 2018*

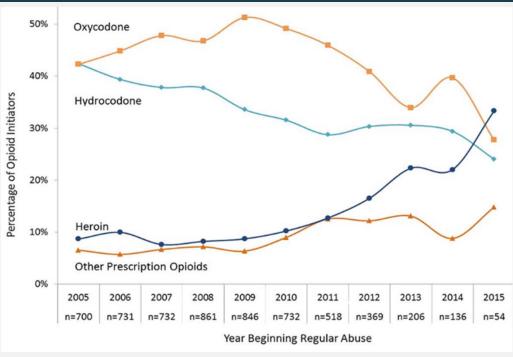
www.fda.gov, ONDCP 2019

Since 2011 MME decline by 43%

2018 largest MME decline at 17%

Trends of 1st Opioid Used Leading to OUD



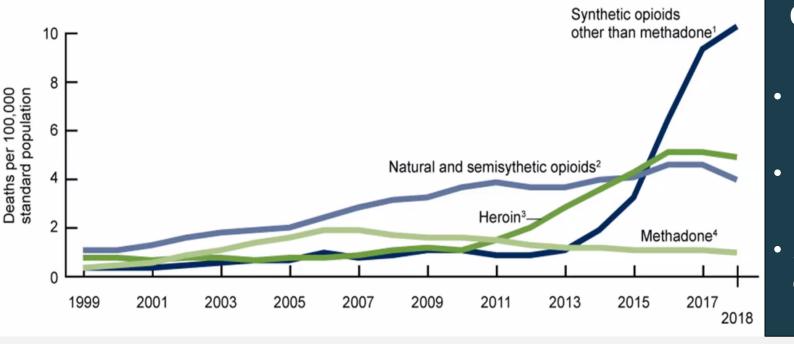


Cicero T et al. JAMA Psychiatry. 2014

Cicero T et al. Addictive Behaviors. 2017

- 1960s: >80% started with heroin
- **2000s**: >75% started with prescription opioids
- 2010-2015: Increasing initiation with heroin

Trends in Opioid Overdose Deaths



Overdose Deaths 6/2019-6/2020

- >83,000 overdose deaths
- Highest number in a 12-month period
- 21% increase compared to the previous year

Prescription Opioids before OUD or Overdose

- Cross-sectional study (n=227,038) of opioid prescribing 1 year prior to diagnosis of OUD or opioid overdose
 - 35% not prescribed an opioid in the year before their diagnosis
 - 65% received an opioid prescription prior to their diagnosis, most were prescribed >20mg MME; only 13% were prescribed >150mg MME
- From 2006–2016, proportion **not** receiving a prescription opioid in the year before their OUD or opioid overdose diagnosis increased by 86%
- Study highlights the limitations of opioid prescription-focused interventions to prevent OUD and opioid overdose

Treatment Gaps Following Opioid Overdose

- Retrospective cohort study, large national commercial insurance database patients (n=2,848) receiving chronic opioid therapy for noncancer chronic pain who had a nonfatal opioid overdose
- After the overdose, 91% of patients received at least 1 opioid prescription
- The 2-year cumulative incidence of repeat overdose was 9% with low dosage, 15% with moderate dosage, and 17% with high dosage

Acute Pain and Opioids

Treating Acute Pain in the Emergency Department

- Guidelines never recommended opioids for acute musculoskeletal pain
 - 2008 2016 up to 25%¹ of ED visits for ankle sprain received an opioid prescription
- Patients in the ED with acute extremity pain, there was no statistically significant or clinically important difference in pain reduction at 2 hours among single-dose treatment with
 - NSAID + APAP or
 - 3 different opioid + APAP combination analgesics²
- 1. Delgado MK et al. Ann Emerg Med. 2018
- 2. Chang AK, et al. JAMA. 2017

Opioid Pill Consumption After an ED Visit

- Data from study promoting safe opioid use after ED discharge for back pain, renal colic, fracture/dislocation, musculoskeletal injury
 - 260 patients completed medication diaries
 - 3,975 pills of hydrocodone-APAP were prescribed (median 12 pills per patient)
 - Patients with renal colic used the least opioids
 - Patients with back pain used the most opioids
- 92.5% of patients had leftover pills
- 52% (2,077) of pills were unused

Opioid Prescribing after Surgery

Surgery	Unused Opioids	Reference
Thoracic	71% taking half or less	Bartels et al. <i>Plos One</i> . 2016
C-section	83% taking half or less	Bartels et al. <i>Plos One</i> . 2016
Upper extremity	77% taking half or less	Rodgers et al. J. Hand Surg. 2012
General surgery	71% of pills not taken	Hill et al. Annals Surgery. 2016

