

Care for People with Pain during COVID-19:

Real-World Implications for Person-Centered Policy, Practice, and Education



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INNOVATION IN PAIN MANAGEMENT DELIVERY AS A RESPONSE TO OPIOID MISUSE AND OVERDOSE AND COVID-19

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Pain Management in the Context of COVID-19: The Good, The Bad, and The Ugly

- Caring for people with pain has changed dramatically in the context of COVID-19
- The nature of the COVID-19's effects varies widely, depending on a number of factors
- Some changes present significant opportunities to improve pain care
- Others represent threats to people with pain and their clinicians
- The long-term impact of COVID-19 on pain care is unknown, but very worthy of our attention

The Good

- Increased access to some types of care through telehealth applications, with improved payment
- Innovation in complementary and integrative treatments so telehealth delivery is possible
- Lowered barriers to prescribing for pain and opioid use disorder treatment

The Bad

- People without technical savvy and/or up-to-date technology are limited in using telehealth
- Some treatments—even self-management—are unavailable, disrupting continuity of care
- Increased access for people with pain does not mean more clinicians are available
- Increased baseline stress increases anxiety and depression, which, in turn, increases pain
- Exacerbation of some social determinants

The Ugly

People with pain often have conditions, or treatments, that make them more vulnerable to catching the virus and dying as a result

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Health Policy & Civil Rights Attorney



CONSEQUENCES FOR PATIENTS IN PAIN



KATE NICHOLSON, JD

THE LAY OF THE LAND

- **Existing Crisis in which Pain is Inadequately Treated Relative to its Prevalence and Disabling Consequences.**
- **Overlay of the Opioid/Overdose Crisis on access to medication and care before COVID-19** (Pendulum swing on prescribing has created barriers to access to care; these barriers compound w/ intersection with race).
- **New problems and disparities from COVID-19, and from our actions to allay the spread of SARS-CoV-2.**

CHRONIC PAIN: A VULNERABLE POPULATION

- **People with chronic pain may be more vulnerable to COVID-19.**
 - Many of the diseases that cause chronic pain may leave patients immune compromised.
 - Many people with chronic pain have multiple co-morbidities.
 - Many of the treatments for pain-generating conditions may leave people immune compromised as well (chemo, steroids, opioids).
 - Pain intersects with race, age, disability (those already most susceptible to COVID-19 and poor outcomes from it).

ACCESS TO MEDICATION

- **Hoarding of Hydroxychloroquine.** A study published in *JAMA Intern Med.*, showed spikes in sales of the drug **tripled** after well-known public figures lauded it.
- **Concerns with shortages for people with Lupus and Rheumatoid Arthritis.** (Opinion piece in *Washington Post* by Kayla Behbahani, a psychiatrist at Brigham and Women's).

PostEverything • Perspective

I have lupus. Stop hoarding the drug I need to survive.

Coronavirus anxiety is causing a run on drugs that may or may not prevent or treat it.

[Visual Description: photo of headline from Washington Post on hoarding medication.]

ACCESS TO MEDICATION (CONT.)

- **Supply Issues: Shortage of Opioids for Ventilator Patients.**

Painkillers, sedatives in short supply during COVID-19 pandemic

Hospital groups push for increased supply of drugs to ease patient struggles



- FDA/DEA are working to shore up supply.
- DEA raised its ceiling by 15%. (But these shortages due to blanket cuts were foreseeable (seen prev. in parenteral opioid shortage/2018)).

[Visual Description: Photo of EMT workers taking someone from an ambulance]

ACCESS TO MEDICATION (CONT.)

- **DEA Changes in Prescribing of Controlled Substances.**
- Positive changes in which the DEA authorized an exception to the Ryan Hatch Act permitting providers to prescribe controlled substances based on a telemedicine visit without a prior in-person visit (or telemed. in a DEA-registered facility).
- Impact: I've heard from patients who have found that this works swimmingly. I have also heard from patients in states where this is not permitted under state law.
- Concern recently expressed by authors Villars, Widera, & Kollas in Health Affairs that palliative care patients, especially the elderly, may not have audio-visual access.
- I still hear from patients who are being denied fills (one recently whose doctor was sick, w/ suspected COVID19, and the on-call physician refused to prescribe the opioid medication).

ACCESS TO SERVICES AND CARE

- **Expanded telehealth has been valuable** for mental health services, addiction treatment, and in many other areas.
- **But a lot of maintenance care for pain, including many integrative treatments we address, are hand-on** and have been closed. There can be real consequences in terms of flare ups when these are stopped.
- **Screening and routine blood work may also be postponed.** From a rheumatoid arthritis patient on twitter: “I was supposed to see a rheumatologist last month. We were making progress figuring out why I’m in constant pain and now it’s just eternal limbo. Labs need to be done. Telehealth is no use here. I was so close.”
- **Interventional and non-emergency surgical techniques** have also been postponed.

PATIENT HYPO

Coronavirus has created a crisis for primary care doctors and their patients

How the coronavirus is making America's health care access problems even worse.