Over 50% of states have enacted laws restricting opioid prescribing for acute pain¹

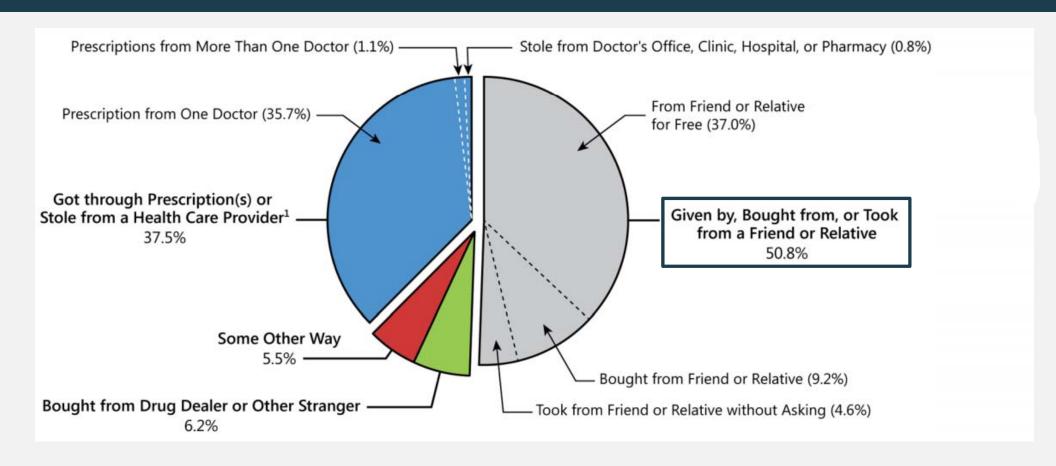
Opioid prescriptions for acute pain decreased (2012-2017)²

• **68% decrease** in new prescriptions for more than **7-day** supply

¹Davis CS et al. *Drug Alc Depend.* 2019

²Zhu W et al. *N Engl J Med*. 2019

Source of Prescription Opioid Misused



SAMHSA. (2020). 2019 National Survey on Drug Use and Health

Risk Factors for Developing Long-term* Opioid Use

*greater than 3 months

3-5%
of opioid-naïve
patients receiving
an opioid became
long-term opioid
users

Risk factors associated with long-term opioid use

Male (OR 1.34)

Older than 50 years old (OR 1.74)

Drug use disorder (OR 3.15)

Alcohol use disorder (OR 1.83)

Benzodiazepine use (OR 1.82)

Antidepressant use (OR 1.65)

Depression (OR 1.15)

Deyo RA, et al. *J Gen Intern Med*. 2017 Clarke H, et al. *BMJ*. 2014 Sun EC, et al. *JAMA Intern Med*. 2016

Oral Analgesics for Minor Surgical Postop Pain

Analgesic(s)	Dose (mg)	NNT vs Placebo > 50% maximum pain relief over 4-6 hours			
SINGLE AGENTS:					
Ibuprofen	600	2.7			
Acetaminophen (APAP)	1000	3.6			
Oxycodone	15	4.6			
Codeine	60	12.0			
COMBINATIONS:					
Ibuprofen + APAP	400+1000	1.5			
Ibuprofen + oxycodone	400+5	2.3			
APAP + oxycodone	325+5	5.4			
APAP + codeine	300+30	6.9			

~50,000 participants

~460 high-quality studies (mostly dental extractions)

Moore RA, et al. *Cochrane Library.* 2015

How Much Opioid Should be Prescribed After Surgery?

- Postop opioids and refills from 642 patients undergoing 5 outpatient procedures
 - Wide variation in opioids prescribed for same operation
 - Only 28% of opioids prescribed were taken, less than 2% needed refills
- Recommended # of pills needed for 80% of patients for each operation
- Encouraged patients to use APAP and NSAIDs first, and only take opioids for persistent pain
- Opioids decreased by 53%, only 0.4% required an opioid refill
- 85% used either an NSAID or acetaminophen

Chronic Pain and Opioids

Chronic Pain is Complex

Acute Pain Life sustaining symptom

 Adaptive by eliciting motivation to minimize harm and allow healing

Chronic Pain

Can be a disease in itself

- Maladaptive, pathologic, disorder of the somatosensory pain signaling pathways influenced by genetic and epigenetic factors
- Associated with higher risk of fatal and nonfatal suicide attempts*

"PAIN has an element of blank;



It cannot recollect when it began, Or if there were a day when it was not.

It has no future, but itself, Its infinite realms contain its past, enlightened to perceive new periods of pain".