Apr 27, 2020, 7:50am EDT



Dania Palanker with her daughter and husband in the front yard of her Washington, DC, home.

Dania Palanker, an assistant research professor for the Center on Health Insurance Reforms at Georgetown's Health Policy Institute.

[Visual description: photo of a mother with brown hair and glasses and her young brunette daughter seated on front steps outside of a white brick house while husband/father looks on.]

DANIA'S WORDS

- The article follows Dania as she drives to Philadelphia from the Washington, DC, area to get a nerve block treatment because her regular clinic in DC stopped all outpatient services.
- Dania ponders: “Is maintaining your health ... urgent care? Not something we usually put in the box of ‘urgent,’ but if we don’t take care of it, it’s going to get urgent or emergent.”
- On the consequences for someone with CP: “I feel very intense pain pretty much everywhere in my body,” she says. “Yeah, it’s not life or death, but it’s not just quality of life. There’s pain that impedes on your quality of life and there’s pain that impedes your life.” She goes on to talk about how she can’t care for or play with her daughter.

CONSEQUENCES OF ISOLATION

- **Psychological consequences** of isolation for people in chronic pain who are already at higher risk for depression, anxiety & suicidal ideation. (I've given a lot of talks on resilience and social and cultural supports are a big part of maintaining mental fortitude).
- **Practical consequences for people with pain who have disabilities that require the assistance of caregivers.** One of the primary problems people with disabilities are experiencing is abandonment by direct care workers with inadequate PPEs or who fear exposure.
- **For some, this may mean relocation to an institutional care setting** – which, given the exposure rates in group homes, is the last place most any of us would want to be right now.

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Alliance to Advance
Comprehensive
Integrative
Pain Management

Care for Chronic Pain during COVID-19: Real-World Implications for Person-Centered Policy, Practice, Research, and Education

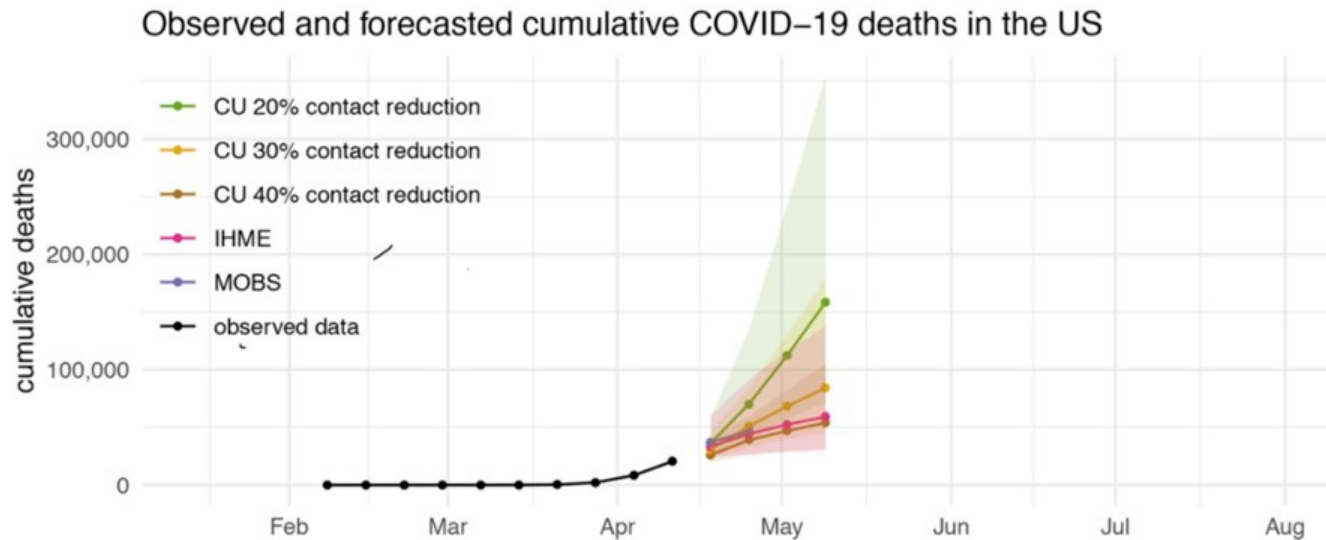
May 14, 2020

Andrey Ostrovsky, MD | Managing Partner | Social Innovation Ventures | @andreyostrovsky

Disclosures

- I reference portfolio companies of Social Innovation Ventures

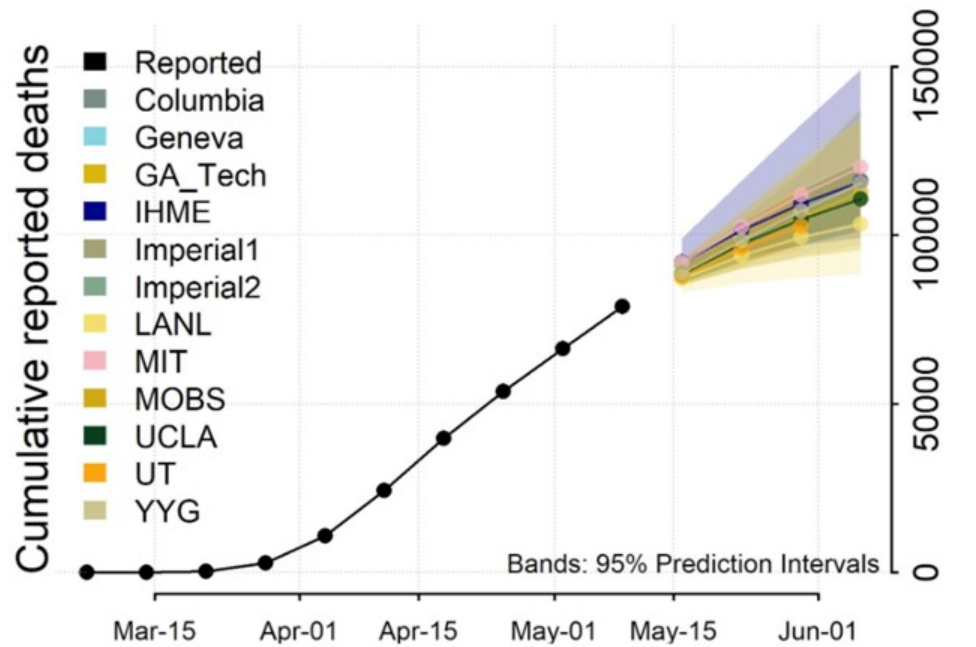
COVID19: 41,758 US deaths (as of 4/22/20)



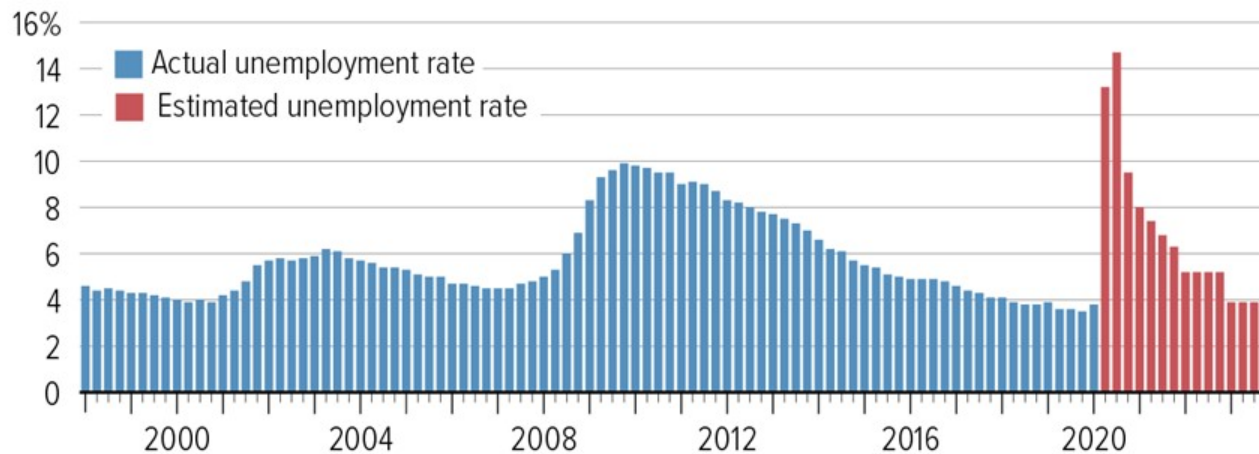
The IHME and MOBS models are conditional on existing social distancing measures continuing through the projected time-period shown. The CU models make different assumptions about the effectiveness of current interventions. Intervals shown are at the 95% uncertainty level.



COVID19: 82,246 US deaths (as of today)



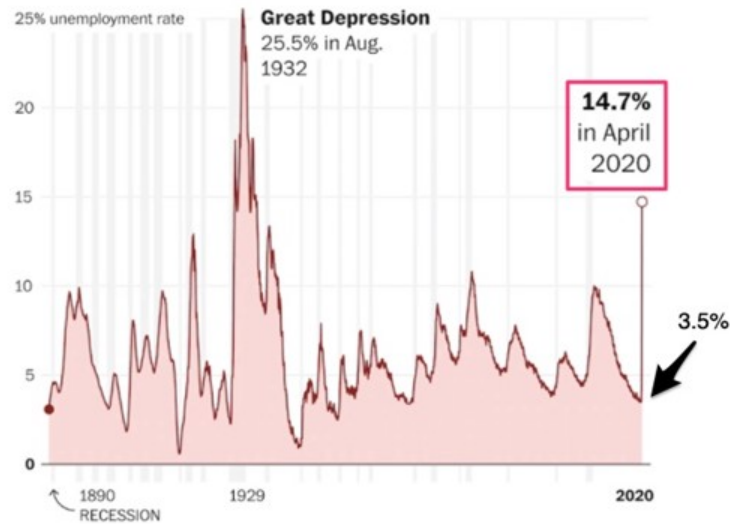
US unemployment rate jumped to 13.5% (22M) as of 4/22/20