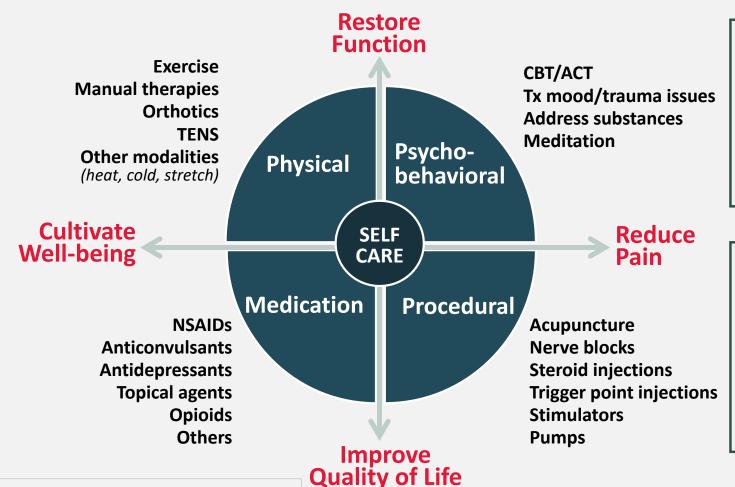
- Emily Dickinson (1890)

Dzau VJ, Pizzo PA. *JAMA*. 2014 Walk D, Poliak-Tunis M. *Med Clin N Am*. 2016

Argoff CE, et al. Pain Med. 2009

* Petrosky E, et al. Ann Intern Med. 2018

Multidimensional Care for Chronic Pain



Studies on pharmacologic and nonpharmacologic treatments for chronic pain are ≤ 12 months, vast majority are ≤ 12 weeks

Tayeb BO, et al. Pain Med. 2016

Multimodal approaches are more cost-effective than single modality options

Flor H, et al. *Pain* 1992 Roberts AH, et al. *Clin J Pain*. 1993 Patrick LE, et al. *Spine*. 2004 Kamper SJ, et al. *Cochrane Review*. 2014

Image courtesy of **Seddon Savage, MD, MS**

Opioid Efficacy for Chronic Pain

Meta-analyses (1-6 month follow-up)

- Opioids v placebo
 (high quality evidence)
 Statistically significant improvements in pain^{1,2} and functioning.²
- Opioids v placebo (neuropathic pain)
 (low-mod quality evidence)
 Clinically relevant pain relief and
 reduction of disability³
- Opioids v nonopioids
 (low-mod quality evidence)

 Similar benefits²
 - 1. Meske DS, et al. J Pain Res. 2018
 - 2. Busse JW, et al. JAMA. 2018
 - 3. Sommer C et al. Eur J Pain. 2020

RCT⁴ found **opioids**not superior to
nonopioids for improving
musculoskeletal painrelated function over 12
months

Study limitations:⁵

- Excluded patients already on long-term opioids
- 89% of eligible patients declined to be enrolled
 - 4. Krebs EE, et al. JAMA. 2018
 - 5. Webster L. Pain Med. 2019

Two longer
term follow-up
studies found
44.3% on
chronic
opioids for
chronic pain
had at least
50%
pain relief 6

6. Noble M, et al. Cochrane Syst Rev. 2010

Longer Term Opioid Efficacy for Chronic Pain

- Systematic review and meta-analysis of RCTs (opioids vs placebo) with open-label extensions with a study duration of 6.5 months - 3 years
- 15 studies, 3,590 participants with low back, osteoarthritis and neuropathic pain
 - 13 studies funded by pharma
 - One-third of patients benefited (reduction of pain and disability) from longer term chronic opioids
 - Drop out rate due to adverse events increased with study duration
- **Authors conclusion**: chronic opioids can be considered in **selected** patients who experience a clinically meaningful pain reduction with tolerable adverse events during short-term opioid therapy

Bialas P et al. Eur J Pain. 2020

Opioid Risks

- Allergies are rare
- **Side effects** are common (nausea, sedation, constipation, urinary retention, sweating)
- Organ toxicities are rare
 - Suppression of hypothalamic-pituitary-gonadal axis (osteoporosis)
- Immunosuppression (lymphocyte and natural killer cell function)
 - Increased risk of invasive pneumococcal dz and community acquired pneumonia
- Worsening pain (hyperalgesia in some patients)
- Addiction (Opioid Use Disorder)
- Respiratory Depression and Overdose
 - Higher doses and when combined w/ other sedatives

Dunn KM et al. Ann Intern Med 2010 Li X et al. Brain Res 2001 Doverty M et al. Pain 2001 Angst MS, Clark JD. Anesth 2006 Wiese AD, et al. Ann Intern Med. 2018

Problematic Opioid Use

Systematic review from 38 studies (26% primary care settings, 53% pain clinics)