Source: Actual: Bureau of Labor Statistics; Estimated: Goldman Sachs quarterly estimates from 2020 and 2021 and annual estimates for 2022 and 2023, (April 1 2020)



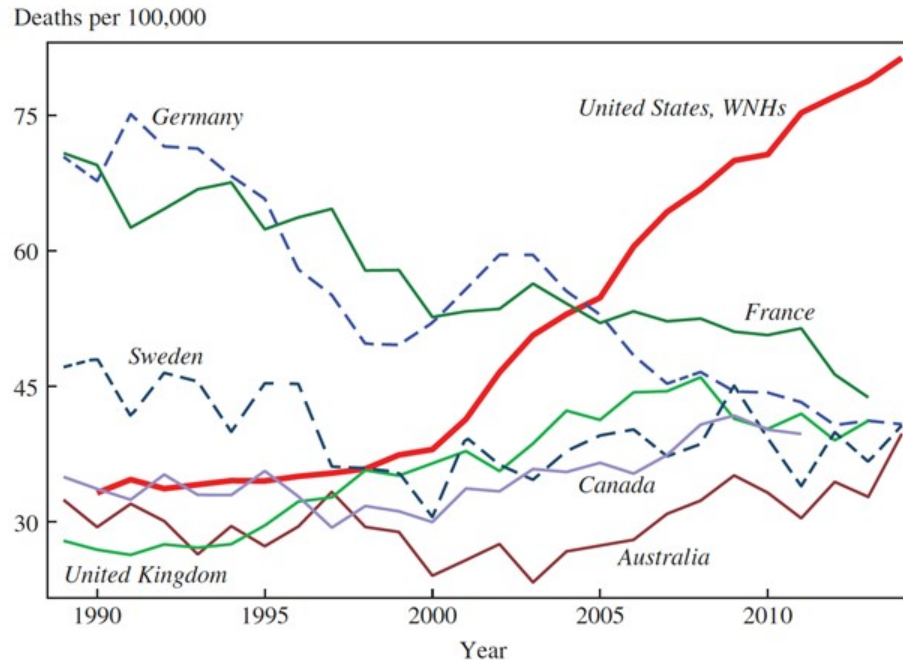
US unemployment rate jumped to 14.7% (36M) and rising



Note: Seasonally adjusted; figures from before 1948 are estimates
Sources: Labor Department (1948-present); Annual estimates from David Weir (University of Michigan) in Research in Economic History disaggregated to monthly data by Nicolas Petrosky-Nadeau (San Francisco Fed) and Lu Zhang (Ohio State University) in Journal of Monetary Economics
THE WASHINGTON POST

Link between SES and Deaths of Despair (OD, EtOH, Suicide)

Figure 5. Deaths of Despair by Country for Age 50–54, 1989–2014^a



What needs to happen: Policy

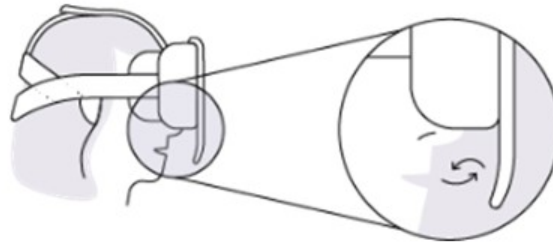
- Increase Medicaid FMAP to 12% (in addition to 6.2% increase from Families First Coronavirus Response Act to full)
- Increase payment to Medicaid providers
- Expand Medicaid

Manage pain non-pharmacologically in your home: AppliedVR

Technology that aims to deliver safe and effective prescription virtual reality (VRx) therapeutics to improve clinical outcomes for patients with serious health conditions



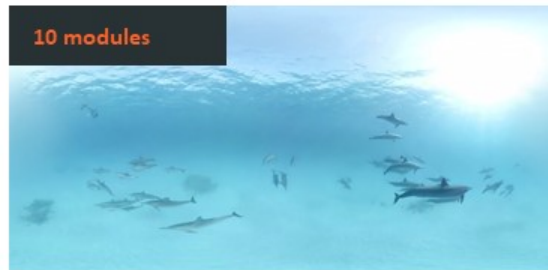
Building the First FDA-Approved Portfolio of Prescription VR Therapeutics (VRx)



Dynamic Breathing



Guided Relaxation



Interactive Games



Evidence

- Published Studies: 5 about 500 patients
 - 49% reduction in acute pain (n=120)*
- Completed Studies (not yet published): 7 with about 500 patients
 - Chronic pain study (n=109)
 - 34% reduction in pain intensity
 - 41% reduction in pain related insomnia
 - 49% reduction in pain related stress
 - 48% less pain intrusion with mood
- Active Studies: 9 with about 500 patients
- In Planning or IRB Review: 12 > 1,000 patients

*Source: Spiegel B et al. Virtual reality for management of pain in hospitalized patients: A randomized comparative effectiveness trial. Virtual reality for management of pain in hospitalized patients: A randomized comparative effectiveness trial. PLoS ONE 14(8): e0219115. 2019.



FDA pipeline

PARTNERS	PRODUCT	INDICATION	DISCOVERY	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3
  Geisinger	RelieVRxtm	Acute pain					
 Geisinger	EaseVRxtm	Chronic pain					
	AnxietyVRxtm	Acute anxiety					

Avoid isolation through virtual peers: Inquisit Health

Platform to support an empathetic workforce of peer mentors that serve as a remote team of “digital community health workers (dCHWs)”



Evidence

Evidence
Randomized clinical

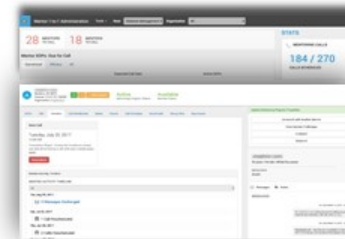


\$2.4M +
5 years

1. Mentor Training Program
2. Mentoring Platform
3. Management System



Turnkey Solutions
Peer support →



Montefiore Study

Patient population: HbA1c > 9%

Enrollment: 794 patients

Intervention: 42 mentors worked with each patient 1-on-1 for up to 12 mo. Average Engagement Per Patient: 20 phone calls, 278 phone minutes

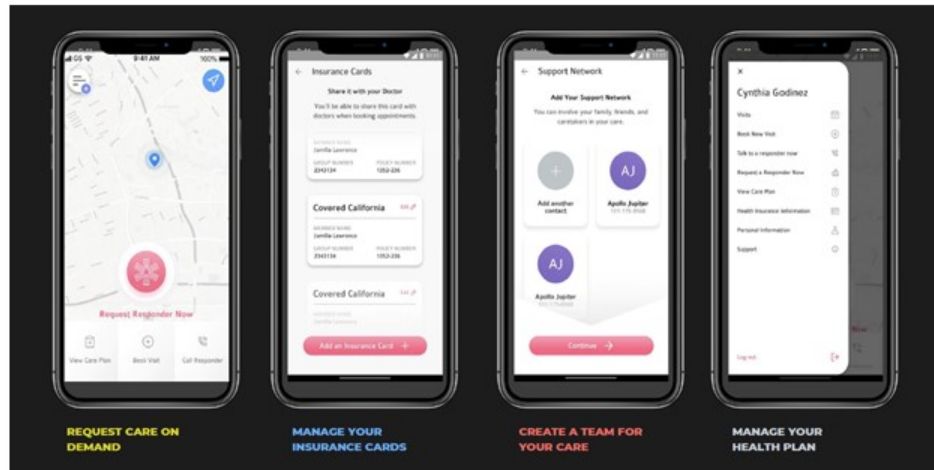
Methods: Pre-/post- HbA1c lab data was analyzed

Results: -1.7 point change in HbA1c [pre-/post- analysis] vs -0.4 in nurse CDE intervention control



Bring urgent care into the home: Ready Responders

EMTs sent to patient's homes with telemedicine support from physician to help prevent avoidable emergency room use



Evidence (*preliminary*)

- 97% satisfaction
- ED utilization: 50% compared to control group
- Per-patient annualized net savings of \$3,100
- Note: Not peer-reviewed



Reduce Stigma: Shatterproof

- Non-profit working to eliminate overdose deaths
- Developed Stigma program for Opioid Use Disorder



Any questions?



Social Innovation Ventures

Thank you!

Andrey Ostrovsky, MD

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Daniel Blaney-Koen, JD

Senior Legislative Attorney
American Medical Association






Patients with pain haven't gone away during COVID-19

Daniel Blaney-Koen, JD
May 2020

Learning objectives

- Identify pre-COVID state and national policies to mitigate opioid-related harms with drug overdose morbidity and mortality data
- Discuss COVID-specific policies designed to help patients with pain and what is needed to implement them
- Suggest post-COVID next steps for COVID-specific policies, including the role of organized medicine and patient advocates