Misuse rates: 21% - 29%

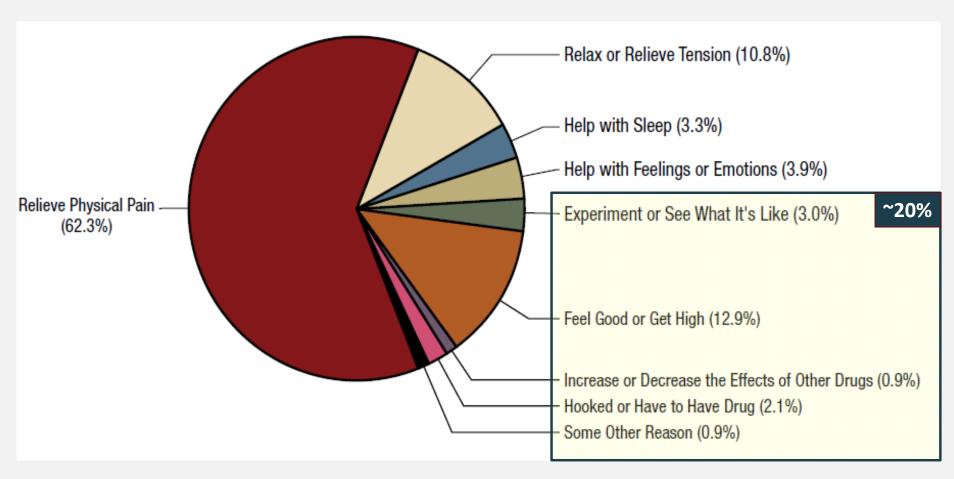
Misuse: Opioid use contrary to the directed or prescribed pattern of use, regardless of the presence or absence of harm or adverse effects.

Addiction rates: 8% - 12%

Addiction: Pattern of continued use with experience of, or demonstrated potential for, harm (eg, "impaired control over drug use, compulsive use, continued use despite harm, and craving").

Vowles KE et al. Pain. 2015

Reasons for Prescription Opioid Misuse



SAMHSA. (2017). 2018 NSDUH

Opioid Risk Factors

Patient-related Factors

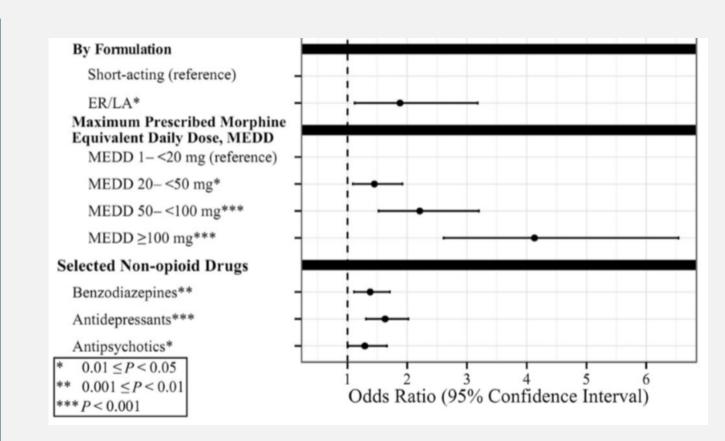
Mental health disorder (e.g. depression, anxiety)	overdose	addiction
Substance use disorder (e.g., alcohol, nicotine, illicit & prescription drug)	overdose	addiction
Family history of substance use disorder		misuse
Adolescent		addiction
Age >65	overdose	
Sleep-disordered breathing	overdose	
Legal history (e.g., DUI, incarceration)		misuse
History of sexual trauma		misuse
History of overdose	overdose	

Akbik H, et al. *J Pain Symptom Manage*. 2006 Ives J, et al. *BMC Health Serv Res*. 2006 Liebschutz JM, et al. *J Pain*. 2010 Michna E, et al. *J Pain Symptom Manage*. 2004 Reid MC, et al. *J Gen Intern Med*. 2002 Volkow ND et al. *N Engl J Med* 2016

Opioid Risk Factors

Medication-related Factors

- Retrospective study of VA (2010-2012)
- n=8,987 dispensed opioid
- n=817 had lifethreatening opioidrelated respiratory/ CNS depression or overdose