Pre-COVID policies and data affecting patients with pain



Lase Ajayi, MD
Member since 2013

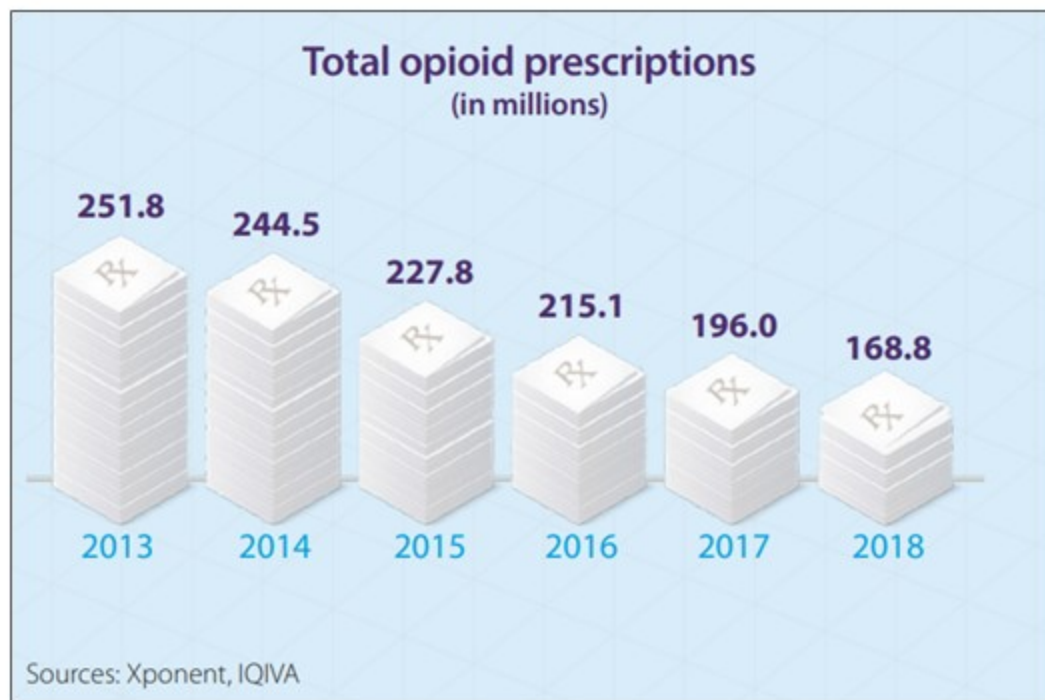
Patient care starts with the patient-physician relationship

- The nation's opioid epidemic did not begin with patients who had chronic pain, cancer, in hospice or needed palliative care
- The nation's response to the opioid epidemic began as a state-by-state effort
- While exceptions to opioid prescribing exempted chronic pain in statute, implementation has been arbitrary at best

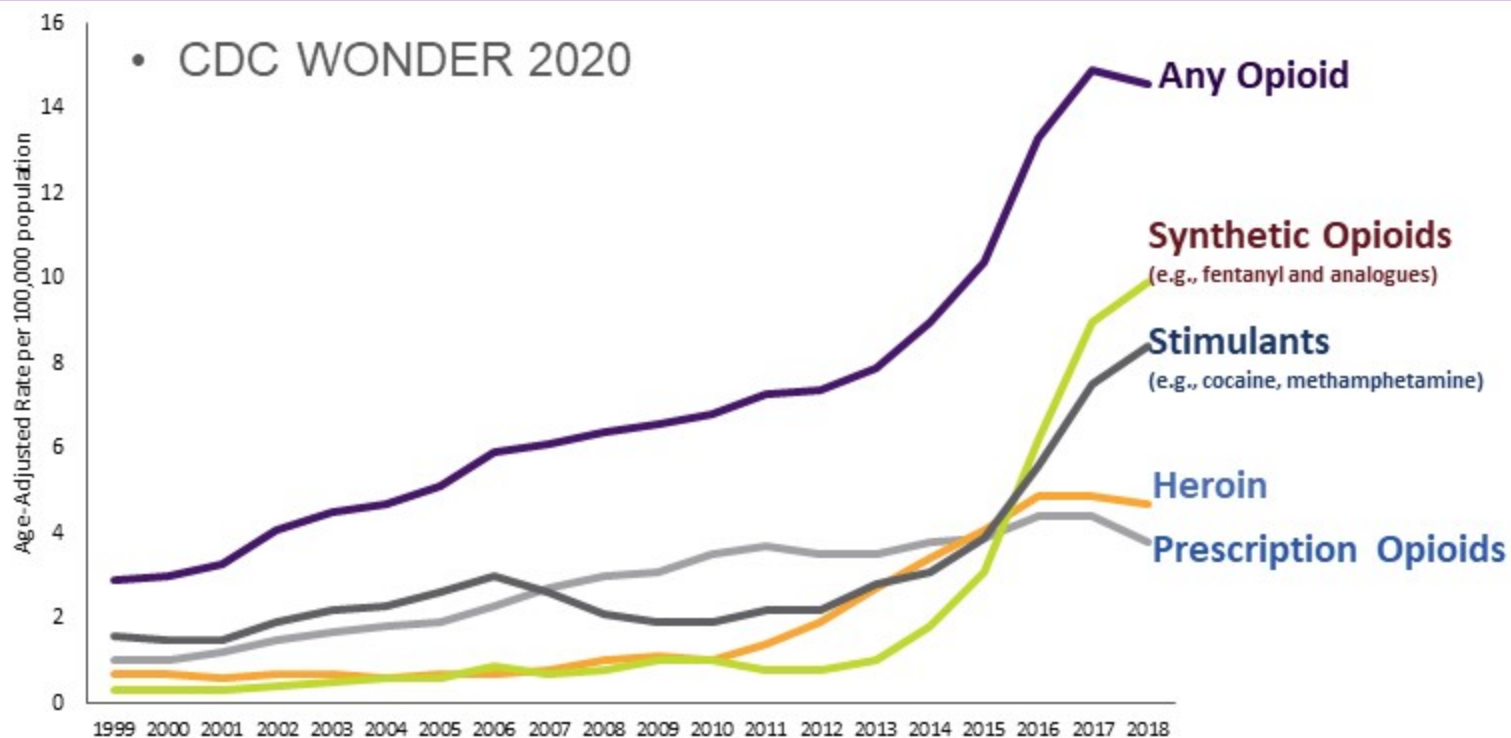


Opioid Prescribing Down 33 Percent

- Between 2013 and 2018, the number of opioid prescriptions decreased by more than 80 million — a 33 percent decrease nationally.
- Every state has seen a decrease in opioid prescriptions over the last five years; state-based restrictions pursued 2016-2018.
- Pharmacy chain, payer, PBM restrictions began largely 2017-2018.