Zedler B et al. Pain Med. 2015

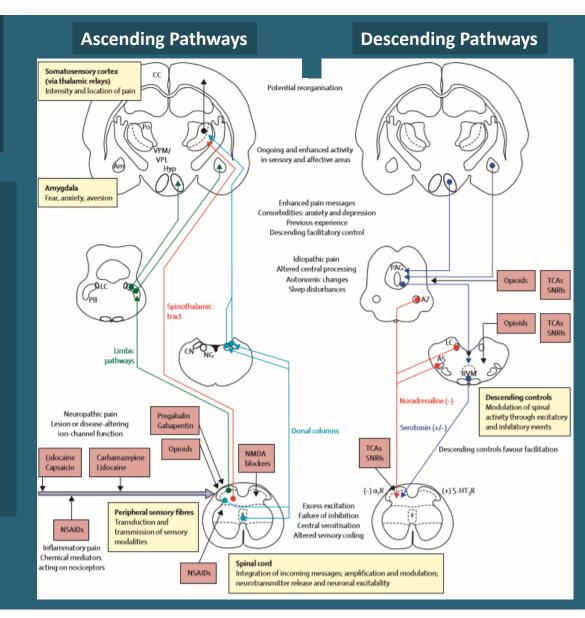
Safer Opioid Prescribing for Chronic Pain

Neuro-Pathways and Pharmacologic Targets

"Rational Polypharmacy"

- Combination therapy to target multiple mechanisms and increase therapeutic index
 - Maximize efficacy (additive, synergistic)
 - Minimize dose-limiting side effects (smaller doses)

Li JX. *Neuropharm.* 2019 Gilron I et al. *Lancet Neurol.* 2013 Mao J et al. *J Pain.* 2011



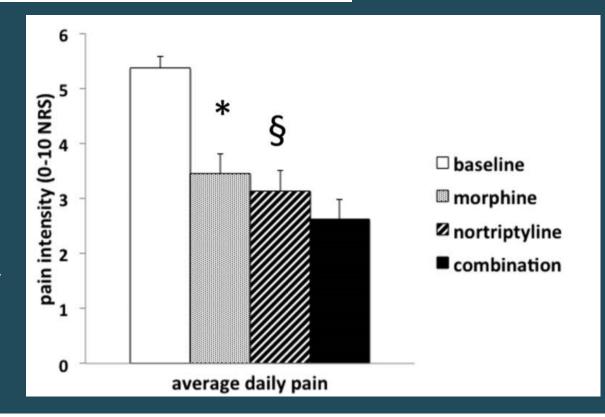




Combination of morphine with nortriptyline for neuropathic pain

lan Gilron^{a,*}, Dongsheng Tu^b, Ronald R. Holden^c, Alan C. Jackson^d, Deborah DuMerton-Shore^e

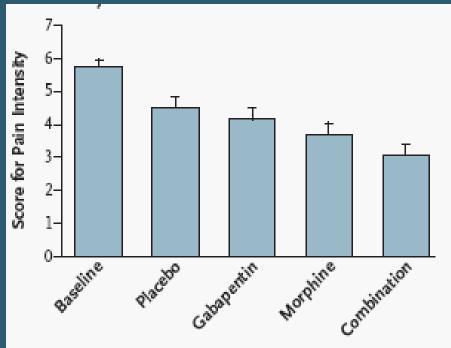
- Randomized, double-blind crossover trial, patients with neuropathic pain
- 39 patients completed at least 2 treatment periods
- Average daily pain (0-10) and Brief Pain Inventory scores for average and present pain were significantly lower for combination vs each monotherapy

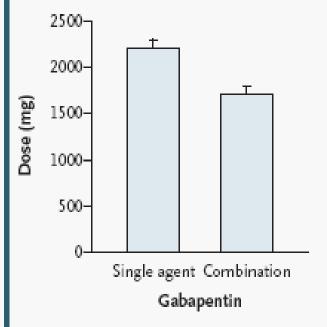


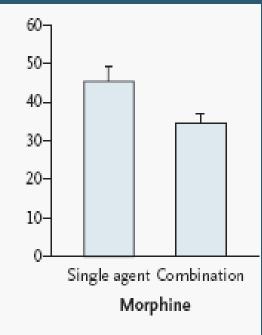
Gilron I et al. Pain. 2015

Morphine, Gabapentin, or Their Combination for Neuropathic Pain

 Randomized, double-blind, active placebo—controlled, four-period crossover trial, N=57, 5 week treatment







Gilron I et al. N Engl J Med. 2005

Opioids and Gabapentinoids and Overdose Risk

- Retrospective cohort study (2011–2016) of receipt of gabapentinoid and/or opioids and overdose over 12 months
 - 71,005 Medicare beneficiaries with fibromyalgia, low back pain, neuropathy, or osteoarthritis, newly prescribed either medication (or both) following a 6-month period without a prescription for either
 - People with previously SUD or overdose were excluded
 - Adjusted for socio-demographics, disability, medical and psychiatric comorbidities, benzodiazepine prescriptions, healthcare access and utilization
- Compared with the opioid-only, opioids co-prescribed with gabapentinoids was associated with increased overdose risk
- Increased doses of either medication associated with increased risk