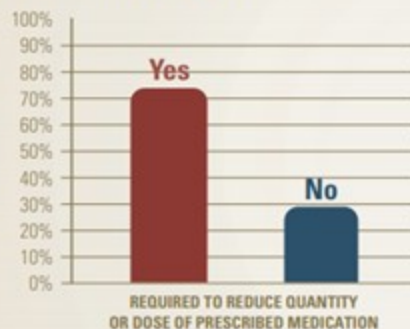
Trajectories of the epidemic: Patients Continue to Die



Second Annual Survey of Pain Medicine Specialists Highlights Continued Plight of Patients with Pain, And Barriers To Providing Multidisciplinary, Non-Opioid Care

Opioid prescription limits

Q: When prescribing opioid analgesics for chronic pain, have you or your patients been required to reduce the quantity or dose of the medication?



72% of pain medicine specialists said that they – or their patients – have been required to reduce the quantity or dose of medication they have prescribed

Requirement of Prior Authorization for non-opioid therapies

Q: When prescribing a non-opioid medication or treatment, have you ever been required to submit a prior authorization for the patient to receive such treatment?



92% of pain medicine specialists said that they have been required to submit a prior authorization for non-opioid pain care – with the physicians and their staff spending hours per day on such requests; and

66% of pain medicine specialists said that they have had to hire additional staff to handle the prior authorization requirements

<http://abpm.org/uploads/files/abpm%20survey%202019-v3.pdf>



COVID-related policies designed to help patients with pain

Saby Karuppiah, MD
Member since 2008



Post-COVID next steps

Hari Iyer
Member since 2017

AMA Opioid Task Force

2015 Recommendations: Actions Physicians Can Take

<p><i>PDMPs</i></p> <p>Register for and use your state PDMP to make more informed prescribing decisions</p> <p>TAKE ACTION ></p>	<p><i>Education</i></p> <p>Ensure you have the education and training on effective, evidence-based treatment</p> <p>TAKE ACTION ></p>	<p><i>Treatment</i></p> <p>Support and advocate for comprehensive care for patients in pain and those with a substance use disorder</p> <p>TAKE ACTION ></p>
<p><i>Stigma</i></p> <p>Removing stigma is essential to ending the nation's opioid epidemic</p> <p>TAKE ACTION ></p>	<p><i>Naloxone</i></p> <p>Expand access to naloxone in the community and through co-prescribing</p> <p>TAKE ACTION ></p>	<p><i>Safe Storage and Disposal</i></p> <p>Work with your patients to promote safe storage and disposal of opioids and all medications</p> <p>TAKE ACTION ></p>

2019 Recommendations: Actions Policymakers Can Take

<p><i>Access to MAT</i></p> <p>Remove prior authorization, step therapy and other inappropriate administrative burdens or barriers that delay or deny care for FDA-approved medications used as part of medication-assisted treatment (MAT) for opioid use disorder (OUD).</p> <p>TAKE ACTION ></p>	<p><i>Mental health</i></p> <p>Support assessment, referral and treatment for co-occurring mental health disorders as well as enforce meaningful oversight and enforcement of state and federal mental health and substance use disorder parity laws.</p> <p>TAKE ACTION ></p>	<p><i>Comprehensive pain care and rehabilitation access</i></p> <p>Remove administrative and other barriers to comprehensive, multimodal, multidisciplinary pain care and rehabilitation programs.</p> <p>TAKE ACTION ></p>
<p><i>Maternal and child health</i></p> <p>Support maternal and child health by increasing access to evidence-based treatment, preserving families, and ensuring that policies are non-punitive.</p> <p>TAKE ACTION ></p>	<p><i>Civil and criminal justice reforms</i></p> <p>Support reforms in the civil and criminal justice system that help ensure access to high quality, evidence-based care for OUD, including MAT.</p> <p>TAKE ACTION ></p>	<p><i>2015 Recommendations</i></p> <p>AMA Opioid Task Force Recommendations for Physicians</p> <p>TAKE ACTION ></p>

www.end-opioid-epidemic.org

Opportunities to help patients with pain

- 2020 state legislative sessions will resume
- 2021 state rate and form filing June-August