Zhou L, et al. Addiction. 2020

Opioid Rotation

Restore analgesic efficacy Limit adverse effects Decrease overall opioid dose

- Based on intra-individual variation in response to different opioids and different variants of mu-opioid receptors
- Based on surveys and anecdotal evidence, promising but needs validation
- Caution when using opioid equi-analagesic tables
 - Derived from relative potency ratios using single-doses in opioid-naïve subjects
 - Based on limited doses or range of doses
 - Most tables do NOT adjust for incomplete cross-tolerance

Inturrisi CE. *Clin J Pain*. 2002 Fine PG, Portenoy RK. *J Pain Symptom Manage*. 2009 Smith HS, Peppin JF. *J Pain Res*. 2014 Treillet E, et al. *J Pain Res.* 2018 Webster LR, Fine PG. *Pain Med.* 2012 Pereira J, et al. *J Pain Symptom Manage.* 2001

"Universal Precautions" when Prescribing Opioids

(not evidence-based but has become "standard" of care)

- Misuse risk assessment
- Patient Provider Agreements (PPA)
- Medication Management
 - Opioids should not be 1st line, begin with immediate-release opioids, prescribe the lowest effective dose. (caution with any dose, if possible avoid doses >90 mg MME)
 - Avoid dangerous combinations (e.g., benzodiazepines)
- Frequent face-to-face visits (Document risks and benefits)
- Risk mitigation, monitor for adherence, addiction and diversion
 - Urine drug testing (UDT) and pill counts
 - Prescription Drug Monitoring Program (PDMP) data
 - Naloxone co-prescribing

Gourlay DL et al. *Pain Med* 2005 Dowell D et al. *MMWR* 2016

Opioid Risk Mitigation Practice Trends (2013-2016)

- National SCOPE of Pain 6,889 registrants baseline report of 5 safer opioid prescribing practices (treatment agreements, educate about safe storage and disposal and overdose risk, monitoring for safety [UDTs, PDMP])
 - Over 70% reported use of at least 1 risk mitigation practices for "most" patients
 - Only 28% performed all 5 practices for "all" patients prescribed opioids
 - Clinicians from states with high opioid overdose rates reported significantly higher implementation of most practices, compared with clinicians from states with low rates
- Safer opioid prescribing education should emphasize universal implementation of opioid risk mitigation practices

Alford DP et al. Pain Med. 2019

Assessing for Prescription Opioid Addiction Risk

Systematic Review

Can clinicians identify patients with pain for whom prescription opioids can be safely prescribed?

- Despite widespread use, opioid misuse risk screening tools were based on lowquality studies
- Among higher quality studies, risk assessment tools demonstrated poor performance in identifying patients at high vs low risk
- History of OUD or other SUD, certain mental health diagnoses (e.g., personality disorder), and concomitant prescription of certain psychiatric medications were useful for identifying patients at high risk
- Only the absence of a mood disorder was associated with a lower risk

Klimas J et al. JAMA Network Open. 2019

Patient-Provider Agreements (PPA)

- Survey 430 individuals from 43 states (primary care [64%], pain specialty [18%])
 - 66% of respondents thought PPAs were "often" or "always" worth the effort
 - Only 28% considered them "often" or "always" effective in reducing opioid misuse
- 121 PPAs samples from 34 states with similar specialty type as the survey
 - PPA reading burden surpassed recommended patient education standards, with only 2.5% at or below fifth-grade reading level
 - PPAs focused more on rules and consequences of patients' noncompliance than on a shared treatment plan

Prescription Drug Monitoring Programs (PDMP) Systematic Review (2011-2018)

- Over 60% of states mandate use before prescribing controlled substances
- All studies examining the association between PDMP and overdose had methodological shortcomings, including inadequate to no adjustment for confounding factors and competing laws and policies that might affect overdoses
 - 10 studies suggested a decrease in fatal overdoses with PDMP implementation
 - 3 studies suggested an increase in heroin overdoses after PDMP implementation
- Authors conclusions: Evidence that PDMP implementation either increases or decreases nonfatal or fatal overdoses is largely insufficient

Opioid Discontinuation



Drug Safety Communications

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

The NEW ENGLAND JOURNAL of MEDICINE

Medical News & Perspectives

Limits on Opioid Prescribing Leave Patients
With Chronic Pain Vulnerable

No Shortcuts to Safer Opioid Prescribing

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

Rita Rubin, MA

jama.com JAMA Published online April 29, 2019

Tapering Opioids

- No validated protocols in patients on opioids for chronic pain
- Systematic review found very low quality evidence suggests that several types of opioid tapers may be effective and that pain, function, and quality of life may improve for some patients with opioid dose reduction
- CDC guideline recommends decrease of 10% per month if patient on opioids for years and decrease of 10% per week if patient on opioids for weeks to months