IN THE GENERAL ASSEMBLY STATE OF _____

An Act to Prohibit Corporate Interference in the Patient-Physician Relationship

- 1 Be it enacted by the People of the State of _____, represented in the General
- 2 Assembly:
- 3 **Section 1. Title.** This act shall be known as and may be cited as the "An Act to Prohibit
- 4 Corporate Interference in the Patient-Physician Relationship."
- 5 **Section 2. Purpose. Prohibition against interference with the Patient-Physician**
- 6 **Relationship.**
- 7 A. A pharmacy, pharmacy benefit manager or health insurer doing business in this state shall
- 8 be prohibited from implementing any policy that interferes with a pharmacist licensed in
- 9 this state from carrying out his or her corresponding responsibility under the federal
- 10 Controlled Substances Act.
- 11 B. A pharmacy, pharmacy benefit manager or health insurer shall, prior to implementing a
- 12 policy that limits or otherwise places a restriction on the quantity or dosage of a
- 13 prescription for a controlled substance, or the means of dispensing a prescription for a
- 14 controlled substance, shall be required to submit said policy to the state medical board,
- 15 state pharmacy board and any other appropriate regulatory board charged with regulating
- 16 health care professionals for review prior to implementation.



What does a sufficient pain care formulary look like?

American Medical Association supports comprehensive options for patients

QUESTION: For the treatment of neuropathic pain, what are 5-10 treatment options (imp. non-pharmacologic options) that may be helpful or would be effective for a patient? This may include procedures (e.g. nerve blocks), modalities, guided imagery).

PHYSICIAN RESPONSE:
Various desensitization techniques, contrast baths, mirror therapy, cognitive behavior therapy, yoga, mindfulness meditation, close-fitting garments, acupuncture, aerobic exercise, distraction including work, education, postural retraining, virtual reality therapy, heat/cold therapy, stress reduction interventions

Gabapentin, pregabalin, acetaminophen, NSAIDs, tricyclic antidepressants, SNRI antidepressants, opioids, buprenorphine, anticonvulsants

Nonpharmacologic interventions (e.g., TENS, central and peripheral nerve blocks, cognitive behavioral therapy, massage, guided imagery) are useful for neuropathic pain as well as adjuvant analgesics (e.g., anticonvulsants, antidepressants, and some sodium-channel blockers); opioids and non-opioid analgesics also can be of benefit

Nerve blocks (many), neuromodulation (such as dorsal column stimulation, dorsal ganglion stimulation), psychology, cognitive behavioral therapy, desensitization, PT, PT, virtual reality

Nerve blocks, rhizotomy, neurectomy, eliminate neural compression (discectomy or microvascular decompression), physical therapy, exercise, biofeedback, pain psychology, neuromodulation (spinal, cranial, or peripheral nerve stimulation), ablative procedures (radio frequency ablation, cryoablation, DRG), intrathecal drug delivery

Education about pain, cognitive behavioral therapy is essential for all professionals managing chronic pain, graded exercise, occupational therapy, mindfulness training, peer support

Topical agents, cognitive behavioral therapy, osteopathic manipulation, yoga, blocks

Tricyclics, gabapentin, SNRIs (duloxetine)

Local anesthetics, gabapentin/pregabalin, acetaminophen, clonidine, celecoxib, ketamine, anti-seizure medications, buprenorphine for patients who may need opioids

PT (for some conditions), orthotics, nerve blocks, acupuncture

Spinal cord stimulation, peripheral nerve stimulation, intrathecal drug delivery, sympathetic nerve blocks, TENS, cognitive behavioral therapy (e.g. pain coping skills training, biofeedback, mindfulness meditation), physical therapy (desensitization training, mirror therapy for Phantom Limb Pain)

QUESTION: For the treatment of nociceptive pain, what are 5-10 pharmacologic options that may be helpful or would be effective for a patient?

PHYSICIAN RESPONSE:
Anti-neuropathic agents such as the anticonvulsants, selected antidepressants, non-opioids (NSAIDs/acetaminophen), and in very select cases, psychotropic drugs, and opioids, unrestricted access to buprenorphine for pain management not just for MAT, lidocaine-topical, OTC products, ice sleeves and pumps

Opioids, NSAIDs, acetaminophen, tricyclic antidepressants, SNRI or similar psychotropic medications, benzodiazepines, NSAIDs, opioids, adjuvants (e.g. anticonvulsants or antidepressants) may also benefit as well as physical therapy, blocks, cognitive behavioral therapy, and guided imagery

TCAs, NSAIDs, hyaluronic acid, acetaminophen, dexamethasone, eliminate the nociceptive stimulus, acetaminophen, NSAIDs, buprenorphine, neuromodulation such as dorsal column stimulation, dorsal root ganglion stimulation, intrathecal pumps, peripheral and central nerve blocks

Buprenorphine, NSAIDs (oral and topical), acetaminophen, muscle relaxants, short term OTC topical countermeasures NSAIDs, acetaminophen, tramadol, opioids

NSAIDs, opioids, acetaminophen

Acetaminophen, ketorolac, other NSAIDs, clonidine, local anesthetic, opioids, gabapentin, ketamine

Duloxetine, opioids (if moderate to severe pain), corticosteroids (for short course)

Duloxetine, nortriptyline, NSAIDs, acetaminophen, tramadol





Thank you