Trends of Opioid Tapering

Trends in the rate and rapidity of tapering among 99,874 individuals receiving chronic opioids in a large US claims database (2008-2017)

- Annual percentage undergoing tapering increased from 13% in 2008 to 23% in 2017
- Tapering was significantly more likely among women and patients with higher baseline opioid doses
- 27% of tapers had a maximum dose reduction rate exceeding 10% per week

Fenton JJ, et al. JAMA Netw Open. 2019

Opioid Discontinuation Risks

- Observational cohort study 1.3 million US veterans with an outpatient opioid analgesic prescription over 2 years
- Opioid discontinuation was associated with an increased risk of death from overdose or suicide regardless of the length of opioid treatment
 - Risk increased with the longer the patient was prescribed opioids (hazard ratios:
 1.67 [≤30 days], 2.80 [31-90 days], 3.95 [91-400 days], and 6.77 [>400 days])
- Patients with SUD (HR, 2.48) and mental health diagnoses (HR, 1.54)
 were at most risk for overdose or suicide

Opioid Discontinuation and Overdose Mortality

- Retrospective cohort study (2010-2015), 572 patients on chronic opioids for chronic pain in an urban primary care clinic
 - 75% had mental health conditions, 33% had history of SUD
 - 60% had opioids discontinued over the study period, mostly initiated by providers (80%)
- Overall mortality in the cohort was 20% (4.7 per 100 person-years) with 4% dying of a definite or possible overdose
- Opioid discontinuation was significantly associated with overdose death (hazard ratio, 2.9)

Patient-Centered Opioid Tapering

- Study found 62% of 82 patients in a pain clinic remained in a voluntary, patient-centered opioid taper over 4 months
 - Self-help book and a slow, individually designed taper with up to 5% decrease for up to 2 dose reductions in 1st month to minimize negative physical and emotional response, and facilitate confidence in the process
 - Months 2-4, taper as much as 10% per week; but tailored to the patient
- Median decreases in MME from 288 mg to 150 mg
 - Likelihood of >50% opioid dose reduction was not predicted by starting dose,
 baseline pain intensity, years prescribed opioids, or any psychosocial variable
 - Neither pain intensity nor pain interference increased with opioid reduction

Darnall BD et al. JAMA Intern Med. 2018

Comprehensive Pain Care During Opioid Taper

- 140 patients with chronic pain enrolled in comprehensive interdisciplinary pain management program to enhance self management and reduce opioid use
 - Free, outpatient, 5d/w x 3 w including CBT, pacing, self-help book, graduated upgrading of activities, self-calming /relaxation, coping strategies and planned opioid reduction
- Post-program, opioid use was significantly reduced and maintained over 12months follow-up
 - Opioid discontinuation was associated with more substantial and consistent improvements in usual pain, depression severity, pain interference, pain-related disability relative to those who reduced their opioids but did not stop them
- Study supports training in pain self-management is a viable alternative to longterm opioid use by some patients with chronic pain

Mistrust and the Patient Experience

PERSPECTIVE & COMMENTARY

Ethics Forum

You Present like a Drug Addict: Patient and Clinician Perspectives on Trust and Trustworthiness in Chronic Pain Management

- Qualitative study
- Adults with low back pain
- Patient and provider themes

Buchman DZ et al. Pain Med. 2016

Patient Theme 1: Threats to Trustworthiness and latrogenic Suffering

 Perceptions that their clinicians have demonstrated a lack of care, empathy, and respect...affecting patients' assessments of clinician trustworthiness...negative interactions with clinicians caused them further suffering.

SUSAN: "You could just tell that he just didn't believe me that I was in as much pain as I was. He was just very unsympathetic. He would literally walk away while I was in the middle of a sentence."

Patient Theme 2: Motive, Honesty, and Testimony

 Patients' doubts that their clinicians believed that they were being honest about their motives for seeking treatment (e.g., drug misuse or drug diversion). Patients described being perceived as untrustworthy by clinicians

LUDWIG: "When I was in [hospital] just a couple of weeks ago...the ambulance drivers just took one look at me and it was, like—the look in their eyes was like, 'Oh, he's just a junkie looking to get stoned.' They didn't believe that I was actually suffering and in pain. They thought I was faking it completely..."

Clinician Theme 1: Challenges of the Practice Context

 Physicians highlighted the challenging context in which chronic pain management is delivered. They recalled several difficult interactions and the impact these interactions had on their approach to care

DR. JOHN: "The things that we remember are the times that we got burned, right . . . You may get burned one in 100, but that one in 100 is enough to burn an impression in your mind that makes you wary of all patients potentially."

Buchman DZ et al. Pain Med. 2016

Clinician Theme 2: Complicated Clinical Relationships

 Chronic pain management involving opioid analgesics can prohibit or destabilize the development of trusting clinical relationships. Physicians...did not necessarily see their role as a collaborative partner...[they] saw themselves in a defensive role of interrogator

DR. HENRY: "In most doctor-patient relationships we learn to listen to the patient and accept their testimony...in some instances, to be quite honest, we are interviewing the patient as if we are a police officer or a lawyer and we're trying to find flaws in their story...So there is a different relationship here."

"Pain Medication and Regulation: It Is Personal"

- It takes a second to process what the secretary at the Internal Medicine desk just did...Then you focus on the piece of paper she just gave you: it's not the prescription you came in to pick up; it's a lab slip.
- Of course. She's sorry. Of course. She can't release the pain med script until
 you go downstairs. And pee in a bottle...
- The woman at the lab desk,...stops you as you head into the bathroom. Can't bring that in with you, she says, pointing her chin at your bag. She doesn't seem all that sorry, just a little bored and low-level irritated.

Unger DNS. J Gen Intern Med. 2017

- At least she isn't patting you down—making sure you don't smuggle in a clean sample...at least for you—they aren't requiring observed urination.
- But the annual, mandatory, Pain Management Agreement is a living document, ever-growing, morphing, and contorting—forcing you to constantly stretch and adjust, as well...
- On the compliance side, they want to see that you're only peeing metabolites for the drugs you've been prescribed—no freelancing and no doctor shopping.
- Peeing clean? That's potentially criminal. You're not taking your pills? Who
 is? Are you selling them? Trying to cut back? Not acceptable!

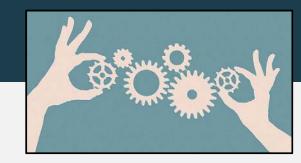
- The agreement is, potentially, a One-Strike-and-You're-Out contract: a
 lifetime ban on pain medication by any practitioner in the entire network...
- You fork over the bag, duck into the bathroom, urinate—as ordered. On emerging, you hand over the warm plastic bottle, reclaim your property, head back upstairs to pick up your prescription.
- At the pharmacy they need to see ID, both when you drop the prescription off and after ten minutes of sitting in view when you pick it up. The young woman who rings you up is. . . sorry. Nothing personal; just rules.

- At any rate, this is a better result than what can happen...when your physician is on vacation. We're not comfortable, is the term of art with which the covering physician often begins, renewing this for you at this time... So that refusal isn't...personal...
- And it's not really a refusal either, it's just—we're sure you understand—a
 matter of respecting the comfort level of the medical professional...who is
 refusing to address your pain in accordance with the treatment plan laid out
 and amply documented by your primary care provider.

- You consider using the analogy of insulin: If a covering physician refused to renew an insulin prescription—uncomfortable—simply suggested the patient come back next week, would that not be construed as medical malpractice? But arguing is bad; it makes things...personal.
- Yelling—most especially, but really any kind of demonstrated intensity—would be a very bad idea at this point: it's suggestive of drug-seeking behavior, and that's a phrase you really don't want jotted down in your permanent record.
- Of course if you don't argue, well, that's a pretty clear indicator that your pain can't be all that serious after all.

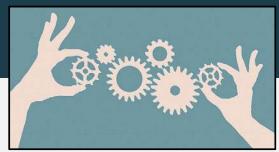
- And if you know, with too high a degree of precision and specificity, what does and does not work for you, as a matter of medication or dosage. . . that's a little disturbing—and suspicious.
- Insulin! you want to scream. Would you accuse a diabetic of knowing too
 much about what would or would not effectively control their blood sugar?
 Isn't that what a responsible, educated, and involved patient is supposed to
 do?
- But—of course!—I understand. There's an opioid crisis; precautions need to be taken. I'm sorry if I made you feel that this was - personal.

Putting it Together



- Limit the amount of opioid prescriptions for acute pain
- Consider combination therapy for acute and chronic pain to improve the therapeutic index (maximize benefit, minimize harm) of each medication
- Opioids should never be first line therapy for chronic pain and are just one tool
 in a multimodal approach
- Minimize opioid doses escalation as much as possible and talk to patients about risks of high doses
- Employ universal precautions but individual care based on risk factors
- During opioid tapers, considered a patient-centered approach and include aggressive pain treatment

Putting it Together (continued)



- While implementing safer opioid prescribing guideline-based practices don't forget about the patient experience...
 - How do your patients perceive the safer opioid prescribing procedures...agreements, urine drug testing, pill counts?
 - How do your clinical staff perceive the patients with chronic pain on chronic opioid therapy?
- Requires training and re-training your clinical staff...

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Thank you!

Questions?

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